Advancing Power Assisted Exercise for People with Stroke

RACHEL ELIZABETH YOUNG

A thesis submitted in partial fulfilment of the requirements of
Sheffield Hallam University
for the Degree of Doctor of Philosophy

November 2022

Candidate Declaration

1. I have not been enrolled for another award at the University, or other academic or professional organisation, whilst undertaking my research degree.

2. None of the material contained in the thesis has been used in any other submission for an academic award.

3. I am aware of and understand the University's policy on plagiarism and certify that this thesis is my own work. The use of all published or other sources of material consulted have been properly and fully acknowledged.

4. The work undertaken towards the thesis has been conducted in accordance with the SHU Principles of Integrity in Research and the SHU Research Ethics Policy.

5. The word count of the thesis is 78, 192 (inclusive of published article content).

Signature:

[redacted]

Name	*Rachel Elizabeth Young*
Date	*November 2022*
Award	*Article Based PhD*
Faculty	*Health, Wellbeing and Life Sciences*
Director(s) of Studies	*Dr Christine Smith*

Abstract

Background

The prevalence of stroke is increasing and the estimated societal cost per year in the UK is £26 billion. Exercise interventions for people with stroke decrease the risk factors for recurrent stroke, improve mobility and enhance psycho-social wellbeing. However, stroke rehabilitation services are focussed on recovery of functional independence and do not deliver the recommended dosage of aerobic or resistance training. Barriers to long term engagement in exercise following stroke include inaccessible equipment, transport and low self-efficacy. Power assisted exercise equipment is available in selected leisure and rehabilitation venues within the UK and represents an exercise solution for people with impaired mobility following stroke. The purpose of this doctoral programme of research was to explore the use of power assisted exercise equipment by people with stroke and advance, through co-design, the equipment to enable a tailored prescription to meet their bespoke requirements.

Methods

This programme of research used both qualitative and quantitative methodologies. Phase one examined the feasibility of a programme of power assisted exercise for people with complex neurological impairment. Feasibility was defined in terms of participant's ability to safely access the equipment, attain regular attendance and complete the programme. In phase two, initially a systematic review of qualitative studies which explored the experiences of venue-based exercise amongst people with stroke was conducted. Thereafter, an in-depth, interpretative analysis of the lived experience of using power assisted exercise equipment was undertaken. Phase three reported on a funded programme of research underpinned by the medical device technology framework. Co-design and usability evaluation methods were implemented to develop a new graphical user interface synchronised with effort detection technology on the power assisted exercise equipment.

Findings

Phase one established that power assisted exercise equipment is safe and accessible for use by people with complex neurological impairment. The findings from phase two suggested that venue-based exercise tailored towards people with stroke had a positive effect on reported functional ability and was associated with restoration of an internal locus of control. Participation in power assisted exercise at a specialist stroke venue facilitated transition from NHS rehabilitation and was associated with reported improvements in strength, control of movement and mobility. Adoption of the medical device technology framework in phase three ensured effective user engagement in the co-design and usability evaluation of the new graphical user interface.

Future research

Future research on power assisted exercise for people with stroke is recommended including an examination of its feasibility within the in-patient setting and evaluation of impact upon physiological risk factors and functional ability amongst community dwelling people with stroke.

Conclusion

Power assisted exercise equipment is accessible and acceptable for use by people with stroke. The development of effort detection technology synchronised with the co-designed graphical user interface has realised the potential of power assisted exercise equipment for the effective prescription and monitoring of exercise amongst PwS, including those with very limited mobility. This novel body of work further adds to the evidence base of exercise for people with stroke and has proposed an accessible alternative solution for people with neurological impairment.

Table of Contents

Background and Positionality

My determination to contribute towards improved outcomes for people with stroke was inspired by my job as a health care assistant in a nursing home during the early 1990's. I cared for several people with stroke and often thought that they might have had the potential to recover more independence and movement if long term rehabilitation had been available. I subsequently qualified as a physiotherapist in 1995 and have sustained a specialist interest in neurological rehabilitation throughout my career across multiple sectors.

Over the past 20 years, research evidence has established the benefits of exercise interventions for people with neurological impairment. However, access to conventional exercise equipment can present a challenge for people with motor or sensory impairment. In 2013, I met the Shapemaster Global* team at a rehabilitation conference. I recognised the potential of the power assisted exercise equipment as an exercise solution for people living with neurological impairment. Through my academic role at Sheffield Hallam University, I developed a collaborative relationship with Shapemaster as we identified the need to explore the application of the equipment amongst clinical populations.

Commencement of doctoral study in 2016 created an opportunity to progress the field of research on power assisted exercise equipment. Between 2016 and 2018 I sustained my role as a senior lecturer at Sheffield Hallam University alongside the doctoral programme. This enabled me to apply and share new knowledge with students as exemplified in Article One. Between 2018 and 2020 I transitioned into an associate role at Sheffield Hallam University in order to focus on the doctoral programme and gain experience in the independent sector. In 2021 I was delighted to be appointed as a Senior Research Fellow at the newly opened Advanced Wellbeing Research Centre at Sheffield Hallam University. This role has enabled me to move towards completion of the doctoral programme and created opportunities to apply and implement the knowledge and skills gained.

Throughout the doctoral programme the supervisory team and I have sustained a collaborative relationship with Shapemaster as a commercial stakeholder. The importance of an impartial perspective and academic integrity was emphasised to all parties and an Intellectual Property Agreement exists between Shapemaster and Sheffield Hallam University.

*In 2022 Shapemaster Global rebranded and are now known as Innerva.

Acknowledgements

I would like to take this opportunity to express gratitude towards my supervisory team, Dr Christine Smith, Professor Karen Sage and Professor David Broom. Their collective expertise combined with time committed to provide guidance and feedback has been fundamental to this programme of research and my development as a researcher.

I would like to thank Howard Blackburn (MD) and the Shapemaster team for their support throughout the completion of this PhD. I would also like to thank my clinical colleague and director of Sheffield Neuro Physiotherapy, Emma Richards, who has enabled me to sustain the flexibility required when balancing part time study alongside a clinical caseload.

I would like to express a heartfelt thank you to my husband, children, family and friends for their positivity and support throughout this programme of research which helped me to maintain a work-life balance and wellbeing.

Finally, I would like to dedicate this thesis to the memory of my dad, Tony, who's example of work ethic, quiet determination and patience enabled me to navigate the challenges and believe that completion was possible.

Article Based Statement

The format of an article-based thesis is substantially different to the traditional monograph PhD., however the regulations and assessment criteria for the award remain the same. Sheffield Hallam University's guidance on article-based theses describes the approach as a thesis format in which a number of research articles are produced by the PhD candidate during their period of candidature. These articles will either already be published or will be accepted for publication in peer-reviewed journals at the time of submission. Five published articles plus a final sixth article which has been accepted for publication subject to minor amendments are included in this thesis.

This thesis is presented in three overarching sections. Part one contains chapters one and two which comprise the introduction and literature review. The purpose of part one was to identify the clinical challenge and proposed solution which underpinned the programme of research. Part two contains chapters three, four and five which collectively include six published research articles across the three phases of the research programme. Each chapter incorporates a critical discussion focussed on the underpinning methodology and reflection upon the contribution of each output. Part three is a discussion of the findings and includes identification of the next steps beyond the programme of research reported in this thesis.

This thesis was created in Microsoft word. The content of the six published articles has been integrated into the main body of the thesis and adjustments to referencing styles and abbreviations from the published version have been made to ensure consistency within the document. Figures and tables are numerated according to the sequence of the thesis document, although the within article numeration is included in brackets.

Outputs and Contribution

The programme of research comprised three phases which are summarised below:

Phase one

Phase one is reported in article one; it is a preliminary feasibility study which aimed to determine whether power assisted exercise equipment is safe, feasible, acceptable and accessible intervention for people with neurological impairment.

Phase two

Power assisted exercise is typically undertaken in a venue-based setting rather than the home environment. Having established the safety and acceptability of the equipment amongst a convenience sample of people with neurological conditions including people with stroke in phase one, the research team sought to explore the experiences of venue-based exercise for this clinical population. Article two is a systematic review which synthesised qualitative research focussed on venue-based exercise interventions for people with stroke and article three implemented interpretative methodology to explore users' experience of using power assisted exercise equipment at a community venue. The findings from article three substantiated the need for digital advancement of the equipment which encouraged and enabled the team to secure Grow MedTech funding (£30,000) for phase three of the doctoral programme.

Phase three

Articles four, five and six report on a funded programme of research which aimed to advance power assisted exercise equipment through the development and evaluation of a co-designed user interface with biofeedback. The medical device technology framework was adopted to ensure an iterative approach towards user involvement throughout design and evaluation of the new technology. Articles four and five report on the user involvement and co-design methods implemented to develop the user interface. Article six is a quantitative study which evaluated the usability of the user interface.

Article One

Title: Power assisted exercise for people with complex neurological impairment: a feasibility study

Source: International Journal of Therapy and Rehabilitation, June 2018, Vol 25, No 6, p. 262-271

Authors: Rachel Young, Emma Richards, Neha Darji, Suchitra Velpula, Christine Smith, David Broom, Sara Goddard

International Journal of Therapy And Rehabilitation
Vol. 25, No. 6
https://doi-org.hallam.idm.oclc.org/10.12968/ijtr.2018.25.6.262

IJTR

Research

Power-assisted exercise for people with complex neurological impairment: a feasibility study

Full Reference Contribution Statement

This piece of work was led by Rachel Young who undertook all aspects of the research process from idea to publication.

Narrative

The aim of this article at the outset of the programme of research was to establish the feasibility and acceptability of power assisted exercise as an intervention for people with complex neurological impairment including people with stroke. This unfunded study established the safety, accessibility and acceptability of power assisted exercise equipment amongst a heterogenous convenience sample of seven people during a four-week programme of assisted exercise.

Permissions: Confirmed

Article Two

Title: Experiences of venue-based exercise interventions for people with stroke in the UK: a systematic review and thematic synthesis of qualitative research

Source: Physiotherapy, 2021, Vol 110, p. 5-14

Authors: Rachel Young, David Broom, Karen Sage, Kay Crossland, Christine Smith

ELSEVIER

Physiotherapy

Physiotherapy 110 (2021) 5–14

Systematic review

Experiences of venue based exercise interventions for people with stroke in the UK: a systematic review and thematic synthesis of qualitative research

CrossMark

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Full Reference Contribution Statement

This piece of work was led by Rachel Young who undertook all aspects of the research process from idea to publication.

Narrative

Power assisted exercise equipment is available in selected leisure and rehabilitation venues within the United Kingdom. An understanding of the perspectives of venue-based exercise amongst people with stroke was required to determine whether exploring power assisted exercise equipment as an exercise solution for people with stroke in this context was valid. This qualitative systematic review synthesised the reported experiences of venue-based exercise and concluded that people with stroke perceived multiple benefits associated with tailored exercise programmes in de-medicalised venues.

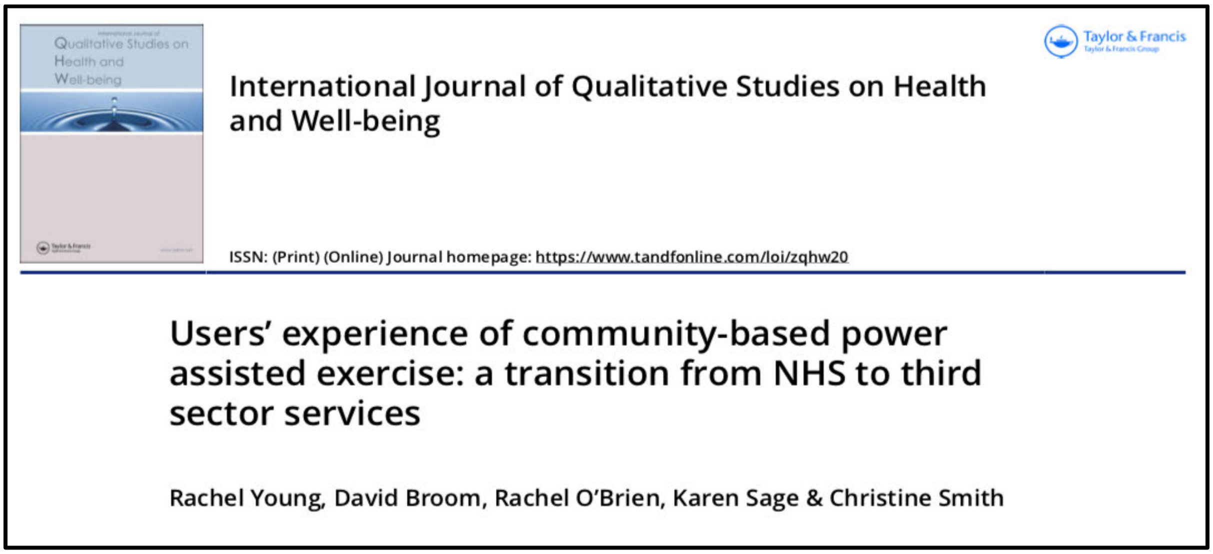
Permissions: Confirmed

Article Three

Title: Users' experience of community-based power assisted exercise: a transition from NHS to third sector services

Source: International Journal of Qualitative Studies on Health and Well-being, July 2021, Vol. 16, p. 1-16

Authors: Rachel Young, David Broom, Rachel O'Brien, Karen Sage, Christine Smith



International Journal of Qualitative Studies on Health and Well-being

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/zqhw20

Users' experience of community-based power assisted exercise: a transition from NHS to third sector services

Rachel Young, David Broom, Rachel O'Brien, Karen Sage & Christine Smith

Full Reference Contribution Statement

This piece of work was led by Rachel Young who undertook all aspects of the research process from idea to publication.

Narrative

Articles one and two established the feasibility of power assisted exercise for people with stroke and confirmed positive experiences associated with venue-based exercise. An understanding of the lived experience of using power assisted exercise equipment amongst people with stroke was required to identify research and development priorities from the users' perspective. In-depth interviews were conducted at a specialist third sector stroke centre with power assisted exercise equipment. Participants associated the uptake of power assisted exercise alongside venue membership as a turning point in their adjustment to life following stroke. Recommendations for future development of the equipment including biofeedback were identified.

Permissions: Confirmed

Article Four

Title: Using nominal group technique to advance power assisted exercise equipment for people with stroke.

Source: Research Involvement and Engagement, 2021, Vol. 7:68, p. 1-12

Authors: Rachel Young, Karen Sage, David Broom, Katherine Broomfield, Gavin Church, Christine Smith

Young *et al. Res Involv Engagem* (2021) 7:68
https://doi.org/10.1186/s40900-021-00311-z

Research Involvement and Engagement

RESEARCH ARTICLE Open Access

Using nominal group technique to advance power assisted exercise equipment for people with stroke

Rachel Young[1*], Karen Sage[2], David Broom[3], Katherine Broomfield[4], Gavin Church[5] and Christine Smith[6]

Full Reference Contribution Statement

This piece of work was led by Rachel Young who undertook all aspects of the research process from idea to publication.

Narrative

This article reported on stage one of the medical device technology framework. The research team were required to select three power assisted exercise machines from a range of nine for implementation of the new technology. Nominal group technique was identified as an appropriate consensus method to ensure user representation in the selection of the three priority machines. Two nominal group technique events were conducted with expert and professional users. The structured group discussion enabled the team to categorise user centred priority features for the digital technology and three power assisted exercise machines were selected through participant consensus.

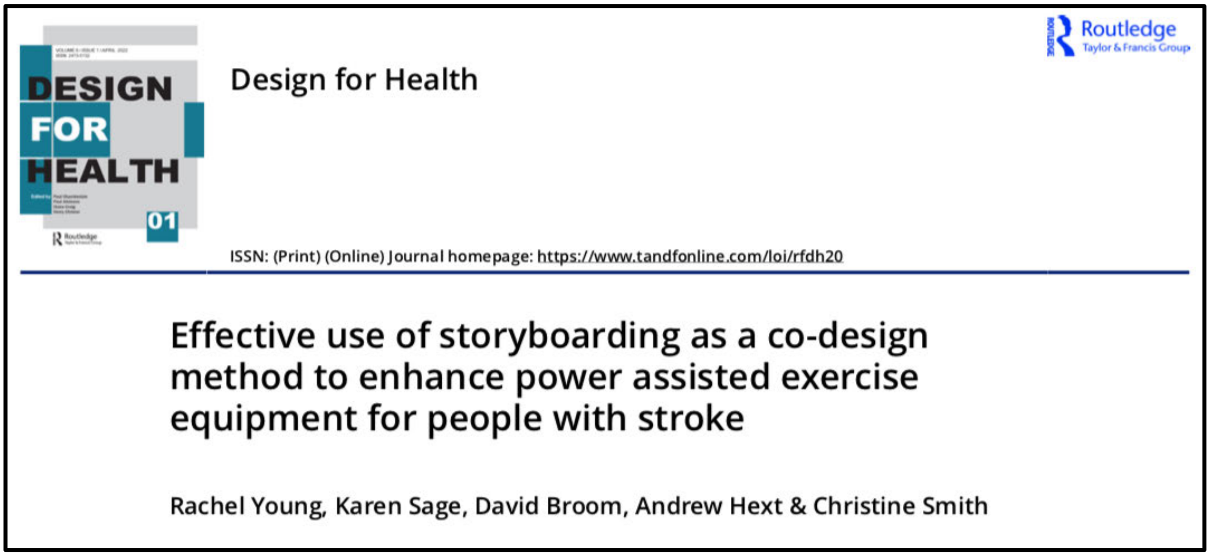
Permissions: confirmed

Article Five

Title: Effective use of storyboarding as a co-design method to enhance power assisted exercise equipment for people with stroke

Source: Design for Health, August 2022, Vol.6, No. 2, p. 244-275

Authors: Rachel Young, Karen Sage, David Broom, Andrew Hext, Christine Smith


Design for Health

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/rfdh20

Effective use of storyboarding as a co-design method to enhance power assisted exercise equipment for people with stroke

Rachel Young, Karen Sage, David Broom, Andrew Hext & Christine Smith

Full Reference Contribution Statement

This piece of work was led by Rachel Young who undertook all aspects of the research process from idea to publication.

Narrative

This article reported on stage two of the medical device technology framework during which storyboarding with participatory analysis was implemented to create a co-designed user interface. The user perspective was triangulated with external sources to ensure alignment with published guidelines and research evidence. A high-fidelity prototype was created and is presented within the article.

Permissions: Confirmed

Article Six

Title: Evaluating the usability of a co-designed power assisted exercise graphical user interface for people with stroke

Source: Journal of Neuro Engineering and Rehabilitation

Authors: Rachel Young, David Broom, Karen Sage, Andrew Hext, Nicky Snowdon, Christine Smith

Full Reference Contribution Statement

This piece of work was led by Rachel Young who oversaw and was actively involved in all of the research processes at each stage.

Narrative

This article reported on stage three of the medical device technology framework. Virtual usability evaluation of the co-designed technology was conducted with a sample of ten professional and ten expert user participants. Multiple usability methods including think aloud, task completion and user satisfaction were conducted on two sequential versions of the user interface.

Acceptance status: Subject to minor revisions

Track your submissions

Evaluating the usability of a co-designed power assisted exercise graphical user interface for people with stroke

Corresponding Author: Rachel Young

Journal of NeuroEngineering and Rehabilitation

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1 Reviewer(s) accepted *06 Sep 22*

Awaiting their report

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Abbreviations

ACSM	American College of Sports Medicine
ADL	Activities of Daily Living
ASA	American Stroke Association
AVERT	A Very Early Rehabilitation Trial
BBS	Berg Balance Scale
BDNF	Brain Derived Neurotrophic Factor
COREQ	Consolidated Criteria for Reporting Qualitative Research
CPET	Cardio-Pulmonary Exercise Test
CVA	Cerebro Vascular Accident
ESD	Early Supported Discharge
EU	Expert User
ERS	Exercise Referral Scheme
FAC	Functional Ambulation Category
FES	Functional Electrical Stimulation
FITT	Frequency Intensity Type Time
fMRI	Functional Magnetic Resonance Imaging
GDNF	Glial cell Derived Neurotropic Factor
GUI	Graphical User Interface
HCPC	Health Care Professions Council
IPA	Interpretative Phenomenological Analysis
MDTF	Medical Device Technology Framework
MS	Multiple Sclerosis
NGT	Nominal Group Technique
NICE	National Institute for Clinical Excellence
NIHSS	National Institute of Health Stroke Scale

PACT	People Activities Context Technology
PAE	Power Assisted Exercise
PAEE	Power Assisted Exercise Equipment
PEDro	Physiotherapy Evidence Database
PHE	Public Health England
PPI	Patient Public Involvement
PSSUQ	Post Study System Usability Questionnaire
PU	Professional User
PwS	People with Stroke
QoL	Quality of Life
RCT	Randomised Controlled Trial
RPE	Rate of Perceived Exertion
RPM	Repetitions Per Minute
RTP	Repetitive Task Practise
Sa02	Saturation of Oxygenated Blood
SSNAP	Sentinel Stroke National Audit Programme
TBI	Traumatic Brain Injury
TFA	Theoretical Framework of Acceptability
TIA	Transient Ischaemic Attack
TUG	Timed Up and Go
UK	United Kingdom
UPDRASIII	Unified Parkinson’s Disease Rating Scale
USA	United States of America
VAS	Visual Analogue Scale
VEM	Very Early Mobilisation
VT	Ventilatory Threshold

Glossary of Terms

6MWT	Six Minute Walk Test
10MWT	Ten Metre Walk Test
cW	Walking Economy
METS	Metabolic Equivalents
VO2	Volume of oxygen uptake

PART ONE: INTRODUCTION AND LITERATURE REVIEW

Chapter 1 Introduction

1.1 Stroke

Stroke is a sudden onset condition which occurs when there is a disruption of blood supply to the brain cells due to an ischaemic or haemorrhagic event in the cerebral circulation (Bartels, Duffy and Beland 2016). The global prevalence of stroke in 2019 was 12.22 million (Stark et al. 2021) and stroke has been identified as the second leading cause of death worldwide (Avan et al. 2019). In the United Kingdom (UK) there are more than 100,000 strokes each year and over 1.2 million people living with stroke (National Institute for Clinical Excellence (NICE 2019a). The prevalence of stroke in the UK is projected to increase to 2.1 million by 2035 (King et al. 2020). First time strokes are occurring at an earlier age with a rise from 33.7% to 38.2% strokes reported amongst the 40-69 age group between 2007 and 2016 (Public Health England (PHE) 2019).

Stroke can cause complex impairments affecting motor, sensory and cognitive ability (Gittins et al. 2021) and more than 50% of People with Stroke (PwS) live with long term disability (NICE 2019a). Risk factors for stroke include hypertension, atrial fibrillation, hyperlipidaemia and diabetes mellitus (NICE 2022a). The five-year risk of stroke recurrence in the UK is 26% (NICE 2022b) and internationally, a higher incidence of recurrence has been reported amongst people with moderate disability compared with minimal disability (Park and Ovbiagele 2016). Weight gain following stroke has been reported; in which the contributing factors included social isolation, depression and impaired ability to manage diet and weight (Homer et al. 2015). Effective management of hypertension, dyslipidaemia and modifiable lifestyle factors including exercise, physical activity and nutrition are emphasised in current guidelines focussed on recurrent stroke prevention (Kleindorfer et al. 2021).

The estimated total societal cost of stroke per year in the UK is £26 billion (Patel et al. 2020) and this is projected to increase to £75.2 billion by 2035, with a 250% proportional increase in societal cost (King et al. 2020). Physical impairment is a reported barrier to returning to work following stroke (Balasooriya-Smeekens et al. 2016) and physical recovery, specifically walking speed, has been identified as a strong predictor for return to work (Jarvis et al. 2019). Exercise interventions are associated with improved mobility following stroke (Pogrebnoy et al. 2020) and the National Stroke Service Model outlines a commitment to long term personalised care and support including access to physical activity (NHS England 2021). The newly published National Clinical Guideline for Stroke (2023) stipulates increased quantity of therapy during early recovery and a long term exercise prescription. Investment in effective and accessible exercise interventions has the potential to improve mobility and productivity amongst PwS and yield cost savings to society.

1.2 Exercise

Several definitions of exercise and physical activity have been proposed over the past few decades and for clinical populations, the distinction between exercise and physical activity can be a source of uncertainty (Kinnett-Hopkins et al. 2019). Physical activity has been defined as any bodily movement that increases energy expenditure above resting levels (>1.6 metabolic equivalents) and may include household chores, vocational activity, organised sport or active recreation (PHE 2019). Exercise has been defined as 'a potential disruption to homeostasis by muscle activity that is either exclusively, or in combination, concentric, eccentric, or isometric' (Winter and Fowler 2009). Exercise is planned, structured and repetitive bodily movement which is undertaken to improve or maintain one or more components of physical fitness (American College of Sports Medicine (ACSM) 2018).

Components of physical fitness include cardiovascular endurance, muscular strength, muscular endurance and flexibility (ACSM 2018). Aerobic training prescribed at an effective duration and intensity will improve cardiovascular endurance (Conraads et al. 2014) and resistance training is normally employed for conditioning skeletal muscle as well as maintaining physical function (Giuliano et al. 2016). Clinical practice guidelines pertaining to exercise following stroke include guidance on healthy lifestyle, exercise as a means of further stroke prevention and exercise to support rehabilitation goals (Church et al. 2022). Published guidelines reflect clinical practice at a given point in time and the best evidence available; best practice can change rapidly as new information becomes available (Winstein et al. 2016). Exercise guidelines for stroke currently recommend aerobic training 3-5 days per week for 20-40 minutes at a moderate intensity and resistance training 2-3 days per week at 30-50% of repetition maximum (National Clinical Guideline for Stroke 2023, Kim et al. 2019). However, published clinical guidelines provide limited detail on specific equipment, staff training and tailored approaches which are required to meet the complex needs of PwS (Church et al. 2022). Patient fatigue, severe impairment and lack of suitable equipment have been identified as barriers to implementation of stroke guidelines amongst rehabilitation professionals (Halls, Murray and Sellar 2021).

Exercise trials for PwS that explore efficacy have examined responses to aerobic training, resistance training and multi-modal training interventions. A recent Cochrane review (Saunders et al. 2020) concluded that aerobic training improved cardiorespiratory fitness, gait speed, gait endurance and physical function. Resistance training led to increased muscle strength and improved balance performance and mixed interventions recorded improved gait speed, gait endurance and balance. Meta-analysis of combined aerobic and resistance training interventions aligned with published guidelines by the American Stroke Association (ASA) (Billinger et al. 2014) indicated significant improvements in gait speed, walking endurance and timed up and go performance; but no difference between groups was detected for stair climbing or sit to stand ability (Pogrebnoy and Dennett 2020). Additional benefits of aerobic training amongst PwS include a reduction in fasting glucose and systolic blood pressure (Brouwer et al. 2021).

Multiple psychosocial benefits associated with exercise and physical activity interventions for PwS have been reported. Exercise interventions have resulted in improved health related quality of life (QoL) amongst PwS, with programmes of at least 12-week duration and including resistance exercise having most benefit on reported mental and physical health (Ali et al. 2021). A meta-analysis of 13 studies concluded that structured exercise programmes reduced depressive symptoms amongst PwS, with greater effect detected amongst higher intensity interventions (Eng and Reime 2014). PwS who have engaged in tailored exercise programmes have reported enhanced confidence and increased feelings of personal control (Sharma et al. 2012). Physically active PwS have reported improved levels of participation, mobility and recovery compared with inactive PwS (Cook, Sunnerhagen and Persson 2020).

Despite the strength of evidence for physical and mental health benefits associated with exercise following stroke, the duration, frequency and intensity of physical activity recorded amongst PwS is significantly lower than age matched controls (Duran et al. 2021). Engagement in exercise and physical activity after stroke is influenced by social networks and formal programmes are important for PwS who lack confidence or prior experience with exercise (Espernberger, Fini and Peiris 2021). Multiple intrinsic and extrinsic barriers to engagement in exercise amongst PwS have been identified. Extrinsic factors include lack of professional support on discharge from hospital, transport, cost and access to suitable venues; intrinsic factors include belief in capability, limited knowledge on how to practice exercise and stroke related impairments (Pacheco et al. 2019; Nicholson et al. 2014). Barriers identified by exercise professionals include lack of knowledge of stroke impairments and limited access to suitable equipment (Condon and Guidon 2018). Implementation of exercise programmes is inconsistent across services and influenced by multiple factors including professional knowledge, suitable equipment and systems networks (Gaskins et al. 2021).

Home based exercise programmes may address some of the extrinsic barriers to exercise identified by PwS and have led to improvements in cardiorespiratory performance and walking endurance amongst ambulant PwS (Marsden et al. 2016). Hybrid programmes which integrate home and venue-based exercise have reported declined adherence with home exercises following discharge from group exercise, indicating that some level of extrinsic support is required to sustain engagement (Jurkiewicz, Marzolini and Oh 2011). Motivators for adherence with home-based exercise include routine, social support and caregiver knowledge; barriers include fear of falling, caregiver stress and home environment deemed unsuitable (Scorrano, Ntsiea and Maleka 2018). Exercise interventions delivered in clinical settings may address concerns regarding safety, space and equipment, but preclude opportunities for social interaction and associated psychosocial benefits (Lloyd et al. 2018). Adapted equipment, for example, motorised static bikes, have been successfully trialled in leisure facilities to enable people with more complex motor impairment following stroke to participate in community exercise (Kerr et al. 2019). However, the availability of adapted equipment and specialist staff in public venues is limited (Gaskins et al. 2021) with reports of very limited provision for non-ambulant PwS (Best et al. 2012).

1.3 Assisted Exercise

Assistive rehabilitation technologies have been identified as an exercise solution for people with limited mobility following stroke (Lefeber et al. 2021, Linder et al. 2015). Rehabilitation technologies and products have the potential to enhance recovery and independence for PwS. Assisted exercise devices can enable people with motor impairment to initiate and sustain movement and have been identified as an alternative to conventional exercise equipment in clinical and community-based exercise programmes (Kerr et al. 2019, Linder et al. 2017). Benefits associated with assisted exercise devices include the attainment of a higher cadence and longer duration of exercise than would be achieved without motorised equipment (Linder et al. 2015).

A range of commercially available assisted exercise devices are available and include assisted cycling machines, ergometers and robotic exoskeletons; the feasibility and safety of these devices for use by PwS has been established (Lloyd et al. 2018, Stoller et al. 2014a). Assisted walking interventions have led to improvements in cardiovascular function, walking endurance (Lloyd et al. 2018) and lung function (Alqahtani et al. 2020). Assisted cycling interventions have resulted in enhanced motor recovery, walking capacity and cardiopulmonary performance (Linder et al. 2019; Linder et al. 2015). In some protocols, assisted cycling has been combined with functional electrical stimulation (Alon, Conroy and Donner 2010) and robotic exoskeleton training has been conducted on a body-weight support treadmill (Lefeber et al. 2021). The use of specialist equipment including electromechanical devices may be feasible within a rehabilitation setting, but the cost, space and staff training requirements may pose barriers to their implementation in community or leisure venues (Lloyd et al. 2018).

Whole body Power Assisted Exercise Equipment (PAEE) was initially conceived during the early 1900s and targeted at females who desired a slender, toned physique. The concept was applied within rehabilitation in 1936 by Bernard Stauffer to promote recovery amongst people affected by polio. A copy of the original patent can be viewed in Figure 1. The recumbent machines were modified tables with powered, hinged components which assisted movement of the trunk and limbs. Adoption of the early devices was limited in rehabilitation, however, during the 1950s, the concept of cosmetic toning evolved, and assisted exercise machines were developed as a vanity product to facilitate inch loss. Recumbent machines assisted movements which were assumed to promote a trim waistline and toned limbs, for example lateral trunk flexion and hip extension. The target market was middle aged females and as the commercial potential for the equipment was recognised, there was a growth of high street venues which offered a circuit model of different toning tables. The toning concept boomed during the 1980s and 'lady's only' high street salons were commonplace across Europe and the United States of America (USA), although queries regarding the effectiveness of a 'no sweat' workout were raised (LA Times 1988). The market experienced a dramatic downturn during the 1990s and most manufacturers of PAEE diversified or went out of business.

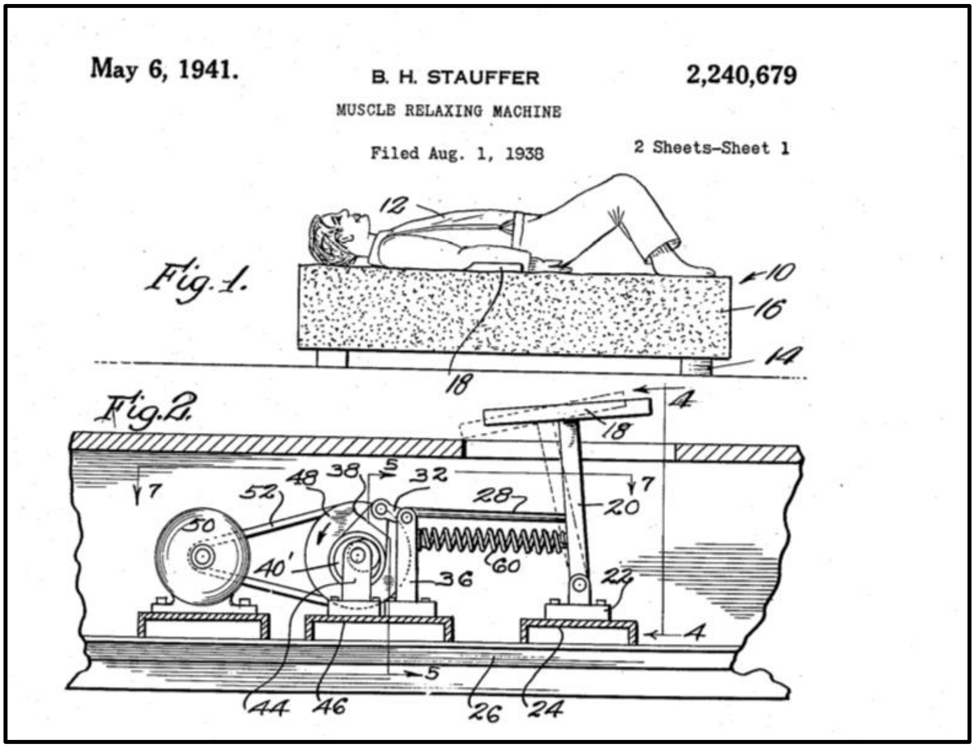

Figure One: Patent of early power assisted exercise machine

Shapemaster is a surviving manufacturer of PAEE and have facilitated the transition of the machines from the vanity market towards an inclusive exercise product aimed at older adults and people living with limited mobility. The range of equipment offered by Shapemaster comprises ten seated and six recumbent machines which collectively assist whole body, multi-directional movement. Examples from the recumbent and seated range are featured in Figure 2. The commercial model promoted by Shapemaster is a circuit of equipment which users move around, spending between three to five minutes on each different machine. At the time of commencing this programme of doctoral study, one study, commissioned by Shapemaster, had focussed on the efficacy of Power Assisted Exercise (PAE) using Shapemaster equipment (Jacobson et al. 2012). Jacobson et al. (2012) examined the impact of a 12-week programme of PAE on 27 ambulatory older adults and reported significant improvements in muscle endurance, balance and functional capacity compared with an age matched control group.

Participants in the intervention group were instructed to generate concentric muscular effort during the assisted exercise by attempting to speed up the assisted movement. These findings indicated that PAE with concentric muscular effort may lead to physical health benefits for ambulant older adults. However, multiple questions regarding the feasibility, application and efficacy of PAE remained.

Figure Two: Power Assisted Exercise Equipment

1.4 Co-design and usability evaluation methods

Assistive technologies have the potential to enable people to access fundamental freedoms and participate in society across the life course (Desmond et al. 2018). Desmond et al. (2018, pg. 438) differentiated between assistive products and assistive technologies. An assistive product was defined as ‘any product specially designed and produced or generally available, whose primary purpose is to maintain or improve an individual’s functioning and independence and thereby promote wellbeing.’ Assistive technology systems were defined as ‘the development and application of organised knowledge, skills, procedures, and policies relevant to the provision, use, and assessment of assistive products.’ Assistive products and technologies should act as an interface between the person and their environment, preserving independence and enabling effective management of health or age-related changes (Sumner et al. 2021, Desmond et al. 2018).

The distinction between assistive and rehabilitation technologies has not always been clear. Writing in 2012, McPherson, Kayes and Hale (2012) stated; ‘for some people, the word "technology” in rehabilitation brings to mind equipment and assistive devices. For others - it is a brave new frontier where robotic advance means many of the functional consequences of impairment are/will be alleviated, and many roles health professionals and carers currently perform will disappear.’ More recently, rehabilitation technologies were summarised as devices which enable repetitive task and context specific intensive training (Jayasree-Krishnan et al. 2021). Adoption of rehabilitation technologies is dependent on their accessibility, adaptability, accountability and engagement (Jayasree-Krishnan et al. 2021). Design flaws in rehabilitation technology have been highlighted as a barrier to adoption and the importance of meaningful involvement of end users throughout the design process has been emphasised (Louie et al. 2020).

Alongside the evolution of assistive and rehabilitation technologies, methodological approaches which facilitate user engagement in the design of new devices or systems have developed (Sumner et al. 2021). User-centred design has been described as a paternalistic approach in which trained researchers observe or interview passive users (Sanders and Stappers 2008). Participatory approaches aim for a more equal partnership between users and designers through shared ideation of new concepts (Sumner et al. 2021). Co-design and co-creation are concepts which have more recently been applied to the design of services and technologies. Multiple definitions and theoretical models have been proposed (Design Council 2019, Charles and McDonough 2017, Shah, Robinson and AlShawi 2009). Co-design approaches comprise several stages including ideation, prototyping and usability testing (Sumner et al. 2021). In the context of stroke, an adaptive approach, shared understanding and presence of a skilled facilitator to identify imbalances in participation have facilitated implementation of effective co-design processes (Lindblom et al. 2021).

1.5 Summary and purpose statement

The prevalence of stroke is increasing with implications for societal cost and healthcare burden within the UK and globally. Multiple benefits associated with exercise for PwS have been established including improved mobility, participation, quality of life and reduced risk of stroke recurrence. Guidelines for exercise prescription following stroke have been published, but intrinsic and extrinsic barriers to their attainment have been reported including limited availability of suitable venues and accessible equipment. Rehabilitation technologies including exoskeletons and assisted cycling devices enable people with motor impairment to exercise through assisted movement. These interventions have improved cardio-pulmonary performance and mobility for PwS but are only routinely offered in clinical settings. There is a need for assistive exercise equipment to be made more widely available to enable PwS to participate in accessible group exercise.

Whole body PAEE evolved during the 20th century and was originally a cosmetic product designed to promote inch loss and improve body image. The current range of equipment manufactured by Shapemaster is available in selected leisure and community rehabilitation centres across the UK. The circuit of machines which collectively assist multi-directional movement of the trunk and limbs may represent an exercise solution for PwS. User involvement and testing in the development of rehabilitation technologies are essential to ensure a product which is accessible, acceptable and engaging to the user. The purpose of this doctoral programme of research was to explore the use of PAEE by people with stroke and advance, through co-design, the equipment to enable a tailored prescription to meet their bespoke requirements.

The aims of each phase of this doctoral programme of research are outlined below:

Phase one:

- To establish whether PAE is a feasible exercise intervention for people with complex neurological impairment.

Phase two:

- To organise and summarise the results of contextually rich studies through thematic synthesis to gain an in-depth understanding of venue-based exercise from the perspective of PwS.
- To explore both ambulant and non-ambulant PwS experiences of and the perceived effects associated with participation in PAE in a third sector community stroke centre.

Phase Three:

- To co-design with professional users and expert users a graphical user interface synchronised with effort detection technology to advance PAEE for use by PwS.
- To implement usability methods to evaluate the co-designed graphical user interface with representative professional users and expert users.

Chapter 2 Literature Review

The purpose of this narrative literature review is to identify and examine the research evidence relevant to the three phases of research which underpin this programme of doctoral study. The length is befitting of a doctoral thesis that includes a systematic review in chapter four in which the principal investigator demonstrates the skills of literature searching, synthesis and critical analysis.

Section one of this narrative literature review explores the acute and subacute management of stroke to gain an understanding of current practice and identify the factors which may contribute towards an optimal long-term outcome. Section two reviews research evidence focussed on exercise interventions for PwS and aims to summarise the physical impact of exercise interventions following stroke. Section three focusses specifically on assisted exercise interventions for PwS to examine the physiological responses and impact on function, recovery and physiological parameters. Section four reviews examples of co-design methods and usability testing in the development of rehabilitation technologies.

2.1 Stroke Rehabilitation Pathways

The onset of stroke can cause immediate physical impairment with loss of mobility and a subsequent rapid decline in aerobic capacity and muscle mass in the first few weeks (Aydin et al. 2021, Kelly et al. 2003). The acute and subacute therapeutic management of PwS is likely to be a large determinant of long-term outcome (Alawieh, Zhao and Feng 2018). A recent overview of stroke pathways provided in the UK highlighted the importance of integrating evolving research evidence into national clinical guidelines and treatment protocols (Rodgers and Price 2017). The aim of this section of the literature review is to review evidence pertaining to inpatient rehabilitation and Early Supported Discharge (ESD) to identify factors which contribute towards the decline in muscle mass and aerobic capacity amongst PwS.

2.1.1 Inpatient Rehabilitation

Accurate diagnosis through imaging and administration of indicated vascular and pharmacological interventions including thrombectomy, anti-coagulant treatment and restoration of homeostasis are prioritised in the hyper acute management of stroke (NICE 2019b). The safety and efficacy of early mobilisation in the management of acute stroke was examined by the 'A Very Early Rehabilitation Trial' (AVERT) trial collaboration group (AVERT Group 2015). Phase two of the AVERT programme of research was a single blind Randomised Controlled Trial (RCT) which investigated the safety and feasibility of a Very Early Mobilisation (VEM) protocol compared with standard care within the acute stroke units of two large teaching hospitals. The VEM protocol prescribed mobilisation within 24 hours of symptom onset and intervals of activity throughout the day including getting out of bed, standing and stepping according to ability. Seventy-eight participants were recruited and the VEM participants received a significantly higher dosage of therapy and fewer immobility related adverse incidents than the standard care group. It was concluded that VEM was feasible and altered the schedule and nature of therapy delivered (van Wijk et al. 2012). Phase three of the AVERT programme was a pragmatic, parallel group, single blind, multi-centre international RCT which aimed to examine the impact of VEM on functional recovery, walking ability and incidence of immobility related complications. A favourable outcome according to the modified Rankin Scale at three months was reported for 480 VEM participants compared with 525 participants who received standard care; adjusted analysis indicated that this difference was statistically significant (P=0.004) (AVERT Group 2015). It was concluded that VEM significantly reduced the odds of favourable outcome at three months and these findings are reflected in updated clinical guidelines (NICE 2019b).

Examination of the phase two and phase three studies highlighted that standard care changed over the course of these trials. During phase two, participants randomised to standard care commenced mobilisation at 30.8 (median) hours following symptom onset whereas during phase three, this had decreased to 22.4 (median) hours. The AVERT group reported a trend towards earlier mobilisation within standard care protocols of 28 (median) minutes per year (AVERT Group 2015) and therefore the difference between standard care and the VEM protocol during the phase three trial was reduced. One smaller RCT which recruited 86 patients concluded that VEM was associated with improved functional status according to Barthel Index scores at three month follow up (Chippala and Sharma 2015). Comparable with the phase two AVERT trial (van Wijk et al. 2012), the standard care group commenced mobilisation at 30.6 (median) hours following onset of symptoms and VEM was commenced at 18 (median) hours (Chippala and Sharma 2015). The Barthel Index and modified Rankin Scale are frequently used to measure disability after stroke. Comparison between the two scales has indicated that the modified Rankin Scale is better to discriminate patient's functional global status at three months post stroke (Cioncoloni et al. 2012) which was the time point of greatest interest in the AVERT trials. The findings from the three VEM studies cited above underwent meta-analysis alongside six other RCT's focussed on VEM in acute stroke (Xu et al. 2017). Xu et al. (2017) concluded that VEM was not associated with an increased likelihood of adverse events; however, there was no evidence to support the hypothesis that VEM improved functional outcome. These findings indicate some uncertainty still exists regarding the optimum timepoint for mobilisation following stroke. It was recommended that future research is focussed upon dose-response analysis to determine optimum intensity and frequency of mobilisation in acute stroke (Xu et al. 2017).

The VEM protocols prescribed out of bed activity which included sitting out of bed, standing and walking according to the ability of the participant; attainment of a targeted intensity of aerobic activity was not specified. It is important to distinguish between mobilisation and aerobic exercise in the management of acute stroke as cardiorespiratory fitness declines rapidly in the early weeks following stroke (Kelly et al. 2003). It is possible that in-bed, recumbent exercise may enable a targeted exercise intensity without the haemodynamic demand associated with sitting and standing (Sandberg et al. 2021). The potential neuroprotective responses triggered by aerobic exercise following induced ischaemic or haemorrhagic stroke has been investigated in laboratory research. A systematic review of 47 animal studies identified that forced exercise using a motorised treadmill, running wheel or rotating rod was associated with reduced lesion size, decreased cellular death and increased neurogenesis (Austin et al. 2014). The review concluded that moderate intensity exercise induced significant benefits on short term physiological responses and recommended that the findings should be translated to pre-clinical research trials with precise brain imaging to determine the immediate effects of moderate intensity, assisted exercise in acute stroke.

Early aerobic exercise interventions have been trialled in acute stroke, although published research on human participants remains limited. The haemodynamic responses to in-bed cycling exercise were investigated in a dual centre, parallel, prospective RCT which recruited 52 participants within 24-48 hours of stroke onset (Sandberg et al. 2021). The intervention group completed a three-week programme of in-bed cycling which resulted in a significant increase in blood pressure responses to exercise which reflected a more normal pattern of autonomic regulation when compared with the control group. The mean modified Rankin Scale score of 4.4 indicated that this study recruited people with impaired mobility whose ability to engage in a VEM protocol may have been limited. The extent to which participants engaged in active rather than assisted or passive cycling was not reported which would have provided interesting data on their ability to generate muscular effort.

Thelandersson et al. (2016) examined the effects of in-bed cycling on intracranial pressure and haemodynamic responses amongst a group of critically ill participants with either traumatic brain injury or stroke. A protocol of assisted cycling set at 20 repetitions per minute was associated with significant increases in stroke volume and mean arterial pressure, but no change in intracranial pressure, heart rate or oxygen saturation. It was concluded that the intervention was safe and may have improved venous return as indicated by the increase in stroke volume. This study was a single centre, prospective design with no control group. Only five of the 20 participants had a diagnosis of stroke and on average, participants were recruited to the study at seven days post injury or stroke. The studies conducted by Thelandersson et al. (2016) and Sandberg et al. (2021) indicate that in-bed assisted cycling interventions are feasible and safe for people with acute stroke, although further research into efficacy and optimal dosage is required.

Scientific evidence from animal models has indicated that optimal neuroplasticity occurs between one- and three-weeks following stroke and substantial increases in the dosage and intensity of therapy offered in the first month of stroke have been recommended (Krakauer et al. 2012). The intensity and quantity of inpatient rehabilitation has been the focus of several observational studies. A study published by Foley et al. (2012) recorded all therapeutic contact with patients of duration longer than five minutes on a Canadian stroke rehabilitation unit. Data from 123 patients indicated that they received on average 37 minutes of physiotherapy per day. A comparison between activity levels in an acute stroke unit and four rehabilitation units in Sweden indicated that time engaged in moderate or high intensity activity was not significantly different between the settings and patients in both settings spent over 50% of their waking time alone in their bedroom (Astrand et al. 2016). The study by Foley et al. (2012) relied on clinical therapists to record contact time whereas independent observers were employed to document patient activity in the study published by Astrand et al. (2016). A more scientific approach was adopted by Barrett et al. (2018) in a study which used Actiheart monitors with PwS to record activity and heart rate responses during inpatient rehabilitation on a Canadian stroke unit. Data captured from 19 participants indicated that patients were sedentary for 86.6% of their waking hours and time engaged in therapies comprised 5% of total weekday time. The heart rate data indicated that 61.57 % of time in physiotherapy was sedentary with an average metabolic demand of 1.65 Metabolic Equivalents (METS) recorded during sessions. This intensity of activity is comparable to sitting at a desk. The introduction of group activities and exercise sessions was recommended to reduce sedentary time and achieve a higher intensity of aerobic activity.

Inpatient stroke rehabilitation in the UK is audited by the Sentinel Stroke National Audit Programme (SSNAP) and a report published prior to the COVID-19 pandemic identified that stroke patients in the NHS needed to be offered a greater intensity of rehabilitation (SSNAP 2020). Factors influencing the delivery of inpatient rehabilitation in the UK were explored in a mixed methods case study approach project which purposively sampled eight stroke units across four English regions (Clarke et al. 2018). Data collected through process mapping, observation and interviews were analysed and seven factors which influenced therapy provision were identified, including time spent in information exchange, limited therapist knowledge of guidelines regarding intensity of therapy and limited therapy timetabling. Although patients and carers were interviewed, their perspectives were not clearly represented in the published results. Group activities were considered, however, the potential role of assistive or rehabilitation technologies to augment therapy were not explored as a solution (Clarke et al. 2018). An earlier narrative synthesis focussed on factors shaping inpatient therapy included 18 studies from the UK and similarly identified factors such as communication systems and discharge planning as barriers to direct patient contact (Taylor, McKevitt and Jones 2015). Equipment and availability of space were also reported as factors which limited intensity and duration of therapy and novel models of rehabilitation including group activities were proposed.

2.1.2 Community rehabilitation

Early supported discharge interventions allow care to be transferred from an inpatient to community setting with the same intensity of expert rehabilitation that would be received in hospital (NICE 2016). A recent analysis of SSNAP data indicated that 80% of UK stroke services offer ESD with 47.2% of PwS accessing community-based rehabilitation on discharge home (Gittins et al. 2020). The National Stroke Service Model stipulates that ESD services must be available in all areas (NHS England 2021). ESD services were developed during the late 1990's and in 2005, a meta-analysis of 11 trials including 1597 patients from six countries concluded that ESD significantly reduced the odds of death or institutional care (P=0.02) and decreased average length of hospital stay by 7.7 days (p=0.0001) (Langhorne et al. 2005). No significant differences in Activities of Daily Living (ADL) scores or self-reported health and mood were detected, and it was concluded that people with moderate disability benefitted the most. Amongst the 11 studies reviewed, heterogeneity between the ESD services was identified which may have diluted the strength of findings within some of the selected outcomes. Subsequent studies have indicated that ESD facilitates faster recovery of independence (Rafsten et al. 2019), goal attainment (Georgy 2021) and reduced inpatient length of stay (Neale et al. 2020). Most ESD studies have recruited people with mild or moderate disability according to their National Institute of Health Stroke Scale (NIHSS) score and the need for further research focussed on optimal management of people with severe impairment alongside stratification of rehabilitation pathways has been identified (Georgy 2021). A deficit in care for people with mild disability following stroke was also identified by Gittins et al. (2020) who identified that over 50% of this group received no community rehabilitation.

A comparison of activity monitoring data captured during inpatient and subsequent community-based rehabilitation indicated that physical activity levels doubled following discharge home with community rehabilitation (Kerr et al. 2016). However, despite the increase in detected activity, the median percentage of time spent standing or walking at home was 7.0% and 1.8% respectively which was still below the recommended levels of activity for health. The ESD interventions reported above included ADL practise, standing, walking and travel by public transport (Neale et al. 2020, Rafsten et al. 2019). Exercise interventions or physical training were not reported within the ESD packages. A qualitative exploration of the experiences of ESD amongst PwS in Norway identified that participants felt that exercise instruction was lacking and that group rather than individual rehabilitation would have created opportunities for social interaction (Taule et al. 2015). The approach to data analysis used by Taule et al. (2015) were an interpretive description which adopts a disciplinary perspective (Marrocco and El-Masri 2021). The disciplinary background of the research team who conducted the study by Taule et al. (2015) was not stated and despite a systematic approach to data analysis, there was limited evidence of researcher reflexivity in the interpretation of findings. However, the lack of exercise instruction reported by ESD participants does concur with the protocols described in the quantitative research.

In summary, acute and subacute stroke rehabilitation pathways do not attain the quantity of activity recommended to optimise recovery and minimise the deleterious effects associated with neurological impairment. VEM is not recommended and despite extensive laboratory research indicating neuroprotective responses to assisted exercise, there is a paucity of clinical research in this area. The inpatient therapy interventions reported above were low intensity and community therapy was focussed on ADL practise and functional mobility. Exercise interventions to improve aerobic or muscular function were not reported and group activities were limited. There is some evidence that people with minimal or severe impairment following stroke receive the most limited rehabilitation packages. The studies reviewed above reflect international practice and there is a global need to develop tailored solutions to augment activity and introduce structured exercise within stroke rehabilitation pathways.

2.2 Exercise Interventions for People with Stroke

Since 2000 there has been an exponential increase in the number of studies which have investigated exercise or physical training interventions for PwS. Concerns that strength or resistance training may exacerbate hypertonicity were dispelled by a meta-analysis of strength training interventions for PwS which concluded that there was very little effect on spasticity, with positive effects on strength and activity reported (Ada, Dorsch and Canning 2006). Guidance on the safe prescription of aerobic training for PwS published in 2008 emphasised the benefits associated with aerobic exercise on overall cardiovascular risk and recommended that structured exercise programmes should be considered for all PwS (Ivey, Hafer-Macko and Macko 2008). The most recent Cochrane review focussed on stroke and physical training interventions identified 75 studies involving 3017 participants and reported improved disability scores, aerobic fitness and mobility associated with aerobic or combined training interventions (Saunders et al. 2020). It was concluded that exercise interventions for PwS are safe and further research is needed to determine optimal exercise prescription in stroke rehabilitation alongside greater representation of non-ambulant PwS.

Clinical exercise prescription should stipulate the frequency, intensity, type and time of the intervention, a formula which is frequently abbreviated to 'FITT' (Ranasinghe et al. 2019). In addition, exercise programmes should be underpinned by the principles of exercise training which comprise specificity, overload, progression, reversibility, baseline values and diminishing returns (Khushhal et al. 2020, Ammann et al. 2014). A review of 37 RCT's investigating aerobic (n=18), resistance (n=8) or combined (n=11) training amongst PwS examined the extent to which training principles and FITT prescription were reported (Ammann et al. 2014). Only one study described all six training principles and 32.4% of the reviewed studies described just one or two training principles. Reporting of the FITT prescription was also inconsistent with only 51.4% of included studies describing all four components. Intensity was the least defined and monitored component and it was suggested this may be partially attributable to limited equipment and technology. This review highlighted the need for more robust exercise prescription in stroke research; although the authors did not directly analyse the inter-relationship between exercise type and intensity monitoring. This would have enabled clinicians and researchers to directly address specific areas of shortfall in exercise prescription. A more recent systematic review of 14 group exercise interventions for PwS directed specific attention to the reporting of progressive intensity training (Church et al. 2019). Only two studies implemented maximum heart rate testing and monitoring to determine exercise intensity and it was concluded that more robust measurement of intensity aligned with specific targets is required. The review published by Church et al. (2019) included a diverse range of exercise interventions including water-based exercise, Tai Chi and circuit training which may account for the inconsistencies reported.

Despite challenges associated with exercise prescription and monitoring, multiple outcome measures have been implemented in research to examine the efficacy of exercise or physical training interventions on PwS. The following sections will review literature which has reported on the impact of exercise interventions on physiological parameters, functional and physical performance. The influence of engagement in exercise on personal wellbeing and participation will be explored in articles two and three in the methods section of this thesis.

2.2.1 Exercise and risk factor management

Management of vascular risk factors including hypertension, lipids and blood glucose to prevent recurrent stroke has been identified as a global priority (Kleindorfer et al. 2021). The effect of aerobic training interventions on vascular and metabolic risk factors for recurrent stroke was examined through meta-analysis of nine RCT's comprising 527 participants (Brouwer et al. 2021). The interventions included overground walking, treadmill training and leg ergometry with significant improvements in systolic blood pressure and fasting glucose reported. The meta-analysis conducted by D'Isabella et al. (2017) of 18 studies (n= 930 participants) included any combination of aerobic or resistance training interventions. Statistically significant improvements in systolic blood pressure and fasting glucose were reported in addition to a beneficial increase in high-density lipoprotein. No significant effects on diastolic blood pressure, low density lipoprotein or body mass index were reported in either meta-analysis (Brouwer et al. 2021, D'Isabella et al. 2017). D'Isabella et al. (2017) did not clearly distinguish between the resistance training and aerobic training interventions included in the meta-analysis, but it was suggested that resistance training may be effective in increasing high-density lipoprotein. Resistance training alone has been associated with improvements in blood pressure, glucose metabolism and body mass index with an effect size of 0.66 calculated from pooled analysis of four studies (Veldema and Jansen 2020). These findings indicate that combined aerobic and resistance training protocols have greatest benefit on reducing the risk of recurrent stroke.

Six of the studies included in the meta-analysis by Brouwer et al. (2021) were also included in the review by D'Isabella et al. (2017). Studies with a PEDro (Physiotherapy Evidence Database) score lower than six were identified for qualitative analysis but excluded from the quantitative meta-analysis conducted by D'Isabella et al. (2017). The quality of studies included in the meta-analysis by Brouwer et al (2021) was independently rated by two reviewers according to PEDro criteria with scores ranging between four and eight out of ten. The most common causes for risk of bias were lack of concealed allocation and assessor blinding. Brouwer et al. (2021) did not report on the ambulatory status of participants included in the meta-analysis, whereas D'Isabella et al. (2017) observed that only one included study had enrolled non-ambulant participants. Lloyd et al. (2018) conducted a systematic review and meta-analysis of 33 studies on non-ambulant PwS. Mobility was determined according to the Functional Ambulation Category (FAC) with a score of two or less being the cut-off point, which is defined as needing intermittent or continuous light touch assistance to assist balance and coordination. The interventions were predominantly either technology assisted walking using a body weight support treadmill or robotic exoskeleton, or cycle ergometer training. Only four of the 33 studies examined impact of exercise intervention on blood pressure and meta-analysis of the data indicated no significant effect. However, the meta-analysis of blood pressure data divided the four studies according to type of intervention. Examination of individual results indicated a trend towards benefit on systolic blood pressure associated with assisted walking training.

2.2.3 Exercise and aerobic capacity

Aerobic capacity is a strong predictor of cardiovascular risk, functional independence and quality of life frequently quantified through VO2 (volume of oxygen uptake) Peak testing or walking endurance observed through the Six Minute Walk Test (6MWT) (Lee and Stone 2020). Improving aerobic capacity is a priority in the management of people with cardiovascular pathology including PwS and those referred for cardiac rehabilitation following myocardial infarction or diagnosis of coronary heart disease. A meta-analysis of 19 studies (n=485 participants) which examined the impact of cardiac rehabilitation programmes comprising aerobic exercise with additional components of resistance training and education on aerobic capacity reported a pooled mean difference of 2.08mL/kg per minute on VO2 Peak testing (Regan et al. 2019). This was very similar to the pooled mean difference of 2.20mL/kg per minute reported by Boyne et al. (2017) from a meta-analysis of 15 studies which investigated the effect of isolated aerobic training amongst PwS. Pooled analysis of assisted walking training interventions (n=3 studies) for non-ambulant PwS also indicated a mean difference of 2.73mL/kg per minute (p=0.01) (Lloyd et al. 2018).

Differentiation between high and moderate intensity protocols demonstrated greater improvement associated with high intensity training (3.8mL/kg per minute) compared with moderate intensity protocols (1.6mL/kg per minute) (Boyne et al. 2017). In contrast, the meta-analysis of combined aerobic and resistance training interventions by Stone and Lee (2020) concluded that intensity did not have a significant effect on VO2 Peak. The impact of additional programme components including education and resistance training were not directly examined by Regan et al. (2019). Of the three studies on non-ambulant PwS pooled by Lloyd et al. (2018), only one reported on intensity of the intervention, making it difficult to draw any conclusions on the impact of exercise intensity with assisted walking. However, the collective findings from these reviews indicate that high intensity aerobic training or moderate intensity aerobic training combined with resistance training are similarly effective at improving VO2 Peak amongst PwS.

High intensity interval training has also been associated with improved walking economy (cW) and Ventilatory Threshold (VT1) (Wiener et al. 2019). These outcomes reflect aerobic and metabolic capacity during steady state activity which is more representative of functional mobility and activities of daily living than maximal exercise testing. Wiener et al. (2019) concluded that high intensity interval training was more effective than moderate intensity continuous training at increasing cW and VT1. However, meta-analysis was not performed due to overlapping outcome measures across a small number of included studies. Overground walking, treadmill walking, and static cycling were the most widely implemented types of aerobic training reported (Lee and Stone 2020, Wiener et al. 2019, Regan et al. 2019, Boyne et al. 2017). Treadmills or static bikes have the functionality to quantify performance and grade intensity (Wiener et al. 2019). However, the ability to initiate and sustain bilateral movement is a pre-requisite for using conventional exercise equipment. A meta-analysis of studies investigating aerobic training amongst people with subacute stroke (less than six months since onset) reported highly significant improvements in VO2 Peak ($p=0.00001$) but highlighted the need to develop more appropriate devices to enable people with limited mobility to engage in aerobic training (Stoller et al. 2012).

Improvement in 6MWT performance associated with physical training interventions amongst PwS has been reported across multiples studies. Pogrebnoy and Dennett (2020) reported a mean difference of 39.2m for 6MWT performance which increased to 51.1m following sensitivity analysis associated with combined training interventions but suggested that this gain may have been predominantly achieved through the aerobic training component. The recent Cochrane meta-analysis reported a mean difference of 33.41m with aerobic training, 24.98m with resistance training and 35m with combined training (Saunders et al. 2020), indicating some benefit associated with resistance training, although below the clinically meaningful improvement of 34.4m stipulated for PwS (Flansbjer et al. 2005). These findings suggest that the addition of resistance training to aerobic training may enhance walking endurance and it has been suggested that resistance training prescribed according to the principles of specificity will be more effective (Pogrebnoy and Dennett 2020).

Further reviews of combined training interventions have reported significant improvements in 6MWT performance (Regan et al. 2019, Lee and Stone 2020, English and Hillier 2011). The review published by English and Hillier (2011) aimed to investigate the effectiveness of circuit training therapy in improving mobility amongst PwS (n=292 participants). Although a rigorous approach towards study identification and risk of bias detection was adopted, the description of the circuit training interventions was limited in terms of intensity of prescribed exercise. There was a strong emphasis on walking practice within the circuit training protocols which resulted in a pooled mean difference of 76.57m. It is possible that the specificity rather than aerobic demand of the intervention had a direct effect on walking performance. Synthesis of physical training interventions for PwS further supports the impact of task specificity on task performance with seated exercise, for example static cycling, having less impact on walking endurance than protocols which include overground or treadmill walking (Regan et al. 2019, Boyne et al. 2017). Boyne et al. (2017) suggested that seated aerobic training could be conducted prior to walking practise to minimise risk and optimise effects of task specific practise. The review by Boyne et al. (2017) only included ambulant PwS; the review by Regan et al. (2019) included non-ambulant participants, although the ability to cycle at 50 revolutions per minute was stipulated.

2.2.3 Exercise and mobility

Walking velocity is directly measured through the ten-metre walk test (10MWT) (Ofran et al. 2019). A meta-analysis of 22 studies (n=952 participants) concluded that high intensity interval training was effective at increasing gait speed (Luo et al. 2019). The inclusion criteria clearly defined high intensity interventions in terms of target heart rate and reported exertion. Thirteen of the 22 studies had used treadmill training, and the remaining eight had implemented cycle ergometry. Treadmill training interventions were more effective than cycle ergometry for increasing self-selected walking speed. Comparable results were reported by Boyne et al. (2017) with a pooled increase of 0.09m/s (metres per second) associated with aerobic walking training compared with 0.05m/s calculated for seated aerobic training. Pooled analysis of the impact of assisted walking interventions (n=8) on maximum gait speed amongst non-ambulant PwS reported a significant improvement of 0.10 metres per second (Lloyd et al. 2018).

The Timed Up and Go test (TUG) reflects gait velocity in addition to the ability to transfer from a chair and turning (Ofran et al. 2019). The impact of physical training interventions on TUG performance is inconclusive. High intensity interval treadmill training has been associated with significant improvement in TUG outcomes (Leo et al. 2019). However, the review of combined aerobic and resistance training published by Pogrebnoy and Dennet (2020) concluded that there was low level evidence of no significant effect. Church et al. (2019) reported intervention over time improvements, but these were not sustained and there was no pooled analysis to quantify extent of the reported effect. Circuit class training with an emphasis upon walking practise was associated with a pooled improvement of -3.08 seconds (p= 0.018) by English and Hillier (2011), but only –1.89 seconds (p=0.38) by Bonini-Roche et al. (2018). The minimal detectable or smallest real difference for the TUG is 2.9 seconds (Flansbjer et al. 2005), indicating that the change reported by English and Hillier (2011) may have had borderline clinical significance. Meta-analysis of resistance training interventions amongst PwS has reported limited impact on measures of activity including the TUG, despite significant improvements in strength performance (Dorsch, Ada and Alloggia 2018). The TUG is short in duration and therefore may not be responsive to improvements in aerobic capacity. It also requires interplay between the motor and sensory systems to judge distance and turning which are skills not typically replicated in resistance training protocols. Components of the TUG are of functional importance for PwS and the current uncertainty regarding impact of exercise interventions on TUG performance highlights the importance of task specific practise within training protocols.

The Berg Balance Scale (BBS) is a multicomponent ordinal measure of balance comprising tasks including transfers, reaching in standing and standing on one foot. It has been identified as a predictor of independent walking amongst PwS (Jenkin et al. 2021). Neither high intensity training nor circuit training interventions have any significant pooled effect on BBS scores amongst PwS (Luo et al. 2019, Bonini-Roche et al. 2018, English and Hillier 2011). Likewise, assisted walking training for non-ambulant PwS had no significant effect on BBS in comparison to control groups, although two studies did report longer-term improvements in BBS associated with walking training (Lloyd et al. 2018). Comparable with the TUG, the BBS reflects aspects of visual, proprioceptive and vestibular processing which are not typically targeted in aerobic or resistance training programmes.

In summary, aerobic training programmes have been associated with significant improvements in systolic blood pressure, fasting glucose, VO2Peak and 6MWT performance. Combined aerobic and resistance training programmes can lead to multiple benefits including improved mobility, an increase in high density lipoprotein and greater improvements in aerobic capacity than aerobic training in isolation. High intensity interval training has been associated with improvement in multiple measures of bodily function and mobility including VO2Peak, cW, VT1, gait velocity and TUG performance. Circuit training interventions with an emphasis on walking practice have reported improvements in 6MWT and TUG performance. Resistance training interventions delivered in isolation have decreased systolic blood pressure, fasting glucose, body mass index and been associated with small improvements in 6MWT performance. Assisted walking interventions for non-ambulant PwS have reported improved VO2Peak and 6MWT performance at follow up. Walking interventions including overground and treadmill training are more efficacious than seated interventions such as cycle ergometry at improving mobility outcomes.

2.3 Assisted exercise interventions

2.3.1 Assisted exercise definitions and devices

The impact of seated assisted exercise interventions has been examined in a body of literature dated from 2009 (Ridgel, Vitek and Alberts 2009). Several different terms have been used to describe assisted exercise including ‘forced exercise’ (Kohler et al. 2019, Linder et al. 2015), ‘assisted cycle training’ (Holzapfel et al. 2019) and ‘power assisted exercise’ (Bossink et al. 2017, Jacobson et al. 2012). Forced exercise has been defined as ‘a novel exercise model which augments, but does not replace, the voluntary efforts of a participant to facilitate sustained aerobic training’ (Linder et al. 2019). An alternative definition by Kohler et al. (2019) stated; ‘forced exercise is an accelerated exercise beyond the subject’s preferred pace during voluntary exercise and within a specified aerobic intensity range.’ Forced exercise interventions reported in the literature which have comprised motorised static cycling and will be henceforth referred to as assisted cycling in this section of the review. Although isokinetic and assisted cycling interventions are comparable insofar as the technology controls the speed of movement; isokinetic equipment requires the user to move against resistance whereas assisted exercise interventions assist the direction of movement (Pontes et al. 2019).

The earliest assisted cycling device reported in the literature was a static tandem cycle on which a physical trainer generated the cadence and power on the front seat whilst the research participants engaged in the assisted cycling action on the rear seat (Ridgel, Vitek and Alberts 2009). This model has been superseded by the motorised static cycle manufactured by global companies including Moto-Med and Thera-Trainer (Holzapfel et al. 2019, Alberts et al. 2011, Stuckenschneider et al. 2015). The user is supported in either a recumbent or upright seated position whilst their feet are attached to pedals and a motor generates the cycling action at a cadence determined by the user or operator. The user can apply their own lower limb effort in addition to the motor generated action; this will not influence the cadence, but the effort is detected by the technology and recorded as watts. The consistent cadence may promote more symmetric kinematics across both limbs which will benefit people with neurological impairment (Holzapfel et al. 2019). Much emphasis has been placed on the higher cadences attained during assisted cycling compared with voluntary cycling interventions (Linder et al. 2019, Alberts et al. 2011); the proposed neurophysiological impact of this is explored in section 2.3.3. Seated power assisted exercise machines, as described in the introductory sections and manufactured by Shapemaster, also assist movement at a consistent speed with multiple directions of movement involving all four limbs and the trunk assisted across a range of different machines (Bossink et al. 2017, Jacobson et al. 2012). However, the number of Repetitions Per Minute (RPM) is typically slower than reported for assisted cycling interventions.

2.3.2 Purpose

The purpose of this section of the literature review is to examine published research which has evaluated the immediate and longer term physiological and functional responses to assisted exercise interventions. The physiological demand of assisted exercise in terms of acute aerobic response and watts detected is summarised, followed by a review of evidence on its impact on aerobic capacity. Neurophysiological responses to assisted exercise are examined and the effect of assisted exercise on motor control, gait, balance and cognitive performance is reviewed. Various clinical populations including PwS, people with Down Syndrome and people with Parkinson's disease have been recruited to assisted exercise trials and are considered in this section. The focus of this section is on seated, assisted exercise devices. Studies which have examined robotic and exoskeleton devices are not included as the mechanical design and clinical implementation of these devices is substantially different to motorised static bikes or the PAEE manufactured by Shapemaster.

2.3.3 Real time intensity of assisted exercise

Research evidence dating back to the 1980's and 1990's indicated that the aerobic and physical demand associated with recumbent assisted exercise was not sufficient for gains in fitness or body composition (White and Bemben 2004). Given the uncertainties surrounding the physical demand of assisted exercise an examination of evidence which has measured aerobic effort or quantified physical output from users was required. Cardiopulmonary Exercise Testing (CPET) is the most accurate measurement method to evaluate the aerobic demand of a specific activity (Stoller et al. 2014a). To the author's knowledge, CPET measurement has not been conducted in real time during assisted exercise. Therefore, heart rate responses and watts generated during assisted exercise provide the most accurate reported measures of the real time intensity of assisted exercise.

Several studies have compared heart rate responses to assisted exercise with voluntary exercise. The mean heart rate recorded amongst a group of participants (n=5) with Parkinson's disease who engaged in 24 sessions of assisted cycling was 116.8 beats per minute, compared with 121.2 beats per minute recorded amongst the voluntary cycling group (n=5) (Ridgel, Vitek and Alberts 2009). Although this difference was not statistically significant (p=0.65), it should be noted that the mean age amongst the assisted cycling group was 58 years compared with 64 years for the voluntary exercise group. Since the relative intensity of exercise and heart rate responses is age adjusted (Lovell et al. 2009), the younger age combined with the lower heart rate responses reported for the assisted cycling group could indicate that the aerobic demand associated with voluntary cycling is higher than for assisted cycling. However, the mean heart rate of 116.8 beats per minute recorded amongst the assisted exercise group (mean age = 58) reflects an exercise intensity greater than 70% of their age predicted maximum heart rate which would challenge the cardiorespiratory system and lead to improvements in aerobic capacity (Lefeber et al. 2021).

In a more recent study on PwS, the percentage heart rate reserve reported amongst a voluntary exercise group (n=7) and assisted exercise group (n=7) was 55.9% and 56.6% respectively (Linder et al. 2017), indicating a moderate to high exercise intensity and minimal difference between aerobic responses to assisted and voluntary cycling. Similarly, the mean heart rate recorded amongst a group of nine participants with Parkinson's disease (mean age = 61.0 years) who engaged in a 50-minute session of assisted cycling was 120.5 beats per minute (Alberts et al. 2016). In contrast, the mean heart rate during assisted cycling amongst a group (n= 22) of PwS reported by Holzapfel et al. (2019) was 90.3 beats per minute which was only 27.8% of heart rate reserve. The motorised cycle used by Linder et al. (2017) was sensitive to user effort and adjusted the level of assistance accordingly, whereas the motorised cycle described by Holzapfel et al. (2019) sustained the selected cadence regardless of user effort. Alberts et al. (2016) used a static tandem with a physical trainer on the front to generate effort and sustain cadence. It is likely that the physical trainer responded to varying levels of effort generated by the participants in a similar way to the effort detection technology used in the Linder et al. (2017) study. Although these studies recruited only small numbers of participants and described different FITT prescriptions within the protocols, the collated findings indicate that assisted cycling can be a moderate intensity aerobic activity and that devices which are sensitive to user effort may be more effective at enabling attainment of a target heart rate.

Power or effort in watts recorded during aerobic exercise represents an absolute metric of user output. The existing research indicates that the watts generated during assisted cycling is slightly lower compared with voluntary cycling. A comparison between mean watts recorded from PwS randomised to either voluntary cycling or assisted cycling interventions reported a mean of 32.4 watts during assisted cycling and 35.8 watts during voluntary cycling (Linder et al.

2021). Lower values of 22.1 watts during assisted cycling and 26.6 watts during voluntary cycling amongst people with Down syndrome were reported by Holzapfel et al. (2015); the difference between the groups was not statistically significant (p=0.396). Watts recorded by a power meter on static tandem cycling devices amongst people with Parkinson's disease were higher, with mean wattage of 46.9 (Alberts et al. 2016) and 47.0 (Ridgel, Vitek and Alberts 2009) reported. Ridgel, Vitek and Alberts (2009) detected a greater difference in wattage between assisted and voluntary cycling of 47 (+/-16) watts and 67 (+/-24) watts respectively, although this did not meet statistical significance (p=0.17). However, it is possible that the small sample size combined with large standard deviations meant that this analysis was underpowered.

A commonality across the assisted cycling research is the higher cadence achieved during assisted compared with voluntary cycling. Tandem assisted cycling achieved a mean cadence of 85.5 RPM compared with 59.8 RPM (p=0.002) (Ridgel, Vitek and Alberts 2009). Motorised assisted cycling amongst PwS reported a cadence of 79.5 RPM compared with 51.5 RPM during voluntary cycling (p=0.001) (Holzapfel et al. 2019). A smaller difference of 74 RPM during assisted cycling and 59 RPM during voluntary cycling was reported by Linder et al. (2019), although this difference still reached statistical significance (p=0.008). The repetitions of each movement per minute on the seated PAEE used by Jacobson et al. (2012) was 12-14, indicating that the velocity of seated PAEE is slower than assisted cycling.

In summary, real-time heart rate and wattage data indicates that assisted cycling is an active form of exercise, although the average user effort required may be slightly lower than that generated during voluntary static cycling. There is substantial evidence that higher cadences are achieved on assisted cycling compared to voluntary cycling devices. The seated PAEE used in the trials by Jacobson et al. (2012) and Bossink et al. (2017) did not have effort detection technology and therefore no measure of wattage was available. Heart rate was monitored amongst people with profound intellectual and multiple disabilities during their use of PAEE, but the real time data were not reported (Bossink et al. 2017). Technological development of seated PAEE to detect user effort and monitor heart rate responses is required to quantify the real time physical responses to this novel form of exercise.

2.3.4 Impact of assisted exercise on aerobic capacity and muscular performance

Longer term physiological responses to assisted exercise interventions can be established from studies which have adopted a graded exercise approach within the protocol. Ridgel, Jerrold and Alberts (2009) estimated V02max through application of a submaximal ergometer test in a group (n=10) of people with Parkinson's disease who were randomised to an eight-week assisted cycling or voluntary cycling intervention. The baseline estimated VO2max was 26.1 mL/kg/min amongst the assisted cycling group and 22.5 mL/kg/min for the voluntary cycling participants, with 11% and 17% improvement in aerobic capacity reported respectively. The 6% difference in improvement recorded between groups was non-significant, although the post intervention data was not included in the article. The estimated values and incomplete reporting of aerobic performance data from this study makes it difficult to draw firm conclusions regarding the impact of the eight-week programme on aerobic capacity.

Maximal exercise testing using CPET technology was used by Linder et al. (2015) in a case study on a 46-year-old male who was 10 months post stroke. His baseline VO2Peak was 13.7mL/kg/min and this increased to 17.8mL/kg/min following 24 sessions of assisted cycling during an eight-week programme. Improvement in 6MWT performance corroborated this improvement in aerobic capacity with an increase from 367m to 410m. A subsequent pilot study to compare assisted cycling (n= 6) and voluntary cycling (n=6) combined with Repetitive Task Practise (RTP) reported 1.3mL/kg/min and 2.4mL/kg/min increases in VO2Peak respectively (Linder et al. 2017). The improvement amongst the voluntary exercise group did reach statistical significance ($p<0.01$) although the increase reported for the assisted cycling group was non-significant. The 6MWT data collected from this study were combined with a further RCT which implemented a matched protocol (Linder et al. 2021). The collated findings reported significant improvements in 6MWT performance across the assisted and voluntary exercise groups of 63m and 31m respectively. Although this data implies greater improvement occurred amongst the assisted cycling group, a clinically detectable difference in baseline values between the groups was noted indicative of more severe mobility impairment amongst the voluntary cycling (296m) compared with the assisted cycling (417m) group. This may have obscured the impact of the cycling interventions on aerobic performance as assessed through the 6MWT.

Neither of the studies conducted on seated PAEE used CPET testing, although weekly resting heart rate and oxygen saturation (SaO2) levels were recorded on people (n=19) with intellectual and multiple disabilities who engaged in a 20-week programme of seated PAE (Bossink et al. 2017). A significant increase in mean SaO2 from 90.9% to 96.3% was reported, indicating an improvement in oxygen uptake and transportation associated with the exercise. Bossink et al. (2017) did not explore the possible physiological mechanisms by which this increase in SaO2 may have occurred. One possible explanation is that the seated PAEE machines which assist lateral flexion and rotation of the trunk may have mobilised the thoracic cage and therefore improved lung capacity.

Muscular performance was the focus of a randomised study on a 12-week programme of seated PAEE amongst a group of older adults (n=27) (Jacobson et al. 2012). The intervention protocol emphasised concentric muscular effort to avoid delayed onset muscle soreness associated with eccentric muscular activity. Significant improvements in muscular endurance during repeated arm curl, bench press, leg extension and triceps extension techniques were reported. The testing protocol involved performance of full repetitions against resistance as described by Golding, Myers and Shinning (1989). However, the intensity of effort instructed during delivery of the intervention and measures to optimise the reliability of testing were not described by Jacobson et al. (2012).

In summary, the available evidence indicates that assisted exercise prescribed at a targeted intensity with monitoring can lead to mid- term gains in aerobic performance, but these may be slightly lower than the improvements gained from voluntary exercise. Reporting of aerobic outcomes associated with assisted cycling and seated PAE has been a secondary outcome in the studies cited above. Similarly, to the author's knowledge, the impact of assisted cycling or exercise on muscular performance in terms of strength, endurance or power has only been addressed by Jacobson et al. (2012). Given the importance of combined resistance and aerobic interventions to optimise physical outcomes for PwS (Pogrebnoy and Dennett 2020), further examination of the efficacy of assisted exercise interventions on aerobic and muscular performance should be identified as a research priority.

2.3.5 Neurophysiological Responses to Assisted Exercise

Exploration of the impact of assisted exercise on neurophysiological responses originated from an incidental observation of improved handwriting following a tandem cycling holiday by a person with Parkinson's disease (Alberts et al. 2016). Laboratory research has established that forced exercise, during which animals run at a faster than self-selected pace on treadmill devices leads to multiple physiological responses including synaptogenesis, improved mitochondrial performance, increased Brain Derived Neurotrophic Factor (BDNF), increased Glial cell Derived Neurotrophic Factor (GDNF) and increased dopamine availability (Alberts et al. 2011). The potential for assisted exercise to enhance neuroplasticity and improve motor control has been the focus of much of the research in people with Parkinson's disease, stroke or Down syndrome. However, it should be noted that the laboratory mechanism of forced exercise during which the animal has generated the extra speed without assistance is different to the clinical application in which the devices de-weight and assist the higher rate of movement.

A mechanistic study which aimed to compare the acute effects of assisted cycling to the effects of antiparkinsonian medication on patterns of brain activity using functional Magnetic Resonance Imaging (fMRI) reported a strong correlation between percentage signal change between the 'on-medication' condition and immediately following a bout of assisted cycling (Alberts et al. 2016). Participants (n=9) completed a 10-minute warm up followed by a 40-minute main set at 80-90 RPM at a target heart rate of 65-80% of age predicted maximal heart rate. The fMRI detected increased signalling in the supplementary motor cortex, primary motor cortex and basal ganglia; in addition, a 48% improvement in the Unified Parkinsons Disease Rating Assessment Scale (UPDRAS III) was reported (p=0.001). This compared to a 37% improvement measured following administration of antiparkinsonian medication (p=0.002). Examination of the exercise protocol indicated that no cool down was included at the end of the workout and fMRI was initiated within five minutes of termination of the exercise. Future research could measure whether inclusion of a cool down diminishes the responsiveness of the central nervous system and examine longevity of effect.

The impact of assisted cycling on upper limb motor function has been explored in multiple studies. Immediate and accumulative improvements in upper limb function have been associated with assisted exercise (Linder et al. 2019, Holzapfel et al. 2019, Holzapfel et al. 2015, Ridgel et al. 2009). The protocol conducted on PwS (n=20) described by Linder et al. (2017) comprised a 45-minute assisted cycling session, including warm up and cool down, at a cadence 30% greater than self-selected RPM followed by a 45-minute session of RTP. Fugl Meyer Assessment indicated significantly greater improvements in the assisted cycling group compared with the voluntary cycling and no cycling groups. Immediate improvements in upper limb dexterity following a single bout of assisted cycling amongst participants with Down syndrome (n=18) were reported by Holzapfel et al. (2015). Greater improvements in reaction time amongst people with Down syndrome were reported following an eight-week assisted cycling programme compared with voluntary cycling (Ringenbach et al. 2016). Due to heterogeneity between outcome measures and diagnostic groups, comparison between the immediate and accumulative benefits of assisted exercise on motor function are difficult to examine. However, a review of seven studies focussed on assisted cycling amongst people with Parkinson's disease (n=179) concluded that longer programmes of eight-week duration or more were more effective than short or single interventions (Evens and Clark 2017).

The effect of assisted cycling on upper limb motor function does indicate centrally mediated responses to assisted lower limb exercise. Holzapfel et al. (2019) compared the effect of assisted cycling with voluntary cycling on lower limb motor coordination. The lower extremity motor coordination test detected significant improvements in the paretic and non-paretic lower limbs following a bout of assisted exercise, compared with improvement in only the non-paretic lower limb following voluntary exercise. The bilateral improvement associated with assisted cycling was attributed to the more symmetric kinematics facilitated by the motorised device.

In summary, there is substantial evidence supportive of the hypothesis that assisted exercise may stimulate centrally mediated responses which enhance neuroplasticity and motor control to a greater extent than non-assisted aerobic exercise. The protocols described by Linder et al. (2015) and Linder et al. (2017) combined assisted cycling with a programme of upper limb RTP. The improvements in motor control were attributed to increased intrinsic and extrinsic feedback associated with assisted cycling at a high cadence. This approach was recommended for PwS to simultaneously decrease cardiovascular risk factors and enhance motor recovery. The effect of seated, whole body PAE on motor control has not been explored. It is possible that the lower velocity of movement assisted on seated PAEE may not stimulate the same neurophysiological response as reported for assisted cycling. However, it is possible that the intrinsic, proprioceptive stimulation of whole body, multi-directional assisted movement will trigger a central response and this question represents an area for further investigation.

2.3.6 Impact of assisted exercise on mobility and balance

The impact of assisted exercise on mobility outcomes has been directly evaluated in three publications (Shen et al. 2018, Stuckenschneider et al. 2015, Jacobson et al. 2012). A systematic review and meta-analysis conducted by Shen et al. (2018) included 19 RCTs (n=1099 participants), all of which were conducted in China and reported on the effect of assisted cycling on the recovery of mobility within the first three months of stroke. Meta-analysis indicated a mean 0.85 improvement in FAC score compared with control groups which was statistically significant (p=0.00001). The intervention protocols comprised assisted cycling combined with conventional therapy. The frequency and duration of assisted cycling sessions was varied across the different studies with limited reporting of target intensity. The FAC provides an indication of ambulatory independence, but is insensitive to changes in gait symmetry, stride length or velocity. Stuckenschneider et al. (2015) conducted a detailed analysis of the impact of active and passive assisted cycling on gait parameters amongst people with Parkinson's disease (n=24). Statistically significant improvements in gait velocity, stride length and monopedal stance phase were reported amongst both groups following a 12-week programme. Improvements were sustained at 12-week follow up amongst the active assisted cycling participants, but not the passive assisted cycling group.

Seated exercise on PAEE manufactured by Shapemaster was associated with improvements in the TUG and BBS amongst a group of ambulant older adults (n=53) (Jacobson et al. 2012). The mean TUG scores recorded from participants randomised to the 12-week programme decreased from 13.52 seconds to 10.57 seconds (p=0.013) and the BBS scores improved by 33%. Potential for bias within this study was identified as there was no blinding of assessors and procedures to optimise reliability and validity of data collection were not described. However, the findings reported by Jacobson et al. (2012) indicate that seated PAE may have a positive impact on mobility and balance.

In summary, assisted cycling interventions are associated with improvements in aerobic capacity, walking endurance and mobility amongst PwS or Parkinson's disease. There is also substantial evidence to indicate that assisted cycling interventions stimulate centrally mediated responses which lead to an increase in neurotrophic factors and neurotransmitters. These neurophysiological responses have been attributed to the higher cadence achieved during assisted exercise which enhances proprioceptive feedback. Assisted cycling as a precursor to RTP has been recommended as a treatment model. There has been limited investigation into the impact of assisted cycling on muscular performance and strength and this represents a gap in the published literature. Seated, multi-directional PAE has been associated with improved balance, mobility and oxygen saturation. The PAEE used in the reported studies did not feature effort detection technology, and therefore, quantification of user performance was not possible. Future research should examine the aerobic and neurophysiological responses to multi-directional PAE and muscular responses to assisted cycling interventions. The introduction of effort detection technology to PAEE will enable more precise prescription of exercise intensity and monitoring.

2.4 Co-Design and Usability Testing in Stroke Technologies

User involvement in the design and testing of technologies intended for PwS is associated with an enhanced understanding of the user perspective and the development of better-informed prototypes (Williamson et al. 2015). Early, structured and sustained involvement of key stakeholders should be central to the development of new rehabilitation technologies (Charles and McDonough 2017). Components of good practice in user involvement include relationship building in an accessible venue, use of plain language and regular communication. User involvement activities should be substantially resourced to enable availability of experienced researchers, payment to participants and good standards of hospitality (Williamson et al. 2015). The following section of the literature review represents a summary of reported co-design and usability testing methods implemented to develop technologies for PwS. A critical review of design models and approaches is included in chapter four.

2.4.1 Co-design approaches

The importance of understanding the home environment and support network from the perspective of the end user has been emphasised in examples of co-design with PwS (Nasr et al. 2016). The preliminary phase of co-designing a robotic device for repetitive hand and wrist movement comprised the introduction of cultural probes into the homes of six PwS across the UK, Italy and The Netherlands. Factors likely to influence engagement with technology in the home included personal relationships, previous use of technology, physical capability and rehabilitation goals. Participants identified multiple features expected of a home-based technology including easy storage, adaptability to different capabilities, real time feedback on performance and regular monitoring by a rehabilitation professional (Nasr et al. 2016). The importance of feedback and encouragement whilst engaging with home-based rehabilitation technologies was also emphasised by PwS and carers interviewed during the development of 'ActivABLES,' a novel technology intended to promote engagement with home-based exercise for PwS (Olafsdottir et al. 2020).

A quantitative approach towards capturing users' priorities and expectations of an upper limb gaming technology was adopted by Na et al. (2016) who recruited PwS (n=10) to complete a pre-game survey. Comparable with findings from Nasr et al. (2016) and Olafsdottir et al. (2020), the importance of regular monitoring from rehabilitation professionals was highlighted, alongside ease of use, appropriate level of difficulty and motivating games. The importance of non-intrusive technologies which can be integrated with daily routines and be accepted by all members of the support network was emphasised during qualitative interviews (Olafsdottir et al. 2020, Nasr et al. 2016). Although the participants were community dwelling and, in many cases, discharged from formal rehabilitation, clinical feedback was important indicating that medical endorsement of new technologies is expected by users (Olafsdottir et al. 2020, Nasr et al. 2016, Na et al. 2016). The three studies cited above implemented early user involvement in the co-design of novel technologies, however, the extent to which the findings were translated into the development of prototypes was not directly reported.

The double diamond model (Design Council 2019) was used by Jie et al. (2019) to adapt the user interface on a gait sensor feedback system for use by PwS. The preliminary discovery phase entailed a search of the evidence base to understand the characteristics of the stroke population and identify the features of user interfaces from related projects (Jie et al. 2019). Priority features included large font, high colour contrast, use of pictures and large icons. The focus on interface features and characteristics of PwS was different to the preliminary evidence synthesis conducted by Olafsdottir et al. (2020) which focussed on the development of the intervention rather than technological features. The comparison between these two projects exemplifies the diverse application of co-design approaches in the development of new technologies for PwS, ranging from user interface design (Jie et al. 2019) to the introduction of a multi-component exercise intervention with supporting software and hardware (Olafsdottir et al. 2020).

The implementation of cultural probes into the home environment did facilitate in-depth exploration of day-to-day life for PwS (Nasr et al. 2016). Factors likely to influence engagement with technology were multi-faceted and included relationships, previous use of technology, physical capability, information technology literacy and goals. Participants shared that their relationships had been strained and changed by stroke and that the adoption of a new technology would be a network rather than individual decision. Qualitative data captured from PwS were also central to the development of the ActivABLES intervention developed by Olafsdittier et al. (2020). The participants with stroke emphasised that they wanted technologies to help to manage the challenges associated with physical impairment and to frame exercise within the context of everyday life. These priorities were at the centre of the design of the prototype ActivABLES technology and evaluation included follow up interviews with PwS and caregivers to explore the extent to which the priorities articulated during the co-design phase had been achieved.

Exploration and examination of early prototypes by representative users can stimulate discussion regarding design features and anticipated usability (Moineau et al. 2021). This process is distinct from summative usability testing during which participants are required to complete designated tasks on a functioning prototype (Dumas and Reddish 1999). The perspectives of end users including clinicians on a Functional Electrical Stimulation (FES) garment were interpreted through an inductive content analysis of data collected during focus groups which included a visual and tactile inspection of the technology (Moineau et al. 2021). Suggestions included an emergency ‘off’ button and easy to use openers or fasteners to enable don and doff. Discussion regarding acquisition and commercialisation of the technology emphasised the importance of education, training and sustained end user support (Moineau et al. 2021). No supporting framework or model underpinned the methods implemented in this study and the garments were not donned or doffed, an activity which would have generated broader discussion surrounding design and ease of use. Description of the focus group procedure was very limited with no details of topic guide, participant combination or numbers reported. However, practical suggestions to enhance viability of the technology were generated alongside consideration of a commercialisation strategy.

In summary, examples of co-design methods conducted with PwS have implemented qualitative methods to understand users’ priorities. Recurring themes expressed by participants include ease of use, clinical monitoring and goal oriented. Data collection methods have mostly comprised focus groups and interviews with PwS and caregivers. This may have disadvantaged representation from people with communication or cognitive impairment (Luck and Rose 2007). Purposive sampling to ensure inclusion of people from diverse socioeconomic or cultural backgrounds was not reported which may have biased the perspectives shared by recruited participants (Kannan et al. 2019). Although participants were invited to explore and evaluate early prototypes, data collection activities did not include artefact creation or evaluation which may have facilitated two-way communication between participants and the research teams (Cappelen and Andersson 2021). In some examples cited above (Moineau et al. 2021, Nasr et al. 2016), a specific model or theoretical framework to underpin product design and development was not identified which may have compromised the structure and rigour of data collection and analysis.

2.4.2 Usability evaluation

There are multiple examples of usability evaluation conducted on technologies for PwS including robotic devices (Nasr et al. 2016), virtual reality games (Na et al. 2016) and exercise programmes (Olafsdittir et al. 2020). The 'BrightBrainer Grasp' is an adapted game controller designed to enable PwS to engage in a virtual reality gaming system to train cognitive and motor function (Burdea et al. 2021). The newly developed prototype with a suite of graded games was evaluated through observation of errors, timeout occurrences and a customised feedback questionnaire. Two healthy participants with no neurological impairment attended four sessions during which they were instructed to progress towards more challenging games with reduced verbal guidance. Burdea et al. (2021) justified the selection of healthy participants to avoid bias associated with cognitive and motor impairment. However, usability evaluation should include participants who are representative of the user population (Dumas and Reddish 1999). The healthy participants recruited by Burdea et al. (2021) reported that the device was easy to use and that they did not experience fatigue associated with the intervention. It is likely that inclusion of PwS would have identified additional limitations with the technology associated with stroke related impairment.

Na et al. (2016) evaluated a Kinect P5 glove designed to enable engagement with virtual reality games for PwS. The House of Quality process was adopted to guide development of the product through user engagement to identify priorities and create a step-by-step plan (Hauser and Clausing 1988). Ten community dwelling PwS participated in a pre-game survey and usability evaluation of the technology. The priorities identified included proven clinical efficacy, motivating games and clinical scoring. Participants reported that the glove was difficult to don, although they enjoyed the gaming intervention. Usability was not quantified in terms of task completion, task duration or error occurrence (Na et al. 2016). In contrast, observation of errors during use of the 'BrightBrainer Grasp' informed the subsequent iteration of the technology which included an increase in visual cues and recalibration of the gaming controller (Burdea et al. 2021).

Return to computer use is an important goal for many PwS but challenges associated with use of a conventional mouse can impede its attainment. The 'Nouse' was developed to enable PwS to engage in computer use through head tracking (Mah et al. 2015). Ten PwS participated in a usability evaluation of the technology which comprised task completion, task duration and a satisfaction questionnaire adapted from the Post Study System Usability Questionnaire (PSSUQ) (Sauro and Lewis 2016). Task completion ranged between 50% to 100% and task duration data were varied between participants. The PSSUQ responses indicated high levels of overall satisfaction, although the ease of use and functionality sections attained lower scores (Mah et al. 2015). This usability evaluation was not underpinned by an identified design framework or model and there was disproportionate representation of younger males in the sample.

Robotic devices have the potential to enable RTP within the home environment, however, bulky, expensive equipment has limited implementation. Nasr et al. (2016) developed a prototype robotic device guided by their in-depth exploration of participants' everyday lives and environments. The prototype was introduced to two participants within their home environment to capture preliminary feedback on usability. Both participants required assistance to don the device and expressed that they would prefer to be able to do this independently. Different perspectives regarding feedback and scoring were articulated, demonstrating diversity of preferences amongst even a very small sample. The usability of a soft robotic glove designed to detect and assist intended hand movement was evaluated by 10 PwS during a six-week trial in the home environment (Palmcrantz, Plantin and Borg 2020). The usability was evaluated through weekly, structured telephone interviews and an end of intervention semi-structured interview. Reported usability of the glove was varied across the sample and some participants had discontinued use; reasons included difficulties with donning, limited perceived effectiveness and unforeseen personal circumstances. However, some participants reported that the glove had helped with ADL and improved hand function. The robotic technologies evaluated by Nasr et al. (2016) and Palmcrantz, Plantin and Borg (2020) were both tested in the home environment and captured qualitative insights into the user experience. However, quantitative examination of the technologies was very limited. Observation of prescribed tasks or activities may have highlighted specific usability issues which would have informed development of the technologies.

Walking, physical activity and ADL are often central to the goals identified by PwS; technologies which promote engagement and provide feedback in these activities may enhance rehabilitation outcome. 'Stappy' is a sensor mediated technology designed to give feedback on walking and the double diamond model (Design Council 2019) was adapted by Jie et al. (2019) to co-design and evaluate the device for PwS. Early prototypes were evaluated in the laboratory setting and participants were required to provide feedback on features including colours, readability, instructions, language and feedback. Summative usability evaluation was not reported in the article published by Jie et al. (2019) although the findings from the formative evaluation did guide the development of the technology.

The design and evaluation of ActivABLES, the multi-component therapeutic exercise programme intended for use by PwS in the home environment (Olifsdittir et al. 2020) was underpinned by the Medical Research Council framework for the development of complex interventions (Craig et al. 2008). ActivABLES was evaluated by a purposive sample of seven community dwelling PwS within the home setting. Qualitative interviews indicated that the technology did facilitate integration of therapeutic activities into activities of daily living and increased user motivation. The use of lights, music and games within the biofeedback was effective, however, caregivers reported that there was a lack of resources to assist exercise (Olifsdittir et al. 2020). The methods reported by Jie et al. (2019) to develop ‘Stappy’ and Olifsdittir et al. (2020) to design ‘ActivABLES’ were underpinned by widely established frameworks which ensured a structured and iterative approach towards design and evaluation (Design Council 2019, Craig et al. 2008). However, quantitative evaluation of usability was limited in the published reports.

‘Sleepio,’ a digital cognitive behavioural therapy intervention for insomnia was evaluated by a sample of 11 PwS (Smejka et al. 2022). Unlike the technologies described above, ‘Sleepio’ was not developed specifically for PwS or neurological impairment. Nine participants did complete the programme, although several required support from their caregivers to navigate the intervention and some activities, for example, progressive muscle relaxation, were difficult for people with neuromotor impairment (Smejka et al. 2022). It was concluded that a supplementary resource tailored to the needs of PwS would enhance its usability amongst the stroke population. Smejka et al. (2022) conducted qualitative, semi-structured interviews to evaluate the experience of using the technology, although specific design limitations were articulated by participants which may inform future developments of the programme interface.

In summary, there are several examples of qualitative and quantitative usability evaluation on stroke technologies which have guided product iteration and development. The methods and approaches reported range from discrete, clinic-based usability tests (Mah et al. 2015) to longer term trials in the home environment (Olafsdittir et al. 2020). Burdea et al. (2021) described specific changes to their robotic technology guided by observation of task performance. However, the extent to which usability evaluation influenced the subsequent iteration of technologies was not reported by most of the authors cited above. The studies cited above recruited small samples, although diverse perspectives on the usability and perceived value of the technologies were articulated (Palmcrantz, Plantin and Borg 2020, Nasr et al. 2016). Identification of and alignment with established frameworks for co-design and usability testing was limited in most cases. There is a need to develop and implement a more structured approach to usability evaluation in rehabilitation technologies to ensure robust methods of observation are combined with meaningful capture of the user's perspective.

PART TWO: METHODOLOGIES AND PUBLICATIONS

Overview

Part two comprises chapters three, four and five and is focussed upon the methodologies and approaches which underpinned the six publications included in this thesis. Chapter three is focussed upon the feasibility study conducted at the outset of the doctoral programme. Chapter four reflects upon two qualitative outputs; a synthesis of qualitative research focussed on venue-based exercise followed by the phenomenological exploration of the lived experience of PAE amongst PwS. Chapter five includes articles four, five and six which report on the user involvement, co-design and usability testing methods implemented in the development of a new graphical user interface to advance PAEE for PwS.

A diverse range of methodological approaches have underpinned and guided the methods implemented throughout this programme of doctoral study. Phase one was aligned with a post positivist perspective, phase two adopted an interpretative approach and phase three was influenced by transformative principles through meaningful user engagement. The theoretical underpinnings for each phase are explored and critically discussed in each respective chapter.

Chapter 3 Phase One Feasibility Study

3.1 Introduction and overview

At the outset of this programme of research, anecdotal evidence of use of PAEE by people with complex neurological impairment existed, however, the safety and accessibility of the equipment amongst a neurological population was not reported. Feasibility studies in health research may aim to examine a specific intervention or the feasibility of a research protocol including participant recruitment, intervention delivery and outcome measurement. To establish the feasibility of PAE for PwS, an unfunded trial of the equipment was conducted on a convenience sample of people with complex neurological impairment. The PhD candidate (RY) negotiated free loan of the equipment to the University, developed the protocol and closely supervised two MSc students during delivery of the intervention and data collection.

Outcomes to evaluate the feasibility of assistive interventions for people with neurological impairment include accessibility, tolerability, acceptability, learnability, safety and risk (Kozlowski et al. 2017). The safety of an intervention is frequently measured through reporting of adverse incidents (Stuart et al. 2009), although Visual Analogue Scores (VAS) have been used to evaluate perceived safety by participants and caregivers (Burnfield, Cesar and Buster 2021). Completion rates and attendance are widely reported to evaluate the feasibility of both a study protocol and the intervention embedded within it (Quirk, Glazebrook and Blake 2018). Accessibility can be determined by the proportion of participants who proceed to use an assistive device at least once (Kozlowski et al. 2017). The additional reporting of assistance required to access an intervention as detailed in Article One represents a more novel approach to accessibility evaluation.

Acceptability is a widely used term in the evaluation of novel interventions and multiple definitions have been proposed. Sekhon, Cartwright and Francis (2017) aimed to develop the

Theoretical Framework of Acceptability (TFA) to guide the development of health care interventions. A temporal perspective was applied to reflect the prospective, concurrent and retrospective components of acceptability. Facets of the framework included perceived burden, intervention coherence and perceived effectiveness (Sekhon, Cartwright and Francis 2017). The framework has been implemented in examples from the mental health and public health literature (Sekhon and Straten 2021) through analysis of qualitative interview data. Although the TFA was not directly applied to the feasibility study reported in Article One, the content of the TFA has guided reflection outlined in section 3.4.

The purpose of the study reported in Article One was to investigate the feasibility of the PAEE intervention for people with neurological impairment. Feasibility was defined in terms of participant's ability to access the equipment, attain regular attendance and complete the programme. The secondary aim was to explore the participant's perceptions of the exercise programme through semi-structured interviews. Timed Up and Go data were recorded to provide an indication of mobility at baseline and upon completion of the programme to describe trends. Whilst feasibility studies typically recruit 30 or more participants (Brito et al. 2020), this unfunded study only recruited seven as it was deemed that the sample would enable the team to determine whether the intervention was acceptable and accessible for people with complex neurological impairment. Comparable feasibility studies with neurological populations have similarly recruited small samples to examine adherence with and completion of novel interventions [Kwok et al. 2022, Hollywood et al. 2022).

A mixed methods approach was implemented to collect quantitative and qualitative data which examined the feasibility of the intervention during a four-week programme. Attendance and interview data were analysed to determine the acceptability of the PAEE and identify ways in which it could be improved (Huynh et al. 2015). Adverse events were recorded to establish the safety of the exercise intervention. The assistance required to mount and use the PAEE was recorded to determine the accessibility of the equipment. The TUG performance was recorded prior to and at the end of the intervention to detect any change in mobility amongst the participants (Chan et al. 2017).

Seven participants were recruited; the completion rate was 100% with 96% attendance across all scheduled sessions. The therapist reported data indicated that the intervention was accessible for people with complex neurological impairment, although some assistance was required by participants with very limited mobility. No serious adverse events occurred, although mild symptoms including temporary shoulder pain and increased fatigue were documented. Interview data indicated that participants had enjoyed using the PAEE and felt that they had benefitted from it. The TUG performance improved across all participants who were able to complete the test. It was concluded that PAEE is safe for people with complex neurological impairment, although adaptations to improve accessibility were recommended and the assistance of therapists or suitably trained individuals may be required to enable people with very limited mobility to mount the equipment.

3.2 Methodology

3.2.1 Mixed Methods Research

A paradigm is a world view that represents the beliefs and values in a discipline and underpins the methods and approaches implemented (Shannon-Baker 2016). Described as 'a system of beliefs and practices that influence how researchers select both the questions they study and methods that they use to study them' (Morgan 2014), paradigms provide a framework from which researchers can align their values and choices (Creswell 2017). Historically, positivist and constructivist paradigms have represented two distinct worldviews, with positivism defined through scientific approaches which aim to objectively measure phenomena through quantitative methods and constructivism focussed upon understanding behaviours, social values and context through qualitative methods (Clarke and Braun 2013). However, research paradigms are not synonymous with qualitative or quantitative approaches as these terms guide methods of data collection and analysis rather than a worldview (Shannon-Baker 2016).

The emergence of mixed methods research, which spans multiple disciplines including sociology, education and healthcare has enabled researchers to know and understand the extent of a situation (Ozawa and Pogpirul 2013). It has been argued that the results generated through mixed methods research are greater than the sum of the parts (Crewell 2017). However, agreement on the philosophical position of mixed method approaches has not been reached (Shannon-Baker 2016, Ozawa and Pogpirul 2014). Multiple paradigms exist which could arguably align with mixed methods research including pragmatism, dialectics and critical realism. Pragmatism seeks to answer real world questions through balance between subjectivity and objectivity, dialectics is focussed on the convergence and divergence of perspectives and critical realism seeks partial theories on phenomena through identification of non-linear inference and patterns (Shannon-Baker 2016).

Several essential processes should guide mixed methods research which include (Creswell 2017);

- Collection and analysis of qualitative and quantitative data in response to research questions and hypotheses
- Integration of the two forms of data and their results
- Organisation of procedures into specific research designs
- Framing of procedures within a theoretical framework and underpinning philosophy

Multiple frameworks to guide mixed methods research have been proposed including sequential explanatory and convergent parallel (Ozawa and Pogpirul 2014). Sequential parallel methods are modelled on the initial collection of quantitative data which are subsequently explored through qualitative methods. In contrast, convergent parallel mixed methods collect quantitative and qualitative data simultaneously. Although the qualitative interviews followed the collection of quantitative data in the feasibility study (Article One), the quantitative findings did not shape the topic guide or content of the semi-structured interviews. Therefore, application of sequential parallel methods cannot be claimed, and the methods implemented align more accurately with a convergent parallel approach to data collection.

3.2.2 Epistemological and ontological position

Ontology is concerned with whether the social and natural worlds exist in a consistent way and the extent to which there is an external reality that exists independent of peoples' beliefs or understandings about it (Baskarada and Kornios 2018). Ontological positions exist along a spectrum which spans from realism to relativism. A realist perspective assumes a knowable world in which there is 'one truth' which can be established through application of appropriate research methods. In contrast, relativist ontology suggests that multiple constructed realities exist which are influenced by experiences, beliefs and the course of time (Clarke and Braun 2013). Multiple ontological perspectives are positioned along a spectrum between realism and relativism, including critical realism and pragmatism which frequently underpin mixed methods research (Deforge and Shaw 2012). Pragmatism is based on the investigation of real-world problems and aims to combine scientific methods of enquiry with values of democracy and social justice (Allemang, Sitter and Dimitropoulos 2022). Critical realism argues that behaviours and responses are influenced by local context and time, but demi-regularities which capture non-linear patterns and trends can be identified (Summers 2020, Deforge and Shaw 2012).

Pragmatism is focussed on enquiry into physical reality where there is a consequence for human life, recognising that environment and context influence human behaviours. Since health interventions are often intended to make practical changes in people's lives, pragmatism would appear to be a natural fit with health research (Deforge and Shaw 2012). The congruence between pragmatism and patient-oriented research has been highlighted through the mutual emphasis on democratic approaches and examination of human experience to build knowledge (Allemang, Sitter and Dimitropoulos 2022). However, disagreement about the nature of physical reality exists amongst pragmatists and consensus regarding the position of pragmatism along the positivist to pluralist continuum has not been reached (Zyphur and Pierides 2019, Deforge and Shaw 2012). Critical realism has evolved from the framework developed by its founding philosopher, Roy Bhaskar, who identified three domains; empirical, actual and real (Summers 2020). The empirical domain reflects observed, reported phenomena, whereas the actual domain represents what really happened, which may be different to what was observed and reported through research methods. The real domain acknowledges the invisible real, generative mechanisms which produce behaviours and responses (Deforge and Shaw 2012).

Mixed methods research is still in its infancy and in the absence of consensus regarding an underpinning paradigm and ontological position, it is arguably nothing more than triangulation (Baskarada and Kornius 2018). Realist approaches which seek to establish facts through observation of phenomena have been criticised for not acknowledging the value-laden nature of the human lens. The belief that quantitative methods are 'value neutral' has been described as naïve (Zyphur and Pierides 2019). However, the application of a realist position in mixed methods health research has been advocated over pragmatism due to pragmatism being based on serving purpose of the local context rather than uncovering the hidden reality behind phenomena (Allmark and Machaczek 2018). Critical realism arguably addresses this gap through application of the three underpinning domains and acknowledgement of unseen generative mechanisms (Summers 2020). Baskarada and Kornius (2017) emphasise the need to integrate elements of interpretivist and positivist ontologies with synthesis of the qualitative and quantitative lens to develop and new and consolidated viewpoint to underpin mixed methods approaches.

Epistemology is the study of the nature, scope and justification of knowledge (Bowleg 2017). An objectivist epistemology assumes variables can be impartially measured through deductive methods using surface level tools on participants who are viewed as subjects being studied (Mirhosseini 2018, Carter and little 2007). In contrast, constructivist epistemologies uphold that knowledge of any phenomenon should be contextually gained through processes of meaning making and iterative methods (Mirhosseini 2018). From a constructivist perspective, knowledge is created with participants and perpetually provisional. The epistemological contribution to research is theoretical but inescapable as assumptions which guide the creation of knowledge shape the selected methodology and underpinning theoretical frameworks (Bowleg 2017, Carter and Little 2007). Sport and exercise science incorporates physiology, biomechanics and psychology combined with multiple humanistic and environmental factors (McFee 2010). The creation of knowledge across a diverse spectrum of disciplines represents a challenge to those who seek to identify a consistent epistemological perspective (Carter and Little 2007).

Mixed methods research aims to combine and bridge elements of qualitative and quantitative research methods to benefit from the strengths of both. Pragmatism aims to utilise human experience to build knowledge and is accepting of different ways of knowing (Allemang, Sitter and Dimitropoulos 2022). However, writing in the context of educational research, Mirhosseini (2018) argues that pragmatism has dominated thinking in mixed methods research and alternative epistemological considerations have been marginalised. Health and exercise science appears to encounter the same challenge with the epistemological foundations of quantitative methods being incongruent with the philosophical assumptions which underpin qualitative approaches (McFee et al. 2010). In mixed methods research it is difficult to argue that the knowledge we seek is both experimentally objective and subjectively constructed (Mirhosseini 2018).

Analysis of the ontological and epistemological positions which underpin the mixed methods feasibility study (Article One) has facilitated application of the perspectives outlined above and reflection upon the methodology implemented. On initial inspection, a pragmatic approach could be assumed as the research team sought to investigate a real-world problem, using multiple data sources to determine whether PAEE is safe, accessible and acceptable amongst people with neurological impairment. However, pragmatism emphasises the importance of democratic processes with participants combined with explicit reflexivity on the environmental context and influence of humanistic factors (Allemang, Sitter and Dimitropoulos 2022). Examination of critical realism also revealed incongruence with the methods implemented in the feasibility study as there was minimal acknowledgement of the generative mechanisms which may have influenced participant engagement or exploration of causal mechanisms (Deforge and Shaw 2012).

The feasibility study reported in Article One assumed a tangible, physical reality surrounding feasibility of the intervention and the protocol was paternalistic comprising a pre-determined intervention and measurement methods. Although qualitative data were captured through semi-structured interviews, the implementation of framework analysis aimed to categorise and reduce the dataset rather than explore and expand upon the context of the reported experience (Ward et al. 2013). This approach is incompatible with the principles which define critical realism or pragmatism. Despite the qualitative strand within this mixed method study, it was based on a postpositivist worldview and an ontology which assumed an objective reality and sustained a detached relationship between the participants and the research team. The underpinning epistemology assumed an impartial observation of phenomena to create new knowledge without acknowledgement of wider context or positionality.

3.3 Article One

Power Assisted Exercise for People with Complex Neurological Impairment: A Feasibility Study

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Abstract

Background/Aims: Participation in physical activity and exercise presents a challenge for adults with complex neurological impairment. Power assisted exercise facilitates combined limb and trunk movement and may be a feasible exercise option for people with movement impairment. The aim of this study was to determine whether power assisted exercise is a feasible activity option for people with complex neurological impairment.

Methods: Seven adults with complex neurological impairment were recruited to take part in a four-week programme of twice weekly power assisted exercise. Programme attendance and completion was recorded and adverse events or effects documented. Mobility was monitored using the Timed Up and Go test (TUG). Upon completion of the programme, participants were interviewed regarding their experience of using the equipment.

Findings: All seven participants completed the programme and the overall attendance was 96%. No adverse events occurred; two participants reported minor adverse effects which were temporary. The TUG scores improved and participants enjoyed the programme, reporting perceived benefits in physical function and wellbeing.

Conclusions: The findings of this study demonstrate that people with complex neurological impairment can participate in a programme of power assisted exercise. Reported improvements in physical mobility suggest that further research in this area is indicated.

Key words:

Power Assisted Exercise; Neurology; Feasibility; Mobility.

INTRODUCTION

Long term neurological impairment results from disease or injury to the brain, spinal cord or peripheral nerves. It is estimated that ten million people in the UK have a neurological diagnosis; the most prevalent adult neurological conditions in the UK include stroke, Parkinson's disease, multiple sclerosis and traumatic brain injury (Neurological Alliance 2015). People who live with a neurological condition often experience impaired movement, sensory changes and communication difficulties. These symptoms can impact physical function, reduce independence, limit participation in recreational activities and severely affect quality of life (Perez et al. 2007).

Reported levels of physical activity amongst neurological groups are lower than the general population (English et al. 2014). Low levels of physical activity are associated with reduced physical fitness and aerobic capacity (Morie et al. 2010). Limited cardio-respiratory performance is a risk factor for the development of a range of comorbidities including heart disease and diabetes (Soares-Miranda et al. 2015, Gill and Cooper 2008). There is increased focus on the promotion of exercise and physical activity for people living with a neurological condition. Improvements in function, cardiovascular fitness and mental health are reported for neurological participants who have engaged with exercise programmes (Sandberg et al. 2016, Marzolini et al. 2014, Billinger et al 2012).

Most exercise intervention studies have excluded participants with complex or severe neurological impairment, stipulating independent mobility of at least 5 metres within the inclusion criteria (Sandberg et al. 2016, Marzolini et al. 2014, Latimer-Cheung et al. 2013, Billinger et al. 2012). Interestingly, the neurological population also perceive that balance and independent mobility are prerequisites for participation in an exercise programme (Simpson et al. 2011). However, it has been demonstrated that people with moderate or severe motor deficits can engage with and benefit from supervised exercise programmes (Kim, Lee and Lee 2014).

Barriers to exercise for individuals with a neurological condition include access to facilities and ability to use equipment (Simpson et al. 2011, Rimmer et al. 2008). The fitness industry is focussed on developing equipment and facilities which accommodate the specific needs of individuals with long term conditions (English Federation of Disability Sport 2017). Conventional resistance machines can be accessed by people with neurological deficits and are associated with improved agonist recruitment as the machine facilitates a linear motion (Vinstrup et al. 2016). However, the use of resistance machines does require a minimum level of activity to activate and sustain muscular contraction through the available range of movement that might limit their use by people with neurological deficits.

Research has explored the use of isokinetic equipment with neurological participants. Findings indicate that isokinetic exercise can improve strength performance for PwS, but its impact upon mobility and function is inconclusive (Chen et al. 2015, Lee and Kang 2013). Power assisted exercise machines are comparable to isokinetic equipment in that the machine generates the movement. The ethos of PAE is to offer an inclusive, client centred exercise experience as an alternative to more conventional exercise programmes. Power assisted exercise has been associated with increased muscular performance, balance and function in healthy older adults (Jacobson et al. 2012). The machines are designed to support the limbs and simultaneously generate bilateral movement; participants are encouraged to move with the machine to stimulate an exercise response from the cardiorespiratory and muscular systems. To date, the feasibility of a power assisted exercise programme for participants with a neurological condition has not been explored.

The primary aim of this study was to determine the feasibility of a power assisted exercise programme for individuals with complex neurological impairment. Feasibility was defined in terms of participant's ability to access the equipment, commit to regular attendance and complete the programme. The secondary aim was to explore the participant's perceptions of the exercise programme through semi-structured interviews. Timed Up and Go data were recorded to provide an indication of mobility at baseline and upon completion of the programme to describe trends.

METHOD

Setting

The feasibility study was located in the research suite at Sheffield Hallam University. Participants volunteered to undertake a four-week power assisted exercise programme through convenience sampling from two private physiotherapy services in Sheffield.

Ethics

Ethical permission was gained from the Faculty of Health and Wellbeing Ethics Committee at Sheffield Hallam University (SHU 66359) who permit research to be conducted within the institution in accordance with the Helsinki declaration of 1975 (revised in 2000). All participants provided informed, signed consent and understood that they could withdraw from the study at any time.

Participants

In order to be eligible for inclusion in the study participants needed to:

1. have a long term neurological condition
2. be able to transfer with assistance of one
3. be able to provide informed consent

Participants with significant cardio-vascular instability or other contraindications to exercise as identified by the American College of Sports Medicine (ACSM 2013) were excluded from the study.

Ten potential participants were provided with an information sheet and had the opportunity to discuss the study with the research therapists (ER and RY). Three people declined due to concerns regarding the time commitment. Seven participants were recruited and their respective General Practitioners' were contacted by the research therapists to gain approval for their involvement in the study. The anonymity and confidentiality of all data were assured through use of code numbers for each participant. The exercise programme was supervised by two physiotherapists (SV and ND) who were Health Care Professions Council registered. For monitoring purposes, blood pressure and heart rate were recorded at the start and end of each session to ensure that participants were working within recommended cardiovascular parameters as stipulated by the ACSM (2013)

Intervention

A four week programme of exercise was conducted in which participants attended a group session two times per week. Attendance was monitored and recorded by the research therapists. Two physiotherapists (SV and ND) supervised the exercise sessions and assisted participants on and off the equipment as required. Each exercise session lasted 40 minutes. During the first session participants were assessed to determine how much assistance was required to access the equipment. A step and some bolster cushions were used by smaller participants to enable access to the machines. Two participants with a history of stroke required additional straps to secure their paretic hand to the equipment.

Six PAE machines which facilitated upper limb, lower limb and trunk movements were used in this study (Figures 3 and 4). Participants spent 5 minutes on each machine and rested for approximately two minutes between each machine. In order to facilitate group support, participants attended the sessions together, meaning that the sequence of accessing each machine varied from one session to the next. Participants were advised to warm up by working at a Rate of Perceived Exertion (RPE) of three out of ten on the first machine. This was achieved by instructing participants to "move with" but not to try to "speed up" the machine.

The main component of the workout involved exercising on predominantly the seated machines. Participants were instructed to work at an RPE of six or seven out of ten. This was achieved by instructing participants to try to "speed up" the movement generated by the machines. The aim was to stimulate active assisted movements through concentric muscle contraction. A cool down phase was included by having each participant complete their work out on one of the supine lying machines. They were instructed to allow the machine to stretch the body without generating muscular activity. Figure 5 illustrates an example of a typical workout in terms of machine sequence and the targeted RPE. The duration of the exercises and guidance related to perceived effort remained the same throughout the course of the study.

1: Hip abduction/adduction plus shoulder horizontal abduction/adduction
2: Hip flexion/extension plus shoulder and elbow flexion/extension
3: Hip and knee flexion/extension plus elbow extension/flexion
4: Trunk flexion and extension plus hip flexion/extension

Figure 3: Seated machines (Article 1, Figure 1)

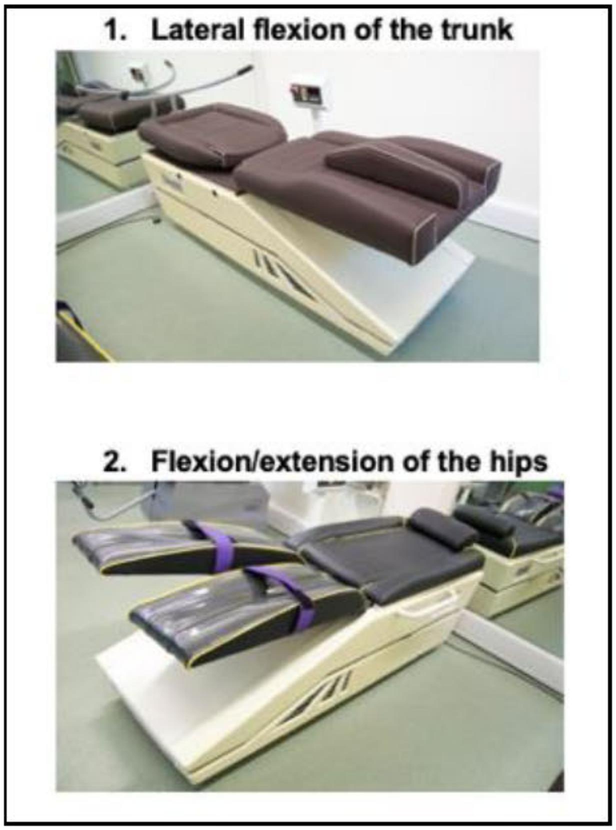

Figure 4: Supine machines (Article 1, Figure 2)

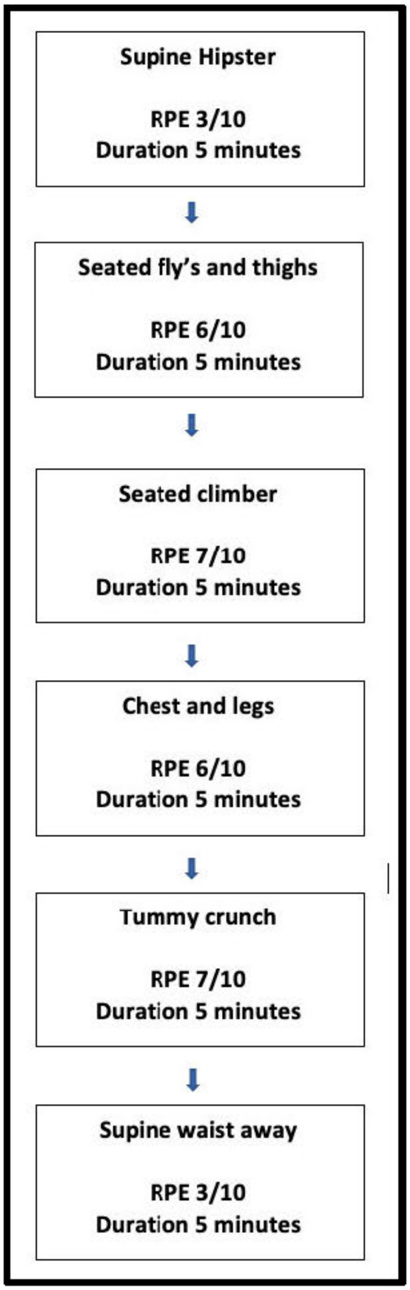

Figure 5: Exercise programme (Article 1, Figure 3)

Taxi transport was provided to access the facility on the university campus. The participants continued to receive their usual physiotherapy treatment during the intervention period.

Measurement

Feasibility was defined by attendance and ability to safely use the equipment. Attendance at the exercise sessions was monitored and adverse events such as falls, pain or individual concerns were recorded. Participants were asked at the start of the session to report if they had experienced any pain or discomfort following the previous session. They were also observed for any signs of pain during their exercise sessions. The amount of assistance required to use the equipment was noted for each participant.

The participant's experience of the exercise intervention was explored through semi-structured interviews scheduled one week following completion of the intervention period. All seven interviews were conducted by a physiotherapist (SV) in the participant's homes and recorded with a digital voice recorder. The topic guide detailed in Table 1 included questions related to their experience of using the equipment, perceived benefits, limitations and suggestions for future use.

Table 1: Topic Guide (Article 1, Table 1)

Perceptions of the equipment Were the machines easy to use? Did you feel safe and comfortable whilst using the equipment? Did you identify any limitations associated with the machines? Would you suggest any modifications to the machines?
Delivery of the exercise programme Did you enjoy working in a group or would you prefer a one to one session? How regularly would you like to use the equipment? Is five minutes per machine a suitable duration for each exercise? How much assistance or supervision is needed to use the machines safely?
Impact of the exercise programme Did you notice any benefits from using the machines in terms of your physical function? Did you experience any pain during or after the exercise session? Did you notice any unwanted or adverse effects from using the equipment? Would you continue with the exercise programme if it was available?

Mobility was assessed through the TUG test (Nilsagard et al. 2007). The test has been validated as a measure of balance and mobility amongst people with neurological deficits (Bonnyaud et al. 2015). One participant (PO5) did not have sufficient mobility to attempt the test, but did partake in the interviews. The TUG test was conducted upon the six remaining participants. A three metre walkway was measured and a 50cm chair with arms was positioned at the start point. Participants were allowed to use their usual walking aid to complete the test. Each participant was required to practise the test once before measurements were recorded. A five minute rest was scheduled between the practise and formal testing procedures. The test was timed using a stopwatch by the second research therapist. The TUG test was scheduled at baseline prior to the exercise programme and repeated at the end of the programme one hour following the final exercise session.

Data Analysis

Overall attendance and programme completion were calculated as a percentage score for each of the participants. Reported adverse incidents or responses were recorded in text format. Data recorded from the interviews were transcribed. Framework analysis was used to facilitate the grouping and synthesis of identified themes with individual cases. This method generates transparent results which can be related back to the original data (Ward et al. 2013). Following initial familiarisation with the data, VP and ND independently coded the first three interviews. The themes identified and agreed through this process were charted and case by case data from the remaining interviews were added by the first research therapist. The data were mapped and interpreted to generate a descriptive summary; specific quotes from the transcripts were selected to illustrate key points.

Data from the TUG were recorded for each participant at baseline and on completion of the four-week programme. The TUG data provided an indication of baseline ability in the sample and enabled observation of any mobility trends amongst the participants.

FINDINGS

Seven local service users volunteered to take part in the study and all participants completed the four week trial period. The age range of the participants was 30-84 years and the diagnostic backgrounds were multiple sclerosis, stroke or traumatic brain injury. Information regarding age, gender and diagnosis are detailed in Table 2.

Table 2: Participant Information (Article 1, Table 2)

Gender	Age	Diagnosis and code number	Type of motor deficit	Time since onset (years)
Female	73	CVA (P01)	Left Hemiparesis	5
Male	69	CVA (P02)	Left Hemiparesis	2
Male	84	CVA (P03)	Right Hemiparesis	3
Female	39	MS (P04)	Ataxia	8
Female	55	MS (P05)	Tetraparesis	17
Male	30	TBI (P06)	Ataxia	9
Male	54	TBI (P07)	Ataxia	14
Mean (SD)	**57.7 (17.6)**			**8.2 (5.1)**

Table Key: CVA = cerebrovascular accident; MS = multiple sclerosis; TBI = traumatic brain injury

Access and attendance

There was 100% completion with all seven participants finishing the four- week schedule. Attendance was 96% with all participants completing at least seven of the eight scheduled group sessions (Table 3). Four of the participants (P02, P04, P06, P07) were able to access the equipment with supervision only. The three remaining participants (P01, P03, P05) required assistance from the physiotherapists to mount the machines. A step and bolster cushion were used to facilitate access for these individuals. An adapted hand strap was used by P01 and P03 to enable attachment of their paretic upper limb to the machines. Once positioned on the machines, all participants were able to independently continue the machine assisted exercise.

Table 3: Attendance and support record (Article 1, Table 3)

Participant Number	Programme completion (yes/no)	Sessions attended (maximum 8)	Support required	Adverse event or effect
1	Yes	7	Assistance of one therapist to access machines. Step, bolster cushion and hand strap for seated machines.	None
2	Yes	7	Supervision	Shoulder pain post first session, resolved within 2 days
3	Yes	8	Assistance of one therapist to access machines. Hand strap for hemiplegic upper limb.	None
4	Yes	8	Supervision	None
5	Yes	8	Assistance of two therapists. Bolster cushion and hand strap for seated machines.	Increased fatigue reported
6	Yes	8	Supervision	None
7	Yes	8	Supervision	None
Total % completion	100%			
Total % attendance		96%		

Adverse events

No falls or adverse events occurred during any of the sessions. One participant (P05) reported increased fatigue during the course of the study; the participant was able to continue with the programme and attended all eight sessions. A different participant (P02) reported a brief episode of shoulder pain on the paretic side at the start of the programme; this resolved spontaneously and the participant was able to continue with the programme without interruption or adaptation.

Three central themes emerged through analysis of the data; experience of using the equipment, physical response to the programme and recommendations for future developments.

Experience of using the equipment

All participants confirmed that they had enjoyed the programme and looked forward to the sessions. The participants reported feeling safe whilst using the equipment, although two participants (P01, P05) did recall experiencing some anxiety about using the machines during the first session. The specialist support of a physiotherapist was important during the initial session for those participants with greater mobility restrictions (P01, P03, P05). The physiotherapists advised on the use of steps, bolster cushions and hand straps according to height and mobility. This helped reduce initial anxiety and facilitated sustained engagement with the programme:

> *I was anxious the first day; I looked at the equipment and thought 'goodness, I have to climb onto them.' But the step helped a lot and then I was okay after that.* (P01)

Following the initial session, there was variation in the perceived need for assistance to use the equipment. Two participants (PO2, PO6) reported that they felt that they could use the equipment without any direct assistance. Those participants with more significant motor impairment did indicate that they needed some physical assistance throughout the programme:

> *I needed help to get on and off the machines and also to secure my limbs with the extra strap. My left leg and arm would have kept flopping down without that strap.* (P03)

All participants thought that continuous supervision was required throughout the programme, but several commented that this would not necessarily need to be a physiotherapist:

I think we need someone to keep an eye and monitor what we are doing. I think we may not, say, need a physiotherapist; just somebody there to call on. (P07)

Feedback about the group activity was positive and the participants perceived that a friendly and supportive atmosphere was generated during the sessions. Communication and comparison between group members was important and several participants indicated that they gained confidence and reassurance through the support of other group members:

I think the group worked out well, we all came to know one another. I would prefer group work rather than one to one sessions for this type of exercise. (P02)

Six of the participants felt that two sessions per week was manageable and indicated that they would commit to a longer term programme on this basis. One participant with multiple sclerosis (P04) did experience increased fatigue following the exercise sessions;

I noticed my eyes getting foggy and headache and I think that's fatigue setting in. Overall I think doing twice a week might have been too much for me with my MS. (PO4)

Physical response to the programme

All seven participants stated a general improvement in their physical health during the intervention period. The perceived physical benefits included increased strength, decreased stiffness and improved symmetry. With the exception of P04, remaining participants described feeling energised during the course of the programme.

Decreased stiffness was reported by both participants with multiple sclerosis (PO4, PO5):

I feel it's made me much looser in my frame and I feel that I can move better. (PO5)

Two of the stroke participants also described feeling more flexible and linked this to the exercise programme:

The main benefit was stretching….feeling that the body was getting moved for the first time in ages. I liked the combined leg and upper body movements. (PO3)

All participants felt that their balance and symmetry improved during the programme. Specific Improvements in mobility and gait pattern were also described by three participants (PO2, PO6, PO7):

I feel like I'm taking better strides with my left leg, more equal. (P02)

I noticed that my walking is more controlled. I definitely feel more controlled when out and about. (PO6)

*I'm steadier and feel like I can walk a bit further. (*PO7)

Changes in leg strength were noted by several participants (PO4, PO5, PO6). One participant (PO5) with a diagnosis of multiple sclerosis and severe motor impairment reported enhanced lower limb movement and strength which was most apparent during regular hydrotherapy sessions:

It helps the strength in my thighs; when I have gone swimming I noticed a lot more activity in my bad leg and I have been able to use my thigh muscles more effectively in water. (PO5)

Pre-existing musculoskeletal symptoms appeared to respond positively to the intervention with three participants (P03, P05, P07) commenting that they had long term low back pain which noticeably decreased during the study. One participant (P01) with a history of stroke had a stiff and painful shoulder on her non-paretic side prior to commencing the study. This resolved during the intervention period with reported recovery of full, pain free range of movement in the symptomatic joint.

The routine monitoring of blood pressure and heart rate was reassuring for several participants. Although this data were not analysed, three participants reported that they had noticed decreasing trends in blood pressure and heart rate during the intervention period and this boosted their overall perceived health status:

> *I have always been concerned about my blood pressure so it was interesting to see it go down after a bit of exercise. I am glad that it seemed to do some good.* (PO5)

Recommendations

All seven participants suggested that the duration of each machine should be increased from five to approximately seven or eight minutes:

> *Probably a bit more time on each equipment. Well, you get used to it and you feel that effort is stretching you so you want it to continue because it's a good feeling like the movement in your body.* (PO3)

Two participants (PO2, PO6) also commented on the rate of the assisted movement, indicating that a graduated warm up and cool down would improve the effectiveness of the programme:

> *You build your heart rate up in the first three minutes and then down again. I really liked the way you could adjust the speed.* (PO6)

Adaptations to improve access to the equipment were suggested by several participants (PO1, PO3, PO5). The recommendations included fold away footrests, adjustable handles, adjustable range settings, and flat foot plates. The availability of an access step, bolster cushions and hand straps were also important for smaller participants (PO1) and those with severe motor impairment (PO2, PO5).

All seven participants reported that they would like to continue with the exercise programme and felt that this type of equipment should be available within community fitness settings or rehabilitation centres.

Mobility Measurement

Six of the seven participants completed the TUG. One participant (P05) did not have sufficient mobility to complete the mobility assessment. The range of baseline scores was 8.8 to 25.2 (mean 17.36) seconds. The follow up TUG scores recorded upon completion of the programme ranged from 7.1 to 22.4 (mean 11.96) seconds.

Table 4: TUG Results (Article 1, Table 4)

Participant	Pre Intervention TUG (s)	Post intervention TUG (s)	Pre and post intervention difference
PO1	15.0	14.3	0.7
PO2	8.8	7.0	1.8
PO3	25.2	22.4	2.8
PO4	18.1	13.1	5.0
PO6	19.0	7.9	11.1
PO7	18.1	7.1	11.0
Mean (SD)	**17.36 (4.9)**	**11.96 (5.48)**	**5.4 (4.19)**

DISCUSSION

Attendance and adherence

The primary purpose of this study was to determine the feasibility of using PAE for a neurological population This adds to a growing body of research focussed on exercise interventions with a neurological population. The unique contribution of this paper is the implementation of novel assistive equipment to explore its feasibility for people with complex, long term impairments. The participants in this study were varied in terms of age, neurological diagnosis and the nature of their physical impairment. They all completed the programme and the recorded attendance was 96%.

Exercise programmes with twice weekly sessions are associated with improved attendance and adherence when compared to more intensive schedules (Sandberg et al. 2016). Most of the participants felt that twice weekly sessions were manageable, although one participant (PO4) with multiple sclerosis did report increased fatigue related symptoms during the study period and suggested that one session per week would have been preferable. Evidence related to the impact of exercise upon reported fatigue in multiple sclerosis is inconclusive (Heine and Groot 2016, Latimer-Cheung et al. 2013). Future studies could explore the optimal frequency of power assisted exercise sessions in relation to the management of specific symptoms.

Other factors which may have supported attendance on the programme was the provision of transport and availability of professional personnel. Limited transport and concerns regarding staff expertise are recognised barriers to engagement with community based exercise amongst the neurological population (Rimmer et al. 2008). This aside, the attendance and completion recorded in this study indicate that the programme was enjoyed by the diverse group of neurological participants. No major adverse events were recorded and all participants were able to safely access and use the equipment. The reported shoulder pain was recorded as an adverse effect. The participant was monitored by the research team and the symptoms subsided quickly; no further occurrence was reported. Once the power assisted mechanism was started all participants were able to continue independently, enabling an autonomous exercise experience.

According to the TUG data collected at baseline, all except one participant had impaired mobility (Kear et al. 2017, Barron and Guidon 2011) and one participant was not able to complete the test. Most of the participants included in this study would not have met the mobility criteria for the larger studies which have investigated exercise interventions on neurological populations (Saunders et al. 2016).

Ploughman et al (2014) also recruited a heterogeneous population which aimed to measure the effectiveness of a community exercise programme for people with moderate to severe neurological disability. The 10-week intervention achieved a high completion rate of 93%; and 44% of participants continued to engage with the programme following the study period. These findings indicate that people with moderate or severe neurological disability can sustain engagement with exercise programmes.

Experience of using equipment

Previous research on the use of PAEE amongst older participants established that it is perceived as a non-threatening exercise option (Jacobson et al. 2012). The participants in this study reported that they enjoyed using the equipment and did not experience any notable physical discomfort during or after the exercise sessions. The participants were encouraged to generate an effort of up to 7/10 RPE but this was not quantified. Newer models of the manufactured equipment incorporate sensitivity to the force generated by the user and will provide visual and numerical feedback related to performance. Future research will process this additional data to enable more accurate analysis of effort muscular recruitment.

It has been hypothesised that PAE does not require eccentric muscle contraction as key muscle groups work concentrically with the direction of movement (Jacobson et al. 2012). Eccentric contraction can induce micro-injury at a greater frequency and severity than other types of muscle actions, causing delayed soreness following exercise (Cheung, Humpe and Maxwell

2003). The proposed avoidance of eccentric muscle contraction in power assisted exercise may contribute to its acceptability amongst complex populations. However, the importance of eccentric muscle contraction during every day activities such as sitting from standing is recognised; therefore, an effective exercise programme should include components of eccentric muscle work. The current study did not accurately record the muscular activity generated by participants; this could be the focus of future research.

The support of qualified personnel has been identified as a key facilitator for engagement with community based exercise amongst the stroke population (Simpson et al. 2011). The participants in this study felt that some level of professional support was required, but the continuous supervision and support of a qualified physiotherapist was not necessary. Future research could explore the staffing requirements for power assisted exercise programmes for people with complex neurological deficits.

Peer support has been identified as an important factor in sustaining engagement with exercise for neurological groups (Simpson et al. 2011). Power assisted exercise equipment does facilitate interaction between participants as users can see and speak to each other throughout the session. Group cohesion is correlated with adherence in exercise groups (Spink et al 2014). The participants in this study reported positive group support despite considerable variation in age and demographic status within the group.

Physical response

All participants interviewed in this study reported perceived improvements in their physical status. Participants across the three diagnostic groups felt that their balance and strength had improved. Improved flexibility was reported by those participants with a history of stroke or multiple sclerosis; in comparison, the participants with traumatic brain injury felt that their walking had improved. These perceived areas of improvement do concur with the mobility scores recorded through the TUG test as the participants with a history of traumatic brain injury demonstrated the greatest improvements, whilst those people with a history of stroke gained only marginal changes in TUG score.

The purpose of recording TUG scores on completion of the exercise programme was to observe overall trends in mobility as it is acknowledged that the small sample size does not enable valid statistical analysis of the numerical data. Observation of individual TUG data for the participants with a history of traumatic brain injury are comparable to that recorded by Vaz et al (2008) who implemented the test to monitor the impact of treadmill training on two comparable adults with ataxia. The possibility of a test learning component should be acknowledged in relation to these scores. The validity of TUG measurements could have been improved by calculating the mean time across three trials per participant (Bonnyaud et al 2015). Further research to explore the effect of power assisted exercise upon functional mobility is indicated.

Interestingly, the participants did not comment on their general levels of physical activity in relation to participation in the programme. This reflects a limitation within the topic guide as it would have been relevant to directly ask the participant about their overall physical activity levels. Previous research has identified a trend of decreased physical activity associated with the uptake of specific exercise amongst a neurological population (Elsworth et al. 2011). Exploring the effect of a PAE programme upon overall physical activity levels could be the focus of future studies.

Blood pressure and heart rate were monitored to ensure participant safety throughout the study. This data were recorded for screening and safety purposes only but the effect of power assisted exercise on health outcomes is an important area of enquiry. One participant specifically commented upon the downward trend in blood pressure over the course of the four weeks. It is possible that blood pressure may have been elevated during the initial sessions due to anxiety related to the new intervention (Edmondson et al. 2015); therefore, the observed reduction in blood pressure cannot be directly attributed to the exercise programme. Saunders et al. (2014) identify limited evidence related to exercise and blood pressure amongst the stroke population, particularly interventions which have included strength training. Future research could formally record and analyse blood pressure data.

Recommendations

Responses from interviews did generate numerous recommendations for the future development of the machines. All participants recommended that the default duration for each exercise should be set between 6-8 minutes. This would allow for a gradual warm up, an interval of intense activity and cool down on each machine. It was recognised that transition between the machines was difficult for some of the participants which may have contributed towards the perception that a longer duration on each machine would be preferable.

Limitations

It is acknowledged that this study was conducted on a small convenience sample. The diverse range of participants enriched the evaluation of feasibility, but valid statistical analysis could not be conducted on the TUG data. The duration of the study was four weeks; this enabled an evaluation of feasibility in terms of safe use of the equipment for this population group. The physiological effect and functional impact of the programme could be more accurately measured through the implementation of a longer programme. This would also establish whether sustained engagement with the intervention can be achieved.

The effort generated by participants and types of muscle contraction recruited were not measured. This limits the depth of physiological understanding related to power assisted exercise and also the impact of the programme upon physical performance during the study period. The programme did not incorporate any specific progression targets within the four week period. Future research could explore ways in which a power assisted exercise programme can be progressed to support the achievement of physical goals. Although the type of motor deficit was recorded for each participant, the severity of impairment was not measured. Future studies could aim to evaluate the longer term impact of a power assisted exercise programme with a neurological population with examination between severity of impairment and response to the programme.

Interestingly, the participants did not comment on their general levels of physical activity in relation to participation in the programme. This reflects a limitation within the topic guide as it would have been relevant to directly ask the participant about their overall physical activity levels. Previous research has identified a trend of decreased physical activity associated with the uptake of specific exercise amongst a neurological population (Elsworth et al. 2011). Exploring the effect of a power assisted exercise programme upon overall physical activity levels could be the focus of future studies.

CONCLUSION

This is the first study to explore the use of power assisted equipment for people with complex neurological disabilities. The study offers a unique contribution to the growing field of research evidence surrounding exercise with the neurological population. The diverse sample included participants with very limited mobility who would not have met the inclusion criteria for conventional exercise programmes. All participants completed the programme and the findings indicate that the sample experienced a positive response to the intervention. High attendance and minimal reporting of adverse effects indicates that PAE is a feasible option for people with complex neurological impairment. Power assisted exercise enables people to experience continuous movement without direct assistance and has potential as a cost-effective option for the neurological population. Further research to explore the physiological impact and longer - term effects of power assisted exercise upon the neurological population is required.

3.4 Summary

3.4.1 Reflection

Several limitations within the feasibility study reported in Article One are acknowledged. Due to limited time and resource, the inclusion criteria broadened from PwS to a wider neurological sample. The heterogeneity within the sample added breadth to the applicability of the findings but diverted from the specific focus on stroke. The participants were recruited from independent therapy services and therefore it can be assumed that they were invested in committing time and resource towards their continued recovery. It is possible that if participants had been recruited through alternative networks, the levels of engagement with the programme may have been different. The semi-structured interviews explored the acceptability of the intervention; however, the concept of acceptability was not defined at the outset of the project. The author has since become aware of the TFA developed by Sekhon, Cartwright and Francis (2017) and would implement this in future research focussed on the acceptability of an intervention.

3.4.2 Contribution

The feasibility study reported in Article One is a novel contribution to the literature and represents an essential component of this programme of research. Despite the limited time and resource, the research team achieved the aims which underpinned the study. Essential processes which guide mixed methods research were followed including the collection, analysis and integration of qualitative and quantitative data (Creswell 2017). The *International Journal of Therapy and Rehabilitation* aims to be an accessible, international resource for allied health professionals and provide a forum for new ideas. Publication of Article One in the IJTR represents a foundation for future research and development in multiple directions including product development, user experience, measurement of efficacy and implementation.

Chapter 4 Phase Two Qualitative Research

4.1 Introduction and overview

Engagement in exercise or physical activity interventions designed for PwS is influenced by multiple intrinsic and extrinsic factors including beliefs about capabilities, environmental context and social influence (Nicholson et al. 2014). Qualitative research methods aim to examine and explore people's experiences within the wider context and are therefore well suited to developing an understanding of perspectives on exercise (Hennink, Hutter and Bailey 2020). Having established the feasibility of PAEE, the research team sought to understand the experiences of venue based exercise amongst PwS. PAEE is available in selected leisure and therapy centres within the UK. Due to the size of the equipment and the commercially recommended operating model of a circuit of machines, PAE is a venue-based option and not a form of exercise which can be delivered within the home environment.

Models of exercise referral for clinical populations in the UK aim to manage and treat specific health conditions using supervised exercise over a set period and are most frequently delivered in leisure or public exercise venues (Rowley et al. 2018). Several small-scale qualitative studies have reported on the experiences of exercise referral or venue-based exercise programmes for PwS. The systematic literature review reported in Article Two aimed to organise and summarise the results of contextually rich studies through thematic synthesis to gain an in-depth understanding of venue based exercise from the perspective of PwS. Thematic synthesis comprises the identification of the main, recurrent or most important themes arising from a body of literature (Pope, Mays and Popay 2007). This method has been previously used to explore older people's perspectives on participation in physical activity which informed the recommendation of tangible strategies to enhance participation (Franco et al. 2015). Alternative approaches to synthesis of qualitative research include meta-ethnography and narrative synthesis (Pope, Mays and Popay 2007). However, challenges associated with meta-ethnography include reporting and judgement surrounding translation of content (France et al. 2019). Although narrative synthesis is a flexible method suited to the juxtaposition of multiple findings, it may be open to the possibility of bias due to dredging and over-interpretation of the data (Pope, Mays and Popay 2007).

The systematic review reported in Article Two synthesised the findings from seven publications and identified commonalities and differences associated with the experience of different models of venue based exercise amongst PwS. To build upon and apply the qualitative foundation developed in Article Two, an individualised understanding of the experience of using PAEE by PwS was identified as the next step in this programme of research (Article Three). Interpretative Phenomenological Analysis (IPA) is an approach utilised in qualitative research which emphasises the importance of lived experience and personal context in the exploration of human perspectives (Smith, Larkin and Flowers 2008). Interpretative phenomenological analysis has previously contributed to an understanding of the lived experience of somatosensory impairment following stroke (Connell, McMahon and Adams 2014). Given the unique experience of living with stroke and influence of contextual factors in the temporal adjustments which occur following stroke (Theadom et al. 2019), IPA was identified as an optimal approach to gaining an in-depth understanding of the individualised experience of using PAEE.

4.2 Methodology

Qualitative methods are historically aligned with the constructivist research paradigm which emphasises context, social values and the contribution of the individual. The synthesis of qualitative research has been academically contested as systematic reviews have been associated with positivism and an assumption that the accumulation of research findings will arrive at a single ‘truth’ (Florczak 2018). The meta-aggregative approach towards qualitative evidence synthesis is founded in pragmatism (Hannes and Lockwood 2011) and examples of pragmatic thematic synthesis have been published (Aerts et al. 2020, Franco et al. 2015).

Uncertainties surrounding the underpinning paradigm of thematic synthesis affect ontological and epistemological considerations. Qualitative research is aligned with a relativist ontology and subjectivist epistemology, and some authors of thematic synthesis have stated this position (Clarke and Braun 2013). However, in view of the pragmatic influences which shape some approaches towards qualitative thematic synthesis, consensus has not yet been reached. Qualitative synthesis entails a process of re-interpretation and re-analysis of findings to bring together and combine findings from several studies into a whole that moves beyond the findings of any individual study (Pope, Mays and Popay 2008). The review reported in Article Two aimed to collate and compare findings from individual studies to develop an overview of how PwS experience venue based exercise in the UK. It was not the intention of the research team to dilute the rich, relativist content within the original reports, rather to create a new layer of knowledge to capture the national picture and inform future practice.

Interpretative phenomenological analysis was developed from the discipline of psychology and has its roots within an interpretative research paradigm (McCormack and Joseph 2018). The emphasis upon an idiographic approach towards data collection, analysis and interpretation is aligned with a relativist ontology and a subjective, constructivist epistemology (Smith, Larkin and Flowers 2008). The researcher sought to uphold and sustain the principles which underpin interpretivist research throughout the gathering and interpretation of the rich data set, although elements of a positivist lens were evident, as exemplified through inclusion of mobility scores. A more detailed account of the methodology and methods is embedded within the content of Article Three.

4.3.1 Article Two

Experiences of venue based exercise interventions for people with stroke in the UK: a systematic review and thematic synthesis of qualitative research

Source: Physiotherapy, 2021, Vol 110

Authors: Rachel Young, David Broom, Karen Sage, Kay Crossland, Christine Smith

Abstract

Background

The physical benefits of exercise following stroke are research evidenced and the UK stroke population is increasingly encouraged to engage with exercise interventions. A synthesis of qualitative research is required to further understand the perceived experience and psychosocial effect of exercise for people with stroke.

Objectives

To provide a systematic search and synthesis of evidence about the experiences and reported impact of participation in venue based exercise following stroke in the UK.

Data sources

Eligible studies were identified through a rigorous search of Medline, Cinahl, AMED, PsycINFO, SportDiscus, Proquest and ETHOS from January 2000 until December 2017.

Study eligibility criteria

Full text qualitative studies or service evaluations conducted in the UK which explored the reported experience of venue based exercise amongst people with stroke.

Study synthesis and appraisal

Included studies were evaluated through application of the Consolidated Criteria for Reporting Qualitative Research. Data synthesis using a thematic approach generated descriptive and analytical themes.

Results

Six research studies and one service evaluation met the inclusion criteria; methodological quality was variable. These studies highlighted that people with stroke gain confidence and renewed identity through exercise participation. Perceived improvements in physical function were reported and participants enjoyed stroke specific exercise programmes in de-medicalised venues.

Limitations

The studies only accessed people who had completed the exercise programmes; non-completers were not represented.

Conclusion

Venue based exercise programmes have a positive effect on perceived wellbeing following stroke. Further research into the reasons for discontinuation of exercise participation following stroke is required.

Systematic review registration number: Prospero 2017:CRD42017072483

Contribution of paper

- This qualitative synthesis provides a detailed analysis of how people with stroke perceive their experiences of participation in venue based exercise programmes
- The review explores the reported impact of varied models of programme delivery; the findings are relevant to the development of future stroke specific exercise schemes

Keywords:

Stroke; Exercise; Qualitative; Venue; Systematic review.

BACKGROUND

There are 1.2 million people with stroke in the UK and it is a leading cause of disability (Stroke Association 2017). Between 2014 and 2017 there was a 2.9% increase in incidence of reported stroke and an 11.8% increase in the 50-59 year-old group (SSNAP 2016). The effectiveness of aerobic, strength or combined training interventions to optimise outcome following stroke are increasingly recognised (Royal College of Physicians 2016). Exercise following stroke leads to reduced physiological risk factors, improved physical function and mobility (D'Isabella et al. 2017, Saunders et al. 2016). Significant improvements in quality of life associated with exercise participation following stroke are reported (Dunn et al. 2017) and qualitative data related to the effect of exercise following stroke suggest that participants perceive improvements in physical function, participation and psychosocial wellbeing (White et al. 2013, Norris et al. 2013).

Engagement with exercise amongst the UK stroke population does not meet published recommendations (Paul et al. 2016, Billinger et al. 2014). It is recommended that people with stroke or Transient Ischaemic Attack (TIA) should engage in a weekly schedule of combined physical training and be supported in accessing exercise opportunities to improve fitness which is individualised and targets personal goals (Kim et al. 2019, Royal College of Physicians 2016). Exercise interventions can be delivered and sustained in the home environment but adherence does decline without the added support of venue based sessions (Jurkiewicz et al. 2011). There are various models of venue based exercise programme for people with stroke in the UK, including the national Exercise Referral Scheme (ERS) and these represent the advantage of equipment and space required for progressive strength and aerobic training (Rowley et al. 2018).

Exercise referral scheme participants from a range of diagnostic groups report improved mental wellbeing and increased personal autonomy associated with being part of a gym based programme (Morgan et al. 2016). However, there are also reports of ERS participants feeling intimidated in the traditional gym environment and long- term adherence to exercise referral programmes is less than 50% (Morgan et al. 2016). The transition from physiotherapy led stroke rehabilitation to exercise programmes supervised by fitness instructors exemplifies a sustainable delivery model; exercise professionals increasingly recognise the need to address the specific needs of people with stroke (Condon and Guidon 2018, Clague-Baker et al. 2018).

The barriers to exercise participation following stroke are complex and survivors can experience frustration when there is dissonance between their motivation and capability to be active (Morris et al. 2014). Multiple barriers to accessing the external world are reported following stroke including lack of confidence to navigate public settings and perceived stigma of disability (Reed et al. 2012). In order to understand the experiences of the UK stroke population when participating in venue based exercise programmes, exploration of relevant qualitative data were undertaken. This synthesis of qualitative data will enrich insight into the perspectives of people with stroke, inform the design of stroke specific exercise programmes and highlight areas for future research.

Aim

The aim of this review of qualitative data is to provide a systematic search and synthesis of evidence about the experiences and reported impact of participation in venue based exercise following stroke in the UK.

METHODS

Definition of a venue based exercise intervention

Preliminary scoping work facilitated the definition of the exercise intervention. For the purpose of this systematic review a venue based exercise intervention was defined as a programme based outside the individuals place of residency, delivered by a physiotherapist, exercise instructor or exercise professional. It was determined that the model of programme delivery could be in the form of a group or individual activity and the intervention should include elements of aerobic, strength or combined training to align with conventional components of an exercise intervention.

Review methodology

A thematic synthesis of included research was selected as it comprises the identification of the main and recurrent themes arising within a body of evidence (Pope, Mays and Popay 2008). This technique facilitates the organisation of qualitative data from selected studies and generates a summary of findings, whilst preserving the essential context of qualitative research (Thomas and Harden 2008). Thematic synthesis represents a process for identifying, grouping and summarising qualitative findings with lower risk of bias than associated with narrative synthesis methods (Pope, Mays and Popay 2007). The ENTREQ framework was used to guide the reporting of findings from the review (Tong et al. 2012). The methods are described in detail in the protocol that was developed and registered on the PROSPERO database (Prospero 2017:CRD42017072483).

Literature Search strategy

A comprehensive search was conducted between August and December 2017. The following databases were accessed: Medline, Cinahl, AMED, PsycINFO, SportDiscus, Proquest and ETHOS. Reference lists of selected articles were hand searched and authors were contacted in case of further publications. The grey literature search extended to contact with known researchers in the field. This generated contact with specific leisure service providers known to have reported on exercise interventions for people with stroke. Search terms included stroke, cerebrovascular accident, exercise, physical activity, exercise referral, qualitative, interview, perspective, focus group and opinion. Keyword and MeSH terms were integrated in the search process, the controlled search term strategy search can be accessed in supplementary materials (Appendix 2). In order to ensure currency of findings the search was limited to studies published from 2000. The search was led by the principal investigator (RY) with guidance from the information scientists at Sheffield Hallam University. The search process was summarised in a Prisma flowchart (Figure 6).

Eligibility criteria

The scope of the review was limited to the UK due to global variation in stroke service delivery (Johnson et al. 2016) and to contribute towards the evidence base on exercise uptake amongst clinical populations in the UK (Rowley et al. 2018). The inclusion criteria were: (1) studies which had recruited community dwelling people with diagnosis of stroke or TIA, (2) studies which had evaluated the impact of a venue based exercise programme located in a leisure, health centre or outpatient venue, (3) studies which had incorporated qualitative data collection methods, (4) studies which had adhered to a recognised research or service evaluation protocol.

The aim was to maintain a focus upon the experiences of venue centred exercise. Therefore, the following exclusion criteria was applied; (1) studies which evaluated inpatient programmes or exercise interventions delivered at the participant's home or place of residency, (2) studies which evaluated specialist rehabilitative technology, (3) studies focussed on gaming interventions or specific therapeutic approaches, (4) studies which included participants without a diagnosis of stroke or TIA.

Two reviewers (RY, KC) independently screened titles and abstracts to identify relevant studies which met the inclusion criteria for full text screening. Uncertainty regarding suitability for inclusion of selected publications was resolved through discussion with two other members of the review team (CS, DB).

Quality assessment

The consolidated criteria for reporting qualitative research (COREQ) was used to facilitate an explicit and comprehensive evaluation of study quality (Tong, Sainsbury and Craig 2007). The COREQ comprises a checklist devised to identify opportunities for bias, is well suited for focus group or interview data collection methods and more sensitive than alternative quality assessment tools (Peditto 2018). Two members of the review team (RY, KC) independently applied the 32- point criteria which evaluate the reporting related to research team, study design, analysis and findings. Since this review adhered to a thematic methodology, the quality assessment was used to inform the findings of the review and identify recommendations for future research. No publications were excluded due to methodological limitations.

Data extraction

Data extraction was standardised through development of a tabulated format adapted from Pope, Mays and Popay (2008). In line with the methods recommended by Thomas and Harden (2008), all text labelled as results or findings including participant quotes and author's interpretations were extracted for analysis and generation of themes.

Data synthesis

The data synthesis process followed three key stages; data coding, development of descriptive themes and generation of analytical themes (Thomas and Harden 2008, Pope, Mays and Popay 2007). An iterative approach was adopted by the principal investigator (RY) to gain in-depth familiarity with the included studies. Line by line coding was conducted by three members of the review team (RY, DB, CS) and a coding tree was developed (Figure 7). Scheduled workshops with the review team facilitated discussion and agreement on the descriptive themes which emerged from the data. Comparison of findings facilitated exploration of relationships between the studies and generated a third order interpretation by the principal investigator (RY). The emergent analytical themes were explored and agreed by the review team (CS, DB, KS) (Tong et al. 2012)

RESULTS

Study selection

The combined search terms for stroke, exercise and qualitative data retrieved 730 references. After screening for duplicates, 492 articles were shortlisted for title and abstract screening. Eighteen papers were read in full and six published references were selected for inclusion in the review. The Prisma flowchart (Figure 6) outlines the article selection process. The search for grey literature identified two service evaluations based within leisure centre venues. One complete report was accessed and accepted for inclusion within the review. A full report of the second service evaluation was not available.

The total number of participants across the selected studies was 76 (n = 48 male, n = 28 female) aged between 18 and 84 years. Time since stroke ranged from 6 months to 13 years. None of the studies had captured the perspectives of non-completers and two studies (Hillsdon, Kersten and Kirk 2013, Reed et al. 2010) incorporated an educational component. A summary of the studies and respective interventions is detailed in Table 5.

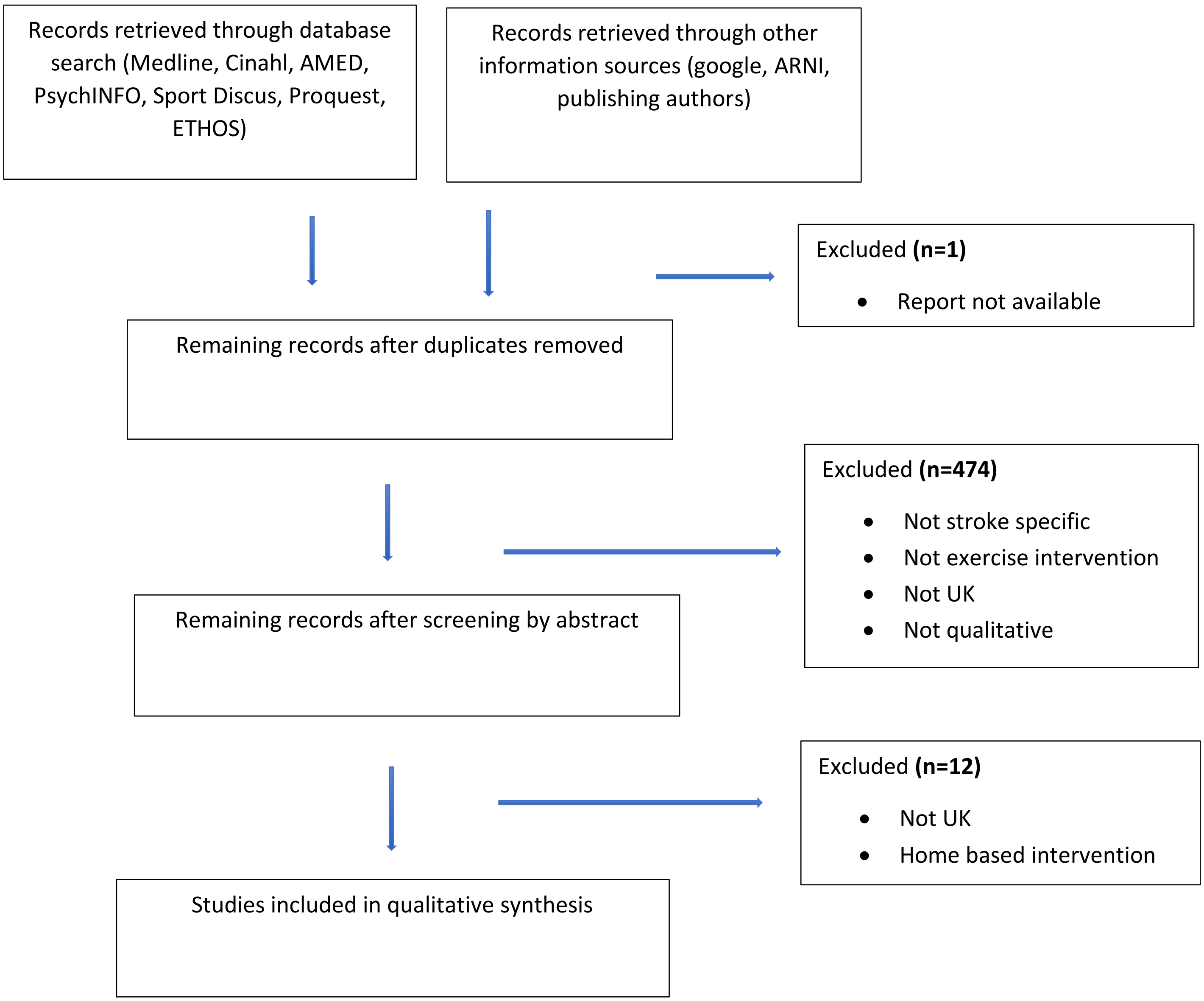

Figure 6: Prisma flow chart (Article 2, Figure 1)

Table 5: Summary of included studies (Article 2, Table 1)

Study characteristics	Participant characteristics	Intervention and setting	Data findings & themes
Carin-Levy et al (2009)			
Pragmatic, qualitative programme evaluation using semi-structured interviews. Follow up from a quantitative randomized exploratory trial which compared exercise and relaxation classes.	Independent and ambulant community dwelling people with stroke. Four males and two females who had been randomized to the exercise group. Age range 49-76 years, mean age 65.3 years. Data from relaxation class participants not included in the review.	Intervention entailed three group sessions per week at a rehabilitation hospital. The class was delivered by an exercise instructor and included circuits, resistance training and flexibility exercises. Duration of programme was 12 weeks.	Five themes identified; enjoyment, motivation, self-perceived quality of life, empowerment and long term effects. Some common benefits identified between exercise and relaxation class. Exercise class participants emphasised perceived physical benefits.
Hillsdon. Kirsten and Kirk (2013)			
Pre-planned qualitative arm of a randomized controlled trial which compared standard care with cardiac rehabilitation following minor CVA or TIA. Semi-structured interviews conducted in participant homes or the hospital.	Independent and ambulant community dwelling people with history of minor stroke or TIA. Seven males and three females who had been randomized to cardiac rehabilitation participated in the interviews. Age range 47-84 years.	There was one group session per week for eight weeks comprising of a cardiovascular circuit session plus education integrated with the established cardiac rehabilitation programme. The sessions were based in a health centre and instructed by the cardiac rehabilitation team.	Four primary themes identified; information delivery, comparison with others, psychological impact and risk factor reduction. Authors concluded that the sessions had lacked specificity to people with cerebrovascular disease.
Norris et al (2013)			
Qualitative study drawing on interpretative traditions. Data collected through four focus groups conducted in the leisure centre.	Ambulatory or wheelchair dependent community dwelling people with stroke. 16 males and 8 females participated in the four focus groups. The age range was 19-84 years.	One group session per week for 12 weeks at a newly built leisure centre. The sessions were based on the ARNI approach and lead by two ARNI instructors.	Key themes were; "I never thought I'd be able to do that again," "It challenges you," "whatever you do don't medicalise it." Authors commented that group support and leadership from peers with history of stroke were central to the positive impact of the programme.

Sharma et al (2012)			
Qualitative study using semi-structured interviews within a constructivist framework to explore experiences of a group exercise referral scheme for people with stroke.	Four females and five males participated in interview. The age range was 37-61 years with a mean age of 51. The level of physical function amongst participants was not reported.	Intervention was a stroke specific group exercise referral scheme comprising of two sessions per week for up to three months. Sessions were based in a leisure centre and included individually tailored exercises overseen by a physiotherapist.	Four primary themes were identified; exercise engagement, improvement, control and confidence. The authors generated a master theme: "exercise referral scheme as a catalyst for regaining independence." Authors commented that the sessions had facilitated a transition from external to internal locus of control.
Reed et al (2010)			
Qualitative study using a phenomenological approach to explore whether a community stroke scheme met the needs of people with stroke. Data were collected through semi-structured interviews.	Five males and seven females participated. Minimum Barthel Index score was 10/20 and most participants were aged > 70 years. Mean time since stroke was 26 months.	Intervention was a stroke specific group exercise and education scheme based in leisure or community venues. Sessions were scheduled twice per week for an eight-week duration.	Three primary themes were identified; creating a social self, provision of responsive services in the community and informal support network. The authors concluded that people with stroke need a variety of internal and external resources to reconstruct their lives.
Wiles et al (2009)			
Qualitative data were collected from participants through semi-structured interviews. Fitness instructors were interviewed and local physiotherapists participated in a focus group.	Eight males and one female participated. Age range was 18-78 years, with a mean age of 56. The physical ability of participants was not reported.	Intervention was an exercise on prescription scheme, led by fitness instructors and based in leisure centres. Participants followed an individual programme. Duration and frequency of sessions is not reported.	Four primary themes were identified; continuity with physiotherapy, risk and safety, monitoring and scheme improvement. Authors concluded that the scheme offered limited social support and was viewed as a substitute for physiotherapy.
Smith et al (2013)			
This was a service evaluation which implemented semi-structured interviews to capture the experiences and impact of the programme on participants.	Six people with stroke participated. Four were ambulant and two were wheelchair users. The age range was 52-72 years.	The programme was based on the ARNI approach and comprised weekly group sessions for 6 weeks plus monthly follow up. Sessions were in a leisure centre and led by ARNI instructors.	Multiple data categories were identified including impact on mobility, activities and future goals. The authors concluded that the group setting generated peer support and that the ARNI intervention re-introduced experimentation following stroke.

Quality assessment and sensitivity analysis

The COREQ defines 32 criteria for quality appraisal which detail reporting on the research team, study design and data analysis (Tong, Sainsbury and Craig 2007). Two members of the review team (RY, KC) independently applied the criteria to the seven selected studies. The individual scores were discussed by RY and KC to establish agreement for each study (Table 6). Quality ratings using the COREQ ranged from 14-30 with a mean score of 21/32. Studies with lower scores tended to provide insufficient information about the research team which refers to how the researchers critically examined their own role, potential bias and influence during data collection. Studies with lower scores were included because of the value of the content associated with reported physical impact of the interventions.

Table 6: COREQ criteria (Article 2, Table 2)

Domain 1: Research Team	Study						
	Carin-Levy (2009)	Hillsdon (2013)	Norris (2013)	Reed (2010)	Sharma (2012)	Smith (2014)	Wiles (2008)
1. Interviewer/facilitator	Y	Y	Y	Y	Y	Y	N
2. Credentials	Y	N	N	N	Y	N	N
3. Occupation	Y	N	Y	N	Y	N	Y
4. Gender	Y	Y	Y	Y	Y	N	Y
5. Experience & training	N	N	Y	Y	Y	Y	N
6. Relationship established	N	N	Y	N	Y	Y	N
7. Participant knowledge of interviewer	N	N	N	N	Y	N	N
8. Interviewer characteristics	N	N	Y	N	Y	N	N
Domain 2: Study Design							
9. Methodological orientation/theory	Y	N	Y	Y	Y	N	Y
10. Sampling	Y	Y	Y	Y	Y	Y	Y
11. Method of approach	Y	N	N	N	Y	N	Y
12. Sample size	Y	Y	Y	Y	Y	Y	Y
13. Non-participation	Y	Y	Y	N	Y	Y	Y
14. Setting of data collection	Y	Y	Y	Y	Y	N	Y
15. Presence of non-participants	N	Y	Y	N	Y	N	Y
16. Description of sample	Y	Y	Y	Y	Y	Y	Y
17. Interview guide/Pilot	Y/N	Y/N	N/N	Y/Y	Y/Y	Y/N	N/N
18. Repeat interviews	N	N	N	N	N	Y	N
19. Audio/visual recording	Y	Y	Y	Y	Y	N	Y
20. Field notes	N	N	Y	Y	Y	N	N
21. Duration	N	Y	Y	Y	Y	N	Y
22. Data saturation	N	Y	N	N	Y	N	N
23. Transcripts returned	N	N	N	N	N	N	N
Domain 3: analysis and findings							
24. Number of data coders	Y	Y	Y	Y	Y	N	Y
25. Description of the coding tree	Y	Y	Y	N	Y	N	N
26. Derivation of themes	Y	Y	Y	Y	Y	Y	Y
27. Software	Y	N	Y	N	Y	N	N
28. Participant checking	N	Y	Y	N	N	N	N
29. Quotations presented	Y	Y	Y	Y	Y	Y	Y
30. Data and findings consistent	Y	Y	Y	Y	Y	Y	Y
31. Clarity of major themes	Y	Y	Y	Y	Y	Y	Y
32. Clarity of minor themes	Y	Y	Y	Y	Y	Y	Y

Data analysis

Three members of the review team (CS, DB, RY) initiated independent coding of the selected papers. Twenty three individual codes were identified and two overarching thematic categories were identified: perception of programme and impact on self. Six descriptive themes emerged from these two categories; sustained behaviours (1), psychosocial impact (2), physical impact (3), influence of group (4), programme design (5) and comparison with healthcare services (6). The themes and their supporting codes are represented in the coding tree (Figure 7). Comparison between and synthesis of the descriptive themes facilitated the development of inductive, analytical themes (Table 7).

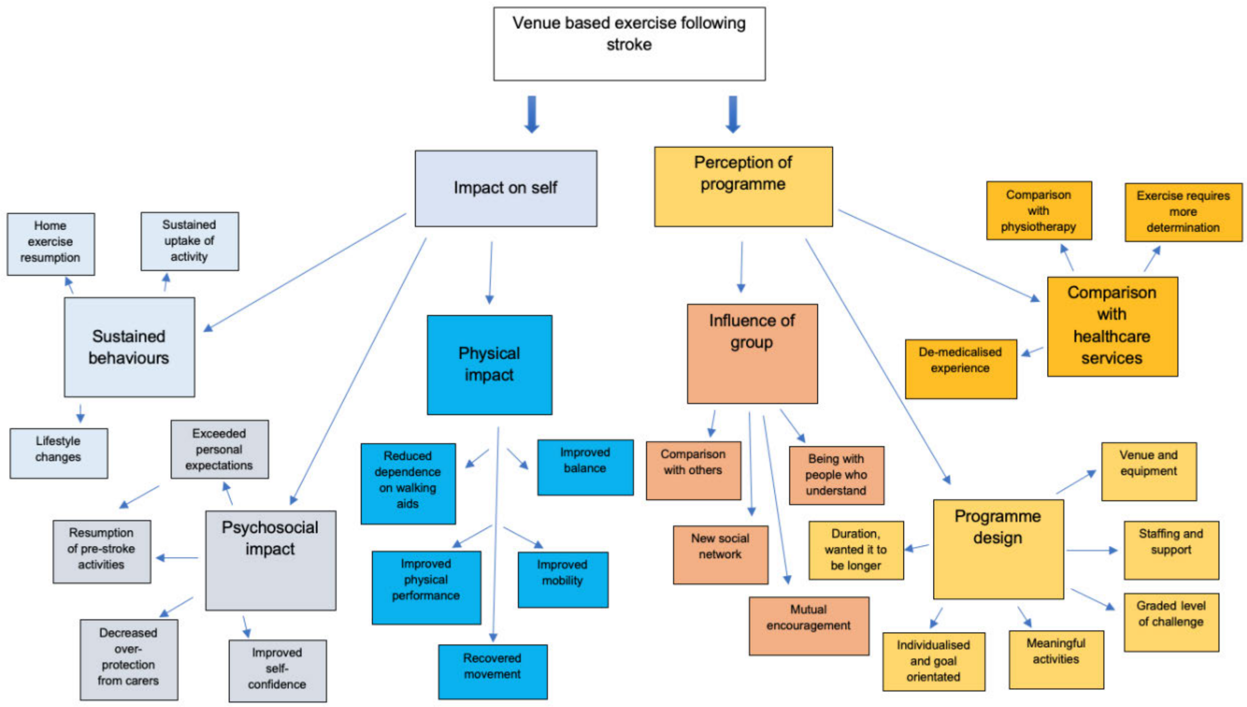

Figure 7: Coding tree (Article 2, Figure 2)

Descriptive themes

1. **Sustained behaviours**

Sustained activity behaviours were explored in several studies (Norris et al. 2013, Hillsdon, Kersten and Kirk 2013, Sharma, Bulley and Wijck 2012, Reed et al. 2010, Wiles et al. 2008). Engagement with home exercise programmes was variable, the participants from the Carin-Levy et al (2009) study shared mixed views, with fear of falling identified as a barrier to continuing with exercises at home. Several studies specifically reported an increased commitment to community based physical activity (Smith, Joy and Parsons 2014, Reed et al. 2010, Norris et al. 2013, Wiles et al. 2008) including swimming, exercise classes and gym membership. Two studies (Hillsden, Kersten and Kirk 2013, Reed et al. 2010) had incorporated an educational programme. A greater awareness of lifestyle factors and risk reduction was reported, however, the impact of this knowledge on lifestyle was variable.

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2. **Psychosocial impact**

The psychosocial impact of exercise participation was a strong recurrent descriptive theme across the included studies. Three studies (Smith, Joy and Parsons 2014, Reed et al. 2010, Norris et al. 2013) reported that participants had exceeded their personal expectations. With the exception of Wiles et al (2008), the data from all studies associated exercise participation with the resumption of pre-stroke activities including hobbies, spiritual fellowship, vocation, family and social engagements. Improved self-confidence were strongly reported in four studies (Smith, Joy and Parsons 2014, Norris et al. 2013, Sharma, Bulley and Wijck 2012, Carin-Levy et al. 2009) and two studies (Smith, Joy and Parsons 2014, Reed et al. 2010) described the creation of a "new self," triggered by the exercise programme. A positive impact on relationships was identified as over-protective behaviours from carers or partners decreased (Smith, Joy and Parsons 2014, Norris et al. 2013, Hillsdon Kersten and Kirk 2013).

3. **Physical impact**

The perceived physical impact of the exercise programme was reported by all included studies. The gym setting appeared to be associated with improved physical performance in terms of strength, stamina and technique (Smith, Joy and Parsons 2014, Norris et al. 2013, Sharma, Bulley and Wijck 2012, Carin-Levy et al. 2009, Wiles et al. 2008). Participants described improved mobility (Smith, Joy and Parsons 2014, Sharma, Bulley and Wijck 2012, Wiles et al. 2008), reduced dependence on walking aids [Smith, Joy and Parsons 2014, Norris et al. 2013, Sharma, Bulley and Wijck 2012), improved balance (Smith, Joy and Parsons 2014, Wiles et al. 2008) and recovered movement (Smith, Joy and Parsons 2014, Norris et al. 2013, Sharma, Bulley and Wijck 2012). The impact of exercise upon ADL was mixed, with participants from two of the studies (Carin-Levy et al. 2009, Wiles et al. 2008) suggesting that they did not experience improved performance in ADL. In contrast, participants who had engaged with the ARNI programmes identified specific improvements in ADL including eating, dressing and household tasks (Smith, Joy and Parsons 2014, Norris et al. 2013).

4. Influence of group

The influence of the group and impact of peer support was a major recurrent theme. Participants shared that they had compared themselves to other people with stroke (Hillsdon, Kersten and Kirk 2013, Sharma, Bulley and Wijck 2010, Reed et al. 2010). Downward comparison with other group members was reported by Hillsden, Kersten and Kirk (2013), this was mostly alongside people with a cardiac diagnosis which was perceived as more serious than minor stroke or TIA. Those studies which had collected data from stroke specific exercise programmes reported high levels of mutual encouragement and group support between participants (Smith, Joy and Parsons 2014, Norris et al. 2013, Reed et al. 2010, Wiles et al. 2009). In contrast, participants recruited from the standard ERS described by Wiles et al. (2008) commented on limited opportunity to meet with or speak to other people within the gym setting.

5. Programme design

Attendance at an external venue was viewed as an opportunity to “get out of the house” (Norris et al. 2010, Wiles et al. 2008). Although some individuals had regarded public gymnasiums with trepidation (Sharma, Bulley and Wijck 2012) the overriding opinion was that the participants enjoyed building confidence within a de-medicalised setting (Norris et al. 2013, Sharma, Bulley and Wijck 2012, Reed et al. 2010, Carin-Levy et al. 2009). Participants also identified accessible car park, good transport links and the coffee shop as important factors related to their experience of the venue (Norris et al. 2013). Two studies (Hillsden, Kersten and Kirk 2013, Carin-Levy et al. 2009) were based within health rehabilitation centres, this did not appear to directly influence the reported experience. Positive relationships with the professional team were described (Norris et al. 2013, Sharma, Bulley and Wijck 2012, Reed et al. 2010) and several participants would have liked the duration of the programme to be increased (Smith, Joy and Parsons 2014, Norris et al. 2013, Sharma, Bulley and Wijck 2012, Reed et al. 2010).

6. Comparison with healthcare services

Comparison with health service rehabilitation and physiotherapy was the final descriptive theme identified within the thematic analysis. The sentiment that exercise required mental toughness and determination was shared across several studies (Sharma, Bulley and Wijck 2012, Reed et al. 2010, Carin-Levy et al. 2009). Participants referred to the need for willpower and determination to engage with exercise and optimise their physical outcome. Exercise referral schemes were perceived as a substitute for physiotherapy (Reed et al. 2010, Wiles et al. 2008). In contrast, participants from the Norris et al. (2013) study shared that they had felt "mollycoddled in hospital" and that the ARNI programme was the opposite to "half-baked physiotherapy." Overall, participants across all of the included studies had appreciated the opportunity for further physical progression following stroke rehabilitation within a de-medicalised setting.

Analytical themes

Three analytical themes evolved from in-depth analysis of the descriptive themes; these are summarised alongside illustrative quotes in table 3.

1. "Training principles as a foundation for programme design"

Training principles including specificity, overload and progression were implicit in the views shared by participants. Specificity of training response is identified as those interventions which focussed on functional mobility (Smith, Joy and Parsons 2014, Norris et al. 2013) triggered perceived improvements in balance and walking ability. The interventions which had emphasised conventional aerobic and resistance training activities (Sharma Bulley and Wijck 2012, Carin-Levy et al. 2009, Wiles et al. 2008) were associated with changes in physical performance, for example, improved strength and stamina. In alignment with the principles of overload and progression, the programmes were recalled as challenging; participants were encouraged to push their physical boundaries and progress during the course of the intervention. Participants enjoyed being challenged in a "place of work" and the perceived intensity of the intervention made the sessions worthwhile.

2. "I'm not just a stroke patient anymore"

The exercise programmes facilitated transition from being a stroke patient to a new identity as an exerciser. The participants felt that they had to do it for themselves with tapered support from the professional team. This was in contrast to the experience of health care rehabilitation in which participants had felt protected but disempowered (Norris et al. 2013, Sharma, Bulley and Wijck 2012). The distinction between conventional rehabilitation and exercise interventions was evident across the included studies. Although perspectives regarding the respective value of fitness instruction compared to traditional physiotherapy were mixed, there was an overriding sentiment of personal achievement associated with completion of the exercise interventions. The importance of peer support in group interventions is highlighted and these findings indicate extended value generated through group interventions. Intervention delivery in de-medicalised venues normalised the experience and participants were empowered to recover their pre-stroke identity.

3. "Restoration of an internal locus of control."

Restoration of an internal locus of control is evident as recovery of personal autonomy and valued life roles is strongly associated with the exercise interventions. Participants recovered a sense of control over their own destiny through exercise and physical achievement. They reported that they started to feel that they could move forwards from the impact of their stroke, resume their previous roles and re-engage with valued activities (Sharma, Bulley and Wijck 2012). The reported effect of the intervention extended beyond physical changes as the restoration of the "old self" is evident. Participants felt elevated and their standing within family and social circles was enhanced. The evaluation of exercise interventions following stroke needs to routinely incorporate measurement of reported quality of life and participation to ensure a valid reflection of their real value.

Table 7: Analytical themes and illustrative quotes (Article 2, Table 3)

Theme	Participant quote	Author interpretation
Analytical theme 1: "Training principles as a foundation for programme design."	"I'm finding I can stand up now without having to push myself up on my hands. I'm doing that more often. I've even tried a couple of times from the settee, which is low down, and I've done it" (Smith et al 2014). "Challenging, I found it was very challenging, just the first day when we had to sort of actually walk on a mat without a stick. . .I felt that was really challenging. . .but also encouraging, to do more than I thought I could" (Norris et al. 2013). "Once they've assessed you, you've got this key you put in the machine, it tells you how long you've got to do and everything. With a computer you don't need an instructor" (Wiles et al. 2008).	All participants had experimented with attempting new things, and tasks they thought they could not do. Participation in the ARNI programme had re-introduced experimentation which is likely to have increased confidence (Smith et al. 2014). The training was described as a physical challenge both in its intensity but also the activities undertaken in the programme (Norris et al. 2013). Some participants viewed the focus of gyms to be on fitness rather than rehabilitation and whatever they did in the gym would not further their functional ability (Wiles et al. 2008).
Analytical theme 2: "I'm not just a stroke patient anymore"	"The fact that I could contribute and I still had something to give, I wouldn't say to society. But I wasn't just a has-been. When you do come home from having stroke you do feel that you are a has-been" (Reed et al. 2010). "Whatever you do don't medicalise it . . . I think one of the key benefits of this is that it's not another bloody appointment. You know it's not the hospital . . . it's also a community facility . . . it introduces you and makes other things accessible" (Norris et al. 2013). "Because when I do exercise, when I go out, it puts me back to normal. And when I see others walking, what would make me not walk? I am not disabled. The stroke has not made me disabled, so I walk" (Sharma et al. 2012).	The post stroke self was portrayed as fragile. Lack of confidence and purpose and perceptions of how people viewed them post stroke made it easy for participants to retreat into "safe environments" (Reed et al. 2010). There was a sentiment that the individuals' capacity had been artificially limited and that was now being tested. Implicit in many of these comments was the idea that the individual had been challenged to reconceive their own possibilities (Norris et al. 2013). The ERS facilitated increases in activity levels within sessions, and outside the ERS. Increased activity generated feelings of normality and independence (Sharma et al. 2012).
Analytical theme 3: "Restoration of an internal locus of control"	"I felt very proud of myself at that stage because I'd been through so much and I'd been, I suppose you'd call it brave but that's being big-headed. But brave as in I've not let it beat me" Reed et al. 2010). "I started work and I was able to start where I left off. . .and if I had not gone through this I would not have had the confidence. . ..it is not the medication that has made me better, it is the exercise" (Sharma et al. 2012).	Stroke survivors wish to continue to work towards reconstructing their lives post stroke. In order to do this they need internal resources of confidence and sense of purpose, to 'create their social self', external resources in the form of 'responsive services'; and an 'informal support network', to support and encourage the development of their internal resources (Reed et al. 2010). Locus of control appeared to shift from predominantly external during rehabilitation, to more internal during ERS (Sharma et al. 2012).

DISCUSSION

This review provides a synthesis of qualitative studies after a systematic search for the perspectives of people with stroke who have participated in venue based exercise programmes. The findings facilitate a more comprehensive understanding of the perceived benefits and reported experiences associated with exercise following stroke in the UK. Three analytical themes contribute to our understanding of how people with stroke perceive their experience of participation in venue based exercise.

Training principles as a foundation for programme design

Generic training principles for physical training should be applied to the stroke population (Ammann et al. 2014) and there are clear links between the activities performed and perceived physical benefits reported. A continuum of variety should underpin all training programmes to avoid onset of tedium and achieve greater improvements (Farrow and Robertson 2017). Norris et al. (2013) concluded that a group intervention combined with a focus on individual needs is critical to the capacity to develop a challenging environment. People with stroke respond positively to high intensity training as there is perceived benefit associated with working hard (Signal et al. 2016). This sentiment is shared amongst the participants included in this review who felt that they could push the boundaries and achieve beyond their expectations in alignment with the principles of overload and progression.

I'm not just a stroke patient anymore

The second analytical theme encapsulates a change in identity associated with the exercise programmes; participants liked being challenged in a working environment. The location of the programmes symbolised a step away from medicalised systems, although the transition from physiotherapy to an exercise professional led intervention generated mixed views (Norris et al. 2013, Sharma, Bulley and Wijck 2012, Wiles et al. 2008). The findings of this review indicate that physiotherapy guided interventions delivered by supported exercise professionals may have the optimal perceived benefit (Sharma, Bulley and Wijck 2012). Exercise professionals are interested in working with people with stroke but report a perceived lack of relevant experience and training (Condon and Guidon 2018). Increased collaboration between physiotherapy services and exercise professionals may enhance uptake and engagement in exercise following stroke, enabling people with stroke to progress towards a de-medicalised identity.

Internal confidence following stroke should be facilitated by creating opportunities for positive social interaction (Reed et al. 2012) and stroke specific exercise groups emerged as the preferred model amongst the studies reviewed. The resourcing of group interventions with integrated individual support represents a challenge for leisure providers (Condon and Guidon 2018); cost-benefit analysis of different exercise delivery models for people with stroke is required. The integration of people with stroke into a cardiac rehabilitation programme appeared to generate a social dynamic of downward comparison between group participants and a higher dropout rate was recorded (Hillsdon, Kersten and Kirk 2013). Cardiac rehabilitation teams report limited confidence in supporting people with stroke (Clague-Baker et al. 2018); further training and programme adaptation is required to effectively integrate cardiac and stroke rehabilitation.

Restoration of an internal locus of control

The emergence of an internal locus of control through which participants felt empowered and in charge of their own destiny is evident. The psychological benefits of exercise following stroke are increasingly reported alongside the physical benefits and contributes to functional autonomy and improved quality of life (Belfiore et al. 2018). Improvements in mood and self-esteem are key motivators for sustained engagement (Poltawski et al. 2015). Across the studies reviewed there are recurrent reports of resumption of pre-stroke activities alongside enhanced social and familial roles. The severity of physical impairment did not appear to influence the reported experience or value of participating in exercise. In fact, those with the mildest impairments appeared to place less value on exercise (Hillsdon, Kersten and Kirk 2013). The majority of trials which have evaluated exercise following stroke have excluded non-ambulatory participants (Saunders et al. 2016). Future research should prioritise the development of exercise facilities and programmes which meet the needs of non-ambulant people with stroke.

Strengths and limitations of this review

This review of qualitative research included primary studies and grey literature. The application of COREQ criteria highlighted the strengths and limitations of the selected research publications. Sensitivity analysis and exclusion of inadequately reported studies from qualitative systematic reviews is debated in the literature (Carroll, Booth and Lloyd-Jones 2012). In this review, higher rated studies generated those themes focussed on the psychological effect of the intervention (Norris et al. 2013, Sharma, Bulley and Wijck 2012). In contrast, the lower quality publications informed development of themes which reflected the physical impact of the intervention and experience of the environment [Smith, Joy and Parsons 2014, Wiles et al. 2008). A potential source of bias is the geographical representation of the included samples; with one exception, (Carin-Levy et al. 2009) all of the studies were based in south England. The influence of regional demographics can have a significant bearing upon exercise beliefs and behaviours (Jackson, Merver and Singer 2016) and further research is required to capture the views and experiences of the UK wide stroke population.

The scope of the review was limited to the UK as this enabled a specific focus upon the UK health service combined with third sector partners. Similar research has been conducted within the international community (White et al. 2013) and a larger scale review would facilitate a global perspective. The included studies only captured the views of participants who had completed the programmes. Future research should prioritise following up people who do not enrol on or adhere to exercise programmes following stroke. This would enable training providers to identify those factors which disengage people from exercise following stroke which may include fear, tedium or progression to other forms of physical activity (Farrow and

Robertson 2017). A further area for future study could focus on comparison between home and venue based exercise programmes as home based or non-traditional exercise settings may be preferred by some people with stroke (Poltawski et al. 2015).

Conclusion

The results of this systematic review highlight that exercise for people with stroke has a positive impact on perceived physical ability, identity and participation. Stroke specific groups engender peer support and a new social network. De-medicalised venues are associated with a positive challenge and restoration of an internal locus of control. The findings of this review suggest that people with stroke will benefit from sustained support in exercise participation and programmes adapted for all levels of physical ability should be available. Rehabilitation services need to collaborate with exercise providers to facilitate a positive transition towards long term exercise participation. Future qualitative research should focus on people who opt out of exercise interventions following stroke and a multi- regional perspective across the UK is required in relation to this field of evidence.

Author declaration

No funding sources were accessed to support the development of this review. The authors declare that there are no conflicts of interest.

4.2.3 Article Three

Users' experience of community-based power assisted exercise: a transition from NHS to third sector services

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Abstract

Purpose

People with stroke experience physical and psychosocial benefits associated with engagement in exercise, but access to equipment can be a barrier to sustained engagement. Seated PAEE is an accessible exercise mode for people with limited mobility following stroke and is available at a small number of community-based venues. The purpose of this qualitative study was to understand the lived experience of using PAE amongst PwS in a community venue and identify recommendations for the development and advancement of PAE equipment.

Method

Semi-structured interviews were conducted with 8 participants (PwS) attending a community stroke venue where PAE equipment was available. Transcribed data were analysed using IPA.

Results

Three overarching themes emerged from the analysis; 1) *Don't tell me I've plateaued;* 2) *PAE facilitates the transition into long-term recovery*; 3) *Reframing the experience of stroke.* Participants associated the uptake of PAE alongside venue membership as a turning point in their adjustment to life following stroke. In addition, recommendations for future development of the equipment were identified.

Conclusion

These findings indicate that membership of a stroke venue alongside engagement with PAE facilitated transition from early stroke rehabilitation into longer term recovery. The results of this study have informed the need for future product design and highlighted PAE is an effective mode for continued rehabilitation in third sector services.

Keywords

Stroke; community based venue; assisted exercise; qualitative; interview; phenomenology.

INTRODUCTION

Worldwide, there are over 13 million new cases of stroke annually and it is a leading cause of adult disability (Lindsay et al. 2019, Johnson et al. 2019). Although physical rehabilitation services are typically finite [Miller, Lin and Neville 2019], PwS have long-term potential for neuroplastic adaptation and functional recovery (Sun and Zehr, 2019, Bunkertorp-Kall et al. 2017). Strength, aerobic and functional exercise interventions are known to improve mobility, reduce physiological risk profiles and enhance participation for at least five years beyond the onset of stroke (Young et al. 2019a, D'Isabella et al. 2017, Saunders et al. 2016, Poltawsky et al. 2015). Supporting PwS to transition from rehabilitation services into longer term exercise programmes has been identified as a priority within published guidelines (Royal College of Physicians 2016, MacKay-Lyons et al. 2020). Purposed services and venues which specifically target the needs of PwS are limited (Schouten et al. 2011) and the need for closer partnerships between health care and community wellness programmes has been identified (Miller, Lin and Neville 2019).

Qualitative research has facilitated an understanding of and insight into the experiences of exercise amongst PwS and service providers (Condon and Guidon 2018, Signal et al 2016); the barriers to engagement in exercise following stroke include beliefs about personal capability and availability of accessible resources (Nicholson et al. 2014). Group sessions in de-medicalised external venues are associated with enhanced life participation and self-efficacy (Poltawsky et al. 2015) and a systematic review of the qualitative literature indicated that perceived benefits may outweigh measured physical impact (Young et al. 2019a). However, fitness professionals report that they have limited confidence in supporting the specific needs of PwS (Condon and Guidon 2018) and inaccessible equipment has been identified as a barrier to the uptake of exercise amongst the stroke population (Nicholson et al. 2014). Exercise programmes can be effectively delivered in the home environment (Galvin, Stokes and Cusack 2014) but barriers to exercising at home include fear of falling, caregiver addressing other priorities, unsuitable environment and limited confidence with correct exercise technique (Scorrano, Ntsiea and Maleka 2018, Galvin, Stokes and Cussack 2014).

People with severe or complex physical impairment following stroke are under-represented in exercise research due to the challenges associated with access and physical ability (Saunders et al. 2016). The ability to walk independently has been a fundamental inclusion criterion for participation in most exercise trials for PwS (Marzolini et al. 2020, Galloway et al. 2019) and thereby excludes those individuals with limited mobility. The challenges associated with promoting and enabling exercise amongst non-ambulant PwS are particularly complex (Valkenborghs et al. 2019). Advances in assistive interventions and adapted models of service delivery are essential to enable people with moderate or severe motor impairment to experience physical training following stroke (Kerr et al. 2019, Stoller et al. 2014b).

Improvements in physical function and exercise behaviours are reported amongst people with complex impairments who have participated in adapted or assisted exercise interventions [Kerr et al. 2019, Lloyd et al. 2018). The impact of assisted pedalling interventions for PwS include increased aerobic capacity, enhanced neuroplasticity and improved motor coordination (Linder et al. 2019, Linder et al. 2015, Holzapfel et al. 2019). Seated PAE machines go beyond assisted pedalling as the range of equipment is designed to assist repeated, multi-directional, global movement patterns. The equipment has been adopted by providers of rehabilitation and therapy services who have identified the potential benefit of multi-directional assistive equipment. Investigation into the feasibility of PAE for people with complex neurological impairment recorded a 100% programme completion rate, 96% attendance at sessions in which the participants engaged with and complied with all prescribed exercises and no serious adverse events were recorded (Young et al. 2018). Participants in the trial reported perceived improvements in their physical and psychosocial wellbeing. An enhanced understanding of the user experience is required to optimise design and implementation of the equipment for complex populations.

To date, research on assisted exercise following stroke has focussed on quantified physical impact of laboratory based assisted pedalling and there is a paucity of qualitative research on the perceived effects of assisted exercise or the experience of accessing community-based venues. The motivators for and perceived value of self-initiated engagement with PAE following stroke have not been elucidated. Participation in exercise is an individualised experience influenced by numerous intrinsic and extrinsic factors including physical ability, self-efficacy and environment (Eynon et al. 2019). Qualitative exploration of the lived experience can facilitate a comprehensive understanding of the individual, their context and the influence of the setting; which in turn, may inform the effective development, implementation and evaluation of rehabilitation programmes (Merali et al. 2019).

Interpretative phenomenological analysis is a qualitative approach which explores the reported lived experience and is well suited to the exploration of health behaviours and novel concepts (Smith 2007). By capturing the essence of the lived experience, IPA has previously facilitated the development of stroke rehabilitation strategies which enhanced user empowerment and optimised achievement of meaningful outcomes (Williams and Murray 2013, Garrett, Immink and Hillier 2011). IPA emphasises an individualised approach towards data analysis to gain an understanding of the factors influencing their reported experience (Alase 2017) and has been previously applied to the development of exercise interventions amongst populations with complex needs (Wheeler et al. 2018). Using IPA, this article addresses the gap in the qualitative literature on assisted exercise at a community-based venue by reporting on the lived experiences of people who use PAE equipment; exploring perceived physical and psychosocial outcomes associated with this form of exercise amongst ambulant and non-ambulant PwS.

Aims

The aim of this study is to explore both ambulant and non-ambulant PwS experiences of and the perceived effects associated with participation in PAE in a third sector community stroke centre. After interpretation, user- centred recommendations for the development and advancement of PAE equipment will be compiled.

METHODS

This study received ethical approval from Sheffield Hallam University (registration number ER6774925). The data management plan ensured compliance with General Data Protection Regulations.

Methodological approach

Given the complexity and uniqueness of the experiences and perceived effect of using PAE equipment amongst PwS, IPA was used to facilitate an appreciation of individuals' values and meanings (Alase 2017). This study was grounded within the interpretivist paradigm, focussing upon contextual factors and the mutual interdependence between causes and effects. The ontological assumptions which underpinned the study were relativist, recognising that the reality of human experience is subjective; the epistemological position was founded upon the construction of knowledge through human interaction between the researcher and participants (Cuthbertson, Robb and Blair 2019). IPA is well suited to understanding health behaviours and recognises interconnectedness between the individual and the world (Smith 2018). Stroke is a complex condition, affecting multiple components of physical and psychosocial wellbeing; outcomes should not be considered in isolation but in the context of the whole person and their wider circumstances (Pringle, Drummond and McLafferty 2013).

Application of the hermeneutic cycle in IPA ensures that the parts are related to the whole, and the whole to the parts, enabling a holistic and context centred understanding of human experience (Smith 2007). Interpretative studies typically recruit a small, homogenous sample to facilitate an in-depth and rich understanding of the phenomena of interest in the context of participants' broader life experiences (Smith, Larkin and Flowers 2008). IPA is based on the premise that people continually reflect upon and make sense of their experiences; the role of the interviewer in IPA is to invite the participant to share their view of the world and how they make sense of it (Smith 2018).

Sample population, venue and recruitment

Convenience sampling in qualitative research facilitates the identification of people with specific life experience relevant to the research aim (Newton-John 2018). It was first necessary to identify an operator which offered PAEE for use by PwS. The machines manufactured by Shapemaster Global LTD represent a unique design in the global marketplace due to the combination of multi-directional assisted movements which enable the user to simultaneously engage all four limbs and the trunk whilst seated. Through consultation with the manufacturer the research team identified a third sector (registered charity independent of government) venue in the north of England dedicated to the long- term support of PwS. A visit to the centre was arranged during which the lead author met with the team and took the opportunity to view the gymnasium area which comprised six seated PAE pieces of equipment, a motorised treadmill, assisted pedalling machine (Moto-Med) and static parallel bars. The centre offered a range of membership packages and support services including physiotherapy; PwS in the locality could self-refer or be signposted by a healthcare professional. Membership criteria was wholly inclusive to people with any type or severity of physical, communication or cognitive impairments following stroke, although attendees were required to resource their selected package. This may have been a barrier for attendance for people from economically disadvantaged households.

A poster and flyers were placed in the venue and the site manager circulated participant information sheets to interested members. Variation in age and stroke severity and a combination of male and female participants was sought to capture diverse experiences.

Meetings were scheduled between potential participants and the lead author (RY) by the centre manager to enable the opportunity for members to explore any questions and understand the requirements of participation. The meetings facilitated the development of a relationship between the participants and the interviewer to build trust and enhance the richness of data shared during the subsequent interview (Morse 2015). This informal meeting enabled the interviewer to screen eligibility for inclusion in the study and, on completion of written, informed consent, a date and time for each interview based at the centre was scheduled.

Inclusion and exclusion criteria

The inclusion criteria were; a diagnosis of stroke confirmed by the centre manager; experience of using PAE within the previous 12 months; ability to provide informed consent and ability to communicate verbally in spoken English at a level comprehensible for an audio recording. Specific frequency or duration of PAE engagement was not stipulated as this was explored during data collection. The exclusion criterion was an inability to respond to verbal questions for the purposes of an interview.

Power assisted exercise

Six seated PAE machines were sited at the venue, the combined limb and trunk movements assisted by each machine are described in Table 8. The machines were operated by a console which featured start/stop and speed settings between one and ten (Figure 8). The default duration of each machine was five minutes; a workout using all six machines would typically take 35-40 minutes including time to transfer on and off the equipment. In order to use the equipment safely, members needed to have independent sitting balance and weigh less than 24 stone (152 kg). Non-ambulant people could use a transfer aid to access the equipment. Users were supervised by support staff at the venue and encouraged to generate a physical effort by moving with the machine.

Table 8: PAE machines (Article 3, Table 1)

Machine Name	Actions assisted	Image
Chest and Legs	Shoulder; mid-range flexion and extension Elbow; mid-range flexion and extension Hip; mid-range flexion and extension Knee; flexion and extension	
Seated climber	Shoulder; flexion into elevation Elbow; flexion into end range extension Hip; mid-range flexion and extension Knee; flexion and extension	
Seated abductor	Hip; abduction and adduction Shoulder; horizontal abduction and adduction	
Side bend stepper	Trunk; lateral flexion Reach or push down through arms Hip; flexion and extension Knee; flexion and extension	
Rotatory torso	Trunk rotation Elbows and shoulders supported in flexion	
Tummy crunch	Trunk; flexion and extension Hips are flexed Shoulders are elevated	

Figure 8: Console of the PAE machine (Article 3, Figure 1)

Data collection

Baseline demographic data were recorded by the first author and included participant’s age, gender, ethnicity, time since stroke and occupation. Participants were allocated a numerical code to ensure anonymity.

Power assisted equipment at the venue was used by people who were independently mobile alongside people with very limited mobility. A baseline measurement of mobility was recorded using the FAC (Merholz et al. 2007). The FAC is an ordinal scale which allocates mobility on a spectrum of 0 to 5; a score of 0 indicates that the individual cannot walk, whilst a score of 5 is allocated to people who can walk independently anywhere. The FAC was used to capture an overview of functional ambulation and explore whether severity of impairment influenced the reported lived experience of using the equipment. Observation of walking ability was scored by the lead author according to the FAC on recruitment to the study. The lead author observed each participant perform a transfer between seated surfaces and attempt to walk along a flat 5 metre walkway in the centre. A member of the centre team who had moving and handling skills and knowledge of the individual participant supervised or assisted the assessment as required. Two participants were able to perform these tasks independently and were subsequently observed whilst attempting to walk up and downstairs to determine whether they gained a score of 4 or 5.

Semi-structured interviews were conducted by the lead author who is a neurological physiotherapist with 25 years' experience working in clinical practice and higher education with a specific interest in exercise interventions for PwS. The interviews were scheduled at a mutually convenient time and based in a quiet space within the venue. Carers or partners were invited to accompany the interviewee and their comments were included in the analysis. Recent debate has criticised IPA as a 'therapy-oriented' research methodology rather than a phenomenological approach (Van Manen 2017). The data captured during our study were for the purpose of understanding the use of PAE amongst PwS to address a current gap in the qualitative literature. The lead author was mindful of her background as a therapist (albeit physical rather than psychological) and used a reflective journal to promote a sustained focus on data collection rather than counsel during the interviews.

An interview schedule containing open questions was developed by the research team and used in a flexible manner; questions explored pre-stroke lifestyle, memories of early stroke recovery and experiences of engaging with PAE to capture an understanding of how uptake of PAE related to the wider experience of living with stroke (Appendix 3). The interviews were audio-recorded on an Olympus digital voice recorder (WS-811) and brief field notes on observed, non-verbal communication were documented by the interviewer. Thereafter, all interviews were transcribed verbatim by the lead author using Microsoft Word software to facilitate emersion and familiarisation with each item.

The value of member checking in ensuring rigour in qualitative research has been questioned (Smith and McGannon 2018). However, given the communication and cognitive changes which can occur following stroke, participants were given the opportunity to comment on their transcript and check for accuracy. The transcripts were returned to each participant between two and four weeks following the interview. No amendments were requested.

Data analysis

Interpretative phenomenological analysis aims to provide an account of participant experiences and is underpinned by a process of coding, organising, integrating and interpreting data (Smith, Larkin and Flowers 2008). Three members of the research team (RY, KS, RB) adopted an idiographic approach towards data analysis which comprised repeated reading of individual transcripts to familiarise with the participants and gain a context-oriented understanding of their account. Content which explored recall of early stroke, the initiation of PAE and how this influenced the reported experience of stroke recovery was organised through development of preliminary descriptive codes. Subsequent linguistic coding identified subtleties in the data, for example, how participants applied different types of deictic reference during the interview which facilitated an interpretative insight into their respective sense of empowerment at different stages of stroke recovery. The descriptive and linguistic codes were expanded to create conceptual codes which captured an impression of the reported lived experience and enabled the research team to identify individual emergent themes. Connections between emergent themes were grouped into units of meaning alongside supporting quotations (Smith, Larkin and Flowers 2008). The ideographic approach was sustained through the development of an interpretative summary for each participant which encapsulated their experience of PAE embedded within the context of their pre-stroke self, early rehabilitation, current mobility, social and cultural influences. While cross case analysis in IPA has not aimed to generate broad generalisations, a theoretical transferability of findings might be expected to emerge (Smith, Larkin and Flowers 2008). Cross case analysis allowed for recognition of shared and divergent experiences across the sample and tendencies associated with age, gender, occupation, time since stroke and mobility across the data set were explored and emergent trends were tabulated. Multiple superordinate themes which reflected the recall of stroke onset, hospital, rehabilitation and uptake of PAE were distilled to create overarching themes rooted in the context of each individual account and the shared but varied experiences of assisted exercise following stroke.

Rigour

Data collection and analysis was based on a relativist position with an emphasis upon fidelity to the insights and experiences shared by the participants and utility in terms of the synergic relationship between the research design and aims (Smith and McGannon 2018). A responsive approach was adopted during each interview to enhance credibility of the data generated and this ideographic approach was sustained throughout the data analysis. The lead author adopted a reflexive approach through continuously evaluating potential biases which may have influenced the interpretation of the data and recording key insights in a reflective journal (Berger 2013). Confirmability of the research was enhanced through regular peer debriefing with the research team and analytical triangulation (Morse 2015). Two co-authors (KS, RO) independently coded their allocated transcripts before discussing their individual interpretation with the lead author. An equal voice was given to all three members of the coding team to promote rigour in triangulation (Smith and McGannon 2018). Strong conflict in opinion did not arise but the three authors shared alternative emphases in perspective which enriched the interpretative analysis. The final overarching themes represented the integrated interpretation of all three members of the coding team.

RESULTS

Nine members of the third sector centre expressed interest in participation after viewing the poster. All met the inclusion criteria and provided their informed consent; one participant dropped out prior to interview due to illness that was not related to participating in PAE.

The study recruited eight PwS (6M; 2F) who were regular members at the third sector centre. The mean age in years was 60.1 years (range 42-76, SD 10.69) and mean time in months since stroke was 48 (range 14-90 months SD 31.92). At the time of having their first stroke four participants were in employment, three participants were retired and one participant was two weeks postpartum (Table 9). One participant had experienced a second stroke. Two male participants (M2, M5) attended the interview with their female partner. Mean interview duration in minutes was 35.59 (range 18.23-55.26, SD 10.79). All participants stated their ethnicity as white British. Seven participants presented with hemiparesis and one participant was ataxic (Table 10). Functional ambulation category scores ranged from 0/5 to 5/5 (mean 2.87).

Table 9: Demographic and condition related data (Article 3, Table 2)

	Mean (SD)	
Age (years)	60.12 (10.69)	
Time since stroke (months)	48.12 (31.92)	
	Number	**(%)**
Gender		
Male	**6**	**(75%)**
Female	**2**	**(25%)**
Marital status		
Married/partnership	**4**	**(50%)**
Separated/divorced	**2**	**(25%)**
Single	**2**	**(25%)**
Employment status		
Employed (paid)	**0**	
Unable to work (disability)	**5**	**(62.5%)**
Retired	**3**	**(37.5%)**
Ethnicity		
White British	**8**	**(100%)**
Functional Ambulation Category		
0-2	**3**	**(37.5%)**
3-4	**3**	**(37.5%)**
5	**2**	**(25%)**

Table 10: Individual condition and impairment data (Article 3, Table 3)

Code	Age	Gender	Time since stroke (months)	Stroke impairment	FAC
M1	53	Male	16	Right hemiparesis	3/5
M2	76	Male	42	Left hemiparesis	0/5
M3	68	Male	48	Right hemiparesis	3/5
M4	52	Male	82	Ataxia	3/5
M5	62	Male	14	Left hemiparesis	2/5
M6	62	Male	18	Left hemiparesis	2/5
F1	42	Female	98	Right hemiparesis	5/5
F2	66	Female	67	Right hemiparesis	5/5

All participants had been attending the venue for at least six months; frequency of visits ranged from two to five sessions per week. Seven out of the eight participants reported using the equipment during each visit, the eighth participant was adjusting to a bereavement at the time of interview and had not used the machines for the two months prior to interview. The recall of pre-stroke lifestyle and account of current routines were summarised for each participant alongside a pseudonym (Table 11) to facilitate an ideographic visualisation of the data throughout the results section.

Table 11: Expanded individual data and context (Article 3, Table 4)

Participant	Lifestyle prior to stroke	Current lifestyle	Centre membership	Therapy and exercise routine
M1 (Mike)	Employed as a senior manager in industry. Was in the process of moving house when stroke occurred. Recalled being very sporty as a young male but had 'no time spare' during adult life.	Lives with wife who goes out to work and was described as the 'breadwinner.' Grown up children live further afield.	Signposted at the end of NHS rehabilitation by Occupational Therapist approximately one year prior to interview. Visits the centre 2-3 days per week.	X2 sessions of PAE per visit (4-6 per week). 10 minutes on assisted pedals per visit. Unable to use treadmill. Physio session x1 per month.
M2 (Tom)	Retired joiner and craftsman. Active retirement including holidays abroad, DIY and gardening.	Lives with wife and has carers to help with ADL twice per day. Goes to church and enjoys frequent visits from family and friends.	Daughter had heard about it through an incidental conversation whilst out shopping. Joined the centre one year prior to the interview. Visits the centre twice per week.	X1 session of PAE per visit (2 per week). 5 minutes on assisted pedals per visit. Unable to use treadmill. Intermittent access to NHS physiotherapy.
M3 (Syd)	Retired IT consultant and analytics manager. Had been retired for four years prior to stroke. Active retirement including gardening, DIY, lip reading course and busy social life.	Lives with wife and is independent in all self-care. Active member of PPI and service user groups in the area. Visits the centre twice per week and also does Pilates.	Was initially introduced to the equipment at Sheffield Hallam University and an incidental conversation with a taxi driver made him aware of the centre and its facilities.	X2 sessions of PAE per week. 2x10 minutes on assisted pedals per week. Unable to use treadmill. Attends pilates x1 per week at a separate venue.
M4 (Pete)	Self-employed as a tradesman. Busy family life with two teenage children. Loved sport, especially golf.	Unable to work as tradesman since stroke. Volunteers at a charity shop twice a week and enjoys seeing his now adult children.	Heard about it through a family friend. Visits the centre five days per week.	X5 sessions of PAE per week. Arrives early to access machines and sometimes extends to 10 minutes per machine. Does not use assisted pedals. Unable to use treadmill.
M5 (Colin)	Retired falconer. Frequent holidays to USA with his wife to visit son. Busy social life with friends.	Gradual resumption of social contact with friends. Feels unable to travel overseas.	NHS psychologist recommended the centre. Visits the centre twice per week.	X2 sessions of PAE per week. 2x10 minutes on assisted pedals per week. Unable to use treadmill.
M6 (George)	Employed as an administrator for electronics company. Enjoyed visiting art galleries and often walked lengthy distances between exhibitions. Lived with elderly parents.	Unable to return to work. Tried to resume catching bus to the shops but fearful of falling and also experiences narcolepsy on occasions. Lives with elderly mum as father passed away. Self -caring in ADL.	Stroke Association representative recommended the centre. Joined approximately one year prior to interview. Currently visits twice per week.	X2 sessions of PAE per week. 2x10 minutes on assisted pedals per week. X2 sessions with the centre physio per month.

F1 (Liz)	Two weeks post-partum when stroke occurred. Active lifestyle which included running a small holding and frequent exercise sessions.	Initial impairment was severe, has gradually regained mobility and now walks 10km per day. Still lives at the small holding and is mother to her son and a volunteer at the centre.	Ex-partner had heard about the centre and she joined approximately two years following the stroke. Attends as user and volunteer helper 4-5 days per week.	X4 sessions PAE per week. Does not use assisted pedals or treadmill.
F2 (Wendy)	Employed as an accountant. Active life with friends and frequent visits to see grandchildren who lived a two-hour car journey away,	Did not return to previous employment following first stroke. Lives alone and is independent in all ADL. Gradually resumed social and family activities. Attends the centre most days.	Signposted by NHS psychologist to the centre a few months after first stroke. Now volunteers as well as using the equipment and facilities there.	Usually does x3 sessions of PAE per week plus 0.5 mile on treadmill per visit. Not currently exercising due to recent bereavement.

Key Findings

All participants reported perceived value in the combined package of exercise facilities in a supportive, social venue. Although the PAE equipment was a key incentive for joining the centre, the exercise experiences reported were intrinsically connected with peer relationships and appreciation for the team employed at the centre. Analysis of emergent themes highlighted a collective determination to sustain long term recovery; uptake of membership at the stroke centre was recalled as a brave and positive step towards reframing the lived experience of stroke. Three overarching themes evolved through cross case analysis of the data set which encompass multiple experiences associated with stroke recovery and PAE; 1) Don't tell me I've plateaued, 2) PAE facilitates the transition into long-term recovery, 3) Reframing the experience of stroke. Patterns associated with FAC score and gender were identified; previous occupation, age or time since stroke did not appear to influence the reported experience.

Overarching theme 1: Don't tell me I've plateaued.

Overarching theme one encapsulated the reported experience of hospital-based care and adjustment to life back at home. There was exploration of the expectations associated with stroke recovery and resistance to the concept of recovery plateau was expressed by several participants.

1.1 Hospital was safe but sedentary

The overriding impression of hospital-based care was of feeling safe but disempowered. Recall of hospital was as a sedentary period with rehabilitation limited in terms of quantity and clinician led. Wendy had experienced two strokes and recalled:

> *Very little (rehabilitation) at the hospital, you know, they are limited, **they** give you a bit of a walk up and down. (Wendy, 66)*

The third person reference to hospital-based rehabilitation was echoed by Colin:

> *In hospital, **they** did physio with me, and I walked in the bars, I used to walk along with them. But not very much. (Colin, 62)*

The rehabilitation teams were recalled in extrinsic terms; they were perceived as people living outside the participants' experiences. Syd described how he resisted offers of help from hospital staff in order to pursue his own recovery of independence:

> *I spent about two hours one day sitting on the side of my hospital bed, trying to put my socks on. But I wouldn't let any of the nurses come and help. (Syd, 63).*

Timescales along the care and recovery pathway were recurrent themes mentioned by most participants with specific recall of duration of admission and discharge dates. The stay was likened to a period of captivity from which they were eventually "released." Mike commented:

> *It took forever……. end of June before I was released (from hospital. (Mike, 53)*

The term "released" was also used by another male participant, George (62), in the context of his referral to the early supported discharge team which he termed the '*early release scheme.'*

1.2 Rediscovering self

Discharge from hospital to the home environment was pivotal and symbolised a shift towards ownership over recovery, particularly amongst the male participants. Recovery of mobility was recalled in specific detail amongst those participants with lower FAC scores. The language used suggested that rehabilitation became an intrinsic experience rather than something “done unto” them, reflecting a gradual transition from an external to internal locus of control:

> *I started trying to walk (without frame) in the house, it’s easier said than done. (Mike, 53)*

Pete recalled challenges associated with his home environment which he had not anticipated during his hospital stay. He was determined to recover enough mobility to avoid extensive structural adaptations to the property:

> *About three weeks in I got up steps and started sleeping upstairs, I got up and down, with help of course, only once a day. (Pete, 52)*

In common with other participants, Mike and Pete recalled their hospital stay in third person terms. The shift to first person language signifies a sense of empowerment and meaningful engagement with rehabilitation, exercise and goals within the home environment. Guidance from professional teams was valued particularly by those participants with more severe mobility impairment.

Although transition to the home environment was recalled in positive terms, it was also described as a challenging time. Adjusting to the effects of stroke and rebuilding a new way of life was hard; participants viewed recovery as an indefinite process, recovery timescales were uncertain and there was an expectation that change would continue to occur over a long time period.

NHS rehabilitation services were continued through community and out-patient therapy for all participants. This was highly valued with specific memories of individual therapists and meaningful achievements. However, a sense of abandonment could be detected upon discharge from NHS rehabilitation. Liz, who was also adjusting to early motherhood alongside the stroke recalled:

> *Home, then six weeks physio and OT and all manner of things and then that stopped. (Liz, 42)*

The six-week rehabilitation package was also reported by Mike:

> *You're left to your own devices…..six weeks training and then that's it. There's no more and you're left to get on with. (Mike, 53)*

1.3 Recovery beyond rehabilitation

The participants felt that there was nowhere else to go and four out of the eight people interviewed had heard about the stroke centre through informal word and mouth rather than being signposted by rehabilitation professionals. Colin recalled his discharge from out-patient therapy with feelings of anger and frustration:

> *They dumped me! I had to listen to it……I was really pissed off because they said "you're beginning to plateau" ……ah hell. (Colin, 62)*

The suggestion of recovery plateau conjured a sense of despair and anger; his emotions were projected towards the rehabilitation team and invoked a determination to prove that he was able to make further improvements. A sense of resistance was shared by several male participants against the expectations communicated in the earlier stages of recovery; rather than accepting the limitations imposed by stroke, there was a determination to explore their abilities and recover their pre-stroke sense of self:

I've made the necessary steps to move away from hospital and be back in charge again (laughs)…. well kind of. (Mike, 53)

The importance of continual goals was emphasised, particularly amongst those with low FAC scores:

Never give up, you've got to have something, if it's only a small thing, something to keep achieving for, to keep looking for. (Tom, 76)

The terms 'back in charge' and 'keep achieving' indicate a sense of autonomy and empowerment which had been recouped following stroke.

Syd described himself as having an analytical approach to all situations and articulated his perspective that recovery following stroke was stepped rather than linear:

The truth is that you have a slowing down of your progress, it's almost as if there's a re-grouping, and then when you feel internally comfortable then you start improving more. (Syd, 68)

The suggestion here was that the body and brain needed time to adjust to improvements, stabilise and prepare for further changes. A strong commonality across all eight participants was a firm belief that they were still making progress; a combination of intrinsic drive and external support was reflected in their accounts of stroke and recovery. All participants described active lives prior to experiencing stroke; committed to jobs, sport, family or leisure activities. There were no clear patterns associated with the nature of previous occupation and the perceived experience of using the equipment, but the intrinsic drive recognised in their pre-stroke self was evident in the approach taken towards stroke recovery:

I was hellbent on sport when I was young, now I'm hellbent on getting better. (Mike, 53).

In summary, overarching theme 1 highlights that the early recovery pathway following stroke comprised in-patient care in hospital which was recalled as a provider of extrinsic support where participants felt safe but sedentary; followed by community rehabilitation, where a sense of ownership over progress was facilitated by therapy teams. The provision of a time limited service was significant to participants, and one participant, Tom, experienced considerable anger and frustration at the point of discharge from rehabilitation. The concept of recovery plateau evoked strong emotional responses amongst some male participants with the perspective that the term was misused to justify termination of therapy.

Overarching theme 2: PAE facilitates the transition into long-term recovery

All participants reported experience of PAE on the machines sited at the stroke centre. One participant (Wendy) shared that she was not currently using the equipment due to a recent bereavement; the other seven participants were regular users, with use ranging from two to six exercise sessions per week.

2.1 Accessible, user-friendly equipment

The accessibility of the seated PAE equipment in terms of ease of mounting, combined with the assistive mechanism were features recognised by several participants. Participants reported that less mobile people were able to transfer onto the equipment from wheelchairs or through using stand aid equipment such that the opportunity to exercise was opened up in a way which might not have been feasible in a conventional gym setting. Syd and Pete compared the PAE equipment to the facilities available in a standard gym:

> *Somebody who has had a stroke just cannot get on the equipment because there is no adaptations, because, once you sit on the bicycle for instance, there's nothing to stop you from falling off; there's no adaptations. (Syd, 68)*

> *I used to go to the local leisure centre, er but I would say that I could go on the low bike….there were a few that you could sit on and do things like that ….but I've never*

really seen the variety like they've got here. To me, what they're got here on the different machines, they haven't got that at other gyms. (Pete, 52)

The benefits of assisted movement for people with motor impairment included initiation of movement and the ability to exercise for a longer duration:

It helped me to find the movement again, my right arm just started to join in more and more. (Wendy, 66)

Differences between participants were detected when they were probed about their favourite machine. Each participant expressed a preference for a specific machine and no clear pattern or consistency was expressed across the data set. Some value was recognised by most participants for all six machines and Syd applied his analytical skills to explain variability of preference according to his current goals:

Some of the machines were more beneficial to me because they coincided with the goal that I had in place at the time. They were moving the muscles that I was trying to…. Over time, because the goals have changed, so have my favourites changed, because I know I need to do something, how do I achieve it. (Syd, 68).

Participant variation was also evident with regards to preferred speed settings on the machines. Some participants felt that the faster settings stimulated a higher intensity workout, whilst others thought that slower speeds encouraged them to work harder. When asked about limitations associated with the equipment, several male participants thought that visual feedback on effort generated would be valued. Quantified data pertaining to physical performance would enable users to track progress over time and incentivise sustained engagement with the equipment:

I'd like to see the boxes (consoles) changed over from what you see now to show how much input you've actually put into the machine, so you can see if you've actually put input in or whether the machine is just working itself. (Mike, 53).

There was some comparison between the PAE equipment and the standard treadmill available at the centre. Most participants were unable to access the treadmill due to the severity of their mobility impairment and, for Colin, the treadmill symbolised a meaningful goal. He had attempted to use it but found it too difficult. His partner commented:

He got quite obsessed with wanting to try it (the treadmill) but then upset when I couldn't actually do it. (Colin's partner)

2.2 PAE as a facilitator of neuromuscular improvement

The overriding sentiment expressed by the participants was that PAE is a facilitator for continued physical recovery following stroke. The accessible design combined with the assistive mechanism opened up an opportunity to exercise for people with limited mobility and motor impairment. Several participants emphasised the importance of user engagement, a balance between the external assistance of the equipment and intrinsically generated effort:

It's you who has to put the effort in…..it's hard, very, very hard. I've noticed here, the individuals who go on the machines, do want to learn, they do want to recuperate. (Mike, 53)

The interviews probed participants to consider the perceived physical effects of PAE. A range of changes associated with the equipment were reported including improved strength and reduced joint stiffness amongst those participants with lower FAC scores; improved control of movement was emphasised by participants with higher FAC scores. The importance of joining in with the movement generated by the machines was emphasised:

The machines made me stronger….using your strength to push them has helped…...you feel breathless. (Mike, 53)

Perceived increases in strength were expressed by several participants and reflections upon improved movement control were insightful, indicating an understanding of the physiological adaptations which occurred during stroke recovery. The concept of neuroplasticity was applied by some participants:

You've got to re-bond, make new tramlines in your head that allow you to use your legs and arms. (Mike, 53)

In-depth insights into the effect of the equipment on movement and muscular activation were described. Challenges associated with the ability to inhibit muscle activity following stroke were identified and it was felt that PAE could improve motor control:

By using the equipment I found I was able to shorten the gap between telling the muscles to switch off and them actually switching off. (Syd, 68)

PAE was directly associated with upper limb recovery by Wendy following her second stroke. She had initially required assistance to maintain contact between her right hand and the exercise machines; through repetition she experienced meaningful improvement in her ability to use her right arm:

My right arm, I even found it hard holding a cup of tea and carrying it. So now I can do that…. one of the girls held my hand onto the machine for me, initially and then I could do it myself. And I think my face must have been like those that first walk. (Wendy, 66)

The multi-directional combination of movements assisted by the six machines was viewed as advantageous. Participants described feeling looser following their exercise sessions with perceived benefit from the sensory stimulus. George specifically focussed on improvements in pain symptoms associated with the equipment, stating:

> E*xercise it tends to help, to decrease my sensitivity. It's not numb, I'm not sure how to describe it, tickly I suppose. (George, 62)*

In summary, overarching theme 2 highlights that PAE was associated with perceived improvements in strength, movement control, flexibility and mobility. The exercise represented a forum for social engagement and the physical changes attained through PAE are associated with positive changes in lifestyle and participation for both male and female participants of all ages and abilities.

Overarching theme 3: Reframing the experience of stroke

Reflection upon the physical stimulus of PAE was interwoven with the wider social experience of membership at the centre. This final overarching theme explores transition into a third sector centre for PwS, illustrating the importance of context and environment when evaluating an exercise intervention.

3.1 PAE as a social facilitator

Several male participants recalled that the equipment was a key incentive for taking up membership at the centre; they had not sought a social network, just somewhere to exercise and progress their physical recovery. However, the peer support generated through use of the equipment was valued by all participants and a key incentive to continued engagement. Comparison of ability and recovery between users was evident, particularly amongst those participants with lower FAC scores:

There's some a lot worse than me and some a lot better than me …those that are a bit better give you encouragement you see, and those that are worse than me I hope I give them encouragement as well. (Tom, 76)

I talk to them and like to see how they're progressing on the machines. And it's good to hear them say how good I'm doing, it's good to hear it. (Colin, 62)

The company of other users also served as a positive distraction from the exercise, making the minutes go faster and created an element of fun alongside the activity.

PAE was associated with positive changes in participation and lifestyle. Female participants and partners reflected upon resumption of family and social activities. Wendy shared that she had recovered her identity as "fun grandma" and talked about gaining the confidence to use a local green gym with her grandchildren:

There's a park and over the other side they've put those exercise machines for everyone to use. ….and they used to have me going on those, 'come on grandma, you do it at your group so do it here,' it's great fun to do it outside and with them. So if I'd not been using the gym here I would not have ever attempted those there. (Wendy, 66).

Family relationships were also emphasised by Liz (42) who stated that her son was at the centre of all of her goals and her drive for recovery and improvement.

Changes in social engagement were also recognised by Colin's partner; she specifically recalled:

One of our friends, she owns a pub so since the stroke we go in there periodically and she said, only a couple of weeks ago, "I've really seen an improvement in him recently, he's a lot more engaged in what he's doing, and he's sitting up straighter." (Colin's partner)

A recurrent sentiment was enjoyment; participants looked forward to their exercise sessions. This reflected the value of wider social and support services surrounding the equipment. Although the PAE machines were an incentive for membership, people could attend the centre knowing that the option to use the equipment was flexible according to what was appropriate for them at any given time.

3.2 We're lucky to have this place

All participants expressed that they felt very lucky to be able to access the centre. It was viewed as a unique offering and there was a sense of great privilege that it was available in their locality. Beyond the exercise facilities, there was appreciation for the wider services available including assistance with finances, relaxation sessions for carers, high quality catering and professional entertainers such as singers and comedians. The combined package facilitated motivation and enabled people to explore their boundaries in a safe environment:

> *I think a lot of it is partly the socialisation but also the machines because he's really trying hard with them, aren't you? And again, like walking about and it's easy to say at home "do your exercises" but it's motivating yourself to do it, whereas here, you come along and have to. (Colin's partner)*

The opportunity to socialise with other people who have shared the experience of stroke is important:

> *There's the talking to other people*; *just talking to other people who have similar symptoms to me. (George, 62)*

Mike saw the centre as being pivotal in his life following stroke. His partner went out to work and he felt that he would be bereft if the centre was not available:

I've come out of my shell more when I'm here….without it? It would have been a big heartache…..stuck at home, stuck in the house. (Mike, 53)

Other participants shared the sentiment that it would be difficult to fill time if the centre were not available. George recalled instances when bad weather had prevented him from attending:

And not coming here means there's a day to do nothing, I look to try and do bits of things to do at home. (George, 62).

Wendy described how her second stroke had occurred whilst she was at the centre. She attributes her survival of this to the quick and professional action taken by the site team who ensured rapid hospital admission where she received thrombolysis.

3.3 A renewed identity

Both female participants had taken on supporting roles at the centre as volunteers which generated a sense of renewed identity. Wendy explained that she felt very proud to be associated with the centre and its members:

It's strange because you feel like you're living a completely different life, and I know this is going to sound really, really strange, but I feel more contented now because I'm not striving to achieve this, striving to achieve that. (F2)

A complete faith in the people who founded and managed the centre was described and Liz felt delighted to be able to "give something back." She reflected on the impact that the centre and equipment had on people's lives and the positive changes observed amongst members, specifically mentioning one individual:

He came first in a wheelchair, and now he walks up from the car park, with his stick……because he's been pushed on by what he can actually achieve and didn't know he could. (Liz, 42)

It was evident that membership at the centre represented an important component of overall identity for all participants. It had triggered the evolution of a renewed persona and enabled people to view stroke from a different perspective. Alongside the evolution of a "new self", some participants expressed recovery of their "old self." The loss of autonomy associated with early stroke had been restored:

It's good to feel more like me again. (Mike, 53)

The symbiotic relationship between members and the centre was summarised in a closing statement:

You're the one it's happening to and if you can't motivate yourself, I mean they do it here for you, they give you all the motivation you need. But you have to take it away with you as well. (Wendy, 68).

In summary, the centre symbolised a turning point for all eight participants. They described a transition from the vulnerability associated with early stroke to an emergence of a renewed self. The benefits attributed to using the exercise equipment were viewed in the context of the centre as a holistic offering. The perceived social and physical changes were interwoven, illustrating the importance of the environment and setting when evaluating exercise interventions for PwS. There was some indication that mobility influenced the perceived physical effects of using PAE equipment; people with limited mobility reported strength gains whilst independently mobile participants associated the equipment with improved movement patterns. Female participants emphasised changes in participation and life roles associated with membership at the centre; in contrast, some male participants had experienced frustration during early rehabilitation and were determined to continue a trajectory of physical improvement. Cross case analysis did not identify any clear trends associated with age, time since stroke or previous occupation and the reported experience of using the PAE equipment. The accessibility of the equipment when compared to conventional gymnasiums was emphasised, advancement of the software to generate feedback on user effort was suggested.

DISCUSSION

This study explored the personal experiences and perceived effects of engagement with PAE at a community-based venue for PwS. The application of interpretative phenomenological methodology generated a deeper understanding of engagement with PAE amongst PwS and the complex inter-relationship between venue membership and exercise facilities. Application of the hermeneutic cycle through IPA facilitated exploration of PAE in the broader context of adjustment to life with stroke and the venue in which the equipment was sited.

The participants in this study vividly recalled stroke as a sudden and devastating event, following which they transitioned through a health system which comprised hospital-based care followed by community rehabilitation. Previous phenomenological stroke research indicated that PwS recall feeling safe but disempowered within the hospital environment (Garrett et al. 2011). The findings from this study suggest that hospital care engendered an external locus of control. Rehabilitation was perceived in extrinsic terms as an occasional intervention administered to the participants, rather than an integral component of the care provided.

The participants in this study described meaningful achievements in terms of improved mobility within the first few weeks of returning home following stroke; this corroborates with quantitative evidence which reported increased physical activity levels amongst PwS following discharge home from hospital (Kerr et al. 2016). A positive team dynamic between the participants and rehabilitation team evolved and rehabilitation goals were focussed on the home environment and family. The participants in this study recalled improved confidence and sense of autonomy back in their home environment, which may reflect a process of reconnection as previously described by Pringle, Drummond and McLafferty (2013). However, uptake of exercise was not directly considered at this point in the recovery pathway.

Termination of health service rehabilitation was associated with feelings of abandonment and isolation. The findings of this study indicate a distinct need in the UK to ensure that PwS are further supported in accepting the termination of health service rehabilitation and access guidance in the uptake of community based, third sector services.

Challenges associated with timely and effective provision of information to PwS have been widely documented (Clague-Baker et al. 2017, O'Connell et al. 2009). The findings of this study indicate that the participants could not recall receiving advice on lifestyle, exercise or continued support services, and were in congruence with previous qualitative findings which found that people felt that there was nowhere else to go (Schouten et al. 2011). Miller et al. (2019) recognised current shortfalls in supporting PwS transition between different phases of the recovery pathway and outline five recommendations which include appointment of transition specialists and partnerships with community wellness programmes.

Several participants in this study recalled conversations with healthcare professionals pertaining to recovery plateau and this invoked feelings of anger and frustration. Participants in this study described ongoing physical gains several years after the onset of stroke and anticipated an indefinite trajectory of recovery. Exercise interventions are associated with improvements in motor performance, function and participation amongst people with chronic stroke [Linder et al, 2019]. The concept of a recovery plateau following stroke has been repeatedly challenged (Sun, Boots and Zehr 2015, Page, Gater and Bach-Y-Rita 2004), but the findings of this study suggest that the term is still used in some areas of clinical practice. Dispelling the myth of recovery plateau amongst clinicians, general public end users, and media might empower and motivate PwS to engage in long term exercise rehabilitation (Sun, Boots and Zehr 2015).

The uptake of PAE was synonymous with initiating membership at the stroke centre for nearly all of the participants. The exercise equipment represented a key incentive for joining the centre, although the value of the social dimension was emphasised by all participants. Recommendations for advancing the PAE equipment focussed on the development of effort detection software to enable users to gain feedback regarding their physical performance on an upgraded version of the console. The PAE mechanism enabled people with varying physical ability to participate on an equal footing which facilitated positive comparison and reciprocal support. Previous research has reported that long-term engagement with exercise following stroke required internally and externally sourced motivation (Scorrano, Ntsiea and Maleka 2018), the expectations of other people enhanced commitment to exercise (Signal et al. 2016) and exercise participation in a venue was more motivating than the home environment (Poltawsky et al. 2015). In-keeping with these previous findings, the value of positive peer support in a motivating and supportive setting was emphasised in the current study.

Several participants commented that PAE had made them feel fitter, stronger and more confident, with one participant commenting that she had restored her identity as 'fun grandma.' Muscle weakness and aerobic deconditioning are a known consequence of stroke (Galloway et al. 2019, Ryan et al. 2017, Scherbakov et al. 2013). Combined aerobic and resistance training programmes are effective at improving physical function for PwS (Marzolini et al. 2018). However, the ability to generate and sustain repeated or resisted movements on the paretic side is a prerequisite for participation in conventional exercise interventions. Treatment strategies devised to address this clinical challenge include Functional Electrical

Stimulation combined with cycling (Shariat et al. 2019) and robotic exoskeleton training (Stoller et al. 2014b).

The combined reciprocal, bilateral movements which occur during PAE were likely to stimulate a physiological response in the aerobic, sensory and muscular systems; this might have contributed towards the perceived improvements in mobility and function reported in this study. The accessibility of the PAE machines was also identified as a key attribute of the equipment. Five of the eight participants were of working age but stroke related impairments had enforced early retirement, and 75% of the participants in this study had a FAC score of three or less. Those participants with low FAC scores identified improved muscle strength as a perceived effect of using the equipment. The PAE machines were considered preferable to conventional gym equipment due to the variety and perceived safety. The need for inclusive and accessible exercise interventions for people with very limited mobility following stroke has been highlighted (Saunders et al. 2016).

Inclusion of non-ambulant PwS in exercise trials has been limited and mostly centred on assisted walking interventions (Lloyd et al. 2018). PAE might represent a feasible option for the inclusion of people with severe motor impairment in future stroke research.

An awareness of neuroplasticity and improved motor control was applied to the experience of PAE by some participants with higher FAC scores; perceived changes in their ability to control movement were associated with PAE. One participant (M3) described how his preferred machine changed according to his kinesiological goals. Assisted pedalling devices are available in many rehabilitation settings and some selected leisure venues (Kerr et al. 2019). The seated PAE equipment explored in this study may stimulate recovery of sagittal, frontal and transverse motor responses through the range of bimanual and bilateral movements assisted by the equipment. However, the space implications associated with accommodating the range of equipment may preclude smaller venues. Future research should determine whether seated PAE machines do enhance outcome in comparison to assisted pedalling devices and examine which machines may add most benefit.

The functional gains associated with PAE in this study might be at least partially attributable to neuroplastic adaptation triggered through engagement with assisted exercise. Assisted cycling enhanced neuroplastic potential and motor coordination for PwS (Holzapfel et al. 2019). Assisted exercise prior to physical rehabilitation interventions has been associated with enhanced neuroplastic potential (Linder et al. 2019). Some of the participants in this study also accessed the physiotherapy service available at the centre; service development could focus on implementing PAE to prepare people for therapeutic interventions.

Perspectives on optimal speed settings when using PAE equipment were varied amongst the participants as some believed that a fast pace generated a more intensive workout whilst others perceived the slow settings to be harder. Assisted cycling intervention protocols have stipulated a faster pace of movement than would be voluntarily initiated by the participant (Linder et al. 2019, Holzapfel et al. 2019) and this was deemed to enhance neuroplasticity and improve motor coordination. However, it may be hypothesised that improvements in muscular endurance and postural control could be more effectively stimulated through slowly paced assisted movement. Quantitative investigation is required to explore the physiological responses to PAE correlated with adjustment to speed settings.

The psychosocial benefits of PAE at the stroke centre was expressed by all participants, some of whom described a return of their pre-stroke sense of self, whilst others embraced a new positive identity following stroke. Although two participants had taken on voluntary roles at the venue; of the five participants who were of working age, none had felt able to resume their pre-stroke employment. Previous investigation into the experience of stroke amongst younger persons explored the devastating sequalae associated with loss of work in terms of self-identity, financial security and family role (Kuluski et al. 2014). The eclectic range of support services offered at the stroke centre precluded attributing psychosocial changes to PAE in isolation; the value of a combined package in an inclusive environment was clearly emphasised. Venue based conventional exercise interventions following stroke were associated with restoration of confidence and self-efficacy, precipitating resumption of valued activities and recovery of vocational or family roles (Young et al. 2021a). The participants in this study shared this perspective, indicating that type of exercise is not a strong determinant of psychosocial response.

Methodological quality

The role of the researcher in IPA is to invite the participant to share their sense-making of life experiences, and in turn, through linguistic and conceptual interpretation, it is the task of the research team to make sense of the data generated (Smith 2018). To this end, our study was consistent with IPA; a strength of this paper was the exploration of pre-stroke lifestyle and experiences of early care to capture the shift from the pre-reflective sensory experience to reflective awareness of illness (Toombs, 1993, cited in Smith, 2018). This depth of context highlighted the multi-faceted nature of adjustment to life with stroke and the complex interface which exists between intrinsic and extrinsic drivers.

The study sample comprised participants from one specialist venue which represented a unique facility for the local stroke population and the focus on PAE represents a novel contribution. Convergence in the findings facilitated recognition of common experiences and generated a foundation from which recommendations for service implementation and equipment advancement will be developed. The interpretation generated through the broader exploration of stroke onset and recovery corroborated with previous qualitative research, indicating attainment of theoretical generalisability between current findings and established perspectives (Smith, 2018). However, all participants identified as being white British and there was no representation from low socioeconomic groups which is possibly because of the membership fee required to access to the facilities. All participants described active lifestyles prior to the onset of stroke and had self-initiated their programme of PAE. Negative case analysis (Morse 2015) may have captured an insight into the experiences of people who have disengaged from PAE and is identified as a future research priority in this field.

The lead author has a specific interest in PAE and the potential for “pink elephant” bias was recognised at inception of the study (Morse 2015). The lead author kept a reflective journal and engaged all members of the research team in frequent debriefing sessions to facilitate reflexivity in the development of the research design, data analysis and synthesis of findings. The lead author sought to build a relationship with participants through repeated visits to the venue and a familiarisation meeting prior to the scheduled interview. However, it is debatable as to whether this constituted a true prolonged engagement or persistent observation (Houghton et al. 2013). Repeated interviews or ethnographic observation of user engagement with PAE at the venue would have enriched the data collected.

Future Research Actions and Recommendations

The application of IPA during data analysis has been the catalyst to understanding the lived experience of PwS and explored transition from NHS rehabilitation to a third sector venue. PAE is a novel intervention for PwS and to the author’s knowledge this is the first in-depth qualitative exploration of the experience of using PAE in PwS. Perceived benefits were reported alongside suggestions for advancement of the machines including the development of effort detection technology to quantify user effort and enable operators, clinicians and researchers to record user performance. Suggestions for advancement of the machines has been realised through the securing of research funding with the remit to implement a participatory design and usability project to upgrade the software on PAE machines. This technology will enable more robust quantitative evaluation of the impact of PAE and enable differentiation between psychosocial influences and physical impact of the intervention.

The perspectives of people who opt out of exercise interventions following stroke continue to be an under represented population in the published evidence (Young et al. 2021a). Future research should explore the perspectives of people who have discontinued a programme of PAE which will be a future area of enquiry for the research team and we encourage others to do the same.

CONCLUSION

This study explored the lived experience and perceived effect of PAE amongst ambulant and non-ambulant PwS in a third sector stroke venue. It was anticipated that a deeper understanding of the lived experience of using the PAE equipment in the community would facilitate insight into outcomes of most importance to users of the equipment and guide future service and product development which has been realised. Participants recruited to the study recalled frustration on the termination of routine rehabilitation and sought a continued trajectory of physical recovery through engagement with PAE. The exercise equipment was associated with reported improvements in strength, movement and function but it was suggested that the equipment could be enhanced through the introduction of software designed to provide feedback on detected user effort. Use of the equipment was synonymous with the wider experience of membership at the venue, which was associated with regaining a renewed sense of identity following stroke.

Geolocation

North England, United Kingdom

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Disclosure statement

The work published in this manuscript is part of a programme of research examining power assisted exercise as part of the lead investigators doctoral study. An academic collaboration between the equipment manufacturer and Sheffield Hallam University exists in which machines have been provided for use in kind. There is no restriction or clauses on publishing negative findings.

4.4 Summary

The qualitative outputs reported in Articles Two and Three transcended across pragmatic and interpretivist paradigms to gain an understanding of how various models of venue based exercise are experienced by PwS. Although the methods implemented within the two studies were diverse, multiple commonalities in the content of the findings were identified. In summary, PwS recalled hospital-based care and early rehabilitation as a paternalistic experience. Engagement in venue based exercise marked the creation of a new identity and recovery of an internal locus of control. Participants experienced improvements in their physical and psychosocial wellbeing and associated engagement in exercise with resumption of life roles and re-engagement with their network. The value of peer support and comparison with others were findings within both articles. A limitation identified across both studies was no access to or data from non-completers of the respective exercise programmes.

The systematic review reported in Article Two was published in *'Physiotherapy,'* a journal which sustains a wide readership amongst physiotherapists practising within the UK. The key messages within this article included a need for greater empowerment of PwS during early rehabilitation and support in transitioning into exercise programmes. Participants included in the review were heterogenous in terms of time since stroke and impairment severity. These factors had minimal effect on the perceived effectiveness and enjoyment of the programme. Rehabilitation therapists need to recognise the indefinite potential for change and improvement amongst PwS and collaborate with fitness professionals to develop solutions to address the frequently cited barriers to exercise participation.

The IPA study reported in Article Three was published in the '*International Journal of Qualitative Studies on Health and Wellbeing.'* The journal aims to develop an understanding of qualitative research through examples of rigorous qualitative methodology. The application of IPA to a novel field of study is reported in detail and will serve as an example to novice researchers seeking to develop their skills in interpretative methods. Although the original aims of the study focussed on the experience of using PAEE, the importance of context and the venue was central to the conclusions reached. Positivist methods may have failed to identify this. Importantly, a desire for more advanced technological features synchronised with the PAEE was shared by the participants. This finding substantiated the application for subsequent research funding and steered the programme of doctoral study towards co-design and usability evaluation which is reported in Chapter Five.

Chapter 5 Phase Three Co-Design and Usability Testing

5.1 Introduction and overview

The purpose of the proposed technology developed through the methods reported in this chapter was to create a Graphical User Interface (GUI) which enabled users of PAEE to select from a menu of programme options and access feedback on their exercise performance. Funding was granted in Autumn 2019 from Grow MedTech, a major UK programme which provides support for innovation in medical technologies across the Leeds and Sheffield city regions, to conduct a proof-of-concept study. The original aims stated on the funding application were:

1) To co-design with PwS and clinicians bespoke post-stroke PAE programmes with enhanced biofeedback.

2) To evaluate the feasibility of the new software within Shapemaster's PAE equipment in a real-world leisure setting.

3) Explore routes for commercialisation of the PAE technology

Due to the restrictions imposed during the COVID-19 pandemic, the second objective was renegotiated, and remote methods of usability evaluation were implemented which are reported in Article Six.

The development of health technologies to deliver or augment rehabilitation interventions has transformed service delivery and the experience of end users. Rehabilitation technologies have the potential to optimise user engagement, enable remote monitoring and create a progressive, tailored prescription based on individual needs. However, challenges to the implementation and utilisation of health technologies include context or regional differences, diverse range of users and cost-effectiveness (Ahmed, Dannhauser and Philip 2019). The importance of user involvement in the design and evaluation of health technologies is increasingly recognised. However, user involvement can be tokenistic with limited representation of hard-to-reach groups and inaccessible consultation methods (Lopes et al. 2016). Adoption of an iterative framework centred upon continuous end user consultation was identified as a priority at the outset of the proof-of-concept programme.

Multiple design method approaches have been proposed to promote meaningful engagement with service users and service providers in the development of rehabilitation technologies (Bonello et al. 2022, Beristian-Colorado et al. 2021, Jayasree-Krishnan et al. 2021, Design Council 2019, Charles and McDonough 2017, Shah et al. 2009). Commonalities identified between the approaches include an emphasis upon user engagement, iterative prototype development and usability evaluation. Examples from the literature have implemented qualitative methods during the preliminary stages to facilitate exploration of users' priorities and ideas which may include artefact creation alongside spoken narrative (Bonello et al. 2022, Thilo et al. 2017). Design teams typically categorise and distil qualitative or artefact data through thematic or content analysis to generate a design solution and create prototypes (Jie et al. 2019). Usability evaluation may comprise qualitative and quantitative methods to identify issues associated with the technology leading to advanced prototype development and ultimately commercialisation. Table 12 outlines examples of current design frameworks which have been applied to health technologies.

Table 12: Outline of design frameworks

Title	Aim	Approach	Example
Double Diamond (Design Council 2019)	To create a flexible road map to guide creative processes across multiple sectors	Discover: *understand the problem* Define: *define the challenge* Develop: *respond to challenge (co-design with stakeholders)* Deliver: *test solutions*	Design of a new user interface for a sensor-feedback system to facilitate walking in PwS (Jie et al. 2019)
People Aesthetics Context Technology (PACT) Framework (Charles and McDonough 2017)	To guide the design of gamified rehabilitation systems, placing emphasis upon people, aesthetics, context and technology.	People: *clinician, researcher, patient user, caregiver, game designer, system developer* Aesthetics: *interface, interaction, visualisation, experience, fun* Context: *user type, goals, monitoring, setting* Technology: *deployment software/hardware, game design patterns, gamification*	Development of the GAMER (Charles and McDonough 2017)
Medical Device Technology Framework (Shah, Robinson and AlShawi (2009)	To develop an acceptable and generic theoretical framework for involving various types of users in the medical device technology development process.	Stage 1: *Idea generation and conceptualisation* Stage 2: *Device design and prototype development* Stage 3: *Testing (in-house and field)* Stage 4: *Production and deployment*	Development of a wearable fall detection device (Thilo et al. 2017, Thilo et al. 2019)
SMART Habilitation Device Framework (Bonello et al. 2022)	To develop a multi-user participatory based approach to recognise requirements, ensure a positive interaction and reduce rejection rate.	Outset: *Develop user profiles based on representative users* Focus groups: *stakeholders include children with CP, parents, occupational therapists* Design engineers: *create framework based on stakeholder requirements* Usability testing: *primary, secondary and tertiary users* Evaluation: *lead to finalised framework and device*	Multi-user experience approach to design habilitation devices for children with cerebral palsy (Bonello et al. 2022)

Conceptual framework for serious games in physical rehabilitation (Beristain-Colorado et al. 2021)	To develop a framework based on structured activities of software engineering applied in a user centred design approach with an iterative process that allow visualisation of prototypes.	User centred design: *iterative process with continuous active involvement of end users* Structural activities in software engineering: *communication, planning, modelling, construction, deployment* Gamification: *flow enhancement, immersive factors, progress, rewards, feedback and challenge*	Standardising the development of serious games for physical rehabilitation: conceptual framework proposal (Beristian-Colorado et al. 2021)

The Medical Device Technology Framework (MDTF) (Shah, Robinson and AlShawi 2009) was selected by the research team to guide the co-design and evaluation of the GUI to advance PAEE for PwS. Although the potential for serious game development within the GUI was acknowledged, this was not the central purpose of the new technology and therefore the People, Aesthetics, Context Technology (PACT) framework (Charles and McDonough 2017) and the conceptual framework proposed by Beristain-Colorado et al. (2021) may not have facilitated the breadth of exploration required to co-design and test the new GUI. The Double Diamond model (Design Council 2019) may be applied to a diverse range of sectors whereas the MDTF was developed through a health-related context and distinguishes between the stages required to develop a new technology or upgrade an existing device. The MDTF can be applied to a diverse range of health technologies and is not specific to a particular clinical population. The objective of the Grow MedTech funded PAEE project was to implement a new device to market as the existing PAEE did not have any effort detection or biofeedback capacity. This aligned with 'Scenario A' outlined by Shah, Robinson and Alshawi (2009) which would involve an iterative process between design and prototype development stages. User involvement streams are clearly defined within the MDTF and enabled the research team to distinguish between Expert Users (EU) who were PwS and their caregivers; and Professional Users (PU) who included rehabilitation therapists, exercise professionals, leisure operators and marketing teams.

The MDTF is detailed in the supplementary materials of the publication by Shah, Robinson and AlShawi (2009). It outlines four key stages to guide technology development; 1) idea generation and conceptualisation, 2) device design and prototype development, 3) prototype testing including in-house and field evaluation, 4) device production and deployment. A range of data collection and analysis methods are recommended to progress through the design and development stages including brainstorming, focus groups, interviews, seminars and usability tests (Shah, Robinson and AlShawi 2009). Previous examples of its application include the development of a wearable fall detection device (Thilo et al. 2017) in which stage two involved demonstration of a mock-up device and qualitative semi-structured interviews with 22 older adults (Thilo et al 2017). Stage three comprised field testing of the device with representative users followed by qualitative focus groups (Thilo et al. 2019). It was concluded that the development of health devices should consider technical aspects in the context of users' habits, preferences, daily routines and skill (Thilo et al. 2019). Although the device development process reported by Thilo et al. (2019) is a relevant example of application of the MDTF, user involvement was not incorporated during stage one. Instead, idea generation and conceptualisation were developed from the nursing experience of the authors, interdisciplinary discussion with engineers and research evidence (Thilo et al. 2017).

At the outset of the Grow MedTech funded programme, co-design and usability evaluation methods to address each stage of the MDTF were selected. An early priority was to identify three seated machines from the range of nine manufactured by Shapemaster on which to pilot the new technology. Nominal Group Technique (NGT) was selected as a consensus method to enable PU and EU streams to rank their preferences on the range of equipment and explore their perspectives upon the digitisation of PAEE through structured, chaired discussion. This preliminary user consultation activity aligned with stage one of the MDTF and is reported in Article Four. Methods to progress device design and prototype development were required to achieve stage two of the MDTF. Focus groups centred around storyboarding activities were selected to facilitate artefact creation and discussion between PU and EU participants. This multi-component stage of the study which comprised storyboarding, participatory analysis and prototype development is reported in Article Five. A mixed method approach towards usability testing was selected to evaluate the technical capacity of the GUI alongside an understanding of the user experience. The synchronous remote usability evaluation conducted in 2020 during the COVID-19 lockdown is reported in Article Six. Figure 10 illustrates three stages of the MDTF applied to the Grow MedTech funded programme of work.

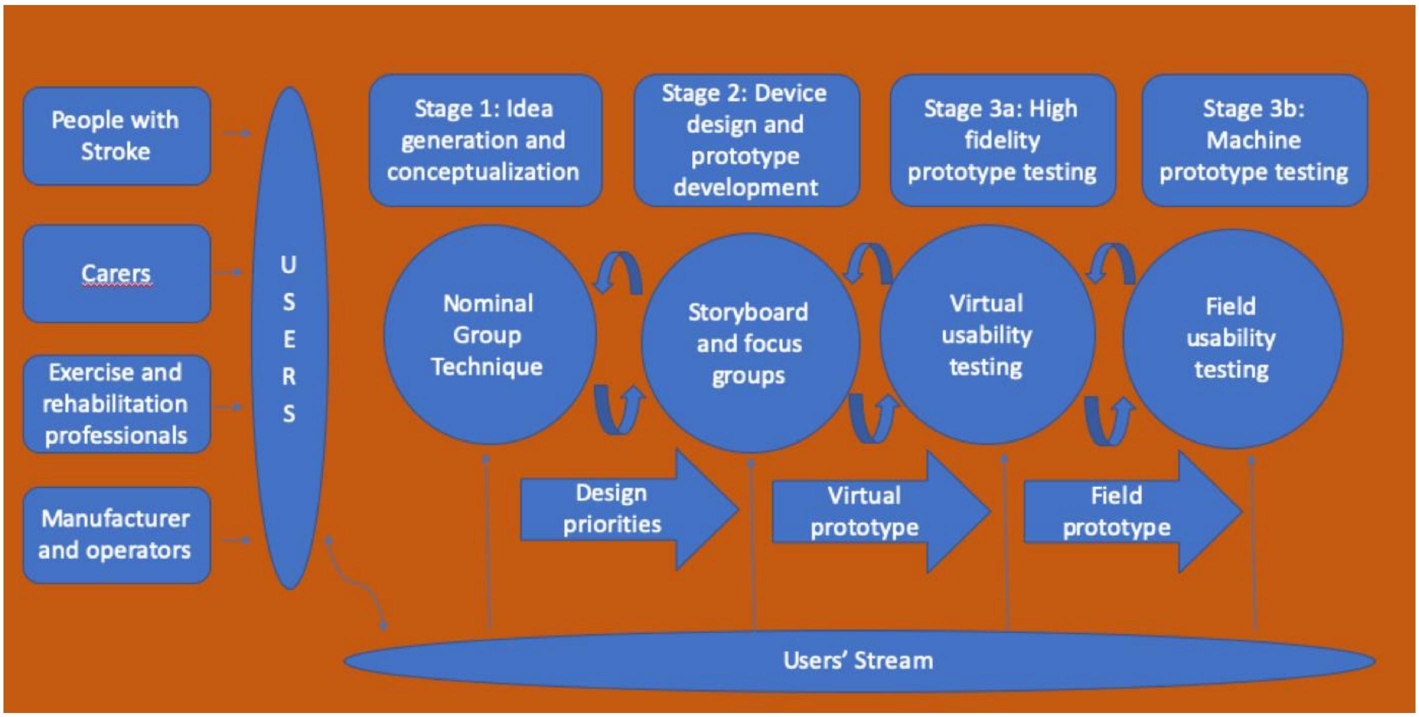

Figure 9: Application of the Medical Device Technology Framework

5.2 Methodology

Participatory research methods recognise that participants are uniquely knowledgeable about their own social and physical reality and challenge the traditions of positivist enquiry and elitist research through a collective approach driven by collaborative approaches (Higginbottom and Liamputtong 2015). A transformative paradigm shaped this phase of the programme of research as we sought to empower representative users to co-design and evaluate the new technology (Chilisa and Kawulich 2005). Transformative research approaches aim to emancipate marginalised communities and have evolved from critical theory, feminist perspectives and neo-Marxism (Higginbottom and Liamputtong 2015). The ontological position is based on the view that a discoverable social reality does exist, however, it is historically bound and constantly changing. Proponents of transformative research approaches recognise that reality has multiple layers, and, from an epistemological perspective, knowledge is constructed from the participants' frame of reference. The hierarchies which dominate positivist and interpretivist paradigms are levelled to enable emancipation of both participant and researcher (Wagner, Garner and Kawulich 2011).

Public involvement in health research has been identified as a moral duty which will enhance the efficiency of research processes and ensure accountability (Greenhalgh et al. 2019). However, challenges associated with meaningful user engagement include limited diversity within nominated or self-selected user representatives (Wicks et al. 2018) and reinforcement of oppression rather than integration of marginalised communities within models of medical education (Cartmill et al. 2022). Empowerment of staff who deliver clinical services has also been identified as a complex challenge, reflective of critical social theory which is based on the premise that certain groups within society and organisations maintain subordinated positions (Kennedy, Hardiker and Staniland 2015). In the context of nursing and health technologies, the importance of clinician involvement throughout all stages of development and implementation has been emphasised (Ronquillo et al. 2021). The MDTF promotes PU and EU engagement at all stages of device development; broad inclusion participant criteria were adopted across all three stages of co-design and usability evaluation to maximise diversity of user representation.

Although we aimed to adopt and sustain transformative principles throughout the Grow MedTech funded programme of research, the selection of data collection methods was determined by the research team. A wholly transformative, non-hierarchical approach would have involved consultation with marginalised and representative user groups to shape the data collection process. However, challenges associated with enabling user groups to understand the process of participatory research methods are reported (Wicks et al. 2018). Participatory analysis of the storyboard data created with representative user groups (Article Five) did enable meaningful discussion with the participants regarding the data and its interpretation. However, challenges in communicating the purpose of participatory analysis were encountered and the discussions tended to digress away from the data towards broader narrative regarding technology preferences.

5.3.1 Article Four

Using nominal group technique to advance power assisted exercise equipment for people with stroke.

Source: Research Involvement and Engagement, 2021, 7:68

Authors: Rachel Young, Karen Sage, David Broom, Katherine Broomfield, Gavin Church, Christine Smith

Plain English Summary

Seated power assisted exercise machines assist different combinations of movement and can help people with stroke to take part in exercise programmes. Nine seated machines are manufactured in the UK. It was identified that the machines could be improved through development of technology to detect and display the user's physical effort during exercise. The research team successfully applied for funding to design and develop a new programme to display and measure user effort whilst exercising on the equipment.

At the outset of the project the research team needed to make decisions about the capabilities of the new technology and select three machines from the range of nine to be prototyped. We used a method called nominal group technique during which end users with stroke, rehabilitation and exercise professionals were invited to structured meetings to share their ideas. At the end of the meetings the groups voted on their preferred machines.

The ideas expressed during the meetings were listed and guided the ongoing development of the technology. The importance of a user-friendly interface was emphasised. The three machines which were allocated the most votes across the user groups were selected to be redesigned and developed with the new technology. The involvement of users at the outset of the design project ensured that they directly influenced the selection of machines and features of the new technology. Nominal group technique was an effective way of ensuring that all attendees had the opportunity to share their ideas and perspectives.

Abstract

Background

Power assisted exercise is accessible and acceptable for people with stroke. The potential for technological advancement of the equipment to improve the user experience has been identified. Involvement of end users and service providers in the design of health technologies is essential in determining how said technology is perceived and adopted. This project invited people with stroke and service providers to influence design features and determine machine selection in the preliminary stages of a codesign research programme.

Aims

To capture the perspectives of people with stroke and professionals working with people with stroke about proposed digitalisation of power assisted exercise equipment and select machines for prototype development.

Methods

Nominal group technique was used to capture the perspectives, ideas, preferences and priorities of three stakeholder groups: people with stroke (n=3, mean age 66 years), rehabilitation professionals (n=3) and exercise scientists (n=3). Two questions underpinned the structure of the events; *'What does an assistive exercise machine need to do to allow the person with stroke to engage in exercise?'* and **'***Which machines would you prioritise for use with People with Stroke?'* Attendees were invited to cast votes to indicate their preferred machines.

Findings

Synthesis of the data from the NGT identified four domains; software and interface, exercise programme, machine and accessories, setting and service. Three preferred machines from a range of nine were identified through vote counting.

Conclusion

Nominal group technique directed the selection of machines to be included in the development of the proposed technology. The vision shared by users during the structured discussion shaped the subsequent steps in the design and testing of the new technology.

Patient and service provider contribution

The opinions and preferences of people with stroke, rehabilitation professionals and exercise scientists were central to key decisions which will shape the digitalisation of power assisted equipment, influence future research and guide implementation of the new technologies.

INTRODUCTION

Involvement of end users and service providers in the design of health technologies is essential in determining how said technology is perceived and adopted (Nasr et al. 2016). User involvement is fundamental for creating a positive technology-based experience that is meaningful for the end-user (Shah, Robinson and AlShawi 2009). The adoption of user involvement principles in the development of new assistive technologies generates a partnership between consumers and providers and shifts the traditional dynamic of “doing for” the user to “doing with” (Desmond et al. 2018). An understanding of the experiences and priorities of future users guides co-design projects and mixed methods are used to capture a rounded user perspective (Nasr et al. 2016).

User involvement in technology design refers to an iterative, cyclic approach to product development during which clinicians, patients and carers influence and evaluate the new technology (Petersen and Hempler 2017, Nasr et al. 2016). The four stage MDTF proposed by Shah, Robinson and AlShawi (2009) emphasised continuous user involvement, starting with idea generation to visualise the new product. Patient and Public Involvement (PPI) can facilitate early collaboration between patients, service providers and researchers (Pandya-Wood, Barron and Elliott 2017). Effective PPI enhances transparency in research processes and is particularly crucial in the development and implementation of assistive technologies (Williamson et al. 2015).

Inclusion of end users is evolving as they have become active partners in their own disease management and, as such, take part in research ‘with’ the research team rather than being participants of research done ‘to’ or ‘about’ them (Higginbottom and Liamputtong 2015, National Institute for Health Research 2021). However, reported barriers to effective and inclusive patient involvement in health technology decision making include under-representation, limited transparency and inaccessible consultation methods (Lopes et al. 2016). The reporting of PPI has been inconsistent with little information about the context, process or impact of public/end user involvement (Staniszewska et al. 2017). Volunteers who engage in user consultation have indicated that they would like their involvement to be more visible including during dissemination (Daveson et al. 2015). Guidelines to support the reporting of PPI have been developed to enhance awareness of PPI activities and the subsequent influence on research design, interpretation of outcomes and dissemination (Staniszewska et al. 2017).

The boundaries between PPI and research can be blurred and different perspectives regarding the remit and reporting of PPI have been articulated (Staniszewska et al. 2017, Williamson et al. 2015). Qualitative research requires data collection and analysis for the purpose of an improved in-depth understanding of a topic and development of new theoretical perspectives; whereas PPI entails user group consultation to ensure end users' active involvement in decisions about research priorities, design and conduct (Hoddinott et al. 2018). Integrated partnership approaches which involve data collection and analysis for the purpose of decision making and change has been identified as a third division positioned between PPI and qualitative research (Hoddinott et al. 2018).

The MDTF (Shah, Robinson and AlShawi 2009) was selected to underpin this iterative design project focussed on PAE for PwS. The application of the MDTF ensured that an inclusive approach to user involvement was sustained and disseminated from the point of preliminary idea generation to the development and testing of the new technology. The four-stage framework comprises 1) idea generation, 2) device design, 3) prototype testing, 4) field testing. This report describes the idea generation stage which was succeeded by co-design through storyboarding (stage two) and usability testing (stage three). Shah, Robinson and AlShawi (2009) emphasised the importance of diversity in the identification of stakeholders and their model stipulates inclusion of professional users and expert end users. Strategies to enable PwS to engage in PPI include support and reimbursement for travel, tiered levels of involvement and dedicated professional support to manage challenges associated with communication and concentration (Harrison and Palmer 2015).

Power Assisted Exercise for People with Stroke

People with limited mobility following stroke experience difficulty in accessing conventional exercise interventions and are under-represented in the growing body of evidence informing exercise for PwS (Lloyd et al. 2018). PAE machines are accessible and acceptable for people with complex neurological impairment and limited mobility following stroke; the multi-directional, global movement patterns facilitated by the equipment are associated with improved mobility and user independence (Young et al. 2018). Users need to have independent sitting balance and be able to process brief instructions or demonstration to use the equipment safely (Young et al. 2018).

Guidance on exercise interventions for PwS stipulate specific parameters for aerobic conditioning and resistance training to optimise physiological response (Mackay-Lyons et al. 2020). PAE machines offer varied speed settings but the duration and intensity of exercise is not based upon the exercise prescription detailed in published guidelines (MacKay-Lyons et al. 2020). Furthermore, the existing software does not measure or quantify the physical effort generated by the user. Real-time feedback during exercise has been associated with physical improvements amongst PwS (Lewek et al.2012). Digitalisation of rehabilitation interventions creates the opportunity to optimise performance feedback and the potential to introduce cloud-based rehabilitation and monitoring (Hossain et al. 2018). Advancement of PAEE to align the training stimulus with published guidelines for individual users and generate digitised biofeedback on user effort is currently being explored through a proof of concept co-design project. Resource planning at the outset of the project required the research team to select three priority machines from a range of nine to establish the proof of feasibility of the proposed technology. This paper reports on a user involvement exercise which aimed to capture the perspectives of service providers and PwS and rank the nine machines according to user preference during the planning phase of the project.

Nominal Group Technique

Nominal group technique is a consensus method which incorporates idea generation and collection, ordered group discussion and anonymous ranking of preference through voucher allocation by individual members (Daveson et al. 2015). Nominal group technique is a formal consensus development method based on structured group discussion; the method prevents individual participants from controlling the discussion and ensures all groups members have the opportunity to share their suggestions and opinions (Harvey and Holmes 2012). It aims to achieve agreement or convergence of opinion around a particular topic and gauge the strength of that convergence and may be applied to determine priorities (McMillan, King and Tully 2016).

Nominal group technique is well suited to user involvement as it promotes equal representation from all participants through chaired discussion and vote counting (Daveson et al. 2015). The translation of NGT findings into the preliminary phases of co-design projects ensures meaningful representation of the user perspective (Harvey and Holmes 2012). Nominal group technique has been applied previously to obtain views and gain consensus on interventions for supporting PwS and is an accessible method for participants with communication impairment which is experienced by one third of the stroke population (Stroke Association 2021, Condon et al. 2019, Hinckley et al. 2014). Nominal group technique is particularly useful where participants are likely to have diverse views on a subject or where limited research evidence is available (McMillan, King and Tully 2016).

Aims

The aims of the NGT process were to capture the user perspective of the proposed digitalisation of PAE equipment for PwS, identify and categorise priority design features and select three specific machines for prototype development.

METHODS

PPI Framework

Tritter (2009) created a framework for conceptualising PPI which identified direct or indirect; individual or collective; and reactive or proactive models of involvement. The model of PPI adopted through this application of NGT was collective, direct and proactive as it captured a group perspective to shape and influence the focus of the proposed project. People with stroke, exercise scientists, rehabilitation experts and researchers came together to determine machine selection and priority design features for the advanced equipment. An ethos of collaboration was promoted through the chaired and structured discussion integral to NGT and the use of anonymous votes to determine machine selection. Separate sessions were scheduled for the PU group and EU group to ensure an honest exchange of opinion between the PU group and optimise empowerment amongst the EU group (Harrison and Palmer 2015, Shah, Robinson and AlShawi 2009).

NGT members

At the outset of the project, a team of experts was identified to ensure representation from PwS, health care services and academia. To be considered for invitation to the PU meeting, expertise in either stroke rehabilitation, clinical exercise prescription or PAE equipment was required. Seven experts employed by the host institution comprising four physiotherapists and three exercise scientists were invited to the PU meeting**.** To be considered for invitation to the EU meeting, service users were required to have a diagnosis of stroke and experience of using PAE equipment. Five members of the service user group at the host institution who met this criterion were identified and invited to the EU meeting. The NGT meetings were chaired by the first author (RY) who is a research physiotherapist and directly supported by a Professor of Rehabilitation (KS). In addition, a specialist neurological physiotherapist (HL) with experience of qualitative research methods for PwS supported the EU meeting to facilitate communication and inclusion of all attendees (Harrison and Palmer 2015).

Ethical considerations

An ethically conscious approach was adopted throughout the NGT sessions held with the PU and EU groups (Pandya-Wood, Barron and Elliott 2017). Ethics committee approval was not required as the remit of this activity was PPI to facilitate user involvement at the outset of the programme. Written information about the meeting was circulated to potential attendees two weeks in advance. Signed permission was obtained from all attending NGT members which included authorisation to audio record the event and publish findings. The users involved in the NGT meetings were made aware that they could withdraw their contribution during or up to one week following the meeting to allow time for reflection upon the session and their contribution.

Meeting Format

The NGT meetings took place in accessible seminar rooms at the host institution. Transport was provided for attendees of the EU event and travel costs were reimbursed for attendees of the PU event (Harrison and Palmer 2015). Ground rules and objectives were communicated at the outset to set the tone of the session and promote a shared understanding of its context. The meeting addressed two questions and followed a structured format which comprised individual ideas generation in silence (written down), sharing one by one from each participant until no further ideas remained unsaid, structured discussion as a group to allow ideas to group into themes and individual voting (Table 13). The technique prevents individual participants from controlling the discussion and ensures all groups members have the opportunity to share their suggestions and opinions (Harvey and Holmes 2012). The events were recorded on an Olympus WS-811 Dictaphone and field notes were retained for analysis.

Table 13: Nominal group steps common across both meetings (Article 4, Table 1)

Step	Activity
One	Introductions, NGT objectives and ground rules. Summary of the nine machines presented by lead author through PowerPoint software.
Two	**Question one:** *'What does an assistive exercise machine need to do to allow the person with stroke to engage in exercise?'*
Three	Attendees write their list of ideas in silence.
Four	Attendees invited in turn to share aloud their ideas, taking it in turns to offer one idea at a time from their written list until all the ideas were shared. Field notes documented on flipchart by RY.
Five	Group discussion and merging of topics
Six	**Question two: '***Which machines would you prioritise for use with PwS?'*
Seven	Attendees consider their options in silence
Eight	Attendees provided with 10 vouchers each. They were asked to allocate the vouchers across any number of machines and can indicate strength of preference through number of vouchers allocated. The machines were represented on A4 photographs laid out on the table.

Analysis

As this was a PPI activity rather than primary research, the intention was to summarise and categorise the ideas shared in response to the questions posed rather than to generate new theories or perspectives. The audio recordings were transcribed verbatim and the written lists generated by participants were copied into the transcription. The first author (RY) familiarised herself with the content through repeated reading and note taking.

Key stages which underpin qualitative content analysis were adopted to interpret and organise the information captured during the NGT events (Erlingsson and Brysiewicz 2017; Graneheim, Lindgren and Lundman 2017). Two rehabilitation experts from health care services (KB, GC) were identified to support the lead author (RY) in the organisation and categorisation of the transcripts. The three analysts independently coded and categorised the content of the transcripts. The interpretation and categorisation of the transcripts remained close to the manifest content to ensure a concrete rather than abstracted interpretation of the written and verbal suggestions (Graneheim, Lindgren and Lundman 2017). Alignment of content back to the topics which had emerged during step five of the events ensured that the interpretation and categorisation of the transcripts remained close to the priorities emphasised by the NGT event attendees. Discussion between the analysts led to agreement upon four domains (Hsieh and Shannon 2005). The content of the domains was tabulated with columns to represent the perspectives articulated by the PU and EU groups respectively.

The number of votes allocated to each machine were counted and recorded by RY at the end of each event. The count from the EU group (n=3) was adjusted through multiplication to equalise with the proportion of votes from the PU (n=6) group. The top three preferred machines were determined by the highest total count.

RESULTS

Membership of the Professional User meeting

Six out of seven invited experts in rehabilitation or exercise science attended the PU meeting. The PU group included a clinical physiotherapist, research physiotherapist, a higher degree physiotherapy graduate with a specialist interest in PAE and three exercise scientists with expertise in physiology, muscular performance and clinical populations. The Managing Director of the PAE equipment manufacturer attended the meeting to answer any queries, observe the discussion and capture insight into the perspectives of the invited experts.

Table 14: **PU** attendees (Article 4, Table 2)

Attendee I.D.	Profession	Longevity of experience (years)	Gender identity	Specialist interest	Highest qualification
P1	Physiotherapist	19	Female	Neurological rehabilitation and technology	MSc
P2	Physiotherapist	3	Female	Rehabilitation and PAE	MSc
P3	Physiotherapist	29	Female	Neurological rehabilitation	MSc
ES1	Exercise scientist	18	Male	Physical activity for special populations	PhD
ES2	Exercise scientist	10	Male	Clinical exercise physiology	PhD
ES3	Exercise scientist	11	Male	Neuromuscular physiology	PhD

Membership of the Expert User meeting

Three out of five invited service users with a diagnosis of stroke and experience of using PAE machines attended the EU meeting. The three attendees of the EU meeting were female with one-sided weakness following stroke. Detail regarding experience of PAE is detailed in Table three.

Table 15: **EU** attendees (Article 4, Table 3)

Attendee number	Age	Time since stroke	Gender identity	Impairment	Functional Ambulation Category	Experience of PAE*
E1	76	12 years	Female	Left hemiparesis	2/5	1 session per week for previous 6 months
E2	67	5 years	Female	Right hemiparesis and aphasia	3/5	2 sessions per week for previous 6 months
E3	56	4 years	Female	Left hemiparesis	4/5	2 sessions per week for previous 6 months

Group discussion

Four content domains were identified through analysis of the written notes and transcripts captured during steps three, four and five of the NGT meetings. These were; 1) software and interface, 2) exercise programme, 3) machine and accessories, and 4) setting and service. The features suggested by the expert groups associated with each of these categories are detailed in Table 16. Priorities identified across both groups are indicated in bold font.

Table 16: Features for PAE suggested by the expert groups ((Article 4, Table 4)

	Category	Subcategory	EbP Priority*	EbE Priority**
FOUR DOMAIMS	Software and Interface	Interface	**User friendly** **Clear visual display** Fun and motivating Gamification Demonstration video	**User friendly** **Clear visual display** Easy to reach
		Feedback	**Inter-session comparison** **Meaningful** **Individualised** Watts and power generated Heart rate monitoring Symmetry of effort Baseline comparison	**Inter-session comparison** **Meaningful** **Individualised** Sensitive to small effort Accurate and continuous Generate digital record Calculated calorie expenditure
	Exercise programme	Movement	**Functional and efficient** **Simple patterns** **Goal orientated** **Adjustable speed** **Reciprocal movement** Machine initiated Optimal limb alignment Resisted movement option	**Functional and efficient** **Simple patterns** **Goal orientated** **Adjustable speed** **Reciprocal movement** Multiple movements
		Physiological demand	**Improve motor control** **Soft tissue stretch** **Decrease hypertonicity** Physiological overload Cross education Eccentric and concentric Aerobic demand Progressive trajectory	**Improve motor control** **Soft tissue stretch** **Decrease hypertonicity** Manageable duration
	Machine and accessories	Accessibility	**Safe transfer on and off** Hemiplegia friendly Fits with transfer aid equipment	**Safe transfer on and off** Reachable components Able to access independently Height adjustable
		Accessories	**Bespoke limb support** **Quick release components**	**Bespoke limb support** **Quick release components** Secure walking aid storage Reach bar to secure balance
	Setting and service	Team	**Good knowledge of equipment** Ability to educate users Ability to support goal setting Ability to manage expectations	**Good knowledge of equipment** Available to help Understand movement patterns Understand limited mobility
		Environment	**Client centred service** Social and peer support	**Client centred service** Integrated therapy service

***bold font indicates PU and EU priority**

1. Software and interface

This domain summarised the content relevant to the suggested features, functionality and aesthetics of the user interface to enable the user to engage in programme selection and receive feedback on their exercise performance. There were two subcategories; a) interface and b) measurement of performance.

a. Interface

A user-friendly visual platform for the software was prioritised by both expert groups and the EU attendees highlighted the need to be able to reach the interface from either the right or left side. The PU group emphasised the importance of a fun and motivating interface using 21st century technology, and potential for gamification of exercise through the interface.

b. Measurement of performance

Comparison of performance between sessions was identified as a priority feature by both groups. Amongst the PU group, the exercise scientists emphasised the importance of inter-session comparison and identified several options for units of measurement including watts, power, range of movement, heart rate and calorie expenditure. However, it was acknowledged that values such as watts and power may not be meaningful to end-users. The EU group also identified the potential value of inter-session comparison;

> *If there was something that kept…nowadays you would expect something computerised, technology. You'd log in …. it would have kept the data for you. Week by week. (E2)*

The physiotherapists in the PU group specifically emphasised the potential value of feedback on symmetry in terms of the effort detected from the right and left side.

2. Exercise Programme

This domain encompassed the exercise stimulus created by the machine and the exercise programme relayed through the interface. There were two subcategories; a) movement stimulus and b) physiological demand.

a. Movement stimulus

Functional, simple and efficient patterns of assisted movement were prioritised by both expert groups. The physiotherapists in the PU group and EU members highlighted the importance of machine-initiated movement for people with neurological impairment and suggested that the perfect machine would facilitate good alignment and direction of movement. The physiotherapists in the PU group and EU attendees identified reduced muscle tightness and tone as desired response to the exercise programme:

> *The machines need to be encouraging me to focus on extension because obviously flexion is like, well I do it far more than I want to…. I would like to see that reflected in the way that the machines work and record the effort so you could actually do more of that which I want to do, not this (indicates flexion) because I do that plenty. (E3)*

The exercise scientists suggested that the option to progress from assisted to resisted movement would be an additional asset to align with overload principle of training whereby the physical challenge is incremented to promote improved strength and fitness. The PU group identified those machines which assisted trunk movement as important as they enabled a stretch which would not be possible to achieve independently:

> *Well that one (side bend stepper) did so much, I was so thrilled with it that I said could she put it on for a couple minutes more? Because, from my physio, I know that my back needs stretching. Because otherwise the muscles just tighten up. (E1)*

b. Physiological demand

The attendees of the PU group emphasised the importance of creating physiological overload through progressive levels of physical challenge to stimulate adaptation to the demand of the exercise. Improvements in various aspects of muscular performance were specifically highlighted by the exercise scientists, alongside the option to adapt the target intensity according to fluctuations in user wellbeing:

There needs to be options for progression and regression (ES2)...Yes, so not because you can't be bothered today but if they've got other issues and comorbidities and today is a bad day but they still want to be able to exercise. (P1)

3. Machine and Accessories

This domain was emphasised more by the EU group; although the PU group also highlighted the importance of safe and accessible machines. This domain is subdivided into two categories; a) accessibility and b) features and accessories.

a) Accessibility

The importance of being able to safely transition on and off the machines with minimal assistance was emphasised by both groups. The physiotherapists in the PU group specifically suggested equal access from either side and safety features to minimise risk of injury. The EU group wanted the machines to be height adjustable, to enable easier mount and dismount from the seated equipment:

I'm only five foot two inch, I need a step to get on some of the machines, getting on can feel like a workout in itself. (E3)

b) Features and accessories

Bespoke support structures for the limbs, hands and feet were suggested by both groups alongside the importance of user-friendly, removable attachments for the limbs. The physiotherapists from the PU group emphasised the need for effective support of posture and alignment. Additional features suggested by the EU group included secure walking aid storage and a reach bar to enable users to secure their balance whilst mounting and dismounting the equipment.

4. Setting and service

Attendees of both groups indicated the importance of types of setting and service where PAE for PwS may be offered and another category emerged as a result: a) team and b) environment.

a. Team

Both groups identified the importance of a skilled team to support users during their programme of PAE. Essential skills of a service provider team identified by the EU group included knowledge of the machines, movement patterns and the availability of staff or volunteers to provide assistance when required. The PU group identified the ability to educate, provide reassurance and support realistic goals.

b. Environment

A client centred service which was adapted to the needs of each individual was highlighted as important by both groups:

> *Well, sometimes, the helpers come to help me, and I've finished on one machine and they want to go straight onto the next…and I say I'm sorry, I've got to rest for a minute. Because I can't rush from one thing to another. I need the time to get around. And then I'm aware that someone else is obviously waiting for your machine. (E1)*

The EU group also identified the value of the physiotherapy led guidance when using PAE machines. The PU group emphasised the importance of social and peer support in exercise venues and the creation of an atmosphere which facilitates the development of friendships between users.

Machine preferences

The anonymised machine preferences indicated by vouchers placed on a photograph of each machine were recorded and the votes from the EU (n=3) group were multiplied twofold to ensure equal representation of machine preference with the PU group (n=6). The three most popular machines were the Cross Cycle (23), Chest and Legs (22) and the Rotatory Torso (18). The least popular machines were the Tummy Crunch (4) and Seated Abductor (4).

The Side Bend Stepper was most popular amongst the EU group, gaining 7 out of the total 30 tokens available. However, only 3 tokens were placed on this machine from the PU group making it the fifth ranked machine overall. All nine machines gained a minimum of two tokens from the EU group whereas the Tummy Crunch and Seated Abductor gained no tokens from the PU group. The machines which predominantly assist limb movement gained the majority of votes from the PU group in contrast to the EU group who indicated more preference for those machines which assist movement of the trunk. The ranking of machines is displayed in Table 17.

Table 17: Voucher allocation per machine (Article 4, Table 5)

Machine and action	Token allocation PU group	Token allocation (x2) EU group	Ranking
Cross cycle Pedalling motion of legs and combined flexion extension of the arms.	17	3 (6)	1
Chest and legs Bimanual flexion and extension of legs and arms.	14	4 (8)	2
Rotatory torso Rotation of the trunk with shoulders and pelvis moving in opposite directions.	8	5 (10)	3
Seated climber Stepping action of legs and alternate reach upwards with arms	11	2 (4)	4
Side bend stepper Lateral flexion of the trunk and stepping action with legs.	3	7 (14)	5
Ab pullover Elevation of upper limbs, flexion of trunk and hips.	5	2 (4)	6
Tricep dip leg curl Extension of elbows and flexion of the knees.	2	3 (6)	7
Tummy crunch Flexion of the trunk and hips.	0	2 (4)	8
Seated abductor Horizontal abduction and adduction of shoulders and hips.	0	2 (4)	8

DISCUSSION

The use of NGT methods generated novel ideas linked to the question and provided a focus for understanding user priorities at the outset of the co-design project. The NGT method elicited a list of suggested features to enhance the equipment and structured group discussion captured the importance of an individualised, science informed exercise programme. Expert consensus enabled the selection of three specific machines through token placement and ranking. The value of a motivating and progressive PAE programme which can be used independently was articulated by both expert groups. Areas of convergence between the expert groups were identified.

Value of diverse user involvement

The features associated with the proposed PAE programme combine elements of exercise training and therapeutic rehabilitation. The exercise scientists emphasised the training overload principle to elicit a physiological response; whereas the physiotherapists and EU group discussed the value of efficient, goal oriented, reciprocal movement patterns. The range of priorities expressed illustrated the value of consultation with diverse experts in the preliminary phase of the co-design project. Published exercise guidelines for PwS have focussed on improvements in aerobic capacity and muscular performance (MacKay-Lyons et al. 2020); whereas physical rehabilitation for PwS has prioritised quality of movement and functional recovery (Michielsen et al. 2019). Assisted exercise enhances motor recovery and improves aerobic capacity for PwS (Linder et al. 2019) and therefore may bridge the historical gap which has existed between exercise and rehabilitation perspectives.

Embracing a digitalised future

The introduction of assistive technologies in rehabilitation has the potential to enable users to gain empowerment over their recovery and move towards a therapist-directed rather than therapist-dependent rehabilitation programme. Both expert groups emphasised the importance of a user-friendly interface which can be operated independently by the end user. Prioritised suggestions included motivational features, graded progression and real time feedback. Previous exploration of home-based technology through co-design with PwS also highlighted the value of user feedback, motivational gamification and independent use (Nasr et al. 2016).

Assistive technologies may be perceived as detached and impersonal (Bedaf, Marti and DeWitte 2019), the importance of an individualised user experience was articulated during the group discussions. In the context of PAE, an individualised user experience would facilitate the user to develop a bespoke relationship with the interface to enable an adaptable, goal-oriented exercise experience and access personalised digital information regarding progress and achievements. The emotional response triggered by interaction with technology may be influenced by the product's quality, function and individual meaning (Nasr et al. 2016). Customizable health technologies matched to the users' needs and preferences has been identified as a priority (Bedaf, Marti and DeWitte 2019).

Both groups embraced the prospect of a digitalised programme able to generate a numerical record of performance and achievement. The digitalisation of user data can enable remote supervision of rehabilitation programmes by healthcare professionals (Nasr et al. 2016). However, a recent study to introduce wearable technologies to monitor activity amongst exercise referral scheme participants was abandoned due to poor recruitment and retention (Hawkins et al. 2019). Achieving the required balance between support, supervision and monitoring amongst older adults has been identified as a challenge by physiotherapists; individualised behaviour change interventions integrated with exercise prescription may enhance retention and reported experience (Arkkukangas et al. 2017).

Service and setting

Discussion regarding the setting and service was initiated by attendees during both NGT events. Attendees of the expert groups envisaged a client centred, accessible facility operated by knowledgeable staff. PwS have reported perceived improvement in physical performance and participation associated with venue-based exercise (Young et al. 2021a), although leisure service providers have reported feeling under-confident with the stroke population due to challenges associated with their ability to access standard exercise equipment (Condon and Guidon 2018). Assisted exercise programmes have been reported as acceptable and feasible for PwS in leisure settings and, for some participants, represented a stepping stone towards the use of conventional equipment (Kerr et al. 2019).

Preferences

The preferences shared by the members of the NGT enabled the selection of three machines from a range of nine to be prioritised for technological advancement. The EU group were all regular users of the range of equipment and their preference pattern suggested a level of appreciation for all nine machines in comparison to the PU group who indicated a greater preference for the machines which predominantly assisted limb movement. Our findings indicated that the EU group valued those machines which assist trunk movement and this highlighted the importance of capturing the perspective of the end user in decision making (Hoddinott et al. 2018). Trunk control is an important predictor of mobility following stroke (Verheyden et al. 2007) and assistive interventions have been previously recommended to address deficits in trunk movement (Criekinge et al. 2017). The PU group expressed a preference for those machines which more closely resemble conventional gym equipment. The three prioritised machines include a combination of conventional and novel models, representing the views of all stakeholders. This divergence in opinion emphasised the importance of user involvement; continued engagement with PU and EU representatives will be sustained throughout the programme of research.

Application of Nominal Group Technique to Patient Public Involvement

This user involvement report has shown the importance of early stakeholder engagement at the outset of a programme of research aimed at improving PAE for PwS. Historically, the way in which PPI has been conducted has been criticised as being tokenistic and professional led [9]. NGT has been previously implemented in PPI activities (Daveson et al. 2015) and, in our experience, enabled all attendees to share their perspectives, ideas, experiences and preferences. NGT enabled the adoption of a collective, direct and proactive model of PPI (Tritter 2009), which empowered PwS and service providers to shape key priorities and direct important decisions.

The research team acknowledge limitations associated with the NGT exercise reported in this paper. On reflection, a collective event which combined EU and PU representation may have generated cross fertilisation of perspectives and greater depth of discussion. Subsequent user involvement methods employed during stage two of the design project did integrate PU with EU groups. Some experience of using PAE equipment was considered necessary to be eligible as an EU. This limited the number of PwS able to make an informed contribution to the events, and of the five identified experts by experience, only three were able to attend. All of the EU attendees with stroke were female and had committed to investment in their recovery through third sector exercise and rehabilitation services, the opinions and preferences expressed may not have been representative of the wider stroke population. Narrow user representation has been previously reported as a limitation in patient involvement in health technology funding decisions (Lopes et al. 2016). It was also noted that there was a gender split across the PU group, with an all-male representation from the exercise scientists and all-female group of physiotherapists. Future activities should aim for an optimal balance of representation to promote equality and diversity of perspectives shared.

However, this report exemplifies how NGT can generate a vision for an intelligent, individualised, goal orientated technology centred around users' preferences and priorities. In the context of this project is facilitated the development of more targeted digitalisation of PAE machines for PwS which are subsequently more likely to be acceptable to the user population. The use of NGT enables the capture a range of perspectives which can enrich research design and implementation.

CONCLUSION

This article has summarised the application of NGT to facilitate user involvement in the priorities identified at the outset of a programme of research focussed on technological advancement of PAE for PWS. The findings indicated a readiness amongst the stroke rehabilitation community to embrace digitalisation and progress the development of intelligent technologies. Congruence and divergence in the opinions and emphases shared amongst the selected attendees were identified, and perspectives were aligned with different fields of knowledge and experience represented across the expert groups. The importance of an empowering and positive user experience was emphasised by all attendees. The structured discussion and consensus voting generated ideas which will shape the digitalisation of PAE, influence future research and guide implementation of the new technologies.

The perspectives captured from this initial user involvement exercise determined which machines were selected to be prototyped to test the feasibility of the new technology. The vision for the user interface generated during the NGT discussion represented the first stage of the MDTF which underpinned the overall design and feasibility testing programme. The perspectives and ideas captured shaped the subsequent methods implemented to design and prototype the new technology. The prototyped technology will be tested during stages three and four by representative users in laboratory and field settings to determine feasibility and promote an iterative approach towards ongoing development.

5.3.2 Article Five

Effective use of Storyboarding as a Co-Design Method to Enhance Power Assisted Exercise Equipment for People with Stroke

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Authors: Rachel Young, Karen Sage, David Broom, Andrew Hext, Christine Smith

Abstract

Power assisted exercise equipment designed to assist multi-directional movements represent an exercise solution for people with stroke. Users identified digitisation of the equipment through a new GUI to display feedback on exercise performance as a development priority. The MDTF was adopted to structure the four-stage digitisation programme and ensure meaningful user involvement. This paper reports on stage two of the digitisation programme, the aim of which was to create a prototype GUI. Storyboarding followed by participatory data analysis was selected as a co-design method to engage professional (n=6) and expert (n=8) end users to create artefacts and express preferences relevant to the design of the GUI. Four overarching themes emerged from thematic analysis of the data; a) aesthetic format, b) functional features, c) exercise programme, d) motivation and reward. The data were crystallised with external sources to generate a design criterion matrix which directed the first iteration of the prototype GUI. Storyboarding with participatory analysis was an effective method for engaging participants in the design of the GUI and associated user experience. This paper represents a novel application of storyboarding to the MDTF in user centred digital design.

Keywords

Co-design; Storyboarding; Participatory analysis; Power Assisted Exercise; Stroke rehabilitation

INTRODUCTION

Supporting engagement with exercise for PwS has been identified as a priority to optimise physical recovery, reduce risk of recurrent cardiovascular events and enhance psychosocial wellbeing (Young et al. 2021a, Saunders et al. 2020, Valkenborghs et al. 2019, D'Isabella et al. 2017). However, complex motor impairment and reduced cardiovascular capacity, which are frequently reported consequences of stroke, can limit attainment of the sustained physical effort required to achieve the recommended duration and intensity of exercise for PwS (Reynolds et al. 2021).

Power assisted pedalling enables PwS to achieve a specified duration and intensity of physical activity, as the assistive mechanism enables the user to sustain effort despite any impaired neural innervation (Kerr et al. 2019, Linder et al. 2019). However, power assisted pedalling devices are limited in terms of variety and functionality of the movement performed. Power assisted exercise machines manufactured by Shapemaster Global Ltd enable multi-directional movements of the trunk and limbs. The machines are accessible and acceptable for PwS (Young et al. 2018), and PwS have associated use of the equipment with improvements in their mobility, social engagement and ability to self-manage their condition (Young et al. 2021b). Despite the clear physical, psychological and social benefits, regular users of the equipment have identified that the existing console does not quantify or feedback the physical effort generated during the assisted exercise (Young et al. 2021b). Strong, rewarding stimuli to reinforce motor skill achievement has been identified as a priority in stroke recovery (Widmer, Lutz and Luft 2019). Digitisation of the PAEE through development of effort detection software and advancement of the GUI was therefore required to align the training stimulus with published guidelines and generate biofeedback on user effort. This article reports on stage two of a digitisation programme for power assisted exercise machines aimed at PwS. A participant centred technique known as storyboarding was employed to facilitate user involvement in the co-design of the GUI.

The need for guidelines to underpin GUI design was emphasised by Blair-Early and Zender (2008) who differentiated between interface parameters and interface principles. Interface design principles included consistent logic, feedback and landmarks; interface parameters were defined as content type, content delivery, user intention and interface type. Feedback and consistency are also emphasised by global leads in software products, alongside aesthetic integrity, deference and clarity (Apple.com 2022). Gestalt theory has been applied to the principles of interface design with an emphasis upon visual balance and general organisation of graphical elements (Reynoso and Romo 2020). Gender, age and motivation can influence engagement with health technologies and it is important that these are factored through a user centred approach which seeks to understand the users' values, attitudes and technical experiences (Vaziri et al. 2016). Older adults have identified a clear and consistent menu structure with readable font size as essential components of GUI usability (Boll and Brune 2015).

Various methodological approaches have been applied to facilitate user involvement and integrate co-design techniques in the development of health technologies; key stages typically involve scoping, identification of user requirements, prototype development and testing (Design Council 2022, Bevan-Jones et al. 2020, Petersen and Hempler 2017). The MDTF proposed by Shah, Robinson and AlShawi (2009) stipulated four stages of technology development: 1) idea generation; 2) device design and prototype development; 3) prototype testing; 4) device deployment. The four-stage framework promotes an iterative, cyclic approach to product development and integrates continuous involvement of professional and expert end users, including informal carers and service providers. It promotes an understanding of the influence of end users' preferences and habits in the context of a new technology (Thilo et al. 2017) and is aligned with global principles of empowerment and advocacy (Desmond et al. 2018).

Assistive technologies enable users to engage in meaningful activities and have a primary purpose of maintaining or improving function (Desmond et al. 2018). User engagement in the development of assistive technologies has become widely endorsed and considered imperative to the successful implementation of new products (Matthew-Maich et al. 2016). Involvement of service users, informal carers and healthcare professionals is needed to ensure the development of relevant, user-friendly technologies (Wentink et al. 2019). Co-design is an approach which facilitates user engagement and emphasises the importance of sustained collaboration with all potential users in the development of a product (Bevan-Jones et al. 2020). Co-design techniques go beyond consultation with end users and aim to create an ethos of partnership and mutual exchange with participants who are experts in their own needs and experiences that occurs throughout a project life cycle (Desmond et al. 2018).

Nominal group technique was applied during stage one of the digitisation programme to stimulate idea generation and select three preferred power assisted exercise machines; priorities identified by the participants included a user-friendly visual platform, accurate measurement of performance and a tailored exercise programme (Young et al. 2021c). Storyboarding was selected to generate design artefacts during stage two; it is a method which challenges participants to work together and think creatively about the design of a GUI (Lupton and Leahy 2019). Storyboarding has previously enabled co-design teams to depict the user journey through a proposed technology (Jamin et al. 2018). Although, to the author's knowledge, storyboarding has not been previously reported as a method used within the MDTF, it was identified as an appropriate method for stage two as it facilitates the transition from idea generation towards design and prototype development (Lupton and Leahy 2019). Participatory analysis, whereby primary data are explored and interpreted by research participants, enables meaningful sustained involvement of end users (Yap et al. 2020). We aimed to sustain iterative user engagement during phase two through participatory analysis of the storyboard data.

The purpose of this paper is to report on the application of storyboarding with subsequent participatory analysis as a co-design method to develop a new GUI to advance power assisted exercise equipment for PwS.

METHODS

Ethical considerations

This project was granted approval by the research ethics committee at the host university, code number ER20492475.

Methodological approach

Stage two of the co-design programme comprised: 1) storyboarding; 2) participatory analysis of storyboard data; 3) creation of a design criterion matrix; 4) development of a high-fidelity prototype. Co-design participants were allocated into Professional User (PU) and Expert User (EU) streams as defined by Shah, Robinson and AlShawi (2009). The PU group included exercise and rehabilitation professionals; the EU group comprised PwS and their carers.

Participants

Convenience sampling through local clinical and academic networks was employed to recruit participants. Expert user participants were identified through the service user group assigned to the Allied Health Professions department at the host university; additionally, clients with a local independent neurological rehabilitation service were invited to consider participation. To be eligible for participation as an EU, the person would have a diagnosis of stroke or be a primary carer for a person with stroke, ability to provide informed consent and an ability to understand English at a level which would enable comprehension of the context and activity. Prior experience of power assisted exercise equipment was not required.

To be eligible for participation as a PU, the person would have a Bachelors or higher degree in a subject relevant to rehabilitation or exercise science plus knowledge of long-term conditions or age-related changes. PU participants were identified through a local independent neurological rehabilitation service and from the academic staff employed within the host university. Direct experience of working with PwS was not stipulated to facilitate translation of knowledge from the broader exercise science community.

Potential participants were approached through an invitation email which included a participant information sheet. Respondents were given the opportunity to speak with the lead author (RY) regarding the project. Signed consent was obtained from all participants and a minimum data set which included age, diagnosis (EU), experience of power assisted exercise equipment and professional qualifications (PU) was recorded.

The target recruitment was eight participants from each user stream to enable formation of four mixed groups of comparable size to previous storyboarding workshops (Lupton and Leahy 2019). Prior research on co-design team formation has indicated that moderate rather than high diversity within co-design teams was associated with development of more feasible design concepts (Trischler, Kristensson and Scott 2017) and co-design participants have reported feeling daunted by working with people from different professional backgrounds (Pallesen et al. 2020). An atmosphere of participant led errorless creation was fostered in which all ideas were given space to be explored.

A total of eight PwS, one informal carer, five exercise scientists and three rehabilitation therapists were recruited. Due to illness, one EU participant was unable to attend and two exercise scientists from the PU group were unable to attend due to unforeseen work commitments. Details of the attending participants are summarised in Table 18 and Table 19.

Table 18: Expert User Participants (Article 5, Table 1)

Attendee number	Age (years)	Time since stroke (years)	Gender identity	Impairment	Experience of PAE
EU1	76	12	Female	Left hemiparesis	1 session per week for previous 9 months
EU2	67	5	Female	Right hemiparesis and aphasia	2 sessions per week for previous 9 months
EU3	56	4	Female	Left hemiparesis	2 sessions per week for previous 9 months
EU4	68	8	Male	Right hemiparesis and aphasia.	2 sessions per week for previous 9 months
EU5	65	5	Male	Left hemiparesis.	2 sessions per week for previous 3 years
EU6	62	3	Female	Right hemiparesis	Used equipment during her 40's and 50's for general exercise
EU7	53	6	Female	Left hemiparesis Mild hemianopia	None
EU8 (Informal carer to EU4)	65	NA	Female	NA	Attends sessions with EU4 x2 per week

Table 19: Professional User Participants (Article 5, Table 2)

Attendee number	Profession	Longevity of experience (years)	Gender identity	Specialist interest	Highest qualification
PU1	Physiotherapist	19	Female	Neurological rehabilitation and technology	MSc
PU2	Physiotherapist	2	Female	PAE and exercise prescription	MSc
PU3	Physiotherapist	29	Female	Neurological rehabilitation	MSc
PU4	Exercise scientist	18	Male	Physical activity for special populations	PhD
PU5	Exercise scientist	10	Male	Clinical exercise physiology	MSc
PU6	Exercise scientist	11	Female	Exercise referral programmes	MSc

Phase one: Storyboarding event

The storyboard event was hosted in a large room at a research centre within the host institution. A detailed schedule was developed to guide the three-hour event (Appendix 1.0). There was a brief introduction to the three priority PAE machines nominated for advancement during stage one of the digitisation programme (Young et al. 2021c). The three selected machines were aligned with specific types of exercise programme; aerobic, strength and stretch (Table 20). In addition, the event aimed to develop a generic user assessment programme available on all machines and designed to generate a tailored exercise prescription with an effort target specific to individual abilities and goals (Young et al. 2021a).

Table 20: Power Assisted Exercise Machines (Article 5, Table 3)

Machine and action	**Image**	**Programme type**
Cross cycle Pedalling motion of legs and combined flexion extension of the arms.		Aerobic
Chest and legs Bimanual flexion and extension of legs and arms.		Strength
Rotatory torso Rotation of the trunk with shoulders and pelvis moving in opposite directions.		Stretch

The four programmes underpinned the focus of each storyboard group; A) generic user assessment, B) aerobic, C) strength, D) stretch (Table 21). The groups were arranged to ensure a combination of PU and EU in each. Three templates (Appendix 5) which depicted the key steps and programmes options to be made available on the GUI were developed by the lead author (RY) through triangulation of published exercise guidelines with data captured during stage one (Young et al. 2021c, MacKay-Lyons et al. 2020).

Table 21: Storyboard Groups and Tasks (Article 5, Table 4)

	Group A **User Assessment**		**Group B** **Cross Cycle (aerobic)**		**Group C** **Chest and Legs (strength)**		**Group D** **Rotatory torso (stretch)**	
Participants	EU5	PU2 PU5	EU6 EU3	PU4 PU6	EU2 EU4 EU8	PU3	EU1 EU7	PU1
Tasks	**1. Template 1** • Login • Programme selection **2. Template 2** • Assessment • Duration • Feedback • Statistics **3. Presentation** 7-page storyboard of generic user assessment programme		**1. Template 1** • Login • Programme selection **2. Template 3** • Duration • Intensity • Feedback • Achievements **3. Presentation** 7-page storyboard of the' Cross Cycle' aerobic programme		**1. Template 1** • Login • Programme selection **2. Template 3** • Duration • Intensity • Feedback • Achievements **3. Presentation** 7-page storyboard of the 'Chest and Legs' strength programme		**1. Template 1** • Login • Programme selection **2. Template 3** • Duration • Intensity • Feedback • Achievements **3. Presentation** 7-page storyboard of the 'Rotatory Torso' stretch programme	

Conduct

Within the EU group, two participants had expressive aphasia and one participant reported visual changes associated with stroke impairment (Table 18). The PU group was diverse in terms of longevity of experience and specialist skills (Table 19). The experienced neurological therapists (PU1, PU3) were grouped with those participants who had complex communication or visual impairments as it was anticipated that they would be able to facilitate their engagement. It was of paramount importance that all participants had an equal opportunity to express their ideas. The event schedule was designed to ensure enough time for all participants to contribute to each task, intersected with breaks to prevent onset of fatigue. An ethos of equality and collaborative contribution was emphasised during the event introduction and sustained throughout the co-design activities by highly skilled group facilitators (KS, CS) who circulated between groups so that each group was supported approximately 50% of the time. They encouraged quieter participants to express their ideas and ensured the scribing was shared amongst group members. All suggestions were openly explored without judgement or correction.

Task One

All four groups were issued with copies of template one and provided with multiple colour pens. The purpose of task one was to design the opening pages of the GUI which comprised login and programme selection. Participants were encouraged to reflect on their experiences of using digital technologies with interfaces to develop features which would enable ease of navigation and motivation for users of the GUI. Design features which would optimise user engagement were prioritised (Thilo et al. 2017) and reflected through three guiding questions:

- What would motivate you?
- What would put you off?
- How can exercise be fun?

Participants were encouraged to include written text and illustrations on the storyboards with attention to preferred colours, wording and imagery.

Task Two

Group A was issued with copies of a second template 2 which depicted the key stages of the user assessment. Groups B, C and D were issued with copies of template three which outlined options required within the specific exercise programmes. Participants were encouraged to reflect upon their experiences of using exercise equipment and digital interfaces to generate user-friendly and motivating ideas to populate the new GUI. As with task one, written text, icons and illustrations were encouraged to create artefacts which would guide the design of the GUI.

Task three

A representative from each group was nominated to display their final templates and deliver a five-minute audio-visual recorded presentation to explain the content and ethos of the storyboard.

Storyboard data

The storyboard templates populated during the event were converted into electronic Jpeg images. The audio-visual presentations were transcribed verbatim by the lead author. Two members of the research team (RY, CS) were familiarised with the content of the storyboard templates and transcripts in preparation for the participatory analysis sessions. In-depth analysis of the data were not conducted at this stage to avoid introduction of confirmation bias during the subsequent participatory analysis sessions.

Phase two: Participatory Analysis

The purpose of the follow up participatory analysis focus groups was to ensure an iterative, user-centred approach to interpretation of the data alongside generation of new ideas. Due to restrictions imposed by the COVID-19 pandemic which occurred shortly after the storyboarding event the analysis sessions were operated through remote media using secure Zoom software. Participants EU1 and EU2 were unable to use Zoom software. The lead author (RY) attempted to enable their access, but due to the challenges associated with remote connectivity this was not successful and these two participants did not take part in the participatory analysis. Three groups which comprised the remaining participants from the EU and PU groups were formed in new combinations to facilitate the intertwining of ideas and perspectives (Table 22). Two separate, sequential sessions were scheduled for each group to enable exploration of the entire data set.

Table 22: Participatory analysis groups (Article 5, Table 5)

Group	Participants
1	EU3, EU5, PU2, PU5
2	EU4, EU8, PU1, PU4
3	EU7, EU6, PU6, PU3

The format of the participatory analysis included re-familiarisation with the storyboards and narration of the presentation transcripts. Examples of participatory analysis in co-design methods are limited; in contrast to the process reported by Yap et al. (2020), it was not our intention to ask the participants to elucidate emergent themes from the data. Instead, we aimed to encourage the participants to share their interpretation of the ideas presented within the storyboards and explore the topics and questions raised. Each storyboard template was considered in turn and the discussion was structured through reference to the topic guide (Table 23). The Zoom sessions were chaired by the lead author (RY), recorded and saved as MP4 files. The audio content was transcribed by RY.

Table 23: Participatory Analysis Topic Guide (Article 5, Table 6)

Activity
Introduction and outline of event Remit of the event, ie. to make sense of the data and understand the participant's impressions of it.
Display storyboards one page at a time and narrate the respective section of transcript. Participants to note the points which were emphasised and identify any comments which did not make sense to them.
Topic Guide per page: 1. What are the most striking features on this page? 2. Are there any ideas or images that you don't feel comfortable with? 3. Which of these ideas or images could work well? 4. Which of these ideas or images could be confusing or problematic?
Summary of the event and future plans

Data analysis

An inductive approach to data analysis was adopted to capture the breadth, richness and context of data collected through storyboarding and participatory analysis. The approach to thematic analysis described by Clarke and Braun (2013) was applied as the flexibility inherent within this method facilitated assimilation of the diverse data generated from the storyboarded artefacts and participatory analysis (Clarke and Braun 2017). The storyboard workshops generated the storyboarded artefacts and accompanying presentations. In contrast, the participatory analysis sessions captured the responses to the content of the storyboards and generated group discussion on preferences pertaining to the design and functionality of the GUI. Three members of the research team (RY, DB, KS) initially familiarised with and individually coded the content of the storyboard templates and transcripts from the participatory analysis sessions. The team (RY, CS, DB, KS) collectively reviewed the codes identified through individual analyses to generate categories. Two members of the team (RY, CS) reviewed the coded data and aligned it with the categories. The categories were continually reviewed in the context of the data until overarching themes were defined and agreed by all members of the research team. Disagreements arising during interpretation of the data were resolved internally through verbal discussion. The participants were not involved in the final interpretation of the data.

Phase three: Design Criterion Matrix

The purpose of the design criterion matrix was to crystallise the co-design data with external sources to create a comprehensive design brief for the design engineer (AH). Crystallisation in qualitative research encourages researchers to gather multiple types of data to open up a more complex and in-depth understanding of the topic (Tracy 2010). It was not the intention of the research team to dilute or overwrite the content of the co-designed data, rather to augment and enrich it. The research team had prior knowledge of the research evidence and guidelines which underpin exercise prescription for PwS and an awareness of the principles of accessible design features which guide the development of digital products. However, integration of the storyboard data with relevant external sources followed the co-design activities to minimise confirmation bias in the interpretation of the user generated data.

A matrix was created which comprised the overarching themes represented as rows. Findings from the storyboard data, relevant research evidence, published guidelines and market comparison were summarised in the columns. The search strategy and approach to source identification is summarised in Table 24. The selection of sources and data was factored by their context, relevance and currency.

Table 24: Search strategy (Article 5, Table 7)

Domain	Sources	Search terms	Criteria
Research evidence	CINAHL MEDLINE	Exercise, stroke, aerobic, strength, flexibility, duration, intensity, digital design, accessible design	Published since 2015. Exercise trials to have been conducted on PwS. Digital design research to have included PwS.
Published guidelines	American Heart Association American College of Sport Medicine (ACSM) National Institute for Clinical Excellence (NICE) WP3 Stroke Association	Exercise, stroke, guidelines, recommendations, policy, digital design, accessible, aphasia friendly	Guidelines or recommendations published by a recognised authority on exercise prescription for PwS OR inclusive digital design digital.
Market comparison	Local knowledge of: Leisure services Clinical services Google	Inclusive exercise equipment Accessible exercise equipment Digitised exercise equipment Rehabilitation technologies Assistive technologies	Currently available for market purchase. Designed to improve physical ability or performance. Target market/end user includes PwS.

The findings relevant to the overarching themes captured from the search were collated with the storyboard data to generate a design matrix of categorised design criteria to optimise the usability of the co-designed GUI. Recommendations or ideas which were recurrent in the storyboard/participatory analysis data, or detected in two or more different sources were included in the matrix.

Phase four: Prototype Development

The design engineer (AH) familiarised with the manufacturer's branding, design matrix and raw data generated from the storyboards. In discussion with the lead author (RY), a high-fidelity prototype (v1) of the interface was designed using adobe software. V1 comprised a 7-page 'quick start' exercise programme and was purposed to the Cross-Cycle machine. However, the data from all storyboard groups guided the design and content of the GUI. The content and functionality of the prototype GUI was checked against the design criterion matrix to determine which design descriptors had been attained.

RESULTS

Four overarching themes emerged from the integrated thematic analysis of the populated storyboards, group presentations and transcripts of the participatory analysis sessions. The themes were; a) aesthetic format, b) functional features, c) programme options, d) engagement and feedback.

a. Aesthetic format

This theme comprised content which informed the visual appearance and layout of the interface including colour schemes, use of icons and imagery. The storyboards created by groups A and B which included a greater proportion of exercise scientists contained more text-based suggestions in contrast to groups C and D who included more imagery.

Different perspectives regarding colour schemes were initially expressed by the storyboard groups ranging from bright colours to paler, calming shades:

> *We felt the machine should be almost like a nice pale blue background, quite attractive to touch. [Group C, Fig 11]* In contrast to; *Bright welcoming colours, like orange, yellow and green. [Group A, Fig 11].*

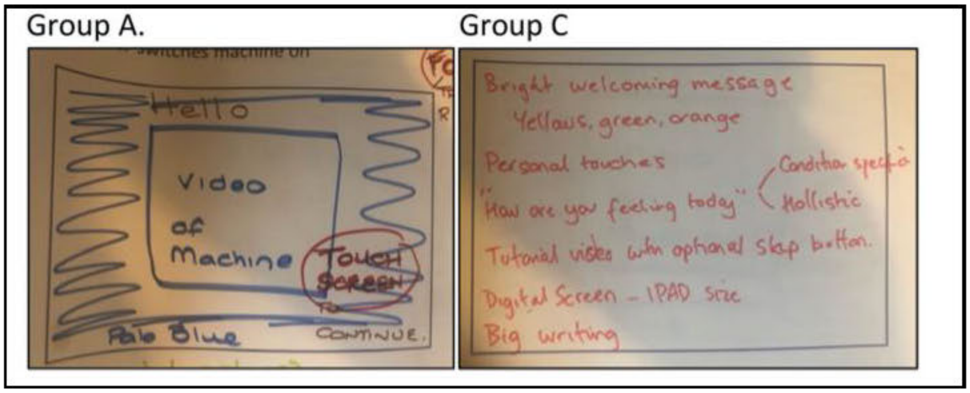

Figure 10: Aesthetic format (a) (Article 5, Figure 1)

As the dialogue developed during the participatory analysis sessions it was acknowledged that users do habituate to colour schemes if the overall design is intuitive:

> *You stop noticing colours if the design is user friendly. [EU7]*

One participant (EU5) had vocational experience of digital design and recommended reference to the World Wide Web Consortium (W3C) for guidance on font selection and colour combinations to ensure accessibility for people with reading difficulties such as dyslexia. He emphasised the need for a non-intrusive background with dark font to ensure ease of reading text. The importance of branding evolved during the participatory analysis sessions with recognition that the interface should be consistent with the colour schemes promoted by the manufacturer.

Traffic light colours were suggested to provide an indication of effort or difficulty associated with the exercise (Group B, Fig 12; Group D, Fig 12). This generated in-depth discussion during the participatory analysis sessions with divided opinion regarding the interpretation of traffic light colour schemes. Some participants thought that red colouration may indicate a warning, whilst others felt that green, amber or red could be feedback regarding about intensity of detected effort, with red indicating a positive, hard effort.

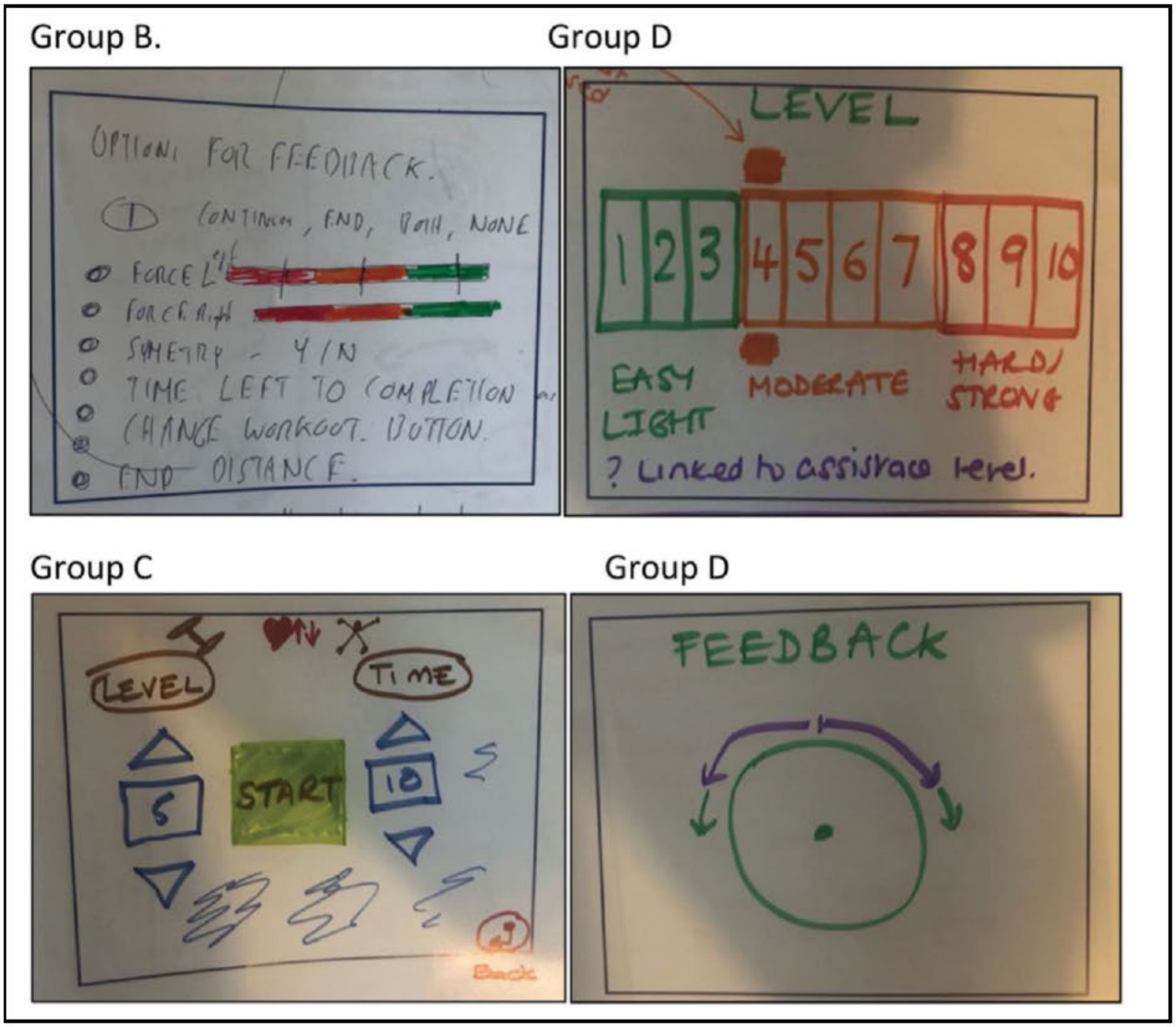

Figure 11: Aesthetic format (b) (Article 5, Figure 2)

Review of the storyboards during the participatory analysis sessions acknowledged that some of the co-designed pages were too busy. All of the groups emphasised the importance of clear, minimalised text. The visual and perceptual changes which can occur following stroke were explored; taking account of these needed to be central to the development of the GUI:

> *There needs to be consistency between the pages, like a menu bar ideally across the bottom, not on the left side because many people with stroke have affected vision on their left. [PU3].*

Centralised orientation of icons and features on the screen was visualised on Group C's storyboard and the importance of this point for the stroke population was further explored and recognised during the participatory analysis sessions.

Images illustrated on the storyboard templates included emojis, pictures of the exercise machines, weight training equipment, cycling, trophies and stick men. The aerobic, strength and stretch groups all indicated a type of feedback bar or dial:

> *We have drawn a dial on page 6 as an example of visual, of how far you've gone and whether you've gone a bit further than the machine. [Group D].*

The concept of feedback beyond its visualisation is explored in the *engagement and feedback* category.

b. Functional features

The functionality of the interface is presented as a theme in terms of features to enable efficient and independent user navigation through the GUI. The ideas generated included user authentication systems, quick navigation and assistance alert. All groups suggested that familiar, universal icons, for example, 'audio', 'home' and 'play' should be used.

Groups A, B and C suggested a fob based or biometric identification system to enable users to log in to the interface without the need for typing a username or password. This assumed the development of an 'intelligent' system with integrated data analytics including individualised exercise history, exercise prescription, medical history and links to a designated healthcare professional:

We thought a wrist band would be a good idea, you can just sort of beep on and it knows it's you….linked in with that we could have things like medication, health problems, contraindications, that's done prior so we've got that whole database of information within that wristband. [Group A].

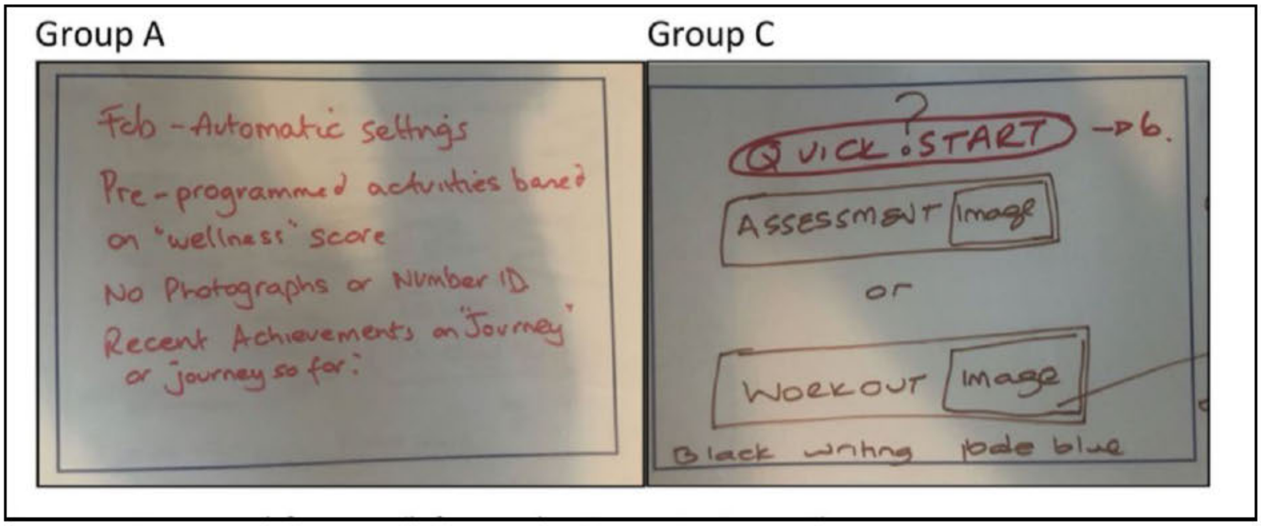

Figure 12: Functional features (Article 5, Figure 3)

This concept was endorsed during the participatory analysis sessions by EU and PU representatives with the view that an intelligent system would reduce the onus on service users and operators to recall information and input exercise preferences at the start of each session.

Groups A, B and C suggested a 'quick start' or accelerated navigation option for users or operators who did not want to commit time to a more specialist or individualised exercise programme:

Our group felt quite strongly that you should be able to press 'quick start' to move past some of the choice selection pages. Group C.

The importance of accelerated navigation to the workout page was further explored during the participatory analysis sessions with specific consideration of different levels of functionality determined by the service setting and end user (PU or EU). For example, a rehabilitation setting may have the capacity to support a broader range of programme choices than a leisure centre. An optional video demonstration of the machine was suggested as an option by groups B, C and D and all groups emphasised the importance of a ‘call assistance’ icon on each page. Groups B and C also suggested that there should be a ‘back’ option on all pages to enable users to deselect options or start again if they so wished.

c. Programme options

In this context, the programme referred to the type, duration and intensity of exercise displayed by the interface. Each group was tasked with a focus on a specific programme or type of exercise and this generated in-depth consideration of the terminology used in rehabilitation and exercise prescription. Group D commented that the term ‘assessment’ may be intimidating for some users and suggested that ‘check-up’ was the selected terminology to guide a user towards a measurement of their exercise performance (Figure 14).

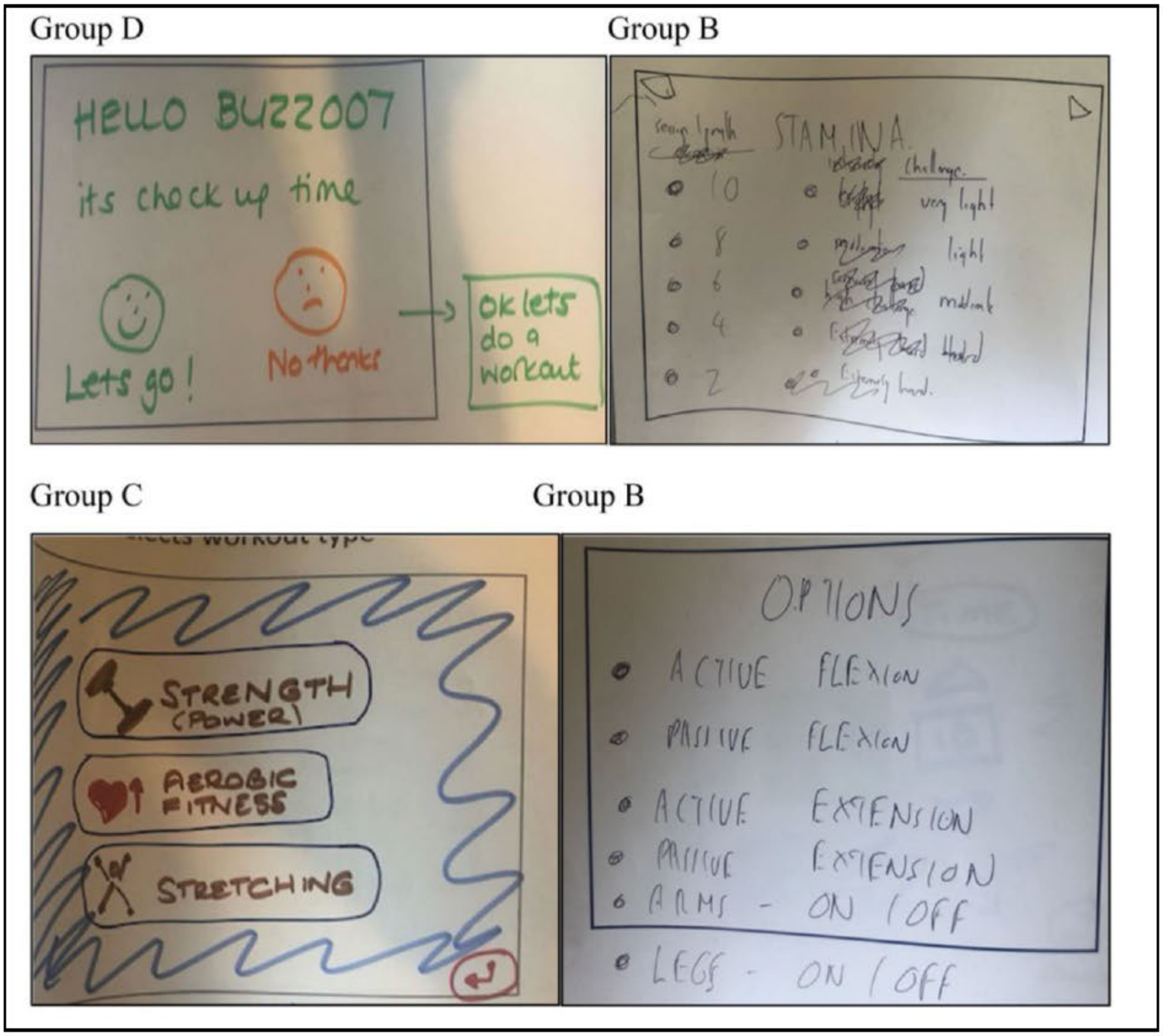

Figure 13: Programme options (Article 5, Figure 4)

'Stamina' was identified as a preferable alternative to 'aerobic' by Group B:

> *When we looked at the type of session we talked about aerobic, cardiovascular, cardio and it was decided by our table that stamina might be a word that would appeal more to everybody and was a bit more inclusive and not create any barriers. [Group B].*

Group C explored alternative wording for ‘strength’ including ‘power’ or ‘strengthening’ as illustrated in Figure 14. Terminology associated with strength training was further explored in the participatory analysis sessions with one EU participant commenting:

> *One rep max…is that a sport science thing? How does that work for stroke patients who can’t get their limbs to move? [EU1]*

Group D also identified the dissonance which can exist between scientific terminology and meaningful language for service users:

> *We talked quite a lot about different words so we called it spinal stretch, but as a physio I’d call it rotation, but it didn’t mean anything our end user, so we were trying to think about all those different words. [Group D].*

The option of adjusting the target intensity of the exercise programme was recommended by Groups A, B and D. Group A identified the fluctuating nature of fatigue and stated that the user should be able to override the default setting. Group B specifically addressed intensity and suggested a numerical choice range and also introduced the concept of limb isolation for a more targeted exercise intervention:

> *We’ve got different options for type when it comes to stamina, so 2, 4, 6, 8, 10 potentially….we’ve also got options to turn the arms off so you’re just using the legs, or turn the legs off and just use your arms. [Group B].*

Group A recommended that user performance targets displayed during the exercise programme should include heart rate, range of motion and symmetry. This would require development of advanced hardware and sensors on the power assisted exercise equipment.

d. Engagement and feedback

Engagement and feedback was the most diverse of the emergent themes in terms of range of topics covered. The research team sought to capture the features suggested during the co-design activities which would empower and motivate users to engage with the system and feel positive about their exercise experience. This category included welcome messages, feedback on exercise performance and gamification.

Strategies to engage users at the start of their session included an interactive feature to enable users to input how they were feeling on a given day. It was identified that therapy or supervised exercise sessions would usually encourage clients to report on their subjective status. Group A suggested:

> *We had a wellness score, so you could ask, 'how are you feeling today?' You could even score it from one to ten. [Group A]*

The concept of feedback both during and at the end of exercise generated mixed perspectives. The ideas generated on the storyboards included progress bars, feedback dials and images of specific activities such as cycling up a hill (Group C, Figure 15). Some participants felt that feedback during exercise should be optional as it may be distracting for some users.

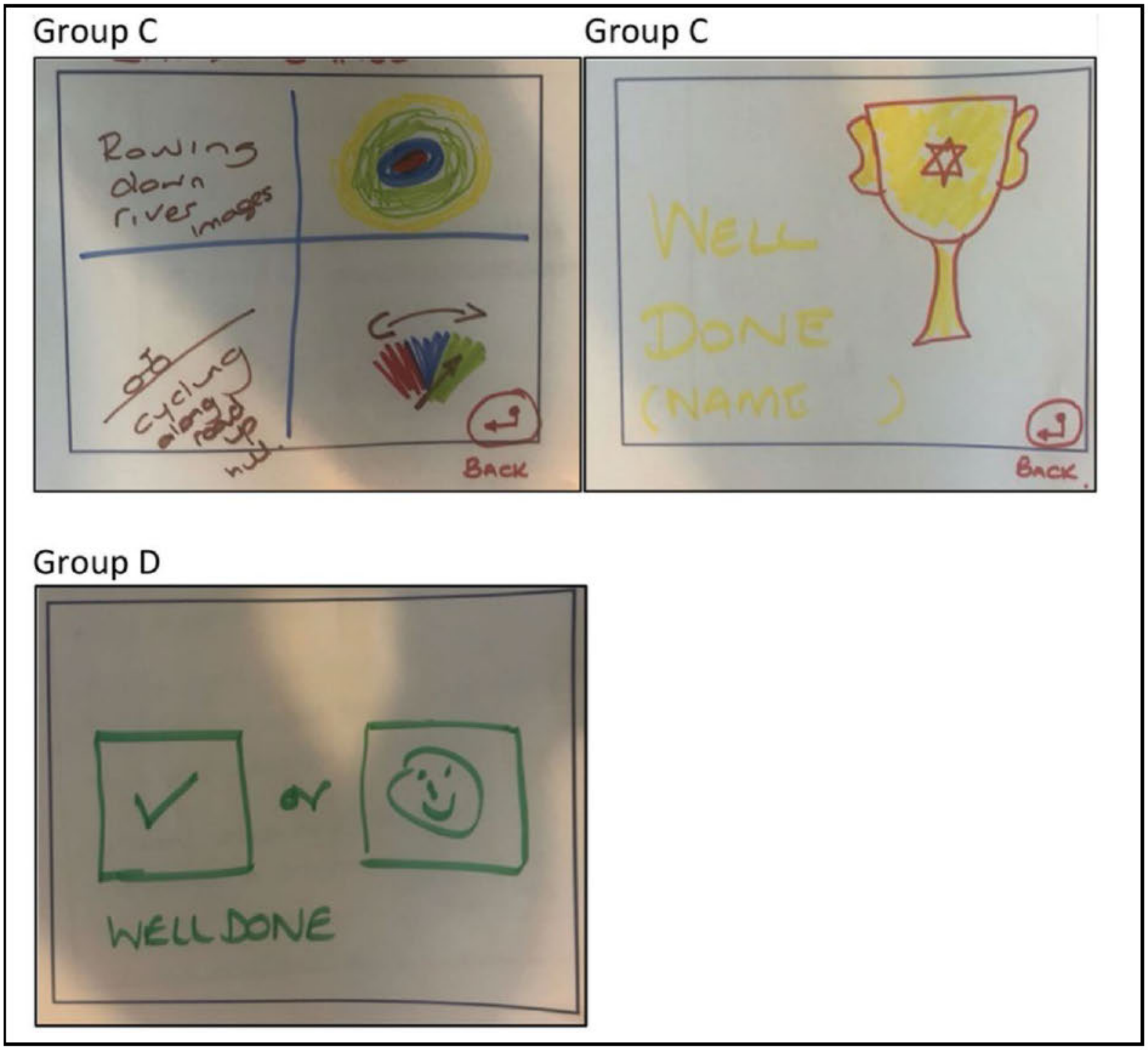

Figure 14: Engagement and feedback (Article 5, Figure 5)

> *One of our group felt that all of this should be optional, they like the equipment as it is and think these upgrades may be distracting. [Group B].*

A visual feature to indicate upcoming targets was recommended to help users to pace their effort. The concept of celebration of performance was exemplified with ideas such as congratulatory pop ups, images of trophies and audio of crowds cheering; although it was acknowledged that some individuals may find such features patronising or juvenile.

During the participatory analysis, one participant from the EU group stated:

> *Feedback can be simplified to three things; target achieved, level and comparison with previous performance. [EU5]*

The potential for an intelligent user identification system was discussed in the context of feedback and reward. The option of being able to view and reflect upon exercise sessions through a mobile app was explored during the participatory analysis sessions, with potential for exercise, rehabilitation or medical team members having access to the data to monitor progress.

Design Criterion Matrix

Sources accessed included randomised controlled trials, published guidelines and websites for comparable, commercialised products. The matrix is summarised in Table 25. Descriptive recommendations were recorded by RY from the collated data and features or concepts which recurred at least twice were included in the design matrix. A total of 26 criterion were identified; five specific to aesthetic format, nine specific to functional features, seven specific to exercise programme options and five specific to user engagement and reward.

Table 25: Design criterion matrix (Article 5, Table 8)

Data source	Aesthetic format	Functional features	Programme options	Engagement and reward
Participant data	Colours to visualise experience [AF1], but traffic light colours problematic. Pale background with dark font [AF2]. Not busy or cluttered [AF3]. Use pictures [AF4].	Biometric or fob ID system [F1]. Accelerated navigation options, ie. 'quick start' [F2]. Familiar, consistent navigation icons [F3]. Optional audio [F4]. Centralised content [F5]. Synched with an app [F9].	Adjustable intensity [P1]. Adjustable duration [P2]. Isolated to specific limbs [P6]. Align with perceived exertion [P7]. Based on initial assessment [P5]	Personalised system [E1]. Optional gamification [E2]. Visualisation of progress [E3]. Positive feedback [E4]. Trophies or emojis to celebrate achievement [E4]
Research evidence	Minimalistic interface [AF3] [Hart et al 2014]. High contrast colours [AF2,AF1] & use of relevant pictures [AF4][Li-Juan et al 2019].	Consistent menu structure and format [F6], avoid pop ups [F7] [Boll and Brune 2015].	Vigorous vs moderate exercise [P3] [Boyne et al 2017]. Low volume strength training [P4] [Lee and Stone 2019]. Moderate intensity [P1] duration up to 30 minutes [P2] aligned with perceived exertion [P7] [Kerr et al 2019,	Personalised system [E1] [LiJuan et al 2019]. Visual biofeedback [E3] [Druzbicki et al 2015]. Emojis to indicate performance [E4] [LiJuan et al 2019].
Published guidelines	Sufficient contrast between foreground and background [AF2] [WC3]. Clear, good quality pictures [AF3] under text [Stroke Association].	Familiar symbols and icons [F3] with central, clear headings, short sentences and clear wording [F8], optional audio [F4] [WC3]. No unnecessary content and use active statements [F8], centralised content [F5] [Stroke Association].	Aerobic exercise 40-70% HRR* [P1] for 20-60 minutes [P2] [AHA]. Resistance 1-3 sets @ 10-15 RM ** [P4] [Kim et al 2019].	Personalisation [E1] to enable repeated access to preferred settings [WC3].
Market comparison	White background with purple icons [AF2] and animated exercises [AF5] [Digital product]. White background with black images [AF2][Rehabilitation product].	Wrist fobs scanned by operators [F1] [Exercise equipment].Consistent navigation icons [F3] [Rehabilitation product]. System and ID synched with an app [F9]	Assessment includes body scan software [P5] [Exercise equipment]. Select duration [P2] and body part [P6] [Rehabilitation product].	Picture of trophy for high scores [E4] [Digital product]. Personalised [E1] with emojis to give feedback [E4] [Exercise equipment]. Feedback on repetitions and duration [E5] [Rehabilitation product].

Summary of findings	AF1: consistent colour scheme AF2: pale background with dark foreground AF3: minimalistic AF4: pictures and imagery AF5: animation	F1: intelligent ID system F2: accelerated navigation F3: universal icons F4: optional audio F5: centralised content F6: consistent format F7: avoid pop ups F8: concise and clear text F9: synched with an app	P1: adjustable intensity P2: adjustable duration P3: interval training P4: repetition training for strength P5: individual prescription P6: limb specific P7: perceived exertion	E1: personalised E2: optional gamification E3: visual feedback E4: celebrate achievement E5: performance specific feedback

*Heart rate reserve

** Repetition Maximum

Prototype

The v1 prototype (Figure 16) created by the design engineer (AH) comprised 7 pages which included user login, navigation to a 'quick start' exercise programme, the option to select duration of workout, real-time visual feedback on effort detected and a summary of distance travelled and watts achieved at the end of the exercise session. The menu bar included a 'help' icon which activated an 'assistance called' page.

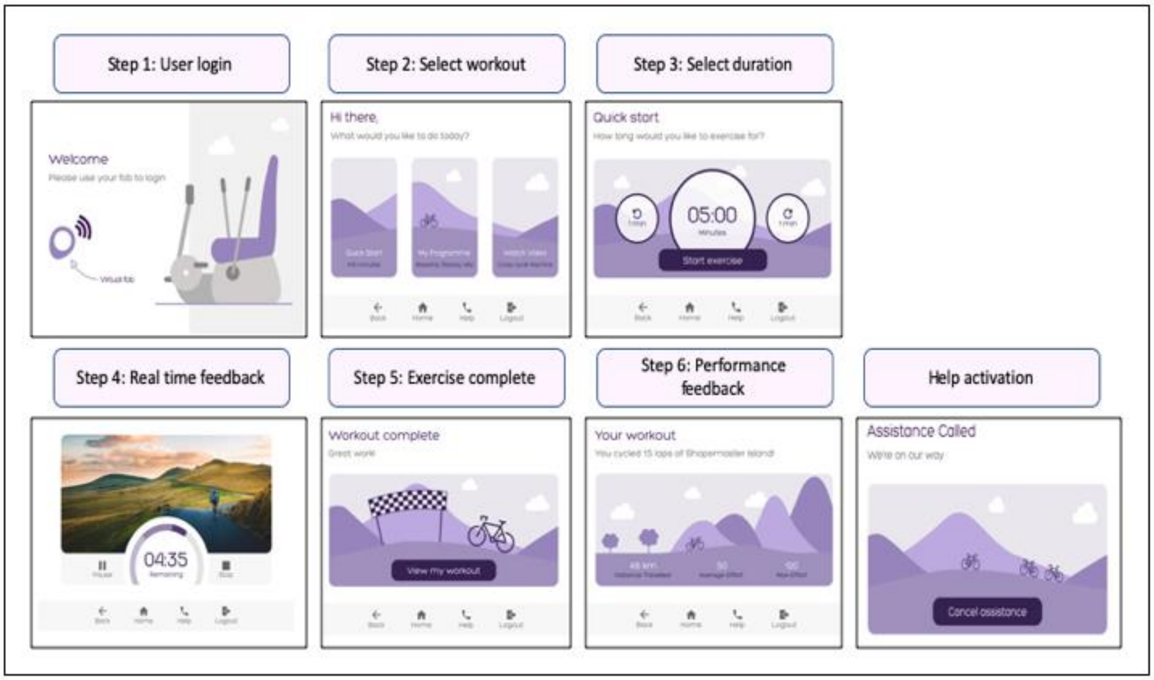

Figure 15: v1 prototype GUI (Article 5, Figure 7)

V1 was scored on two separate occasions by the lead author (RY) to ascertain the extent to which the criterion had been attained. Fifteen out of 26 design criteria were directly achieved on v1, with two further criteria within the 'programme options' theme identified as being feasible within the first iteration of the extended 'my programme' area. It was agreed within the research team that the usability of v1 would be tested to identify initial usability problems prior to development of the extended 'my programme' area. Criteria which were not attained on v1 were those features which required a user identification system, virtual reality technology, an audio system or detection of limb specific effort. These features would require new hardware embedded within the PAE equipment, for example, biometric sensors and additional invertors which were beyond the scope of this project.

Table 26: Attainment of design criterion (Article 5, Table 9)

Aesthetic format		Functional features		Programme options		Engagement and reward	
Feature	Attainment	Feature	Attainment	Feature	Attainment	Feature	Attainment
AF1	Yes	F1	No	P1	MP*	F1	No
AF2	Yes	F2	Yes	P2	Yes	E2	No
AF3	Yes	F3	Yes	P3	MP*	E3	Yes
AF4	Yes	F4	No	P4	No	E4	Yes
AF5	Yes	F5	Yes	P5	No	E5	Yes
		F6	Yes	P6	No		
		F7	Yes	P7	No		
		F8	Yes				
		F9	No				

*'My Programme' pathway

DISCUSSION

The application of storyboarding as a co-design method facilitated user engagement in the development of a GUI for power assisted exercise equipment. Power assisted equipment is an exercise solution for PwS; representation of the stroke population in the design process was considered imperative to create a user-friendly and engaging GUI. Storyboarding is a co-design method well suited to the creation of design artefacts and participatory analysis. In our example, it informed the design and format of the GUI and shaped the envisaged user experience. The involvement of users in the design and development of new healthcare technology has been associated with enhanced product quality and accelerated commercial success (Thilo et al. 2019, Dabbs et al. 2009). However, some manufacturers' do not share this perspective, seeing user involvement as time consuming and an unwise expenditure of resource (Money et al. 2011). Examples of failed commercialisation of co-designed assistive technologies do exist, outcomes of user-involvement are contingent on multiple factors, including the representativeness of the sample and stage of design (Fischer, Peine and Ostlund 2019).

The sample recruited to participate comprised a heterogeneous group of EU and PU. Within the EU group there was a range of participants with different types of motor, visual and communication impairment and varied experience of using power assisted exercise equipment, plus one informal carer. The PU group included rehabilitation and exercise professionals with varied levels of experience. Challenges associated with the balance of input from the PU and EU participants emerged as the PU participants tended to adopt the lead in each group. Akin to the co-design experiences reported by Kirk et al. (2021), the research team were required to implement skills in communication, facilitation and negotiation to ensure an equal voice across the participant streams. Historically, manufacturers have indicated a preference towards the opinions of senior professional staff (Money et al. 2011). The importance of multiple end user involvement in the co-design of stroke technologies has previously been reported due to service providers, informal carers and PwS requiring differing experiences or support from the same resource (Wentnick et al. 2019). The degree of user involvement has been classified into three categories; consultation (minimal involvement), collaboration and user controlled (maximum involvement) (INVOLVE 2012). The definition adopted for the purposes of our study was collaborative as an ongoing partnership was developed with participants, with shared influence over the end product (Fischer, Peine and Ostlund 2019, INVOLVE 2012).

Storyboarding enabled the participants to visualise the user pathway in the context of the GUI and facilitated creation of artefacts and text. This project facilitated development of the user experience and design of the GUI, although the key features and stages were predetermined within the pre-prepared storyboard templates. Groups A and B, which included a greater proportion of exercise scientists, presented detailed text to guide the exercise prescription. Groups C and D comprised experienced rehabilitation therapists alongside people with aphasia, and their storyboards contained more coloured imagery with less text content. The content of the storyboards created by Groups C and D was centralised which is a widely advocated format for PwS who may have visual field or language impairment (Stroke Association 2012). The integration of exercise science and rehabilitation expertise generated rich data which were ultimately organised into the final four themes; aesthetic format, functional features, exercise programme and user engagement/reward. Comparable co-design studies have developed similar themes which reflect the visual, prescriptive, motivational and individualised features requisite in digital exercise technologies (Robinson et al. 2021; Novak and Loy 2019).

The development of the design criterion matrix ensured integration of the user perspective with published sources and comparable commercialised products. Comparison between the evidence-based matrix and ensuing prototype indicated the extent to which the co-design methods shaped and influenced the evolving technology. Twenty-six features were specified on the design matrix and fifteen of these were attained on the v1 high-fidelity prototype. Key design features specified on the design matrix including use of imagery, dark font on a pale background, centralised content, programme options and consistent menu bar were achieved. The integration of branding influenced the final colour scheme. Previous co-design projects have developed matrices to categorise user requirements alongside published sources prior to the development of prototyped technologies (Rothgangel et al. 2017). Similar co-design projects with PwS have acknowledged a gradual tailoring of content with the final product residing somewhere between all contributors (Kulnik et al. 2019). Ultimately, the research team exercised control over definition of the emergent themes and development of the prototype GUI which affirms the perspective that truly equalising power in co-design is difficult to achieve (Farr 2018).

The concept of an intelligent user identification system with a connected digital application was recurrent in the data; the supporting technology for an intelligent, data analytics system has not yet been developed, however it has been identified as a future priority. Gamification was also a recurrent concept aligned with the ‘engagement and reward’ theme. Virtual reality and gamification have been widely adopted in stroke rehabilitation technologies and are associated with improved motor function and engagement (Mubin et al. 2019, O’Brien et al. 2019). Immersion in gamified technology may erode the peer support associated with engagement in power assisted exercise (Young, Brrom, O'Brien et al. 2021), although creation of avatars can promote peer engagement within the virtual environment (Novak and Loy 2018).

The participants from both user groups reported that they enjoyed being part of the co-design team and appreciated the opportunity to shape and influence the design of the new interface. All participants who contributed to the co-design tasks will be invited to take part in the subsequent usability testing during stage three of the project. Learning and sense of participation have been identified as benefits associated with user involvement in technology design (Fischer, Peine and Ostlund 2019). Empowerment connected with engagement in participatory design has been reported by older adults as it stimulated creativity and reinforced their problem-solving capability (Veldmeijer et al. 2020).

Throughout the co-design project we ensured a structured and iterative approach to user involvement in the development of the assistive technology. This approach was in line with the second stage of the MDT Framework (Shah, Robinson and AlShawi 2009). The application of storyboarding as a co-design technique enabled participants to influence the proposed technology and represented a focal point for iterative discussion during the participatory analysis sessions. Previous instances of MDT Framework application include user involvement in the development of a wearable fall detection device (Thilo et al. 2017). In this example, participants were invited to evaluate mock up designs of the proposed technology which had been developed by the research and engineering teams, attaining a consultative rather than collaborative level of user involvement. Our project went a step beyond this by inviting participants to create and analyse key features of the GUI to promote meaningful user involvement throughout the design process (Desmond et al. 2018). The development of a high-fidelity prototype at the end point of this project stage represented movement from level two to level three on the technology readiness level scale (Olechowski et al. 2020). The involvement of end users in the usability testing of the GUI will ensure their sustained influence over the end product (Shah, Robinson and AlShawhi 2009).

Reflection and practical application

Limitations associated with the co-design study reported in this article are acknowledged by the research team. Our intention was to facilitate the development of original ideas and perspectives from the users without preliminary influence from external or pre-existing sources. The design engineer did not attend the storyboarding session; guidance from a design expert would have accelerated the development of feasible concepts and improved the efficiency and cost-effectiveness of the co-design process. The groupings of participants at the storyboarding event did not always facilitate optimal opportunities for interaction between the exercise and rehabilitation professionals. The storyboards created reflected their respective skills and knowledge, resulting in an imbalance of text and imagery across the groups. The follow up participatory analysis did mitigate for this as the groups were reorganised which generated in-depth discussion and cross fertilisation of perspectives. However, two EU participants were unable to operate the remote Zoom technology and could not sustain their involvement.

Participatory analysis was not sustained beyond initial interpretation of the storyboards; however, the prototype GUI will be usability tested on a representative user group including some of the participants included in this study. The four themes which emerged during data analysis may be more accurately described as domains with an emphasis upon topic rather than meaning (Braun and Clarke 2021). The themes did evolve from the data collected, however, it is acknowledged that shared meaning within the themes was limited and the aims of the co-design process were likely to have influenced the coding and organisation of the data. The commercial and academic sources identified to crystallise the user generated data and create the design criterion matrix were selected according to their relevance and context as determined by the research team. It was not the intention of the team to conduct a systematic review of external sources as this may have de-valued the co-design process.

Strengths associated with the co-design project reported in this article include the integration of PU and EU streams and sustained adherence with the MDTF developed by Shah, Robinson and AlShawi (2009). The participatory analysis sessions generated further in-depth discussion which created a second data set. The combination of imagery, written text, video and audio transcript data encapsulated the contribution of all participants. Thematic analysis enabled the research team to weave and structure the compound data set to create a design brief which reflected the divergent and convergent data generated by the heterogenous group of participants. The research team navigated the challenges created by the 2020 COVID-19 lockdown to effectively complete data collection and analysis using remote media to enable ongoing user involvement.

CONCLUSION

This paper has reported on the second stage of a co-design project underpinned by the MDT framework (Shah, Robinson and AlShawi 2009) to develop a new GUI to aid the navigation through the setup of power assisted exercise for PwS. PU and EU streams were combined throughout stage two to generate a synthesised spectrum of perspectives and priorities. Storyboarding was successfully implemented as a co-design technique and facilitated the generation of artefacts which provided a focal point for group discussion. The populated storyboards represented a tangible data set which aided an inclusive approach to participatory analysis. The participatory analysis created an opportunity for further exploration of user preferences and represented a sequential data set which was synthesised with the preliminary data through thematic analysis. Triangulation with published and commercial sources ensured a sense check of the user generated data. Preferences regarding aesthetic, functional, prescriptive and interactive features were distilled and translated onto the data matrix which enabled identification of twenty-six recommended features.

To our knowledge, this co-design project represents a novel approach to stage two of the MDT framework. The implementation of storyboarding has not been previously reported in this context and in our experience was an effective technique to facilitate user involvement. The subsequent high-fidelity prototype adopted 15 of the 26 recommended features. Development of a digital user identification system and gamification have been identified as priority areas for future developments to ensure attainment of those features not embedded at this stage. The digitisation of power assisted exercise has the potential to enhance the stroke recovery pathway and support PwS as they transition between sectors. The co-designed GUI will optimise user independence on the equipment and facilitate long term engagement with power assisted exercise programmes. We encourage other groups to use storyboarding during product development.

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Declaration of interest statement

The work published in this manuscript is part of a programme of research examining power assisted exercise as part of the lead author's doctoral study. An academic collaboration between the equipment manufacturer and Sheffield Hallam University exists in which machines have been provided for use in kind. There is no restriction or clauses on publishing negative findings.

5.5.3 Article Six

Title: Evaluating the usability of a co-designed power assisted exercise graphical user interface for people with stroke

Source: Journal of Neuro Engineering and Rehabilitation

Authors: Rachel Young, David Broom, Karen Sage, Andrew Hext, Nicky Snowdon, Christine Smith

Abstract

Background

Digital advancement of PAEE will advance exercise prescription for PwS. This article reports on the usability evaluation of a co-designed GUI. The aim of this study was to evaluate the usability of two sequential versions of the GUI.

Methods

We adopted a mixed methods approach. Ten PU (2M/8F) and 10 EU participants (2M/8F) were recruited. Data collection included a usability observation, a 'think aloud' walk through, task completion, task duration and user satisfaction as indicated by the PSSUQ. Identification of usability issues informed the design of version 2 which included an additional submenu. Descriptive analysis was conducted upon usability issues and number of occurrences detected on both versions of the GUI. Inferential analysis enabled comparison of task duration and PSSUQ data between the PU and EU groups.

Results

Analysis of the 'think aloud' walkthrough data enabled identification of 22 usability issues on version 1 from a total of 100 usability occurrences. Task completion for all tasks was 100%. Eight usability issues were directly addressed in the development of version 2. Two recurrent and 24 new usability issues were detected in version 2 with a total of 86 usability occurrences. Paired two tailed T-tests on task duration data indicated a significant decrease amongst the EU group for task 1.1 on version 2 (P=0.03). The mean PSSUQ scores for version 1 was 1.44 (EU group) and 1.63 (PU group) compared with 1.40 (EU group) and 1.41 (PU group) for version 2.

Conclusions

The usability evaluation enabled identification of usability issues on version 1 of the GUI which were effectively addressed on the iteration of version 2**.** Testing of version 2 identified usability issues within the new submenu. Combining usability evaluation methods was effective in identifying and addressing usability issues in the GUI to improve the experience of PAE for PwS.

Keywords: Assistive Technology; Co-Design; Graphical User Interface; Power Assisted Exercise; Rehabilitation technology; Stroke; Usability evaluation

BACKGROUND

Power Assisted Exercise

Engagement in physical exercise following stroke is associated with improved mobility, aerobic fitness, muscular strength and psychosocial wellbeing (Young et al. 2021a, Pogrebnoy and Dennett 2020, Regan et al. 2019). Importantly, aerobic exercise sustained at a moderate to high intensity reduces vascular and metabolic risk factors for recurrent stroke (Brouwer et al. 2021). Guidelines on the optimal intensity, type and duration of exercise for PwS have been published (MacKay-Lyons et al. 2020). However, people with complex motor impairment resulting from stroke experience difficulties in accessing conventional exercise equipment (Barstow et al. 2020) and motor impairment can impede achievement of the required intensity for health benefits (Gothe and Bourbeau 2020). Whole body PAEE manufactured by Shapemaster Global Ltd is safe and accessible for people with complex neurological impairments (Young et al. 2018) or profound intellectual and multiple disabilities Bossink et al. 2017). Shapemaster Global Ltd operate a global distribution model through which the PAEE operating model comprises a circuit of between 8 to 12 machines and users transition around the circuit in sequence. Evaluation of the equipment amongst a sample of older adults indicated improved strength and balance associated with a 12-week programme of power assisted exercise (Jacobson et al. 2012). People with stroke who engage in PAE report physical and psychosocial benefits (Young et al. 2021a) and assisted cycling is known to improve aerobic fitness following stroke (Linder et al. 2015). People with stroke and rehabilitation professionals identified that the development of effort detection technology synchronised with the PAEE would enable users to access a tailored exercise prescription and gain real time feedback on their exercise performance (Young et al. 2021b).

Individualised performance targets with real time feedback to optimise goal attainment has been identified as a priority in the design and development of technologies for PwS (Bauer et al. 2021). Biofeedback has been synchronised with gaming and virtual reality programmes to enhance the experience and efficacy of stroke rehabilitation interventions (Doumas et al. 2021, Enam et al. 2021, Park et al. 2021, Cameirao et al. 2016). The development of assistive technologies in stroke rehabilitation is rapidly evolving; meaningful public involvement in their design, testing and evaluation is essential to ensure implementation of effective products which are fit for purpose in the intended setting (Williamson et al. 2015).

Medical Device Technology Framework

This study reports on the usability of a high fidelity, prototyped GUI designed to provide feedback on exercise performance using effort detection technology on the power assisted exercise equipment. The four-stage MDTF proposed by Shah Robinson and AlShawi (2009) was adopted to ensure a user-centred, iterative approach towards the co-design and usability evaluation of the new technology. The framework was previously adopted to design and test a novel fall detection system for older adults (Thilo et al. 2019). In their example, early mock ups were used to stimulate discussion during focus groups with representative users during stages one and two (Thilo et al. 2017). The design and testing of a novel flexible functional electrical stimulation system for upper limb functional activity practice was also underpinned by the MDTF(Sun et al. 2018) and included development of a model to predict set up time for the technology (Smith et al. 2018). In the project reported in this article, stages one and two comprised user engagement and co-design methods with regular input from expert user and professional user groups (Young et al. 2022a, Young et al. 2021b). The outcome of the first two stages was a co-designed GUI which enabled users to select and navigate through a range of power assisted exercise programmes and view real time feedback on their exercise performance. This article reports on stage three of the process which comprised a two-part procedure to examine the usability of two versions of the GUI.

Alternative design approaches include the double diamond design process model (Design Council 2019) which was adopted to design and test a new interface for ‘Stappy,’ a sensor feedback system for walking performance. Prototype devices were introduced to participants during the initial discovery phase of the design cycle to stimulate discussion focussed upon user requirements (Jie et al. 2019). Cultural probes have been introduced in previous user centred design examples to develop stroke technologies intended for use in the home environment (Nasr et al. 2016), however, PAEE is typically used in leisure or rehabilitation venues rather than the individual's setting. The MDTF (Shah Robinson and AlShawi 2009) emphasises inclusion of multiple end user groups comprising EU who live with health changes and PU defined as the professionals involved in the implementation and prescription of the technology. Commercialisation and continued development of new technologies is directly considered in stage 4.

Usability evaluation

Assistive technologies can enable PwS to independently perform functional activities and rehabilitation technologies are designed to facilitate achievement of therapeutic goals (Jayasree-Krishnan et al. 2021). Ease of use has been identified as a strong predictor of intention to use a particular technology (Albu, Atak and Srivastava 2015). Usability evaluation of new rehabilitation technologies enables identification of recurrent usability issues, measurement of task duration and evaluation of user satisfaction (British Standards Institute 2018). It calls for representative users to perform representative tasks to identify the strengths and shortfalls of a device in order to bring about improvements (Dumas and Reddish 1999). Technologies for PwS previously evaluated through usability testing include an assistive game controller (Burdea et al. 2021), sensor feedback system for gait (Jie et al. 2019), wearable functional electrical stimulation garments (Moineau et al. 2021) and virtual reality gaming system (Na et al. 2016). Data collection methods which have been implemented in the testing of novel assistive technologies include user satisfaction questionnaires (Feingold-Polak, Oren and Levy-Tzedek 2021), task completion [Sun et al. 2018), task duration (Smith et al. 2018) and comparison between different devices (Thilo et al. 2017). Recurrent usability issues include difficulty donning and doffing (Burdea et al. 2021), failure to complete tasks (Mah et al. 2015) and difficulty accessing emergency stop function (Jie et al. 2019). The importance of trust in assistive and rehabilitation technologies for PwS has been emphasised and features which facilitate sustained successful engagement include task variety, clear communication, fatigue management and reward (Feingold-Polak, Oren and Levy-Tzedek

2021). Usability evaluation is central to the development of acceptable and meaningful technologies which will be adopted by service providers and utilised by end users (Dumas and Reddish 1999).

Overview of Article

The study reported in this article recruited representative user groups to evaluate the usability of two sequential versions of the co-designed GUI to optimise the usability and functionality of the new technology. For the purposes of this manuscript, usability is defined as "the effectiveness, efficiency, and satisfaction with which specified users achieve specified goals in particular environments" (British Standards Institute 2018). Users in the context of this study are either PU, i.e. rehabilitation professionals or clinical exercise physiologists, or EU i.e. PwS, including people who have prior experience of PAE equipment. The methods section defines four objectives which underpinned the study and describes the synchronous remote usability testing procedure conducted on two sequential versions of the co-designed GUI. The approaches adopted to collect and analyse quantitative and qualitative data are explained and justified. The results section reports on the findings and is organized according to the four underpinning objectives. The findings and their interpretation are explored in the discussion section and compared with previous relevant examples in the published literature.

METHODS

Aim

The aim of this study was to evaluate the usability of a co-designed GUI to enable PwS and rehabilitation professionals to effectively utilise power assisted exercise equipment. The objectives were to: 1) evaluate the usability of version 1 of the GUI; 2) use the findings from version 1 to develop and evaluate a second iteration (extended version) of the GUI; 3) compare the usability of version 1 with version 2; and 4) Analyse usability as experienced by EU and PU's.

To achieve this aim, we adopted a mixed methods approach. Quantitative methods were used to examine task completion, task duration and user satisfaction using the PSSUQ (Sauro and Lewis 2016). Task completion is a strong indicator of the usability of digital rehabilitation technologies (Hu et al. 2022) and task duration data provides an indication of set up time which is a key determinant in the adoption of rehabilitation technologies (Smith et al. 2019, Smith et al. 2018). The PSSUQ was selected to measure user satisfaction as it distinguishes between system usability, quality of information and quality of the interface (Sauro and Lewis 2016). Think aloud was adopted as a qualitative method to gain insight into the users' experience of navigating the GUI and identify specific usability issues (Thilo et al. 2019). All usability evaluations were conducted with both EU and PU.

Version 1 of the GUI was specifically designed for the cross-cycle machine (Figure 17) as previous user involvement indicated that this machine was the most popular (Young et al. 2021b).

Figure 16: Cross Cycle: *Co-designed GUI was intended for this machine* (Article 6, Figure 1)

It was envisaged that the GUI would be adapted to the range of machines manufactured by Shapemaster Global. Figure 18 is an image of the chest-and-legs machine which was ranked second most popular through consensus methods (Young et al. 2021b).

Figure 17: Chest and Legs: ***Machine ranked second through consensus methods in use by an EU, supported by PU.*** **(Article 6, Figure 2)**

The version 1 prototype GUI (Figure 19) comprised 7 sub-menus, namely; 1) user login; 2) programme selection; 3) duration selection; 4) real time feedback; 5) exercise completion; 6) performance feedback; and 7) assistance alert. The real time exercise feedback phase of the programme (step 4) was defaulted to play for a 30 seconds duration to enable animation of the virtual effort detection display. The virtual effort was displayed on the semi-circular dial with darker shades of purple indicating increased effort. A menu bar at the bottom of the page enabled navigation to the homepage or previous page. This was positioned centrally rather than as a sidebar to account for the spatial awareness impairments which can occur following stroke (Pedrazzini and Ptak 2020). Activation of the 'help' icon navigated directly to an 'assistance called' message intended to assure users that a team member had been alerted.

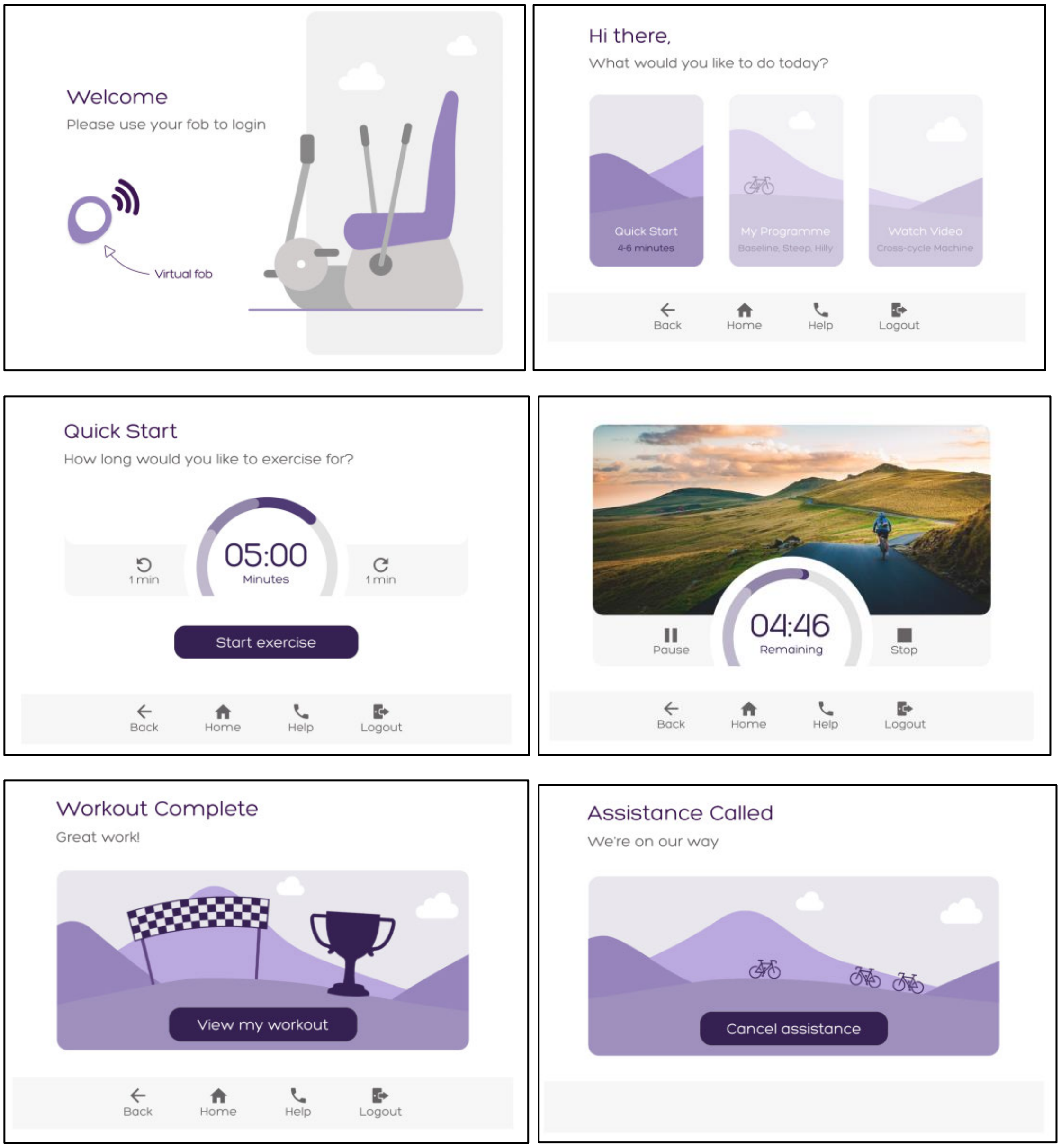

Figure 18: Graphical User Interface Version 1: ***this version was created to test the 'quick start' programme and help activation function*** **(Article 6, Figure 3)**

Both PU and EU's experiences of using the newly designed GUI were gleaned to identify usability issues to help inform future iterative redesign processes. The usability evaluations consisted of assisted user virtual walkthroughs of the interface using 'think aloud' and cursor observation to highlight usability issues, and a post testing user questionnaire, the PSSUQ. Specific tasks were developed to evaluate the usability of the GUI. The tasks were devised to replicate priority functions of the GUI in a real-world setting and incorporated exercise programme selection, programme duration, interpretation of detected user performance and access to assistance. Efficient navigation through the console was deemed a priority to prevent delays or disruption to the operational circuit, therefore timing of task duration was included. Setup time is an important, but neglected research area in the field of rehabilitation technologies (Smith et al. 2018). A target of 25 seconds from user login to exercise commencement was identified as a benchmark by the manufacturer. The use of multiple evaluation tools allowed for the triangulation of data.

Testing was scheduled during a period of government imposed national lockdown in the UK due to the covid-19 pandemic. Virtual versions of the GUI were therefore created in adobe XD and the tests were conducted remotely using Zoom media. Ethical approval for this study was granted by the host university (ER26319972).

The data generated during the first round of usability testing shaped the design of version 2 of the GUI which included extended programme options and comprised 16 submenus.

Sample size

Preliminary testing has been implemented in usability evaluation to determine the probability of error detection (Vandewalle et al. 2020). Due to resource and timescale restrictions this was not feasible and so the probability of error detection was estimated at 0.15. The probabilistic model of problem discovery described by Sauro and Lewis (2016) was applied to determine sample size with a target of 95% chance of observation. We therefore aimed for a 95% likelihood of detecting usability problems with an estimated 15% probability of occurrence. A sample size of 19 participants was required (Sauro and Lewis 2016).

Recruitment

Convenience sampling was implemented to identify participants for the EU and PU groups. The criteria for participation across both groups was inclusive to capture a range of perspectives and user priorities. The inclusion criteria for the EU representation were; diagnosis of stroke; access to a Wi-Fi connected laptop or digital tablet; able to follow verbal instructions in English; and able to provide informed consent. No prior experience of PAE was stipulated. People who were unable to provide informed consent due to severe cognitive impairment were excluded from participation. Participants for the EU group were identified through a local independent rehabilitation service and the service user network at Sheffield Hallam University. The inclusion criteria for the PU group were; employment relevant to rehabilitation or exercise prescription for people with long term conditions, access to a Wi-Fi connected laptop or digital tablet; able to follow verbal instructions in English and able to provide informed consent. Participants for the PU group were identified through academic teams at the host university, independent practitioners known to the research team and service providers known to the manufacturer.

Potential participants were identified by the lead author (RY) and invited to consider participation via email with an accompanying participant information sheet. The target recruitment was 10 participant per group. Consent was confirmed through completion and submission of an electronic form.

Participants

Ten EU participants (6M/4F) and ten PU participants (2M/8F) consented to participate. The mean age of the EU participants was 61.7 years (SD 10.2) and mean time since stroke was 60.9 months (SD 24.7). Fifty percent of the participants had prior experience of PAE and 40% of the participants in the EU group had contributed to prior user involvement and co-design stages of the technology project (Table 27). One participant (EU05) was unable to activate the remote-control mouse icon on Zoom. After several attempts the participant decided to withdraw from the study.

Table 27: Expert user participants (Article 6, Table 1)

Code	Months since stroke	Impairment	Gender	Age (Years)	Occupation	Experience of PAE	Earlier co-design participant
EU1	63	Left hemiparesis	Male	62	Medical professor	Yes	No
EU2	76	Ataxia (L>R)	Male	77	Retired farmer	No	No
EU3	73	Right hemi	Male	69	Retired data analyst	Yes	Yes
EU4	86	Right hemi/aphasia	Male	71	Retired sailor	Yes	Yes
EU5	76	Right hemi/aphasia	Female	68	Retired sales manager	Yes	Yes
EU6	9	Left hemi	Female	52	University lecturer	No	No
EU7	24	Quadriparesis	Male	44	Foreman (unable to work since stroke)	No	No
EU8	76	Left hemi	Female	53	Accommodation officer	No	No
EU9	62	Right hemi	Male	65	Engineer	No	No
EU10	64	Left hemi	Female	56	Civil servant	Yes	Yes
Mean months since stroke: 60.9 (SD10.2)			**6M/4F**	**Mean age: 61.7 years (SD24.7)**			

The mean age of participants in the PU group was 42.3 (SD 6.09) years and included representation from sport sciences, rehabilitation physiotherapists and industry. Fifty percent had direct experience of PAE and 60% had contributed to earlier stages of the project (Table 28). A participant in the PU group (PU5) withdrew from the study prior to test two due to work pressures.

Table 28: Professional user participants (Article 6, Table 2)

Code	Occupation	Gender	Age (Years)	Experience of PAE	Co-design participant
PU1	Physiotherapist	Female	43	Yes	Yes
PU2	PAE marketing expert	Female	44	Yes	No
PU3	Exercise scientist	Female	36	No	Yes
PU4	Physiotherapist	Female	42	Yes	No
PU5	Occupational Therapist	Female	47	No	No
PU6	Physiotherapist	Female	38	Yes	Yes
PU7	Sport scientist	Male	32	No	No
PU8	Research physiotherapist	Female	45	No	Yes
PU9	Sport scientist	Male	42	No	Yes
PU10	Physiotherapist	Female	54	Yes	Yes
		Mean age: 42.3 (SD6.09)			

Usability testing procedure

All tests were conducted via remote digital media by the lead author (RY). The virtual meetings were password protected and the meeting room was locked once the participant had entered the system. A short familiarisation session was scheduled to ensure that the remote technology could be accessed by each participant. The Zoom media 'remote control' function was synced with a screen share of the adobe interface. The participants were supported through activation of the remote-control mouse icon and supported in briefly navigating through the virtual GUI to ensure that they could activate the functions and view the interface from their selected device. Test one was scheduled during each familiarisation session. The familiarisation meeting, test one and test two were recorded directly to the lead author's device into a secure digital storage system at the host university.

Test one evaluated the usability of version 1 of the GUI and comprised three specific tasks (1.1, 1.2, 2.0) in the 'Quick Start' programme (Table 29). Participants were asked to verbalise their thoughts about navigating through the GUI using a 'think-aloud' technique (Dumas and Reddish 1999). Alongside the 'think aloud' data task completion rates and task duration data were collected. Each task was completed twice. During the first attempt at each task, participants were encouraged to 'think aloud' as they navigated through the interface and identified the icons which would enable task completion. They were prompted to explain their decisions and verbally share their experience of navigating the interface. The second attempt was conducted in silence and participants were required to directly navigate through the task under timed conditions.

Test two was scheduled between four to six weeks after test one and evaluated the usability of version 2 of the GUI. Tasks 1.1, 1.2 and 2.0 were repeated and four additional tasks (3.1, 3.2, 4.1, 4.2) were introduced to evaluate the extended 'my programme' submenu of the GUI. The purpose of repeating the test one tasks was to establish whether the changes implemented between version 1 and version 2 affected the usability of the GUI. In order to optimise consistency of testing conditions, each task was repeated twice, with the first attempt being a 'think aloud' walkthrough of the GUI and the second attempt a timed test conducted in silence.

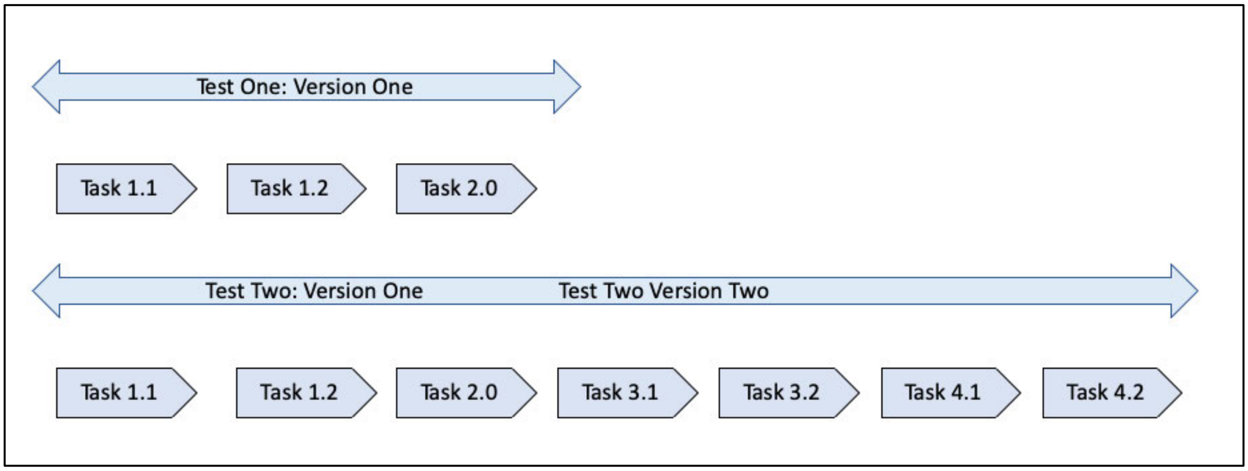

Figure 19: Timeline to represent tasks conducted on version one and version two: ***The first three tasks were conducted on versions one and two. The final four tasks were specific to the new submenus created within version 2.*** **(Article 6, Figure 4).**

Table 29: Usability tasks (Article 6, Table 3)

Version 1 and 2	Completion criteria	Timed components
Task 1.1 You want to do a 6-minute workout in the 'quick start' programme. **Task 1.2** You will view your results at the end of the exercise.	• Access quick start • Select 6 minutes • Activate virtual exercise programme • View results	**1.1:** Time lapsed from login and virtual exercise **1.2:** Time lapsed from login to opening the results menu
Task 2.0 You want to do a 4-minute workout in 'quick start.' As the machine starts to move you realise your hand is not secured to the moving component and you decide to call for help.	• Access quick start • Select 4 minutes • Activate virtual exercise • Activate 'help' icon	**2.0:** Time lapsed from login to opening assistance called menu
Version 2 only		
Task 3.1 You want to complete a baseline assessment in the 'my programme' area. Assistance is available. **Task 3.2** You decide that you would like to increase the target intensity during exercise and view your results on completion.	• Access 'my programme' • Access 'baseline assessment' • Activate virtual exercise • Increase target intensity • View results	**3.1**: Time lapsed from login to virtual exercise **3.2:** Time lapsed from login to opening the results menu
Task 4.1 Please choose either the 'hilly' or 'steady' option in the 'my programme' area. **Task 4.2** You decide that you would like to decrease the target intensity during exercise and view results on completion.	• Access 'my programme' • Select 'hilly' or 'steady' • Activate virtual exercise • Decrease target intensity • View results	**4.1:** Time lapsed from login to virtual exercise **4.2:** Time lapsed to opening the results menu

The research team were cognisant of ensuring a positive participant experience throughout all testing procedures. The lead author advised that the tasks were not intended to test the capabilities of the participant and that any difficulties encountered whilst completing the tasks reflected shortfalls in the design of the GUI. The lead author is an experienced neurological physiotherapist with knowledge of the communication and processing impairments which can occur following stroke. Verbal instructions and prompts were adapted according to responses from each participant and rest time was offered between each task.

Usability observation form

Test one and test two were audio-video recorded to enable identification of usability issues, record task completion and task duration. A usability observation form was used to document all findings (Appendix 6). Cursor tracking was observed on the video footage of each virtual test; errors, hesitation or delays in navigation through the GUI were documented as a usability occurrence. The 'think aloud' data were initially summarised onto the usability observation form by the lead author. Four of the recordings alongside the respective usability observation forms were sense checked by a second member of the research team (NS). Discussion between RY and NS led to agreement that the 'think aloud' data would be transcribed verbatim onto the usability observation form to ensure the user experience was fully captured. Narrative which indicated user uncertainty, hesitation or dissatisfaction with the GUI was documented as a usability occurrence.

Participant satisfaction

The PSSUQ was selected to capture participants' experience of the GUI on completion of each test. The PSSUQ is a 16-item standardised questionnaire devised to measure users' perceived satisfaction of a software system (Table 30). The PSSUQ has concurrent validity (Lewis 2002), very high scale and subscale reliability and construct validity (Lewis 1992). Participants were required to complete a 7-point Likert scale with responses ranging from strongly agree (1) to strongly disagree (7) (Table 31). An overall mean score is calculated from PSSUQ responses plus individual scores for three subsections: system usefulness, information quality and interface quality (Table 30). Lower mean scores indicate higher user satisfaction (Sauro and Lewis 2016). Participants were issued with an on-line version of the questionnaire at the end of each test and requested to complete it and submit responses within 24 hours.

Table 30: Post-Study System Usability Questionnaire (Article 6, Table 4)

Subsection	Questions
System usefulness	1. Overall, I am satisfied with how easy it was to use this system
	2. It was simple to use this system
	3. I was able to complete the tasks and scenarios quickly using this system
	4. I felt comfortable using this system
	5. I believe I could be productive quickly using this system
	6. I believe I could become productive quickly using this system
Information quality	7. The system gave error messages that clearly told me how to fix problems
	8. Whenever I made a mistake using the system I could recover easily and quickly
	9. The information provided with this system was clear
	10. It was easy to find the information I needed
	11. The information was effective in helping me complete the tasks and scenarios
Interface quality	12. The organisation of information on the systems screens was clear
	13. The interface of this system was pleasant
	14. I liked using the interface of this system
	15. This system has all the functionalities and capabilities I expect it to have
	16. Overall, I am satisfied with this system

Table 31: Post-Study System Usability Questionnaire Scoring Scale (Article 6, Table 5)

On a scale from Strongly Agree to Strongly Disagree, please rate the following statements								
(Positive Statement)	1	2	3	4	5	6	7	NA

Data analysis

Descriptive and inferential statistics were conducted in Excel (Microsoft) and SPSS (IBM version 28.0.0.).

Usability issues

Usability occurrences recorded on the usability observation forms were collated to identify the total number of incidents detected through cursor tracking and 'think aloud' data on version 1 and version 2 of the GUI. Usability incidents which recurred across participants were clustered to develop a definitive list of usability issues. The identified usability issues were coded according to four a-priori categories developed during stages one and two of the research programme (Young et al. 2022a, Young et al. 2021b, Shah Robinson and AlShawi 2009). The categories were; 1) system safety; 2) operational efficiency; 3) programme effectiveness; and 4) user engagement.

To determine which usability issues required prioritisation, the frequency of occurrence was collated and severity was scored. Frequency was recorded on a modified user by problem matrix (Table 32) (Dumas and Reddish 1999). Total issue occurrence was summated to enable comparison between the user streams and incidence of problems on versions 1 and 2 of the GUI.

Table 32: User by Problem Matrix (Article 6, Table 6)

		Participant code																			Fr*	S**
Usability issues category	**EU1**	**EU2**	**EU3**	**EU4**	**EU5**	**EU6**	**EU7**	**EU8**	**EU9**	**EU10**	**PU1**	**PU2**	**PU3**	**PU4**	**PU5**	**PU6**	**PU7**	**PU8**	**PU9**	**PU10**		
Safety																						
Operational																						
Programme effectiveness																						
User engagement																						

*Frequency of problem

**Severity of problem

The problem severity scale developed by Dumas and Redish (1999) was adapted to identify features which may cause risk of injury, impede programme effectiveness or reduce user engagement. Table 33 indicates the adapted categories in italics. All detected usability issues were scored to determine severity.

Table 33: Problem severity scale (Article 6, Table 7)

Level 1	Prevents task completion • *may lead to user injury* • *may cause programme to be ineffective* • *may cause user disengagement*
Level 2	Creates significant delay or frustration • *significantly impedes programme effectiveness*
Level 3	Problems have minor effect on usability • *may have minor effect on programme effectiveness* • *may cause minor user uncertainty*
Level 4:	Subtle and possible enhancements/suggestions

Descriptive analysis of the user by problem matrix was conducted to examine the pattern of usability issues across the a-priori categories and compare sequential versions of the GUI.

Two members of the research team (RY and AH) discussed each usability issue, considering the frequency and severity to determine which usability issues would be addressed in the iteration of version 2 of the GUI. Usability issues with a severity score of four were automatically addressed.

Task completion

Task completion was defined as navigation through all required submenus within the GUI to access the exercise programme, user performance or assistance request stipulated in the task descriptor. No time limit was applied. Instances in which a participant made an error but was able to self-correct and navigate to the intended menu were recorded as task completion. Task completion data were recorded and collated on the usability observation form.

Task duration

Shapiro-Wilks tests (significance 0.05) were conducted on task time to determine normal distribution. Calculation of the task duration geometric mean mitigated for the positively skewed data distribution which is a common occurrence with timed tasks (Sauro and Lewis 2016). One sample T-Tests were conducted on the geometric means calculated for tasks 1.1 and 4.1 to determine the probability of 95% of users commencing exercise within the benchmark target of 25 seconds.

Two-tailed T-Tests are considered robust to the positive skew associated with task duration data and log transformation is not required (Sauro and Lewis 2016). Two-tailed paired t-tests were conducted on the mean difference scores between version 1 and version 2 for tasks 1.1, 1.2 and 2.0 to detect any statistically significant difference in repeated task times. Independent T-Tests were conducted on all task time data to detect any statistically significant difference in completion times recorded between the EU and PU groups.

User satisfaction

Shapiro-Wilks tests (significance 0.05) were conducted on task time to determine normal distribution. Total PSSUQ scores were analysed in addition to analysis of the individual sub-sections. An independent samples T-Test was conducted on the difference in scores between the user streams for version 1 and version 2 of the GUI.

RESULTS

The results are presented in alignment with the underpinning objectives of the study.

1. Evaluate version 1 of the GUI

The total occurrence of usability issues detected and recorded during the examination of version 1 was 100. Each incident was described and coded to the relevant a-priori category which enabled identification of recurrent usability problems. The distribution of usability incidents across the four categories on version 1 was 24% safety, 28% operational, 22% programme effectiveness and 26% user experience.

Twenty-two different usability issues were identified during the testing of version 1 (Table 34), a detailed listing of these can be accessed in the supplementary materials 2.0. Each problem was analysed by two members of the research team (RY, AH) and the decision regarding whether to directly address the problem in the iteration of version 2 was determined by the issue frequency, severity and feasibility of adapting the underpinning technology.

Table 34: Usability issues according to category (Article 6, Table 8)

Category	Number of detected usability problems
Safety	4
Operational	8
Programme effectiveness	6
User engagement	4

Safety

Features which could lead to the machine commencing or sustaining unintended movement were identified as a safety risk, alongside difficulties associated with requesting help. The usability tests completed on version 1 of the GUI indicated that the 'help' icon was not visible enough and the 'assistance called' text was easy to miss. Ten participants reported feeling unsure about the difference between the stop/pause/help functions visible during live exercise. To address these problems, the menu bar visible during the live exercise phase of the programme was reconfigured to display distinct icons for pause, stop and help. The icons were slightly larger and the 'help' icon was positioned on the end of the menu bar. On the 'assistance called' page, the 'cancel' icon was relocated to the bottom of the page with the 'assistance called' text centralised (Figure 21).

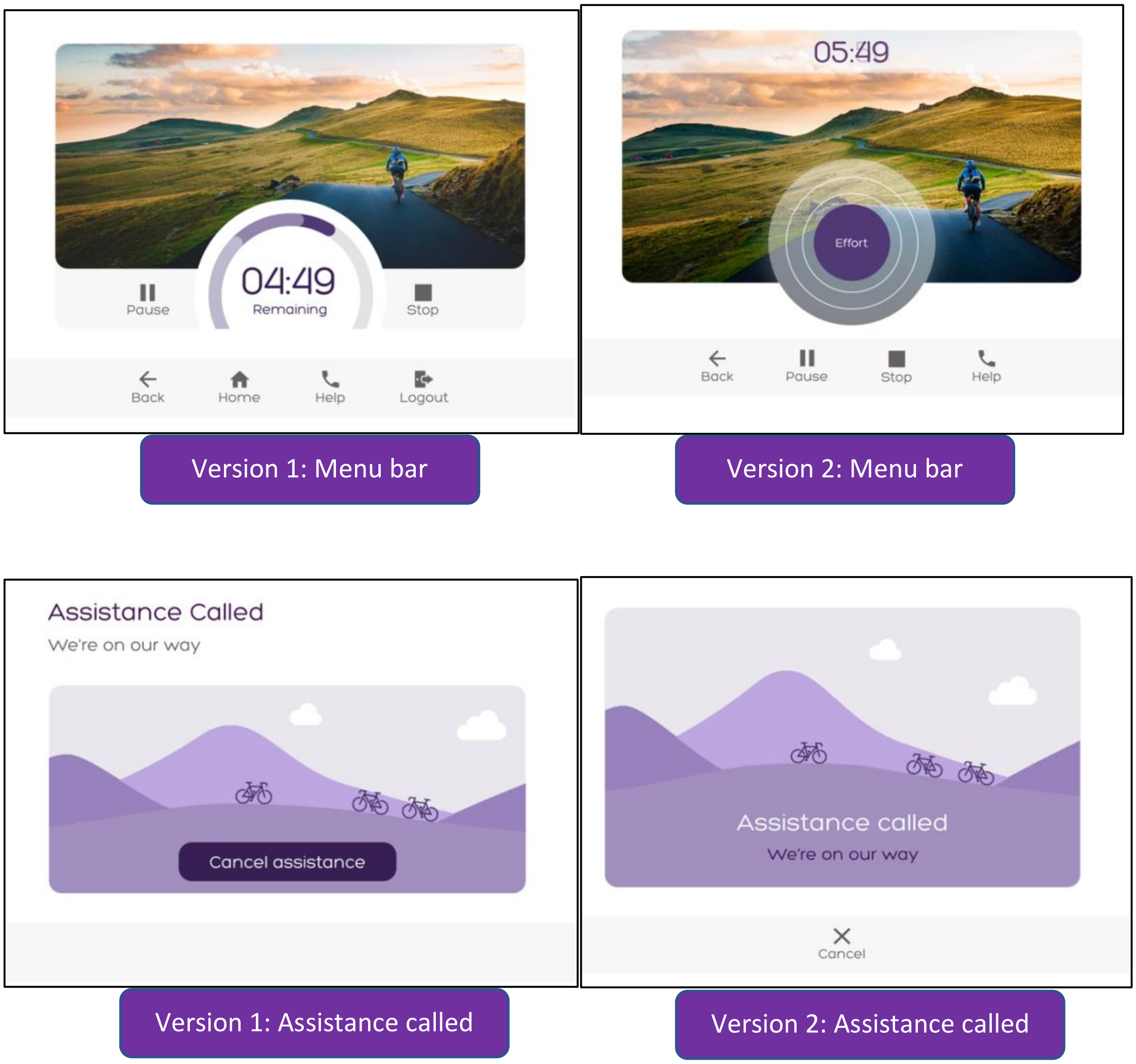

Figure 20: Safety problems addressed: *Stop and pause icons were added to the menu bar and the 'assistance called' message was centralised.* (Article 6, Figure 5)

Operational

Usability issues which could lead to a delay in users operating the equipment or cause them to require frequent guidance from support staff were coded within the operational category. Eight operational problems were identified on version 1; the most frequently occurring usability problem was associated with the duplication of activating the 'start/play' icons to commence exercise. Delays in identifying the 'start' icon were observed amongst nine participants. Five participants across both groups verbally reported that the repeated clicking to activate the machine could cause frustration or confusion. These issues were directly addressed in version 2 of the GUI. Instead of clicking a ‘start’ and then ‘play’ icon to initiate exercise, activation of ‘start exercise’ triggered a three second countdown with no repeated clicks required. The background to the ‘select duration’ page was adjusted to ensure that the functional icons were distinct (Figure 22). Six operational issues with low frequency and severity scores were not addressed.

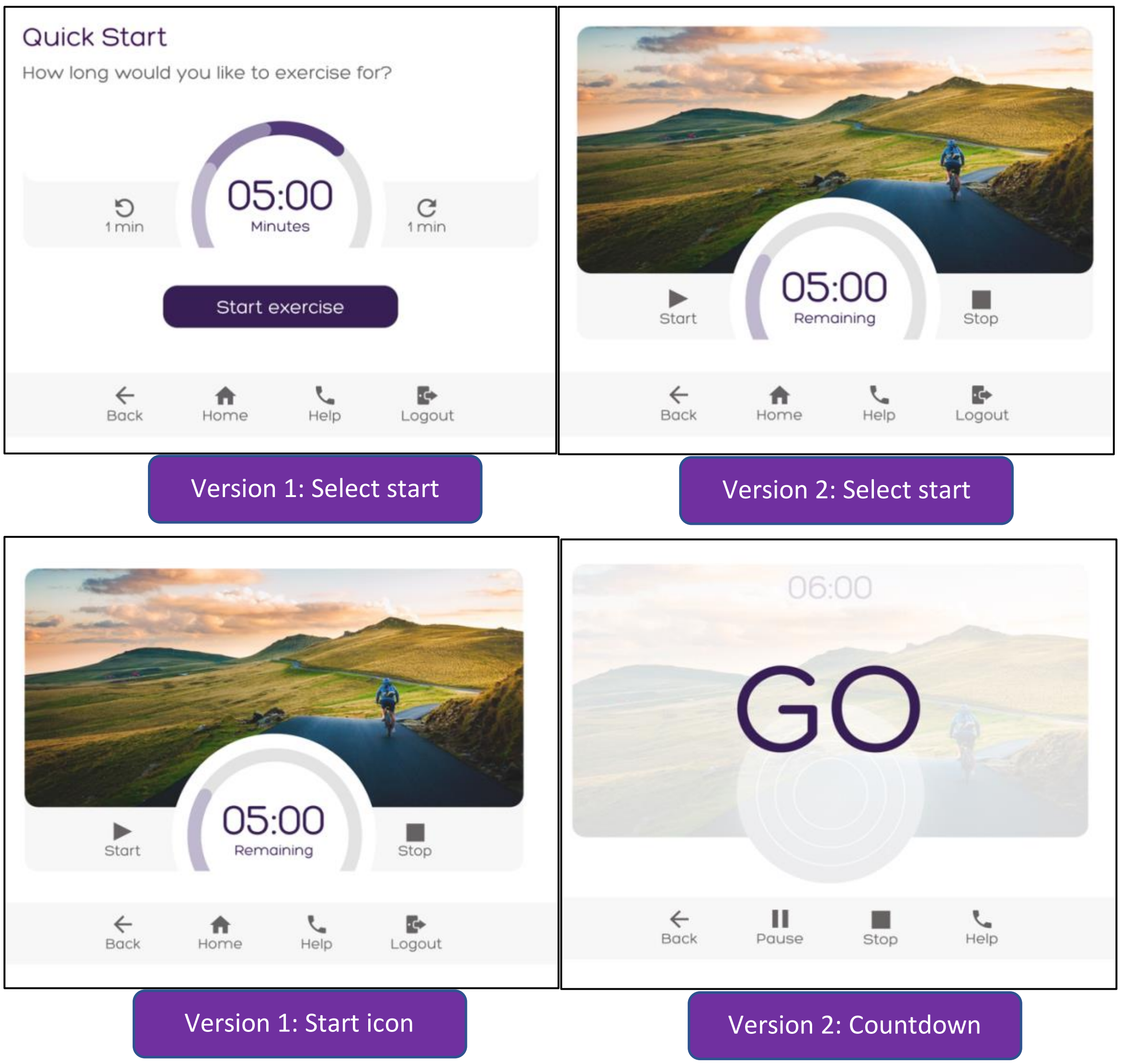

Figure 21: Operational problems addressed: ***On version 2, activation of the ‘start exercise’ icon triggered a countdown to commencement of movement avoiding the need for a second click on the ‘play’ icon.*** **(Article 6, Figure 6)**

Programme effectiveness

The programme effectiveness category identified those problems associated with the GUI which had the potential to impede users in engaging in an optimal intensity of exercise or quality of movement. Real time feedback regarding intensity of effort was a pivotal feature of the co-designed GUI; however, usability testing of version 1 indicated that 13 of the 19 participants misinterpreted the effort feedback dial. The real time visualisation of detected effort was identified as a priority for amendment in version 2 of the GUI. The redesign introduced an expanding and contracting balloon as an alternative to the feedback dial visualised in version 1. (Figure 23).

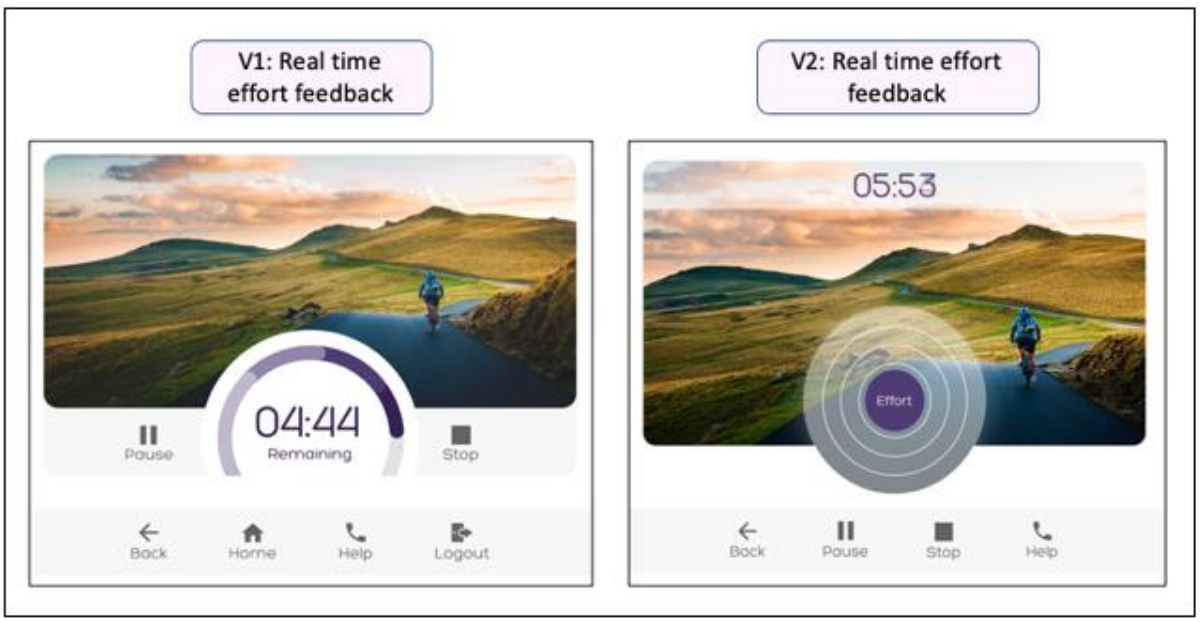

Figure 22: Programme effectiveness problems addressed: ***The effort biofeedback was re-designed on version 2. The expanding circle replaced the dial used on version 1. (Article 6, Figure 7).***

User engagement

Concerns regarding clarity of performance results and motivational features were categorised into this section. Usability testing of version 1 indicated that nine participants did not understand Watts as a performance metric. Eight participants reported that the concept of cycling up a 'col de Shapemaster' was not meaningful and two participants shared that the still image was uninspiring. Version 2 of the GUI displayed standalone numbers and the ‘col de Shapemaster’ concept was replaced by ‘Shapemaster Island.’ (Figure 24).

Figure 23: User engagement problems addressed: ***The concept of ‘Col-de Shapemaster’ was replaced by ‘Shapemaster Island’ and watts were removed from the metric details (Article 6, Figure 8)***

Task completion rates and task duration

Analysis of task completion and duration enabled the research team to quantify the usability of the GUI in the context of specific tasks aligned with its projected purpose. During the testing of version 1, EU7 experienced difficulties with remote control connectivity causing the completion times for tasks 1.1 and 1.2 to be invalid and not included in the descriptive analysis; task 2.0 was abandoned. Task completion and duration data are detailed in Table 35.

Table 35: Version 1 task duration and completion (Article 6, Table 9)

Participant	Task 1.1 (s)	Task 1.2 (s)	Task 2 (s)
EU1	12	51	31
EU2	20	63	30
EU3	19	56	32
EU4	27	67	26
EU6	33	77	38
EU7	280 *	380*	Terminated
EU8	16	55	19
EU9	26	66	32
EU10	21	59	13
PU1	9	48	24
PU2	20	57	25
PU3	16	55	25
PU4	21	59	20
PU5	21	55	28
PU6	15	53	18
PU7	12	51	19
PU8	11	48	34
PU9	11	47	22
PU10	13	57	22
Range	**9-33**	**47-77**	**18-38**
Median duration	**17.5**	**55.5**	**25**
% Task completion	**100%**	**100%**	**100%**

*Invalid data due to connectivity

The completion rate for all tasks was 100% except for Task 2.0 for EU7 which was attributed to failed connectivity rather than navigation through the GUI.

The benchmark duration for Task 1.1 was 25 seconds which was the maximum duration from opening the GUI to commencing exercise stipulated by representative commercial operators. For this analysis, the EU and PU group data were analysed individually as the intention was for EUs to operate the GUI independently in a real-world setting.

Calculation of the geometric mean using log transformation of task duration data generated a better estimate of the central values and has less error or bias than the standard mean for small samples of usability data (Sauro and Lewis 2016). One tailed T-tests were conducted on the geometric means calculated from Task 1.1 data recorded from version 1 of the GUI for the EU and PU groups to determine the probability of 95% of users achieving the benchmark target (Table 36).

Table 36: Version 1 task 1.0 benchmark comparison (Article 6, Table 36)

	Geometric Mean (SD) in seconds	Benchmark in seconds	P-Value	Probability
EU Group	18.4 (1.48)	25	P=0.03	96.62%
PU Group	13.7 (1.35)	25	P=0.0001	99.99%

User Satisfaction

All participants who completed the usability test on version 1 (n=19) submitted PSSUQ responses. Analysis of PSSUQ scores indicated high levels of user satisfaction across both user groups and favourable comparison with PSSUQ normative data. Due to limitations associated with published normative values, inferential analysis would not have represented a meaningful comparison (Sauro and Lewis 2016). The 'information quality' subsection attained the lowest satisfaction scores across both user groups and this pattern is mirrored in the published normative data (Sauro and Lewis 2016).

Table 37: PSSUQ data (Article 6, Table 11)

PSSUQ Section	PU Group Version 1 (n=10)	EU Group Version 1 (n=9)	Whole Group Version 1 (n=19)	PSSUQ Norms
	Mean (SD)	Mean (SD)	Mean (SD)	Mean
System usefulness	1.52 (0.31)	1.38 (0.36)	1.44 (0.33)	2.80
Information quality	1.85 (0.24)	1.61 (0.62)	1.72 (0.49)	3.02
Interface quality	1.60 (0.47)	1.33 (0.48)	1.45 (0.48)	2.49
Overall score	1.63 (0.24)	1.44 (0.46)	1.52 (0.38)	2.82

NB. Lower score indicates higher satisfaction [27]

The scores submitted by the EU group were slightly lower than the PU group indicating greater satisfaction amongst the EU group. An independent samples T-Test was conducted on the difference in scores between the two groups, no statistically significant difference in satisfaction between the user groups was detected (P=0.296, confidence interval -0.19 - 0.58).

2. Develop and evaluate an extended version 2 of the GUI

Development of version 2

Version 2 of the GUI addressed eight of the usability issues identified during the testing of version 1 and these are detailed in Table 38.

Table 38: Summary of usability problems addressed (Article 6, Table 12)

Category	V1 Problem	V2 Amendment
Safety	Help button not visible enough	Help icon more centrally positioned on menu bar
	Assistance called message not visible enough	Assistance called message centralised
	Distinction between stop/pause/help functions not clear	Menu bar reformatted
Operational	Repeated clicks to start exercise	'Start exercise' icon triggered a countdown to exercise
	Select duration/start exercise icons not visible enough	Background and icon boundaries amended to be more distinct
Programme effectiveness	Effort detection dial misinterpreted	Effort detection displayed as an expanding balloon
User experience	Performance metrics (watts) not understand by users	Standalone numbers displayed
	'Col-de-Shapemaster' concept not meaningful	'Shapemaster Island' concept introduced

Version 2 also included an extended range of programme options underpinned by an individualised baseline assessment. The intention was to develop a tailored prescription of exercise at an optimal intensity for the individual user. The 'baseline assessment' programme would be completed with supervision from an exercise or rehabilitation professional to ensure an appropriate intensity and duration of exercise (Figure 25).

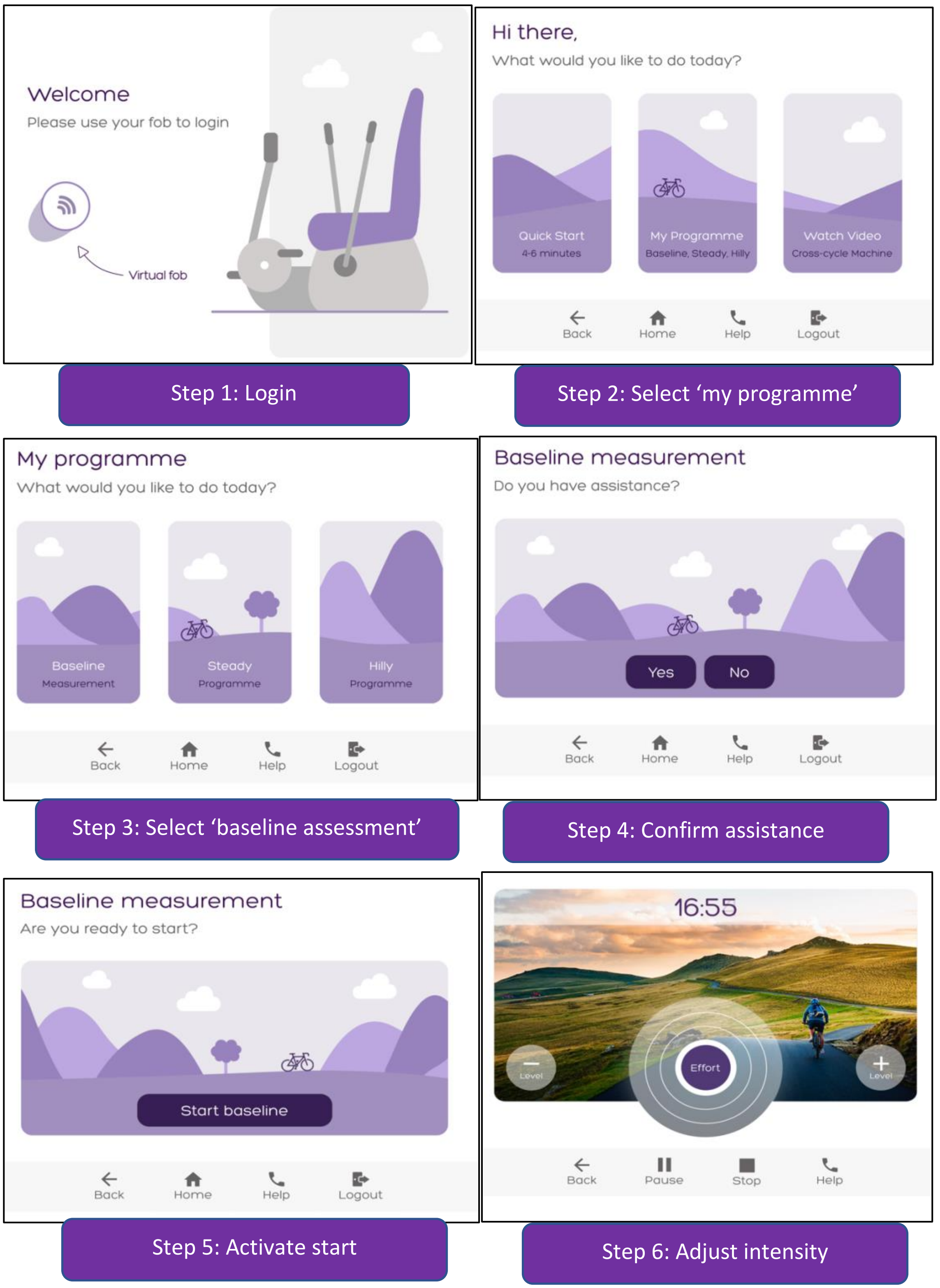

Figure 24: Graphical User Interface version 2 baseline assessment menu (Article 6, Figure 9)

The ‘my programme’ menu also included the choice of either a ‘steady’ or ‘hilly’ interval programme. The target intensity was indicated by a white balloon, with detected purple effort expanding within it (step two in Figure 27).

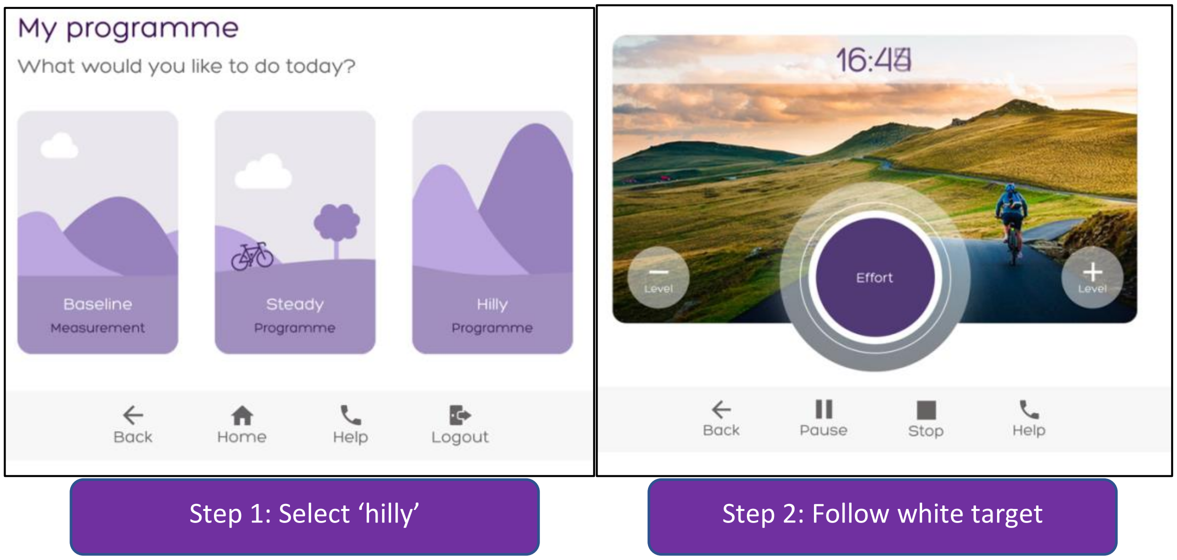

Figure 25: Graphical User Interface Version 2 hilly exercise programme menu (Article 6, Figure 10)

Evaluation of version 2

The total occurrence of usability issues detected during the evaluation of version 2 was 86. Each incident was described and coded to the relevant a-priori category which enabled identification of arising and recurrent usability problems. The distribution of usability incidents across the four categories on version 2 was 12% safety, 29% operational, 40% programme effectiveness and 19% user experience (Table 39). Two recurrent issues identified during testing of version 1; identification of the ‘help’ icon and interpretation of effort detection feedback. 24 new usability issues were identified.

Table 39: Version 2 Usability Incidents (Article 6, Table 13)

Category	Number of recurrent usability problems	Number of new usability problems
Safety	1	3
Operational	0	5
Programme effectiveness	1	10
User experience	0	6

Safety

Usability testing on version 2 of the GUI indicated that identification of the 'help' icon remained an issue for two participants and three new usability problems were detected. Four participants reported that a new countdown feature did not allow enough time to prepare for machine movement. One PU participant was concerned that the plus and minus icons on the live exercise page could be mistaken for speed adjustment and three participants were concerned that users would proceed without assistance during a baseline assessment.

Operational

Testing of version 2 of the GUI indicated that the operational problems observed in version 1 did not recur. However, the introduction of the extended 'my programme' area of the GUI did create five new usability problems associated with the new features. The concept of a baseline assessment, intended for new users or people wishing to review their progress, created confusion amongst PUs and EUs It was suggested that substantial explanation and support would be needed to support users in navigating this programme option. The omission of duration selection option for the 'hilly' or 'steady' workout options was identified by five participants and has the potential to cause operational disruption if not amended in future iterations.

Programme effectiveness

Usability tests completed on version 2 indicated that the new iteration of the real time effort feedback was much clearer than version 1, with only one participant (EU9) expressing uncertainty. However, the new features introduced into the 'my programme' area generated a range of new usability issues. The most frequently occurring problem was associated with uncertainty regarding the purpose of the white circle which was intended to indicate the target intensity. The other problems were associated with the intensity selection function, absence of temporal tracking, speed selection and heart rate feedback.

User experience

The unquantified numbers on the results page raised a concern by six participants across the PU (3) and EU (3) groups who reported that a metric was needed. Three different participants, two from EU and one from PU groups, observed that the 'Shapemaster Island' concept was not consistently embedded across the menus of the GUI. The importance of feedback regarding symmetry of feedback was expressed by two PU participants and two different PU participants noted that the intensity level was not included in the results page. Usability issues with a severity score of 4 or occurrence greater than 25% are summarised in Table 40 and will be considered for amendment in the next iteration of the GUI.

Table 40: Serious usability issues identified on version 2 (Article 6, Table 14)

Category	V2 Problem	Proposed amendment
Safety	Countdown to machine starting too short	Increase from 3 seconds to 5 seconds
	Potential for user to proceed into baseline assessment without assistance	Create a security code for this area of the submenu
	Help icon not visible enough	Explore colour options, e.g. red icon
Operational	Concept of baseline assessment unclear	Address through staff training and information video
	Purpose of assistance for baseline assessment unclear	Address through staff training and information video
	Did not notice the 'measurement/programme' subtext	Increase size and darken colour of font
	Cannot select duration in 'my programme' menu	Add this function in the same format as used in 'quick start' menu
Programme effectiveness	Purpose of target intensity circle not obvious	Include explanation in information video and review biofeedback graphics
	Selected intensity not displayed	Add the selected number to the 'live exercise' menu
	No feedback if you press the plus or minus icons for intensity	Display intensity number selected
User experience	Unquantified metrics do not represent meaningful feedback on performance	Continue user involvement programme to identify optimal metrics

Task completion and duration

The completion rate for all tasks was 100%. Individual duration of each task for each participant is summarised in Table 41.

Table 41: Version 2 task completion and duration (Article 6, Table 15)

Participants	Task 1.1 (s)	Task 1.2 (s)	Task 2 (s)	Task 3.1 (s)	Task 3.2 (s)	Task 4.1 (s)	Task 4.2 (s)
EU1	12	52	21	17	56	10	48
EU2	14	64	25	34	75	47	88
EU3	10	52	23	18	65	16	46
EU4	25	72	49	31	75	19	66
EU6	34	77	45	29	71	17	58
EU7	34	79	34	15	53	34	75
EU8	16	57	20	18	58	13	51
EU9	20	89	43	29	69	15	45
EU10	16	54	16	20	54	12	46
PU1	13	49	16	21	56	12	49
PU2	11	49	23	20	63	13	50
PU3	14	54	20	20	59	12	51
PU4	15	53	26	21	58	14	52
PU5	W/D*	W/D*	W/D*	W/D*	W/D*	W/D*	W/D*
PU6	15	53	19	20	59	15	48
PU7	14	52	17	19	63	12	54
PU8	12	52	22	19	65	9	48
PU9	13	53	18	22	60	12	48
PU10	14	52	20	23	67	12	51
Range (sec)	11-34	49-89	18-49	17-34	53-75	9-47	46-88
Median duration (sec)	14	53	21.15	20	61.5	13	50.5
% Task completion	100%	100%	100%	100%	100%	100%	100%

*Participant withdrawn

Repeated analysis of achievement of the 25 second benchmark duration for task 1.1 was repeated on the task duration data recorded during the testing of version 2. The geometric mean using log transformation of task duration data were calculated for each user group and one tailed T-tests were conducted. The results summarised in Table 42 indicate the probability of 95% attainment of the target benchmark across both user groups.

Table 42: Task 1.1 benchmark comparison (Article 6, Table 16)

	Geometric Mean (SD) in seconds	Benchmark in seconds	P-Value	% Achievement
EU Group	17.1 (1.48)	25	P=0.0153	98.46%
PU Group	13.3 (1.10)	25	P=0.0001	99.99%

The baseline assessment programme evaluated during Tasks 3.1 and 3.2 required a user induction or formal review which would be supervised, therefore the benchmark target duration was not applicable. However, Task 4.1 was intended to evaluate independent navigation through the GUI and the 25 second benchmark target was applicable. Analysis of user group attainment of this is detailed in Table 43.

Table 43: Task 4.1 benchmark comparison (Article 6, Table 17)

	Geometric Mean (SD) in seconds	Benchmark in seconds	P-Value	% Achievement
EU Group	19.3 (1.55)	25	P=0.074	92.53%
PU Group	12.2 (1.16)	25	P=0.0001	99.99%

The probability of attaining the 25 second benchmark amongst the EU group was below 95% indicating that this programme option may have the potential to cause operational disruption due to user delay.

User Satisfaction

All participants who completed the usability test on version 2 submitted PSSUQ responses, however, two data sets from the PU group were discarded due to a technical issue with the survey software. The 'information quality' subsection attained the lowest satisfaction scores amongst the EU group, whereas 'interface quality' was the aspect of lowest satisfaction amongst the PU group. Comparison with normative PSSUQ data indicated good levels of user satisfaction (Table 44).

Table 44: User satisfaction scores (Article 6, Table 18)

PSSUQ Section	PU Group Version 2 (n=7)	EU Group Version 2 (n=9)	Whole Group Version 2 (n=15)	PSSUQ Norms
	Mean (SD)	Mean (SD)	Mean (SD)	Mean
System usefulness	1.26 (0.18)	1.23 (0.27)	1.24 (0.23)	2.80
Information quality	1.49 (0.31)	1.69 (0.69)	1.61 (0.55)	3.02
Interface quality	1.57 (0.51)	1.27 (0.31)	1.40 (0.42)	2.49
Overall score	1.41 (0.30)	1.40 (0.32)	1.41 (0.30)	2.82

The scores indicated by the EU group were slightly lower than the PU group indicating greater satisfaction amongst the EU group. An independent samples T-Test was conducted on the difference in scores between the two groups, no statistically significant difference in satisfaction between the user groups was detected (P=0.827, confidence interval -0.30-0.37).

3. Comparison of the usability of version 1 and version 2

Direct comparison between the ‘quick start’ programme on version 1 and version 2 aimed to evaluate differences recorded pertaining to problem occurrence, type of usability issues detected and performance of tasks 1.1, 1.2 and 2.0. The extended menus explored on version 2 created a new user experience and therefore statistical comparison of user satisfaction as reported in the PSSUQ was not explored.

Usability issues

Five usability issues were identified on the ‘quick start’ submenu on version 2, compared with 22 on version 1. Two of the issues identified on version 2 were recurrent; visibility of the ‘help’ icon and clarity of the effort detection biofeedback. However, the frequency of problem occurrence was lower, with one participant reporting difficulty associated with interpretation of the biofeedback on version 2 compared with 13 participants during the testing of version 1. Three new usability issues were associated with the changes made between version 1 and version 2. The countdown feature was considered too short and potentially unsafe by four participants; six participants did not like the absence of performance metrics and three participants reported that the 'Shapemaster Island' theme was inconsistent.

Task performance

With the exception of the connectivity issues which affected EU7 during the testing of version 1, there was 100% task completion for tasks 1.1, 1.2 and 2.0 across versions one and two of the GUI.

Shapiro-Wilks (significance 0.05) tests conducted on task duration data indicated normal distribution. Log transformation of raw task duration data is not required for comparison between mean values as two-tailed t-tests are considered robust to the positive skew associated with this type of data set (Sauro and Lewis 2016). Paired two tailed T-tests were performed on the mean difference between version 1 and version 2 completion times to detect any statistically significant difference between version 1 and version 2 task duration data (Sauro and Lewis 2016) (Table 45). Participants with incomplete task duration data sets (PU5, EU7) were excluded from this stage of analysis.

Table 45: Mean difference in task duration scores (v1-v2) (Article 6, Table 19)

EU Group (n=8)	Mean (SD) difference v1-v2 (s)	P Value (2 tailed) Confidence interval		PU Group (n=9)	Mean (SD) difference V1-V2 (s)	P Value (2 tailed) Confidence interval
Task 1.1	-3.37 (3.62)	P=0.03* (0.35-6.39)		**Task 1.1**	-0.77 (4.20)	P=0.59 (-2.46-4.01)
Task 1.2	+2.87 (8.74)	P=0.38 (-10.1-4.41)		**Task 1.2**	-1.11 (4.64)	P=0.49 (-2.46-4.69)
Task 2.0	+2.62 (11.08)	P=0.52 (-11.87-6.62)		**Task 2.0**	-3.11 (5.13)	P=0.10 (-0.84-7.06)

Duration was significantly faster for Task 1.1 on version 2 of the GUI compared to version 1 amongst the EU group (p=0.03). A non-significant increase in duration of tasks 1.2 and 2.0 on version 2 was recorded amongst the EU group. A non-significant decrease in all task duration between Versions 1 and 2 amongst the PU group was recorded.

4. Analyse usability as experienced by EU and PU participants

Comparison between the EU and PU groups aimed to ensure that the GUI was accessible and intuitive for use by PwS and supporting professionals. Detection of significant differences in task performance and user satisfaction would enable the team to identify features on the GUI which may require specific amendment. The occurrence of usability problems and task performance data were analysed to detect any differences between the usability as experienced by the two user groups. The distribution of problem occurrence across user groups on the two versions of the GUI is summarised in Table 46.

Table 46: Frequency of problem occurrence (Article 6, Table 20)

User group	V1 Safety	V2 Safety	V1 Operational	V2 Operational	V1 Programme effectiveness	V2 Programme effectiveness	V1 User experience	V2 User experience	Total
EU	9	4	11	10	9	18	11	9	**81**
PU	15	6	17	15	13	17	15	7	**105**
Total	**24**	**10**	**28**	**25**	**22**	**35**	**26**	**16**	**186**

During the testing of version 1, 40 usability incidents were detected amongst the EU group compared with 60 incidents amongst the PU group. The PU group were more likely to encounter or identify concerns regarding the safety, operational efficiency and effectiveness of the system when compared with the EU group. On version 2, the distribution of usability incidents was 41 for the EU group, compared with 45 amongst the PU group. Aspects of the extended 'my programme' menu on version 2 were unclear to both user groups, particularly the target intensity circle and selection of programme intensity. This accounted for the high occurrence of usability issues amongst PU and EU participants in the programme effectiveness category of version 2.

Task duration was compared between the EU and PU groups to detect any statistically significant differences in usability experienced by PwS. Independent two-sided T-Tests were conducted to compare mean completion time between the EU and PU group (Table 47).

Table 47: Comparison of task duration between Professional and Expert Users (version 1) (Article 6, Table 21)

Version 1

Task 1.1		Task 1.2		Task 2.0	
EU Mean (SD) (s)	PU Mean (SD) (s)	EU Mean (s)	PU Mean (s)	EU Mean (s)	PU Mean (s)
21.7 (6.67)	14.2 (4.14)	61.7 (4.55)	53.0 (4.55)	27.6 (2.84)	23.2 (1.58)
P = 0.018* (-13.5 to -1.53)		P = 0.023* (-16.0 to -1.44)		P = 0.204 (-11.5 to 2.76)	

Table 48: Comparison of task duration between Professional and Expert Users (version 2) (Article 6, Table 22)

Task 1.1		Task 1.2		Task 2.0	
EU Mean (SD) (s)	PU Mean (SD) (s)	EU Mean (s)	PU Mean (s)	EU Mean (s)	PU Mean (s)
18.3 (7.8)	13.4 (1.3)	64.4 (13.5)	51.8 (1.7)	30.2 (13.1)	20.1 (3.1)
P = 0.06 (-11.51 to 1.65)		P = 0.033* (-24.1 to -1.36)		P = 0.067 (-21.1 to 0.99)	

Task 3.1		Task 3.2		Task 4.1		Task 4.2	
EU Mean (SD) (sec)	PU Mean (SD) (s)	EU Mean (SD) (s)	PU Mean (SD) (s)	EU Mean (SD) (s)	PU Mean (SD) (s)	EU Mean (SD) (s)	PU Mean (SD) (s)
23.4 (7.19)	20.5 (1.33)	64.0 (8.9)	61.1 (3.5)	17.0 (7.4)	12.3 (1.65)	58.1 (15.2)	50.1 (2.08)
P = 0.268 (-8.45-2.67)		P = 0.388 (-9.98-4.21)		P = 0.123 (-1.59-10.92)		P = 0.156 (-3.75-19.75)	

The PU participants were significantly quicker than the EU participants to complete Task 1.2 on both versions of the GUI. Although the PU participants were quicker to complete Tasks 1.1 and 2.0, the difference was only statistically significant on Task 1.1 in version 1. The PU participants were quicker to complete Tasks 3.1, 3.2, 4.1 and 4.2 but the difference between the user groups did not reach statistical significance (Table 48).

DISCUSSION

This study evaluated the usability of a high-fidelity prototype GUI which was co-designed to enable PwS to choose from a range of exercise programmes and view real time feedback of their exercise performance during exercise. Two sequential versions of the GUI were evaluated with two user groups using online remote media with version 2 amended in response to usability problems detected on version 1 and extended to offer a range of programme choices.

Integrated multiple methods of usability evaluation were implemented to detect usability problems and evaluate the user experience. Empirical, performance-based metrics including task completion rates and task duration were used to evaluate the usability of the GUI. In comparison, the 'think aloud' data and video footage captured qualitative insights into the users' experience and facilitated identification of specific usability issues across all of the a-priori categories. Triangulation of different usability evaluation methods increases the chance of identifying usability issues and heuristic evaluation conducted by usability experts may further enhance methodological robustness (Dumas and Reddish 1999). However, examples from the literature indicate high similarity between the findings detected through heuristic evaluation and usability testing with representative end users (Albu et al. 2015).

The 'think aloud' data and usability observations were combined to create a descriptive list of categorised issues. The total number of recorded usability incidents on version 1 was 100 with 22 different usability issues identified. Eight of the 22 detected issues were prioritised according to severity and frequency and directly addressed in version 2. The total number of usability incidents on version 2 was 86, with 24 new usability issues identified. Most of these were associated with the new, extended programme menus, indicating that the amendments made to the 'quick start' menu did improve usability. This descriptive approach will enable specific usability issues to be ranked and addressed on future iterations of the interface (Fan et al. 2019). Although the 'think aloud' data enabled insight into participant's experience of navigating the GUI, comparable usability studies have captured rich qualitative data through focus groups or interviews to gain a more in-depth understanding of the participant's perspectives on a novel technology (Bauer et al. 2021, Thilo et al. 2019).

Although the amendments implemented on version 2 of the 'quick start' menu did improve its usability, the occurrence and seriousness of usability problems detected on version 2 suggests that further amendments are required before the technology is implemented. The ability to stop assisted movement quickly and call for assistance is a priority for safe use of power assisted exercise and the EU group were slower to complete this task on version 2 compared with version 1. On reviewing version 2 it was recognised that the 'help' icon was positioned more peripherally on the menu bar. This is particularly pertinent considering impairment in spatial awareness is widely reported amongst PwS which can impact ability to process visual input (Pedrazzini and Ptak 2020). The use of red, centralised icons has therefore been recommended to ensure rapid activation of safety functions such as 'stop' or 'quit' on devices designed for PwS (Jie et al. 2019).

Task completion and task duration data benchmarked against the commercial target indicated that the 'Quick Start' programme on both versions of the GUI would enable users to commence exercise independently and within the required timescales. Comparison of task duration between version 1 and version 2 indicated a non-significant decrease in task duration amongst the PU participants and significant decrease for Task 1.1 amongst EU participants. This apparent improvement in usability may be attributed to the changes implemented on version 2. It is also possible that repeated exposure to the GUI may have contributed to the participant's ability to navigate through it more quickly (Nilsson et al. 2014).

The safety and operational usability categories exemplified the divergence which can exist between operational efficiency and safety. Adjustments implemented on version 2 did reduce the occurrence of operational and safety problems, although access to support and supervision will need to be monitored during implementation of the technology. The co-designed GUI was intended to promote user independence, although the value of a supported induction to the equipment and availability of support throughout exercise was emphasised during the co-design stages of the research programme (Young et al. 2022, Young et al. 2021b). The safety of rehabilitation technologies is service and setting specific (Burdea et al. 2021, Lo, Stephenson and Lockwood 2020). Factors which should be considered in the implementation of rehabilitation devices in stroke rehabilitation include physical space, staff capacity, user ability and technological features (Lo, Stephenson and Lockwood 2020).

One of the key features for the new technology was the introduction of effort detection capability and provision of biofeedback to enable users to observe, adjust and compare their exercise performance to previous sessions. Sophisticated gamification, augmented or virtual reality technology was beyond the resource available for this early iteration of the GUI but could be potentially incorporated in the future. The effort feedback dial featured on version 1 was widely misinterpreted as an indication of remaining duration; the dial was replaced by the effort balloon on version 2 which was very quickly understood by nearly all participants. Identification of the misinterpretation was detected through the ‘think aloud’ data. Analysis of think aloud data in the evaluation of digital apps for use by older adults has previously enabled categorisation of usability issues according to severity and types of barrier detected (Wildenbos et al. 2019). This exemplifies the value of ‘think aloud’ data compared with usability studies which have focussed on user satisfaction and adverse events to quantify usability (Guillen-clement et al. 2021).

The baseline assessment on version 2 was intended to create an individualised prescription for each user. Baseline assessment has been previously integrated with gaming technologies for PwS to develop a programme which was adaptive to different users and responsive to their fluctuating cognitive and motor ability [Burdea et al. 2021, Nilsson et al. 2014)]. The purpose of the paler target intensity balloon introduced on version 2 was not clear to most participants and it was suggested that this would require verbal explanation to new users of the technology. Quantification of user performance was an area of dissonance between participants during the testing of version 1 and version 2. Positive reward about performance and a system which is responsive to all levels of ability is important to sustain user engagement (Wildenbos et al. 2019). Achievement of an effective and sustained exercise intensity is a challenge for providers of stroke recovery services as patients typically do not sustain the level of effort required for physiological benefit (Gothe and Bourbeau 2020). Assisted exercise with real-time feedback represents a potential solution as the motorised mechanism enables movement in the presence of motor impairment (Linder et al. 2021). Sophisticated human-in-the-loop feedback systems synchronised with detected mechanical work rate have been piloted on similar technologies to optimise user attainment of target intensity (Stoller et al. 2014b).

The PSSUQ data captured an impression of the user experience and indicated that reported satisfaction was high with a non-significant increase recorded for version 2. However, the PSSUQ was not sensitive to specific usability issues and did not directly inform the amendments implemented on version 2. User satisfaction scores were slightly higher amongst the EU group. Evaluation of similar assistive technologies has also reported higher satisfaction amongst expert users compared with professional users (Bauer et al. 2021, Moineau et al. 2021).

The anticipated operators of digitised power assisted exercise equipment include leisure centres, community venues and rehabilitation services, with the target user groups comprising PwS, supported by therapy teams or exercise professionals. Rehabilitation and exercise professionals were recruited alongside PwS to capture the perspectives of multiple end users. This combination was intended to optimise detection of usability issues across the a-priori categories. PU participants detected more potential issues than the EU group during the testing of version 1. Interestingly, this disparity was not identified during the testing of version 2. It is possible that the EU participants required longer to understand the usability testing process and gain confidence in identifying and articulating potential issues. PU participants focussed on operational and safety issues, whilst the EU participants commented more on the programme effectiveness and user experience. Comparable usability studies examining stroke related technologies have selected only healthy participants to avoid the potential for bias associated with motor or cognitive impairment (Burdea et al. 2021). Expert users and those with lived experience remain under-represented in the development of new technologies and systems devised to optimise rehabilitation outcomes (Jie et al. 2019, Burdea et al. 2021). Participants with neurological impairment have critical views on assistive technologies and their perspective should be complicit in the development and implementation of new equipment and products (Moineau et al. 2021).

This study reported on stage three of a co-design and usability evaluation centred on the digital advancement of PAE equipment. Effort detection technology and a range of programme menus to guide the user through the setup process were developed and evaluated. The potential to further develop the technology was identified by research participants and the project team. Integration of heart rate sensors on the handles would enable specific monitoring of exercise intensity (Alzahrani et al. 2015), whilst haptic or auditory signalling may improve accessibility of the technology for people with visual or perceptual impairments (Sigrist et al. 2012). The real time feedback displayed on the GUI could be gamified or developed as an immersive virtual reality experience (Mubin et al. 2019). Development of a user identification system has been identified as a commercial priority and will enable data analytics, intelligent exercise prescription and connectivity with referring services (Burdea et al. 2021).

This application of the MDTF has integrated co-design techniques (Young et al. 2022a, Young et al. 2021c) with mixed method usability testing of two sequential versions of a new GUI. Due to the restrictions imposed by the COVID-19 pandemic, face to face usability testing was not possible and in order to navigate this challenge, synchronous remote testing was implemented. This study adds to the small number of examples of remote usability testing with hard to reach user groups which offers the advantage of cost effectiveness compared with in-house usability tests (Hill et al. 2021). Although numerous usability issues were detected and addressed, the team recommend field testing of a late stage prototype prior to commercial implementation of the new technology. As the horizon for digital, robotic and assistive technologies expands, methodological approaches to optimise their design and usability are a priority in the field of rehabilitation engineering and robotics. The medical device technology framework ensures involvement of PU and EU groups and promotes a logical and yet iterative approach. The methods reported in this article have the potential to serve as an example in the development of future technologies.

Methodological considerations

Data were collected during a period of national lockdown imposed by the government during the covid-19 pandemic; the original proposal to field test the GUI was adapted through implementation of remote media to enable virtual testing.

The objectives of the study were attained insofar as two sequential versions of the GUI were developed and evaluated capturing a diverse range of user experiences. The tasks which guided the usability testing were relevant to the proposed long-term use of the GUI and were effective in highlighting usability problems.

Several limitations are acknowledged in that the remote testing of a technology devised for venue-based exercise inevitably situated the user experience out of context. On several occasions, participants commented that the usability problems encountered would have been less likely to occur if they had been engaged with the machine in a real-world setting such as in a gym environment or in a rehabilitation centre. However, the remote technology did enable more effective capture of the data. Stage 3 of the MDTF does stipulate real field testing of prototypes and this has been previously achieved by design teams who have conducted usability trials within the home environment (Thilo et al. 2019). In addition, field testing enables identification of technical problems due to hardware issues (Feingold-Polak, Barzel and Levy-Tzedek 2021).

The testing procedure was dependent on reliable internet connectivity, access to a digital device and an ability to use Zoom software. This excluded individuals with limited digital access or ability from participation which is an area of increasing concern in healthcare provision and research (Senbekov et al. 2020). Although the 'think aloud' data allowed some exploration of the participants' qualitative perspective, the approach to data collection and analysis was primarily empirical. Comparable usability studies have included semi structured interviews to capture an in-depth insight into the users' perspective and experience (Moineau et al. 2021). The same sample of participants tested version 1 and version 2 of the GUI which enabled direct intra-subject comparison between the versions. However, it is acknowledged that this may have introduced bias as the amendments were based on the participant's initial feedback (Dumas and Reddish 1999). Introduction of new participants to version 2 would have strengthened the design of the study. The sample size was based on a 95% likelihood of detecting usability problems with an estimated 15% probability of occurrence (Sauro and Lewis 2016). A larger sample would have increased the likelihood of error or usability issue detection.

CONCLUSIONS

Robust co-design and usability evaluation methods are integral to the development and implementation of new assistive technologies in stroke rehabilitation. Remote testing of two sequential versions of a co-designed GUI with two user groups enabled identification of usability issues and evaluation of user satisfaction. The changes implemented on version 2 successfully addressed serious usability problems detected on version 1. However, the extended range of programme options introduced on version 2 created new usability problems; these mostly reflected concerns regarding therapeutic effectiveness of the technology rather than its operational efficiency or safety features. The 'think aloud' data combined with the observation of task walk performance was effective in detecting specific usability issues, whilst the task completion and duration data provided an indication of the operational readiness of the technology. The PSSUQ scores provided an overall impression of user satisfaction and enabled comparison between user groups and the two versions of the GUI.

The recruitment of EU and PU representatives enabled the research team to identify and address a range of usability problems. Diverse user perspectives were captured which improved the usability of the GUI and generated a vision for future technology advancement. The findings from this study will facilitate the transition from a high-fidelity prototype, to a market ready version of the technology which will enable end users of PAE to identify, monitor and progress rehabilitation goals. The next step in this process will comprise field testing of a late stage prototype in rehabilitation settings with a new sample of PU and EU representatives. The iterative model which underpins the MDTF will ensure sustained user involvement throughout implementation and evaluation of the new technology.

5.6 Summary

The MDTF facilitated a structured, iterative approach towards the codesign and usability evaluation of the GUI with sustained PU and EU involvement throughout. The application of NGT to explore user priorities and determine machine selection ensured that users' perspectives had a tangible influence over the programme of research from the outset. *Health Expectations* is an inter-disciplinary journal which aims to promote critical thinking about all aspects of patient and public involvement and engagement. Our report on the application of NGT adds to a growing number of examples of this consensus method in the development of stroke rehabilitation.

The use of storyboarding and participatory analysis during stage two enabled the research team to visualise the GUI and consider in detail the functionality required of the new technology. *Design for Health* is an international journal which aims to build knowledge and practice in the context of the design of interventions and products that positively impact on health. Examples of storyboarding in the co-design of health technologies are limited (Lupton and Leahy 2019) and Article Five represents a novel contribution in terms of the methods adopted to create and crystallise co-design data in this field. The *Journal of NeuroEngineering and Rehabilitation* is focussed upon the way neuroscience and biomedical engineering are continuing to reshape physical rehabilitation and human movement. The usability evaluation reported in Article Six represented stage three of the MDTF and is an example of a mixed methods approach towards usability testing.

The objectives of the Grow MedTech funded project were achieved and the programme of research continued beyond the outputs reported in the three articles. Further adjustments were implemented on the GUI based on the findings of the usability evaluation reported in Article Six. The effort detection technology was implemented, tested and synchronised with the GUI by the medical engineer assigned to the project. The GUI developed for the Cross Cycle machine was adapted for use on the two other machines selected through NGT. In May 2021 we conducted a laboratory-based pilot study to trial the three prototyped machines on a sample of six PwS.

The limitations of each stage of the research programme are acknowledged in the respective articles. Feedback from peer review teams across the three articles commented on the small samples recruited during each stage of the project. This feedback was defended through reference to comparable studies and the sample size calculation conducted to guide the number of participants recruited to the usability evaluation. However, despite recruitment of user group representatives at each stage of the process, there was limited diversity amongst participants. The EU's were PwS who had invested in independent therapy services and therefore may not have represented the wider stroke population. Across the EU and PU groups there was only one BAME participant and most of the PU representatives held senior appointments. Future research in this field should purposively sample across a broader range of socio-economic and cultural groups to ensure more diverse representation of perspectives.

PART THREE: DISCUSSION AND CONCLUDING SUMMARY

Chapter 6 Discussion

The discussion of this thesis is presented in three sections; 6.1 is an analysis of key findings in the context of relevant literature previously published, 6.2 identifies the strengths and limitations inherent within the programme of research, 6.3 considers implementation of findings and some suggested future research recommendations for this field of research.

6.1 Key findings

The programme of research reported in this thesis implemented quantitative and qualitative methods to develop new knowledge on PAEE for PwS and advance the technology using co-design techniques. The overarching purpose of the doctoral programme of research was to explore the use of PAEE by PwS and advance, through co-design, the equipment to enable a tailored prescription to meet their bespoke requirements. Phase one implemented quantitative methods to establish the feasibility of PAE; phase two used qualitative methods to explore the experiences of venue based exercise and PAEE amongst PwS; phase three employed co-design and usability methods to co-design and evaluate a new GUI to advance the PAEE. The co-designed GUI was developed to enhance PAEE and enable the prescription and monitoring of a tailored programme of PAE for PwS. The findings have been synthesised and will be considered within three overarching sections; 6.6.1) psychosocial experience of exercise engagement, 6.1.2) physical responses to PAE, 6.1.3) PAEE specification.

6.1.1 Psychosocial experience of power assisted exercise equipment

PwS recalled feeling disempowered and mollycoddled when in the hospital setting with examples of participants resisting help from staff in order to recover their independence (Young et al. 2021b, Young et al. 2021a). Provision of in-patient therapy in the hospital was reported as being limited and the hospital stay was described as a sedentary experience (Young et al. 2021b). This affirms the challenges previously identified regarding quantity and intensity of inpatient therapy (Barrett et al. 2018, Astrand et al. 2016). Exploration of in-patient rehabilitation within UK stroke services has similarly identified feelings of disempowerment and frustration amongst PwS which were attributed to dysfunctional therapeutic relationships and a working culture based on an acute, biomedical model which prioritised management of medical issues and prevention of complications (Rosewilliam et al. 2016).

The collective findings indicate that people with acute stroke are not receiving the recommended level of therapy and stimulation required to optimise the response to the heightened window of neuroplasticity which is believed to occur during the first few weeks following stroke (Kraukauer et al. 2012). Evidence indicating reduced functional outcomes associated with VEM has influenced current clinical practise (AVERT Group 2015). However, the newly published National Clinical Guideline for Stroke (2023) stipulates a minimum of three hours per day of functional/motor therapy, with therapy targeted at the recovery of mobility beginning between 24 and 48 hours after stroke onset (Section 4.2). Attainment of this quantity and intensity of therapy represents a challenge to stroke service providers and the introduction of PAEE into in-patient rehabilitation may be part of the solution. Whilst we are confident of our own findings on the safety and feasibility of PAE amongst people with longer term stroke (Young et al. 2018) future research should examine the safety and feasibility of seated or recumbent PAE amongst people with acute stroke.

The qualitative data collected within this programme of research established that participants valued the provision of NHS outpatient and community therapy services following discharge from hospital where goals and activities were put into context and felt more meaningful (Young et al. 2021b). However, it is acknowledged that the sample recruited to this interpretative study had supportive networks which has been identified as facilitator of engagement with community based rehabilitation (Wei, Barr and George 2014). The experience of being discharged from NHS rehabilitation was devastating for some participants as they had been informed that they had reached a plateau in their recovery. One participant stated: '*They dumped me! I had to listen to it……I was really pissed off because they said "you're beginning to plateau" ……ah hell.'* The newly published National Clinical Guideline for Stroke (2023) state that stroke rehabilitation should be needs led and not time limited, with advice on how to re-access services if required (Section 4.1).

The concept of plateau was strongly refuted by participants recruited to our interpretative study who reported continued improvements in functional ability following discharge from NHS services (Young et al. 2021b). Qualitative interview data from an earlier study indicated that recovery plateau was the main reason for discharging PwS from therapy, although, PwS recruited to the same qualitative study perceived staff shortages as a key factor impacting duration of therapy provision (Wiles et al. 2004). The concept of recovery plateau has been challenged through multiple examples of quantified motor improvement amongst people with chronic stroke (Teasill et al. 2012, Moore et al. 2010). Although the physiological mechanisms which enable progress amongst people with chronic stroke are different to the neuroplastic responses which occur in acute stroke, goal attainment at any stage of stroke recovery is a key priority. Further research has been recommended to advance mechanistic knowledge of stroke recovery and develop a neuroscience-informed approach to stroke rehabilitation (Carey et al. 2019).

Initial feelings of anxiety associated with the uptake of exercise were recalled by several participants (Young et al. 2021b); fear of falling, limited information, lack of equipment and severe weather conditions have been identified as contributory factors to anxiety associated with uptake of exercise amongst PwS (Aguiar et al. 2022). Guidance and support from experienced staff helped to relieve concerns and enabled participants to quickly gain confidence within the designated setting (Young et al. 2021b, Young et al. 2021a, Young et al.

2018). Perspectives on the required level and type of qualification required to deliver and supervise exercise sessions were divergent; participants recruited to the feasibility study published in this thesis felt reassured by the presence of qualified physiotherapists during the initial sessions, although they felt that less specialist input was required once they had familiarised with the PAEE (Young et al. 2018). Some participants within the systematic review suggested that exercise instructors were a substitute for physiotherapists, whereas others had felt more challenged by fitness professionals (Young et al. 2021a). Good knowledge of the PAEE and an ability to set realistic goals were attributes emphasised during the NGT discussion (Young et al. 2021c). A recent survey of exercise professionals indicated that only 22% had experience of working with PwS and less than half felt that they had acceptable skills in dealing with stroke related psychological problems (Condon and Guidon 2018). However, limited knowledge of exercise guidelines amongst rehabilitation therapists has also been reported (Clarke et al. 2018). The need to advance the stroke service workforce through the development of interdisciplinary roles centred on relevant skills and competencies has been highlighted (NHS England 2021). Fitness professionals and rehabilitation therapists require specific training in order to develop exercise prescription skills specific to the needs of PwS.

The value of being able to exercise in a de-medicalised setting following termination of NHS rehabilitation was expressed by multiple participants (Young et al. 2021b, Young et al. 2021a). Challenges associated with the availability and accessibility of exercise venues were highlighted (Young et al. 2021b) and the need for more community venues which offer a client centred service with accessible equipment was highlighted (Young et al. 2021c). Widely reported extrinsic barriers to engagement in exercise amongst PwS include availability of suitable venues, transport and presence of staff with the required skills (Pacheco et al. 2021, Marzolini et al. 2021). Cardiac rehabilitation programmes have been offered to PwS, however, the eligibility criteria usually include the ability to walk independently (Marzolini et al. 2020) and PwS have reported feeling embarrassed by their physical impairment (Clague-Baker et al. 2022). Fatigue is a frequently cited barrier to engagement in exercise by PwS; Pacheco et al. (2021)

emphasise that rehabilitation professionals need to advise PwS on the management of fatigue alongside the provision of more specific guidance on accessible exercise facilities.

Enjoyment of exercise was a recurrent sentiment expressed by participants recruited to this programme of research (Young et al. 2021b, Young et al. 2021a, Young et al. 2018). Participants reported that they had looked forward to the exercise sessions, and in the case of time limited trials, missed them once the intervention was completed (Young et al. 2021a, Young et al. 2018). Enjoyment has been identified as an important facilitator of engagement in physical activity interventions amongst PwS (Nayak et al. 2021) and was an important part of the embodied experience of PAE captured during an ethnographic study based within an assisted exercise therapy centre in South England (Meredith et al. 2022). Although typically explored through qualitative methods, enjoyment of an exercise intervention may be quantified through the Physical Activity Enjoyment Scale (PACES) (Murrock, Bekhet and Zauszniewski 2016). The PACES has been effectively implemented on PwS (Enam et al. 2021) and future evaluation of PAE interventions are encouraged to incorporate this measure to capture the self-reported experience of a larger cohort of participants.

Group based interventions fostered peer support, mutual encouragement and social interaction (Young et al. 2021b, Young et al. 2021a, Young et al. 2018). Our data reflected that the offer of exercise equipment legitimised uptake of membership at the specialist community stroke venue and the development of new friendships was an unexpected collateral benefit (Young et al. 2021b). In contrast, PwS recruited to individual exercise referral schemes reported a more isolated experience (Young et al. 2021a). Participants within the EU stream of the co-design phase emphasised the importance of group interaction (Young et al. 2021c) and this sentiment has been shared by PwS from across the global community (Aguiar et al. 2022; Pacheco et al. 2021). Social networking was identified as an important benefit associated with comparable group interventions for PwS as participants valued the opportunity to discuss common problems and develop a sense of belonging (Nayak et al. 2021). Although not specifically aimed at PwS, the ethnographic study conducted at an assistive therapy centre in South England reported that the venue fostered a sense of belonging, togetherness and social engagement amongst users with complex physical impairments and age-related health changes (Meredith et al. 2022). A commitment to sustained community-based support including stroke specific peer support and wider social opportunities is stated in the National Service Model for Stroke (NHS Engalnd 2021). The extended provision of stroke specific exercise groups has the potential to improve physical recovery and facilitate psychosocial adjustment for PwS.

Engagement with venue-based exercise was associated with restoration of an internal locus of control, resumption of pre-stroke lifestyle and adoption of new roles (Young et al. 2021b, Young et al. 2021a). Similarities between the data synthesised within the systematic review (Young et al. 2021a) and the interpretative study (Young et al. 2021b) were identified as participants reported a recovery of their 'old self' and a sense of empowerment. The interwoven, symbiotic benefits of visiting a community venue combined with engaging in exercise were unique to each individual. It was not possible to determine the extent to which participants had gained confidence through social interaction or exercise participation, but the value associated with improved self-efficacy was emphasised (Young et al. 2021b, Young et al. 2021a). Community based exercise has been associated with confidence building amongst PwS and healthy older adults through the opportunity to socially engage, achieve personal goals and recover personal autonomy (Dabkowski, Porter and Barbagallo 2021; Dam and Rhind 2020). The loss of previous lifestyle and fear of being a burden to caregivers has been associated with depression amongst PwS, although social support has been identified as a protective factor for post stroke depression (Liu et al. 2022). However, depressive symptoms have been associated with how PwS perceive the accessibility of exercise interventions (Pacheco et al. 2021). Knowledge of the psychological consequences of stroke and how these may influence self-efficacy and readiness to engage in exercise is essential for professionals involved in stroke rehabilitation and long-term support of PwS (Pacheco et al. 2021, Condon and Guidon 2018).

6.1.2 Physical response to power assisted exercise

The TUG scores recorded at baseline and upon completion of a four-week programme of PAE within our feasibility study indicated that mobility did improve during the intervention period (Young et al. 2018). However, given the small sample size in this study, lack of a control group and the potential for learning effect impacting TUG performance, firm conclusions regarding the physical impact of PAE on mobility and agility cannot be drawn from this programme of research. The design of the study could have been improved by including two pre-test measurements to mitigate for the learning effect and recruitment of a control group. Power assisted exercise equipment enables whole body movement including the trunk. Previous research indicates that core stability exercises do not improve TUG scores amongst PwS (Gamble, Chiu and Peiris 2021); whereas an intensive leg exercise programme for people with chronic stroke led to similar improvement in TUG scores as those reported in our feasibility study (Stock and Mork 2009). Quantitative evaluation of the efficacy of health and functional outcomes of PAE for PwS is a priority to develop knowledge on real time and accumulative mechanistic and clinical responses. Multiple tools have been implemented to measure the impact of exercise interventions amongst PwS, including measures of disability, mobility, physical fitness and physical function (Saunders et al. 2020). Previous research has indicated that seated exercise protocols may have less impact on mobility than gait interventions (Dorsch, Ada and Alloggia 2018); investigation into the impact of seated PAE on mobility outcomes is recommended. The accessibility of PAEE for people with very limited mobility directs future research towards inclusion of outcome measures indicative of secondary risk including cardiovascular fitness, fasting glucose, cholesterol and blood pressure (Lloyd et al. 2018).

Data on the perceived effect of PAE on physical ability were captured during interviews with a total of 15 participants (Young et al. 2021b, Young et al. 2018). Participants interviewed following the four- week intervention within our feasibility study reported increased strength, decreased stiffness, improved gait and symmetry associated with the PAEE (Young et al. 2018). Similarly, participants interviewed during the interpretative study reported improved strength, mobility, stamina and flexibility associated with using PAEE. In addition, some participants applied their knowledge of neuroplasticity and motor control to their experiences of PAE and thought that specific assisted movements had facilitated movement recovery. One participant reflected; *'You've got to re-bond, make new tramlines in your head that allow you to use your legs and arms.'* (Young et al. 2021b). Interestingly, only one participant specifically associated improvements in upper limb function with engagement in PAE, reflecting on recovered ability to perform dextrous tasks such as carrying cups (Young et al. 2021b). Guidelines on upper limb recovery for PwS recommend RTP as the principal rehabilitation approach, although dosage is not specified (National Clinical Guideline for Stroke 2023). Robot assisted training for the upper limb after stroke is not evidenced for people with moderate or severe upper limb impairment (Rodgers et al. 2019) and current guidelines emphasise the importance of functionally relevant upper limb movement (National Clinical Guidelines for Stroke 2023). The repeated upper limb movements stimulated by PAEE are not functionally orientated although there is the potential to stimulate a strengthening response if the technology is developed to prescribe tailored repetitions with targeted effort.

Data synthesised within our systematic review indicated that participants recruited to venue-based exercise interventions reported improved strength, mobility and stamina indicating that the perceived physical benefits of non-assisted exercise are comparable with PAE amongst PwS (Young et al. 2021a). Participants from a range of community exercise groups for PwS which included yoga, Tai-Chi and gym-based activities reported improved flexibility, limb movement, increased gait speed and balance (Dam and Rhind 2020). These findings indicate that PwS associate a diverse range of exercise interventions with enhanced physical ability and the qualitative data does not distinguish between extent of perceived effect. Future research should quantify and compare the physical responses to PAE with alternative types of exercise intervention, however, the external validity of controlled trials in stroke rehabilitation is limited due to the heterogenous nature of the stroke population (Paci, Prestera and Ferrarello 2020).

Perspectives on optimal exercise prescription were captured throughout the programme of research and are considered in terms of the widely used FITT principle. The twice weekly sessions scheduled during the feasibility study sustained very high attendance and participants reported that this frequency was manageable (Young et al. 2018). The interventions reported within the systematic review ranged from one to three sessions per week, with some programmes including an educational component (Young et al. 2021a). Participants recruited to the interpretive study engaged in PAE between one and five times per week with comparable perceived benefits reported across the sample (Young et al. 2021b). Although multiple benefits have been associated with group or venue-based exercise, barriers to frequent attendance include transport, cost, caregiver availability and fatigue (Pacheco et al. 2021). Future research should focus on determining the optimal frequency of engagement in PAE amongst PwS alongside the development of hybrid programmes which integrate digitally supported home based exercise with venue based PAE (Rai et al. 2021).

Current guidelines recommend that PwS engage in between three to five combined training sessions per week (Pogrebnoy and Dennett 2019). Although the research reported in this thesis provides an indication of feasible exercise dosage in terms of frequency, little is known about the physiological responses to PAE which represents a barrier to alignment of PAEE with aerobic or resistance training protocols. Newly published guidelines in the UK recommend that PwS should be offered cardio-respiratory or mixed training regardless of age, time since stroke and severity of impairment at a dosage of at least 30-40 minutes with a frequency of 3 to 5 times a week. The recommended intensity is greater than 70% peak heart rate for cardiorespiratory training or 40-60% of heart rate reserve combined with strength training at 50%-70% one-repetition maximum for a mixed training programme (National Clinical Guidelines for Stroke 2023). Future research focussed on PAEE should seek to determine the aerobic and muscular responses to PAE to enable specific dosage of intensity and type of exercise in alignment with published guidelines.

Qualitative findings reported in this programme of research indicated that participants sought the opportunity to exercise at a high intensity; the gym was regarded as a 'place of work' (Young et al. 2021a) and assistive equipment was viewed as an opportunity to match or exceed the motorised mechanism (Young et al. 2021b). Participants in the interpretative study articulated the appetite for effort detection software to quantify intensity of effort (Young et al. 2021b) and the value of a tailored, progressive exercise prescription was emphasised throughout the co-design programme of research (Young et al. 2022a, Young et al. 2021c). However, usability testing highlighted the challenges associated with conducting a baseline assessment to determine optimal exercise intensity and difficulties with quantifying and displaying exercise intensity (Young et al. 2022b). The assumption that PAE is passive, or a 'lazy exercise' option was also challenged by Meredith et al. (2022) who observed that members of the assisted exercise venue put in a lot of effort whilst using the seated PAEE. Challenges associated with monitoring exercise intensity within exercise interventions for PwS have been previously reported (Church et al. 2019, Amman et al. 2014). High intensity interval training is feasible amongst ambulant and non-ambulant PwS (Lloyd et al. 2018), although concerns about cardiovascular risk have been identified as a barrier to high intensity exercise prescription for PwS (Inness et al. 2020). Graded exercise testing is feasible amongst ambulant PwS (Mustafa and Aytur 2022) although further research to develop safe exercise testing protocols for people with moderate or severe impairment has been recommended (Johnson et al. 2020). Future advancement of PAEE could integrate heart rate sensors synchronised with effort detection technology to enable accurate prescription and monitoring of exercise intensity (Alzhrani et al. 2015).

Findings from the systematic review reported in this thesis indicated that the type of exercise instructed did influence perceived effect, for example, repeated practise of functional movement patterns was associated with improved ability in ADL, whereas conventional resistance training led to reported increases in muscular strength (Young et al. 2021a). Sport scientists who participated in the NGT events focussed on the aerobic and muscular demand of PAE (Young et al. 2021c). Combined aerobic and resistance training amongst PwS has been associated with enhanced improvements in aerobic fitness and muscular strength, compared with aerobic training alone (Marzolini et al. 2018). Future investigation and advancement of PAEE should focus on developing a prescription which incorporates an optimal combination of speed, repetitions and target intensity to achieve aerobic and muscular training benefits. In addition, better knowledge of the physiological demand of each machine determined through muscular and aerobic responses would enable alignment of the PAE prescription with published guidelines (Pogrebnoy and Dennett 2019).

PAEE does enable users to engage in a longer duration of exercise than may be achieved without motorised assistance. Participants in the feasibility study indicated that they would have liked to have exercised on each machine for a longer duration (Young et al. 2018) and users of PAEE reported that they did not want to feel 'rushed around the circuit' (Young et al. 2021c). Usability testing indicated that the option to select duration on each machine was important to users (Young et al. 2022b), however, this presents a challenge to the established circuit model adopted by most commercial operators of PAEE. Published guidelines recommend that PwS perform 20-60 minutes of aerobic exercise per session in addition to multiple repetitions of eight to ten resistance techniques (Pogrebnoy and Dennett 2020). A standard circuit of PAEE will usually take between 30 to 40 minutes to complete, however, the physiological demand of seated PAE in terms of type and intensity has not been investigated. Further research is required to examine the physiological responses to PAE in order to align it with published guidelines.

In summary, qualitative data indicated that participants associated PAE with improved strength, fitness, mobility and stamina. The TUG measurements recorded during the feasibility study indicated that mobility had improved during the four-week intervention, although further quantitative research is required to examine the efficacy of PAE amongst PwS. The aerobic and muscular demand stimulated during seated PAE has not been examined which creates a challenge for researchers and practitioners who seek to align a PAE prescription with published guidelines for PwS. The potential for advancement of the seated PAE towards a robotic intervention, aimed at improving motor control for people with neurological impairment was identified during the co-design phase of the research programme. However, this may narrow the commercial opportunity and reduce the number of venues who choose to invest in a circuit of PAEE.

The newly published National Clinical Guidelines for Stroke (2023) represents a directive to address several challenges identified within this thesis including limited intensity and duration of in-patient therapy, transition between rehabilitation settings and prescription of physical activity within a long term management and secondary prevention plan. Power assisted exercise equipment has the potential to support attainment of the recommendations including recovery of motor impairment (section 4.17), arm function (section 4.18), intensity of therapy (section 4.2) and long term physical activity (section 5.23). The psychosocial benefits of engagement in PAE amongst PwS have been identified within this thesis and an increase in the number of venues offering PAEE within the community could support attainment of the recommendations pertaining to self-management and social interaction (section 4.4). Due to the current paucity of evidence focussed on the physiological responses to, and efficacy of PAE amongst PwS, questions remain regarding how PAEE can support effective delivery of stroke services. If PAE does stimulate an aerobic physiological response, it has potential to be prescribed for cardiovascular conditioning, or to be implemented as a priming intervention to optimise readiness for therapy or high intensity exercise sessions. Equally, if the muscular effort generated is equal to a 50%-70% repetition maximum, there is an opportunity to embed PAEE within strength training interventions. Users of PAEE who generate only a low intensity physical effort may achieve increased range of movement and improved movement control due to the proprioceptive stimulation, alongside psychosocial benefits. Due to the heterogenous nature of the stroke population, intrinsic variables need to be accounted for in the methodological design of future studies which aim to investigate the efficacy of PAE on physical recovery following stroke. It is recommended that a case series design is adopted to determine optimal timing and patient selection for implementation of PAE within the stroke pathway.

6.1.3 Equipment specification

Rehabilitation therapists recruited to the PU stream and PwS in the EU stream within the co-design programme of research emphasised the importance of optimal limb alignment and functional movement patterns (Young et al 2021c). Parallels may be drawn between seated PAEE and robotic therapies for PwS, although robotic therapy has been associated with performance skills, function and independence rather than physical fitness (Mashizume, Zenba and Takahashi 2021). The difference between seated PAEE and robotic therapy is that the movements assisted by PAEE reflect mainstream gym equipment, for example, the Chest and Legs machine is based on the conventional Chest Press; whereas robotic therapy is aligned with functional movement patterns such as reach and grasp (Zhang et al. 2022). Robotic technologies can assist locomotion (Song et al. 2021) or upper limb movement (Mashizume, Zenba and Takahashi 2021). PAEE has evolved for a broad range of user groups, including healthy older adults (Jacobsson et al. 2012) and people who experience social exclusion (Meredith et al. 2022). Advancement of the equipment in line with robotic therapy may taper the market and reduce its commercial potential amongst leisure operators and general therapy centres. However, refinement of the equipment using motion analysis technology combined with mechanistic research to measure the impact of assisted movement on cortical activation would address some of the outstanding questions surrounding PAE, neuroplasticity and functional movement recovery. The seated PAEE manufactured by Shapemaster is not currently registered as a medical device; in the UK the Medicines and Healthcare products Regulatory Agency approve and govern medical devices (GOV.UK 2022). Medical device registration may facilitate implementation and uptake by healthcare and rehabilitation providers, although the potential commercial gains would need to be analysed alongside the initial investment required to gain approval.

User perspectives on the accessibility and structural design of the PAEE were expressed during the feasibility and co-design phases of this programme of research. Participants recruited to the feasibility study suggested fold away footrests, adjustable handles and range of movement settings (Young et al. 2018). Participants across the PU and EU streams who attended the NGT events emphasised the importance of access and recommended that the seating should be height adjustable plus limb supports to optimise alignment (Young et al. 2021c). Although NGT was an effective method to identify user priorities at the outset of the co-design programme, the remit of the Grow MedTech funding did not include revision of the PAEE frame. Examination of co-design approaches within health has identified challenges associated with shared understanding regarding the purpose and aims of the process (Lindblom et al. 2021). The advantages associated with NGT and consensus methods include anonymised voting and structured discussion (Musselman et al. 2021, Condon et al. 2019). However, clarity of the predetermined questions delivered by the event facilitator is important to ensure content of the discussion is relevant to the scope of the project (Harvey and Holmes 2012). The emergent content surrounding access to the PAEE has been identified as a priority for future product development.

The artefacts generated during the storyboarding session reflected the importance of centralised icons and clear font amongst the user groups (Young et al. 2022a). Icons to enable accelerated navigation through the GUI in order to bypass unwanted submenus were recommended by EU and PU representatives (Young et al 2022a). Divergence in perspectives upon colour schemes emerged, although the combination of dark font on a paler background was widely advocated (Young et al. 2022a). The diverse range of participants recruited to the storyboarding study enabled creation of a rich data set, although challenges were encountered in the organisation and interpretation of their design priorities. The design criterion matrix was adopted as a novel approach towards the crystallisation of the co-design data which facilitated categorisation of the data to create a design criterion for prototype development. The storyboarding method implemented was akin to the approach adopted by Jie et al. (2019) insofar as the artefacts developed depicted the user flow through the technology and created a low fidelity prototype. Alternative examples of storyboarding in co-design have encompassed the wider user journey including surrounding environment and activities (Lupton and Leahy 2019, Jamin et al. 2018). Distinction between the user experience and user interface presents a complex challenge in the development and evaluation of health technologies (O'Neill et al. 2022). Influencing factors include the user's behavioural, normative and efficacy beliefs intertwined with perceived usefulness and accessibility of the technology (Kim and Park 2012). More specific attention towards the user experience has been identified as a key area for further exploration in the development of the new PAEE technology.

Use of a variety of usability evaluation methods including task completion data, task duration, 'think aloud' and the measurement of user satisfaction via PSSUQ ensured a comprehensive evaluation of the usability of the GUI. 'Think aloud' combined with task observation enabled the identification of specific usability issues. Task completion and task duration were used to compare the two version of the GUI and the PSSUQ data provided an overall indication of user satisfaction. Usability testing highlighted that robust safety features were a priority amongst user groups. The importance of being able to stop the assisted movement with immediate effect was emphasised and concerns regarding visibility of the 'help' icon with reassurance that support was available if required were recurrent points raised by EU and PU participants (Young et al. 2022b). The purple colour scheme of the GUI was aligned with commercial branding, although participants suggested that the 'help' and 'stop' icons should have been red to optimise visibility (Young et al. 2022b). Comparable technologies for people with neurological impairment have used red icons within muted colour schemes to ensure that users can easily navigate to the 'quit' function (Jie et el. 2019, Palacios-Navarro, Garcia-Magarino and Ramos-Lorente 2015). Evaluation of safety features and reporting of adverse events should be a primary outcome during the field testing of a new technology for PwS (Smith et al. 2019) and was a priority in the user testing conducted beyond the programme of research reported in this thesis.

The value of biofeedback from a user's perspective was identified through qualitative exploration of the lived experience of PAE (Young et al. 2021b). Biofeedback has been described as a process that enables an individual to learn how to change physiological activity for the purpose of improving health and performance (Schwartz 2010). Comparable assisted exercise devices which are sensitive to user effort enable a specific intensity of exercise tailored to the users' prescription (Linder et al. 2017). Further exploration of biofeedback in the context of PAEE indicated that sensitivity to small changes in performance and clear visual features were important to user groups (Young et al. 2022a). Biofeedback on the effort detection created a design challenge with a major modification implemented on version two following testing of version one (Young et al. 2022b). The expanding balloon introduced on version two was correctly interpreted by nearly all participants, however, the team acknowledge that this visualisation of effort remained abstracted from the PAEE. Comparable technologies for PwS have used images which directly reflect the activity, for example, the personified foot named 'Stappy' to facilitate walking (Jie et al. 2019) and the avatars integrated with ReWiiRe technology for upper limb movement (Tsekleves et al. 2016). Contextualised visual biofeedback has been integrated with alternative assisted exercise devices (Karthiga 2020) and additional haptic biofeedback on physical performance has been recommended for people with altered sensory processing (Afzal et al. 2016). Sensors to detect heart rate would further tailor the intensity of the exercise prescription to the individual user (Alzahrani et al. 2015). Future advancement of biofeedback synchronised with PAEE should aim to contextualise the activity and explore multi-modal systems which integrate visual, haptic and auditory information.

Connected with discussion surrounding biofeedback, the concept of gamification emerged during the NGT and co-design sessions with emphasis upon the importance of fun and motivating features (Young et al. 2022a, Young et al. 2021c). However, the risk of the GUI being perceived as childish or patronising was cautioned by several EU representatives (Young et al. 2022a, Young et al. 2022c). This was affirmed through differing opinions on the image of a trophy at the finish line on the prototype version one (Young et al. 2022b). The concept of a mountain or island landscape also evoked diverse responses during the usability evaluation as some participants commented that these themes were inconsistent or out of context (Young et al. 2022b). Gamification should enhance the users' overall value creation; this presents a challenge to programme developers due to the subjective and deeply individual nature associated with what might be construed as a purposeful game across a diverse user group (Huotari and Hamari 2016). Serious games for use in rehabilitation should be meaningful, customizable and show improvement through quantifiable feedback (Arrigoni et al. 2021). Gamification may be introduced as an augmented or virtual reality technology synchronised with biofeedback which can enhance motivation, user experience and attentional focus amongst clinical populations (Luddecke and Felnhofer 2021). Virtual reality rehabilitation can improve outcomes for PwS (Khan, Podlasek and Somaa 2021, Lohse et al. 2014). In the context of PAEE, advancement towards virtual reality may enhance sustained engagement and user performance; however, the risks associated with this include added cost and disrupted social interaction between users.

The potential for remote prescription or artificial intelligence was explored throughout the co-design phase, with participants suggesting digital features to enable inter-session comparison to monitor progress, a biometric identification system and remote monitoring by health service providers (Young et al. 2022a, Young et al. 2021c). Storyboard participants suggested that the functionality of the GUI extended to include user input on self-reported wellbeing (Young et al. 2022a), although the usability testing emphasised the importance of operational efficiency (Young et al. 2022b). Telehealth rehabilitation interventions for PwS synchronised with wearable sensors and feedback mediated through a user interface have enabled therapists to modulate activity prescription and increase intensity of home-based therapy (Burridge et al. 2017, Tsekleves et al. 2016). AI technologies are emergent within gaming technologies for stroke rehabilitation with examples of adaptive algorithms based on previous user performance combined with amplification of the technology according to baseline ability (Burdea et al. 2021). Remote monitoring of user performance during PAE could be realised through introduction of a personalised identification system, which, in turn would enable individualised progression and algorithm development.

6.2 Strengths and limitations

The findings reported in this programme of research addressed the overarching purpose and aims. The feasibility of PAEE for people with complex neurological impairment was established at the outset of the programme. Phase two synthesised the reported experience of venue-based exercise amongst PwS to capture the broader context of the users' perspective prior to refining the focus towards the lived experience of engaging in PAE at a third sector community centre. Phase three adopted the MDTF to co-design and evaluate a new GUI which has since been installed on a prototyped machine.

This programme of research was iterative and yet remained centred on the underpinning subject of PAEE as an efficacious exercise mode for PwS. A mixed methods approach was adopted to evaluate the feasibility of the concept, understand the users' experience and advance the technology to enhance its suitability for PwS. The potential value of effort detection technology synchronised with performance feedback was identified through in-depth qualitative exploration of the users' experience. This data substantiated the successful application for Grow MedTech funding which enabled expansion of the interdisciplinary team and recruitment of a higher number of participants. The team successfully navigated the challenges created by the government imposed COVID-19 lockdowns to achieve the key aims which underpinned the funding award and advance the PAEE technology.

The methodological approaches reported in this thesis traversed positivist, constructivist and transformative paradigms, demonstrating agility within the research team. Data analysis techniques were diverse and included inferential statistical analysis, idiographic interpretative exploration of the user experience, consensus analysis and translation of artefacts for prototype development. A non-hierarchical ethos underpinned the Grow MedTech funded programme with a diverse range of expert and professional users given an equal voice during the design and evaluation of the new technology. Data collection techniques included group events in addition to one-to-one dialogue to capture the benefits associated with group discussion alongside the individual users' voice. The interdisciplinary team comprised stroke rehabilitation therapists, an exercise scientist and a design engineer whose combined expertise ensured a rigorous and comprehensive approach to all aspects of the research process. Throughout the programme of research, a positive relationship with the manufacturer of PAEE was nurtured and sustained.

PAEE has been explored in the context of contemporary pathways for PwS and this thesis has identified challenges faced by providers of acute and long-term stroke services. The complex inter-relationship between NHS rehabilitation, third sector provision and implementation of rehabilitation technologies has been analysed and assumptions surrounding stroke recovery have been challenged. The programme of work reported in this thesis represents a novel contribution to our understanding of venue-based exercise in the UK alongside a proposed solution in the form of PAEE to address the challenges articulated by academics, service providers and expert users. Prior to this programme of research there was no published investigation into the use of seated PAEE for neurological populations. The studies reported in this thesis have established its feasibility, explored the users' lived experience and advanced the technology to enable a quantified prescription of PAE which may be implemented in future research and practice. The methodological approach implemented to co-design and evaluate the new PAEE health technology represents an example which may be adopted by future research and development teams.

Several limitations associated with this programme of research are acknowledged. Although stroke is prevalent globally, the remit of data collection was restricted to the UK. The systematic review could have been broadened to include international studies, although this would have diluted the UK context of the findings which reflected the national offering. Likewise, the remote usability testing could have been extended to an international sample, and this should be considered for the future. A gap remains in the literature surrounding the experience of non-completers of exercise interventions amongst PwS. This represents an ethical challenge in terms of participant identification and recruitment, but an insight into their perspective could highlight unknown barriers and limitations associated with exercise interventions and PAEE. The participants recruited throughout the programme of research had invested in further rehabilitation beyond NHS provision and were not necessarily representative of the overall stroke population in terms of educational attainment and socio-economic status. Engagement with community support groups sited within areas of deprivation may have enabled access to a more diverse range of participants.

The potential for PAEE to be implemented within NHS services has been identified, however, this programme of research did not directly engage with NHS service providers or patients. Multiple complexities would be associated with the implementation of PAEE within NHS premises and consultation with service providers is an essential future step. Even the signposting of NHS patients towards third sector PAEE facilities could create concerns surrounding governance and commercial bias which need to be addressed. The likelihood of unconscious bias within the research team and particularly the PhD candidate is acknowledged. The candidate holds long held beliefs in the value of exercise for physical and psychosocial health and is committed to finding solutions to enable exercise for clinical populations. Although the candidate practised reflexivity throughout the programme of research, the possibility of a positive skew in favour of PAEE during data collection and analysis is recognised.

6.3 Future development and evaluation of PAEE

The programme of research reported in this thesis has identified several priorities for the ongoing development and evaluation of PAEE. Recommendations are considered within the following sections; 6.3.1 PAEE advancement, 6.3.2 future evaluation and implementation of PAEE.

6.3.1 PAEE advancement

The need to enhance the accessibility of the seated machines was emphasised with challenges associated with seat height and projecting components identified (Young et al 2021b, Young et al. 2018). The changes recommended would entail revision of the structural framework of each seated machine alongside piloting of new components such as magnetic quick release pins to enable removal of protruding parts. Features such as adjustable seat height and quick release components would reduce the workload for support staff and caregivers and enable users to mount and dismount the equipment safely and efficiently. A revision of the structural framework may create the opportunity to analyse the movement patterns assisted by seated PAEE and adjust the direction and range of movement to optimise functional relevance. Manufacturers of accessible, non-assistive exercise equipment have developed intelligent adjustment mechanisms to ensure that the seat height and range of moving components are automatically tailored to each individual user (Koller 2019). This level of technology would require development of digitised user identification technology synchronised with the seated PAEE, a step which would also facilitate progress towards the introduction of artificial intelligence.

The GUI developed through co-design and usability testing has visualised a new era for seated PAEE. The integration of universal icons to enable selection of different exercise options combined with effort detection feedback reflected the priorities identified by user groups (Young et al. 2021c, Young et al. 2021b). The potential value of effort detection from each limb was highlighted; this would have required insertion of internal sensors within the PAEE which was beyond the remit of the Grow MedTech funding and has been identified as a priority for future advancement. The biofeedback could have been better contextualised and the potential to continue iteration of the technology along the spectrum of gamification, augmented and virtual reality is recognised. A paradox exists between the social connectivity which may be enabled through technology such as virtual reality and the social connectivity which is already central to the reported user experience of seated PAEE (Meredith et al. 2022, Young et al. 2021b). Advancement of gamification synchronised with seated PAEE would need to be rigorously evaluated to ensure motivational or immersive features do not disrupt the psychosocial benefits associated with group exercise. In context with gamification, further consideration of how user performance is quantified is required. A challenge associated with seated PAEE is the variety of movements assisted during completion of a circuit and this diversity of activities does not naturally translate into metrics such as number of footsteps or distance covered. The concept of a 'Shapemaster Island' may incorporate a combination of bootcamp and adventure activities which reflect each machine and enables performance to be quantified within context of the assisted movement.

6.3.2 Future evaluation and implementation of PAEE

Further research to examine the physiological demand of PAE is required to identify the aerobic and resistance training capability of each machine. This would enable development of a prescription, aligned with published guidelines, to optimise the effectiveness of the user programme (Church et al. 2022). Evaluation of the feasibility and efficacy of PAE amongst people with acute or subacute stroke is an essential step towards implementation of the technology within healthcare services. Seated or recumbent PAEE could represent a solution for the widely reported challenge of sedentary time during inpatient rehabilitation. As noted previously, the PAEE manufactured by Shapemaster is not registered as a medical device and this may be a barrier to procurement by NHS providers. Clinical and mechanistic investigation is required to examine responses to PAE amongst people with acute stroke, determine an optimal FITT prescription and ensure appropriate patient selection. Even when supported by research evidence, barriers to the implementation and scale up of new innovations within inpatient stroke rehabilitation include patient factors, environment and staff capability (Stewart et al. 2020). Limited economic evaluation of rehabilitation technologies has been identified as a shortfall in the published literature which has impeded their adoption (Musselman, Shah and Zariffa 2018). A cost-effectiveness analysis of inpatient PAE would need to rationalise the costs of training, staffing, space and equipment procurement against recorded gains in health-related quality of life and rehabilitation outcome (Hornby et al. 2022).

The findings from the programme of research have established that engagement in PAE is associated with improved physical performance and psychosocial wellbeing amongst PwS (Young et al. 2021b, Young et al. 2018). The concept of recovery plateau was challenged by users of seated PAEE (Young et al. 2021b) and this adds to the body of evidence which indicates that the potential to achieve physical improvement following stroke is indefinite. Measurement of the physical impact of PAE for people in the subacute or long-term stages of living with stroke is required to add to the qualitative findings reported in this programme of research. Protocols should reflect the existing body of research which has examined exercise interventions for PwS (Saunders et al. 2020) and include measurements of mobility, function, impairment and fitness alongside secondary metabolic and cardiovascular risk factors. In addition, it is recommended that the therapeutic model of assisted cycling prior to RTP to enhance neurophysiological response examined by Linder et al. (2017) is applied to seated PAE. Provision of exercise programmes for non-ambulant PwS has been highlighted as a shortfall due to the complexities associated with availability of specialist equipment such as exoskeletons or body weight support treadmills (Lloyd et al. 2018). Seated PAEE can be operated within non-specialist leisure and community venues and may represent a solution for the challenges encountered by non-ambulant PwS who seek to engage in venue-based exercise. Inclusion of non-ambulant PwS in future PAE research would address a shortfall in the current evidence base (Saunders et al. 2020) and enable evaluation of design features intended to improve the accessibility of the PAEE.

6.4 Reflection

Attrition from doctoral study is high and a positive approach towards reflective practice is required to sustain direction and engagement (Service 2012). Self-awareness is central to effective reflective practice and at the outset of my doctoral study, I completed the Myers-Briggs Type Indicator Inventory to develop a deeper understanding of my inherent patterns of perception and judgement (Quenk 2009). The subsequent report indicated that my type indicators comprised extraversion, sensing, thinking and judging (ESTJ). This combination of traits would have naturally aligned with a linear and efficient programme of research which was clearly defined, structured and concrete. In contrast, the iterative, collaborative and diverse methods reported in this thesis have enabled me to adapt my inherent ESTJ type and recognise the importance of context, multiple perspectives and ability to juxtapose with factors beyond my control. Reflective tools adopted throughout the doctoral programme have included an audio-video journal to articulate the ongoing state of play alongside a series of Gantt charts to manage immediate and longer-term tasks.

In-keeping with my ESTJ type, at the outset of doctoral study, I envisioned a programme of research focussed on establishing the efficacy of PAE for PwS. I was a novice researcher with limited experience of data collection and no publication history. I held a positivist perspective towards the evaluation of rehabilitation interventions, focussed upon the importance of mechanistic or objective clinical responses. This is evident in the approach adopted during the feasibility study in which I sought conclusive answers to questions surrounding accessibility and safety of the equipment. The dataset suggested that the PAEE was safe and accessible, but not entirely fit for the purpose we intended to investigate. The attempt to implement a mixed methods approach within the feasibility study served as an example of tokenistic qualitative concepts wedged within a positivist paradigm (McKenna, Copnell and Smith 2020). The need for an in-depth, qualitative investigation of venue based PAEE amongst PwS followed by advancement of the equipment was recognised and marked a significant milestone in this programme of doctoral study and my development as a researcher.

Throughout my programme of study, I sustained a professional role as a clinical physiotherapist. Tensions between practitioner and researcher roles have been previously reported by doctoral students (Richardson, Erol and Bueno 2022), with conflict between the needs of the patient and research protocols identified. I experienced a comparable challenge whilst conducting interviews at the specialist stroke venue (Young et al. 2021b). As a physiotherapist my instinct was to adopt an active, solution seeking approach towards the challenges articulated by the research participants. However, my role as a researcher required me to facilitate the conversation and avoid any action or comment which may have been construed as interventional. The process of completing the interviews enabled me to learn to comprehend and analyse information without offering an immediate response which was polarised relative to my inherent ESTJ type. Since conducting the interviews, I have discovered a framework for sensitive interviewing in qualitative research; essential elements include thorough preparation, relationship building and adoption of therapeutic interviewing techniques (Dempsey et al. 2016). This framework will be implemented in my future practice as a researcher and will enable me to coalesce my identity as a therapist alongside my academic role.

Meaningful engagement with expert and professional users was central to the co-design phase of the doctoral programme. My role in the collection and analysis of the co-design data was to enable participants to express their ideas and preferences which influenced the development of the new technology. Adoption of a transformative paradigm was required to transition from the conventional view of research participants as ‘subjects’ to create a team of co-researchers which comprised expert users, clinicians, academics and industrial stakeholders (Mertens et al.

2007). Patience during lengthy discussions and ensuring that all team members have a chance to contribute can be difficult for people with an ESTJ type (Quenk 2009). I had created a schedule for the co-design events but underestimated the time required for each stage of the process. Levelling the power balance in participatory research and ensuring enough time for all participants to express their perspective is essential to achieve emancipation (Tang Yan et al. 2022). Development of a realistic and flexible schedule to guide co-design events was identified as a key learning point from this phase of the programme.

Researchers have an obligation to disseminate their findings and this programme of doctoral study enabled me to build a publication track record through the submission and acceptance of six peer reviewed articles and a poster presentation at conference. Publication based theses are gaining momentum with associated benefits at individual and institutional level, although potential challenges associated with timely completion have been acknowledged (Jowsey, Corter and Thompson 2020). The importance of publication focussed training and mentorship to optimise productivity and efficiency during completion of article based doctoral programmes has been highlighted (Pearce et al. 2021). In my experience, publication throughout the programme of doctoral study assimilated learning and fostered a positive supervision model. Feedback from peer reviewers was constructive and enhanced my knowledge of the methods and approaches implemented.

Genuine interest in the selected project and a willingness to commit abundant time, energy and intellect are required to enjoy completion of a PhD (Thillainadesan and Wu 2021). My PhD journey has been challenging, exciting and fundamental in changing my perspective upon rehabilitation research. The skills developed through this programme of research have inspired me to drive forwards change to improve the exercise provision for PwS. It has enabled me to recognise the importance of inter connectedness between multiple sectors and the role which technology will have in creating seamless rehabilitation pathways for people with complex needs. The determination inspired through my role as a care assistant in the early 1990's has been reignited as I embrace the opportunities and challenges ahead in implementing research to create meaningful change.

6.5 Conclusion

Exercise interventions for PwS reduce the risk of stroke recurrence, improve physical performance and are associated with enhanced psychosocial wellbeing. Shortfalls in effective exercise prescription exist along the stroke pathway due to limited inpatient therapy, prioritisation of functional independence within community rehabilitation services and inadequate provision of longer-term exercise programmes tailored to the needs of PwS. Inaccessible exercise equipment is a frequently cited barrier to engagement in venue based exercise amongst PwS and inconsistent monitoring of exercise intensity has been identified as a limitation in prescribed exercise protocols. PAEE was identified as a potential solution to the challenges associated with engagement in exercise amongst PwS. The research reported in this thesis implemented multiple methodological approaches to evaluate the feasibility of the concept, explore the user experience and advance the PAEE technology.

PAEE is accessible and acceptable for use by people with complex neurological impairment and psychosocial benefits associated with group exercise were reported. Venue based exercise programmes tailored for PwS were associated with improved physical wellbeing and enhanced self-efficacy. Regular users of PAEE reported multiple benefits related to using the equipment, however, the absence of technology to provide feedback on physical effort was identified as a limitation. The MDTF was effectively adopted to structure a programme of co-design activities and remote usability testing to create a user-friendly GUI which displayed biofeedback on user performance. This advancement of PAEE has gone some way towards realising its potential for the effective prescription and monitoring of PAE performance amongst PwS including those with very limited mobility. Future clinical research should include an examination of its feasibility within the inpatient setting and evaluation of impact upon physiological risk factors and functional ability amongst community dwelling people with stroke.

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Appendices

The appendices section is intended to evidence the audit trail which underpinned ethical permissions, data collection and analysis throughout completion of the PhD.

The appendices are presented in sequence with the published articles included in the thesis. Examples of ethics applications, participant facing information, data analysis, reporting to funders and a rebuttal following peer review are included.

Appendix One

Feasibility study reported in Article One:

1.1: Participant invitation letter

Opportunity for volunteers with a neurological condition to support research project

We are inviting adults who live with a neurological condition to volunteer to take part in a research project aimed at improving exercise equipment for people with limited mobility.

Participants will be required to attend eight exercise sessions on the power assisted exercise equipment at the Robert Winston Building on Collegiate Crescent Campus.

The attached information sheet provides more detail about the study. Please feel welcome to contact me directly via email (r.young@shu.ac.uk) if you have further questions or would like to register your interest.

Yours sincerely

Mrs Rachel Young (MSc, BSc (hons), MCSP)

Physiotherapy Lecturer/Doctoral Student

1.2: Participant Information Sheet

Title of project: Feasibility study to investigate the use of power assisted exercise for people with neurological impairment.

You are invited to take part in a study which aims to investigate the use of Shapemaster exercise machines for people with long term neurological conditions. Access to suitable fitness equipment is a real challenge for people with neurological changes.

The Shapemaster machines assist movement and enable people with limited movement to engage in exercise. This study will enable the team to build our understanding of the equipment and its potential use in rehabilitation and exercise programmes for people with neurological conditions.

What is the purpose of this study?

The purpose of the study is to explore how safe and accessible Shapemaster equipment is in providing an exercise experience for people with a neurological condition.

Who can take part?

To be eligible to take part you need to be living with a neurological condition which has affected your ability to move and walk. This may have been caused by stroke, multiple sclerosis, traumatic brain injury or any other condition which has resulted in changes to your nervous system.

You need to be able to take a few steps to transfer between seated surfaces. You need to be able to follow instructions and verbally communicate in spoken English.

If you have a serious heart condition or have been advised to avoid exercise by a medical or health professional then you will not be able to take part in this study.

Can I use a walking aid?

Yes, we will ask all participants to bring their preferred walking aid with them if they use one.

What will I be required to do?

If you are interested in taking part then you will have an initial telephone call with Rachel Young to ensure that you are eligible to take part in the study. Rachel Young is the Principal Investigator and a neurological physiotherapist and doctoral student.

If you wish to continue then you will be invited to attend an initial session at the Robert Winston Building on Collegiate Crescent Campus. We will arrange transport in a taxi or provide detailed directions as required.

During the initial session you will meet Rachel and two physiotherapists who are studying for their MSc qualification. You will have the opportunity to ask questions and if you are happy to take part in the study you will sign a consent form. We will take your blood pressure and complete a short health questionnaire to ensure your safety for the study.

If you are able to walk five metres or more you will complete the 'timed up and go' test which requires you to stand from a chair, walk around a cone and return to the chair. If you are not able to walk this distance we will omit this test.

We will then schedule eight sessions over a four week period to take part in the Shapemaster assisted exercise programme. Each session will involve exercising for 5 five minutes on six different machines. Four of the machines are seated and two are recumbent (see images):

Seated machines:

Recumbent machines:

The physiotherapists will assist you to get on and off the machines as required.

Each session will last for approximately 45 minutes which will account for 30 minutes on the machines and additional time to get on and off the equipment.

You will be exercising with a small group of participants.

On completion of the eighth session we will repeat the ‘timed up and go’ test if you completed this at the start of the study.Approximately one week following the study we will schedule an interview with you to discuss your experience of using the equipment. This can be conducted in your home or at the Robert Winston Building.

Can my carer or partner be present?

Yes, if you would like a carer, friend or partner to accompany you during the sessions then please let the research team know when we schedule your first visit.

I have a communication impairment so how will I manage?

Many people with a neurological condition experience changes in their ability to communicate. If you have communication changes the lead researcher will identify your needs with you when you consent to take part in the study. Your individual requirements will be met through, for example, using single stage instructions, ensuring enough time to process information and adapting the interview.

What if I don't want to participate?

Your involvement in the study is totally voluntary. You are under no pressure to participate and if you decide not to be involved you will not be required to give any reason.

Are there any risks associated with my participation?

The equipment is used by people with neurological conditions and limited mobility in several centres within the UK and there are no reports of any adverse events. However, any exercise programme does carry a small risk of injury or unexpected response. The initial meeting will check your suitability to use the equipment.

There will be a minimum of two experienced neurological physiotherapists in the room at all times throughout the study. Your needs will be continuously monitored and you will be assisted as required to access the equipment safely. You will be encouraged to tell us if you experience any discomfort whilst using the equipment and the machines can be stopped with immediate effect.

What if I cannot attend every session?

It is common in exercise studies for participants to miss some sessions due to personal reasons, for example, to attend appointments or go on holiday. We will record your attendance but there will be no concern raised regarding missed sessions.

Can I withdraw from the study?

You have the right to withdraw at any point during the study. You will not be asked to provide any reason for withdrawal and it will not impact any future care or opportunities. You may request that your data is deleted and excluded from analysis for up to seven days following the final interview.

Who will be responsible for all of this information when the study is over?

The data and information will be the property of Sheffield Hallam University and the lead researcher, Rachel Young, will be responsible for its secure management.

How will you use what you find out?

The findings will help us to determine whether the assisted exercise equipment is suitable for people who are living with a neurological condition. If the findings are positive we will continue with further research to build our understanding of the equipment and how it might be best used for the neurological population.

Will anyone be able to connect me with what is recorded and reported?

You will be assigned an anonymous code on all of the recorded data. The consent forms which include your name will be stored in a secure cabinet at Sheffield Hallam University.

Will I receive payment?

We cannot offer payment for your participation. However, we will provide taxi transport or reimburse your travel costs depending upon your preference. Drinks and snacks will be available at the exercise sessions.

How can I find out about the results of the study?

The findings will be published in an academic journal and we will share this with all participants. We will also provide a plain English summary.

Principal Investigator

Mrs Rachel E Young, Neurological Physiotherapist, Doctoral student

Sheffield Hallam University

Email: r.young@shu.ac.uk

What if I have a complaint?

If you want to make a complaint about how people have approached you or treated you during the project, please contact Rachel's supervisor: Dr Jackie Hammerton at Sheffield Hallam University on [redacted].

If you **remain** unhappy and wish to complain formally, you can do this through the Data Protection Officer Keith Fildes and the head of SHU ethics Ann Macaskill

You should contact the Data Protection Officer if:	**You should contact the Head of Research Ethics (Professor Ann Macaskill) if:**
• you have a query about how your data is used by the University • you would like to report a data security breach (e.g. if you think your personal data has been lost or disclosed inappropriately) · you would like to complain about how the University has used your personal data DPO@shu.ac.uk	· you have concerns with how the research was undertaken or how you were treated a.macaskill@shu.ac.uk
Postal address: Sheffield Hallam University, Howard Street, Sheffield S1 1WBT Telephone: 0114 225 5555	

Appendix Two

Systematic review reported in Article Two:

2.1: Search strategy

Search strategy:

Databases:

CINAHL

MEDLINE

WEB OF SCIENCE

SPORTDISCUS

AMED

PROQUEST

ETHOS

DART E-THESIS

KEYWORD SEARCH (ABSTRACT)

Stroke

Cerebrovascular accident

CVA

Stroke survivors

MeSH TERM SEARCH

(ABSTRACT)

Condition	**Intervention**	**Methodology**
Stroke Cerebrovascular accident	Exercise Fitness programme Fitness scheme Physical activity Exercise class Exercise group	Qualitative Perspective Opinion Experience Satisfaction Acceptability Feasibility Interview Focus group

2.2: Example of quality appraisal

TITLE: A qualitative study exploring patients experiences of standard care or cardiac rehabilitation post minor stroke and TIA

AUTHOR: Hillsdon, Kerston and Kirk (2013)

Domain 1: Research team & reflexivity	**Guide questions/description**	**Comment**	
Personal characteristics			
1. Interviewer	Which author/s conducted the interview or focus group?	KH & HK	y
2. Credentials	What were the researcher's credentials? (Eg. PhD, MD)	MSc PhD	No
3. Occupation	What was their experience at the time of the study?	Not reported	n
4. Gender	Was the researcher male or female?	M&F	y
5. Experience & training	What experience or training did the researcher have?	Not reported	n
Relationship with participants			
6. Relationship established	Was a relationship established prior to study commencement?	Not reported	n
7. Participant knowledge of interviewer	What did the participants know about the researcher?	Not reported	n
8. Interviewer characteristics	What characteristics were reported about the interviewer?	Not reported	n

	(Bias, assumptions, reasons and interest in the research topic)		
Domain 2: Study design			
9. Methodological orientation and theory	What methodological orientation was stated to underpin the study? (Grounded theory, discourse analysis, ethnography, phenomenology)	General qualitative approach described, methodological orientation not identified	n
Participant selection			
10. Sampling	How were participants selected? (Purposive, convenience, consecutive, snowball)	Recruited from the RCT via TIA OP clinic and Hampshire stroke services	y
11. Methods of approach	How were participants approached? (Face to face, telephone, mail, email)	Invited to participate by independent assessors of the RCT but method of approach not clearly reported	(y) N
12. Sample size	How many participants were in the study?	22	y
13. Non-participation	How many people refused to participate or dropped out? Reasons?	2, no reasons	Y n
Setting			
14. Setting of data collection	Where was the data collected?	Participant's homes, or research offices at hospital	y
15. Presence of non-participants	Was anyone else present apart from participants and researchers?	Family members/carers at participant's discretion	Y (n)

16. Description of sample	What are the important characteristics of the sample? (Demographic data, date)	12 had received standard care 10 had been offered CR, 7 had attended regularly 5F/17M Age range=47-84	y
Data collection			
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Interview guide published	Y N
18. Repeat interviews	Were repeat interview carried out? If yes, how many?	Not reported	n
19. Audio-visual recording	Did the research use audio-visual recording to collect the data?	Audiotaped	y
20. Field notes	Were field notes made during and/or after the interview or focus group?	Not reported	n
21. Duration	What was the duration of the interview or focus group?	Average 45 minutes	y
22. Data saturation	Was data saturation discussed?	Yes	y
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction	No- reasons justified	No
Domain 3: Analysis and Findings			
Data analysis			
24. Number of data coders	How many data coders coded the data?	x3	y

25. Description of the coding tree	Did authors provide a description of the coding tree?	Yes	Yes
26. Derivation of themes	Were themes identified in advance or derived from the data?	Derived from data	y
27. Software	What software, if applicable, was used to manage the data?	Not reported	n
28. Participant checking	Did participants provide feedback on the findings?	Not done but authors reported on this and justify it	y
Reporting			
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? (eg participant number)	Yes	y
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes	y
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes	y
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes	y

Appendix Three

Interpretative qualitative study reported in Article Three

3.1: Ethics application

Summary of Methods

The study methodology will implement Interpretative Phenomenological Analysis (IPA) as this approach is aligned to capture the exploration of personal perceptions and experiences. IPA facilitates an individualised approach to data collection and analysis for the generation of complex and rich information relevant to the overarching research aims. IPA seeks to understand the unique experience of each participant; context, setting and researcher reflexivity are central to this relativist methodology. The application of IPA to the proposed exploratory study will facilitate insight into the experiences of people with stroke who partake in power assisted exercise at a local third sector stroke centre. The findings will generate new knowledge and inform the design of a subsequent mixed methods pre-test - post-test evaluation of power assisted exercise following stroke.

Sampling and Recruitment

The proposed study will recruit participants through a purposive sampling method of people who attend the Derbyshire Stroke Centre (DSC). Purposive sampling is a non-random technique designed to specifically recruit individuals who are able to share experiences and perspectives relevant to the research question. Posters will be on display at the centre and participant information sheets will be available at the reception desk. Potential participants will be able to contact the Principal Investigator directly via email or inform the team at DSC of their interest.

Inclusion criteria

- Stroke diagnosis
- Experience of using power assisted exercise equipment within the previous 12 months
- Able to provide informed consent
- Able to verbally communicate in spoken English at a level which will be comprehensible on an audio recording
- Does not have a learning disability or mental impairment

Exclusion criteria

- Unable to respond to verbal questions for the purposes of an interview

Participant selection

The study aims to capture the perspectives of a range of people with stroke who have experienced power assisted exercise following stroke; heterogeneous purposive sampling will be applied to recruit a range of participants all with different levels of experience and functional ability. Recruitment of a purposive sample will aim to represent a range of ages and both sexes reflecting varied experiences of living with stroke. The participant selection process will aim to recruit a combination of frequent and occasional users of power assisted exercise. This will enable exploration of different perspectives on the value of this type of activity. The semi-structured interview method for data collection does require an ability to participate in spoken English. However, people with severe aphasia or very limited spoken English will not be able to participate. People with severe cognitive impairment impacting capacity to provide informed consent will not be included.

Volunteers expressing interest in the study through either email contact with the Principal Investigator or communication with the DSC team will have the opportunity to meet with the Principal Investigator in the Derbyshire Stroke Centre. Potential participants will have the opportunity to ask questions about the study and management of data. The topic guide will be available so that potential participants can gain insight into the nature of the questions and discussion. It will be explained that the interview will be recorded on two encrypted dictaphone devices; data will be transcribed for analysis. They will be assured of anonymity and confidentiality of stored data through a participant coding system and use of password protected files. A partner, family member or carer will be welcome to attend the preliminary meeting if requested by the volunteer. The Principal Investigator will confirm stroke diagnosis and experience in using power assisted equipment. Concerns regarding ability to communicate in spoke English or capacity to provide informed consent will be identified and managed with sensitivity.

If the volunteer meets the inclusion criteria and does wish to proceed with study participation then they will be required to sign a consent form. Reasons for opting out of participation in the research will be anonymously recorded as this may inform the recruitment strategy for a future study. Baseline demographic data (table 1) will be collected at this point and a code number will be assigned to ensure anonymity of data collected.

Demographic data

Participant code: (Initials/DOB)
Gender:
Age:
Date of stroke(s):
Side of stroke:

Data collection

After volunteering, the interview will be scheduled within two weeks of the preliminary meeting and held in a quiet meeting room at the Derbyshire Stroke Centre. Participants will have the option of inviting a partner, family member or carer to accompany them during the interview. Participants will be invited to ask any questions at the start of the interview and reminded that they have the option of withdrawing from the study at any time. In the event of a participant requesting withdrawal during the interview they will be assured that all data will be deleted and they will be accompanied on their return to the reception area of the DSC. Refreshments will be available and participants will be advised that they can request a break at any point during the interview.

This is an exploratory research study designed to develop a better understanding of power assisted exercise following stroke in order to inform a subsequent larger study. The topic guide will facilitate exploration of the underpinning aims; a flexible approach to questioning will be implemented to enhance depth and richness in the qualitative data recorded.

IPA emphasises the importance of context and the individual. Participants will be encouraged to think about their views of exercise prior to stroke and reflect on ways in which the stroke impacted on their activity levels. In order to gather data which will inform outcome measurement selection for future research, the participants will be asked to discuss what they hope to achieve through exercise participation. Further prompts and questions will focus more specifically on the perceived psychosocial and physical impact of power assisted exercise.

Participants will be invited to identify perceived limitations related to the equipment and their experiences of using it. Participants will be asked to consider their preferred frequency and duration of exercise sessions; reflecting on levels of support required to access the equipment. The closing part of the interview will explore the experience of attending the DSC in more general terms including access, range of activities and social support.

The interviews will be recorded on two separate encrypted dictaphone devices to minimise risk of data loss or technical error. The researcher will make brief field notes during and immediately following each interview focussed on non-verbal aspects of communication noted during the interview.

The proposed questions for the topics guide are summarised below:

Topic Guide

- **What does the word "exercise" mean to you?**
- **Before your stroke how active were you? What activities did you enjoy?**
- **How did your stroke affect the exercise or activities that you could do?**
- **What do you want to achieve through exercise?**
- **What are your thoughts on exercising with power assisted equipment?**
- **Questions to explore the frequency, intensity, type of machine, support required**
- **Do you think the machine assisted exercise has had any impact upon your life outside the centre, for example:**
    - **Hobbies**
    - **Vocational activities**
    - **Family roles**
    - **Social life**
- **Have you noticed any changes in your mobility or physical abilities associated with using the exercise equipment?**
- **Have you any ideas for developing or improving the exercise programme?**
- **What are your future exercise goals and plans?**

Data analysis

Audio recordings from the Dictaphone devices will be uploaded immediately to the hard drive on the Principal Investigator's laptop which is password protected. The files will be subsequently deleted from the Dictaphones. The recordings will be transcribed verbatim by the Principal Investigator to ensure immersion in the data.

Data analysis will follow the processes associated with IPA. Repeated reading of transcripts will support familiarisation with the data sets leading to coding. Each data item will be coded individually and patterns for each individual will be identified prior to cross case analysis.

This process will start through familiarisation with each data item leading to coding at sentence level. The coding procedure will involve sweeps of reading and re-reading data items leading to the development of exploratory comments. Initial codes will be descriptive, commenting on key points articulated by the participants. Repeated reading of the data item will generate linguistic comments to facilitate analysis and explore meaning in the words selected to describe feelings or experiences. The final layer of coding will generate conceptual comments, integrating more in-depth commentary on the individual context of their transcript.

Coding through generation of exploratory comments will lead to the identification of emergent themes within each data item. This phase of analysis will aim to capture and summarise the initial interpretation whilst staying close to the participant's experience through re-reading of the transcript alongside the exploratory comments. The emergent themes will provide concise statements about what was important based on a synthesis of the original data item and its initial analysis through coding. Subordinate themes will be identified through searching for patterns amongst the emergent themes. Similar themes will be clustered together to generate superordinate themes which encapsulate the most important and meaningful experiences identified in each individual data item.

Completion of coding and theme generation for each data item will enable cross case analysis where the superordinate themes across the data items will be analysed to explore similarities and differences. As a deeper understanding of the data is developed the themes will be re-worked to generate final overarching themes which represent an analytical interpretation of the complete data set.

Throughout the analytic process a critical reflexive approach towards data construction and analysis will be facilitated as the principal investigator (PI) will take into account their own opinions and values related to exercise and stroke. A coresearcher will read the transcripts and associated themes, and through triangulation shape the development of the final themes. The identified coresearcher is a qualified physiotherapist with extensive experience in the rehabilitation of complex populations and an impartial perspective on power assisted exercise. The coresearcher is aware of the Principal Investigator's values and opinions and will challenge the Principal Investigator on their interpretation of data to facilitate reflexivity during data analysis. This will optimise the validity of the findings.

Data collection and storage

Participants will be required to give informed, signed consent on recruitment to the study. Each participant will sign three paper consent forms; the three forms will be stored as follows:

1. Property of the Chief Executive at Derbyshire Stroke Centre (DSC) and stored in a locked cabinet at the DSC
2. Property of the participant and stored at their home address
3. Property of the Principal Investigator and stored in a locked cabinet at home address

Upon completion of signed consent, each participant will be allocated a code comprised of their initials and date of birth. For example, Joan Hackett, born on 23rd February 1942 (fictional), would be coded as: JH23021942

Consented volunteers will participate in a semi-structured interview with the Principal Investigator (PI). The interview will be held in a quiet meeting room at the Derbyshire Stroke Centre. Participants will have the option of inviting a partner, family member or carer to accompany them during the interview. The interview will comprise of a verbal conversation between the participant and the PI based on the topic guide detailed in the summary of methods. The data will be qualitative, verbal data.

The interviews will be recorded on two separate encrypted dictaphone devices to minimise risk of data loss or technical error. The researcher will make brief field notes during and immediately following each interview focussed on non-verbal aspects of communication noted during the interview. The field notes will be recorded in a notebook, the participant's allocated code will be recorded at the bottom of each page. The notebook will be stored in a locked cabinet separate to the consent forms by the PI. The Dictaphone files will be uploaded immediately to the hard drive on the Principal Investigator's laptop which is password protected. The files will be stored in a folder entitled "DSC data 2018" and each individual audio file will be encrypted and named according to the respective participant's allocated code. The files will be subsequently deleted from the Dictaphones.

The audio files will be transcribed verbatim by the PI using Microsoft word. The word documents will be encrypted and stored in an adjacent folder on the password protected laptop. Each file will be named according to the respective participant's allocated code. Temporary access to the Microsoft word documents will be enabled for three members of the research team who will assist with data analysis. The research team comprise of two senior academics at Sheffield Hallam University and a HCPC registered physiotherapist with access to a Sheffield Hallam email account. The encrypted files will be sent as attachments within the University's email system. The passwords will be detailed in a separate email. The research team will temporarily store the encrypted files on the hard drive of a password protected PC. Upon completion of data analysis the three members of the research team will be instructed to delete the files.

The PI will store the encrypted audio files and transcribed word documents on the password protected laptop for six years. If the laptop is replaced within this time period the encrypted files will be uploaded onto the replacement password protected device and deleted from the original one. At six years from the point of data collection the audio files and word documents will be deleted.

Q1: Recruitment

The proposed study will recruit participants through a purposive sampling method of people who attend the Derbyshire Stroke Centre (DSC). Purposive sampling is a non-random technique designed to specifically recruit individuals who are able to share experiences and perspectives relevant to the research question. Posters will be on display at the centre and participant information sheets will be available at the reception desk. Potential participants will be able to contact the Principal Investigator directly via email or inform the team at DSC of their interest.

Inclusion criteria

- Stroke diagnosis
- Experience of using power assisted exercise equipment within the previous 12 months
- Able to provide informed consent
- Able to verbally communicate in spoken English at a level which will be comprehensible on an audio recording
- Does not have a learning disability or mental impairment

Exclusion criteria

- Unable to respond to verbal questions for the purposes of an interview

Participant selection

The study aims to capture the perspectives of a range of people with stroke who have experienced power assisted exercise following stroke; heterogeneous purposive sampling will be applied to recruit a range of participants all with different levels of experience and functional ability. Recruitment of a purposive sample will aim to represent a range of ages and both sexes reflecting varied experiences of living with stroke. The participant selection process will aim to recruit a combination of frequent and occasional users of power assisted exercise. This will enable exploration of different perspectives on the value of this type of activity. The semi-structured interview method for data collection does require an ability to participate in spoken English. However, people with severe aphasia or very limited spoken English will not be able to participate. People with severe cognitive impairment impacting capacity to provide informed consent will not be included.

Volunteers expressing interest in the study through either email contact with the Principal Investigator or communication with the DSC team will have the opportunity to meet with the Principal Investigator in the Derbyshire Stroke Centre. Potential participants will have the opportunity to ask questions about the study and management of data. The topic guide will be available so that potential participants can gain insight into the nature of the questions and discussion. It will be explained that the interview will be recorded on two encrypted dictaphone devices; data will be transcribed for analysis. They will be assured of anonymity and confidentiality of stored data through a participant coding system and use of password protected files. A partner, family member or carer will be welcome to attend the preliminary meeting if requested by the volunteer. The Principal Investigator will confirm stroke diagnosis and experience in using power assisted equipment. Concerns regarding ability to communicate in spoken English or capacity to provide informed consent will be identified and managed with sensitivity.

This is a non-interventional, exploratory study which aims to develop our understanding of the impact of power assisted exercise following stroke. To be eligible for recruitment, participants will need to have some experience of using power assisted equipment. Participation will involve a short, preliminary meeting with the Principal Investigator followed by a semi-structured interview. The interview will be located at the Derbyshire Stroke Centre; participants will have the option of choosing a relative, carer or friend to accompany them during the interview. The interview will last between 30-45 minutes. There will be no scheduled follow up to the interview, but participants will have the option of reading their interview transcript.

Participants will have the opportunity to share their experiences of exercise following stroke and to reflect on its perceived impact. This may help participants to identify their achievements and consider future engagement with exercise and related goals. The interviewer will not directly counsel participants but having the opportunity to talk about their experiences can help people with stroke to positively adjust to their diagnosis.

There is no risk of physical harm or injury associated with participation. Some participants may recall negative experiences, emotions or memories during the interview and this may cause them to become upset. The participant information sheet does explain this potential negative consequence and it will be mentioned by the interviewer at the point of recruitment to the study. The topic guide will be available during recruitment to the study so that potential participants may identify any sensitive or difficult areas of discussion prior to giving consent. Participants will have the option of choosing a family member, carer or friend to accompany them during the interview. If the interviewer observes that a participant is becoming upset during the interview data collection will be paused and the participant will have the option of taking a break, avoiding specific questions or opting out of the study.

Potential participants will be advised to carefully read the participant information sheet; assistance with this will be offered as required. There will be an opportunity to talk to the Principal Investigator and ask questions related to potential participation in the study. The consent forms will detail the Principal Investigator's details and be printed on A4 paper with the Sheffield Hallam University header. The tick box consent statements include reference to the participant information sheet, right to withdraw and conditions of anonymity and confidentiality. Consenting participants will be required to sign three separate consent forms, the three forms will be stored as follows:

1. Property of the Chief Executive at Derbyshire Stroke Centre (DSC) and stored in a locked cabinet at the DSC
2. Property of the participant and stored at their home address
3. Property of the Principal Investigator and stored in a locked cabinet at home address

Upon completion of signed consent, each participant will be allocated a code comprised of their initials and date of birth.

The participant information sheet states that participants have the right to withdraw from the research at any point up until two weeks following the interview. This right to withdraw without reason or explanation will be verbally explained at the point of recruitment to the study. At the start of each interview the interviewer will explain that the participant can opt out of the process at any point during the interview or avoid specific questions that they do not wish to answer. It will be verbally explained at the end of each interview that the participants can contact the Principal Investigator to request withdrawal from the study and deletion of all data up to two weeks following the date of the interview.

If at any point during the study a participant discloses information which raises a safeguarding concern the Principal Investigator will seek permission from the respective adult to share this information with Julie Wheelhouse (Chief Executive) at Derbyshire Stroke Centre (DSC).

The DSC has a responsibility to protect vulnerable adults under the 2014 Care Act. The policy at the DSC is to contact Derbyshire County Council (DCC) to raise any identified or reported safeguarding concerns. The DCC safeguarding policy can be accessed here: https://www.saferderbyshire.gov.uk/what-we-do/safeguarding-adults/professional-guidance/policy-procedure-and-practice-guidance.aspx

The Principal Investigator is registered with the Health Care Professions Council and has been previously DBS checked. The Principal Investigator will only have contact with participants within the Derbyshire Stroke Centre venue which is manned by a team of professionals and volunteers. The venue is mostly open plan and the interviews will be located in an office area with internal windows. The Principal Investigator and participants will be visible to other staff and users at all times. A renewed DBS check is not indicated for the purposes of this study.

Upon completion of each interview the Principal Investigator will ask the participant how they feel and whether they would like to ask any questions or make further comments. The interview schedule will allow for informal time at the end of each interview to accompany the participant back to the social area of the DSC. The Principal Investigator will offer to provide the participant with a transcript of their interview as either a paper or electronic document according to the participant's preference. The participant will have the contact details for the Principal Investigator (PI) and be assured that they may contact the PI at any future point regarding the study and their participation.

The data will be presented as a qualitative analysis generated through an Interpretative Phenomenological approach. Most of the data will be presented as overarching themes which represent an analytical interpretation of the data set, not specific to the individual participants. Specific quotes which enlighten insight into the participant's perspective may be included in the dissemination of the findings. The gender and age of the respective participant will be attached to each selected quote to enhance the context of the data analysis. It is possible that people who attend the Derbyshire Stroke Centre may be able to identify a participant based on data related to their age and gender. This is explained in the participant information sheet. No images or videos will be used during data collection or analysis.

The Principal Investigator holds an advisory role with the manufacturer of the power assisted equipment to facilitate evidence informed development of the machines. The Principal Investigator will attend the Derbyshire Stroke Centre and conduct the interviews through their capacity as an independent doctoral research student. In order to avoid potential bias in the collection and analysis of data the topic guide has incorporated neutral wording and a balanced range of questions. Data analysis will be assisted by an NHS physiotherapist with no affiliation to the manufacturer.

This qualitative study will enhance our understanding of the experiences and impact of power assisted exercise following stroke from the perspective of the service user. It will facilitate insight into the expectations of exercise following stroke and help us to understand the perceived impact on function and participation. The results of this study will build on the feasibility research conducted at SHU by the Principal Investigator (published June 2018). It will add to the qualitative evidence base related to exercise following stroke and inform the proposal of future research specifically in relation to programme design and outcome measurement.

The results of this study will add to the body of qualitative research published in the UK related to the experiences of exercise following stroke. The findings will be written up as a primary research article with the aim of publication in a rehabilitation journal, for example Disability and Rehabilitation or the International Journal of Therapy and Rehabilitation. The findings will be of interest to the rehabilitation and third sector organisations including the leisure industry. Dissemination through poster or platform presentation at relevant conferences will be pursued.

The arrangements for preserving and sharing data are detailed on the attached Data Management Plan.

The venue is 14 miles from PI home address and is a place that I have visited on several occasions. I am familiar with the journey and will use satellite navigation to ensure the most efficient route. I will ensure that a partner knows of my whereabouts and I will use a tracking app on my mobile phone so that I can be traced if concerns arise. The venue is in an industrial estate with good parking access. The venue is staffed by a team of professionals who will be aware of the interview schedule. The interviews will be scheduled during daylight hours.

My partner will have an anonymised copy of the interview schedule and details of the exact location of the data collection venue. The planned journey route and access to my location through the "find friends" app. I will text my partner on arrival at the venue, departure from the venue and return to home address.

The research venue is a busy centre with a public reception area which is staffed by a team of professionals and volunteers. The venue has an open plan design, the meeting rooms have internal windows meaning that I will be visible to the team throughout data collection. Some participants may have limited mobility. They will be required to use their usual wheelchairs or assistive walking devices to mobilise around the centre to access the meeting room where the interview is scheduled. I will not facilitate manual or therapeutic handling procedures. If a participant does require assistance to move between supportive surfaces then a member of the DSC team or designated carer will be required to help.

3.2: Example of idiographic analysis

Emergent themes	**Original Data**	**Exploratory comments**
Having a stroke is an unpleasant experience causing severe physical symptoms and major impact on life roles. Early stroke rehabilitation is clinical and associated with disempowerment.	Int: So, to start with today, please could you tell me a little bit about your stroke, when did you have it and what happened? PO1: erm (pauses)….the stroke itself happened May the 10th last year Int: yes.. PO1: It was at the, well I was taken to the Don Memorial hospital, released on the Thursday, travelled overnight, travelled down here, stayed overnight at our kids, er, we were meant to be buying a house, in Chesterfield, er on may the 18th. On may the 12th, I felt really, really unwell again, er….and I was taken to hospital, I was at the northern general, then I was in the royal Hallamshire, then I was in Chesterfield, my wife had taken over the property, but it took us to the end of June , June 24t, before I was released. (chuckles) Int: It felt like quite a long stay then, in hospital?	**Descriptive** Onset of stroke was staggered over two episodes. Second admission resulted in 2/12 hospital stay with transfers between different sites. Occurred at the same time as house move so wife had to take over new the property. **Linguistic** "Really unwell" - having a stroke associated with feeling very ill "I was taken to hospital" - passive recipient of early care, being moved between hospital site "Wife taken over the property" - change in life roles and marriage "Released" - suggests being trapped in hospital "It took forever" - duration of hospital stay felt like a very long time "For some reason they wanted me to feel better for myself" suggests limited understanding of the aims of the hospital team at that time. **Conceptual** Having a stroke is an unpleasant experience causing feelings of illness

Surviving a stroke and being comparatively able is associated with feeling lucky.	01: It took forever…but I can remember , for some reason, they wanted me to feel better for myself… Int: Did you feel that you made progress in hospital? PO1: Yes..and no, but yes…..er, four years before this, 2014, August, I had a brain tumour, and, the operation was done, and they left a mark, a stain, that allows them to access it very, very easily, (points to left frontal region) Int: Yes? PO1: And with that, I had problems with my right side, right? But I come over it, over the six months or whatever it is, to make it better, but what happened with my stroke, it made my right side really bad….eh God, when I looked outside..I was at the Royal Hallamshire, ward L? Int: That sounds right..yes PO1: But I was looking over the car park and could I WATCH A CAR? Oh, no way..no way whatsoever…it seemed the stroke had been at the back of the head, but been a mild	and disempowerment as you are moved through the healthcare system. He talks about the duration of hospital stay being long and recognises that life had to carry on without him as his wife moved into their new home. He indicates that the hospital teams lead decisions related to his care and wanted him to feel better, but PO1 does not give the impression that he felt that he was part of the decisions made regarding his early recovery. **Descriptive** Had experienced previous right sided changes due to brain tumour, but describes feeling that he recovered from it. The stroke made his right side really bad and he suggests that it affected his vision. Tablets had potentially caused the stroke. The stroke described as mild. Discharge from hospital was followed up with 12 weeks of rehabilitation at home and hospital, after which he joined the centre. He feels that the centre has been positive for him. **Linguistic** "I comer over it... to make it better" - suggests feeling that he achieved a good recovery from brain tumour. Describes this in first person suggesting that he felt he did this for himself. "Been a mild one... so relatively lucky" - suggests that he thinks that

Recall of NHS rehabilitation is detailed and transition to third sector provision is regarded as a positive move. Pre-morbid lifestyle was very active with deep commitment to an important, stressful job and resilient work ethic.	one…so I was relatively lucky, but they didn't know if it was all the tablets I was taking..and what not, so they've wound some of them back over , so it made quite a differenc to us. Int: Yes, ok, so you came out of hospital, late June, last year, and then did you have some more rehab at home? PO1: Erm, I had rehab at home for six weeks, and then I had rehab at the hospital for six weeks …and , er that was through til the middle of September, but in September, I joined the club, here, you know, and it's done us good, you know, aye, it's done us very good Int: That's great to hear, thank you. OK, so thinking back to before your stroke, and possibly the brain tumour diagnosis as well, what was normal life for you? How active were you? (pauses) Did you enjoy exercise?	his stroke could have been worse, relatively lucky compared to other people. Recalls exact timescales related to NHS rehabilitation, indicates precision in length of service provided. "It's done us very good" - suggests that the centre has offered a positive experience for him. **Conceptual** He had already worked hard to recover from his brain tumour, and done this for himself. Although diagnosed with mild stroke, the impact on his right side and possibly his vision felt severe. He recognises that the stroke could have been worse and describes himself as relatively lucky. He recalls with specific detail the length of community based rehabilitation followed by his transition to the centre. He does not comment on impact of rehabilitation or activities that it included, but he states that the centre has been very positive for him.

Appendix Four: Nominal group technique event reported in Article Four

4.1: Session plan

Copy of session plan

Resources:

- Dictaphone
- PPT slides
- Photos of machines

Facilitators: KS and RY

Support: Howard Blackburn

Panel: ER, DB, SJ, HL, GC, TMW,

Session Plan

Duration (mins)	Activity	Facilitator	Outcome
0-5	**Introductions and consent**	RY	Panel and facilitators all aware of each other's roles and name. Consent forms checked and signed.
5-10	**Context for the event:** "PAE has the potential to enhance exercise engagement for PwS. GMT funding has secured a proposed study which will be based in AWRC. Aim of the event is to capture the opinion of professionals in relevant fields to ensure a comprehensive perspective."	RY	Panel will have a general awareness of the area of interest and purpose of the event.
10-15	**Question one:** *What does an assistive exercise machine need to do to allow the*	KS	Panel will write down three features or effects of the exercise machines which they

	person with stroke to engage in exercise?		consider to be important for PwS.
15-25	**Group discussion** Panel will share their responses with some explanation or justification to support their perspective.	KS facilitate discussion RY write down key words or outcomes.	List of features regarded as important by the panel with supporting information.
25-40	**Machine overview** The need to select three machines from a range of 8 will be introduced. There will be a ppt presentation outlining each machine	RY	Panel will have an awareness of the eight available machines and the remit to select three to take into the AWRC.
40-45	**Machine selection** **Question two:** *"Which machines would you prioritise for use with PwS?"* Each panel member will be given 10 vouchers to express their machine preference. They must select a minimum of 3 machines and can indicate strength of preference through number of vouchers allocated. The machines will be represented on A4 photographs laid out on the table.	KS	The preferences of the panel will be expressed through voucher allocation to each machine
45-55	**Group discussion** The panel will be encouraged to discuss their choices in the context	KS	Explanation and justification shared by the panel will ensure a rounded perspective of opinions to inform the proposed

	of exercise for PwS and the proposed study.		study.
55-60	**Conclusion** Final comments of questions will be shared and addressed. The panel will be thanked for their time.	RY	

Post panel

RY will take photographs and count the vouchers allocated to each machine. The dictaphone recording will be uploaded and the audio file will be encrypted.

4.2 Copy of prizewinning poster displayed at Physio UK 2020 (page 380)

Application of nominal group technique to inform a co-design project on power-assisted exercise equipment for people with stroke

Sheffield Hallam University

shapemaster power assisted exercise

Young, R.[1]; Broom, D.R.[2], Sage, K.[3] and Smith, C.[1]

[1]Sheffield Hallam University, [2] Coventry University, [3] Manchester Metropolitan University

Rationale and Aim

- Power-assisted exercise is an accessible physical activity option for people with stroke [1].
- Co-design research will advance the equipment to quantify detected user effort and align power assisted exercise with published guidelines.

The aim of this Patient Public Involvement activity was to establish priority design features and select three machines from a range of nine for software improvement.

Methods

- Nominal group technique [2] was used with expert exercise scientists and physiotherapists (n=6) and end users with stroke (n=3).
- Group discussion was followed by voucher allocation to preferred machines.
- Content analysis generated a list of specification features.
- Votes from the end user group were multiplied twofold to ensure equal representation.

1. Software & interface

A motivational display to show the user how they're performing (Physiotherapist)

Some gamification to reduce the monotony of training (Exercise scientist)

2. Exercise programme

The movement needs to trigger a physiological stimulus (Exercise scientist)

The machines need to encourage me to focus on extension (End user)

Machine		Expert	User	Total
Cross cycle		17	3 (6)	**23**
Chest and legs		14	4 (8)	**22**
Rotatory torso		8	5 (10)	**18**
Side bend stepper		3	7 (14)	**17**
Seated climber		11	2 (4)	**15**
Ab pullover		5	2 (4)	**9**
Tricep dip leg curl		2	3 (6)	**8**
Tummy crunch		0	2 (4)	**4**
Seated abductor		0	2 (4)	**4**

3. Machine & accessories

If the machines were height adjustable I could get on and off myself (End user)

I'm a scientist rather than clinician, I'd have never thought about access! (Exercise scientist)

4. Setting & service

I found that physio before assisted exercise helped me to reach further (End user)

Group exercise, meeting others who are in the same boat is good (Physiotherapist)

Findings

Emerging domains:
1) software and interface, 2) exercise programme, 3) machine and accessories, 4) setting and service.
Foci:
End users on accessibility; physiotherapists on motivational features; exercise scientists on physiological performance.

Conclusion

Nominal group technique facilitated a structured approach to Patient Public Involvement. All attendees emphasised the importance of an individualised user experience.
The findings enabled selection of three preferred machines for advancement and identification of user-centred priority design features.

1. Young, R., Richards, E., Darji, N., Velpula, S., Smith, C., Broom, D. & Goddard, S. (2018) Power assisted exercise for people with complex neurological impairment: A feasibility study. *International Journal of Therapy and Rehabilitation*, Vol 25 (6) p. 262-271
2. Harvey, N., & Holmes, C. A. (2012) Nominal group technique: An effective method for obtaining group consensus. *International Journal of Nursing Practice*, Vol 18 (2) p. 188-194.

Contact: Twitter @physioyoung; Email r.young@shu.ac.uk

Appendix Five: Storyboard event reported in Article Five:

5.1: Risk assessment

Risk assessment:

Description of the Process/Activity: Storyboarding and Nominal Group events

Hazard	Who could be harmed?	Existing safety precautions	Risk level	Date completed
Transportation of stroke participants to and from the AWRC; risk of road traffic accident	People with stroke recruited to the study	Funding provided to afford taxi transportation from home address of each stroke participant to the venue. Taxi service will be advised that the passengers will have limited mobility to ensure drivers allow for additional time and support of passengers including carriage of wheelchairs in the vehicle. If weather conditions are forecasted to be severe on the date of the event it will be postponed	2	
Movement of stroke participants between AWRC entrance to the allocated room; risk of fall or people getting lost.	People with stroke recruited to the study	Arrival times will be staggered to avoid all stroke participants arriving at the same time. The principle investigator (PI) and a further three student volunteers will be available to meet the participants and assist them to the allocated room Mobile telephone numbers of all participants will be known by the PI and the participants will have access to the mobile number for the PI so that any changes in expected arrival time will be communicated.	2	
Risk of participants becoming distressed or frustrated as they share their experiences and opinions on exercise for people with stroke	Expert and user participants recruited to the study	The objectives of each event will be communicated by the PI at the start of each event to ensure clarity regarding the purpose of the event. Ground rules regarding group conduct and support will be agreed at the start of each event.	1	

		Objectives and ground rules will be summarised on a ppt slide If a participant becomes distressed then a member of the research team or volunteer will lend support as required.		
Risk of expert participants sustaining injury or delay associated with journey to AWRC	Expert participants (SHU academics and therapists)	Travel directions to the AWRC will be provided to all participants including a map and postcode. AWRC parking permits will be offered. Taxi will be provided on request. Travel conditions will be monitored by the PI and participants will be notified by text if adverse road conditions are reported. If the weather forecast is very severe then the event will be postponed,	1	
Risk of injury to PI on recruitment of stroke participants to the study during visits to their home address.	PI (Rachel Young)	The PI will carry a mobile telephone and ensure two members of the PhD supervisory team are aware of scheduled visits to meet potential participants and their address. Participants will be recruited through purposive sampling and will already be known to the research team. Travel conditions will be checked to ensure safe road environment for scheduled visits.	1	
Risk of injury or accusation toward the research team by participants	Research team	All expert participants will be employed in professional roles and hold valid DBS checks. All stroke participants will be screened for severe cognitive or mood related changes at the point of recruitment. The planned research activities are group events so there will be very limited unwitnessed, one on one contact between participants and the research team.	1	

5.2 Ethics review recommendations and response

Collated review

It was felt to be a sound application and carefully considered proposed programme of research. There are a few items which we feel would benefit from some attention and there is one issue that must be addressed prior to commencement of the study. The PIS needs to contain details regarding data protection. Please see the SHU guidance for GDPR.

There is one mandatory issue to be addressed which is to use the SHU guidance for GDPR on PIS. This has been completed, please refer to the updated attached PISV2 documents.

The reviewers provide recommendations for consideration as follows:

1. P2Q7 - recruitment - Please clarify who is making the first contact with patients and professionals and how they will obtain/get access to the contact details. If it is the PI, how will they receive patients' email addresses and do they have clearance to make contact with patients about the study (i.e. have patients agreed for their contact details to be used for recruitment purposes)?

   Participants will be recruited from two services; Sheffield Neuro Physiotherapy and the Service User Group attached to the physiotherapy team at SHU.

   On registration with Sheffield Neuro Physiotherapy new clients disclose their email address and are asked whether they would be interested in research participation. For this study, those who have indicated interest will be extracted from the database and sent information about the study.
   As an associate lecturer at SHU the principal investigator can access the details of the AHP department service user group to alert them to the study.

2. In P2Q2 the term 'expert participant/attendees' is referred to. Who are the expert participants and how are they identified?

   In this context the expert participants fall into three categories; 1) people who have had stroke and are expert by virtue of their experience, 2) neurological physiotherapists who are experts by virtue of their profession and clinical experience, 3) exercise scientists who are expert by virtue of their academic training in exercise physiology

3. P6Q4 - If signs of distress are observed among participants, what is the plan of action? Please clarify what will happen. Will people be signposted to sources of support? Will they be encouraged to leave the room?

The plan of action for a mildly distressed participant will be for a student volunteer to take them to the family room and offer tea and conversation. If the participant becomes very distressed and the principal investigator will call a break and speak to the distressed participant individually. If anyone decides that they would like to leave then transport will be arranged. People with stroke can experience emotional lability and so the principal investigator will discuss this with the participant before the event if this is a known issue and how the person themselves want this to be dealt with in the group.

4. P6Q6 - You state participants can withdraw from the study at any point up until the date of the story boarding event. Why can't they withdraw after this point? I.e. during the story boarding event or before/during the participatory analysis sessions.

For clarity, if somebody wishes to withdraw from either event on the day then this will be supported as detailed above.

5. P3Q12 - please clarify whether any personal contact details like telephone numbers/email addresses will be collected, by who and where they will be stored and for how long.

No personal contact details will be collected from the identification source (see Q1). No personal contact details will be stored in the research data. Please see data management plan now uploaded.

6. Photography - how will people who have not consented to have their photograph taken be identified? e.g. consider having name labels with a mark on them to identify those who do not want to have photographs taken. Also clarify whether people who have not consented to having their photography will be blurred out of photographs/videos or not appear in any shots taken. What is the back-up plan for if no participant wants to be videoed? Please make this clear in the consent form.

All participants will have a preferred name sticker to facilitate groupwork. A yellow dot will be visible on the sticker of those participants who do not want to be photographed. If participants do not want to be videoed we will strategically place the camera so they are not included in the footage. If everyone refuses to be videoed we will audio record and one of the study collaborators will record field notes to capture non-verbal observations.

7. On the day, consider using name labels, clear signage for rooms / toilets, large font agenda etc.. Also it would be good to consider sending reminders to potential attendees a few days before the planned workshop - just to confirm time/date/location etc. and to see if any 'needs' have changed during in the interim.

Thank you for this advice which I am happy to follow.

8. How long will participant be given to decide whether or not to take part in the study? Please include this in the PIS.

Participants will be given one week to consider their participation. Please see revised PIS V2

9. Please upload a data management plan. Also please clarify how long will data be stored? Will it be uploaded to SHURDA at the end of the study?

   Apologies for omitting the DMP on first submission. The data is not planned to be uploaded to SHURDA. I will liaise with Peter Smith librarian about SHURDA system for data for future reference.

10. Although thematic analysis is said to be the method of analysis there is no reference to the literature or any outline details of how this might be performed. We feel it is important to have a clear plan for the analysis.

    Thank you for these comments, there is a clear plan for analysis. Reference sources include Braun and Clark for an overview of thematic analysis and Deborah Lupton for specific examples with storyboarding data.

11. Across the documents particularly in Q1 there are numerous acronyms which interrupt the flow of the text. For the sake of understanding maybe remove some of the acronyms?

    Thank you for this recommendation. I have checked Q1 to ensure that every acronym is explained. Acronyms were used to keep within the character limit required.

12. Across the documents there are instances where "Principal Investigator" is spelt Principle.

    Thank you for pointing this out, it has been rectified.

Further queries made by one of our reviewers:

13. I also have a couple of queries - are the students and/or the exercise/ rehab professional given travel expenses?

    No

14. Is there agreement or arrangements for the exercise/rehab professionals to be released by their employer or is this something they will be doing in their own time?

    Time management will be left to the discretion of the participants

Attachments

Include contact details of the Data Protection Officer and Head of Research Ethics.

Thank you for this; my understanding that the position on today's date, 13/02/2020, that the named individuals are Keith Fildes (0114 225 4530) and Ann Macaskill (0114 225 4604). These names have been added to the formal complaints route on the revised PISV2

1. The participant information sheet (PIS) template used needs to be the current version with GDPR section (available on the SHU intranet). Also include relevant information around General Data Protection Regulation. Also available on the SHU intranet

   The GDPR section has been added to the PISV2 (see attachments)

2. The PIS refers to Don Valley Stadium which is no longer there.

This has been corrected on the PISV2

3. The language of the debrief letter is quite complex and might not be accessible to lay audiences. Please consider revising and having it checked over by a layperson before using. e.g., use of 'interpretation and analysis' could be replaced with 'help us to make sense of the data' - as per the PIS

Thank you for this feedback, I have amended the debrief letter and been assured by two lay persons that it is now reader friendly.

4. The language in the PIS is also quite complex - Given the very user centred nature of this study the PIS is rather cold and uninviting and this jars with the feel of the study. It is also a little over wordy. We suggest this is written in a less formal manner. In line with the Plain English Campaign guidelines the font should also be larger, size 14, particularly as most people with a stroke are older. A version number also needs to be added.

The PIS has been revised with this recommendation addressed. Please refer to the attached PISV2.

5. The consent form should include the version of the PIS referred to.

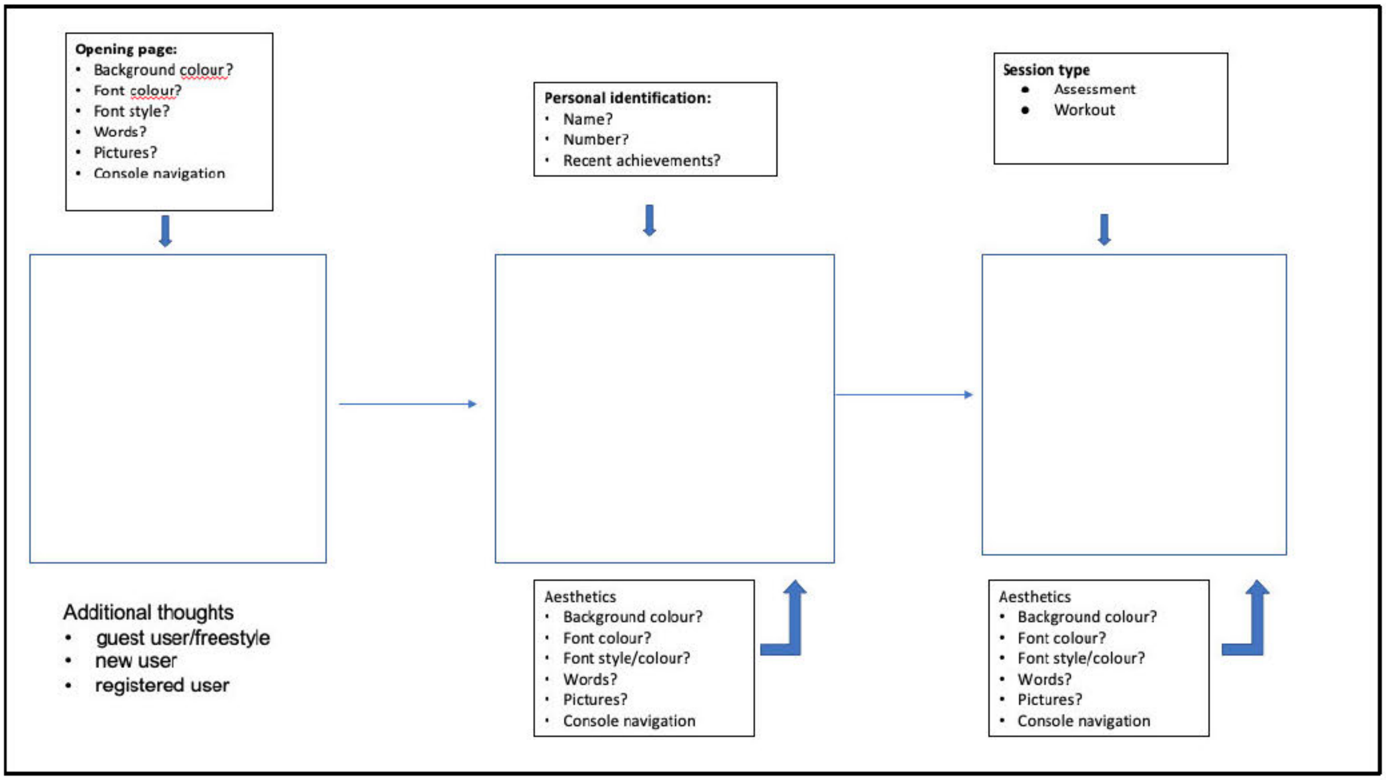
This has been amended, please refer to the updated consent form in the attached documents.

6. The data management plan appears to be missing

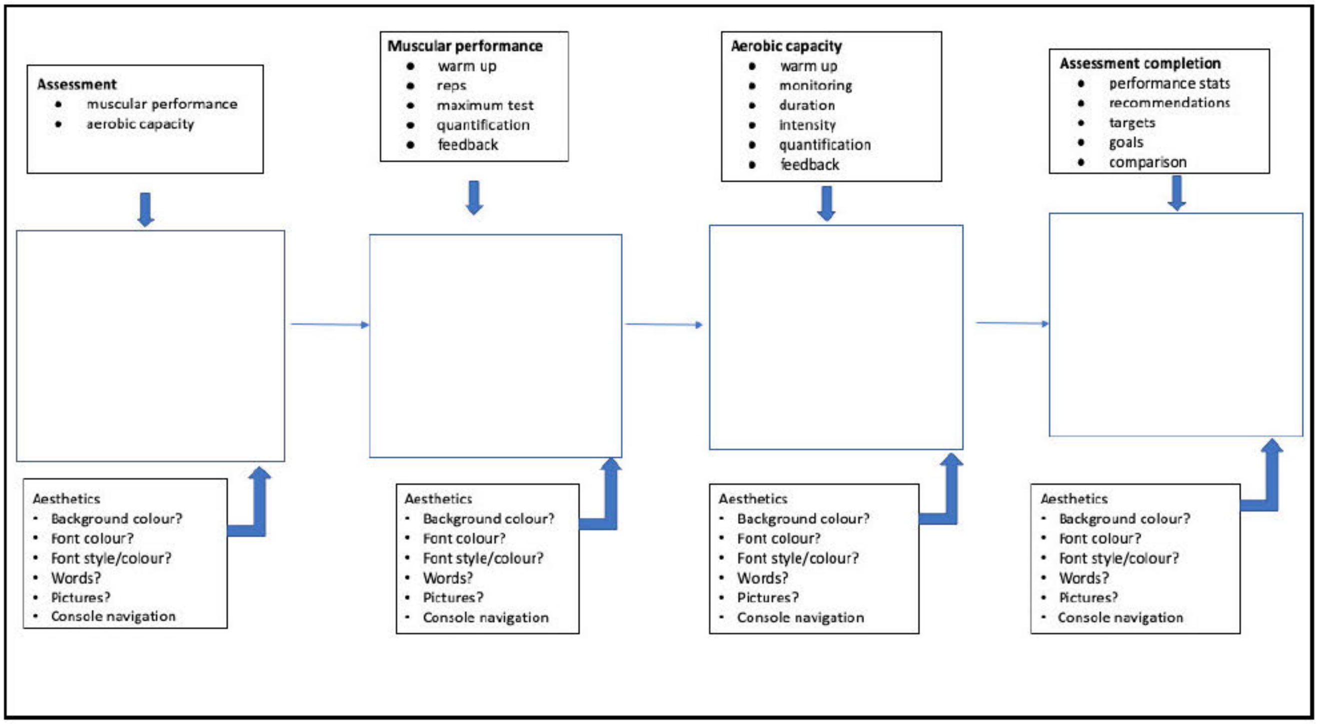
Apologies for this omission, the data management plan is now attached.

5.3: Storyboard Templates

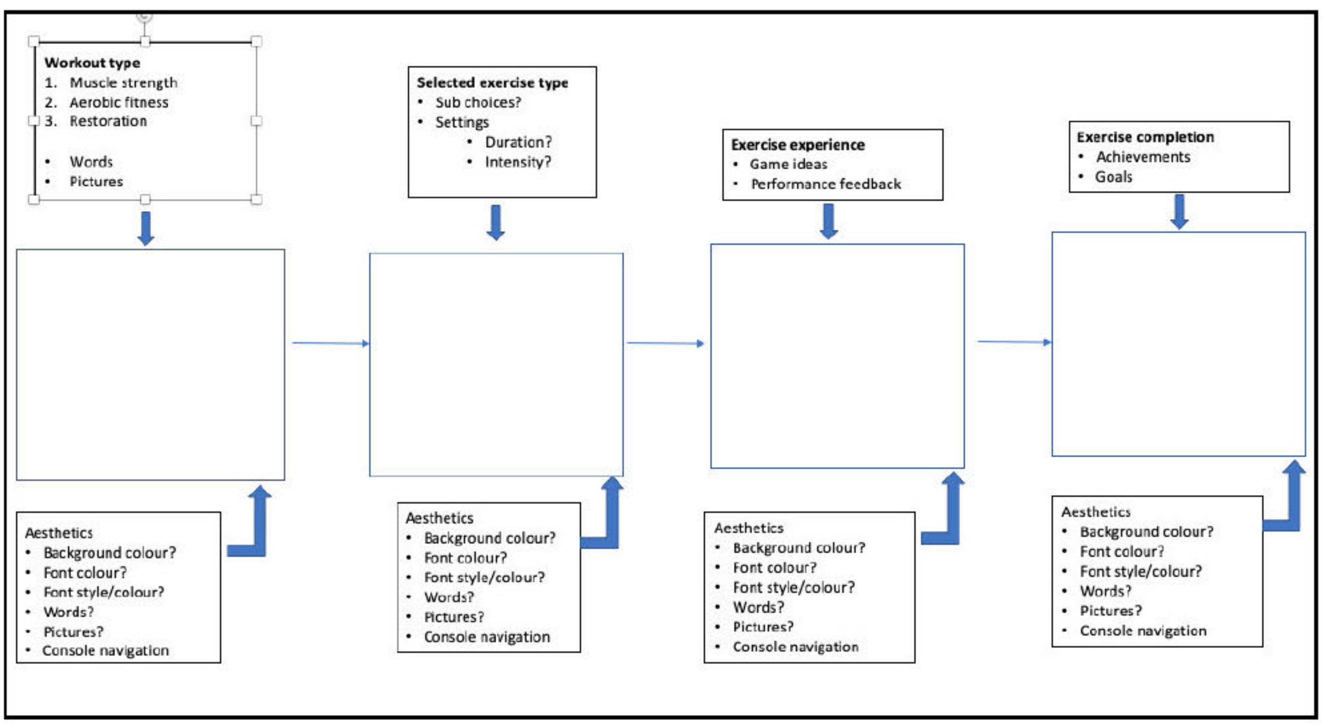
Template 1 for user login



Template 2 for assessment programme



Template 3 for programme selection



5.4: Report to Grow MedTech

Grow Medtech PoF Monthly Project Update

Project Title	*PAE stroke: Feasibility testing of bespoke power assisted exercise prescription software programmes for people living with stroke.*		
Update Month	*Jan-March*	**Project Month**	*June*
POF number	*POF000095*	**Lead Academic**	*Chris Smith*
Completed by	*Dr Christine Smith*	**Role**	*Principle Researcher*
Grow MedTech Technology Innovation Manager for project			*Simon Butler*

Project Milestones				
	Milestone Title/Description	**Due Date**	**Tracking**	**Date Delivered**
1	Ethics approval gained	05/01/20	G	31st January
2	Equipment Analysis	05/02/20	G	14th February
3	Prototype software created	05/03/20	A	May
4	12-15 participants recruited	05/05/20		March
5	Case series programme	05/07/20	R A G	The following work packages have been amended
6	Quantitative impact measurement	05/07/20	R A G	a/a
7	Product evaluation	05/07/20	R A G	a/a
8	Commercialisation plan	05/07/20	R A G	a/a
9	Software modified based on feedback from patients in trial	05/07/20	R A G	a/a
Guidance	• *Delete or insert rows to match the number of milestone in project plan.* • *For tracking select colour flag to show milestone status- on track (green), at risk (amber), delayed or missed (red)- delete flags as appropriate* • *Once a milestone has been met indicate that it has been completed/delivered and the actual completion/delivery date.*			

On track for overall project delivery	G
Guidance. This relates to the project period funded by Grow MedTech- indicate if the project is: on track (green), at risk (amber), delayed (red)- delete as appropriate	

State main activities / achievements over last month	During June a series of six remote participatory group analysis sessions were scheduled with users during which the storyboard data was interpreted and explored. Themes arising reflected the visual features, functionality, programme and user engagement qualities of the co-designed interface. The findings will be translated into a multi-faceted prescription for the architecture, format and performance capacity of the interface. Ben Heller's proposal was accepted and he has officially joined the team in his capacity as sports engineer for software development. The method and findings from the Nominal Group Technique event which underpinned machine selection for the project has been prepared as a draft article for future publication. The machines sited at City Campus and the AWRC have been moved; x1 machine is now sited at Ben Heller's home address to aid his progress with the project; x2 machines are undergoing minor upgrade with the manufacturer to enhance their accessibility.
State any key project risks in delivering next milestone(s) and how these may be mitigated	No risks with amended project which now focuses on the software development rather than testing with volunteers, as this is now not possible due to COVID 19.
Other information to report	Nil
Lessons learnt	How to facilitate group data analysis using remote media
Guidance	***State main activities/achievements over last month:*** *Summarise in brief the main relevant focal points of work over the last month and any outputs resulting from these. Suggested format would be three bullet points which include a brief synopsis of each activity and output. Examples of activities might be: patent application/progression; delivery of outsourced technical work package; completion of significant laboratory work; business case development; regulatory submission; meetings with potential commercial partners.* ***State any key project risks in delivering next milestone and how these may be mitigated:*** *Summarise any risks associated with activities required to maintain delivery of milestone to project timeline. Suggested format would be bullet points describing each risk and planned mitigating actions for each. Examples could be concerned with resource; raw material supply; late delivery of critical equipment; regulatory questions; technical failure. Critical information is how potential delays may be avoided with intervention. Highlight if input from Grow MedTech Executive Board would be helpful.* ***Other:*** *Briefly summarise any relevant information not covered above, especially knowledge or insight that might support other projects or teams in deliveries.* ***NOTE.*** *Any serious risks and issues relating to each project may be recorded using this form but the expectation is that in such an event a focus meeting would be called with the Grow MedTech Technology Innovation Manager as soon as possible.*
Please return to the Technology Innovation Manager assigned to the grant by end of each month	

Appendix Six: Usability evaluation reported in Article Six

6.1: Participant information sheet

Usability testing of a new software programme to advance power assisted exercise for people with stroke

Participant Information Sheet

We are seeking volunteers to take part in testing some new software on a new interface. The aim is for the software to be attached to power assisted exercise machines to help people to exercise as part of their stroke recovery. We are inviting people with stroke and exercise/rehabilitation professionals to provide feedback on the interface in terms of its user-friendliness and motivating features to help with its development. The testing will be completed remotely via a weblink and volunteers will be supported in giving feedback about their experience of using it.

Who can take part?

To be eligible to take part you need to have either a diagnosis of stroke (brain or spinal cord) or a degree level award in a subject relevant to exercise or rehabilitation. You need to be able to understand spoken and written English. People with communication changes following stroke, for example limited or slurred speech are still welcome to participate and your needs will be accommodated. Any specific requirements for communication support can be discussed with the lead researcher. If you live with a partner or carer then they are welcome to take part in the session with you.

You need to have access to a digital device in your home environment, for example laptop, PC or tablet with a stable internet connection. You need to have basic skills in using digital technology, for example, video calling and the ability to use an on-line shopping site such as Amazon. You will also need a personal email address.

What will I be required to do?

If you are interested in taking part then you will have an initial video call with Rachel Young. Rachel Young is the Principal Investigator and a neurological physiotherapist. The video call will be conducted using Zoom software and Rachel will set up the link for the meeting and email it to you. During the meeting Rachel will answer any questions you may have about taking part in the study.

If you decide that you would like to take part in the study then you will need to complete an electronic consent form which will be returned to Rachel via email.

You will take part in three separate usability tests over an approximate six week period. The date and time of each test will be scheduled at your preference.

Prior to the usability tests you will receive a weblink which displays the new programme. During the usability tests you will meet Rachel via Zoom and you will be video recorded whilst navigating through the interface. You will be asked to find different exercise options on the interface. The time taken to complete each task will be documented, and you will be prompted to discuss your thoughts at the end of each task.

Please remember that our intention is to test the new interface and get feedback. We are not testing your digital skills and it is fine to experience problems. If you find the interface confusing to use then this will be noted and the interface will be redesigned accordingly.

Where will this take place?

All testing can be completed in your home or preferred environment. There is no requirement to travel or take part in a face to face meeting at any point in this study.

Can my carer or partner be present?

Yes, if you would like a carer, friend or partner to accompany you during the test then please let the research team know when you consent to take part in the study.

I have a communication impairment so how will I manage?

Almost 40% of people with stroke experience changes in their ability to communicate and it is important that we develop a console which is user-friendly for all of the stroke population. If you have communication changes the lead researcher will identify your needs with you when you consent to take part in the study. Your individual requirements will be met through, for example, allowing longer to familiarise with the interface and adapting the questions asked during the test.

How often will I have to take part, and for how long?

The first test will take approximately 20 minutes. The two subsequent tests will be between 40 and 50 minutes in duration.

What if I don't want to participate?

Your involvement in the study is totally voluntary. You have two weeks following the initial meeting with Rachel to consider whether you would like to take part. You are under no pressure to participate and if you decide not to be involved you will not be required to give any reason.

Are there any risks associated with my participation?

Taking part in the study will entail focussing on a computer programme for up to 50 minutes. This may cause some fatigue. You will be able to request a break during the test if needed. We will encourage participants to ensure that they are comfortable at the start of the test, and have access to a hydrating drink.

Can I withdraw from the study?

You have the right to withdraw from the study at any point before or during the usability tests. You will not be asked to provide any reason for withdrawal and it will not impact any future care or opportunities. You may request that your data is deleted and excluded from analysis for up to seven days following each test.

Who will be responsible for all of this information when the study is over?

The data and information will be the property of Sheffield Hallam University and the lead researcher, Rachel Young, will be responsible for its secure management.

What will happen to the information when the study is over?

The video footage captured through Zoom will be downloaded as a password protected MP4 file and stored on a secure, password protected portal on the university's intranet. The recording will be analysed by the research team. The audio-visual footage will never be displayed in a public forum or shared on internet media.

The data recorded about completion time and error occurrence will be stored on password protected spreadsheets. The data will be stored on a secure, password protected portal on the university's intranet.

Who will have access to the data?

The research team assigned to this project include a small group of rehabilitation professionals and sport engineers. All team members are contracted to work with Sheffield Hallam University and will abide by GDPR guidelines in the handling of all data. More information can be accessed here: https://www.shu.ac.uk/research/quality/ethics-and-integrity/data-management-policy

How will you use what you find out?

The findings will inform the design of the interface which will be attached to the upgraded power assisted exercise machines. The findings from this project will ensure that the interface is user-friendly, effective and motivating for people with stroke and their rehabilitation teams.

Will anyone be able to connect me with what is recorded and reported?

The video footage could lead to identification of individuals who attend the session. The footage will be deleted from the recording device and stored as a password protected MP4 file on a secured portal. Under no circumstances will the video footage be released to any forum which could lead to public view, for example, social media or professional conference.

Will I receive payment?

Participants will be offered a £10.00 retail voucher in gratitude for their time and support.

How can I find out about the results of the study?

The findings will inform the design of the new interface and if you are interested in viewing the versions which are developed then you will be welcome to contact the lead researcher and arrange a viewing of the evolving product. You may be eligible to take part in pilot testing at a subsequent stage of the project and if you are interested then please mention this to the research team.

Principal Investigator

Mrs Rachel E Young

Neurological Physiotherapist

Doctoral student

Sheffield Hallam University

Email:

What if I have a complaint?

If you want to make a complaint about how people have approached you or treated you during the project, please contact Rachel's supervisor: Dr Christine Smith at Sheffield Hallam University on [redacted].

If you **remain** unhappy and wish to complain formally, you can do this through the Data Protection Officer

<table>
<tr>
<td>You should contact the Data Protection Officer if:
you have a query about how your data is used by the University
you would like to report a data security breach (e.g. if you think your personal data has been lost or disclosed inappropriately)
you would like to complain about how the University has used your personal data
DPO@shu.ac.uk</td>
<td>You should contact the Head of Research Ethics</td>
</tr>
<tr>
<td colspan="2">Postal address: Sheffield Hallam University, Howard Street, Sheffield S1 1WBT
Telephone: 0114 225 5555</td>
</tr>
</table>

6.2 Ethics feedback and response

Collated comments

- I would recommend not using Zoom but another platform ie MS Team or WebEx as the security features on Zoom are not sufficient for research. I would also recommend you record the video conference on a separate password protected device ie not through zoom recording, please see the University ethics guidelines on best practice written by Professor Ann Mackasgill.

- Wonder why the PI has chosen surveyMonkey as the questionnaire platform as the University subscribe to Qualtrics not surveymonkey.

- What is the reliability and validity of Post Study System Usability Questionnaire? What data does this capture? It is not clear in the ethics submission.

- Consent forms will contain participant identifiable data and as such will need to be stored on J drive not Q drive. The log of participant information ie name and code needs to be stored on J drive all other anonymised data can be stored on Q drive. The video files proposed from Zoom are likely to show participants and therefore potentially identifiable so should be stored on J drive not Q drive. However, as previously mentioned it is not advised to use Zoom for research purposes, and it is recommended that other more secure platforms such as MS Teams are used instead. Please refer to the University guidance on this issue.

- How are the Sheffield neuro physiotherapy team being contacted? Are they being contacted via a special interest group? Just need to be mindful of recruitment route to avoid breaching NHS ethics approval requirements.

- Are there any eligibility criteria around time since stroke? Does this need to be considered?

- I would like to see a little more detail on how you will debrief participants particularly patients who have had a stroke at the immediate end of the live video conference/task assessment. Participants are likely to be tired possibly slightly emotional if they have found the tasks frustrating or difficult, how will you as PI ensure participant physical and mental well-being at the end of the interaction and ensure the participant is not left feeling deflated, or upset? How much time for example, has been planned for the end of the online process for debriefing, returning to the here and now etc?

- How will you disseminate the results to user groups? And relevant industry?

PIS: I'm not sure it is wise to have your work address on the letter in case participants try to post material including consent forms and you will not be there to collect.

Is the mobile number of the PI a work mobile or personal mobile number? I would recommend not using a personal mobile number.

Has the PIS been reviewed by a patient representative? The wording doesn't feel like it is written for a lay audience; the readability score is a little too high for the general public (currently at 10.2 best to be around grade 8).

The PIS needs to have a section about payment- "Will I receive payment for participating in this study", a section stating who has ethically reviewed the study and I think there needs to be information on where participants can view the University GDPR policy in more detail if they want

to.

Data Management- please see separate file for comments, specifically need clarity around Q drive and J drive for identifiable and non-identifiable data.

Risk assessment- I think there are few details that could be included on the risk assessment – please see separate file.

P6Q2 –Please check that current SHU policy allows the payments listed to research participants (policy does change)

P6Q11 – Please confirm that there are no financial nor other beneficial links between the manufacturer Shapemaster and the PI and her supervisors. It may also be useful to fully

We would like to recommend approval but with attention to the advisory comments above and on the attached documents, to be overseen and approved by the Director of studies.

Converis: ER26319972

Response to advisory comments

1. I would recommend not using Zoom but another platform ie MS Team or WebEx as the security features on Zoom are not sufficient for research. I would also recommend you record the video conference on a separate password protected device ie not through zoom recording, please see the University ethics guidelines on best practice written by Professor Ann Mackasgill.

Thank you for this guidance. Zoom is the preferred media amongst the user group who represent the population under study and I consulted with the SHU TEL team for further guidance. As an associate lecturer at SHU I have a licensed Zoom account. There is a considerable difference between the free version of zoom that has had widespread media scrutiny and the licenced version we have at SHU that has many more layers of security and a completely different server network. SHU checked this out before signing the contract and reviewed it at the time when lockdown was happening and the media attention was on zoom. They were happy and have continued to use it. It is EU and GDPR compliant with local servers being used to house and streamed or recorded content. If recorded in the UK the closest server is housed in Dublin meeting the regulations. The free version uses networks in Asia etc. I will add passwords and waiting rooms to meetings as is standard now.

2. Wonder why the PI has chosen surveyMonkey as the questionnaire platform as the University subscribe to Qualtrics not surveymonkey.

Thank you for this comment. I have explored the SHU intranet and discovered that the Sport Industry Research Centre (SIRC) provide support to develop online surveys. I will contact the SIRC team for further guidance and support. https://www.shu.ac.uk/research/specialisms/sport-industry-research-centre/what-we-do/commercial-services

3. What is the reliability and validity of Post Study System Usability Questionnaire? What data does this capture? It is not clear in the ethics submission.

The Post Study System Usability Questionnaire (PSSUQ) originated from an internal IBM project in the 1980's. Psychometric evaluation of the PSSUQ in 2002 showed very high scale and subscale reliability. Factor analyses has indicated high construct validity and correlation with other usability measurement tools demonstrated concurrent validity. Three subsections within the survey enable analysis of specific areas; system usability, information quality and internal quality.

4. Consent forms will contain participant identifiable data and as such will need to be stored on J drive not Q drive. The log of participant information ie name and code needs to be stored on J drive all other anonymised data can be stored on Q drive. The video files proposed from Zoom are likely to show participants and therefore potentially identifiable so should be stored on J drive not Q drive. However, as previously mentioned it is not advised to use Zoom for research purposes, and it is recommended that other more secure platforms such as MS Teams are used instead. Please refer to the University guidance on this issue.

Thank you for this information. I have requested access to a folder on J drive and will store all identifiable data in this electronic space including consent forms, baseline participant data and the video files. The DMP has been amended accordingly.

5. How are the Sheffield neuro physiotherapy team being contacted? Are they being contacted via a special interest group? Just need to be mindful of recruitment route to avoid breaching NHS ethics approval requirements.

The Principal Investigator (PI) is an associate practitioner with Sheffield Neuro Physiotherapy. The PI will liaise with the service director, Emma Richards, to identify clients who meet the eligibility criteria. All clients self-refer to the service and the service operates independently of the NHS.

6. Are there any eligibility criteria around time since stroke? Does this need to be considered?

Research evidence indicates that people with stroke benefit from exercise interventions from early phases of recovery up until years beyond onset of stroke. Clients of Sheffield Neuro Physiotherapy are typically at least three months post stroke before they self-refer for independent therapy. The eligibility criteria will be amended to reflect this.

7. I would like to see a little more detail on how you will debrief participants particularly patients who have had a stroke at the immediate end of the live video conference/task assessment. Participants are likely to be tired possibly slightly emotional if they have found the tasks frustrating or difficult, how will you as PI ensure participant physical and mental well-being at the end of the interaction and ensure the participant is not left feeling deflated, or upset? How much time for example, has been planned for the end of the online process for debriefing, returning to the here and now etc?

Thank you for raising this point. The testing protocol has been amended to include an initial 'think aloud' run-through at the start of each task to support the participants in familiarising with the task and interface, capturing their initial impression. The retrospective 'think aloud' task has been removed.

At the end of each testing session the PI will thank the participant for their time and reassure them of the value of their shared experience of using the interface. They will be reminded that we were testing the interface, not their IT skills. If the PI detects that the participants feels frustrated or upset then they will be encouraged to talk informally about their experience of using the interface. The PI will continue to counsel that the difficulties encountered where entirely the fault of the interface; the experience observed and shared is valuable for the improvement of the programme. The PI will ensure that at least 30 minutes is scheduled beyond the anticipated end of each testing session to allow for delays or the need to offer counsel.

8. How will you disseminate the results to user groups? And relevant industry?

The usability testing comprises part of a programme of research to co-design and prototype a new interface for use with power assisted exercise equipment. The interface will be adjusted according to the findings of the usability test and this will inform the design of an advanced prototype machine. Further funding to advance and test the prototype will be sought. The participants will be invited to experience the advanced version of the machine through either virtual or real world methods depending upon their preference and the restrictions abided due to COVID-19. The research methodology, data analysis and findings will be disseminated through publication in neuro-engineering journals and relevant conferences.

PIS:

- I'm not sure it is wise to have your work address on the letter in case participants try to post material including consent forms and you will not be there to collect.
  Is the mobile number of the PI a work mobile or personal mobile number? I would recommend not using a personal mobile number.

The postal address has been removed from the invitation letter and the mobile number is allocated for work purposes by the PI.

- Has the PIS been reviewed by a patient representative? The wording doesn't feel like it is written for a lay audience; the readability score is a little too high for the general public

The PIS has been sent to a patient representative with stroke to ensure any complex or unclear use of language is identified and amended.

- I think there needs to be information on where participants can view the University GDPR policy in more detail if they want to.

The SHU policy on research and data management has been added as a weblink in the PIS.

- P6Q2 –Please check that current SHU policy allows the payments listed to research participants (policy does change)

I have reviewed the SHU policy on incentives for participation in research. Retail vouchers which can be used at a wide range of outlets are permitted as gratitude for participants who commit a considerable amount of time to support data collection. I have reduced the amount to £10.00 Amazon voucher to reduce risk of 'incentivised recruitment.' This is now detailed on the PIS.

- Please confirm that there are no financial nor other beneficial links between the manufacturer Shapemaster and the PI and her supervisors.

A legal research agreement exists between Shapemaster and SHU to protect all parties and avoid conflict of interests from arising.

6.3: Extracts from quantitative data analysis

Usability observation form

LIVE EXERCISE PAGE

Test 1 Familiarisation

Usability | **User narrative and interaction with interface**

Problem	Severity 1-4	Participant comments	Observation
		So would I click on start?	Navigated to start after I prompted the machine would be still
		You've got a nice picture of a mountain road, stated she liked it when asked	
		It's something more than staring at a screen full of numbers	

Test 1 Tasks | **Test 1**

Usability | **User narrative and interaction with interface**

Problem	Severity 1-4	Participant comments	Observation
Did not interpret effort feedback		People would maybe need some experience of using technology before, may be videos	
		Everything is labelled, so it's not just a triangle for start, it says start, I think it's clear	Navigated to start icon
		I can see how to pause or stop, I can see how to get help, I can see how to go back, I can see how time is going up and back down	
		Did not recognise the effort feedback but might have been more obvious if on the machine.	
		Help icon visible (when prompted)...you could have the help icon bigger than the others	Task 2: Navigated directly to start exercise and then help icon within 4 seconds

Test 2 | **Test 2**

Usability | **User narrative and interaction with interface**

Problem	Severity 1-4	Participant comments	Observation
		So if you click on effort does it tell you how much effort you're putting in?	
		So now it's an expanding circle, it makes more sense than before.	

Inferential calculation example

PU Version 2 Total PSSUQ	
REP1	1.91
REP2	1.33
REP4	1.066
REP6	1.71
REP7	1.55
REP8	1.28
REP10	1.2
Mean	**1.43514286**
SD	**0.30025291**

EU Version 2 Total PSSUQ	
PWS1	1.33
PSW2	1.61
PWS3	1.47
PWS4	1
PWS5	1
PWS7	1.18
PWS8	1.5
PWS9	1.46
PWS10	2.05
Mean	**1.4**
SD	**0.32756679**

Independent Sample T-Test		
EU Mean	1.4	0.3
PU Mean	1.43	0.32
P value	0.827	
Conf Int	-0.3	0.37

Appendix 6.4: Large images of GUI

6.5: Rebuttal to feedback following peer review by Journal of NeuroEngineering and Rehabilitation

Evaluating the Usability of a Co-Designed Power Assisted Exercise Graphical User Interface for People with Stroke.

Thank you for the opportunity to respond to the reviewer's comments which were comprehensive and constructive and have enabled the team to revise the article with amendments to all sections.

Notably, we have added more direct reference to and comparison with state of the art examples from the usability literature within the background and discussion sections and further justified the methods employed. Ten additional referenced sources are now cited within the manuscript to demonstrate the wider reading guided by the reviewers. The limitations of the current study have been discussed in further detail and we have aimed to further clarify the application of the medical device technology framework and the current state of play achieved through the reported study.

We believe that by addressing the reviewer's comments this has substantially improved the manuscript and we hope that it now meets the journals high standards for publication. However, if further amendments are required we would be more than willing to act on them.

All changes are highlighted in yellow on the revised manuscript and a response to each comment is detailed below in italics font.

Reviewer 1:

I added line numbers to specify comments on parts in the text. If another review round should be needed, the authors should optimally add line numbers in their submission.

Thank you, we have added line numbers.

Abstract: I would suggest revisiting the consistency of numbering (ten or 10), e.g., "twenty-two" issues vs. "24 new usability issues."

Numbers which open a sentence are presented as words whereas numbers inserted within a sentence are numerical. We will be happy to change this format if required.

Line 180; "stage"

Thank you for noting this typo, we have corrected it (L192).

Instead of citing a web consortium ([20]), I would suggest citing the ISO 9241-11 or -210 standards, which provide a validated, commonly agreed-upon definition of usability.

We have accessed and cited the following source: 'BS EN ISO 9241-11:2018: Ergonomics of human-system interaction. usability: Definitions and concepts (2018). British Standards Institute.'

Titles of the figure captions are inconsistent in main manuscript and individual figure documents

Thank you for noting this, the figure captions have been corrected and are now consistent

Figure 1 does not really introduce the device clearly enough. Consider adding a real picture of a user (e.g. PU together with EU), using the Cross Cycle machine.

We have searched the images library and cannot access a photograph of a user on the Cross Cycle machine. However, we have a good image of a user with therapist on the Chest and Legs machine which was ranked second most popular during preliminary consensus methods [13] and this is now featured as Figure 2. We have added two extra sentences (L270-L272) to introduce the machine and broader context of the longer term project.

Most of the technological and scientific state-of-the-art introduced in the discussion is prior work of the authors. Although these findings are indeed relevant, more external references would strengthen the gap addressed and the impact created by this work.

We have added three new references to the introductory paragraph. The article published by Bossink et al. [9] (L155) reports on a trial of whole-body power assisted exercise equipment amongst a group of adults with profound intellectual and multiple disabilities and contributes to the evidence supporting its accessibility. The study by Jacobson et al. [10] examined the physical impact of a 12-week programme of power assisted exercise amongst a sample of older adults which detected improvements in strength and balance performance (L159-161). The research by Linder et al. [12] reports on the physical benefits of motor assisted cycling amongst people with stroke (L162-163).

The authors could better highlight the intention and benefit of the approach taken by Shah et al. by listing examples of state of the art developments that took this approach to e.g. improve technology acceptance and/or usability.

Two previous examples of co-design and usability testing programmes underpinned by the medical device technology framework have been added to the third paragraph of the introduction [21,22,23,24] (L181-187). An additional paragraph which identifies alternative design models/methods and justifies selection of the medical device technology framework has been inserted (L195-206).

I personally find the terms PU and EU a bit confusing. As far as I understand, PU are the secondary user group (clinicians) and EU the primary user group (PwS). If this is the case, this should be better detailed early in the manuscript.

Thank you for highlighting this point. We have introduced a clearer definition of the terms in paragraph four (L203-205) and additional explanation on L234-236.

It seems like graphics from Version 1 and Version 2 of the GUI do not show the exact same tasks and functions. For example, no user login task is mentioned for Version 2. Comparing versions that do not entail the same tasks and functions limit the outcomes of the evaluation and interpretation of the usability improvements. It should be clearly highlighted why this was the case or be listed in the limitations.

Thank you for noting this. Version 2 of the GUI did include the same tasks and functions including user login and programme selection. Figures 8 and 9 has been amended to illustrate this.

I would suggest adding more detail to the figure captions. In the version provided, the captions only consist of titles.

This is a good suggestion. Captions have been added to all figures.

From the abstract and early methods section, it is not abundantly clear that this work entailed a mixed method approach with both quantitative and qualitative (e.g., Think Aloud) methods. Carefully outlining this would further strengthen the scientific value of this work.

The abstract now states that a mixed method approach was adopted (L60). The opening paragraph of the methods section outlines the mixed method approach adopted (L248) and identifies how quantitative and qualitative data was collected and analysed. (L257-262).

If I understand correctly, the same users tested and evaluated both, version 1 and version 2. While such intra-subject comparisons are interesting, a truly unbiased usability testing would request to use a different user group for testing the improved GUI version. Participants are likely to rate the second, "improved" version higher given that they understand this was the work's overall goal. This limitation should be clearly outlined in the discussion.

Thank you for highlighting this and we do agree that this was a methodological limitation. This is now acknowledged in the discussion section (L1158-1161).

Table 3 might be better visualized in – or complemented with - a linear, graphical representation rather than a Table format. It is difficult to understand where in the user journey, version 2 consisted of more/different tasks and features.

We have created a new figure (Figure 4) which illustrates the timeline and schedule of tasks conducted during test one and test two on the two version of the GUI.

The discussion is thorough and helps to connect the results and insights generated. Further, a more extensive comparison to state-of-the-art studies would potentially strengthen the work by highlighting the novelty more clearly.

We have extended comparison with previous comparable studies within the discussion, specifically;

- *Identified studies which have collected and analysed more in-depth qualitative data to gain a rich understanding of the user experience [10, 21] (L996-999)*
- *Compared our experience of collecting 'think aloud' data with the study conducted by Wildenbos et al. [49] and highlighted the additional layer of information generated through 'think aloud' compared with user satisfaction questionnaires [36] (L1041-1045)*
- *Further compared our experience of user satisfaction survey with that reported by Feingold-Polak et al. [35] (L1067-1071).*

The impact of this work beyond the benefit for should be for Shapemaster Global should be further detailed. User-centered design approaches and dedicated usability studies are highly relevant to the field of rehabilitation engineering/robotics. Can this approach be re-used for similar technologies? Did you create or help lead the way to generate evaluation benchmarks?

We have added an extra paragraph towards the end of the discussion (L1112-1125) which summarises our application of the medical device technology framework with specific reference to the adoption of synchronous remote usability testing. The potential for the reported study to serve as an example in the development and testing of future technologies is identified.

Reviewer 2:

1. As the conducted research study is quite huge that should be mount upon large nos. of end users. A higher confidence level requires a larger sample size. Larger sample sizes allow researchers to better determine the average values of their data and avoid errors from testing a small number of possibly atypical samples. The present study has conducted with limited nos. of participants or lesser user groups which is a major limitation of the research study.

Thank you for highlighting this important point. We used the probabilistic model of problem discovery described by Sauro and Lewis to determine sample size based on a 95% likelihood of detecting usability problems with an estimated 15% probability of occurrence (L320-321. We agree that if we had calculated sample size on a higher likelihood of detection (eg. 97.5%) or lower probability of occurrence (eg. 5%) then a larger sample would have been required. We have acknowledged this in the methodological considerations section in the discussion (L1163-1165).

Comparable usability studies on stroke technologies have typically used smaller samples; for example, Moineau et al. [33] recruited 11 PwS, six rehabilitation professionals and two caregivers to evaluate a novel functional electrical stimulation garment. Najin et al. [34] recruited ten PwS to test a virtual reality gaming system and Burdea et al. [32] usability tested an assistive game controller on two healthy participants without any involvement of representative end users.

We detected 22 different usability issues on the testing of version 1 and 24 new usability issues on the extended programme evaluated on version 2. We are confident that given the heterogeneity within the PU and EU samples and the number of usability issues detected that sample size did not adversely affect the robustness of the usability evaluation reported in this article.

2. In the entire manuscript, authors failed to mention about why they have taken selected usability evaluation method, Think Aloud, PSSUQ, among severity scale, among other available options.

We have added justification for the selection of task completion, task duration, PSSUQ and think aloud in the methods section [L255-262].

3. Redundant data should be removed from the entire manuscript.

As identified, this was an extensive usability evaluation which yielded over 40 hours of audio-visual data and the PSSUQ results. In the development of this manuscript, the team were mindful of selecting data pertinent to the four underpinning objectives. We have trawled through the data included in the results section and believe that the data included in tables 8-11 are relevant to objective one, tables 12-17 relevant to objective two, tables 18-19 relevant to objective three and tables 20-22 relevant to objective four. In the most part, median or mean scores are presented to avoid extensive datasets. We acknowledge that the data within tables 9 and 15 is detailed but we wanted readers from clinical backgrounds to be able to recognise trends across the different participants. If you have identified specific sections of data which you believe to be redundant or would be more appropriate within supplementary materials then we will be happy to consider removal from the main manuscript.

4. Though, in the literature, many different research studies have been found published but, in the manuscript, authors didn't mention about the need of conducting such evaluation. What are different benefits/advantages of such usability evaluation.

Thank you for raising this point. We have addressed this gap in the manuscript and added several references (Burdea et al. [32], Jie et al. [26], Moineau et al. [33] and NaJin et al. [34]) to the introductory section. The importance of usability evaluation is highlighted in the context of rehabilitation technologies.

5. Background should be divided into sub-sections named Introduction followed by literature review.

We have added the following subtitles to the background section:

- *Power assisted exercise*
- *Medical Device Technology framework*
- *Usability evaluation*
- *Overview of article*

6. At the end of Introduction, one paragraph must be included describing about the organization of the entire manuscript.

Thank you for this recommendation, we have added a paragraph subtitled 'overview of article' which summarises content and organisation of the manuscript. (L229)

7. Limitations of the research study are not mentioned in the manuscript.

The discussion includes a section entitled 'methodological considerations' (L1130-1165) which identifies five key limitations associated with the study including challenges associated with remote testing and sampling.

8. In abstract, described results and conclusion are not aligned. Both should be rewritten and must be linked to each other.

Thank you for highlighting limitations within the content of the abstract. We have rewritten the methods section of the abstract (L60-L66) and believe this gives more clarity to the summary of the project. The results section outlines the usability occurrences across version one and version two of the GUI, task duration analyses and comparison of PSSUQ scores. The conclusion has been reworded to clarify its alignment with the results reported within the abstract.

9. In the conclusion part, authors are claiming that "the findings from this study will facilitate the transition from a high-fidelity prototype to a market ready version of the technology which will enable end users of PAE to identify, monitor and progress rehabilitation goals". It should be removed from the manuscript as the proposed results in the manuscript can not be generalised as they are based upon smaller sample size.

Thank you for this comment. We selected the word 'facilitate' as we agree that the study reported in this article has progressed but not finalised the development of the new technology. We have added a successive sentence (L1189-1191) which outlines the need to field test a late stage prototype as the next step in this process.

10. Why this research study is carried out. It should be highlighted and mentioned in the manuscript.

We have added a new sentence at the start of the 'overview of article' paragraph (L230-232) which states: 'The study reported in this article recruited representative user groups to evaluate the usability of two sequential versions of the co-designed GUI to optimise the usability and functionality of the new technology.'