



Developing healthcare professional training to promote exercise in prostate cancer patients

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Developing healthcare professional training to promote exercise in prostate cancer patients

By Rebecca R Turner

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

Supervisors: Professor Madelynne Arden, Professor Derek J
Rosario and Dr Elizabeth A Steed

Collaborating organisations: Queen Mary University of London,
Chesterfield Royal Hospital and Sheffield Teaching Hospitals

August 2020

**Sheffield
Hallam
University**

Candidate declaration

I hereby declare that:

1. I have not been enrolled for another award of 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 data within this thesis was carried out as part of a wider project. Where contributions have been made by my colleagues, this has been explicitly stated or references. 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 74,394.

Signed:

Date: 13.08.2020

Name	Rebecca R Turner
Date	August 2020
Award	PhD
Faculty	Social Sciences and Humanities
Director(s) of Studies	Professor Madelynn Arden

Abstract

Background

National Institute for Health and Care Excellence (NICE) recommends all men with prostate cancer undergoing androgen deprivation therapy (ADT) should be offered a 12-week supervised resistance and aerobic exercise programme, delivered twice-weekly, to reduce fatigue and improve quality of life. Healthcare professionals (HCPs) are in a prime position to support delivery of these recommendations, yet very few do.

Methods

The Medical Research Council (MRC) and Behaviour Change Wheel (BCW) guidance were used to develop an intervention for HCPs to provide exercise recommendation, support, and exercise referral for men on ADT. Initially, a systematic review of interventions to promote exercise behaviour in cancer survivors and a rapid review of the cancer clinical exercise recommendations was undertaken. Target behaviours for HCPs were identified from these reviews. Interview transcripts with thirty-five HCPs were then analysed using the Theoretical Domains Framework (TDF) to understand barriers to target behaviours. Intervention functions and behaviour change techniques (BCTs) were selected and the mode of delivery determined. The intervention was refined with the input of key stakeholders in the form rehearsal deliveries, focus groups and a workshop. The training package was delivered and evaluated at two NHS sites.

Results

From the literature reviews, seven target behaviours were identified to support the delivery of the NICE recommendations. Key barriers to target behaviours were identified, these included a perceived lack of time, concerns about patient capabilities to exercise and lack of awareness of the recommendations. Six intervention functions and twenty-two BCTs were included in the intervention. A face-to-face, half-day, interactive and skills-based training-package, with follow-up at 12-weeks was developed and delivered to seventeen HCPs. Delivery of all seven target behaviours was evident, although poor adherence to 'in clinic' audio-recordings limited fidelity assessment.

Conclusions

A feasible and acceptable training package for HCPs was developed that resulted in exercise recommendation, exercise support and exercise referral to men with prostate cancer on ADT. Further evaluation is required to further assess fidelity of the delivered behaviours.

Acknowledgements

I would like to express gratitude to every participant that has been a part of this research. To the NHS prostate cancer clinical teams involved within this research, for always making the time for me. Your enthusiasm for this project has been greatly appreciated. To the patients, hearing about your experiences of the exercise intervention and how it has made a difference to your physical and mental health is truly incredible and a reminder of why this research is so important. Thank you.

I would like to thank my supervisory team, for your guidance, encouragement, and academic expertise. Professor Maddy Arden, who took on the challenge of being my director of studies for the last half of my PhD. Your input has been invaluable, and you inspire me to continue within the field of health psychology. Professor Derek Rosario, thank you for providing me with this opportunity. You have taught me to always question everything and to try to finish my sentences (although, I am still working on the latter). You have always had time for me and guided me when things have been difficult. Most importantly, you have made this journey enjoyable for me. Dr Liz Steed, thank you for supporting me through all the challenges that come with a PhD. I have learnt so much from your great expertise and extensive experience. I have always felt like you have believed in me from the start, which has always been comforting. Professor Liam Bourke, my director of studies for the first half of my PhD and continued senior colleague. I am extremely grateful for your continual support, words of wisdom and the opportunities you have given me.

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Abbreviations

ACSM	American College of Sports Medicine
ADT	Androgen deprivation therapy
APEASE	‘Affordability’, ‘practicability’, ‘effectiveness’, ‘acceptability’, ‘safety/side-effects’, ‘equity’
BAUN	British Association of Urological Nurses
BAUS	British Association of Urological Surgeons
BCT	Behaviour change technique
BCW	Behaviour Change Wheel
BHF	British Heart Foundation
BMI	Body Mass Index
BUG	British Uro-Oncology Group
CALO-RE	Coventry, Aberdeen, and London – Refined
CCG	Clinical Commissioning Group
CNS	Clinical Nurse Specialist
COM-B	‘capability’, ‘opportunity’, ‘motivation’ and ‘behaviour’
COPD	Chronic Obstructive Pulmonary Disorder
CR	Cardiac Rehabilitation
CRF	Cancer-related fatigue
CRUK	Cancer Research UK
DoH	Department of Health
ERS	Exercise referral scheme
EXSEM	Exercise and self-esteem model
FITT	‘Frequency, Intensity, Time, Type’
GP	General Practitioner
HCP	Healthcare professional
HNA	Holistic needs assessment

HRQoL	Health-related quality of life
IM	Intervention mapping
MAP-IT	Matrix Assisting Practitioner's Intervention Planning Tool
MECC	'Make Every Contact Count'
MDT	Multi-disciplinary team
MI	Motivational interviewing
MRC	Medical Research Council
NETSCC	The NIHR Evaluation, Trials and Studies Coordinating Centre
NCCN	National Comprehensive Cancer Network
NCSI	National Cancer Survivor Initiative
NH	Nuffield Health
NICE	The National Institute for Health and Care Excellence
NIH-BCC	National Behaviour Change Consortium framework
NIHR	National Institute for Health Research
NPT	Normalisation Process Theory
PHE	Public Health England
PI	Principle Investigator
PR	Pulmonary Rehabilitation
PROMS	Patient reported outcomes
QoL	Quality of life
RA	Research assistant
RCT	Randomised control trial
SCT	Social Cognitive Theory
STH	Sheffield Teaching Hospitals
TDF	Theoretical domains framework
TTM	Transtheoretical model
WHO	World Health Organisation

Publications

1. **Turner, R. R.**, Steed, L., Quirk, H., Greasley, R. U., Saxton, J. M., Taylor, S. J., Rosario, D.J. & Bourke, L. (2018). Interventions for promoting habitual exercise in people living with and beyond cancer. *Cochrane Database Syst Rev*, 9, CD010192. doi:10.1002/14651858.CD010192.pub3
2. Bourke, L., **Turner, R.**, Greasley, R., Sutton, E., Steed, L., Smith, D., Persad, R., Farrin, A., Hewison, J., & Rosario, D.J. on behalf of all the STAMINA investigators* (2018). A multi-centre investigation of delivering national guidelines on exercise training for men with advanced prostate cancer undergoing androgen deprivation therapy in the UK NHS. *PLOS ONE*, 13(7), e0197606. doi:10.1371/journal.pone.0197606

Conference proceedings

- 1. Turner, R.R.,** Steed, L., Arden, M., Taylor, S., Sutton, E., Reale, S., Bourke, L., & Rosario, D.J. The development of a theory and evidence-based intervention to support healthcare professionals to promote and support exercise in prostate cancer survivors. *Centre for Behaviour Change, Behaviour Change for Health: current and emerging science and technologies'*, Online conference, 16th, 17th and 18th September 2020. **Oral presentation accepted**
- 2. Turner, R.R.,** Arden, M., Rosario, D.J., Taylor, S., Sutton, E., Reale, S., Bourke, L., & Steed, L. Development of a theory and evidence-based healthcare professional intervention to support exercise in men with prostate cancer. *Division of Health Psychology Annual Conference*, Bristol, 23rd-24th June 2020. **Oral presentation accepted but not delivered due to COVID-19 pandemic**
- 3. Reale, S., Turner, R.R.,** Sutton, E., Steed, L., Bourke, L., Taylor, S., & Rosario, D.J. The barriers and facilitators of exercise for men on androgen deprivation therapy for prostate cancer: Application of the Theoretical Domains Framework. *Division of Health Psychology Annual Conference*, Bristol, 23rd-24th June 2020. **Oral presentation accepted but not delivered due to COVID-19 pandemic**
- 4. Turner, R.R.,** Steed, L., Arden, M., Sutton., E., Bourke., L., & Rosario., D.J. (2019). Health professional's perceptions of supporting exercise in men with prostate cancer: Applying the Theoretical Domains Framework. *Division of Health Psychology Annual conference*, Manchester, 10th-11th July 2019. **Oral presentation**
- 5. Turner, R.R.,** Steed, L., Arden, M., Sutton., E., Bourke., L., & Rosario., D.J. (2018). Applying the theoretical domains framework to identify health care professional's barriers and facilitators to recommending and supporting exercise in men with advanced prostate cancer on hormone therapy. *Psychology, Sociology & Politics research conference*, Sheffield Hallam University, Sheffield, 17th December 2018. **Oral presentation**

6. Turner, R.R., Bourke, L., & Rosario., D.J. (2017). Current provision of exercise training for men with prostate cancer on ADT. *BAUS Academic section of urology annual meeting*, London, January 2017. **Oral presentation**

7. Turner, R.R., Steed, L., Arden, M., Sutton., E., Bourke., L., & Rosario., D.J. (2019). Health professional's perceptions of supporting exercise in men with prostate cancer: Applying the Theoretical Domains Framework. *CeBSAP external launch*. Sheffield, June 2019. **Poster presentation**

8. Turner, R.R., Steed, L., Sutton., E., Bourke., L., & Rosario., D.J. (2018). The development of a healthcare professional training package to support exercise behaviour in prostate cancer survivors: (the STAMINA programme). Sheffield Teaching Hospitals Research and Innovation conference. Sheffield, Sept 2018. **Poster presentation**

Dissemination of research

National Institute of Health Research Signal. (11th December 2018) *Supervised exercise sessions increase physical activity and fitness of cancer survivors.*

Retrieved from: <https://discover.dc.nihr.ac.uk/content/signal-000695/supervised-exercise-sessions-increase-physical-activity-and-fitness-of-cancer-survivors>

The wider context of the thesis

I was employed as a Research Assistant (RA) at a local NHS trust throughout my candidature as a PhD student at Sheffield Hallam University. This role as an RA was on a large research project named STAMINA (Supported exercise Trainings for Men with prostate caNcer on Androgen deprivation therapy), within which sits this project. The STAMINA project has received £2.5 million of funding from the National Institute of Health Research (NIHR) for five years. It aims to test whether a long-term supported exercise programme, integrated into the prostate cancer care pathway and delivered by Nuffield Health (NH) in the community, can help to reduce troublesome side-effects of treatment for advanced prostate cancer, androgen deprivation therapy (ADT) and be shown to be cost-effective. The project started in September 2018, with the preparatory work starting in August 2015, see Figure 0.1 for a timeline of the project alongside this thesis. The preparatory work included a national survey to understand usual care for men with prostate cancer on ADT, interviews with healthcare professionals (HCPs) to understand their views on exercise for this patient group and focus groups with patients to understand their determinants of exercise ADT. This work has been published in the following paper:

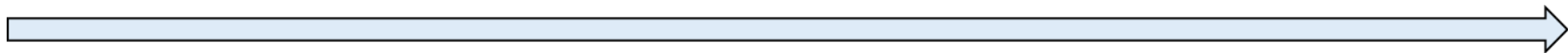
Bourke, L., **Turner, R.**, Greasley, R., Sutton, E., Steed, L., Smith, D., Persad, R., Farrin, A., Hewison, J., & Rosario, D.J. on behalf of all the STAMINA investigators* (2018). A multi-centre investigation of delivering national guidelines on exercise training for men with advanced prostate cancer undergoing androgen deprivation therapy in the UK NHS. *PLOS ONE*, 13(7), e0197606. doi:10.1371/journal.pone.0197606

The STAMINA project main trial will include over 44 NHS sites across the UK and their associated NH gyms being randomised as clusters to either intervention; 12-month supervised exercise intervention delivered as part of cancer treatment or to optimised usual care.

This project has several different work packages (see Figure 0.2). This thesis has specifically focused on understanding the advanced prostate cancer care pathway in two NHS sites (Chapter five). Developing, optimisation and refinement of the HCP intervention (Chapter six, seven and work package two) and delivering and evaluating the HCP intervention before the main trial (Chapter eight and work package three). This development has been running

alongside the development of the exercise professional intervention (NH staff) and the patient intervention; however, it is important to note that this work is outside of the scope of this thesis.

STAMINA timeline					
Programme development grant	Grant application	Programme grant (STAMINA)	Intervention development	Feasibility testing of intervention and refinement of the interventions	Main trial and process evaluation
2015-2016	2016-2018	Sept 2018	Sept 2018 - ongoing	May 2019 - ongoing	Sept 2020 - 2023



PhD timeline			
Healthcare professional interviews	Start of the PhD - Systematic review - Rapid review	Intervention development	Delivery and evaluation of the training package
2015-2016	Feb 2017	Sept 2018 - ongoing	May 2019 - Jan 2020

Figure 0.1: Timeline of the thesis alongside the STAMINA programme

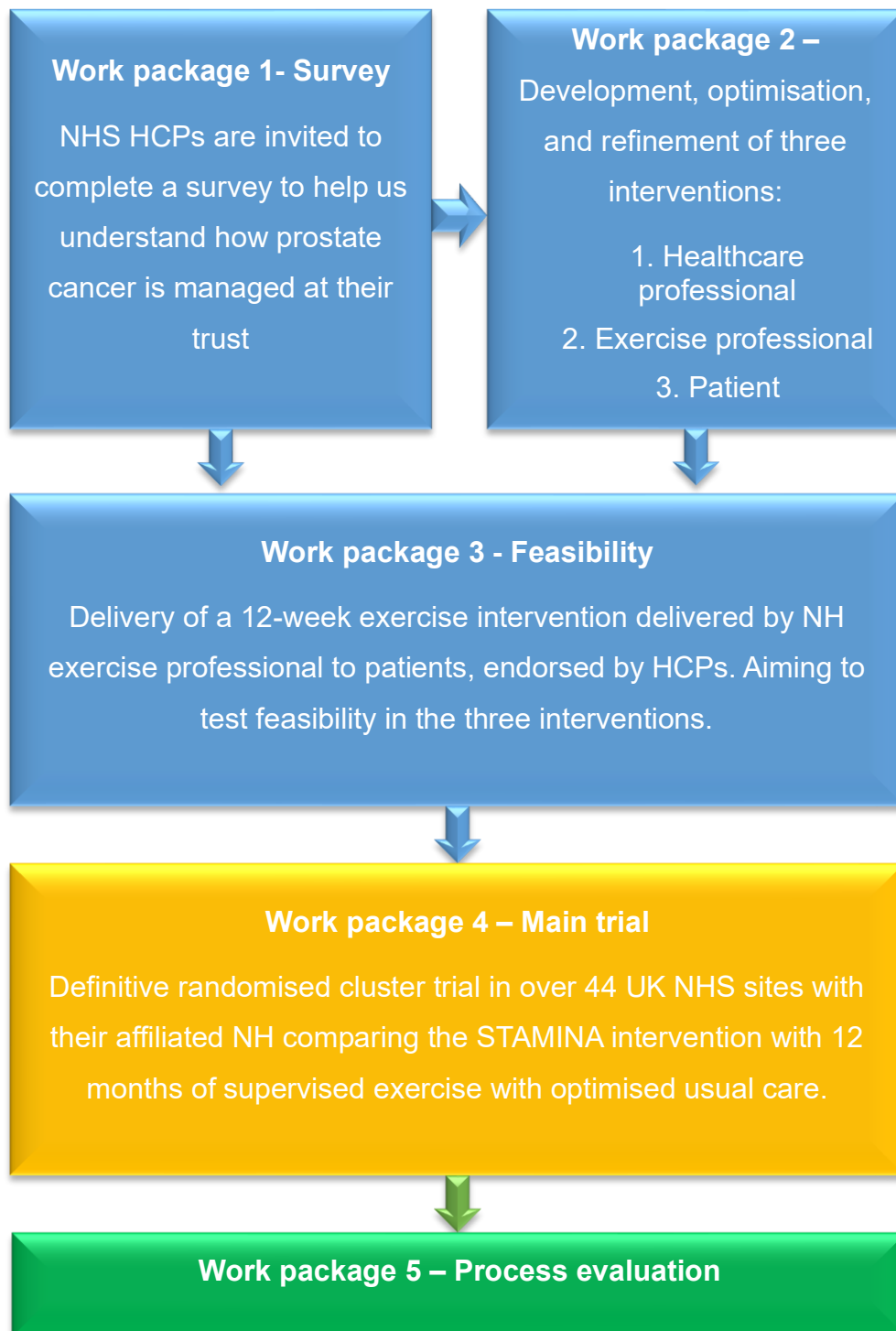


Figure 0.2: Overview of the STAMINA programme

Thesis structure

An overview of the thesis structure presented in a diagram can be found in Figure 0.3.

Chapter one: A review of the literature

A review of the literature is provided in three main sections. The first section includes details on cancer, cancer incidence and prevalence. The common treatments of cancer are discussed, with a focus upon the physical and psychological side-effects of these treatments. Non-pharmacological interventions such as exercise, which help to reduce some of these treatment effects, are introduced. Section two introduces the benefits of exercise to improve the physical and psychological health of cancer survivors. Reasons as to why exercise levels in cancer survivors are low are discussed, key determinants are explored. The important role of healthcare professionals (HCPs) recommending and supporting exercise in cancer survivors and reasons for why this does not reflect standard care is investigated. The literature on clinical behaviour change and embedding discussions about exercise into clinical practice is reviewed. The thesis aims and objectives are introduced.

Chapter two: Methodological overview

This chapter gives an overview of the different approaches to intervention development. The decision to use the Medical Research Council (MRC) and Behaviour Change Wheel (BCW) as intervention development frameworks is justified. As the aim of the thesis was to develop a complex intervention for HCPs, the decisions for methodologies are dictated by the proposed intervention development framework selected for this programme of research; this is presented throughout this chapter.

Chapter three: Identifying strategies for exercise behaviour change: A systematic review of exercise interventions for people living with and beyond cancer

This chapter presents a systematic review which aimed to identify strategies and intervention functions to promote exercise behaviour change in sedentary cancer survivors, particularly in the long-term, and thus would be important for HCPs to address.

Chapter four: What are the existing clinical recommendations for HCPs to follow for exercise in the top four most common cancers?

A rapid review

This chapter presents a rapid review of clinical exercise recommendations in the top four most common cancers, to understand what recommendations HCPs should be advocating in usual care. Integration of prostate cancer recommendations (as stated below) identified as part of the review are then explored as part of this thesis.

Chapter five: Recommending exercise in prostate cancer care

This chapter focuses on the extent NICE guidelines recommendations NG131, 1.4.19, *which state that all people who are starting or having androgen deprivation therapy supervised resistance and aerobic exercise at least twice a week for 12 weeks to reduce fatigue and improve quality of life* do not always reflect usual care and explores HCP barriers to discussing exercise with men with prostate cancer.

The first steps of the BCW process are applied within this chapter, to understand what HCP behaviours need to change and barriers associated with these behaviours.

Chapter six: Translating evidence into a theory and evidence-based HCPs training package to address key barriers using the behaviour change wheel

Following the MRC and BCW intervention development guidance, this chapter presents the first version of the HCP training package, including behavioural content and mode of delivery.

Chapter seven: Iterative refinement and optimisation of the intervention: Rehearsal delivery to one clinical team and using stakeholder workshops to gain feedback

Following the first version of the developed HCP training package, this chapter presents the refinement and optimisation of the training package from feedback in the form of rehearsal deliveries, stakeholder workshops and focus groups with clinical teams. Version two of the HCP training package is then presented.

Chapter eight: Intervention delivery and evaluation

This chapter presents the delivery and evaluation of the developed and refined HCP training package at two NHS sites. Behaviour, behavioural determinants, fidelity and acceptability were all assessed to evaluate of the training package.

Chapter nine: Discussion, conclusion, reflections

A final chapter of the thesis discusses the findings of all the studies within the thesis and considering the research, provides recommendations for future work and practice and conclusions are drawn.

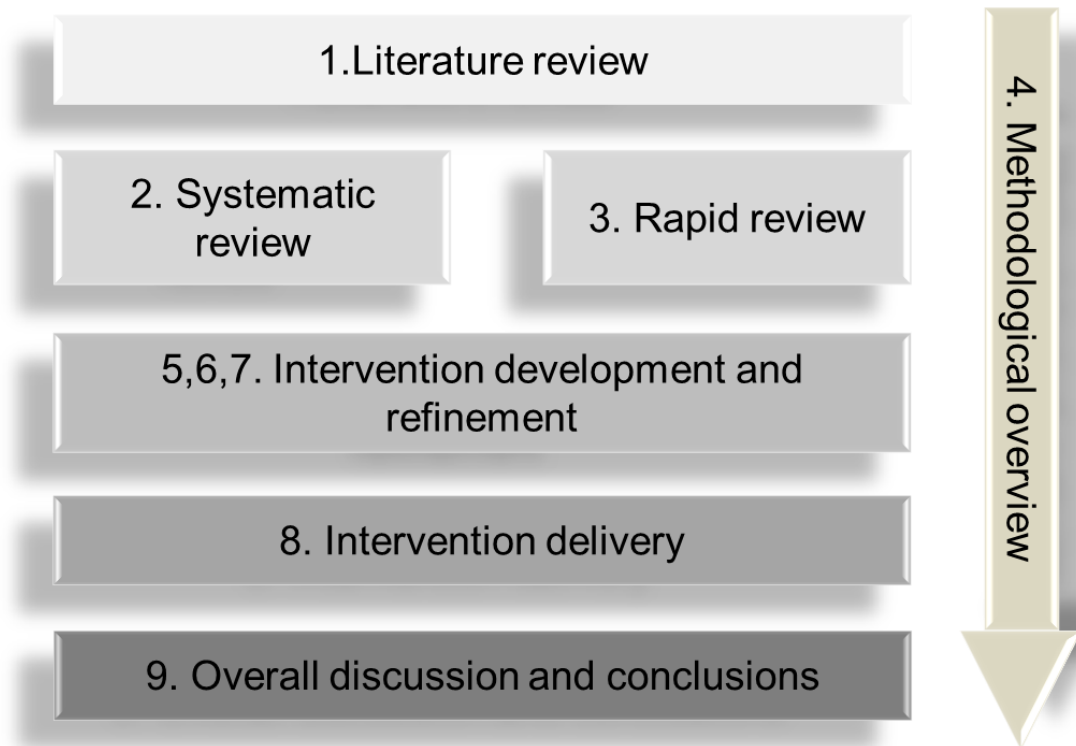


Figure 0.3: Thesis overview

1) Chapter one: A review of the literature

1.1 Cancer, treatment, and side-effects

The following section provides an understanding of cancer and its causes, cancer incidence, prevalence, and treatments. This section then proceeds to explore side-effects associated with treatments and challenges of cancer survivorship. Exercise is introduced as a non-pharmacological intervention to improve and manage treatment effects of cancer.

1.1.1 Cancer, its causes, incidence, and prevalence

Cancer is the term given to a wide-ranging group of related diseases. Cancer can occur anywhere in the body; cells change abnormally due to changes in our genes that control our cell function (NCI, 2015). These cells then divide uncontrollably, spreading into surrounding tissues (CRUK, 2019b; NCI, 2015). As these tumours grow, some of the cancer cells can break off and travel to a different part of the body via blood or lymph nodes, creating secondary cancer (NCI, 2015).

Cancer is a major public health problem and incidence rates are increasing. In 2016, there were over 17 million incidences of cancer across the world (Global Burden of Disease Cancer et al., 2018). In the UK, on average, there are 367,000 new cancer cases in the UK per year (CRUK, 2020). This is equally distributed with around 179,000 new cancer cases in females and around 187,000 in males (CRUK, 2020). Cancer is also a global cause of death; 8.9 million deaths from cancer globally were estimated in 2016 (Global Burden of Disease Cancer Collaboration, 2018) and around 165,000 deaths per year in the UK (CRUK, 2020).

Breast, prostate, lung or bowel cancer are the most common cancers, with over half of new cancer cases being one of these four cancers (CRUK, 2016). The two most common cancers; breast and prostate occur predominantly or exclusively in only one sex (CRUK, 2016). Table 1.1 presents the incidence data for the top ten most common cancers in the UK (CRUK, 2016).

Approximately 2.5 million people are living with and beyond cancer in the UK (Maddams, Utley, & Moller, 2012) with around 13% being over 65 years old (Elliott et al., 2011). The term 'cancer survivor' is commonly used for someone living with and beyond cancer (Macmillan, 2019). The number of cancer survivors is set to increase to four million by 2030 (Maddams et al., 2012). This is due to our increasing lifespan, improved screening and detection of cancer (de Moor et al., 2013). Table 1.1 presents the prevalence of cancer data in the UK for the top four most common cancers (Macmillan, 2015).

Table 1.1: Incidence data for the top ten most common cancers and cancer prevalence in the four most common cancers

Cancer type	Incidence in 2016		Prevalence in 2015
	Females	Males	
1. Breast	54541	355	691,000
2. Prostate	0	47640	330,000 (Male only cancer)
3. Lung	22342	25046	72,000
4. Colorectal	18626	23529	290,000
5. Melanoma skin cancer	8294	8080	
6. Non-Hodgkin Lymphoma	6265	7729	
7. Kidney	4714	8041	
8. Head and neck	3740	8374	
9. Brain, other Central Nervous System & Intracranial tumours	6022	5422	
10. Bladder	2846	7237	

Source: Cancer Research UK (2016) and Macmillan (2015)

1.2 Treatments for cancer

A cancer diagnosis is commonly perceived as traumatic and the different treatments can be disruptive (Cordova, Riba, & Spiegel, 2017). Due to advances in research, there are several treatments now available for cancer. These include; surgery, radiotherapy, chemotherapy, hormone therapy, immunotherapy, targeted therapy, stem cell transplant and precision medicine (NCI, 2019). Despite the increasing success of these treatments, they often come with severe treatment side-effects (Naughton & Weaver, 2014). Healthcare professionals (HCPs) have a pivotal role in prescribing these treatments but also managing the adverse effects for patients.

1.3 Cancer treatment side effects

Cancer survivors face several debilitating physical and psychological problems due to treatment effects. These problems may be short and long-term and persist throughout a cancer survivor's lifetime (Naughton & Weaver, 2014); even post curative treatment. Common experiences and physical side effects for cancer survivors include fatigue, pain, sexual dysfunction and reduced physical ability (Brearley et al., 2011). Psychological problems such as fear of reoccurrence, anxiety and depression are also common in cancer survivors (Jarrett et al., 2013). The accumulation of these problems often results in a poorer quality of life (QoL). HCPs perceptions of the most important side-effects or needs to address are aligned to cancer survivor's concerns. This was identified in a national survey which found HCPs considered the fear of recurrence, fatigue, changes in physical capabilities, anxiety and depression to be important to cancer survivors (Duncan. et al., 2017). I will now explore some of the most common side effects.

1.3.1 Cancer-related fatigue

Cancer-related fatigue (CRF) is reported as the most prevalent side-effect of cancer and cancer treatment and can persist for years even post-treatment (Stark, Tofthagen, Visovsky, & McMillan, 2012). There is no universal definition for CRF, but the National Comprehensive Cancer Network (NCCN) proposes the following definition "*A distressing persistent, subjective sense of physical tiredness or exhaustion related to cancer or cancer treatment that is not proportional to recent activity and interferes with usual functioning*" (Berger et al., 2015, p. 1020).

Prevalence estimates of CRF during treatment range from 25%-99%, dependent upon the patient population, types of treatment and how CRF was assessed (Bower, 2014). The variation in prevalence reporting highlights how CRF maybe underdiagnosed, underreported and undertreated (Berger et al., 2015). The mechanisms that cause CRF are not fully understood. They are thought to be multi-factorial and influenced by demographic, psychosocial, behavioural and biological factors (Bower, 2014). Low levels of physical activity and difficulties in acceptance of an incurable cancer diagnosis have also been identified as factors that are related to fatigue in a six-month observational study (Peters, Goedendorp, Verhagen, Bleijenberg, & van der Graaf, 2016).

1.3.2 Sexual dysfunction

Cancer and the different types of treatment can have detrimental effects on sexual function. A systematic review found these effects can include loss of libido and erectile dysfunction in men (Sadovsky et al., 2010). With women experiencing problems with vaginal dryness and other changes to the genitals (Brearley et al., 2011). Of which, all result in a decrease in sexual activity and sexual dysfunction. This is distressing and can impact upon cancer survivors' QoL and their partners' QoL (Vermeer, Bakker, Kenter, Stiggelbout, & ter Kuile, 2016). The topic of sexual dysfunction, despite its distressing effects, can occasionally go unaddressed in clinical consultations with HCPs. Interview studies have identified barriers to this. These include time-constraints, HCPs feeling uncomfortable to broach the subject, patient characteristics such as age or gender and concerns about not being able to treat sexual dysfunction (Canzona et al., 2018; Hordern & Street, 2007; Stead, Brown, Fallowfield, & Selby, 2003).

1.3.3 Reduced physical functioning

Within the literature it is well-accepted that physical functioning deteriorates following cancer treatment. Typically, if patients suffer from burdensome symptoms, they report reduced physical ability. In a sample of 359 older adults with cancer, physical impairment was associated with a high symptom burden such as feeling drowsy, suffering from pain, disturbed sleep and low mood (Pandya et al., 2019). When measured objectively, physical functioning may be an important biomarker to measure, as it is associated with mortality in cancer survivors (Brown, Harhay, & Harhay, 2015).

1.3.4 Anxiety and depression

Anxiety and depression are common responses to a life-threatening event such as cancer. Cancer survivors experience higher anxiety levels, higher levels of depression and poorer QoL than a healthy population. A systematic review and meta-analysis found that around 10-20% of cancer survivors suffer from depression and or anxiety (Mitchell et al., 2011). Depression and anxiety can lead to poorer QoL and even reduced survival (Pitman, Suleman, Hyde, & Hodgkiss, 2018). Anxiety may also provoke reassurance-seeking behaviours, leading to patients contacting their clinical teams. However, this had been found to only temporarily relieve anxiety (Lewis et al., 2009). Further support needs to

be established to support mental health in cancer survivors (Duncan. et al., 2017).

1.3.5 Health-related Quality of life

The literature around health-related quality of life (HRQoL) contains “a *bewildering array of characterisations*” (Ferrans, 2005, p. 14). Whilst there is no commonly accepted definition for HRQoL, there is a consensus that it is multi-dimensional. Mishra et al (2012) identified from an expert consensus that there are five domains of HRQoL; these are subjective assessments of physical, psychological, economic, social, and spiritual well-being.

The experience of a potentially life-threatening diagnosis and uncertainty can greatly influence a survivors QoL (Franks & Roesch, 2006). A significant proportion of cancer survivors experience poor HRQoL (Duncan et al., 2017) and this has been linked with survival (Hauser, Stockler, & Tattersall, 2006). A cross-sectional survey of 4892 individuals, of which 780 had a previous cancer diagnosis, found cancer survivors were more likely to experience poorer health and well-being in comparison to those with other chronic health conditions or healthy individuals (Elliott et al., 2011).

Despite more people surviving cancer, this does not necessarily mean they are living well. Regardless of the success of advances in current cancer treatment; the burden of the treatment effects and managing the side-effects is a controversial area that needs to be acknowledged. Non-pharmacological lifestyle interventions and survivorship support to help alleviate treatment effects and reduce risks should be explored.

1.4 Survivorship care

New initiatives have been established, such as the National Cancer Survivorship Initiative (NCSI), to prioritise the identification of the needs of cancer survivors within England. Following this, the ‘recovery package’ was developed in collaboration with the NCSI. The recovery package includes a holistic needs assessment (HNA), treatment summary, cancer care review, and a health and wellbeing event (Roberts et al., 2019). One of the key aims of the recovery package is to support self-management in the form of non-pharmacological interventions. More specifically, this includes promoting exercise within care to help with any unmet need’s cancer survivors may have. Whilst the recovery package is beneficial in providing cancer survivors with the

support they need to improve well-being and lifestyle (NCSI, 2013), it is unclear if this reflects usual care.

1.5 Non-pharmacological lifestyle interventions

A non-pharmacological approach can be defined as an intervention that does not involve any drugs or medicine but could include educational interventions, exercise interventions, dietary modification and talking therapies. The beneficial role of lifestyle influencing cancer prevention, treatment effects and survivorship has been shown in observational studies and randomised controlled trials (RCTs). A review of lifestyle factors within cancer survivors found factors such as exercise, smoking cessation and weight management were associated with better outcomes such as QoL and overall health (Vijayvergia & Denlinger, 2015). A review of systematic reviews of non-pharmacological interventions, physical activity was identified as a successful way to improve HRQoL in cancer survivors. However, few studies assessed outcome data beyond three months (Duncan et al., 2017). This finding was supported in a systematic review of exercise RCTs, where improvements in QoL were found in cancer survivors in the short-term (3-6 months), with long-term (over 6 months) data lacking (Mishra et al., 2012). Cognitive behavioural therapy has also demonstrated effectiveness in improving HRQoL (Duncan et al., 2017) and showed benefit in reducing anxiety and depression in cancer survivors (Gordon, Beesley, & Scuffham, 2011). Additionally, a recent systematic review found relaxation and cognitive behavioural therapy combined with physical activity improved CRF during cancer treatment (Hilfiker et al., 2018).

Despite evidence of the benefits of non-pharmacological interventions, they are unfortunately not routinely offered within the cancer care pathway (Duncan. et al., 2017). In comparison to other long-term illnesses, cancer care is behind in terms of provision of interventions such as exercise or psychological support (Howell et al., 2019). Some cancers are now deemed as chronic illnesses, as more people are surviving cancer than ever before. Therefore, non-pharmacological interventions need to be considered. This is also stipulated in the present NHS England long-term plan (NHS, 2019), which highlights the need to improve self-management strategies such as, exercise for cancer survivors, and is a key aspect of the recovery package. Thus, reasons for why

non-pharmacological support is not offered as part of routine care needs to be explored further.

1.6 Exercise as an important treatment component for cancer

This following section defines exercise; the benefits of exercise for cancer survivors are then discussed. The research around the uptake of exercise by cancer survivors and determinants of exercise is then evaluated.

1.6.1 Exercise ‘a healthy behaviour’

The positive effects of exercise on general physical and mental health are well-established within the literature. Exercise has been shown to have long-term benefits on health such as reducing risks of weight gain, obesity, dementia and has shown to improve diseases such as type 2 diabetes, obesity, chronic obstructive pulmonary disease and coronary heart disease (Cai, Li, Zhang, Xu, & Chen, 2017; Lahham, McDonald, & Holland, 2016; Reiner, Niermann, Jekauc, & Woll, 2013 & Woll, 2013; Yohannes, Doherty, Bundy, & Yalfani, 2010). The benefits of exercise have also been found for mental health such as depression (Cooney et al., 2013) and anxiety (Jayakody, Gunadasa, & Hosker, 2014).

The definition of exercise is “*a potential disruption to homeostasis by muscle activity that is either exclusively, or in combination, concentric, eccentric or isometric*”(Winter & Fowler, 2009, p. 451). However, the terms exercise and physical activity are often used interchangeably, as there is little difference between physical activity and exercise (Winter & Fowler, 2009). Throughout this thesis, I will refer to exercise and physical activity as stated by the authors of the papers I am discussing.

1.6.2 Exercise and the side effects of cancer treatment

The research area of exercise oncology has significantly progressed and is ever-expanding. The first association between exercise and cancer was identified in 1945 (Morris, 1945). Figure 1.1 provides a timeline of exercise and cancer research from 1945 until the present time, with recent changes to the exercise recommendations for cancer survivors.

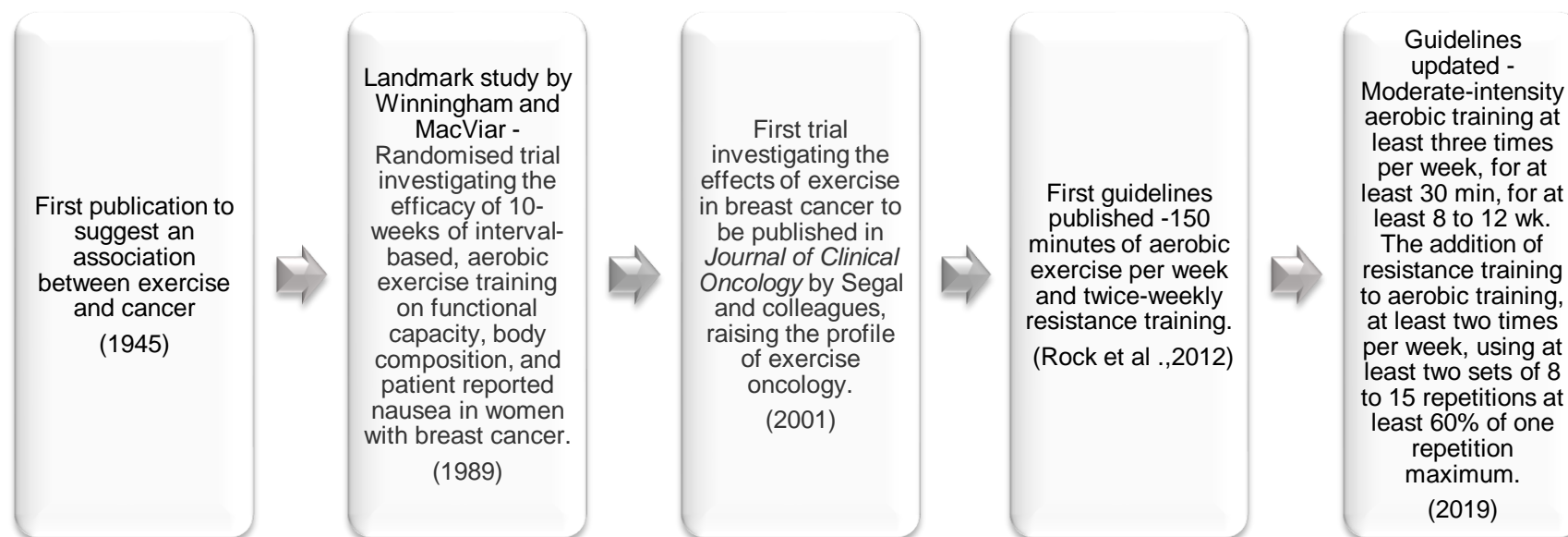


Figure 1.1: Exercise oncology research timeline

There is accumulating evidence including epidemiologic studies, RCTs and systematic reviews that have found engaging in exercise after a diagnosis can have a protective effect against cancer reoccurrence, adverse events of treatment and mortality (Cormie, Zopf, Zhang, & Schmitz, 2017). An overview of systematic reviews investigating the benefits of exercise for cancer survivors is presented in Table 1.2. This data demonstrates improvements in CRF, HRQoL, depressive symptoms, exercise behaviour, physical functioning, and body weight. As well as demonstrating benefit, the current evidence also suggests exercise is safe for cancer survivors, with few adverse events reported in these trials. Due to this evidence, exercise is internationally and nationally recommended to be a part of cancer care (Buffart, Galvao, Brug, Chinapaw, & Newton, 2014; Campbell, Stevinson, & Crank, 2012; Schmitz et al., 2010). However, exercise does not currently represent usual care for cancer survivors (Duncan. et al., 2017).

Table 1.2: Systematic reviews investigating the benefits of exercise for cancer survivors

Authors & date	Number of studies and participants	Cancer	Outcome(s)	Brief overview and findings
(Bourke et al., 2013)	14 RCTs with 648 participants	All cancers	Exercise behaviour	Cochrane systematic review and meta-analysis comparing the effects of an exercise intervention in cancer survivors in comparison to sedentary controls. Six of the trials included exercise prescriptions that would meet the current aerobic exercise recommendations for cancer survivors. No trials reported adherence of 75% or higher for these prescriptions. Despite, problems with adherence improvements in aerobic exercise tolerance were found at 8-12 weeks and six months. Many trials did have a high risk of bias, so caution is warranted.

(Brown et al., 2012)	40 RCTs with 2929 participants	All cancers	Depressive symptoms	Systematic search and meta-analysis to examine the efficacy of exercise to reduce depressive symptoms in cancer survivors. Exercise was found to provide a small overall reduction in depressive symptoms. Depressive symptoms were reduced to the highest degree amongst breast cancer survivors when exercise sessions were supervised.
(Kessels, Husson, & van der Feltz-Cornelis, 2018)	11 RCTs with 788 participants	All cancers	Cancer related Fatigue (CRF)	Systematic review and meta-analysis comparing the effects of an exercise intervention on CRF in cancer survivors in comparison to controls. The exercise demonstrated a large effect size for improvements in CRF. Improvements were found in aerobic and resistance exercise interventions, but the biggest improvements were found in aerobic exercise interventions. Adherence to the programme was found to be important for improvements in CRF, with low or moderate adherence showing small effect sizes.
(Meneses-Echávez, González-Jiménez, &	9 RCTs with 772 participants	All cancers	Cancer-related Fatigue (CRF)	Systematic review and meta-analysis comparing the effects of an exercise intervention on CRF in cancer survivors in comparison to controls. Multimodal exercise interventions including aerobic, resistance and stretching found

Ramírez-Vélez, 2015)				improvements in CRF symptoms. This was also found in patients undergoing chemotherapy.
(Mishra et al., 2012)	40 RCTs with 3694 participants	All cancers	Health-related quality of life (HRQoL)	Cochrane systematic review comparing exercise interventions with usual care for cancer survivors. Significant improvements were found in the exercise intervention arm in HRQoL and fatigue to the usual care arm at six months follow up. Further improvements were identified in specific HRQoL; self-esteem, social functioning and sexuality at six-month follow-up. At 12 weeks there were also improvements in pain, fatigue, emotional wellbeing and sleep disturbances.
(Fong et al., 2012)	34 RCTs	All cancers	QoL, body weight, Body Mass Index (BMI) and physical function	Systematic review and meta-analysis comparing physical activity interventions to usual care for cancer survivors who had completed treatment or still on hormone therapy. Physical activity was found to have positive effects on quality of life, body weight and reduction in BMI. Specifically, in breast cancer patients' improvements were found in physical function.

1.7 Exercise in cancer survivorship

Despite the proven benefit of exercise, several studies have shown cancer survivors currently do not meet exercise recommendations. Data from a national US survey found only 14% of breast cancer survivors and 17% of prostate cancer survivors met both aerobic and resistance exercise training recommendations (Ottenbacher et al., 2015). These low levels of exercise amongst cancer survivors have been found in other large surveys. A survey was undertaken by the department of health (DoH) assessed physical activity levels in cancer survivors. Using a single measure of activity, 20% of cancer survivors were found to be participating in at least 30 minutes of exercise on five or more days per week (DoH, 2012), with 30% of cancer survivors not undertaking any physical activity at all. In comparison with the general public, around 61% of UK healthy adults meet these physical activity recommendations (BHF, 2018).

Research has also investigated whether exercise decreases following a cancer diagnosis. A prospective cohort study of 942 participants measured physical activity and sedentary behaviour before and after a cancer diagnosis. Self-report measures were collected every year for six years. Physical activity decreased after diagnosis, with sedentary behaviour increasing (Fassier et al., 2016). However, there is also some evidence to suggest that healthy lifestyle behaviours may be adopted following a cancer diagnosis which acts as a teachable moment.

1.7.1 The teachable moment

A teachable moment is *“a set of circumstances or particular event which leads to an individual to alter their health behaviour positively”* (Lawson & Flocke, 2009, p. 2). A teachable moment has been suggested to be dictated by three domains (McBride, Emmons, & Lipkus, 2003). 1) The extent to which an event and or experience increases an individual's perceived risk to their health and or outcome expectancies. 2) The extent to which an event and or experience triggers an emotional response. 3) The extent to which an event and or experience redefines an individual's social identity. Teachable moments can be opportunities created through the clinician-patient interaction (Flocke et al., 2014). Messages that may be delivered during this teachable moment may be reinforced by highlighting the benefits of healthy behaviours such as exercise

and discouraging unhealthy behaviours such as smoking (Hawkins et al., 2010). A cancer diagnosis may act as a teachable moment, resulting in positive lifestyle change such as an increase in exercise (Demark-Wahnefried, Aziz, Rowland, & Pinto, 2005; McBride, Clipp, Peterson, Lipkus, & Demark-Wahnefried, 2000).

Within the existing literature, research has demonstrated the concept of the teachable moment in cancer survivors in relation to exercise. An RCT assessing treatment options for men with prostate cancer, (the ProtecT trial), found men with prostate cancer were shown to 'spontaneously' adopt 'healthy behaviours' following a diagnosis (Hackshaw-McGeagh et al., 2015). During the development process of a web-based intervention to improve QoL in cancer survivors, semi-structured interviews were conducted (Corbett et al., 2018). For many of the participants interviewed, the period following a diagnosis did not act as a teachable moment. However, there was a potential for a teachable moment, but HCPs were not using this opportunity to provide consistent advice or support. Often patients felt there was conflicting advice about exercise and a lack of genuine support from their clinical team.

1.7.2 Determinants of the uptake of exercise in cancer survivorship

Exercise levels are low amongst cancer survivors and the literature has identified several barriers to exercise in cancer survivors. The most salient barriers are presented in Table 1.3. The most common barriers cancer survivors have around exercise are around worries about the safety of exercise, exacerbating treatment effects, lack of perceived belief of the benefits of exercise and poor patient education or guidance from HCPs. Other barriers such as lack of time or poor weather were also highlighted. These factors include individual factors and factors outside of the individual's control. The COM-B ('capability', 'opportunity', 'motivation' and 'behaviour') model recognises this. The COM-B model is a model for explaining behaviour and or behaviour change (Michie, van Stralen, & West, 2011). The model proposes behaviour is part of an interacting system and includes individual factors such as perceptions of exercise and external factors such as a HCP discussing exercise with them (Michie, van Stralen, et al., 2011). Within this model there is no precedence placed on individual factors over environmental factors or vice

versa, as they all have an equivalent status on behaviour (Michie, van Stralen, et al., 2011).

Table 1.3: Evidence examining the barriers to exercise for cancer survivors

Authors & date	Type of study	Overview of study	Key barrier(s) identified
(Blaney, Lowe-Strong, Rankin-Watt, Campbell, & Gracey, 2013)	Questionnaire study.	456 cancer survivors completed a questionnaire to assess QoL, CRF and physical activity levels. Barriers to physical activity were also assessed. The questionnaire identified advice regarding how to improve fatigue was rarely given.	<ul style="list-style-type: none"> • Health and treatment-related factors such as fatigue • Environmental factors such as access to a gym or bad weather • Concerns around the safety of exercise
(Clifford et al., 2018)	Mixed methods systematic review	This review aimed to identify barriers and facilitators to exercise for cancer survivors. 19 studies (9 qualitative and 10 quantitative) were included in this review.	<ul style="list-style-type: none"> • Treatment-related side-effects • Lack of time • Insufficient patient education • Lack of belief of the perceived benefits of exercise to help improves fatigue.
(Eng et al., 2018)	Questionnaire study	1003 cancer survivors completed a one-time questionnaire retrospectively to assess predictors of physical activity change.	<ul style="list-style-type: none"> • Fatigue • Lack of motivation • Lack of belief of the perceived benefits of exercise

(Fernandez et al., 2015)	Cross-sectional online survey	30 cancer survivors, participating in a local physiotherapy exercise programme completed a one-time survey to understand barriers to exercise	<ul style="list-style-type: none"> • Received information about the exercise, but not why exercise is beneficial • Lack of awareness of programmes available • Treatment related side-effects
(Kampshoff et al., 2014)	Systematic review	The review aimed to review determinants of exercise adherence and maintenance in cancer survivors. 18 studies were included.	<ul style="list-style-type: none"> • No previous exercise history
(Ormel et al., 2018)	Systematic review	The aim of the review was to identify predictors to exercise for cancer survivors. RCTs comparing an exercise intervention with usual care involving cancer survivors were included in this review. 15 studies were identified with 2279 patients, of which 1383 were randomised to the exercise intervention.	<ul style="list-style-type: none"> • No previous exercise history • Location of the exercise facility • Poor physical functioning • Low motivation to exercise

(Smith et al., 2017)	Interview study	Interviews with 19 cancer survivors were conducted to explore their attitudes, knowledge, and barriers to exercise.	<ul style="list-style-type: none"> • Treatment related side-effects • Insufficient patient education • Weather • Lack of time • Lack of guidance from HCPs
(Wong, McAuley, & Trinh, 2018)	Systematic review	The aim of the review was to identify and differentiate physical activity programming and counselling preferences of cancer survivors. 41 studies were included in this review, which included both quantitative and qualitative studies	<ul style="list-style-type: none"> • Concerns about the format of the programme • Concerns about exercising whilst undergoing treatment • The desire for advice to be given by HCPs or exercise professionals within the cancer centre.

1.8 Capability, Opportunity, Motivation = Behaviour

The COM-B model is extensively used within behavioural science to explain behaviour and behaviour change. The model offers a starting point and can signpost to more specific psychological theories (Barker, Atkins, & de Lusignan, 2016). The model was developed to understand the minimal number of additional factors that need to be considered to explain whether a change in the target behaviour would occur if the motivation was present (Michie, van Stralen, et al., 2011). For this model to be developed the authors drew on several sources; a systematic review of 19 intervention development frameworks, a US consensus meeting of behavioural theorists and an established principle in US criminal law (Michie, van Stralen, et al., 2011).

To give an overview of the COM-B model; it is suggested that each component (see Figure 1.2) interacts in a system to produce a behaviour. Capability is twofold, psychological capability and physical capability. It considers whether an individual has the psychological and physical capacity to engage in the behaviour concerned (Michie, van Stralen, et al., 2011). Thus, is concerned with whether an individual has the necessary skills, knowledge, or memory. Motivation considers reflective motivation; our beliefs, goals and conscious decision making, and it also includes automatic motivation which considers habits and emotional responses. Opportunity is defined as factors that are outside of the individual, including social opportunity; so, factors such as social norms or peer pressures and physical opportunities such as resources, time, and environmental factors. As shown in Figure 1.2, the arrows represent the potential of influence of each component. Both capability and opportunity can influence motivation and enacting a behaviour can alter capability, opportunity and motivation (Michie, van Stralen, et al., 2011).

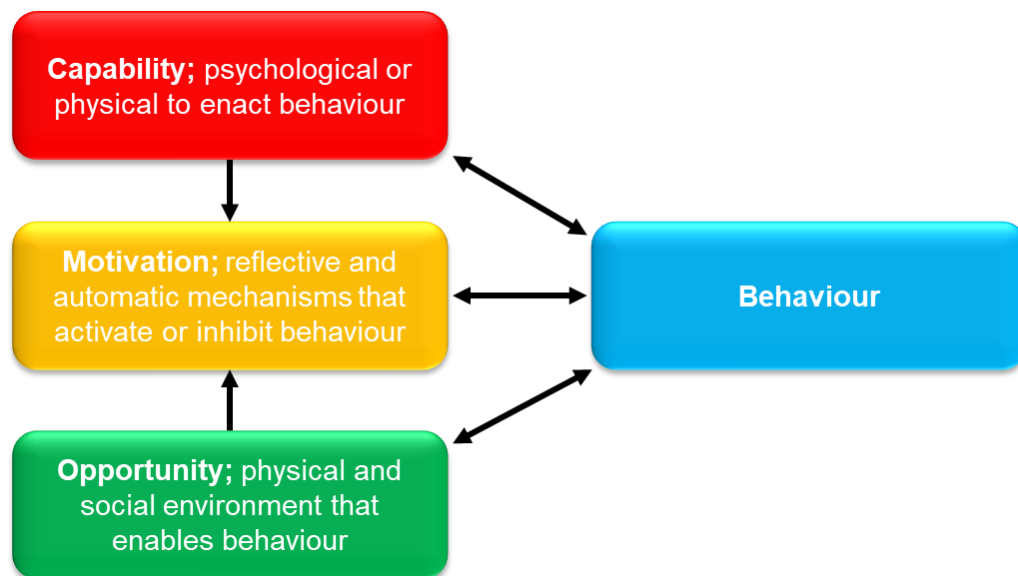


Figure 1.2: 'Capability', 'Opportunity', 'Motivation' = 'Behaviour'

The COM-B model can be and has been applied to several behaviours and contexts, such as understanding barriers to sexual health screening (McDonagh et al., 2018), identifying barriers to sedentary behaviour (Ojo, Bailey, Hewson, & Chater, 2019) and understanding barriers amongst HCPs discussing smoking with their patients (Smith, McNeill, Kock, & Shahab, 2019). Whilst specific psychological theories are context-specific, the COM-B model is a comprehensive model that can be flexible enough to analyse any behaviour in any context (Barker et al., 2016).

Table 1.4: COM-B components

COM-B component	Elements
Physical capability	Physical strength, skill, or stamina
Psychological capability	Knowledge or psychological strength, skill, or stamina
Physical opportunity	Opportunity afforded by the environment e.g.time, resources, location
Social opportunity	Opportunity afforded by social factors- e.g. cultural norms, social cues
Reflective motivation	Reflective brain processes e.g. plans and evaluations
Automatic motivation	Automatic brain processes e.g. desires, impulses, inhibitions etc.

Source (Michie, van Stralen, et al., 2011).

1.9 The role of healthcare professionals

This section of the thesis explores the important role of HCPs in delivering exercise advice to cancer survivors. The barriers to HCPs discussing exercise or following exercise guidelines are discussed in relation to the COM-B model. The literature on clinical behaviour change will then be reviewed.

1.9.1 Healthcare professional's role in exercise support and exercise referral

HCPs are critical and well-placed to support patients with lifestyle behaviours such as exercise. They have a unique opportunity to intervene, especially around the point of the teachable moment (Demark-Wahnefried et al., 2005). Additionally, their role is crucial if they are the gateway to a referral for an exercise programme. The important role of HCPs in supporting exercise is stated in the American College of Sports Medicine (ACSM) guidelines (Rock et al., 2012), National Institute for Clinical Excellence guidelines (NICE, 2013b) and Public Health England Making Every Contact Count Consensus Statement (PHE, 2016) and has been suggested to be cost-effective (Vijay, Wilson, Suhrcke, Hardeman, & Sutton, 2016). The promotion of exercise by HCPs has been shown to significantly improve health, levels of physical activity, QoL and psychosocial outcomes in several different patient groups (Keogh, Olsen, Climstein, Sargeant, & Jones, 2017). A recent trial demonstrated that 80% of participants reported a clinician referral influenced their decision to participate in exercise (Livingston et al., 2015). However, this trial did not aim to integrate exercise into the cancer care pathway, rather it just enabled a clinician to provide exercise advice and referral. Analysis of the 2005 and 2010 National Health interview survey data found HCP's exercise recommendation was associated with higher levels of physical activity among cancer survivors and adults without cancer (Tarasenko, Miller, Chen, & Schoenberg, 2017).

Exercise referral schemes (ERS) within the NHS such as cardiac rehabilitation (CR) demonstrate the importance of HCPs recommending exercise. The lack of HCP and multi-disciplinary (MDT) involvement in CR resulted in poor effectiveness and cost-effectiveness (Doherty & Lewin, 2012). For example, less than 5% of CR programmes across the UK had a doctor involved in the

programme and eligibility was rarely discussed with the MDT. In pulmonary rehabilitation (PR), a qualitative synthesis aiming to explore factors of participation for PR found the majority of patients attended because their doctor stated the benefits (Sohanpal, Steed, Mars, & Taylor, 2015). Additionally NICE identifies gaps in the current data and calls for more research to investigate the influence HCPs can have upon changes in lifestyle behaviour and what infrastructure is effective in supporting the delivery advice (NICE, 2014).

Whilst there is evidence to suggest the importance of HCPs recommending and supporting exercise. It is important to note that it is not always easy for HCPs to discuss exercise with their patients. To have a meaningful conversation around exercise requires more than a simple recommendation. HCPs are rarely discussing exercise or providing exercise support, which involves talking to patients about their thoughts and feelings towards exercise to cancer survivors. A survey of 400 cancer care HCPs identified that over half did not discuss physical activity with their patients (Macmillan, 2011). This was as high as 73% in GPs and 60% in oncologists. Less than a third of respondents from the colorectal cancer survivors Patient Reported Outcome Measures (PROMS) (total number = 15254) recalled a discussion around physical activity with their HCP (Fisher, Williams, Beeken, & Wardle, 2015).

In summary, exercise guidelines for cancer exist and the ACSM and NICE highlight the importance of brief physical activity advice from HCPs, but research suggests this is not happening in practice. Reasons for this need to be investigated further.

1.9.2 Recommending and discussing exercise and the determinants of healthcare professionals

Several barriers have been reported by HCPs to delivering exercise advice to cancer survivors and in other clinical populations. There are several factors for HCPs and clinical teams to change their practice based on new evidence-based guidelines, which may be important to address in future interventions. A systematic review identified 57 clusters of determinants of HCP practice (Flottorp et al., 2013). These included individual HCP factors, patient factors,

and guidelines factors. These are important to consider in the context of this thesis for the future development of a complex intervention.

The literature on HCP barriers are now discussed in relation to the COM-B model (see Table 1.4) which was shown earlier to be a helpful framework to understand any behaviour. Within the COM-B constructs, key themes have been identified and presented below. These findings have been summarised in a diagram using the COM-B model, (see Figure 1.3).

1.9.2.1 Capability

Physical

Skills

Having the appropriate skills to support and motivate patients is necessary. Being unskilled was identified as a barrier to discussing behaviour change with patients in an interview study with doctors and medical trainees (Chisholm, Hart, Lam, & Peters, 2012). Furthermore, research suggests, whilst advising on exercise is important, there should be a focus on addressing barriers and promoting engagement into exercise, therefore behaviour change skills and communication skills such as motivational interviewing would be necessary (Yang et al., 2017). Commonly within the research, HCPs express a want and need for further training in this area (Bourke et al., 2018; Nadler et al., 2017).

Psychological

Lack of awareness of recommendations

Whilst there are several factors involved in implementation of new recommendations into routine cancer care; HCPs firstly need to be aware of such recommendations. A lack of accurate knowledge around the appropriate guidance can act as a barrier to the HCP promoting exercise to patients but can also be confusing for the patient receiving such advice. Roberts et al (2019) interviewed 19 clinical nurse specialists (CNS) working in cancer care across the UK to understand physical activity promotion in their practice. One of the main challenges identified was a lack of awareness of clinical exercise recommendations for cancer survivors. Further challenges came with this, with a lack of knowledge of the benefits of strength training for this clinical

population, despite strength training being important in combatting loss of muscle mass (Keogh & MacLeod, 2012). This often led to the CNS's not discussing exercise, as they did not know exactly what should be recommended. Recommendations need to be specific about what is required and clear about the potential benefits to maximise implementation.

Remembering to discuss exercise

Remembering all the schemes and recommendations available to patients is likely to be difficult due to numerous competing demands. A recent intervention aiming to improve the promotion of physical activity amongst nurses to cancer survivors identified that HCPs needed memory and attention to remember to give brief physical activity advice (Webb, Foster, & Poulter, 2016).

1.9.2.1 Opportunity

Physical

Time pressures and resources

Time pressures and resources are frequent barriers reported amongst HCPs in terms of changing practice, especially within the current NHS climate. This can have an impact on the implementation of new recommendations. Over 50% of oncology HCPs (total n = 43) stated time pressures and not having a programme to refer to as the main barriers for not discussing exercise with cancer survivors in an online survey (Cantwell et al., 2018). This was closely followed by 49% of HCPs reporting a lack of resources, such as information leaflets, as being the third biggest barrier to not discussing exercise with their patients. An online survey with oncology nurses (n=274) specifically also identified time as the biggest barrier to physical activity promotion (Karvinen, McGourty, Parent, & Walker, 2012).

Access to an exercise referral scheme

A barrier to not discussing exercise from an HCP perspective is not having an ERS to refer onto. A questionnaire-based study with oncology HCPs identified that a lack of exercise programmes to refer to was a key barrier to discussing exercise (Hausmann et al., 2018). Furthermore, not having an identified

exercise professional or expert to contact was perceived as an additional barrier.

Social

Patients' support networks

Opinions of families, friends and wider support networks of cancer survivors are important barriers to consider. If the support network around an individual is present within consultations and are recommending 'rest is best' or to avoid exercise, this can act as a deterrent for HCPs to promote exercise with them. A cross-sectional survey of physiotherapists and nurses to understand current exercise promotion activities identified the patients' support networks views against exercise as one of the biggest barriers to broaching the topic of exercise to cancer survivors (O'Hanlon & Kennedy, 2014).

Whole clinical team approach

Members of the clinical team need to be aware that all the team are promoting the same message or following the same guidelines. If this does not happen, it can create issues with professional behaviour change. CNS's reported discussing exercise with patients as part of their role but highlighted that other members of the clinical team need to be promoting exercise, including primary care HCPs (Roberts et al., 2019). A systematic review found support from the whole team and department was associated with increased physical activity promotion in primary care (Huijg et al., 2015).

1.9.2.3 Motivation

Reflective

Assumptions of patients' motivation and capability

An online survey investigating cancer care HCPs (n=460) identified if HCPs thought their advice to cancer survivors would not be acted upon, they were less likely to discuss exercise (Williams, Beeken, Fisher, & Wardle, 2015). This study also identified that HCPs commonly made assumptions about the patients' capabilities; deeming them to be 'too frail or unwell' to take part in exercise.

Lack of perceived benefits for patients

A lack of conviction of the benefits of exercise is often reported from both HCPs (Williams et al., 2015) and cancer survivors (Clifford et al., 2018). Some research does suggest many HCPs are aware of the benefits of exercise for survivors. However, a recent cross-sectional survey found only half of treating clinicians for prostate cancer survivors thought exercise could help with side-effects of treatment and a quarter believing exercise was not safe (Spellman, Craike, & Livingston, 2013).

Safety of exercise for cancer survivors

The perception that exercise is safe for cancer survivors is crucial for HCPs. Roberts et al., (2019) found CNS's were concerned about the risks of exercise for cancer survivors and were overly cautious if they did provide advice around exercise.

Healthcare professionals own exercise behaviour

HCPs own behaviour and healthy habits, such as taking part in regular exercise, has been found to influence whether they support patients in the same healthy habits (McKenna, Naylor, & McDowell, 1998). A systematic review examined the relationship between HCPs own physical activity behaviours and their physical activity promotion practices in cross-sectional surveys (Fie, Norman, & While, 2012). Most studies included in the review found HCPs levels of physical activity was associated with physical activity promotion to patients. In contrast, an RCT evaluated the effectiveness of wearing a pedometer compared to a control group on general practitioners' attitudes to encouraging exercise to patients. No statistical differences were found between the intervention group and the control group for attitudes to engage in exercise or promote exercise to patients (James et al., 2009).

Not perceived as part of their role

Believing the promotion of lifestyle advice is not part of the HCPs role has been identified as a predictor to not discussing lifestyle with cancer survivors in a few studies. An online survey (n=460) found 25% of nurses, surgeons and

physicians do not perceive themselves as best placed to deliver lifestyle advice (Williams et al., 2015). Spellman et al (2013) found similar findings in a questionnaire study (n=31), with 55% of clinicians reporting that discussing exercise with prostate cancer patients was not part of their perceived role. This was further supported in an interview study which found NHS patient-facing HCPs perceived delivering behaviour change interventions outside of their professional remit (Keyworth, Epton, Goldthorpe, Calam, & Armitage, 2019).

Need to maintain a good rapport with the patient

The relationship that is established with the HCP and their patients is important in influencing behaviour. If a good rapport and relationship were in place. HCPs were found to be reluctant to discuss behaviour change with their patients due to potentially evoking an emotional response (Chisholm et al., 2012).

Automatic

Perceived as routine care

For conversations and support around exercise to be embedded into care, the new behaviours need to be carried out multiple times with feedback for the habits to be formed. Often research focuses on changing the habits of an individual, whereas changes to current routines or habits of the HCPs themselves are necessary. There is little published on the role of habits for changing HCP behaviour in cancer care. However, in more general research in this area, there is often a lack of consideration of habit, despite evidence suggesting habit is a predictor of behaviour (Nilsen, Roback, Broström, & Ellström, 2012; Potthoff et al., 2019).

1.10 Summary of factors of professional behaviour

In the current literature, capability, opportunity, and motivation were all found to be important in influencing HCPs behaviour to promote and support exercise. Generally, there is a lack of awareness of recommendations, a lack of resource and time and a desire for a good relationship with their patients. Additionally, there are several assumptions made by HCPs about exercise, patient capabilities, and motivations. There was also a need for further training in this behaviour change support. This literature demonstrates that research has

explored HCPs views on delivering exercise advice and support to cancer survivors, but there is still a lot to learn regarding how we overcome these barriers successfully and practically integrate exercise into the cancer care pathway. Furthermore, the research reviewed highlights gaps in the literature. There is a lack of research on the influence of habit on HCP behaviour in delivering exercise advice. However, this does not mean that this is not important to consider in a future intervention to change professional behaviour. Habit likely plays a big role in this type of behaviour and to try to change this behaviour, consultation habits may need to be broken and new ones formed (Nilsen et al., 2012). Furthermore, there is a lack of research investigating whole clinical team views on providing exercise advice and support. Research predominantly focuses on nurses' views (Yang et al., 2017). Whilst nurses' views are vital in understanding, capturing data from a wider clinical team would allow for further exploration of the barriers and facilitators.

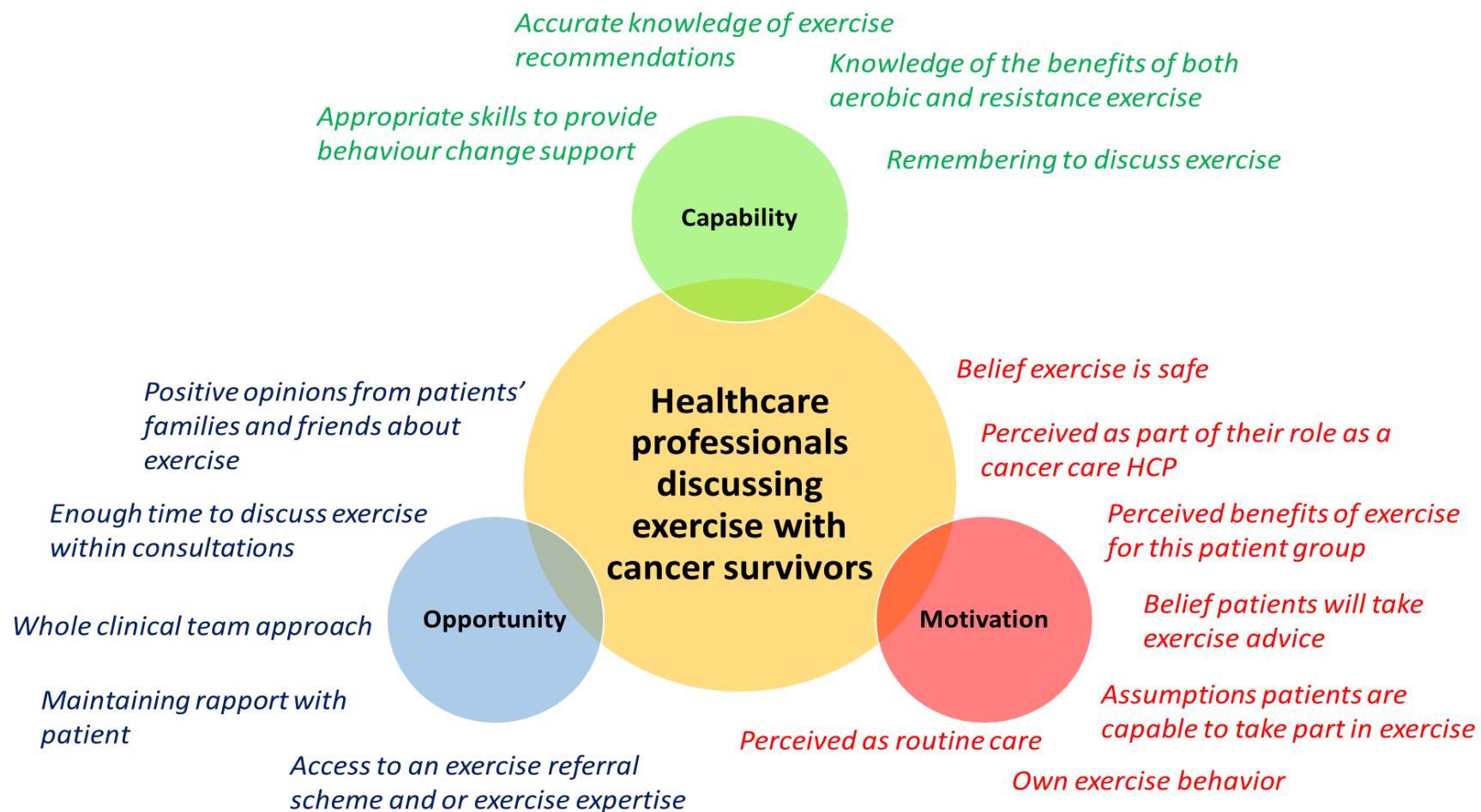


Figure 1.3: Healthcare professional barriers to discussing exercise with cancer survivors

1.11 Changing healthcare professional behaviour

New evidence for practices, breakthroughs with research and new technology within healthcare suggests regular changes to our healthcare system, resulting in improved well-being and QoL for patients (S. Dombrowski et al., 2016). However, new evidence to improve care does not mean implementation and it can be challenging to change HCP behaviour (S. Dombrowski et al., 2016). Within this thesis, I have identified a need for HCPs to understand exercise behaviour change and have the capability, opportunity, and motivation to support cancer survivors with exercise. However, there are multiple barriers reported by HCPs to discussing and supporting exercise and HCPs practice can be influenced by several factors.

Common behavioural interventions are often developed to tackle these barriers and range from educational, auditing and feedback and skills training (Johnson & May, 2015). Often these interventions target individuals as opposed to tackling whole clinical teams or organisations (Colquhoun, Squires, Kolehmainen, Fraser, & Grimshaw, 2017). Educational interventions are the most common type of intervention to target HCP behaviour. Whilst education is necessary to target, knowledge alone is unlikely to change behaviour but can raise awareness of the desired target behaviour (Grimshaw et al., 2001; Michie, van Stralen, et al., 2011). Combining educational interventions with other types of interventions is beneficial. For example, Johnson and May, (2015) carried out a systematic review of systematic reviews of the effectiveness of professional behaviour change interventions to understand specific characteristics that were successful. Results from 67 systematic reviews found key characteristics of interventions based on action such as audit and feedback, use of local opinion leaders and some elements of education were more likely to be successful. Audit and feedback were also found to lead to small but potentially important improvements in professional practice in a systematic review (Ivers et al., 2012). Financial strategies have also been suggested to be effective in changing clinical practice in some reviews, but interventions included in this systematic review had a high risk of bias (Flodgren, Eccles, et al., 2011). Whereas, financial incentives were found to not change clinical behaviour (Chauhan et al., 2017). Chauhan et al., (2017) carried out a systematic review of systematic reviews of professional behaviour change in primary HCPs. Training in communication skills improved knowledge, empathy and

professional expertise, which ultimately improved clinical outcomes in patients with chronic diseases such as cancer (Chauhan et al., 2017; Moore, Rivera, Bravo - Soto, Olivares, & Lawrie, 2018). More specifically, training that was learner-centred, experiential education ran by experienced trainers resulted in improved communication. However, it was unclear what type, duration or intensity of training was most effective (Moore et al., 2018). The use of information technology to aid prescriptions or clinical decision support systems has been shown to be beneficial in improving communication between HCPs and patients, facilitating appropriate anti-biotic prescribing and improving several patient outcomes (Chauhan et al., 2017). Whilst there was some evidence on the benefit of environmental restructuring and modelling in improving professional adherence to guidelines, the evidence was limited.

Overall, current evidence suggests changing clinical behaviours in the short-term. These generally include the use of education alongside the use of audit and feedback. Additionally, training HCPs in communication skills is beneficial for improving practice. This research highlights the importance of multi-modal interventions including several different features to target change. However, a systematic review of systematic reviews comparing the effectiveness of single-component and multifaceted interventions for professional behaviour change found the current evidence on the effectiveness of multifaceted interventions to change HCP behaviour is inconsistent (Squires, Sullivan, Eccles, Worswick, & Grimshaw, 2014).

1.11.1 Embedding exercise into standard practice

It is important HCPs are trained in evidence based approaches to support lifestyle behaviour change such as exercise (Bull & Dale, 2020). Currently, there is a lack of adequate support for HCPs on how to provide behavioural support (Bull & Dale, 2020). Furthermore, there is no formally recognised training package for HCPs on how to deliver exercise advice and behavioural support to cancer survivors. However, there have been a few previous attempts as follows.

A recent intervention to increase the frequency of nurses providing brief exercise advice with cancer patients was developed (Webb, Foster, et al., 2016; Webb, Hall, Hall, & Fabunmi-Alade, 2016). Capability, opportunity, and motivation were all identified as needing to change. The intervention was delivered either online or face-to-face, 44% self-reported an increase in the

frequency of delivering brief physical activity advice, 29% stated no change and 26% did not complete the follow-up survey. However, this intervention did not objectively measure an increase in physical activity advice or measure the quality of these conversations.

Wider approaches to encouraging HCPs to discuss exercise have been introduced by Public Health England (PHE) (Brannan, Bernardotto, Clarke, & Varney, 2019). PHE provides free training to groups of HCPs across England to encourage them to promote physical activity in their everyday practice; this is either face to face or online. This programme is yet to be evaluated but the main aim is to increase knowledge of physical activity amongst HCPs and their confidence in providing brief physical activity advice. Another example of a large initiative is Make Every Contact Count (MECC) (PHE, 2016), which is an approach for HCPs to have conversations around lifestyle. There are online resources available for HCPs involving the promotion of clinical communications skills. This approach has varied in implementation success (Chisholm, Ang-Chen, Peters, Hart, & Beenstock, 2018) and is yet to be evaluated on a large scale in a controlled way. However, this approach has investigated the behavioural determinants of NHS HCPs pre and post MECC training (Chisholm et al., 2020). Change in behavioural determinants except beliefs about their roles providing lifestyle advice were identified, following the completion of a 40-minute online behaviour change module (MECC training). Further feedback from qualitative elements suggested HCPs had felt their behaviour change skills around discussing lifestyle had improved. Bull and Dale (2020) developed a training programme for HCPs to increase their confidence in delivering behavioural support to patients. The training took a blended learning approach, over two days, teaching HCPs techniques to support their practice and person-centred conversational skills. Confidence, competence, and intention was assessed, which all improved significantly following the training, the training was also found to be acceptable. Whilst this approach needs further evaluation, it shows promising changes that could lead to behaviour change.

There have been different approaches in developing training packages or interventions to improve exercise discussions, these have often lacked the involvement of the whole clinical team and wider approaches are yet to be evaluated. A recent systematic review aiming to understand effective guidelines

dissemination strategies on cancer care HCPs' behaviour, recommended future research should focus on including the wider HCP team and not just one profession, which can influence social opportunity (Tomasone, Kauffeldt, Chaudhary, & Brouwers, 2020) and is more realistic as the management of patient usually happens as part of a MDT. Furthermore, interventions targeted HCP behaviour change are often poorly designed and lack comprehensive reported, limiting advances in knowledge (Flodgren, Parmelli, et al., 2011). Additionally, there is often a lack of measures of clinical behaviour within HCP interventions (Hrisos et al., 2009). Further exploration is required of how to overcome the barriers from varied HCPs around providing exercise recommendation and support in the development of a complex intervention.

1.12 Chapter summary

Cancer is a global health problem and numbers are set to increase. The treatment for cancer is multimodal and complex. Whilst new treatments can be effective at treating cancer, they often cause debilitating physical and psychological side effects. These include CRF, common mental health problems, reduced physical functioning; all resulting in poorer QoL. Non-pharmacological interventions such as exercise are effective at alleviating some of these treatment side effects. However, exercise levels are low amongst cancer survivors, despite the proven benefits. Cancer survivors report many barriers to not taking part in exercise; one of these key barriers is the lack of advice and support given from their treating HCP. HCPs have a critical role in promoting and supporting exercise, especially around the point of a cancer diagnosis, which is potentially a teachable moment. However, HCPs rarely discuss exercise due to several barriers including lack of time and resources, a lack of perceived benefit, lack of perceived role in discussing exercise and lack of confidence using behaviour change skills. These issues need to be tackled in a complex intervention, developed systematically to support clinical behaviour change.

This thesis will specifically focus upon why exercise recommendation, exercise support and exercise referral in line with NICE recommendations (NG131 1.4.19), *which state that all people who are starting or having androgen deprivation therapy supervised resistance and aerobic exercise at least twice a week for 12 weeks to reduce fatigue and improve quality of life* (NICE, 2019)

does not reflect usual care. Subsequently, a complex intervention for HCPs to tackle this issue will be developed, delivered, and evaluated. The decision to specifically focus upon prostate cancer care was pragmatic due to my involvement as an RA on the wider project STAMINA before undertaking my PhD as stated in the section on the wider context of this thesis, page 21.

1.13 Thesis aims and objectives

1.13.1 Research aims

The overall aim of this programme of research detailed within this thesis was to develop, deliver and evaluate a theory-based and evidence-based intervention for HCPs to recommend exercise, deliver exercise support and make exercise referrals for men with advanced prostate cancer on long-term Androgen Deprivation Therapy (ADT). All in line with NICE recommendations NG131 1.4.19.

This will make an original contribution to knowledge as a theory and evidence-based training package for HCPs to support the integration of the current NICE recommendations NG131 1.4.19 will be developed and evaluated. Currently, this does not exist, and these recommendations are not reflected in usual care for men with prostate cancer. Furthermore, this research will aim to include the whole clinical team and involve HCPs in the development, something which is often not achieved or reported.

1.13.2 Research objectives

1. Systematically review what specific strategies and or intervention features may improve exercise behaviour in cancer survivors.
2. Review the clinical exercise recommendations for HCPs in the most common cancers.
3. Understand HCP barriers and facilitators to recommending exercise, delivering exercise support, and making exercise referral for people with advanced prostate cancer on long-term ADT.
4. Develop a theory and evidence-based complex intervention for HCPs to recommend exercise, deliver exercise support and make exercise referrals for men with advanced prostate cancer on long-term ADT.
5. Refine and optimise the developed complex intervention using key stakeholders in the form of rehearsal deliveries and stakeholder workshops.

6. Deliver the complex intervention to two NHS clinical teams at two NHS trusts.
7. Evaluate the complex intervention via several assessments of behaviour, behavioural determinants, fidelity of enactment of treatment skills and acceptability.

2) Chapter two: Methodological overview

The methodological choices within this thesis were dictated by the proposed intervention development framework selected for this programme of research. This chapter reviews intervention development frameworks and provides a rationale for the chosen frameworks, subsequent methodologies, and approaches.

2.1 Intervention development frameworks

Complex behaviour change interventions are commonly used in health services research. They are fundamental to effective clinical practice and to improve the health of the public (Michie, Atkins, & West, 2014). Complex interventions contain several interacting components, often have many different outcomes, and target different groups or levels of organisations (Craig et al., 2008). The Medical Research Council (MRC) stated the intervention development phase of complex interventions is the period when the *“intervention must be developed to the point where it can reasonably be expected to have a worthwhile effect”* (Craig et al., 2008, p. 2). It is not a linear process and the start and endpoints are not always clearly defined (O’Cathain et al., 2019). However, they need to be developed critically and should be approached with methodological rigour (Hoddinott, 2015). If this intervention development phase is utilised to its full potential, the higher the chances are that an intervention will be effective and sustainable (O’Cathain et al., 2019). Previously, the 'traditional' approach to intervention design have focused upon defaulting to 'what works' and replicating this, without rigour (Craig et al., 2008). Avoidable mistakes are consequently made, due to insufficient considerations, resulting in research waste (Bleijenberg et al., 2018; Ioannidis et al., 2014).

Guidance has been produced around intervention development to encourage researchers to move away from this 'traditional' approach. O’Cathain and colleagues (2019) recently carried out a systematic review to understand the current guidance for intervention development. Eight categories of approaches to intervention development were identified, these included partnerships, target-population centered, theory and evidence-based, implementation-based, efficiency-based, stepped or phased based, intervention-specific and combination.

2.2 Theory and evidence-based guide to intervention development

One of the approaches to intervention development identified by O’Cathain and colleagues (2019) was a theory and evidence-based approach. The current MRC guidance highlights the importance of using a theoretical model or framework and evidence-base to develop complex interventions (Craig et al., 2008). In reference to behaviour change, theory explains why, when and how behaviour does or does not occur (Michie et al., 2014). As behaviour change is complex, theory allows researchers to identify the influences, understand the effective mechanisms of change, also known as the mechanisms of action in a specific context and inform implementation interventions (Atkins et al., 2017). To maximise the effectiveness of interventions, we need to have a theoretical understanding of behaviour change (Davis, Campbell, Hildon, Hobbs, & Michie, 2015).

This thesis explores theory and evidence-based approaches, due to the importance of developing interventions using theory and evidence. Examples of these intervention development theory and evidence-based approaches can be seen in Table 2.1 and those used in this thesis are discussed further in this chapter. The rationale for the chosen approaches is discussed in this chapter.

Table 2.1: Existing guidance or frameworks for intervention development

Guidance/framework	Authors	Brief description	Strengths	Limitations
Medical research council (MRC) guidance	(Craig et al., 2008)	The MRC guidance describes four phases of intervention development, these are cyclical. The four phases are developing, feasibility/piloting, evaluation, and implementation.	+ Well cited and well used in health services research (Craig et al., 2013).	-Provides little detail about the steps of intervention development (De Silva et al., 2014). -Does not recommend how to incorporate theory into the design and evaluation of complex interventions (De Silva et al., 2014).
Behaviour change wheel (BCW) including the Theoretical domains framework (TDF)	(French et al., 2012; Michie, van Stralen, et al., 2011)	The BCW offers a structured approach to intervention development. The BCW promotes a systematic and comprehensive analysis of the available options for intervention development using evidence and theory. It has three stages to development; understanding the behaviour	+ Comprehensive and practical guide to using theory to develop complex interventions (Michie, van Stralen, et al., 2011). +Integrates context into the framework, which is	- Need for substantial knowledge of the psychological processes to use the BCW (Hansen, Kanning, Lauer, Steinacker, & Schlicht, 2017).

		<p>within the context; identifying intervention options and identifying content and implementation options.</p> <p>The TDF is a comprehensive theoretical framework systematically synthesised from 128 theoretical constructs and 33 theories. It sits within the BCW and maps directly onto the COM-B model. The TDF was originally developed to explore implementation problems of evidence-based practice by clinical teams. The TDF now contains 14 domains of behaviour and provide a framework for understanding barriers and facilitators that need to be considered during intervention development, it is more specifically used within stage</p>	<p>often under-investigated or theorised (Michie, van Stralen, et al., 2011). +Using a comprehensive theoretical framework for behaviour change is better than using a single theory (French et al., 2012).</p>	<p>-Difficult to use and time-consuming (Michie, van Stralen, et al., 2011).</p> <p>-More emphasis is needed on the target population being involved in the intervention development process (Janols & Lindgren, 2017).</p> <p>-There is a lack of detail about how to undertake each step of the BCW when using the TDF (O’Cathain et al., 2019).</p>
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		<p>one of the BCW process. The TDF has four-step systematic approach based on guiding questions:</p> <ol style="list-style-type: none"> 1. Who needs to do what, differently? 2. Which barriers and enablers need to be addressed? 3. Which components could overcome modifiable barriers and enhance enablers? 4. How can behaviour change be measured and understood? 		
Intervention mapping (IM)	(Bartholomew Eldredge LK, 2016)	<p>IM has six structured and comprehensive steps to intervention development: (1) Undertake a needs assessment to develop a logic model of the issue. (2) Produce a logic model of the change process that leads to outcomes. (3) Design the scope, sequence, methods, and practical</p>	<p>+Structured and thorough approach to intervention development (Hansen et al., 2017)</p> <p>+Very rigorous approach (Wight, Wimbush, Jepson, & Doi, 2016).</p>	<p>-Very time consuming and costly (Hansen et al., 2017)</p> <p>-Does not offer the full range of intervention options (Michie, van Stralen, et al., 2011).</p>

		<p>applications of the program. (4) Produce the program including the materials. (5) Plan implementation and maintenance of the program. (6) Develop an evaluation plan.</p>		
Normalisation process theory (NPT)	(Murray et al., 2010)	<p>The NPT identifies factors that influence the implementation of complex interventions into routine care or practice. It focuses upon individuals and groups that enable the intervention to become normalised. There are four main interacting components to the NPT: coherence (sense making), cognitive participation (engagement), collective action (work done to enable the intervention to happen) and reflective monitoring (formal and informal appraisal of the benefits and costs of the intervention). The</p>	+Focuses on wider context issues and the interactions of individuals and groups (Murray et al., 2010)	-There is a lack of detail about how to develop interventions using the NPT (O'Cathain et al., 2019).

		wider context of the intervention such as the organisational context is also considered.		
Matrix Assisting Practitioner's Intervention Planning Tool (MAP-IT)	(Hansen et al., 2017)	The MAP-IT approach is constructed as a logical model following a rationale. It offers a systematic, time-saving, and easy approach to intervention development. The MAP-IT approach creates a matrix determined by the researchers focused on a specific behaviour for a specific age group. The researchers develop a matrix of personal and environmental mechanisms to promote the behaviour and relevant theories and functions of an intervention that could address each mechanism.	+Integrates personal and environmental factors (Hansen et al., 2017). +Easy to use and less time consuming than other approaches, as it addresses the relevant mechanisms and techniques to change behaviour (Hansen et al., 2017).	-It offers detail about one aspect of IM, rather than offering a full approach to intervention development (O'Cathain et al., 2019).

2.2.1 Medical Research Council evaluation framework

The MRC published guidance on developing and evaluating complex interventions (Craig et al., 2008). This guidance includes revisions made to the MRC framework published in 2000 (Medical Research Council, 2000).

Revisions included more emphasis on the intervention development phase, in which context needs to be considered and for the process to be less linear (Campbell et al., 2007). Also, the addition of the integration of a process evaluation is now included in this framework and guidance on this has been published (Moore et al., 2015).

The MRC guidance consists of four phases; developing, feasibility/piloting, evaluation, and implementation (see Figure 2.1). It advocates the development of interventions systematically based on theory and evidence, to then test the intervention in several phases with a definitive evaluation (Craig et al., 2008). Within the development phase, it is suggested existing up to date evidence is identified via high-quality systematic reviews. Theory is identified or developed for the processes of change. Following this, modelling of the complex intervention needs to occur before the full-scale evaluation.

2.2.2.1 Evaluation of the MRC guidance

The MRC guidance, whilst providing a framework for intervention development lacks guidance on how to carry out the processes (De Silva et al., 2014). For example, it is not clear how to incorporate theory into the intervention development process following the guidance (De Silva et al., 2014) or how to carry out a process evaluation (Moore et al., 2015). Having guidance on how to deliver these aspects is crucial for systematic intervention development. The evaluation phase of the MRC guidance has also been criticised for not focusing upon the mechanisms of change and for not providing understanding around this (Bonell, Fletcher, Morton, Lorenc, & Moore, 2012). A lack of consideration of context was a criticism of the original framework (Medical Research Council, 2000), however, researchers are still concerned that the current framework lacks guidance on how to explore how context interacts with the intervention (Bonell et al., 2012). Whilst, there are several criticisms to this guidance, it is widely cited within grant applications and current health services research (Craig et al., 2013). This approach is best used, alongside another framework such as the BCW. There are examples within the literature when combining the

BCW and MRC to intervention development has been undertaken successfully in changing HCP behaviour (Loft et al., 2017; McEvoy et al., 2018; Sinnott et al., 2015).

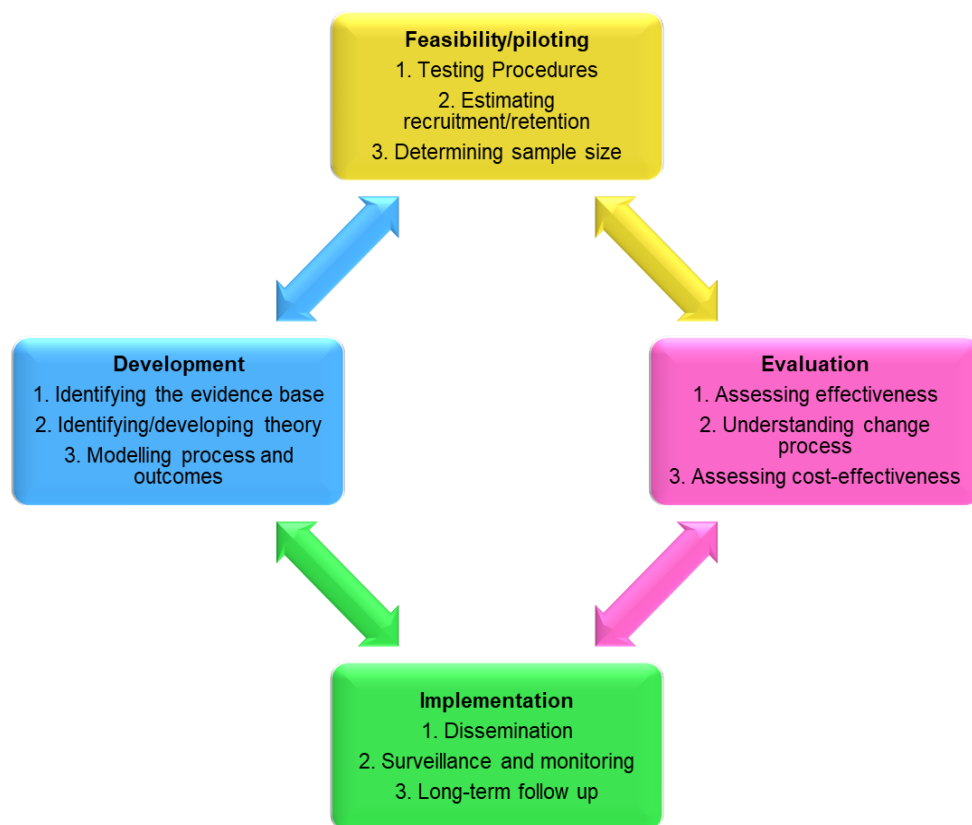


Figure 2.1: Medical research council framework for developing and evaluating complex interventions

2.2.2 Behaviour change wheel approach

The BCW developed by Michie and colleagues aims to aid the process of intervention development, theory development and the evaluation. The BCW was developed due to interventions often being designed without evidence, theory or reference to a formal process (Michie, van Stralen, et al., 2011). It offers a systematic tool for theory selection, which eliminates common issues such as theories being chosen due to personal preference or awareness (Painter, Borba, Hynes, Mays, & Glanz, 2008). It provides a practical guide that aims for behaviour change science to be accessible for all researchers. The BCW consists of three stages to intervention development; stage one: understanding the behaviour, stage two: identify intervention options and stage three: identify content and implementation options.

Michie et al (2011) systematically reviewed the existing frameworks of behavioural interventions, of which 19 frameworks of behaviour change were included. A list of intervention descriptors was generated, that are usable for intervention developers. They were also reviewed for 'usefulness', the criteria for this included comprehensiveness of the framework, coherence, and links to an overarching model of behaviour. The list of intervention descriptors was used to construct a new framework of behaviour; this was then tested for reliability. Key findings from this process suggested terms describing interventions needed to be defined more precisely and a clear distinction was needed between interventions and policies (Michie, van Stralen, et al., 2011). The BCW framework was developed following this systematic process and consists of three layers as shown in Figure 2.2. These three layers consist of the COM-B model (Capability, Opportunity and Motivation = Behaviour), intervention functions and policy categories (see section 1.8, page 49). The TDF is an additional layer to the BCW, which maps directly onto the COM-B model, see Figure 2.3

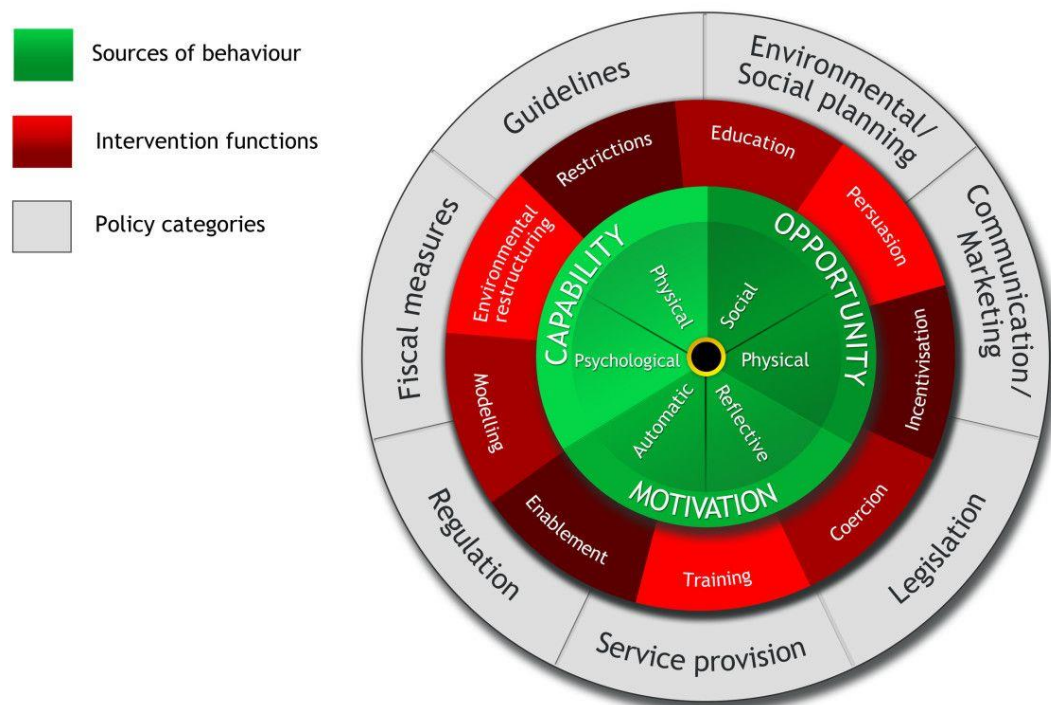


Figure 2.2: Overview of the Behaviour Change Wheel (Source: Michie et al., 2011)

The COM-B model is at the core of the BCW and is a framework for understanding behaviour, see Figure 2.2 and Table 1.4. The model was developed to understand the minimal number of additional factors that need to be considered to whether a change in the target behaviour would occur if motivation was present (Michie, van Stralen, et al., 2011), this model is discussed in more detail in section 1.8, page 49. It directly maps onto the TDF.

The TDF is a comprehensive theoretical framework systematically synthesised from 128 theoretical constructs and 33 theories (Michie et al., 2005), see Figure 2.3. The TDF was developed using expert groups and validation to understand implementation issues of evidence-based practice from HCPs (Michie et al., 2005). The process for this was as follows (i.) identifying theories and theoretical constructs relevant to behaviour change; (ii.) simplifying these theories and constructs into overarching theoretical domains; (iii.) evaluating the importance of the theoretical domains; (iv.) conducting a cross-disciplinary evaluation and synthesis of the domains and constructs; (v.) validating the domain list; and (vi.) piloting a series of interview questions to elicit views about the constructs and domains (Michie et al., 2005). Twelve behaviour change domains were identified from this process. These domains provide a theoretical framework to understand potential barriers and facilitators to the implementation of evidence-based practice.

The TDF was then later refined (Cane, O'Connor, & Michie, 2012). The most current version of the TDF consists of fourteen behaviour change domains following further validation from behavioural experts as presented in Table 2.2, knowledge, skills, social/professional role and identity, beliefs about capabilities, optimism, beliefs about consequences, reinforcement, intentions, goals, memory attention and decision processes, environmental context and resources, social influences, emotion and behavioural regulation (Cane et al., 2012). The majority of these domains relate to individual beliefs, motivations and capability factors; however social and environmental factors are acknowledged (Atkins et al., 2017).



Figure 2.3: Theoretical domains framework domains mapped onto the COM-B model (Source: Atkins et al., 2017).

Irrespective of the TDF being developed initially for exploration of implementation issues of evidence-based practice, the TDF has now been applied in several settings and for clinical behaviours (French et al., 2012). These include the promotion of adherence by clinical staff to national guidelines (Backman et al., 2015), to improve the care of stroke (Craig et al., 2017) and to improve the management of mild traumatic brain injury (Tavender et al., 2015). An in-depth understanding of the domains is required to be able to deliver this approach. Using the TDF at the stage of understanding what needs to change to produce the desired behaviour as stated in the BCW guide (Michie et al., 2014) may be most appropriate.

Table 2.2: Theoretical domains framework definitions mapped onto the COM-B model

COM-B model	TDF domain	Description taken from (Cane et al., 2012)
Psychological capability	Knowledge	An awareness of the existence of something.
	Skills (Physical and cognitive interpersonal skills)	An ability or proficiency acquired through practice.
	Memory, attention, and decision processes	The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives.
	Behavioural regulation	Anything aimed at managing or changing objectively observed or measured actions.
Reflective motivation	Social/professional role and identity	A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting.
	Beliefs about capabilities	Acceptance of the truth, reality or validity about an ability, talent or facility that a person can put to a constructive use.
	Optimism	The confidence that things will happen for the best or that desired goal will be attained.
	Beliefs about consequences	Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation.
	Intentions	A conscious decision to perform a behaviour or a resolve to act in a certain way.
	Goals	Mental representations of outcomes or end states that an individual wants to achieve.
Automatic motivation	Reinforcement	Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus.
	Emotion	A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts

		to deal with a personally significant matter or event.
Physical opportunity	Environmental context and resources	Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour.
Social opportunity	Social influences	Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours.

Source: (Michie, van Stralen, et al., 2011)

Moving towards the outer layers of the BCW, nine intervention functions are defined, see Table 2.3 for definitions as taken from (Michie, van Stralen, et al., 2011) and seven policy categories were identified, see Table 2.4 for definitions as taken from (Michie, van Stralen, et al., 2011). These were developed as intervention terms and policies needed to be distinguished more clearly.

Intervention functions are categories of ways in which an intervention can change behaviour. When developing interventions, it is important to consider all the intervention functions available. Policies can support the delivery of intervention functions. As policies can only influence behaviour through an intervention, policies were placed on the outside of the model.

Following identification of intervention functions and policy categories, the behavioural content is then selected in the form of behaviour change techniques (BCTs). A BCT is defined as “*an active component of an intervention designed to change behaviour*” (Michie et al., 2013, p. 4). A taxonomy of BCTs was developed by Michie and colleagues to provide a standardised language for researchers regarding BCTs due to issues of unclear reporting in interventions (Michie et al., 2013). This taxonomy was developed by multi-disciplinary experts, who generated a taxonomy of BCTs. The reliability of the descriptions of the BCTs were then tested and put into a hierarchical structure. Having decided on the BCTs for the intervention the mode of delivery of the BCTs needs to then be decided to the content of the intervention and often is neglected, which is briefly outlined within the BCW guide. Set criteria assessing Affordability, Practicality, Effectiveness/cost-effectiveness, Acceptability, Safety/side-effects and Equity, named the APEASE criteria (see Table 2.5) is

encouraged to be used throughout to make key decisions about mode of delivery.

Table 2.3: Intervention function definitions as taken from the BCW guide

Intervention function	Definition
Education	Increasing knowledge or understanding
Persuasion	Using communication to induce positive or negative feelings or stimulate action
Incentivisation	Creating expectation of reward
Coercion	Creating expectation of punishment or cost
Training	Imparting skills
Restriction	Using rules to reduce opportunity to engage in the target behaviour (or to increase the target behaviour by reducing the opportunity to engage in competing behaviours)
Environmental restructuring	Changing the physical or social context
Modelling	Providing an example for people to aspire to or imitate
Enablement	Increasing means/reducing to increase capability or opportunity

Source: (Michie, van Stralen, et al., 2011)

Table 2.4: Policy category definitions as taken from the BCW guide

Policy category	Definition
Communication/marketing	Using print, electronic, telephonic, or broadcast media
Guidelines	Creating documents that recommend or mandate practice. This includes all changes to service provision
Fiscal	Using the tax system to reduce or increase the financial costs
Regulation	Establishing rules or principles of behaviour or practice
Legislation	Making or changing laws
Environmental/social planning	Designing and/or controlling the physical or social environment
Service provision	Delivering a service

Source: (Michie, van Stralen, et al., 2011)

2.2.2.2 Evaluation of BCW guidance

The BCW approach has been used to develop interventions to target HCP behaviour since its development in 2011. These interventions cover a diverse range of HCP behaviours such as to increase physical activity advice to cancer patients (Webb, Foster, et al., 2016), to improve mental health support by pharmacists (Murphy, Gardner, Kutcher, & Martin-Misener, 2014) and to reduce imaging in lower back pain by HCPs (Jenkins et al., 2018). Sinnott et al (2015) developed an intervention to change capability, opportunity and motivation using the BCW to improve medication management in multi-morbidity by General practitioners (GPs). Authors found they had to make several pragmatic decisions, which seem to contradict the systematic approach the BCW offers. Additionally, it was found to be time-consuming and resource intensive. Murphy et al (2017) developed a complex intervention using both the BCW and the MRC as frameworks to promote appropriate prescribing and medication in poorly controlled type 2 diabetes, targeting general practitioners. The authors found the BCW to be useful and a practical way of identifying the linked BCTs. However, despite a comprehensive guide having been developed to guide researchers, there are still gaps. For example, the selection of appropriate and

potentially effective BCTs is a very complex task. In-depth understanding of each BCT is needed and an understanding of which BCTs have been effective in similar research, thus an awareness of the potential mechanisms of actions is required (Hansen et al., 2017). There have been further criticisms, as it has been argued there is a lack of emphasis on the need for intervention users to be involved in the development of intervention and the BCW doesn't incorporate this into its guidance or easily allow for this to happen, despite there being a benefit in this process (Bull et al., 2019; Janols & Lindgren, 2017).

Overall, the BCW recognises that behaviour is part of the system and accounts for that within its design. It successfully and widely used, but expertise is required to be able to use this approach effectively. More emphasis on involving key stakeholders is needed alongside this approach.

Table 2.5: APEASE criteria descriptions taken from BCW guide

APEASE criteria	Descriptions
Affordability	Interventions often have an implicit or explicit budget. It does not matter how effective, or even cost effective it may be if it cannot be afforded. An intervention is affordable if within an acceptable budget it can be delivered to, or accessed by, all for whom it could be relevant or of benefit.
Practicability	An intervention is practicable to the extent that it can be delivered as designed through the means intended to the target population. For example, an intervention may be effective when delivered by highly trained staff with extensive resources but in routine practice this may not be achievable.
Effectiveness and cost-effectiveness	Effectiveness refers to the effect size of the intervention in relation to the desired objectives in a real-world context. It is distinct from efficacy which refers to the effect size of the intervention when delivered under optimal conditions in comparative evaluations. Cost-effectiveness refers to the ratio of effect to cost. If two interventions are equally effective, then clearly the most cost-effective should be chosen. If one is more effective but less cost-effective than another, other issues such as affordability come to the forefront of the decision-making process.
Acceptability	Acceptability refers to the extent to which an intervention is judged to be appropriate by relevant stakeholders (public, professional, and political). Acceptability may be different for different stakeholders.
Side-effects/Safety	An intervention may be effective and practicable but have unwanted side-effects or unintended consequences. These need to be considered when deciding whether or not to proceed.

Equity considerations	An important consideration is the extent to which an intervention may reduce or increase the disparities in standard of living, wellbeing, or health between different sectors of society.
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2.3 Rationale for proposed frameworks

Changing the behaviour of HCPs within a clinical team is likely to be challenging. There are several interacting components, resulting in the development of a 'complex' intervention. To address these complexities and factors discussed in chapter one; the MRC framework and the BCW approach were used as complementary frameworks for this thesis.

The BCW builds on the MRC guidance that theory and the best available evidence should be used in the development and evaluation of complex interventions (Craig et al., 2008). The BCW offers a practical guide of how to incorporate theory and evidence, as the latest MRC guidance doesn't provide any clear guidance (Craig et al., 2008). To combine this approach with the BCW would be advantageous. In comparison to other approaches such as MAP-IT (Hansen et al., 2017) and NPT (Murray et al., 2010), the BCW provides a structured and comprehensive approach to intervention development. Whereas MAP-IT for example only offers one aspect of intervention development and lacks a consideration around context (Hansen et al., 2017). Other approaches such as IM that do offer a thorough approach like the BCW, can require years to undertake and is very costly, which was not feasible as part of this thesis (Hansen et al., 2017).

The BCW approach advocates the use of the TDF (French et al., 2012) to understand the behaviours that are being targeted to change, as part of its process (Michie et al., 2014). The TDF was specifically developed for understanding HCP implementation issues of guidelines, so is relevant to this thesis. One of the main criticisms of 'traditional' intervention development processes, is the lack of consideration when choosing a theory to guide the process (Davies, Walker, & Grimshaw, 2010). The TDF offers a theoretical framework, originally developed from thirty-three behavioural or behaviour change theories to help to eliminate the bias and problems with theory selection (Davis et al., 2015). Combining these approaches to guide intervention development offers an extensive framework.

2.4 Methodological approaches within intervention development

Using multiple methods to generate evidence within health services research is commonly recognised (Craig et al., 2013). As this thesis focuses upon the development, delivery, and evaluation of a behavioural intervention for HCPs, the most suitable methodologies were best selected to support the different stages of intervention development as outlined in the MRC and BCW frameworks. This thesis adopted a pragmatic approach using multiple methods due to the different research questions from inter-related studies, as described below.

2.4.1 Research paradigms

Research paradigms are an essential concept in social science research. Paradigms are basic belief systems based on ontological, epistemological and methodological assumptions (Guba, 1994). There are two dominant research paradigms: positivism and constructivism. The research paradigm, positivism, strives for objectivity. Positivism has somewhat been unquestioned and has been the most dominant approach for much of the 20th century. More so than the constructivist paradigm, as the qualitative methodologies associated with constructivism have been considered to be less credible (Teddle, 2009). Positivists believe knowledge is discovered accurately via quantitative methodologies through direct observations or measurements (Krauss, 2005). It is thought that reality is unaffected by the researcher or the research process (Ritchie, 2014). In contrast, the constructivist research paradigm state that there is no objective reality and there are multiple realities that are socially constructed, that are context dependent (Krauss, 2005). Reality is thought to be affected by the research processes and objective value-free research is impossible (Ritchie, 2014). Qualitative methodologies are used within this paradigm.

In more recent years there has been the development of a third paradigm: Pragmatism (Morgan, 2014b). Pragmatism offers an alternative research paradigm in comparison to positivism and constructivism. Pragmatism suggests an approach where the philosophical questions concerned with truth and reality are side-stepped, with the focus being on how to answer the research question appropriately using the most suitable methodology, whether that be quantitative

or qualitative (Feilzer, 2009; Morgan, 2014a). To combine both quantitative and qualitative methodologies has become more common (Creswell, 2011), especially in health services research (Craig et al., 2013). However, it is not without controversy as bringing the two methodologies together causes concern for some researchers. They have been viewed as 'incompatible' due to their differences in philosophical underpinnings (Teddle, 2009). Due to this, the focus within this paradigm should be on the research question and using methods to best answer them, with little concern for the matters around truth and reality.

As advised by O'Cathain and colleagues (2019), the first step to intervention development is identifying whether to be guided by a specific approach or take more pragmatic self-selected action. Whilst this research was driven by specific approaches (i.e. MRC and BCW), it also took a pragmatic stance to intervention development.

2.4.2 Intervention development

MRC Stage 1: Identifying the evidence base

According to the MRC guidelines, one of the first steps to intervention development is to understand the most current and up to date evidence base (Craig et al., 2008). Initially, a systematic review of exercise interventions to understand how to promote exercise in sedentary cancer survivors was conducted, see Chapter three. Systematic reviews despite being the gold standard within research can lack established guidelines (Higgins & Green, 2011) and often due to the vast amount of data being extracted for one review, mistakes can be made, which can influence results (Mathes, Klößen, & Pieper, 2017). A Cochrane methodology is a robust, rigorous, and transparent methodology, with strict guidelines and data extraction by two independent reviewers to minimise bias and mistakes. Cochrane systematic review methodology aims to minimise bias and provide reliable findings in comparison to traditional reviews, this type of review was therefore adopted. The included Cochrane systematic review updated a previous review (Bourke et al., 2013) as the field of exercise oncology is increasing rapidly and there was a lack of reliable findings in the previous review.

Secondly, a rapid review was carried out to understand what clinical exercise recommendations are available for HCPs to follow, see Chapter four. Rapid

reviews allow for a synthesis of data in a shorter timeframe than a systematic review, typically to inform decision making in healthcare settings (Khangura, Konnyu, Cushman, Grimshaw, & Moher, 2012). Whilst rapid reviews are growing in popularity, there is a significant lack of formal methodological guidance available (Hartling et al., 2015). Care needs to be taken to improve the transparency of the methods used (Haby et al., 2016).

The Cochrane and rapid review indicated that HCPs have a key role to play in recommending exercise and providing exercise support for cancer survivors, but this is not being utilised. Additionally, several clinical exercise recommendations were identified for HCP use. This thesis focuses upon developing a complex behavioural intervention for HCPs to recommend exercise, provide exercise support and exercise referral for men with prostate cancer on Androgen Deprivation therapy, in line with clinical exercise recommendations (NG 131 1.4.19) *‘Offer people who are starting or having androgen deprivation therapy supervised resistance and aerobic exercise at least twice a week for 12 weeks to reduce fatigue and improve quality of life’* (NICE, 2019).

BCW Step 1: Define the problem in behavioural terms

The first step of the BCW process is to understand exactly what needs to be changed, the problem needs to be defined, in behavioural terms. This process includes specifying the behaviour that needs to change to solve the problem. Considerations of the location in which the behaviour(s) occur, and which group or individuals need to be targeted also need to be identified.

To integrate exercise in line with NICE recommendations (NG131 1.4.19) into the prostate cancer care pathway, the prostate cancer care pathway needed to be fully understood, touchpoints of care and the HCPs responsibility for care needed to be identified. The care pathway is complex due to patient’s undergoing multiple treatments and care being delivered as part of a multi-disciplinary team (MDT), including both urology and oncology, which often are not based within the same hospital or even trust. As it was anticipated it would be difficult to create a proposed pathway for prostate cancer care across England due to differences between NHS trusts, the pathways were explored at an individual NHS trust level. Two local NHS sites within the North of England that deliver prostate cancer care were selected.

BCW Step 2 and 3: Selecting and specifying the target behaviours

Behaviours occur in part of a wider system and all behaviours that could be changed need to be considered. Key HCPs were recognised within the pathway as discussed above; therefore, the target behaviours of these HCPs were identified. This involved a working group of researchers within the team to identify potential target behaviours for change, considering the APEASE criteria throughout the process, (see Table 2.5).

BCW Step 4: Identifying what needs to change

During the further development of complex interventions, researchers need an in-depth understanding of the determinants of current or potential new behaviours in the relevant contexts, before designing a behaviour change intervention (Michie et al., 2014; O'Cathain et al., 2019). The use of qualitative research to explore these issues is advocated (French et al., 2012; Michie, van Stralen, et al., 2011). In this case, the influences on HCPs behaviours were explored to be able to comprehensively understand what needs to change for the NICE recommendations NG131 1.4.19 to be delivered. Semi-structured interviews were used as this methodology allows for an in-depth exploration of a phenomenon whilst maintaining flexibility. Interviews aim to generate rich and comprehensive data, which is critical for understanding HCP behaviour at this point. The interviews were carried out before the PhD programme commenced. The topic guides were guided by the TDF and the transcripts were reanalysed as part of the thesis using the TDF to gain a deeper understanding of the barriers and facilitators to the targeted behaviours identified to change. The TDF was used to analyse the interviews as it helps to add detail to understanding professional behaviour change.

BCW Step 5: Intervention functions

Within this thesis, once the target behaviours were identified and the behavioural diagnosis had been made links with the relevant TDF domains were made with the intervention functions (see Table 2.3) using the BCW guide solely. When developing interventions, it is important to consider all the intervention functions available. The BCW guide provides links between intervention functions and COM-B and TDF domains developed from expert consensus (Michie et al., 2014). The APEASE criteria was considered throughout this process, (see Table 2.5).

BCW Step 6: Policy categories

The BCW provides an overview of which policy categories (see Table 2.4) are linked with intervention functions, which are most likely to be effective. The process for identifying appropriate policy categories to support the intervention functions has similarities to the method of choosing intervention functions, e.g. the APEASE criteria should be applied. To consider policy categories is an important aspect of the BCW and intervention development. However, this step is outside of the scope and practicalities of the thesis because it had earlier been decided that this would be a service provision intervention.

MRC Stage 2 and 3: Identifying and developing theory and modelling processes and outcomes

Drawing upon theory when developing an intervention is advocated by the MRC and other research (O'Cathain et al., 2019). Theory explains why, when and how behaviour does or does not occur (Michie et al., 2014). As behaviour change is complex, theory allows us to identify the influences, understand the effective mechanisms of change, also known as the mechanisms of action in a specific context and inform implementation interventions (Atkins et al., 2017). Following on from the identification of theory, the next step of the MRC guidance encourages developers to understand how it is theorised that the intervention may work is likely to be beneficial for intervention development and evaluation. The theoretical underpinning of the intervention was then mapped out. Due to the complexities of the intervention, logic models for the key behaviours (recommend exercise, discuss barriers to exercise and make an exercise referral), (see Table 5.2) were presented to highlight the theoretical underpinnings of the intervention. Developing a logic model can help to clarify the theory and assumptions underlying the programme of work (WK., 2004). The logic model was developed following guidance from the MRC (Moore et al., 2015; WK., 2004).

BCW Step 7: Selecting behaviour change techniques

Complex interventions will often include a number of BCTs to enable behaviour change for example; demonstration of behaviour, defined as "*provide an observable sample of the performance of the behaviour, directly in person or indirectly e.g. via film, pictures, for the person to aspire to or imitate*" (Michie et al., 2013, p. 8). This could be an HCP demonstrating how to take an inhaler for

example. This might change behaviour as the person then believes that they have the physical skills and knowledge of how to perform the exercise. To be able to fully understand how an intervention has been or has not been effective, we need to be able to understand the mechanisms of action. BCTs have been identified to behaviours, contexts, or groups of people such as HCPs, therefore, the literature on professional behaviour change and suitable theories identified above were drawn upon at this stage to identify possible effective BCTs for the intervention. The APEASE criteria was considered throughout this process, (see Table 2.5).

BCW Step 8: Mode of delivery

How the intervention is delivered is equally as important to the content of the intervention and often is neglected (Dombrowski, O'Carroll, & Williams, 2016). Dombrowski (2016) argues six key points of why the mode of delivery is important within interventions. One of these points argues how the intervention is delivered may enhance or undermine the effectiveness of BCTs. For example, a study found that delivering a booster session within an intervention can increase implementation intentions, suggesting the intensity of the intervention is important for effectiveness (Chapman & Armitage, 2010). Another point argued by Dombrowski (2016) is that the mode of delivery can also influence engagement, adherence, and fidelity. For example, an online interactive training package for HCPs to improve self-management in patients was only accessed by half of the intervention group due to time and organisational constraints (Sassen, Kok, Schepers, & Vanhees, 2014). Due to these important considerations, the mode of delivery of the intervention and more specifically its behavioural content was considered throughout. Whilst the BCW guide (Michie et al., 2014) offers guidance on how to choose the mode of delivery, this guidance is very brief and only focuses upon the intervention as a whole, rather than how to deliver specific BCTs. Therefore, mode of delivery of the intervention and its components was selected based on the mode of delivery used in the professional behaviour change literature and suggestions from theories used within this intervention. The APEASE criteria was considered throughout this process, (see Table 2.5).

2.4.3 Intervention refinement and optimisation

To optimise and refine the development of the intervention following the above steps, further qualitative work was carried out in the form of a rehearsal delivery, focus group feedback with the clinical teams and a stakeholder workshop. The MRC suggests key stakeholders should be involved in the design process of interventions (Craig et al., 2008), but the BCW or MRC doesn't specify how to involve interventions user's within the process. It is critical for the following reasons; it allows bringing a lived-experience perspective to the research, encouraging support from stakeholder workshops for the research, and allows for stakeholders to have an input into the research that can ultimately affect their care or practice (Greenhalgh et al., 2019; Janols & Lindgren, 2017).

A focus group following a rehearsal delivery was chosen as focus groups allow for data to be generated due to the group's discussions (Ritchie, 2014). Furthermore, capturing feedback during the intervention development phase in a group context i.e., clinical teams, is useful and often research in this area doesn't seek to understand the views of the whole teams (Yang et al., 2017). However, the focus group participants were already a part of an already formed group, in terms of their clinical team. While this can encourage people to be more open and share their views, it may also emphasis a power-dynamic, where more junior HCPs may not feel they can share their views in the presence of a senior colleague. Understanding the dynamics from these groups was essential in the intervention development process (Ritchie, 2014).

Following the above phase of the research, a stakeholder workshop with HCPs, exercise professionals' researchers and patients were carried out and group feedback was captured in a workshop format. The purpose of this was for continued optimisation and refinement of the intervention. A workshop can provide an efficient way of bringing large numbers of people together such as stakeholders (INVOLVE, 2012). However, a workshop has the same problems as focus groups, where depth can be lacked (Bryman, 2012) and power dynamics can become an issue. Nevertheless, the aim of a workshop such as this is not to gain depth of phenomena, but to give the stakeholders a platform in the intervention development phase.

2.4.4 Intervention delivery and evaluation

Following the development of the intervention and refinement including stakeholders' input. The intervention was delivered to two NHS prostate cancer clinical teams at two NHS sites and evaluated. Several outcomes were collected in the evaluation of this study using multiple methods: assessment of behavioural outcomes, behavioural determinants, fidelity of enactment of treatment skills and acceptability data.

The primary outcome of this research was to understand if the intervention developed changed the seven target HCP behaviours, (see Table 5.2), whilst this is a preliminary evaluation and effectiveness cannot be established, it is an essential step for intervention development and further refinement of the intervention. It also important to understand effects on the HCP behavioural determinants. For example, did the intervention improve *Beliefs about consequences*. Assessing behavioural determinants alongside behavioural outcomes can help us understand how the proposed mechanisms of change work or do not work, which is necessary for further developing this work (Chisholm et al., 2020).

Following the delivery of the intervention, fidelity was assessed in several ways, with the collection of qualitative data and quantitative data. Treatment fidelity is the *"ongoing assessment, monitoring and enhancement of the reliability and internal validity of a study"* (Borrelli, 2011, p. 52). In 2004, the National Behaviour Change Consortium (NIH-BCC) developed a fidelity framework that incorporated five areas: design of the study, training providers, delivery of treatment, receipt of treatment and enactment of treatment (Bellg et al., 2004), see Table 2.6 for definitions. The assessment of treatment fidelity should become an integral part of behaviour change intervention development and implementation (Borrelli, 2011). Without assessing and understanding how interventions are delivered as planned, it is hard to fully understand whether the intervention is effective (Walton, Spector, Williamson, Tombor, & Michie, 2019), especially for complex interventions, when there may be multiple components to consider. Despite the importance of assessing fidelity in complex interventions, not many do not assess fidelity. A systematic review of complex behaviour change interventions identified fewer than half of the studies measured fidelity or engagement (Walton, Spector, Tombor, & Michie, 2017).

To measure the fidelity of clinical behaviour, several methods can be used (Mowbray, Holter, Teague, & Bybee, 2003). These can be measured directly and indirectly. Direct measures include observation by a trained observer and video or audio recordings. These generally represent a 'gold standard' measure of behaviour (Hrisos et al., 2009), with multiple researchers rating fidelity (Lorencatto, West, Christopherson, & Michie, 2013). Indirect measures can include self-report, review of medical records or interviewing the clinician (Hrisos et al., 2009; Walton et al., 2017). These measures do have limitations; however, it is important to be pragmatic whilst ensuring fidelity is measured as well as possible. If possible, it is recommended that multiple measures are used (Hrisos et al., 2009; Walton et al., 2017).

Enactment of all seven target behaviours (e.g. did the HCPs all recommend patients exercise) and skills were assessed using audio-recordings and collection of process data.

Acceptability is an important concept to consider in intervention design, delivery and evaluation and is advocated by MRC (Craig et al., 2008). If an intervention is acceptable to participants, it is more likely they will engage, however, acceptability is often wrongly inferred and not measured (Sekhon, Cartwright, & Francis, 2017). Sekhon et al., (2017) proposed acceptability is made up of seven constructs; affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness and self-efficacy, see Table 2.7 for definitions. Acceptability can be measured qualitatively and quantitatively. Within this thesis, acceptability was measured using the framework proposed by Sekhon et al., (2017) via semi-structured interviews with HCPs following their involvement within the intervention, evaluation forms directly following the training and field notes captured by researchers.

Table 2.6: Treatment fidelity areas and definitions

Treatment fidelity areas	Definitions
Treatment design	Consists of factors that should be considered when designing a trial and includes factors that should be reported to evaluate or replicate the trial
Training providers	Involves standardising training between providers, ensuring that providers are trained appropriately and are monitored and maintain skills over time.
Delivery of treatment	Focuses on processes that monitor and improve the delivery of the intervention so it can be established that the intervention was delivered as intended
Receipt of treatment	Ensuring that the participants understand the information provided in the intervention.
Enactment of treatment skills	Consists of processes to monitor and improve the ability of healthcare professionals to perform behavioural skills in everyday life

Source: (Borrelli, 2011; Borrelli et al., 2005)

Table 2.7: Acceptability constructs and definitions

Acceptability constructs	Definitions
Affective attitude	How an individual feels about the intervention
Burden	The perceived amount of effort that is required to participate in the intervention
Ethicality	The extent to which the intervention has a good fit with an individual's value system
Intervention coherence	The extent to which the participant understands the intervention and how it works
Opportunity costs	The extent to which benefits, profits or values must be given to engage in the intervention
Perceived effectiveness	The extent to which the intervention is perceived as likely to achieve its purpose.
Self-efficacy	The participant's confidence that they can perform the behaviour(s) required to participate in the intervention.

Source: (Sekhon et al., 2017).

2.5 Chapter summary

To summarise, several different intervention development frameworks are available to researchers to help guide the process of developing complex interventions. Having a theory and evidence base to intervention development is important and is advocated by the MRC (Craig et al., 2008). Intervention development frameworks that are theory and evidence-based are beneficial as they incorporate the latest evidence and theory helps us understand proposed mechanisms of change which can aid intervention replication and evaluation. The MRC and BCW were selected as complementary intervention development frameworks for this thesis as they offer comprehensive and systematic approaches. The methodologies used were subsequently dictated by these frameworks.

3) Chapter three: Identifying strategies for exercise behaviour change: A systematic review of exercise interventions for people living with and beyond cancer

3.1 Background

This thesis aims to develop a theory and evidence-based complex intervention to assist healthcare professionals (HCPs) to recommend exercise, deliver exercise support and make exercise referrals for people with advanced prostate cancer on long-term Androgen Deprivation Therapy (ADT). The first step to intervention development is to conduct or consult systematic reviews with the most current evidence, to understand how HCPs could support cancer survivors (Craig et al., 2013), (see section 2.4.2, page 89). This work has subsequently been published (Turner et al., 2018).

There are several benefits associated with exercising for cancer survivors (see Chapter one). These benefits have led to the development of national and international exercise recommendations (see Figure 1.1), but only 20% of cancer survivors currently meet these recommendations. To understand what components of interventions are successful in increasing exercise behaviour in cancer survivors is beneficial, as these components would need to be delivered by HCPs.

A comprehensive review was carried out by Bourke and colleagues in 2013 to understand how exercise interventions can promote exercise behaviour in cancer survivors. The review identified 14 trials, involving 648 participants. Exercise interventions were identified that promoted exercise behaviour in cancer survivors but varied in terms of intervention content, design, and delivery. Supervised exercise sessions, behaviour change techniques (BCTs) including setting programme goals, prompting practise and self-monitoring and generalisation of behaviours were found to be associated with higher adherence rates in trials. However, due to poor reporting and bias, such as selective outcome reporting, Bourke et al., (2013) highlighted there was a lack of understanding of how to encourage cancer survivors to meet current exercise recommendations. Updating this review will allow us to understand if new interventions offer any further insight into how HCPs could encourage inactive cancer survivors to meet exercise recommendations.

3.1.1 Research question

What strategies within exercise interventions for physically inactive adult cancer survivors are used to promote and sustain exercise behaviour?

3.2 Methods

A systematic review method was used, following the Cochrane Handbook for systematic reviews (Higgins & Green, 2011).

3.2.1 The team

The core systematic review team was multi-disciplinary: I (RT) led on the majority of aspects of this systematic review under the direction of the supervisory team (LB, DR, and LS) and with advice from the wider systematic review team. The initial protocol was developed previously by LB and was used in the previous systematic review (Bourke et al., 2013). In the previous review study selection and data extraction using a data extraction form was piloted. Electronic searches were carried out by information specialists at Cochrane Gynaecological, Neuro-oncology and Orphan Cancers. Screening of the data, study selection, data extraction and assessment of the quality of the studies was led by RT, with at least one independent researcher (LS, HQ or RG) carrying out these tasks independently to maintain rigour.

3.2.2 Search strategy

3.2.2.1 Electronic searches

The searches were run for the previous review from inception to August 2012. The subsequent searches from the following electronic databases were run from August 2012 to 3 May 2018. The following searches were carried out:

- the Cochrane Central Register of Controlled Trials (CENTRAL; 2018, Issue 5) in The Cochrane Library;
- MEDLINE via OVID August 2012 to April week 4 2018;
- Embase via OVID August 2012 to 2018 week 18;
- AMED (Allied and Alternative Medicine Database; covers occupational therapy, physiotherapy and complementary medicine) August 2012 to May 2018;
- CINAHL (Cumulative Index to Nursing and Allied Health Literature) August 2012 to May 2018;

- PsycINFO (Database of the American Psychological Association) August 2012 to May 2018;
- SportDiscus (Sports Evidence Database) August 2012 to April 2017;
- PEDro (Physiotherapy Evidence Database) August 2012 to April 2017.

The search strategies are presented in Appendix A, with both the 2018 updated strategy and the strategy from the previous review reported (Bourke et al., 2013).

The search strategies were developed with the Cochrane Gynaecological Cancer Group Information Specialist and included Medical Subject Headings and text word terms as appropriate.

3.2.2.2 Searching other resources

To supplement this evidence, snowballing was used to search the references lists of the retrieved articles and currently published reviews on the topic. The database search was expanded by identifying any additional relevant unpublished studies and references in the grey literature. This was done by searching the Open Grey database (www.opengrey.eu/), which includes technical or research reports, doctoral dissertations, conference papers and other types of grey literature. The following clinical trial web pages were searched:

- World Health Organisation <http://apps.who.int/trialsearch/Default.aspx>
- National cancer institute www.cancer.gov/about-cancer/treatment/clinical-trials/search

Further to this, cancer charities and organisations were written to, to enquire about any relevant unpublished papers.

3.2.3 Criteria for considering studies for this review

Randomised control trials (RCTs) involving adults (18 years or over) that randomly allocated participants or clusters of physically inactive participants (i.e., not undertaking 90 minutes of moderate-intensity exercise per week) to an exercise intervention that compared 'usual care' or a 'waiting list' control were included in this review. Participants had to have received a histological or

clinical diagnosis of cancer, regardless of sex, tumour site, tumour type, tumour stage and type of anticancer treatment received.

Studies were only included if the intervention included a component targeted at increasing aerobic and or resistance exercise behaviour with at least a 6 week follow up period. Interventions had to report the frequency, duration, and intensity of aerobic exercise and or frequency, intensity, type, sets and repetitions of resistance exercise behaviour that was prescribed in the intervention. To understand how different interventions might be appropriate to different cancers, only studies that included homogenous cancer cohorts (i.e., participants with the same primary cancer site) were included. Studies that included end of life patients or who were currently hospital inpatients were excluded.

3.2.4 Quality assessment of studies

Risk of bias and methodological quality was assessed following the Cochrane's tool for assessing the risk of bias (Higgins et al., 2011). This tool includes the following seven domains and what constitutes of low, high, or unclear risk of bias. This is reported in Appendix B.

We did not, however, include blinding to group allocation, as it is not possible to blind participants to an exercise intervention. RT and RG independently applied the risk of bias tool. Any discrepancies were resolved by discussion with LB. Study authors were contacted for additional information or further clarification of study methods if any doubt surrounded potential sources of bias.

3.2.5 Outcomes

The outcomes of the systematic review were as follows:

- Strategies and intervention features
- Overview of participants
- Type of exercise
- Level of exercise and adherence
- Measurement of exercise behaviour
- Adverse effects

3.2.6 Screening and data extraction

The results from each database were imported into reference manager software package Endnote X8.1 (2017), duplicates were then removed. Following training on the first 100 references, two review authors, RT and HQ independently screened all titles and abstracts to identify studies that met the inclusion criteria or could not be excluded without an assessment of the full text. Any disagreements were resolved with another review author, LB. After this screening process, all full texts were retrieved for these remaining articles. After training to ensure consistency, the full texts were assessed independently for eligibility by RT and HQ. Multiple publications from the same study were linked in this process. Again, any disagreements were resolved with another review author, LB. If a full text could not be accessed, if further information were required to consider the eligibility of the study for the review or if supplementary information was required the corresponding authors were emailed. Three members of the group worked independently (RT, RG and LS) to extract data from all eligible papers using the data collection form used in the previous review (Bourke et al., 2013) and the risk of bias tool (Higgins et al., 2011). Data extracted included study details, intervention details and participants characteristics. This data was entered into RevMan 5.3.

Data with adherence to the intervention were calculated by the number of prescribed exercise sessions completed as a proportion of the total number of sessions. Interventions were described on whether they had a theoretical underpinning or used a behaviour change theory. Interventions were coded using the 'Coventry, Aberdeen & London Refined' (CALO-RE) taxonomy (Michie, Ashford, et al., 2011). This taxonomy is a validated taxonomy of BCTs, specifically concerned with BCTs that can be used to help people change their physical activity behaviour. Coding interventions using a BCT taxonomy can allow for a better understanding of which BCTs are used within exercise interventions.

3.3 Results

3.3.1 Included studies

Figure 3.1 illustrates the process of literature search and study selection for the review. The updated search identified 5442 unique records from databases

searched. In addition, 2750 records were identified from grey literature and 'snowballing' technique. Details of the prescribed exercise are rarely reported in manuscript abstracts (e.g. frequency, intensity, duration of exercise prescription), this led to the evaluation of many manuscripts at full-text stage (n = 227). From these full-text articles, 212 manuscripts were excluded, leaving 15 publications from 10 unique studies included in the review (40 publications from a total of 23 unique studies combining both the previous review and update), see tables 13 and 14. One study (Bourke et al., 2014) was an efficacy study, following on from a previous feasibility study (Bourke et al., 2011) from the previous review. All included studies used a parallel-group design with a baseline assessment, follow-up of 12 months maximum and were conducted using participant-level randomisation. Sample size ranged from 14 to 222, with a total of 1372 participants included in this review (mean age range 51 to 72).

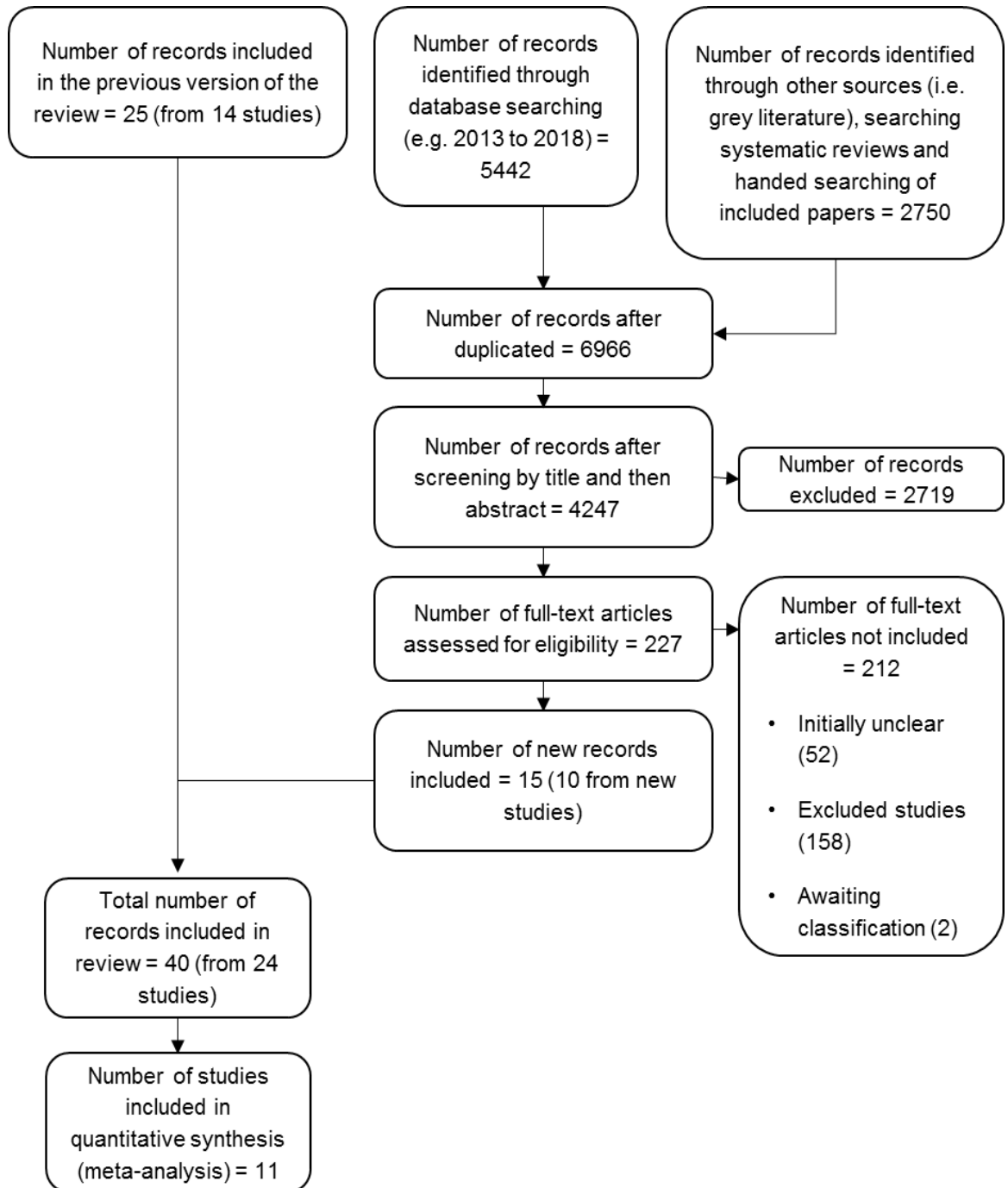


Figure 3.1: PRISMA flow diagram for systematic review

3.3.1.1 Participants

A summary of the characteristics of study participants can be found in Table 3.1. Most included trials were of breast cancer survivors. Two studies were in colorectal cancer, one in prostate cancer and one in lung cancer. Twelve studies included participants who were currently undergoing active treatment. Only one study reported participants with metastatic disease. Six studies were conducted with participants who are classified as obese (i.e., mean BMI > 30kg/m²). Most study participants were white, with only five studies reporting data from an ethnically diverse sample. Comorbidities of the participants were rarely reported or unclear.

3.3.1.2 Type of exercise

Fourteen studies prescribed aerobic exercise only. The remaining studies prescribed a mixture of aerobic and resistance exercise. No studies exclusively prescribed resistance exercise.

3.3.1.3 Level of exercise and adherence

A summary of exercise behaviour across the studies can be found in Table 3.2. Thirteen studies set prescriptions that would meet current exercise recommendations for aerobic exercise (i.e., 150 minutes per week) or resistance exercise (at least two days per week) as stated by (Rock et al., 2012). Only seven of these studies reported 75% adherence to these guidelines.

3.3.1.4 Measurement of exercise behaviour

Ten studies attempted to objectively validate independent exercise behaviour with accelerometers or heart rate monitoring. Seven of these studies attempted to validate self-reported independent exercise behaviour by using accelerometers or heart rate monitors. However, in three studies data either were not supportive of exercise behaviour recorded by participants or were not reported in their entirety.

3.3.1.5 Adverse events

Thirteen studies reported adverse events. These ranged from minor injuries such as musculoskeletal problems to major events such as death. Only five of the studies reported the adverse events were caused by the intervention.

Table 3.1: Characteristics of study participants

Study	Number of participants	Primary cancer diagnosis	Metastatic disease	Age, years: mean (SD)	BMI mean (SD)	Ethnicity	Comorbidities
(Al-Majid, Wilson, Rakovski, & Coburn, 2015)	7,7 (intervention vs control) = 14 total	Breast	No	Exercise group 47.9 +/- 10.4 & Control group 52.7 +/- 10.7	Unknown	Hispanic 29%, Non-Hispanic 71%	Unclear
(Bourke et al., 2011)	9, 9 (intervention vs control) = 18 total	Colorectal	None	Control: 70.3(8.7), Intervention: 67.9(5.7)	Control: 26.0 (3.5), Intervention: 26.9 (3.8)	Unclear	Unclear
(Bourke et al., 2014)	25,25 (intervention vs control) = 50 total	Prostate	20/100 men had metastatic disease	Intervention: 71(6), Control: 71 (6)	Intervention: 29.3 (4.4), Control: 28.1 (4.1)	Unclear	4% previous MI, 3% previous stroke, 5% angina, 7% diabetes, 27% hypertension, 5% hypertension diagnosed since

							ADT commencement
(Cadmus et al., 2009)	37, 38 (intervention vs control) =75 total	Breast	None	Intervention: 56.5(9.5), Control: 55.1(7.7)	Intervention: 30.4 (6.0), Control: 30.1 (7.4)	84% white in both groups	Unclear
(Campbell et al., 2018)	10, 9 (intervention vs delayed control) = 19 total	Breast	Unclear	Intervention: 53.2(7), Control: 26.3(5.7)	Intervention: 26.1 (5.5), Control: 26.3 (5.7)	Unclear	Unclear
(Cantarero-Villanueva et al., 2012)	33,33 (intervention vs control) = 66 total	Breast	Unclear	Intervention: 48(8), Control: 47(9)	Unclear	Unclear	Unclear
(Cavalheri et al., 2017)	9, 8 (intervention vs control) = 17 total	Lung	Unclear	Intervention: 66(10), Control: 68(9)	Intervention: 25 (5), Control 27 (6).	Unclear	Unclear
(Daley, Crank, Mutrie, Saxton, & Coleman, 2007)	34, 36, 38 (intervention, sham, control, respectively) = 108 total	Breast	None	51.6(8.8); 50.6(8.7); 51.1(8.6) (intervention; sham.	28.5 (4.4); 27.6 (4.1); 29.6 (5.1) (intervention; sham; control, respectively)	Two of 108 non-white	45/108 had lymphedema

				control, respectively)			
(Drouin, Armstrong, Krause, & Orr, 2005)	13, 8 (intervention, vs placebo stretching controls) = 21 total	Breast	None	Intervention: 49.4(7), Control 51.9(10)	Unclear	13 African American and 8 Caucasian	Unclear clear
(Hayes, Reul-Hirche, & Turner, 2009)	16, 16 (intervention vs control) = 32 total	Breast	None	Intervention: 59(7), Control: 60(11)	Unclear	Unclear	All had lymphedema
(Irwin et al., 2015)	61, 60 (intervention vs control) = 121 total	Breast	Unclear	Intervention: 62(7), Control = 60.5(7)	Intervention: 30(6.8), Control: 28.7 (5.5)	85% Non- Hispanic white, 2% Hispanic, 10% African American, 2% Asian/Pacific Islander. Control = 84% Non- Hispanic white, 5% Hispanic, 7% African	Unclear

						American, 2% Asian/Pacific Islander, 2% American Indian.	
(Kaltsatou, Mameletzi, & Douka, 2011)	14, 13 (intervention vs control) = 27 total	Breast	Unclear	Intervention: 56.6(4.2), Control 57.1(4.1)	Unclear	Unclear	Unclear
(Kim, Kang, Smith, & Landers, 2006)	22,19 (intervention vs control) = 41 total	Breast	None	Intervention: 51.3(6.7), Control: 48.3(8.8)	Unclear; 33 women who had significantly higher BMI (34.3 ± 10.2) excluded from analysis	78% white reported	Unclear
(Kim et al., 2017)	15, 15 (intervention vs control) = 30 total	Breast	None	Intervention: 56(6.5), Control: 49.3 (4.8)	Intervention: 23.9(2.7), Control: 25(4.7)	Unclear	Unclear
(McKenzie & Kalda, 2003)	7,7 (intervention vs control) = 14 total	Breast	None	Intervention: 56.4(10.4), Control: 56.9(8.2)	Intervention: 29.1(6.6), Control: 25.6(3.3)	Unclear	Unclear

(Mohamady, Elsis, & Aneis, 2017)	15, 15 (intervention vs control) = 30 total	Breast	Unclear	Intervention: 54.6(4.23), Control: 58.25 (2.65)	Intervention: 34.7(3.44), Control: 35.2 (3.36)	Unclear	Unclear
(Musanti, 2012)	Control (n = 13), aerobic group (n = 12), resistance group (n = 17), aerobic and resistance group (n = 13) = 45 total	Breast	None	Overall: 50.5 (7.5)	Unclear	Unclear	Unclear
(Perna et al., 2010)	51 participants in total. Numbers randomly assigned to each arm are unclear	Breast	None	Overall: 50.8(11.8)	Overall: 28.8(6.1)	A large %age of women were black (44.1%), and total ethnic Minority group membership was high (45.1%)	23.5% of women had CESD depression scores above the clinical cut-off
(Pinto, Clark, Maruyama, & Feder, 2003)	12, 12 (intervention vs control)	Breast	None	Overall: 52.5(6.8)	Overall: 26.8(4.1)	All white	Unclear

	control) = 24 total						
(Pinto, Frierson, Rabin, Trunzo, & Marcus, 2005)	43, 43 (intervention vs control) = 86 total	Breast	None	Intervention: 53.4(9.1), Control: 52.9(10.4)	Intervention: 27.5(5), Control: 28.6(5.5)	95% white	Unclear
(Pinto, Papandonatos, Goldstein, Marcus, & Farrell, 2013)	20, 26 (intervention vs control) = 46 total	Colorectal	None	Intervention: 59.5(11.2), Control: 55.6(8.24)	Intervention: 27.9(6.0), Control: 29.4(6.1)	1 of 46 non white	Unclear
(Rogers et al., 2015)	110, 112 (intervention vs control) = 222 total	Breast	Unclear	Intervention: 54.9(9.3), Control: 53.9(7.7)	Intervention: 30.8(6.9), Control: 30.5(6.8)	1.8% Hispanic and 98.2% non- Hispanic	Unclear
(Scott et al., 2013)	47, 43 (intervention vs control) = 90 total	Breast	Unclear	Intervention:55. 8(10), Control: 55.3(8.8)	Intervention: 29.7(3.5), Control: 31.1(5.7)	White	Unclear
(Thomas, Alvarez-Reeves, Lu, Yu, & Irwin, 2013)	35, 30 (intervention vs control) = 65 total	Breast	Unclear	Intervention: 56.5(9.8), Control: 55.1(7.6)	Intervention: 30.8(5.9), Control: 29.4(7.4)	83% white, 17% African American, control = 90% white, 7% African-	Unclear

						American, 3% Asian/Pacific islander.	
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Table 3.2: Summary of study exercise behaviour

Study	Exercise components	Supervision of exercise intervention	Number of participants	Meets Rock et al (2012) guidelines?	Adherence summary	At least 75% adherence?	High risk of bias?
(Al-Majid et al., 2015)	Aerobic	Supervised sessions only	7,7 (intervention vs control) = 14 total	No	Adherence to per-protocol exercise sessions was very high, ranging between 95% and 97%.	Yes	No
(Bourke et al., 2011)	Aerobic and resistance	Combination of supervised sessions and home-based exercise	9, 9 (intervention vs control) = 18 total	Six weeks of resistance exercise twice a week	90% attendance at the supervised sessions. 94% of independent exercise sessions were completed	Yes	No
(Bourke et al., 2014)	Aerobic and resistance	Combination of supervised sessions and home-based exercise	25,25 (intervention vs control) = 50 total	Yes; 6 weeks of resistance exercise	Adherence was 94% for the supervised and 82% of the prescribed independent exercise sessions over the first 12 wk.	Yes	Yes, incomplete outcome data at 6 months.

(Cadmus et al., 2009)	Aerobic	Combination of supervised sessions and home-based exercise	37, 38 (intervention vs control) =75 total	33% reported 150 minutes/week of moderate-intensity aerobic exercise at an average of 76% HR, for six months	75% of women were doing between 90 and 119 minutes of moderate-intensity aerobic activity per week at six months	Yes, for up to 119 minutes per week	No
(Campbell et al., 2018)	Aerobic	Combination of supervised sessions and home-based exercise	10, 9 (intervention vs delayed control) = 19 total	150 mins per week of mod-vigorous aerobic exercise for 24 weeks.	Participants attended 88% of supervised gym sessions and participants met 82% of the prescribed exercise targets. Home session completion was 87% and participants met 87% of the prescribed exercise targets	Yes	Yes, Low trial recruitment rate.
(Cantarero-Villanueva et al., 2012)	Aerobic	Supervised sessions only	33,33 (intervention vs control) = 66 total	Three sixty-minute sessions per	All intervention group completed more than 85% of the 24 water	Yes	No

				week for 8 weeks.	exercise sessions, showing a high adherence rate to the program.		
(Cavalheri et al., 2017)	Aerobic and resistance	Supervised sessions only	9, 8 (intervention vs control) = 17 total	Yes, six weeks of resistance exercise.	Nine of the participants randomised to the EG, four (44%) adhered to exercise training by completing 15 or more training sessions (i.e., ≥60%).	No	Yes, missing patient data in both arms with no reasons given.
(Daley et al., 2007)	Aerobic	Supervised sessions only	34, 36, 38 (intervention, sham, control, respectively) = 108 total	No	77% of the exercise therapy; attended 70% (at least 17 of 24 sessions) or more of sessions	Unclear	Yes, outcome assessors were not blinded to participants' group allocation
(Drouin et al., 2005)	Aerobic	Home based	13, 8 (intervention, vs placebo stretching controls) = 21 total	Unclear	Participants in the intervention group averaged 3.6 days per week of aerobic exercise over an 8-week period	Unclear	No

(Hayes et al., 2009)	Aerobic and resistance	Combination of supervised sessions and home-based exercise	16, 16 (intervention vs control) = 32 total	Unclear	Most women (88%) allocated to the intervention group participated in 70% or more of scheduled supervised exercise sessions	Unclear	Yes, adherence data on an unsupervised aspect of the intervention are not clear
(Irwin et al., 2015)	Aerobic and resistance	Combination of supervised sessions and home-based exercise	61, 60 (intervention vs control) = 121 total	Yes	Women randomly assigned to exercise also reported their exercise prospectively in daily activity logs and reported an average of 119 minutes per week of aerobic exercise, with an average of 70% of strength-training sessions completed. Women randomly assigned to exercise increased their physical activity by an average of 159	No	No

					minutes per week, compared with 49 minutes per week in the usual-care group.		
(Kaltsatou et al., 2011)	Aerobic	Supervised sessions only	14, 13 (intervention vs control) = 27 total	Unclear	Not reported	Not reported	Yes, method of measuring exercise and adherence not reported
(Kim et al., 2006)	Aerobic	Combination of supervised sessions and home-based exercise	22, 19 (intervention vs control) = 31 total	No	Average weekly frequency of exercise was 2.4 ± 0.6 sessions, and the average duration of exercise within prescribed target HR was 27.8 ± 8.1 minutes per session. Overall adherence was $78.3\% \pm 20.1\%$	Yes	Yes, data missing for 45% of the cohort
(Kim et al., 2017)	Aerobic and resistance	Supervised sessions only	15, 15 (intervention vs control) = 30 total	Three sixty-minute sessions per	Vague statement: Two participants did not fulfil the required exercise	Unclear	Yes, Age differences between groups in

				week for twelve weeks.			baseline demographics were present. Adherence data is vague.
(McKenzie & Kalda, 2003)	Aerobic and resistance	Supervised sessions only	7,7 (intervention vs control) = 14 total	No	Unclear	Unclear	Yes, adherence to exercise not reported
(Mohamady et al., 2017)	Aerobic	Supervised sessions only	15, 15 (intervention vs control) = 30 total	No	Unclear	Unclear	Yes, No adherence data.
(Musanti, 2012)	Aerobic and resistance	Home based	Control (n = 13), aerobic group (n = 12), resistance group (n = 17), aerobic and resistance group (n = 13) = 45 total	12 weeks of resistance exercise two or three times per week	Mean %ages of adherence were as follows: flexibility = 85%, aerobic = 81%, resistance = 91% and aerobic plus resistance = 86%	Unclear	Yes, a significant number of dropouts belonged to the resistance exercise group (n = 8/13). Only 50% of activity logs were returned

(Perna et al., 2010)	Aerobic and resistance	Combination of supervised sessions and home-based exercise	51 participants in total. Numbers randomly assigned to each arm are unclear	Three months of resistance exercise three times per week	Women assigned to the structured intervention completed an average of 83% of their scheduled hospital-based exercise sessions (only 4 weeks in duration), and 76.9% completed all 12 sessions. Home-based component (8 weeks in duration)	Unclear	Yes, numbers randomly assigned to intervention and control groups are unclear, as are numbers completing in each arm
(Pinto et al., 2003)	Aerobic	Home based	12, 12 (intervention vs control) = 24 total	Unclear	Participants attended a mean of 88% of the 36-session supervised exercise programme	Yes	Yes; 38% lost to follow-up. Exercise tolerance test was performed but no control group comparison data were reported

(Pinto et al., 2005)	Aerobic	Combination of supervised sessions and home-based exercise	43, 43 (intervention vs control) = 86 total	Unclear	At week 12, intervention participants reported a mean of 128.53 minutes/week of moderate-intensity exercise. However, no changes were reported in the accelerometer data in the intervention group (change score = -0.33 kcal/h)	Less than 75% of the intervention group was meeting the prescribed goal after week 4	Yes, significantly more control group participants were receiving hormone treatment. Accelerometer data do not support the self-reported physical activity behaviour
(Pinto et al., 2013)	Aerobic	Home based	20, 26 (intervention vs control) = 46 total	Three-day PAR questionnaire indicates that 64.7% of the intervention group and 40.9% of the	Correlation between self-reported moderate-intensity exercise and accelerometer data at three-month follow-up, when the only significant between-	No	Yes, accelerometer data were not reported; also, cited correlation is weak (0.32). Further,

				control group were achieving the guidelines at three months	group change is reported: $r = 0.32$		substantial contamination was noted in the control group
(Rogers et al., 2015)	Aerobic	Combination of supervised sessions and home-based exercise	110, 112 (intervention vs control) = 222 total	Yes	Adherence to the intervention was 98 % for supervised exercise sessions, 96 % for update sessions, and 91 % for discussion group sessions.	Yes	Yes, differences in objective and subjective measures of physical activity reported
(Scott et al., 2013)	Aerobic and resistance	Supervised sessions only	47, 43 (intervention vs control) = 90 total	Yes, six weeks of resistance exercise.	Adherence for the intervention group was 80%	Yes	No
(Thomas et al., 2013)	Aerobic	Supervised sessions only	35, 30 (intervention vs control) = 65 total	Yes	The exercise goal was 150 min/ week of moderate-intensity aerobic exercise; 33% of women achieved this amount. 57% of women	No	Yes, not all outcomes were reported and low recruitment rate.

					achieved 80% of the exercise goal or 120min/week, and 75% of women achieved 90min/wk.		
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3.3.2 Strategies and intervention features

Common strategies and intervention features within the studies are reported below.

3.3.2.1 Supervision of exercise intervention

Ten studies used a combination of supervised and home-based exercise. Four studies offered an entirely home-based exercise programme. Ten studies were offered supervised exercise sessions only.

3.3.2.2 Exercise sessions and the role of exercise professionals and healthcare professionals

Contact with exercise professionals or study researchers varied between studies. Some studies offered two to three weekly supervised exercise sessions whereas some studies offered weekly phone calls. Most studies offered supervised exercise sessions two to three times a week. Contact with HCPs was not frequent amongst the studies, with three studies having HCPs carry out medical assessments for eligibility. Two studies had HCPs, specifically oncologists, to refer participants onto the study but it was not stated clearly if they delivered any aspects of the intervention.

3.3.2.3 Theoretical basis

Six studies were explicitly based on a theoretical model. The trans-theoretical model (Prochaska & DiClemente, 1982) was the most common behaviour change model used to underpin these exercise interventions, followed by the social cognitive theory (Bandura, 1986) with one intervention based on the Exercise and Self-Esteem Theory (Sonstroem & Morgan, 1989).

3.3.2.4 Behaviour change techniques

Full details of the intervention BCT coding according to the CALO-RE taxonomy the frequency of BCTs are reported in Table 3.3. It was assumed that all interventions had programme set goals, whilst not specifically stated, which is different for this review to goal setting (behaviour) and goal setting (outcome). The most frequent BCTs were as follows; 8. *Barrier identification/Problem solving*, 9. *Setting of graded tasks* 16. *Prompt self-monitoring of behaviour*, 17. *Prompt self-monitoring of behavioural outcome*, 21. *Instruction provided on how to perform the behaviour* and 26. *Prompt practise*.

3.3.2.5 Mode of delivery of behaviour change techniques

Predominantly the exercise professionals delivered specific BCTs face to face within sessions to individuals or as a group. Some interventions included additional behavioural support supplementary to the exercise sessions. These included weekly phone calls around goal setting and problem-solving and face to face seminars to discuss behavioural strategies such as time management.

Table 3.3: Behaviour change components extracted from the studies

		Al-Majid 2015	Bourke 2011	Bourke 2014	Cadmus 2009	Campbell 2018	Cantarero-Vilanova 2012	Cavalheri 2017	Daley 2007	Drouin 2005	Hayes 2009	Irwin 2015	Kaltsatou 2011	Kim 2006	Kim 2017	Mckenzie 2003	Mohamady 2017	Musanti 2012	Perna 2010	Pinto 2003	Pinto 2005	Pinto 2013	Rogers 2015	Scott 2013	Thomas 2013	Frequency
Based on a theory					TTM													EXSEM	TTM		TTM	TTM SCT	SCT			
Behaviour change techniques																										
1. Provide Info on consequences of behaviour in general			X						X					X					X							4
2. Provide Info on consequences																										0

of behaviour to the individual																									
3. Provide Info about others' approval																									0
4. Provide normative info about others' behaviour																									0
5. Goal setting (behaviour)			X	X			X									X		X	X				X		5
6. Goal setting (outcome)																									0
7. Action planning																									0
8. Barrier identification/Problem solving			X	X			X									X		X	X	X					7
9. Setting of graded tasks			X	X	X	X	X	X		X	X	X		X	X	X	X	X	X		X	X		X	18
10. Prompt review of behavioural goals							X									X				X					3
11. Prompt review of outcome goals																									
12. Prompt rewards contingent on effort or																X		X	X						3

progress towards goal																									
13. Provide rewards contingent on successful behaviour							X																		1
14. Shaping																									0
15. Prompt generalisation of target behaviour		X	X	X												X	X			X					6
16. Prompt self-monitoring of behaviour		X		X			X	X							X	X	X	X	X						9
17. Prompt self-monitoring of behavioural outcome			X	X			X	X							X			X	X	X		X			9
18. Prompt focus on past success							X																		1
19. Feedback on performance provided				X												X		X	X	X					5
20. Information provided on where and when to perform behaviour			X				X									X				X					4
21. Instruction provided on			X	X			X	X			X	X			X	X	X		X	X	X				12

how to perform the behaviour																									
22. Modelling/Demonstration of behaviour												X					X	X				X			4
23. Teaching to use prompts/cues								X										X			X				3
24. Environmental restructuring																		X			X				2
25. Agreement on behavioural contract																		X							1
26. Prompt practise		X	X	X				X	X	X		X	X		X		X	X	X		X	X			14
27. Use of follow-up prompts		X																							1
28. Facilitating social comparison																									0
29. Planning social support/social change			X	X				X										X							4
30. Prompt identification as role																									0

model/position advocate																									
31. Prompt anticipated regret																									0
32. Fear arousal																									0
33. Prompt self-talk																									0
34. Prompt use of imagery																									0
35. Relapse prevention/coping planning				X				X									X				X				4
36. Stress management/emotional control training												X													1
37. Motivational interviewing																									0
38. Time management																									0
39. General communication skills training																									0
40. Stimulation of anticipation of future rewards																									0
A = aerobic, R = resistance TTM = Trans Theoretical Model, SCT = Social Cognitive Theory, EXSEM = Exercise and Self-Esteem																									

3.3.3 Risk of bias in included studies

Seven studies did not include a high risk of bias. Full results of the methodological quality assessment for allocation bias, blinding, incomplete data outcome and selective reporting, with justifications are covered in the 'Risk of bias' tables for each study and are illustrated in Figure 3.2 and Figure 3.3.

Twelve studies were explicit that they had used an intention to treat analysis.

al-Majid 2015	?	?	?	?	+	?
Bourke 2011a	+	+	+	+	+	?
Bourke 2014	+	+	+	-	+	+
Cadmus 2009	+	+	?	+	+	+
Campbell 2017	+	?	?	+	+	-
Cantarero-Villanueva 2012b	+	+	+	+	+	+
Cavalheri 2017	+	+	+	-	+	-
Daley 2007a	+	+	-	+	+	+
Drouin 2005	+	?	?	+	+	+
Hayes 2009	+	?	+	+	+	-
Irwin 2015	+	?	?	+	+	+
Kaltsatou 2011	?	?	?	?	+	-
Kim 2006	+	?	?	-	+	-
Kim 2017	+	+	+	+	+	-
McKenzie 2003	?	?	?	?	+	-
Mohamady 2017	+	+	?	?	+	-
Musanti 2012	+	+	+	-	-	-
Perna 2010	+	+	+	+	+	-
Pinto 2003	?	?	?	-	-	-
Pinto 2005	?	?	?	+	+	-
Pinto 2011	?	?	?	+	-	-
Rogers 2015	+	+	+	+	+	-
Scott 2013	+	+	+	+	+	+
Thomas 2013	+	+	+	+	-	-
Random sequence generation (selection bias)						
Allocation concealment (selection bias)						
Blinding of outcome assessment (detection bias)						
Incomplete outcome data (attrition bias)						
Selective reporting (reporting bias)						
Other bias						

Figure 3.2: Risk of bias summary: review authors' judgements about each risk of bias item for each included study, taken from (Turner et al., 2018).

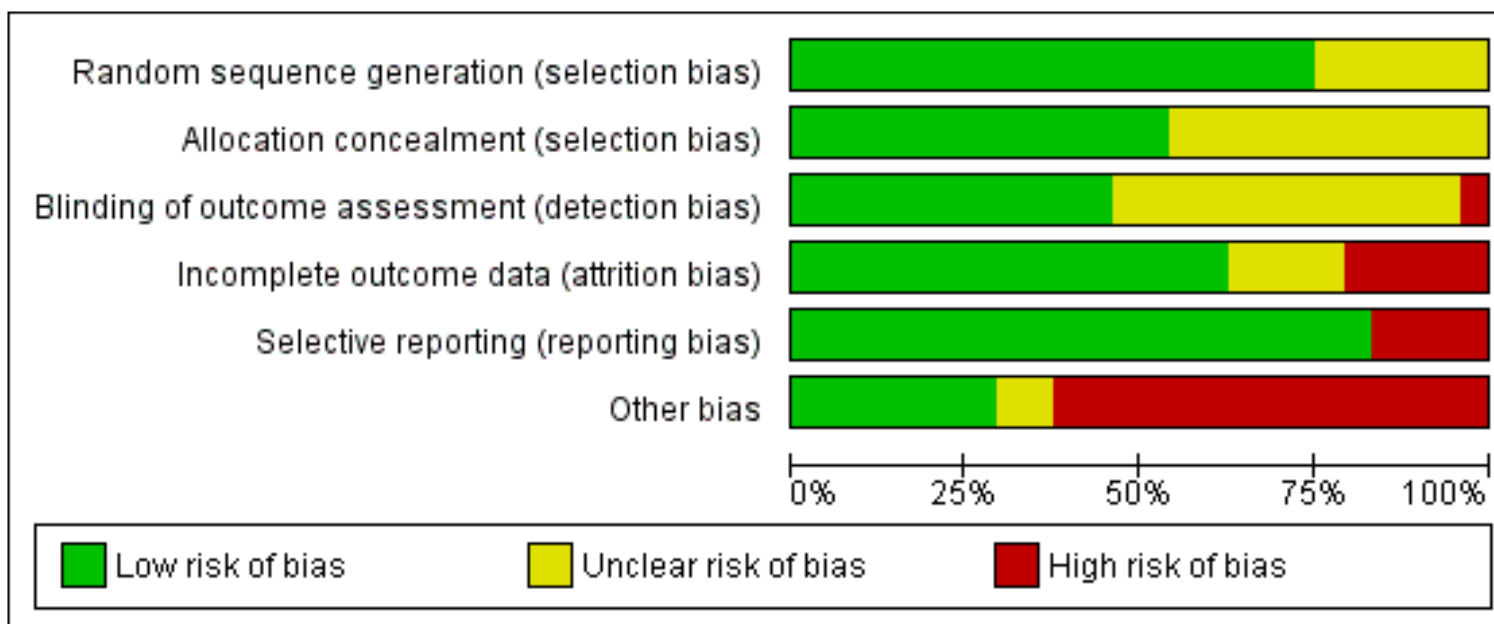


Figure 3.3: Risk of bias graph review authors' judgements about each risk of bias item presented as percentages across all included studies, taken from (Turner et al., 2018).

3.3.3.1 Allocation

Eleven studies had an unclear risk in their description of concealment in randomisation allocation. However, no study was judged to have a high risk of bias in this respect.

3.3.3.2 Blinding

Eleven studies had undertaken the blinding of study assessors. The remaining studies did not include enough information for the review authors to make a definitive judgement on this criterion.

3.3.3.3 Incomplete outcome data

Five of the studies had incomplete data biases: only reported data from 41 out of 74 participants. One study reported that 24% of the cohort did not complete the prescribed 12-week exercise programme. Pinto et al., (2013) did not report any control group data for the exercise tolerance test. Bourke et al., (2014) had incomplete outcome data at six months follow up. Cavalheri et al., (2017) reported missing patient data in both arms without reason.

3.3.3.4 Selective reporting

Four studies omitted outcomes from their results reporting. Mustanti et al., (2012) did not report waist and upper, mid, and lower arm circumference outcomes. Pinto et al., (2013) did not report any control group physiological assessments at 12 weeks of follow up. Thomas et al (2013) did not provide data from food frequency questionnaires that were administered, nor did they report on body fat or lean mass values. Pinto et al (2013) did not report any accelerometer data that was obtained.

3.3.3.5 Other potential sources of bias

There were several other sources of potential bias found amongst these studies. These included low recruitment rates. A lack of adherence data being reported or reported unclearly. Inconsistencies between objective and subjective measures of exercise behaviour. Significant differences in groups at baseline. Insufficient information was reported to make a judgement about a single element of bias due to lack of reporting.

3.4 Discussion

To my knowledge, this is the most comprehensive systematic review of exercise behaviour interventions in physically inactive cancer survivors. In this systematic review, evidence has been identified that exercise interventions for cancer survivors are meeting the Rock et al., (2012) guidelines with 75% adherence. The current guidelines consist of aerobic recommendations (150 minutes of moderate-intensity aerobic exercise) and resistance recommendations (twice-weekly resistance training). Whilst there were seven trials with 75% adherence to these recommendations, this was only to one element of the recommendations: aerobic or resistance. Four trials of the seven had 75% adherence to aerobic exercise guidelines and three of the seven had 75% adherence to resistance exercise guidelines. This was due to the trials only including aerobic or resistance exercise as their set prescription. Also, some trials used the guidelines for one component (i.e., aerobic or resistance exercise) of their prescription and set their own prescription for the other component. Only one trial prescription met the guidelines for both aerobic and resistance exercise and only met 75% adherence or above for aerobic exercise.

Extracting information about strategies used to promote exercise behaviour was a difficult task. These exercise interventions, whilst of high quality, predominantly focused on physiological changes, rather than behaviour change or how to implement exercise. This has been a previous critique of such interventions (Bluethmann, Vernon, Gabriel, Murphy, & Bartholomew, 2015) as even if the interventions do produce desired physiological outcomes, there is not a good understanding of how to promote or maintain exercise behaviour outside of a RCT. During the screening process for this review, it was apparent that there were many exercise interventions in cancer; however, this review stipulated strict criteria for inclusion to ensure 'high-quality' studies such as randomised control trials were included. Therefore, it is assumed that there are examples of exercise interventions that focused upon behaviour change or implementation of exercise were not included in this review. Systematic reviews of these types of interventions have been included in Table 3.4.

Despite this, strategies were identified that could promote exercise behaviour in cancer survivors and delivered by HCPs in the future intervention. These included the use of BCTs and how they were delivered, the frequency of contact

with HCPs and exercise professionals and aspects of supervision. Common BCTs were identified in this review. The aim of this was to understand whether certain BCTs are associated with trials with high adherence. There were no clear trends of the use of BCTs between trials with high adherence and those with lower or unclear adherence. However, trials with higher adherence rates more frequently used the following BCTs; '*goal setting*' (*behaviour*), '*barrier identification*'/'*problem solving*', '*setting of graded tasks*', '*prompt self-monitoring of behaviour and behavioural outcomes*', '*instruction on how to perform the behaviour*' and '*prompt practice*'. BCTs such as '*goal setting*', '*problem-solving*', '*self-monitoring*' and '*instruction to perform behaviour*' are often used within exercise and cancer survivorship, but in other reviews have not been found to be associated with the effectiveness of exercise behaviour change or maintenance (Grimmett et al., 2019). In comparison, a systematic review and meta-analysis that aimed to evaluate physical activity interventions in healthy adults found interventions that included '*setting of graded tasks*', '*demonstration of behaviour*', '*biofeedback*' and '*behaviour practice and rehearsal*' showed larger effect size for physical activity outcomes (Howlett, Trivedi, Troop, & Chater, 2019).

BCTs such as providing '*information on the consequences*' of the behaviour in general and to the individual and providing normative behaviour about others' behaviour were not frequent in these studies. Another systematic review found BCTs about the information on behaviour and health benefits were not associated with successful exercise interventions in cancer survivors (Finne et al., 2018). This supports the evidence suggesting knowledge isn't enough to change behaviour (Michie et al., 2014).

Table 3.4: Overview of important factors to consider for patient behaviour change in relation to exercise

Study	What works and under what circumstances	BCTs/Intervention features in line with BCTTv1 taxonomy (Michie et al., 2013)	Specific features	Other key points
Systematic review and meta-analysis to understand how physical activity can be promoted in cancer survivors (Finne et al., 2018)	Several BCTs within exercise interventions	7.1 Prompts/cues	Use of a workbook, pedometer, or telephone reminders.	Information about consequences (5.1) and social comparison (6.2) used together were associated with smaller physical activity increases.
		7.3 Reduce prompts/cues	Decreasing above prompts over time.	
		8.7 Graded tasks	Increasing frequency or intensity of exercise.	
		10.3 Non-specific reward	Not stated	
		10.4 Social reward	Praise for achievement of goals or progress towards goal.	
Systematic review to identify and evaluate behaviour change techniques in physical activity interventions for prostate cancer survivors (Hallward, Patel, & Duncan, 2020)	Several BCTs within exercise interventions.	3.2 Social support (practical)	Supervised exercise sessions.	If BCTs are solely delivered by the exercise professional, survivors are less likely to use them after the intervention. Ideally BCTs should be taught to cancer survivors.
		7.1 Prompts/cues	Telephone calls or prompts to put on their fridge.	
		4.2 Information about antecedents	Support for prostate cancer survivors to identify their personal	

			antecedents that facilitate and predict physical activity engagement.	
Systematic review and meta-analysis of maintenance of physical activity behaviour change in cancer survivors (Grimmett et al., 2019)	Several BCTs within exercise interventions.	1.4 Action planning	Encouraging a detailed plan on when and where they will exercise.	Apart from BCTs highlighted in this table, there were no difference in BCTs reported in 'promising' and 'non-promising' studies. This indicates there are other contextual factors not reported in these studies that impacting on effectiveness.
		3.1 Social support (unspecified)	Arranging social support or reward. Often motivational interviewing techniques were used here.	
		8.7 Graded tasks	Setting easy tasks that increase in difficulty.	
A systematic review and meta-analysis of the effectiveness of physical activity and/or sedentary behaviour interventions in healthy, inactive adults (Howlett et al., 2019).	Several BCTs within exercise interventions.	1.4 Action planning	Effective for behaviour change at follow-up (post 6 months)	Studies that included the BCTs Problem solving (1.2), Review behaviour goal (1.5) and Feedback on behaviour (2.2) showed smaller effect sizes at post-intervention than studies that did not includes these BCTs.
		1.9 Self-reward	Effective for behaviour change at follow-up (post 6 months)	
		2.6 Biofeedback	Effective for behaviour change post intervention	

		4.1 Instruction on how to perform the behaviour	Effective for behaviour change at follow-up (post 6 months)	
		6.1 Demonstration of behaviour	Effective for behaviour change post-intervention and at follow-up (post 6 months)	
		7.1 Prompts/Cues	Effective for behaviour change at follow-up (post 6 months)	
		8.1 Behavioural practice/rehearsal	Effective for behaviour change post-intervention and at follow-up (post 6 months)	
		8.7 Graded tasks	Effective for behaviour change post-intervention and at follow-up (post 6 months)	

HCPs were not reported as being involved in these exercise trials, which is an important finding. This reflects usual care for cancer survivors as HCPs rarely discuss exercise with their patients (Macmillan, 2011). Studies have shown the importance of HCPs in advocating exercise and the influence this has on patient's exercise behaviour. In a systematic review of studies identifying barriers and or enablers to exercise in patients with lung cancer, encouragement of exercise from HCPs was a key enabler to exercise and a lack of it acted as a barrier (Granger et al., 2017). Research suggests the importance of the teachable moment and the role of HCPs in initiating lifestyle change in cancer survivors (Demark-Wahnefried et al., 2005). The timing of introducing exercise or the role HCPs are not reported in these studies. This is a missed opportunity to be able to motivate or support cancer survivors and should be considered in future exercise interventions and within clinical care. Exercise professionals, however, played a large role in these studies from delivering the exercise sessions to providing ongoing behavioural support. Exercise professionals predominantly delivered the BCTs during supervised sessions. However, the exercise professionals and HCPs did not communicate, and the exercise intervention was separate to clinical care. This is an important finding, as to integrate exercise into the cancer care pathway, there needs to be communication between HCPs and exercise professionals.

This review included 23 studies, all of which were RCTs. Whilst there were studies in colorectal, lung and prostate cancer, these studies predominantly included white females with breast cancer. Other common cancers such as lymphoma did not appear in this review. Further to this, there was very little evidence from developing countries. Many of the studies were all considered high-income nations according to the World Health Organisation (WHO) taxonomy. Adverse effects ranged from minor musculoskeletal problems to main events such as death. However, only five studies explicitly stated that adverse effects were caused by the participant's inclusion of the exercise trial. The overall message from these interventions is that exercise is safe for cancer survivors, this had been found in a previous systematic review assessing exercise for cancer survivors (Segal et al., 2017b). The message that exercise is safe for cancer survivors needs to be conveyed to cancer survivors and their clinical care teams, as previously identified concerns around the safety of

exercise is frequently reported by HCPs (Spellman et al., 2013) and cancer survivors (Mikkelsen, Nielsen, Vinther, Lund, & Jarden, 2019).

3.4.1 Quality of the evidence

Due to poor reporting in these studies, most of the studies in this review were judged to include at least one element of high of non-standard bias, described in the 'other potential source of bias outcome'. Within the studies, high risk of bias was commonly judged from a lack of clarity of randomisation procedures, allocation concealment and blinding of outcome assessors. Additionally, reporting of adherence to exercise behaviour was often unclear or unreported which did have an impact upon the certainty of the evidence. Figure 3.2 and Figure 3.3 provide a summary of the certainty of the evidence.

3.4.2 Strengths

There are several strengths to this systematic review; the review followed a Cochrane methodology which is well-known for its rigour and comprehensiveness. During the screening and data extraction process, two independent authors carried out this process, with assistance if required from another senior independent author. A huge effort was made to identify all the relevant RCTs within this field and to my knowledge, we have identified and evaluated more RCTs involving exercise interventions for cancer survivors who are inactive than any other review known in this field. Over 190 papers were screened at full text in this review; this is in addition to the 400 papers screened at full text in the previous review. 122 emails were sent to corresponding authors of identified papers to request data or to make clarifications to ensure the information used is as accurate as possible.

3.4.3 Limitations

Due to not having access or resource to translation services, we were unable to translate all non-English language studies identified via the search strategy. However, a large effort was made to identify all the relevant literature within this field.

Cochrane reviews were typically designed for drug trials; therefore, using a Cochrane methodology to appraise exercise interventions was somewhat difficult. For example, the blinding of an exercise trial is not achievable. Therefore, this aspect of risk of bias had to be removed from this review.

However, the reasoning behind selecting a Cochrane methodology from the research team was due to their rigour.

This review included studies with 'inactive' participants, which was defined in this review as 'not undertaking 30 minutes or more of exercise of at least moderate intensity, three days per week, or 90 minutes in total of moderate intensity exercise per week'. Whilst the current definition for inactivity is "*the non-achievement of physical activity guideline*" (Tremblay et al., 2017, p. 9), it is important to note, it could be assumed some of these participants were taking part in up to 90 minutes of exercise per week.

The studies included in the review were rarely based on theory, however, reviewing these studies using a theory coding scheme would have improved the rigour of this examination process (Michie & Prestwich, 2010).

Lastly, BCTs were only extracted individually and no further analysis was carried out to understand possible associated effectiveness of BCTs or potential combinations of BCTs in relation to associated effectiveness. This was due to limited resources and time.

3.4.4 Impact for practice

Other previous reviews have highlighted the benefits of exercise in this clinical population for CRF and Quality of Life (QoL) (Kessels et al., 2018; Mishra et al., 2012). This review highlights that exercise is safe and several strategies should be used in such interventions to improve exercise behaviour in cancer survivors. Despite exercise being nationally and internationally recommended to be a part of standard cancer care (Buffart et al., 2014; Campbell et al., 2012; Schmitz et al., 2010), it doesn't reflect standard practice. The role of HCPs involved in exercise trials in cancer is still unclear from this evidence synthesis. Initially, these findings need to be translated into practice, but to achieve this, these exercise interventions need to consider the role of HCPs. If such trials will lead to the development of clinical exercise recommendations, HCPs will be responsible for implementing these in standard cancer care. Without HCP awareness, support, and positive beliefs about exercise for cancer survivors, it will be difficult to implement exercise recommendations into usual care.

3.4.5 Impact for research

As it stands, the research in this field has focused upon exercise trials in white, breast cancer patients with the longest follow-up time point of six months. Exercise trials need to be carried out in other cancer cohorts.

There is still a significant problem with trials underreporting key information that may be useful to other researchers when designing and or evaluating trials. Potential strategies to improve and strength this field of research are as follows:

- Studies need to report behavioural aspects of the study. As it is important to understand how to promote exercise behaviour, to produce the desired outcomes of the intervention outside of an RCT.
- Studies need to use theory to design their interventions and report this, as stated by the MRC guidance (Craig et al., 2013).
- Studies need to explore the inclusion of clinical team in such trials; this may have benefit for the patients.
- Studies need to improve the reporting of adverse events and if they are related to the trial or not. As this review found exercise is safe in this cohort but some trials did not report this key bit of information.
- Studies need to report the frequency, intensity, time, and type (FITT principles), as researchers must understand what 'dose' of exercise had the desired outcomes for specific cancers as this can lead to specific exercise guideline development.
- Studies need to report adherence and in a standardised way such as a single proportion of the cohort who attended/performed exercise according to the exercise prescription. By adherence data being reported and reported clearly, a better understanding of the factors that are associated with adherence could be gained.
- BCTs need to be reported in studies using a standardised language such as using BCT taxonomy. Examples of these taxonomies are the CALORE taxonomy (Michie, Ashford, et al., 2011) and the BCT v1 taxonomy (Michie et al., 2013). This would help researchers understand more about what BCTs are successful in context-specific behaviour change and acceptance.

- Studies should aim to measure exercise objectively to support self-report measures.

It is suggested that the TIDieR framework (Hoffmann et al., 2014), which is a template for intervention description and replication is used when reporting and designing exercise interventions. If future trials were to follow these recommendations, this field could start to establish an acceptable level of rigour, which is currently not being achieved. This could lead to the field moving forward and to the development of exercise guidelines for specific cancers.

3.5 Conclusion

This review has highlighted we have a better understanding of how to promote exercise behaviour in cancer survivors. With evidence to suggest that for cancer survivors to meet (Rock et al., 2012) guidelines is achievable. This includes the role of supervision and the use of commonly reported BCTs such as *'goal setting'* and *'problem-solving'*, which will be considered for HCPs to deliver to patients as part of the future HCP intervention. Very few adverse events were reported, deeming exercise to be safe for this population. This needs to be promoted to cancer clinical teams and cancer survivors themselves. The role of the cancer clinical team is still unclear from the synthesised studies, despite their importance in recommending exercise and lifestyle.

Within this field of research, there are substantial issues with a lack of clear reporting and a lack of long-term follow-up data. Further high quality, longer-term trials are needed to explore whether there are further and longer-lasting benefits of exercise for cancer survivors and how best to support inactive cancer survivors. Additionally, these trials need to include behavioural science and the use of theory within the development.

3.6 Chapter summary

Several strategies to improve exercise behaviour in cancer survivors have been identified that could be implemented by HCPs, however, HCPs are rarely involved in exercise trials, despite proven benefit. It is now important to explore what behaviours and recommendations are recommended in clinical practice to support exercise. The next chapter explores what clinical exercise recommendations are available for HCPs to follow.

4) Chapter four: What are the existing clinical recommendations for HCPs to follow for exercise in the top four most common cancers?

4.1 Background

Exercise advice and exercise support from healthcare professionals (HCPs) is rarely seen as part of the cancer care pathway (Duncan. et al., 2017; Webb, Hall, et al., 2016), despite beneficial effects of HCPs discussing exercise with cancer survivors. A lack of specific clinical guidance or awareness of such guidance for exercise is suggested to be an important aspect of the problem to consider (Nadler et al., 2017; Segal et al., 2017a), given that standard practice and HCP behaviour is influenced by the available guidelines and recommendations (see Chapter one).

Guideline panels develop clinical guidelines which aim to provide evidence-based guidelines and recommendations to improve health and social care in disease. Currently, there is not a comprehensive or objective understanding of what clinical exercise recommendations are available for specific cancers and what these recommendations look like. A systematic review of guidelines and primary research in the exercise and cancer literature demonstrate an overview of what guidelines are available for cancer patients, such as those provided by American College of Sports Medicine (ACSM) (Schmitz et al., 2010) but not for specific cancers (Buffart et al., 2014; Segal et al., 2017a, 2017b). Twenty-three unique exercise interventions for cancer survivors were identified in the systematic review (see Chapter three). Exercise interventions were only present in the four most common cancers (breast, prostate, lung and colorectal). No exercise recommendations specific to these cancers were reported.

The overall generic exercise recommendation such as the ones published by ACSM has been criticised due to the 'one size fits all' approach and falling short of providing precise context, appropriate timing of exercise and the required screening of individuals (Stout, Baima, Swisher, Winters-Stone, & Welsh, 2017). Therefore, having specific exercise recommendations for each cancer or health condition is important. As the effect exercise may have for instance on fatigue may be related to a particular aspect of the exercise intervention; such as Frequency, Intensity, Type and Time, also known as the FITT principles

(Sweegers et al., 2018). Without this clearly being stated in the recommendations, it would be difficult to understand what exercise needs to be delivered to produce the desired outcomes.

A lack of awareness of recommendations can lead to implementation issues (Abrahamson, Fox, & Doebbeling, 2012). There are also other factors associated with a lack of use of guidelines within clinical practice. These factors range from a lack of specificity (Michie & Lester, 2005), lack of quality and rigour of guideline development (Brouwers et al., 2010; Vigna-Taglianti, Vineis, Liberati, & Faggiano, 2006), lack of skills to implement the recommendations and a lack of conviction regarding the proposed outcomes (Abrahamson et al., 2012). Michie and Johnston (2004) propose one of the most cost-effective methods to tackle implementation issues of guidelines is to rewrite current guidelines in specific behavioural terms. They suggest specifying recommendations in behavioural terms such as 'what', 'who', 'when', 'where', and 'how' can serve two purposes. Firstly, it can make implementation more achievable, as the recommendation is clearer. Secondly, it can help us identify what behaviour(s) happen before and after implementation. As it can be a useful way to assess potential barriers and facilitators to implementation of a recommendation. As we know that specifying a recommendation behaviourally, is an important aspect to consider for behaviour change of HCPs.

There is a lack of understanding of what specific clinical exercise recommendations are available for cancer survivors and whether they provide adequate guidance for HCPs to effectively use the. From an intervention development perspective, this is an important first step to understand what current clinical recommendations are available for cancer survivors, how they are presented and whether they are suitable for use by HCPs involved in cancer care. This chapter aims to review and appraise the current clinical exercise recommendations or cancer survivors. This will identify which of these recommendations and how these recommendations can be utilised for intervention development and therefore potentially increase opportunity for HCPs to engage in meaningful and effective conversations with their patients.

Research question

To what extent do guidelines for cancer treatment in the four most common cancers recommend exercise and what are the behavioural specifications of these recommendations?

4.1.1 Objectives

- To carry out a rapid review of the Inter/National guidelines in Western countries in the four most common cancers in the UK.
- To identify and summarise what specific exercise recommendations are available for these cancers.
- To assess how the exercise recommendations are presented for the use of HCPs.

4.2 Methods

4.2.1 The team

The core rapid review team was multi-disciplinary: I (RT) led on all aspects of this rapid review. Uncertainties around inclusion or exclusion of recommendations were discussed with LB and any disagreements discussed with DR (both members of the supervisory team at the time).

4.2.2 Study design

This study employed a rapid review methodology to synthesis firstly guideline panels, secondly, identify relevant clinical guidelines and thirdly clinical 'exercise' recommendations retrieved from these clinical guidelines, definitions of these are provided in Table 4.1.

Table 4.1: Definitions and examples of guideline panels, guidelines and recommendations

Name	Definition and examples
Guideline panels	Guideline panels develop clinical guidelines which aim to provide evidence-based guidance and advice to improve health and social care in disease (Institute of Medicine, 2011). An example would be: National Institute for Health and Care Excellence (NICE)
Clinical guidelines	Clinical practice guidelines are 'systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances' (Field & Lohr, 1990, p. 8). Full guidelines contain information about the evidence base for the recommendations. An example would be: Prostate cancer: diagnosis and management NICE guideline [NG131] Published date: May 2019
Recommendations	Recommendations are published within guidelines and do not contain information about methods or evidence. An example would be: <u>Managing adverse effects of hormone therapy</u> <u>Fatigue</u> 1.4.18 Tell people who are starting androgen deprivation therapy that fatigue is a recognised side effect of this therapy and might not be because of their prostate cancer. [2014]

Step 1: Identifying guideline panel

Initially, guideline panels needed to be identified in this review. As guideline panels are responsible for producing clinical guidelines and therefore recommendations.

The following inclusion criteria were applied. Guideline panels had to:

- Be responsible for developing National or International guidelines that included cancer.
- Develop guidelines for the use within the Western World, defined using World Bank Classification (World Bank, 2018).
- Produce guidelines in the English language, for the use of clinicians, policymakers, and commissioners.
- Produced guidelines for cancer care.

4.2.3 Search methods

Electronic searches

A search strategy was developed and refined for each of the electronic guideline databases searched (see Appendix C) These included NICE evidence, TRIP, National Guidelines Clearing House, International guideline library and BMJ Best practice. These were searched from January 2008 to January 2018 by review author (RT).

4.2.4 Data collection

Selection of guideline panel

All search results were imported into excel. Firstly, guidelines panels were screened for duplicates and were removed by one review author (RT).

Data extraction and management

Review author (RT) extracted the following data using a data extraction form managed in excel.

- Database the guideline panel was identified from e.g. TRIP
- The database website.
- The name of the guideline panel and their abbreviation
- The countries the guideline panel was responsible for developing guidelines for.

- Cancer(s) the guideline panel developed guidelines for.

Guideline panels were screened by one review author (RT) for inclusion criteria. Guideline panels that did not meet the inclusion criteria were removed. All remaining guideline panels were retrieved for further assessment. The further assessment consisted of finding the guideline developer's relevant website, to gain further insight as to whether the guideline developer met the inclusion criteria. Uncertainties on the inclusion of guideline panels were discussed with another review author (LB) and any disagreements were resolved by a discussion with a third review author (DR).

Step 2: Identifying relevant clinical guidelines

The second step of the review was to identify the relevant clinical guidelines. The following inclusion criteria for the guidelines had to be met to be eligible:

- Produce guidelines that covered the 'diagnosis and management' of breast, prostate, lung or colorectal cancers. Guidelines which cover 'screening' or 'at risk of cancer' or 'any other cancer' were not eligible for this review.

4.2.5 Search methods

Electronic searches

For each included guideline panel website, searches for each specific cancer were carried out to identify guidelines. The search terms were as follows:

- Breast cancer
- Prostate cancer
- Colorectal cancer
- Lung cancer

4.2.6 Data collection

Selection of clinical guidelines

Any guidelines identified for breast, prostate, colorectal and lung cancer care were included in this review.

Data extraction and management

The whole clinical guidelines were stored as PDFs and uploaded into Endnote to manage the data.

Step 3: Identifying clinical recommendations on exercise

The third step of this review was to identify the relevant recommendations produced within the identified clinical guidelines. The following inclusion criteria for the recommendations had to be met to be eligible:

- The recommendations were produced as part of a set of guidelines for cancer care.
- They had to encompass exercise and or physical activity recommendations to be eligible.

4.2.7 Search methods

Electronic searches

The eligible identified clinical guidelines were searched for recommendations on exercise, physical activity, or lifestyle. The search terms were as follows:

- exercise,
- physical activity,
- activity,
- lifestyle,
- aerobic,
- resistance

4.2.8 Data collection

Selection of recommendations

Any recommendations including any of the above terms were extracted and managed in a database in by one reviewer (RT). The recommendations were screened and reviewed.

Data extraction and management

Review author (RT) extracted the following data using a data extraction form managed in excel.

- The name of the guideline panel and their abbreviation
- The countries for which the guideline panel were responsible for developing guidelines.
- Cancer for which the guideline panel was responsible for developing guidelines.

- Specific cancer the recommendation was related to e.g. advanced prostate cancer.
- Details of the exercise recommendation.
- The date the recommendation was published.

Recommendations were screened by one review author (RT) for inclusion criteria. Recommendations that did not meet the inclusion criteria were removed. Uncertainties on the inclusion of any recommendations were discussed with another review author (LB) and any disagreements were resolved by a discussion with a second review author (DR).

4.2.9 Analysis

Recommendations are presented and synthesised as a narrative.

4.3 Results

4.3.1 Results of the search

4.3.2 Guideline panels and clinical guidelines

Figure 4.1 illustrates the process of the search and guideline panel, guideline and recommendation selection for the review. 24 guideline panels were included in the review (see Appendix D). A total of 191 unique guideline panels were identified through the searches and 167 guideline panels were excluded due to not meeting the inclusion/exclusion criteria.

351 clinical guidelines were identified and reviewed for the management of breast, prostate, colorectal and lung cancer from 11 guideline panels.

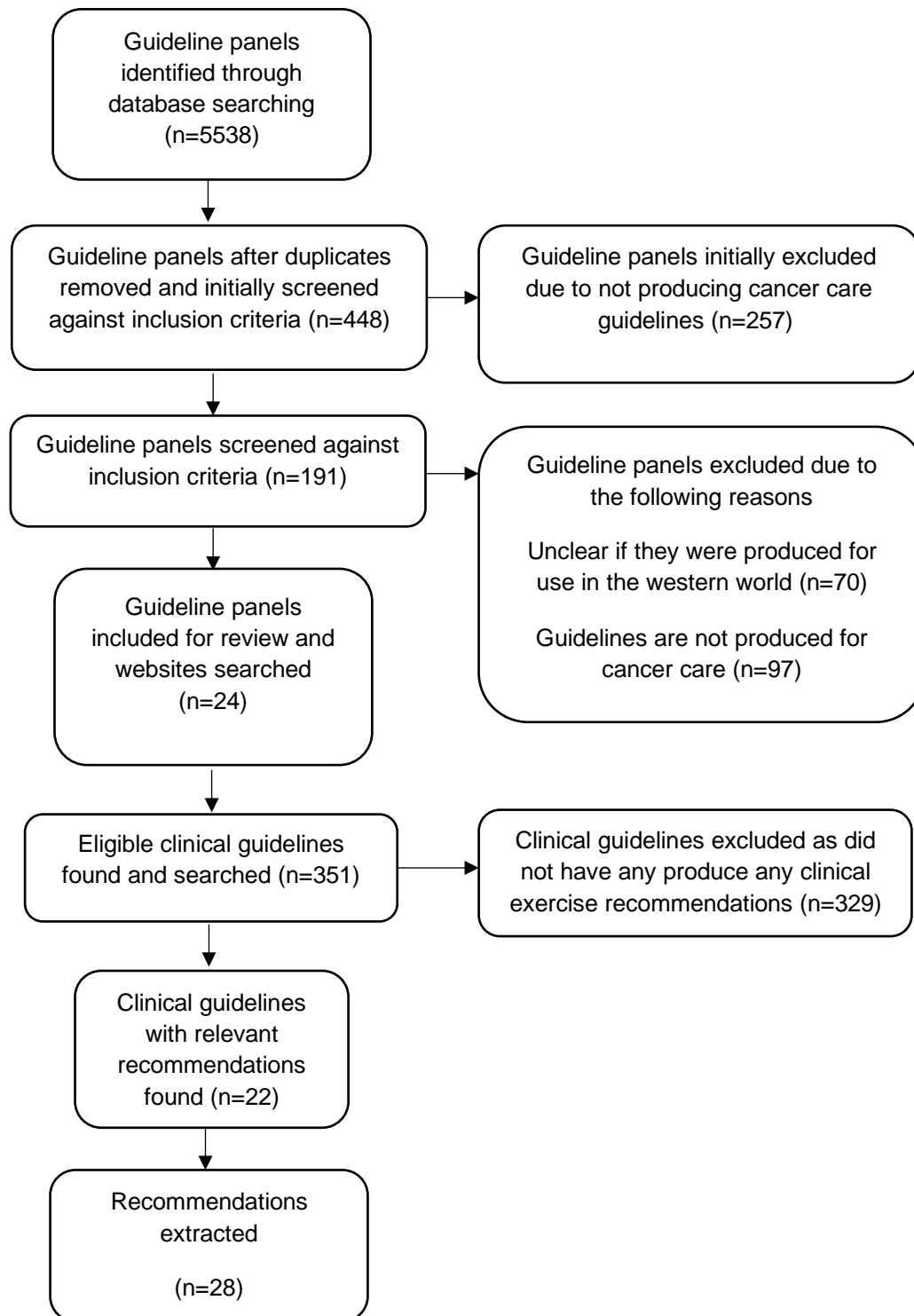


Figure 4.1: PRISMA flow diagram for rapid review

4.3.3 Included recommendations

28 recommendations from 22 guidelines developed by 11 guideline panels were identified from the searches (see Table 4.2); breast cancer (13), prostate cancer (8), lung cancer (5) and colorectal cancer (2). Most of these recommendations were from guidelines published in the USA (11), followed by Canada (6), UK (4), Europe (4), New Zealand, (2) and Scotland (1).

Table 4.2: Exercise recommendations identified from rapid review

Guideline panel	Clinical guideline	Recommendation	Who?	Where?	What?	When?	How?
NCCN (USA)	Lung cancer: Long-term follow up care (2017)	Adopt a physically active lifestyle (regular physical activity: 30 mins of moderate-intensity physical activity on most days of the week).	HCPs involved in lung cancer care	Not clear	Patients should adopt an active lifestyle in line with the below FITT principles: F - most days of the week I - moderate-intensity T - 30 minutes T -not stated	During follow-up care appointments .	Not stated
	Breast cancer: (2017)	The NCCN Panel recommends an active lifestyle and ideal body weight (BMI 20-25) for optimal overall health and breast cancer outcomes as there are reports of proven benefits of exercise and active lifestyle	HCPs involved in breast cancer care	Not clear	Benefits of exercise and an active lifestyle during and after treatment for breast cancer outcomes. FITT principles not stated.	During follow up and or treatment care	Not stated

		during and after treatment. Discussion update in progress					
	Colorectal cancer: Survivorship, healthy lifestyle for survivors of colorectal cancer (2017)	Evidence also indicates that certain lifestyle characteristics, such as smoking cessation, maintaining a healthy BMI, engaging in regular exercise and making certain dietary choices are associated with improved outcomes and quality of life after treatment for colon cancers. Therefore, survivors of colorectal cancer should be encouraged to maintain a healthy body weight throughout life: adopt a physically active	HCPs involved in colorectal survivorship cancer care	Not clear	Cancer survivors should regularly exercise to improve quality of life in line with FITT principles: F – most days I – moderate-intensity T - not stated T -30 minutes	Follow-up and or treatment care	Not stated

		lifestyle (at least 30 minutes of moderate intensity activity on most days of the week).					
SIGN (Scotland)	Lung cancer: Provision of information (2014)	Follow up/end of treatment - highlight the benefit of exercise and a healthy diet.	HCPs delivering follow-up and or end of treatment	Not clear	Highlight exercise is beneficial. Benefits or FITT principles are not stated.	During follow-up care and treatment appointments .	Not stated
CHEST (USA)	Lung cancer: "Diagnosis and Management of Lung Cancer, Published: 21.0 Complementary Therapies and Integrative Medicine in Lung Cancer": (2013)	2.4.3.1. In patients awaiting pulmonary resection for suspected lung cancer with compromised lung function, supervised exercise-based pulmonary rehabilitation is suggested to improve cardiorespiratory fitness and functional capacity (Grade 2C).	HCPs involved in diagnosis and the management of lung cancer	Not clear	Patients should be made aware that a supervised exercise programme would improve cardiorespiratory fitness and functional capacity. FITT principles not stated.	Pre-surgery appointments	Not stated but exercise needs to be supervised. Not discussion of where the programme is delivered or how to access.

	Lung cancer: "Diagnosis and Management of Lung Cancer, Published: 21.0 Complementary Therapies and Integrative Medicine in Lung Cancer": (2013)	2.4.3.2. In post-surgical lung cancer patients with compromised lung function, supervised exercise based pulmonary rehabilitation is suggested to improve cardiorespiratory fitness and functional capacity (Grade 2C).	HCPs involved in diagnosis and the management of lung cancer	Not clear	Patients should be made aware that a supervised exercise programme would improve cardiorespiratory fitness and functional capacity. FITT principles not stated.	Post-surgery appointments	Not stated but exercise needs to be supervised. Not discussion of where the programme is delivered or how to access.
	Lung cancer: "Diagnosis and Management of Lung Cancer, Published: 21.0 Complementary Therapies and Integrative Medicine in Lung Cancer": (2013)	2.4.3.3. In advanced (inoperable) lung cancer patients receiving palliative anticancer therapy and compromised lung function, supervised exercise-based pulmonary rehabilitation is suggested to improve	HCPs involved in diagnosis and the management of lung cancer	Not clear	Patients should be made aware that a supervised exercise programme would improve cardiorespiratory fitness and functional capacity.	In palliative care	Not stated but exercise needs to be supervised. Not discussion of where the programme is delivered or how to access.

		cardiorespiratory fitness and functional capacity (Grade 2C).			FITT principles not stated.		
NICE (UK)	Advanced Breast Cancer 1.5 Managing complications: Lymphoedema (2014)	1.5.1 Discuss with people who have or who are at risk of breast-cancer related lymphoedema that there is no indication that exercise prevents, causes or worsens lymphoedema	HCPs involved in managing breast cancer complications	Not clear	To discuss with patients that there is no indication that exercise prevents, causes or worsens lymphoedema. FITT principles not stated.	During follow up and or treatment care	States for HCPs to 'discuss'
	Advanced Breast Cancer 1.5 Managing complications: Lymphoedema (2014)	1.5.2 Discuss with people who have or who are at risk of breast cancer related lymphoedema that exercise may improve their quality of life.	HCPs involved in managing breast cancer complications	Not clear	To discuss with patients that exercise may improve their quality of life. FITT principles not stated.	During follow up and or treatment care	States for HCPs to 'discuss'
	Advanced Breast Cancer 1.5 Managing complications:	1.5.10 Provide information about and timely access to an exercise programme	HCPs involved in managing breast cancer complications	Not clear	To provide information and access to an exercise	During follow up and or treatment care	States for HCPs to 'discuss'

	Cancer-related fatigue (2009)	for all patients with advanced breast cancer experiencing cancer-related fatigue.			programme to improve cancer-related fatigue. FITT principles not stated.		
	Advanced Prostate Cancer: Fatigue (2014)	1.4.19 Offer men who are starting or having androgen deprivation therapy supervised resistance and aerobic exercise at least twice a week for 12 weeks to reduce fatigue and improve quality of life.	HCPs involved in the management of advanced prostate cancer	Not clear	Offer men access to a supervised exercise programme, in line with the below FITT principles to improve fatigue and quality of life: F - twice a week for 12 weeks I - not stated T - aerobic and resistance T - not stated	Initiation of treatment and or treatment care	HCPs should 'offer' an exercise programme
CCP (Canada)	Patients with early stage breast cancer (2015)	All patients should be encouraged to maintain good "bone	HCPs involved in care of patients with	Not clear	Encourage patients to exercise to improve bone	During follow up and or treatment care	States HCPs should 'encourage'

		health” measures such as: Performing regular weight-bearing, balance and strengthening exercises	early stage breast cancer		health in line with the below FITT principles: F - not stated I - not stated T - weight-bearing balance and strengthening exercises T - not stated		
	Breast cancer: Lymphedema (2015)	Exercise: use of muscle contractions of the affected limb to facilitate the drainage of lymph fluid; strenuous exercises should typically be avoided.	HCPs who treat patients with lymphedema	Not clear	To avoid strenuous exercises	During follow up and or treatment care	Not stated
	Breast cancer: Survivorship (2015)	In addition to other directed treatments, appropriate patient education, encouraging exercise, appropriate rest, and	HCPs involved in breast cancer survivorship care	Not clear	Encourage exercise for patients with breast cancer. FITT principles not stated	During follow up and or treatment care	States HCPs should 'encourage'

		cognitive behaviour therapy should always be discussed.					
	Prostate cancer: Follow up care and psychosocial needs of survivors of prostate cancer.	Men should be encouraged to participate in an exercise program Strategies thoroughly described in PEBC Guideline 19-5.	HCPs involved in prostate follow-up care	Not clear	Encourage men to take part in an exercise program. Benefits and FITT principles not stated.	Follow-up care	HCPs should 'encourage' patients
MoH (NZ)	Breast cancer: Bone density-management of early breast cancer. (2009)	Postmenopausal women taking aromatase inhibitors are recommended to commence treatment with bisphosphonates if the T-score is <-2.0, or <-1.0 in the presence of a vertebral fracture. Secondary causes of osteoporosis should be excluded and standard lifestyle	HCPs involved in the care of women with early breast cancer	Not clear	Standard lifestyle advice should be provided. Benefits and FITT principles not stated	During follow-up and or treatment care	Not stated

		advice on smoking and exercise, calcium supplementation and adequacy of vitamin D intake should also be provided					
	Breast cancer: Bone density-management of early breast cancer. (2009)	<p>A woman with early breast cancer at risk of bone mineral loss should be provided with appropriate advice for good bone health.</p> <p>This includes, but is not limited to:</p> <ul style="list-style-type: none"> • a healthy diet • cessation or continuing abstinence from smoking • maintenance of a healthy body mass index • regular exercise • calcium 	HCPs involved in the care of women with early breast cancer	Not clear	Provide advice for good bone health which includes advising on regular exercise for good bone health. FITT principles not stated	During follow-up and or treatment care	Not stated

		• adequate vitamin D levels					
Australian Cancer Network (Australia)	Breast cancer	Potential complications from cancer treatment. All patients should be encouraged to maintain good “bone health” measures such as: Performing regular weight-bearing, balance and strengthening exercises	Not clear	Not clear	Encourage regular exercise, including weight bearing, balance and strength exercise. FITT principles not stated	During follow-up and or treatment care	States all patients should be encouraged
ESMO (Europe)	Advanced prostate cancer: Management of advanced/metast	Men starting ADT should be informed that regular exercise reduces fatigue and	HCPs involved in the management of	Not clear	Inform patients benefits of regular exercise to improve fatigue	Initiation of treatment	HCPs should 'inform' patients

	atic disease (2015)	improves quality of life [31] [I, A]	advanced prostate cancer		and quality of life. No FITT principles stated		
	Breast cancer: Follow up and survivorship (2015)	Regular exercise should be recommended to all suitable patients after treatment of breast cancer [II, B].	HCPs involved in breast cancer follow up and survivorship care	Not clear	Recommend regular exercise to breast cancer patients. Benefits or FITT principles not stated.	During follow up and or treatment care	States HCPs to 'recommend'
CCP (Canada)	Prostate cancer: Follow up care and psychosocial needs of survivors of prostate cancer.	Men should be encouraged to participate in an exercise program Strategies thoroughly described in PEBC Guideline 19-5.	HCPs involved in prostate follow-up care	Not clear	Encourage men to take part in an exercise program. Benefits and FITT principles not stated.	Follow-up care	HCPs should 'encourage' patients
ASCO (USA)	Prostate cancer survivorship care guidelines Health promotion (2015)	Counsel survivors to achieve and maintain a healthy weight by limiting consumption of high-calorie foods and beverages and promoting increased	HCPs involved in prostate follow-up care	Not clear	Counsel survivors to increase physical activity to 150 minutes per week, benefits not stated. FITT	Follow-up care	HCPs should 'counsel' survivors

		physical activity. Counsel survivors to engage in at least 150 minutes per week of physical activity, this may include weight-bearing exercises.			principles not fully stated.		
ASCO (USA)	Breast cancer: survivorship care guideline. (2015)	Health promotion Physical Activity -It is recommended that primary care clinicians should counsel survivors to engage in regular physical activity consistent with the ACS guideline and specifically: III - Case-control study or prospective cohort study Should avoid inactivity and return to normal daily activities as soon as possible following diagnosis.	Primary care HCPs involved in breast cancer survivorship care	Primary care	To counsel survivors to engage in physical activity. Benefits or FITT principles are not stated.	During follow-up care in primary care	Recommend ed that HCPs should 'counsel' survivors

	Breast cancer: Clinical Domain Recommendation Level of Evidence. (2015)	Should aim for at least 150 minutes of moderate or 75 minutes of vigorous aerobic exercise per week. Should include strength training exercises at least 2 days per week. Emphasize strength training for women treated with adjuvant chemotherapy or hormone therapy.	Not clear	Not clear	Breast cancer survivors should exercise in line with the following FITT principles: F –twice weekly for strength training I – moderate-intensity/ vigorous intensity T – 150 minutes a week for moderate intensity and 75 minutes a week for vigorous intensity T – aerobic and resistance	Not clear	Should 'emphasize' strength training
American Cancer Network (USA)	Prostate cancer: Psychosocial care: (2010)	Men with advanced prostate cancer should be advised that resistance exercise	HCPs involved in prostate follow-up care	Not clear	Advise men with advanced prostate cancer that a supervised	Follow-up and or treatment care	Not stated

		and moderate to strenuous physical activity with expert supervision/support can improve quality of life and muscular fitness and reduce fatigue and the impact of fatigue on daily living. Unstable bone lesions and co-morbidities such as cardiovascular disease are exclusion criteria for studies on this topic and so are likely contraindications for this approach.			exercise programme including aerobic and resistance exercise can improve quality of life, fatigue and muscular fitness. FITT principles not fully stated.		
CCO (Canada)	Prostate cancer: Follow-up Care and Psychosocial Needs of Survivors of Prostate Cancer	Men should be encouraged to participate in an exercise program	HCPs involved in prostate follow-up care	Not clear	Encourage men to participate in an exercise programme.	Follow-up care	HCPs to 'encourage' patients

	Side effects (2015)				Benefits and FITT principles not stated.		
	Colorectal cancer Follow-up Care, Surveillance Protocols and Secondary Prevention Measures for Survivors of Colorectal Cancer. (2016)	Recommendation: despite the lack of high-quality of evidence on secondary prevention in colorectal cancer survivors, the following counselling goals would be reasonable based on lower levels of evidence and the expert opinion of the authors: <ul style="list-style-type: none"> • Maintain an ideal body weight • Engage in a physically active lifestyle 	HCPs involved in colorectal follow-up cancer care	Not clear	Counsel survivors to engage in physical activity. Benefits and FITT principles not stated.	Follow-up care	Not stated

		<ul style="list-style-type: none"> • Eat a healthy diet 					
EAU (Europe)	Prostate cancer: 8.3.2.1 Guidelines on improving quality of life in men who have been diagnosed with prostate cancer	Offer men on androgen deprivation therapy, twelve weeks of supervised (by trained exercise specialists) combined aerobic and resistance exercise	HCPs involved in prostate cancer care	Not clear	Offer a supervised exercise programme to men on androgen deprivation therapy in line with below FITT principles, benefits not stated: F - 2 weeks I - not stated T - aerobic and resistance T - not stated	Follow-up and treatment care	HCPs to 'offer' men
	Prostate cancer: 8.3.2.1 Guidelines on improving quality of life in men who have	Offer men with T1-T3 disease specialist nurse led, multi-disciplinary rehabilitation based on	HCPs involved in prostate cancer care	Not clear	Support lifestyle change after treatment. Benefits and FITT	Follow-up care after treatment	HCPs to 'offer' men

	been diagnosed with prostate cancer	the patients' personal goals addressing incontinence, sexuality, depression and fear of recurrence, social support and positive lifestyle changes after any radical treatment.			principles not stated.		
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4.3.4 Characteristics of the included recommendations

4.3.4.1 Specific cancers

Breast

The highest number of recommendations were found in breast cancer (13), published by panels from the UK (3), Europe (1), Canada (3), USA (3), New Zealand (2) and Australia (1). These recommendations varied. Two recommendations related specifically to lymphoedema and stated that strenuous exercise should be avoided, see Table 4.2. There was no indication that exercise was beneficial or harmful to lymphoedema. Only five recommendations stated why exercise would be beneficial, and these included for improvements in quality of life, fatigue, bone health and overall health improvements. Further to this, only one recommendation offered an exercise prescription that fit with the FITT principles.

Prostate

Eight recommendations were found for prostate cancer, published by guideline panels from the UK (1), Europe (3), Canada (2) and USA (2). Four of the prostate cancer recommendations focused upon advising men specifically on Androgen Deprivation Therapy to carry out aerobic and resistance exercise to improve quality of life or fatigue. Two specifically advised patients should be referred to an exercise programme. No recommendations offered an exercise prescription that fit with the FITT principles.

Colorectal

Two recommendations were identified for colorectal cancer; both recommendations stated the importance of lifestyle factors and were published by guideline panels from the USA and Canada. Only one recommendation highlighted why exercise would be beneficial and this was to improve quality of life and maintain a healthy weight. This same recommendation suggested colorectal cancer survivors should exercise at least for 30 minutes of moderate-intensity activity most days of the week, offering a more specific recommendation. No recommendations offered an exercise prescription that fit with the FITT principles.

Lung

Five recommendations were identified for lung cancer, published in guidance from the USA (4) and Scotland (1). Three of the recommendations stated that supervised exercise-based pulmonary rehabilitation is suggested to improve cardiorespiratory fitness and functional capacity. One recommendation stated the benefit of exercise and a healthy diet should be highlighted. Further to this, one of the recommendations stated that lung cancer survivors should adopt a physically active lifestyle at 30 minutes of moderate-intensity physical activity on most days. No recommendations offered an exercise prescription that fit with the FITT principles.

4.3.4.2 Behavioural specification

Who?

All the recommendations were aimed at HCPs working within cancer care.

Where?

None of the recommendations were clear in terms of where these recommendations should be delivered, except one, which specified it should be delivered in primary care.

What?

Most of the recommendations (26) recommended exercise, physical activity and or lifestyle changes. However, only 12 recommendations highlighted why exercise should be recommended. These benefits were as follows; to improve fatigue, quality of life, bone health, to maintain a healthy weight, physical fitness, and functional capacity.

One specific recommendation was highlighted by NICE for advanced breast cancer, published in 2014, this stated, that there is no indication that exercise prevents, causes, or worsens lymphoedema. Additionally, one Canadian recommendation for breast cancer published in 2015 stated that strenuous exercise should be typically avoided in the limb affected by lymphedema.

It was rarely reported what 'prescription' of exercise HCPs should advise. Six recommendations offered a specific goal of aerobic or resistance exercise in terms of frequency, duration, or intensity. Three of these were in breast cancer and three within prostate cancer. However, only one recommendation fully met

the FITT principles criteria, which was a breast cancer recommendation recommended by ASCO (2015).

When?

The recommendations did not specify when they should be implemented specifically; however, the clinical guidelines responsible for producing the recommendations specified what aspect of care such as follow-up or treatment initiation in which the recommendation should be implemented in.

Behavioural support?

The terms 'encourage' or 'counsel survivors' or 'offer' were often used within the recommendations but no recommendations offered advice or specified in behavioural terms on how HCPs should provide support to patients around exercise.

4.4 Discussion

This rapid review identified 28 exercise recommendations published by 22 clinical guidelines for the four most common cancers in the Western world. No other previous research has synthesised current clinical exercise recommendations in the top four most common cancers. Previous research has only highlighted exercise recommendations, but these were for cancer in general, rather than specific cancers (Segal et al., 2017a). As discussed previously, one of the first steps of for the development of this intervention is having an accurate understanding of the recommendations available for HCPs in supporting their patients in exercise. Until there is clarity and consensus in what should be considered standard care, we cannot develop adequate interventions that are likely to be effective for HCPs.

Recommendations are a necessary first step to changing practice but are not enough to change practice. However, recommendations that are specified behaviourally in terms of 'what', 'who', 'when', 'where', and 'how' are more likely to be implemented (Michie & Johnston, 2004). This review highlighted these exercise recommendations are rarely specified behaviourally and are inadequate in providing clear guidance for HCPs. This indicates a potential issue for the implementation of such exercise recommendations into care. Cardiac rehabilitation (CR), is a good example, of the importance of behaviourally specified recommendations for implementation. CR was

implemented nationally, but a large trial found CR to not be effective at improving mortality, cardiac or psychological morbidity, health-related quality of life or even to be cost-effective (West, Jones, & Henderson, 2012). One of the main reasons for this was that CR was rarely delivered as intended, with very little support from treating HCPs (Doherty & Lewin, 2012). Another reason that it was rarely delivered as intended was the poor guidance available. Following this, NICE published many detailed recommendations on how to deliver CR, what information and support to provide and how to deliver CR and lifestyle support (NICE, 2013a). This has led to an increase in attendance and adherence to CR, improvements in cost-effectiveness of CR (Shields et al., 2018) and improvements in its effectiveness demonstrating the impact of clear and behaviourally specified recommendations (BHF, 2018).

As well as having clear recommendations, other factors need to be considered for HCP uptake of recommendations. HCPs need to understand why the recommendations are likely to be beneficial for patient outcomes. Chapter one identified a lack of awareness of the perceived benefit of exercise a reason for a lack of discussion of exercise (Spellman et al., 2013). Only 12 of the 28 recommendations specified why exercise should be recommended. Additionally, there was no consistent message of what should be recommended or offered within the four cancers. This can further act as a barrier to implementation and has been found in to be confusing for patients (Corbett et al., 2018).

Recommendations were predominantly in breast cancer (13) and prostate (8). Exercise trials within these two cancers, specifically breast cancer is the most common within the literature and this was found in chapter three. However, recommendations within each cancer group still did vary. For example, the exercise recommendations within breast cancer, varied with no specific 'exercise prescription' being present.

4.4.1 Strengths

To my knowledge, this is the first rapid review to synthesis the current clinical exercise recommendations for the four most common cancers in the western world. Previous reviews exploring exercise recommendations in cancers, in general, have been criticised for not exploring more specific recommendations

for each cancer. Generic cancer recommendations that reflect a 'one size fits all' approaches have been criticised previously (Stout et al., 2017).

4.4.2 Limitations

Despite rapid reviews becoming popular in the field of healthcare research, caution needs to be taken when interpreting rapid reviews. In this rapid review, due to practicalities and limited resources, only one reviewer (RT) screened the data. Data was extracted from one reviewer (RT), any concerns were discussed with a second reviewer (LB). If any discrepancies could not be resolved, this was discussed with a third reviewer (DR). To also allow for the rapid review to be carried out in a timely manner, only English language guideline panels and recommendations were searched, and timelines were reduced from 2008 to 2018.

4.4.3 Implications for practice and research

Previous research has highlighted the need for specific clinical exercise recommendations to be identified or developed, to aid the integration of exercise into the cancer care pathway (Stout et al., 2016). This rapid review has highlighted several existing recommendations for exercise which need further development and clarification to be successfully integration into the cancer care pathway as the standard of care. Exercise is rarely seen as part of the cancer care pathway (see section 1.9, page 53), reasons for this are associated with a lack of awareness of such recommendations (Roberts et al., 2019), concerns around the credibility of these recommendations (Roberts et al., 2019) and lack of resources to implement such recommendations (Karvinen et al., 2012). Whilst, raising awareness of these recommendations amongst HCPs will not by itself change clinical behaviour, it is an essential first step.

Recommendations need to be specified behaviourally, include clear exercise prescriptions and state why exercise is beneficial. If recommendations continue to be published as found in the review in this field, implementation will be an issue (Michie & Lester, 2005).

4.5 Conclusion

This review identified 28 clinical exercise recommendations in the four most common cancers in the Western world. These recommendations varied greatly in terms of what was advised and were not specified behaviourally, indicating

problems for implementation. Future work should explore cancer care pathways to understand if these recommendations reflect usual care. Furthermore, HCPs views on these recommendations should be explored to highlight any barriers and facilitators to implementation.

4.6 Chapter summary

This chapter identifies and summarises the current clinical exercise recommendations that are relevant for HCPs to use in their practice. There are common issues across these recommendations such as a lack of information on why exercise should be recommended and a lack of behavioural specification. These are noteworthy issues that will be problematic for implementation. Understanding HCPs views and roles regarding these recommendations would be beneficial, to highlight any barriers and facilitators that could be addressed in a future intervention, chapter five will explore this.

5) Chapter five: Recommending exercise in prostate cancer care

5.1 Preface to Chapter five

As discussed, there are low levels of exercise in cancer survivors and a lack of support from healthcare professionals (HCPs), despite the benefits of exercise for cancer survivors. This problem is consistent across the common cancers. However, the level of evidence for each cancer around exercise differs as discussed in the previous chapters. Research carried out prior to this thesis, identified NICE recommendations published in 2014 (*CG175 1.4.19 Offer men who are starting or having androgen deprivation therapy supervised resistance and aerobic exercise at least twice a week for 12 weeks to reduce fatigue and improve quality of life*) currently do not reflect usual care (Bourke et al., 2018). Following this, it was identified that the integration of these exercise recommendations for locally advanced and advanced prostate cancer, specifically for men with prostate cancer on androgen deprivation therapy (ADT) would be explored as part of this thesis. It is important to note, that during the timeline of this thesis, there was a slight alteration to these recommendations from the above recommendation from CG175 to NG131 as the term ‘**men**’ was changed to ‘**people**’ (*NG131 1.4.19 Offer people who are starting or having androgen deprivation therapy supervised resistance and aerobic exercise at least twice a week for 12 weeks to reduce fatigue and improve quality of life*). This thesis will continue to refer to recommendations NG131 1.4.19.

5.1.1 Prostate cancer

Prostate cancer is a cancer of the prostate gland, see Figure 5.1. Locally advanced prostate cancer is when cancer has spread to nearby tissues such as the rectum, with advanced prostate cancer being when cancer has spread to another part of your body (CRUK, 2019a). This can also be referred to as metastatic prostate cancer. Prostate cancer most commonly spreads to bones and lymph nodes, however, it can spread to any part of the body, see Figure 5.2.

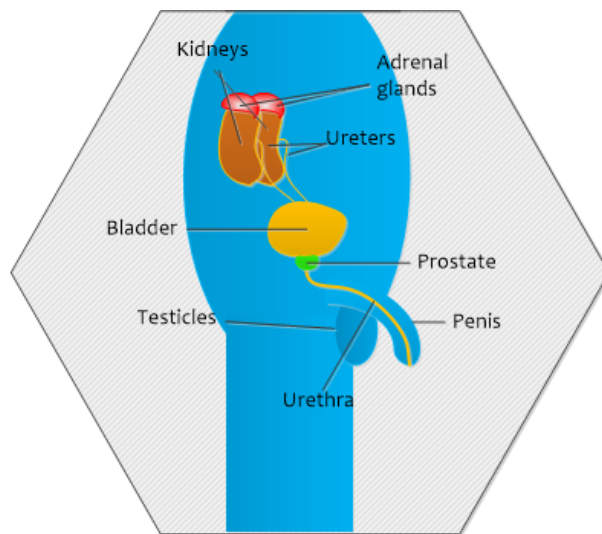


Figure 5.1: Diagram of the prostate

Source: Lifestyle changes to promote better quality of life to promote treatment (patient materials as part of the STAMINA trial)

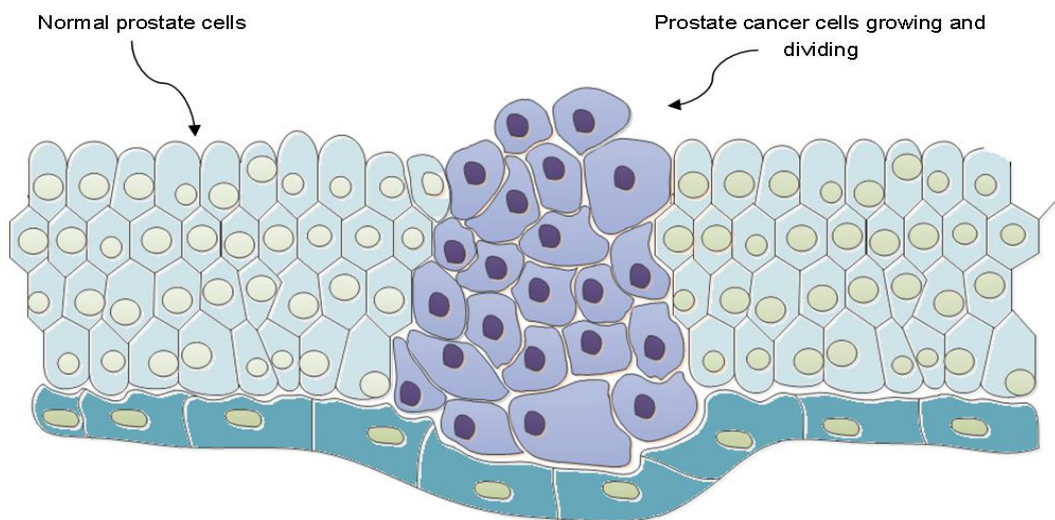


Figure 5.2: Diagram of prostate cancer cells growing in comparison to normal prostate cells

Source: Lifestyle changes to promote better quality of life to promote treatment (patient materials as part of the STAMINA trial)

5.1.2 Incidence and risk factors

Prostate cancer is the most common cancer in men, with around 47,000 men diagnosed each year in the UK and over 1,270,000 men diagnosed each year worldwide (CRUK, 2016; Rawla, 2019). It is estimated that 330,000 men are living with the disease each year in the UK (Macmillan, 2015), with a man's

lifetime risk of getting prostate cancer being one in seven (Siegel, Miller, & Jemal, 2015). There are several risk factors for prostate cancer, but age and ethnicity are the most significant risk factors. Prostate cancer under the age of 40 is extremely rare, the risk increases quickly after the age of 50 (Bashir, 2015). Prostate cancer risk is around 60% higher in white males than in males of African American origin (Bashir, 2015). Other factors increase a person's risk of prostate cancer, such as a family history of prostate cancer (Albright et al., 2015) and obesity (Allott, Masko, & Freedland, 2013).

5.1.3 Prostate cancer treatment

The treatment for prostate cancer is varied, however, ADT is the cornerstone treatment for locally advanced and advanced prostate cancer (Sharifi, Gulley, & Dahut, 2005). ADT is essentially medical castration, as prostate cancer cells require androgen hormones to grow; ADT suppresses these hormones to treat cancer. Whilst ADT is effective at treating cancer, it often comes with several debilitating side-effects; these include cancer-related fatigue (CRF) (Walker, Tran, & Robinson, 2013), increase in weight gain (Braunstein, Chen, Loffredo, Kantoff, & D'Amico, 2014) sexual dysfunction (Ng et al., 2012), increased cardiovascular morbidity and mortality (Bourke, Chico, Albertsen, Hamdy, & Rosario, 2012) and increase risk of type 2 diabetes (Wang, Sun, Zhao, Chen, & Zhao, 2016) all resulting in a reduced health-related quality of life (HRQoL) (Cheung et al., 2017; Dacal, Sereika, & Greenspan, 2006). Distressing psychological effects upon the individual and their partner (Donovan, Walker, Wassersug, Thompson, & Robinson, 2015) are also consequences. Other treatments such as chemotherapy or radiotherapy may be administered alongside ADT and these may produce further adverse effects.

5.2 Background

Men with advanced prostate cancer specifically ADT, report several barriers to engaging in exercise, see Figure 5.3. However, consistently, they report a desire and need for their HCP to provide exercise support and exercise referral from diagnosis (Bourke et al., 2018). NICE exercise recommendations NG131 1.4.19 currently do not reflect usual care, with less than 2% of NHS trusts delivering these recommendations (Bourke et al., 2018). Furthermore, discussions and support about exercise from HCPs is rarely seen as part of the prostate cancer care pathway (Bourke et al., 2018).

HCPs are best placed to provide counsel and motivation to their patients around exercise. Research to understand HCPs views on providing exercise support to different clinical populations is common within the literature. However, the specific reasons behind the NICE recommendations not being delivered as standard care has not yet been explored. As the NICE recommendations are currently the only evidence-based treatment to help alleviate the side effects of ADT, such as fatigue and improve quality of life (QoL), patients' needs are not being met. Furthermore, the present long-term cancer plan (NHS England Long-term plan, 2019) highlights the need to improve self-management strategies for cancer survivors.

As discussed in chapter two, an intervention will be developed using the Medical Research Council (MRC) guidelines (Craig et al., 2008) and the Behaviour Change Wheel (BCW) approach (Michie et al., 2014). This chapter applies the first stage to intervention development from the BCW: understanding the behaviour (see section 2.4.2, page 89). This chapter aims to define the problem in behavioural terms, select and specify target behaviours to change and identify the barriers and facilitators for these target behaviours using semi-structured interviews and framework analysis based on the theoretical domains framework (TDF), see Chapter two.

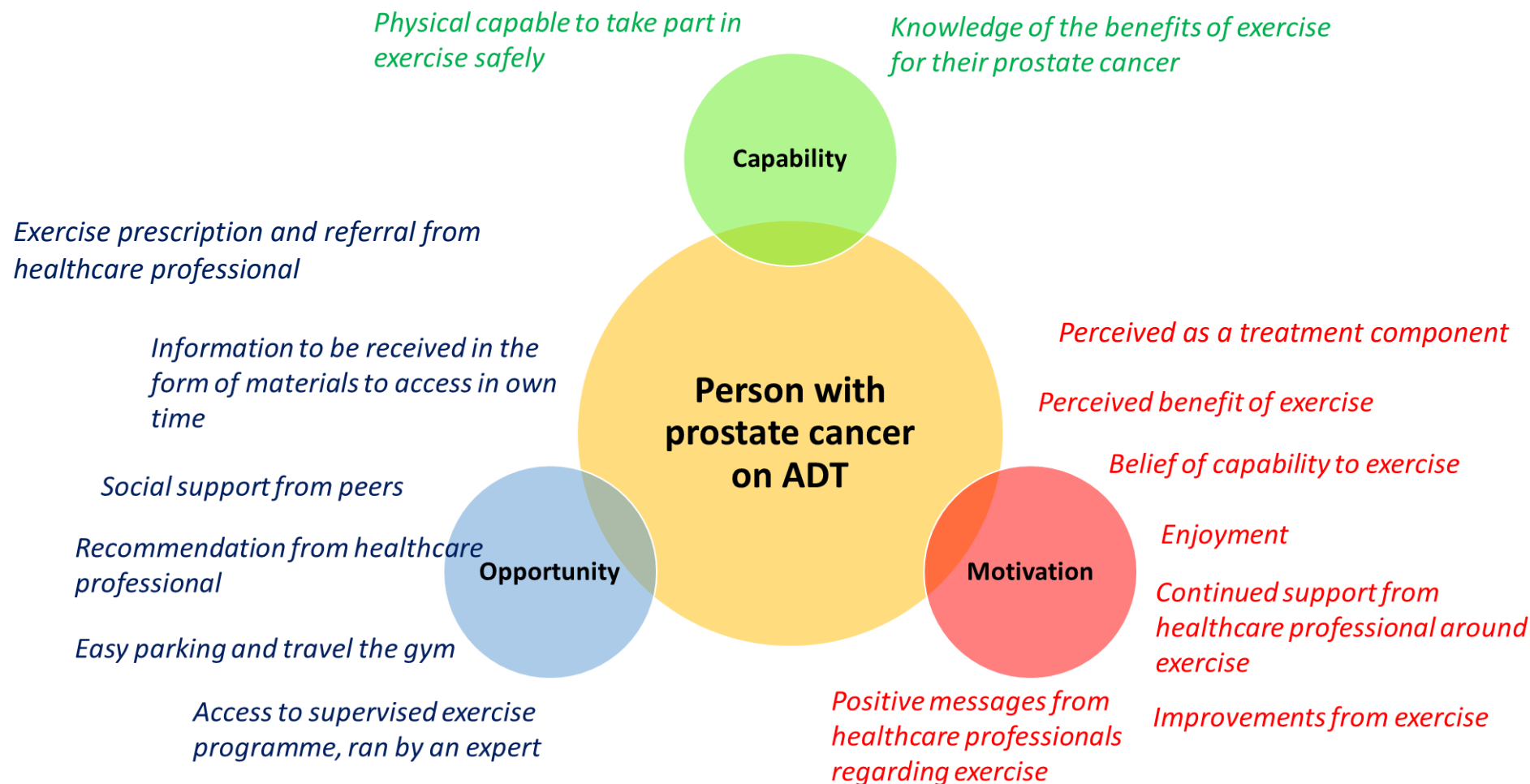


Figure 5.3: Determinants of exercise in men with prostate cancer on ADT (Bourke et al., 2018)

5.3 Research question

What HCP behaviours need to change to implement NICE NG131 1.4.19 recommendations and what are the barriers and facilitators to these behaviours?

5.4 Objectives

- To identify and define the problem to be targeted in the intervention.
- To identify and specify relevant target behaviours to change.
- To carry out a behavioural diagnosis using the TDF and COM-B model in line with the behaviour change wheel guide to identifying barriers and facilitators from HCPs to identified target behaviours.

5.5 Methods

5.5.1 The team

The core intervention development team was multi-disciplinary: I (RT) led on all the intervention development process. Health psychologists (LS & MA), Consultant Urologist (DR) (all members of the supervisory team), Professor of cancer research (LB) and Professor of primary care and public health (ST) provided expertise where applicable.

5.5.2 BCW Step 1: Define the problem in behavioural terms

Two NHS trusts within the North of England were selected to understand the prostate cancer care pathway in place at both NHS sites. This included identifying touchpoints of care and the HCPs responsible for care.

To collect data about the prostate cancer care pathway, several steps were taken:

- 1) Prostate cancer clinical team leads were contacted from both hospitals via email. Each clinical team lead agreed to have discussions within the wider clinical team.
- 2) Presentations followed by a meeting were then held at each hospital with the prostate cancer clinical team and operations management team. This presentation gave an overview of the aim of the wider project STAMINA and the proposed involvement of the clinical teams.
- 3) Key clinical contacts within the prostate cancer clinical teams were identified within these meetings and contact details were taken.

- 4) Meetings with individual key clinical contacts were held, to discuss the prostate cancer care pathway in further detail.
- 5) The lead researcher (RT) continued to make visits and attend routine meetings with HCPs working within prostate cancer care to gain further information about the overall view of the care pathways.
- 6) Schematics of care were developed to represent each pathway; these were shown to key members of the clinical team, allowing them to make refinements.
- 7) Data collection ceased when the schematics were approved by key members of the clinical team.

All data captured during this process was collected using field notes and recorded in intervention logbooks. From the data, key members of the clinical team and key touchpoints of care were identified. Key touchpoints of care were considered opportunities within the care pathway where HCPs were in contact with their patients.

5.5.3 BCW Step 2 and 3: Selecting and specifying the target behaviour

An expert working group consisted of myself (RT), LS, DR, LB & ST initially identified the target behaviours. These were later refined following discussions with RT, MA and DR.

Each target behaviour identified by the group was based on strong evidence identified in stage one of the MRC process and allowed for a realistic modification of an already existing clinical pathway, identified in step one of the BCW process. For each target behaviour proposed the following criteria were considered; Affordability, Practicality, Effectiveness/cost-effectiveness, Affordability, Safety/side-effects and Equity (APEASE), see Table 2.5.

Following the identification of the target behaviours, these were specified in further detail and considering the context. They were specified in behavioural terms; by *who* needs to deliver the behaviour, *what* does a person need to do differently, *when* will it happen and *where* will it take place. *How often* this behaviour is required and *with whom* were also considered.

5.6 Results

5.6.1 Stage 1: Understand the behaviour

Step 1: Define the problem in behavioural terms

The problem was identified as going beyond just the implementation of the recommendations, as other aspects need to be considered such as providing behavioural support to patients about exercise and setting up a referral pathway. Therefore, the behavioural problem identified is a lack of exercise advice, exercise recommendation, exercise support and exercise referral as part of standard prostate cancer care in line with NICE recommendations NG131 1.4.19 from treating HCPs. This has been acknowledged by some HCPs within the pathway, with an expressed want and need for training (Bourke et al., 2018; Sutton et al., 2017).

5.6.1.1 Prostate cancer care pathway at two NHS sites

Figure 5.4 and Figure 5.5 provide overviews of the prostate cancer care pathway at both NHS trusts (Trust one and Trust two). Whilst these pathways operate at two different trusts, there is overlap as to where chemotherapy and radiotherapy are delivered. This is delivered at one oncology hospital. The pathway from diagnosis to follow-up at both sites is the same, however, the HCPs responsible for the care within the pathway differs.

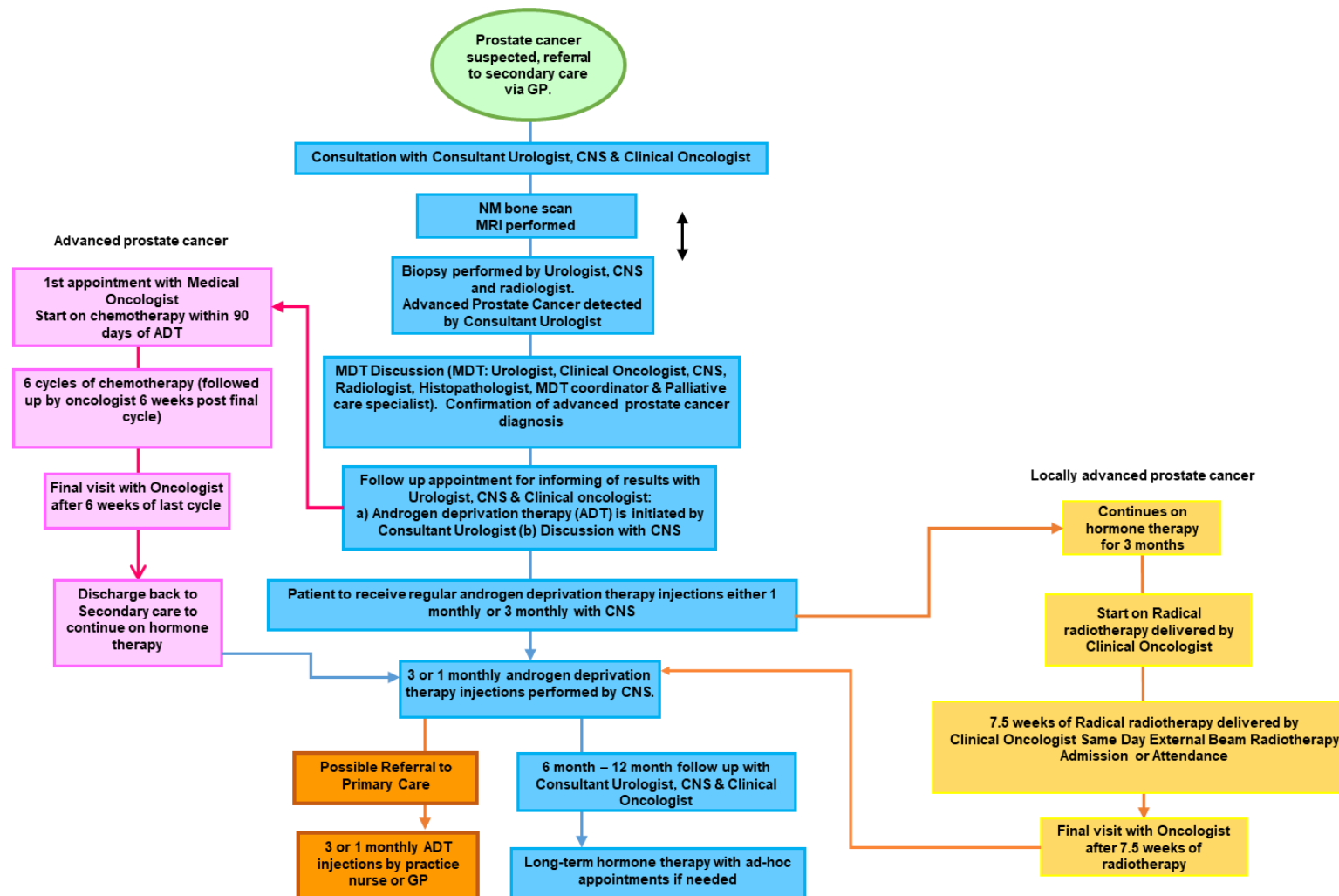


Figure 5.4: Locally advanced and advanced prostate cancer care pathway at trust one

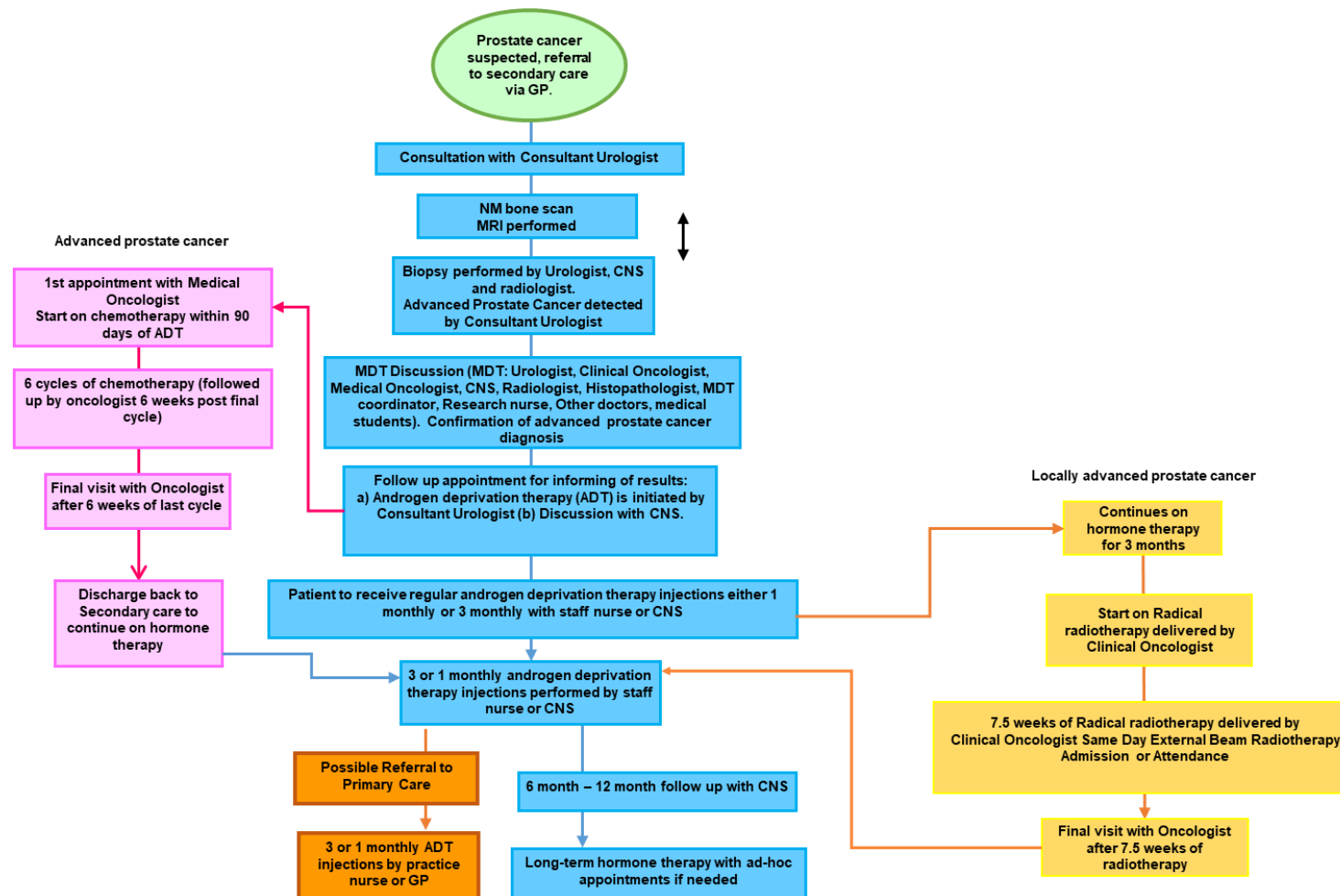


Figure 5.5: Locally advanced and advanced prostate cancer care pathway at trust two

5.6.1.2 Key touchpoints of care

There are four significant touchpoints of care in these pathways; diagnosis, initiation of treatment, treatment delivery and follow up. See Table 5.1 for key touchpoints of care and the key HCP responsible for care across both trusts. There are typically seven varied professionals involved within the care pathway: Consultant urologist, clinical nurse specialists (CNS), medical oncologists, clinical oncologists, GPs, staff nurses and practice nurses. In both sites, the CNS acts as the patient's 'keyworker', a keyworker provides comprehensive care to the patient throughout their period within the pathway. Whilst primary care is sometimes involved within this pathway, this thesis will focus upon secondary care HCPs in the first instance due to pragmatic reasons. These key touchpoints of care represent opportunities for the HCPs to intervene with exercise advice, referral, and support.

Table 5.1: Trust one and trust two touchpoint of care

	Trust one touchpoints	HCP responsible for care	Trust two touchpoints	HCP responsible for care
1	Diagnosis of locally advanced or advanced prostate cancer.	Consultant Urologist and CNS	Diagnosis of locally advanced or advanced prostate cancer.	Consultant Urologist and CNS
2	Initiation of treatment ADT	CNS	Initiation of treatment ADT	CNS
	Initiation of adjuvant chemotherapy	Medical Oncologist	Initiation of adjuvant chemotherapy	Medical Oncologist
	Initiation of adjuvant radiotherapy	Clinical Oncologist	Initiation of adjuvant radiotherapy	Clinical Oncologist
3	Treatment - ADT	CNS/Staff nurse/General practitioner (GP)/Practice nurse	Treatment - ADT	CNS/Staff nurse/General practitioner (GP)/Practice nurse
	Treatment - Chemotherapy	Medical Oncologist	Treatment - Chemotherapy	Medical Oncologist
	Treatment - Radiotherapy	Clinical Oncologist	Treatment - Radiotherapy	Clinical Oncologist
4	Follow up	Consultant Urologist, CNS and Clinical Oncologist	Follow up	CNS

Steps 2-3: Identifying and specifying target behaviours

Initially, nine target behaviours were identified by the immediate and wider research team (RT, DR, LB, ST, LS), reported in Appendix E, with explanations for rejection. These were later reduced to seven target behaviours by RT, MA, LS & DR, presented in Table 5.2, following criteria set within the BCW. This included considering the potential impact of the behaviour change, practicalities of changing the desired behaviours and the spill over effects of change on other behaviours and which behaviours could be easily measured (Michie et al., 2014).

Table 5.2: Identified target behaviours

Target behaviour	Explanation and evidence base	Who and with whom?	Where and When? Secondary care
1. Recommend exercise training at any point within the pathway	NICE NG131 1.4.19 state all people with prostate cancer should be offered an exercise programme who are commencing or undergoing ADT (NICE, 2019).	Any member of the clinical team with men on ADT	At any point within the pathway
2. Discuss barriers and facilitators around exercise training, provide support using BCTs	It is likely patients will need support around exercise training and evidence suggests this has beneficial effects on patient's engagement in exercise (see Chapter one and three).	Keyworker: Clinical Nurse Specialist with men on ADT	At the point of an exercise referral
3. Make referral for exercising training	NICE NG131 1.4.19 state all people with prostate cancer should be offered an exercise programme who are commencing or undergoing ADT (NICE, 2019).	Keyworker: Clinical Nurse Specialist with men on ADT	At any point within the pathway
4. Provide patient with information pack and materials	Patients have expressed a want for information packs and materials to be given around exercise (Bourke et al., 2018).	Keyworker: Clinical Nurse Specialist with men on ADT	At the point of an exercise referral
5. Recognise whether a patient is suitable for exercise	Many patients will be able to exercise with the correct supervision, however, there are some contraindications to exercise that need to be considered by the HCPs for the safety of the patients (see Chapter three).	Any member of the clinical team with men on ADT	At any point within the pathway
6. Read and interpret exercise progress report	Feedback loops between the NHS and exercise professionals have been identified as important for patient support and feedback (Bourke et al., 2018).	Keyworker: Clinical Nurse Specialist or Consultant Urologist with men on ADT	Follow up appointment
7. Provide feedback to the patient on the exercise progress report, provide support using BCTs	Feedback loops between the NHS and exercise professionals have been identified as important for patient support and feedback (Bourke et al., 2018).	Keyworker: Clinical Nurse Specialist or Consultant Urologist with men on ADT	Follow up appointment

5.7 Methods

5.7.1 The team

The core intervention development team was multi-disciplinary: I (RT) on all the intervention development processes and carried out 25 out of 35 interviews prior to starting the thesis. RG (researcher) carried out 10 out of 35 interviews. LS (health psychologist) and ES (qualitative expert) provided expertise where applicable and double coded a sub-set of five transcripts.

5.7.2 BCW Step 4: Identify what needs to change

Using the TDF as the framework for an interview schedule to identify barriers and facilitators to specific target behaviours has been suggested to be appropriate (French et al., 2012). The TDF was used predominantly to explore the barriers and facilitators to the seven target behaviours via semi-structured interviews with HCPs. Semi-structured interviews allow for an in-depth exploration of influences on HCPs behaviour whilst maintaining flexibility. The TDF was used to design the interview schedule for the previously conducted interviews and used as a framework in the analysis. This was then mapped onto the COM-B model to understand what aspects of the COM-B model needed to change.

5.7.2.1 Semi-structured interview schedule design

The semi-structured interview schedule was based upon the TDF (Cane et al., 2012; Francis, O'Connor, & Curran, 2012) (see Appendix F). These interviews covered inter alia HCPs roles, adverse effects of ADT, awareness, and practice with respect to the recent NICE guidelines with offering structured exercise programmes in standard care and the need for further education/training.

Some example questions are as follows:

- *Are you aware of any exercise programmes for other patient groups?
How beneficial do you think exercise/exercise programmes would be for your patients with prostate cancer? (knowledge)*
- *Whose role would you see it as to i) make referrals for exercise programmes ii) delivery of exercise? (social/professional role identity)*

A minor amendment was made to the interview schedule to explore imminent changes to care; this was not specifically based on the TDF (see Appendix G) Some example questions are as follows:

- *Recent data from the STAMPEDE and CHAARTED trial suggest there to be a survival benefit in initiating chemotherapy earlier in the hormone sensitive advanced Prostate cancer pathway. Do you feel the recent findings of the trials will change the standard of care, and to what extent?*
- *How might you change your own practice?*

5.7.2.2 Sampling

Purposive sampling was used in this study, an approach in which participants are selected as they have specific characteristics or features that will allow for appropriate exploration of a specific phenomenon (Bryman, 2012). The study aimed to identify and recruit HCPs working within varied roles in the NHS advanced prostate cancer care pathway. Sampling was carried out until data saturation was achieved. This was determined by no new themes emerging in the data and no repeats of data being expressed (Ritchie & Spencer, 1994; Saunders et al., 2018). The decision to stop sampling for interviews was made by ES and RT after the above criteria were met. This assessment was made on a twice-monthly basis.

5.7.2.3 Recruitment

Professional bodies British Association of Urological Society (BAUS), British Uro-Oncology Group (BUG), British Association of Urological Nurses (BAUN) and clinical commissioning groups were approached to invite clinical members to take part in an interview. Further to this, local clinical contacts of the research team were invited to take part. If participants were interested, they were asked to contact a member of the research team and were sent a participant information sheet via post or email (see Appendix H). They were given 24 hours to consider and then subsequently contacted by a member of the research team. If the participants were interested in taking part in the study, consent into the study was taken, a date and time for the interview was then scheduled.

5.7.2.4 Ethics and data storage

Ethical review was granted 24.08.2015 by REC reference: 15/SW/0260 / IRAS project ID: 178340. All interview data is securely stored on a secure drive at

Sheffield Teaching Hospitals (STH), with only the research team having access to. All hard copies of transcripts are stored in a site file securely on STH premises.

5.7.2.5 Data collection (Semi-structured interviews)

Thirty-five semi-structured interviews with prostate cancer HCPs and commissioners were carried out in December 2015 and June 2016. This was 9 months prior to the PhD commencing, see Figure 0.1. Interviews were conducted either face-to-face (7) or by telephone (28) and lasted between 20 and 50 minutes. They were audio-recorded using a Dictaphone.

5.7.2.6 Data analysis

Framework analysis was adopted to code the data, see Appendix I for the coding manual. Framework analysis key features are that it aims to generate themes; it's systematic and is designed for the analysis of large sets of interview data (Gale, Heath, Cameron, Rashid, & Redwood, 2013). Atkins et al., (2017) guidance was additionally used to analyse the data deductively using the TDF as a framework, however elements of the analysis were inductive to capture any data on behavioural determinants outside of this framework, this methodology has recently been recommended (McGowan, Powell, & French, 2020). Following an overall analysis of the data, a behavioural analysis for each of the seven target behaviours was carried out.

5.7.2.7 Procedure for framework analysis

Each semi-structured interview was audio-recorded and transcribed for analysis. Transcription was completed by an experienced audio typist; all transcripts were checked for accuracy against the audio records.

The five key stages of this analysis were as follows:

a. Familiarisation

The researchers (RT, LS, and ES) initially familiarised themselves with the data by listening to the audiotapes and re-reading the transcripts. During the familiarisation stage, the researchers listed any key ideas, thoughts, and recurrent themes, to gain an understanding, depth, and diversity of the data.

b. Developing an analytical framework

A framework was developed using a deductive approach; based upon the Theoretical Domains Framework (TDF) (Cane et al., 2012), please see coding manual in Appendix I. The TDF acted as a basis for the framework, as other key themes that did not necessarily map to the TDF were included in the framework, taking an inductive approach.

c. Applying the analytical framework

The final analytical framework was applied to each of the transcripts using NVivo software version 11. The lead researcher (RT) systematically went through each transcript, coding each significant piece of text into the framework, this is referred to as 'indexing'. Once all the transcripts were coded by RT, the two senior researchers independently coded a sub-set of the five same transcripts (LS & ES). This coding was then compared, discrepancies were discussed throughout the process and resolved by a group discussion, referring to the TDF domain definitions for reference (Cane et al., 2012). Where text related to more than one domain, it was coded into both. Whilst going through this process, it was discussed that often the interviewees would refer to themselves as HCPs, the patients, and the exercise professionals separately. For example, the HCPs often referred to the patients' capability regarding exercise but would also discuss their capabilities of referring to a programme. It was then decided that the data would be coded into three categories relating to 1) views on HCPs, 2) views on patients and 3) views on exercise professionals, with each category using the TDF as an overall framework. This was a way to manage the amount of data that was present.

d. Charting data into the framework matrix

The data were summarised in a matrix for each theme using Microsoft excel, this allowed the management of a large amount of data. The matrix was comprised of one row per profession and one column per code. Three matrixes were developed in line with the three categories 1) views on HCPs, 2) views on patients and 3) views on exercise professionals.

e. Mapping and interpreting the data

When all the data was charted according to the core themes, the researchers began to bring together key characteristics of the data. Differences and

similarities of the themes were identified and connections between themes were explored. Due to the data being rich, themes generated from the analysis could go beyond description and attempt to explain specific behaviours. A behavioural analysis for each of the seven target behaviours was carried out following the initial framework analysis.

5.8 Results

Step 4: Identifying what needs to change – the behavioural analysis

5.8.1.3 Participants

These participants were working in diverse roles representing different disciplines within the NHS prostate cancer care pathway, see Table 5.3.

Table 5.3: Characteristics of HCPs participating in the interviews

Profession	Number of participants
Consultant urologist	9
Oncologist	10
Clinical nurse specialist	6
General practitioner	3
Physiotherapist	3
Clinical commissioners/service managers	4
Primary care physician	1

5.8.1.4 TDF domains

Ten out of fourteen domains were identified during the analysis as influencing the seven identified HCP behaviours (see Table 5.2) all in line with NG131 1.4.19 recommendations. These ten domains were as follows: *knowledge, behavioural regulation, memory, attention and decision processes, skills, beliefs about capabilities, beliefs about consequences, social/professional role and identity, emotion, environmental context and resources and social influences*. Results are presented according to each theoretical domain, with sub-themes within these domains. An overview table of the main findings is presented in Table 5.4. Key themes and sub-themes are then presented using key quotes to illustrate the sub-themes. The behavioural analysis for each specific target behaviour (n=7) is presented in Appendix L.

Table 5.4: Barriers and facilitators to delivering exercise recommendation, support and referral in line with NG131 1.4.19 recommendations

TDF domain	Sub-themes from the TDF domains			
Knowledge	Exercise oncology 'a new area'			
Behavioural regulation	Feedback loops	Auditing		
Memory, attention & decision processes	Conflicts of attention			
Skills	Behaviour change skills			
Beliefs about capabilities	Perceived capability to assess the ability of patients to exercise safely			
Beliefs about consequences	Lack of conviction of the NICE guidelines	Lack of perceived benefit of exercise	Perceived patient motivation and capabilities	Lack of trust
Social/professional role & identity	Identified key roles	Promoting a whole team ethos		
Emotion	Protectiveness	Experience of working with patients		
Environmental context & resources	Time	Referral pathway		
Social influences	Professional-patient relationship	Organisation pressure		

Knowledge (Psychological capability)

There was a common lack of knowledge of the benefits of exercise for this patient group.

Exercise oncology 'a new area' (barrier)

HCPs commonly discussed having a lack of knowledge of the benefits of exercise for this patient group and were not up to date with the evidence base within this area. Exercise oncology was viewed as a developing field, which appears to conflict previous evidence around exercising with cancer.

"Five years ago, for some of them they were telling patients not to exercise, so this is a real sea change for a lot of them." Clinical Nurse Specialist

Presenting a good level of evidence to the HCPs about the benefits of exercise was suggested to help develop an understanding of the benefits of exercise to this patient group.

"Yeah, I think a basic summary of what's known about the benefits of exercise in prostate cancer would be crucial, otherwise it's just seen as sort of here's another thing to do." General Practitioner

Behavioural regulation (Psychological capability)

HCPs discussed a couple of different approaches to regulating the team's performance regarding integrating exercise into the prostate cancer pathway.

Feedback loops (facilitator)

To successfully integrate exercise into the prostate cancer care pathway HCPs suggested the use of feedback loops to monitor outcomes. Having a complete feedback loop with the exercise professionals, HCPs and the commissioners would allow for good communication and teamwork between the organisations. These feedback loops would be beneficial for all involved to understand how many men are being referred to the exercise programme.

"Having that feedback loop 1) to the referrers, maybe their MDT, and 2) back to the CCGS hopefully who are also part of the funding stream, to say this is how many men we've treated" Physiotherapist

Additionally, having access to feedback from the exercise professionals on the progress of the patients to HCPs to discuss in follow-up appointments was suggested.

"You want feedback; you want something to come back from. What would be nice as a doctor would be to say to the patient oh, I see you did you treadmill test and it took you 10 minutes to walk or you walked half a mile in 5 minutes, that's great" Consultant Urologist

"So, when I click up, I can see this patient's had PSAs, bone density scan, has had cholesterol measured, glucose measured, I might have an exercise report. And I can look that up, that's not a problem" Oncologist

Auditing (facilitator)

Having an audit trail was considered important amongst the HCPs, as auditing can allow for exercise referrals to be monitored. Therefore, if targets are not being met within the department, then this can be followed up.

"Now if any team is not meeting that 50 % referral target, surely, they have to answer why they're not meeting it, you know. I mean, 50 % by any stretch of the imagination is not unachievable. Nobody can stand up and tell me that oh no, more than 50 % of my patients are unfit. Well if they are, then let's have a look at ... let's do a prospective audit of your next 20 patients." Oncologist

Memory, attention and decision processes (Psychological capability)

Working in an ever-changing environment and having the ability to be able to remember to discuss exercise with their patients consistently was seen as a possible barrier amongst the HCPs.

Conflicts of attention (barrier)

Some HCPs expressed that they often have difficulty in remembering to discuss exercise with their patients and/or refer them to relevant schemes. The reasons given for this was due to the vast number of different schemes that may be available to patients, that the HCPs are responsible for remembering.

"I think the reality if all of these things doesn't happen, I think in my short career the GPs have worked on it seem to have ramped up so much that all the

different things that are available just escape the mind and you just cannot keep in your head as to what's available for who and where" Clinical Commissioner/General Practitioner

Skills (Physical and psychological capability)

Having the right skill set to be able to discuss exercise in a supportive way was highlighted as being an area the HCPs wished to improve in.

Behaviour change skills (barrier)

There was a general desire for further communication and behaviour change skills training to help the HCPs 'empower' their patients. With some HCPs being aware of certain techniques such as motivational interviewing (MI) or behaviour change techniques (BCTs), however it was apparent that these weren't generally used to help support patients around exercise.

"It's like yesterday, he said oh I'm walking everyday doctor. I said do you mind if I look at your iPhone? 2,400 average paces a day. I did not show him mine, said wow, come on, you want to do better than me, you've got a problem and I haven't, I'm still walking 10,000 steps a day when I can!" Primary care physician

"I probably would need to do a little bit more work into behavioural change to look at really how you guide someone as expertly as possible to make positive health changes " Physiotherapist

Beliefs about capabilities (Reflective motivation)

HCPs reflected on their capabilities within the proposed exercise and prostate cancer care pathway.

Perceived capability to assess the ability of patients to exercise safely (barrier)

HCPs doubted their own capabilities in assessing whether patients were healthy enough to exercise and were concerned about providing this information to the exercise professionals. This was particularly from the consultant urologists. They also did not want to see this as part of their role, (links with social and professional roles).

"So, somebody is going to have to vet that they're actually fit for that. I don't want that to be me." Consultant Urologist

"it's a bit like prescribing Viagra for old men, you know, you've got to make sure they're physically fit for the treatment, and that's where some people hesitate."

Consultant Urologist

Beliefs about consequences (Reflective motivation)

There were very common views around the uncertainty of the benefits of exercise for this patient group. There were assumptions about the patient's motivation and capability to exercise. Additionally, a lack of trust of the exercise professionals was raised.

Lack of conviction of the NICE guidelines (barrier)

There was a very common lack of conviction of the NICE guidelines CG175 1.4.19 amongst the HCPs, this was twofold. Firstly, HCPs viewed NICE guidelines as *"only guidelines"* and whilst they reflect best practice, they viewed that not all of them can be implemented in NHS standard care. Secondly, HCPs viewed the evidence base for exercise trials with scepticism, as exercise trials were viewed amongst the HCPs as not being as robust as drug trials.

"Well I think NICE guidelines serve a good purpose by and large and I'm all in favour of NICE guidelines by and large, but I think sometimes you have to question that evidence that is looked in to get those guidelines, and one can be sceptical and say that the evidence that they looked at for exercise and put in the guidelines is not as robust as some of the other evidence that is out there and they've forgot to mention those things in the guidelines right?" Oncologist

Lack of perceived benefit of exercise for patient group (barrier)

There were concerns that exercise would not benefit this patient group due to the men having advanced cancer and suffering from weight loss as a side effect from the cancer.

"I don't think it would be appropriate to be telling a patient, you know, who's losing weight because they've got advanced cancer that they should be taking exercise." Oncologist

"I don't think they're really totally convinced that it's going to make much difference." Primary care physician

Perceived patient motivation (barrier)

Additionally, there were common concerns over patient's motivation to exercise, as some HCPs thought that this patient group may be hard to engage with. Some HCPs believed that accessing an exercise programme may not be a priority for them and they would rather accept the consequences of ADT than to exercise.

"I think a number of our patients are quite happy sitting at home watching the telly, drinking beer and smoking, to be perfectly honest! But, um, I think there would be a proportion who would embrace that, particularly the younger fitter chaps. I'd like to refer them, because it's the kind of thing that I think the patients, I think a specific group of patients would be quite keen on doing and, um, you know, they've got to be motivated to do it, so yeah." Oncologist

Perceived patient physical capabilities (barrier)

There was a consensus that men with prostate cancer on ADT may not be physically able to take part in exercise, due to their comorbidities, sequencing of treatment, functional fitness and stage of cancer.

"it's just the metastatic patients, because obviously prostate cancer goes in the bones that we'd just have to be really careful with. So, I don't know whether there'd be different types of programmes aimed at different levels of patients? I mean that would be ideal." Clinical Nurse Specialist

"We have got an ageing population here do the majority of our cancer patients are quite older and, you know, with co-morbidities and are quite fragile " Clinical nurse specialist

Lack of trust (barrier)

A lack of trust was present from the HCPs towards the exercise professionals, a concern was raised regarding whether referrals would be picked up by the exercise team.

"As long as I know who to and, more importantly, I know that they will deliver because the worse thing would be to have the patient pitch back in 3 months with the PSA test saying I'm otherwise doing well but you talked about exercise, nothing happened, I phoned them, they said no no, this is not for you, this is you

know, and then the whole chaos starts and then they lose confidence in the system; they think one part is not knowing what the other part does." Oncologist

Social/Professional role and identity (Reflective motivation)

Identifying which HCPs should be responsible for which roles when integrating exercise into the prostate cancer care pathway, was commonly discussed. The consultant and clinical nurse specialist role were identified as key within the exercise and prostate cancer pathway.

Promoting a whole team ethos (facilitator)

It was highlighted that supporting and referring to exercise schemes should be a shared role, with the whole team involved in the integration of exercise into the cancer care pathway. It was emphasised that it is important for all the clinical team to be providing the same consistent advice to the patients.

"I think there shouldn't be one person, if usual, should come from different people from different angles ... so if the GP knows about it, if the physio knows about it, if the hospital consultant, if the trainee ... if it is a part of a culture then it works." General Practitioner

Identified key roles (facilitator)

There were varied views amongst the HCPs regarding roles and who should have key roles within the pathway. It was advised that consultant urologists should advocate exercise as part of a treatment component due to patients having a great respect for the consultants.

"Yeah, definitely, definitely, I think that yeah, patients generally have high respect for their consultants, so if the consultant is recommending it then I expect uptake will increase greatly." Physiotherapist

Clinical nurse specialists were thought to play an important role in referring current patients to supportive schemes. So, making an exercise referral for the patients as part of their current role, seemed most appropriate.

"I do very much sort of holistic assessment when I see these patients - I spend a lot of time with them, I refer them on to ... we have a relaxation group on a Weds morning, so I refer patients onto that sometimes; I refer them onto our

clinical psychologists if they need help in that department." "We do a lot of sign-posting, that's kind of part of our role yeah." Clinical Nurse Specialist

Emotion (Automatic motivation)

HCPs thought that working with this patient group was rewarding and they could use exercise as something positive they could offer patients. However, worry and concern were common emotions amongst the HCPs in relation to their views on working with exercise professionals.

Experience of working with men on hormone therapy (facilitator)

Working with men with advanced prostate cancer who they felt could be directed to exercise was a rewarding group to work with. Exercise was viewed as a way to help the men overcome some of the adverse effects of their treatment.

"I find working with the men undergoing hormonal treatment who I can direct to exercise, one of the most rewarding group of patients that I see really, because it's so sad that they can be in such an emotional and physical pickle really with their side-effects of their treatment, and to sort of masculinate them a little bit more by sort of encouraging them with exercise" Physiotherapist

Protectiveness (barrier)

HCPs being protective over their patients was discussed in terms of being a barrier to making referrals to exercise programmes.

"Um, no it was pretty difficult at first; the nurses can be very protective over their patients" Clinical commissioner

Environmental context and resources (Physical opportunity)

Environmental factors including time and a complex referral pathway were considered barriers for integrating exercise into the prostate cancer care pathway.

Time (barrier)

A common barrier that was highlighted was the possible lack of time the HCPs would potentially have during consultations to discuss exercise with their patients due to already competing demands.

"We are struggling to even get through the numbers in clinics, ok, so I think that has to be pretty clear; this is what I was meaning, that I can refer the patient but then if you want me to then chase the patient as to why did not you pitch up for exercise? I cannot do that." Oncologist

Referral pathway (barrier)

Concerns were raised over new schemes such as an exercise programme and referral pathways creating extra work for the HCPs as this could act as a barrier towards engagement due to processes being too arduous.

"It needs to be a simple process just to avoid putting people off by the actual process being too complicated and time-consuming." Consultant Urologist

"Please make that as painless as possible." Consultant Urologist

Social influences (Social opportunity)

The HCP's relationship dynamic with both the patients and the 'future' exercise professionals were considered areas of tension. Additionally, the pressures from senior colleagues or the organisation was deemed important for change.

Professional-patient relationship (barrier)

HCPs thought that broaching the subject of exercise with their patients may be problematic as they did not want to be 'preaching' to their patients about exercise.

"it's difficult conversation, you bring it up, patients say I will stop but they don't, and there's a medical reason that you want to keep friends with them, you want to keep their buy-in and again, you know, you don't want to be preaching to them too much but the reality is it's time and effort" Consultant Urologist

Pressure from the organisation (facilitator)

Having pressure from the HCPs organisation was suggested to help bring about practice change within the NHS. This also relates to behavioural regulation.

"so the urology/oncology MDT - every so often and having that agreed area, so then it 1) ensures and kind of puts pressure on and reminds clinicians that that's what's in place, but I would hope that they need to be behind the service, because once that's in place I don't think the clinicians I work with would let it fall by the wayside, do you know what I mean?" Physiotherapist

5.9 Discussion

In this study, the first stages of the BCW process including using the TDF to carry out a behavioural analysis were undertaken for intervention development. It was identified, there was a lack of exercise recommendation, exercise support and exercise referral as part of standard prostate cancer care in line with NICE recommendations NG131 1.4.19 from treating HCPs. Subsequently, seven HCP target behaviours were identified as needing to change, to attempt to tackle the problem. These target behaviours were identified as being the same across two NHS sites in the North of England, but due to the complexities of the pathways in cancer care, different HCPs for the two sites need to be targeted in a future intervention. Furthermore, understanding the specific challenges at site is important and can aid implementation.

As recommendations, NG131 1.4.19 are not specified behaviourally, further efforts needed to be made to understand how these recommendations could be delivered. The seven target behaviours were therefore identified to help support the implementation of the NICE recommendations NG131 1.4.19, but also to allow for further support to be provided for patients around exercise. Cardiac rehabilitation (CR) is a good example of an exercise referral scheme (ERS) that was initially unsuccessful due to limited behavioural recommendations for HCPs. Following a large trial (RAMIT trial), CR was found to not be effective or cost-effective due to the programme not being delivered to protocol and a significant lack of HCP involvement (Doherty & Lewin, 2012). This prompted several new NICE recommendations to be published to encourage HCPs to support patients with CR (NICE, 2013a). It is important we learn from these mistakes and ensure target behaviours reflect the additional patient support required from HCPs.

Barriers and facilitators of these target behaviours were identified using the TDF. The TDF allowed for an in-depth exploration of the influences on HCPs behaviour. Despite the growing evidence around exercise oncology and current recommendations, HCPs expressed several barriers to providing exercise support to their prostate cancer patients. This is consistent with previous research exploring HCPs views on exercise referral schemes. Ten out of the fourteen domains were identified as being influential on HCP behaviour. Sub-themes within these domains established, (see Table 5.4).

There was a deficit in '*knowledge*' around exercise oncology. HCPs had a lack of awareness of the benefits of exercise for this patient group. Exercise oncology was seen as a new area, as traditional approaches such as 'rest is best' were being used not so long ago (Dimeo, 2001). Previous research has identified views such as these from HCPs to be a barrier to exercise for cancer survivors (O'Hanlon & Kennedy, 2014).

Having the ability to remember different schemes such as exercise was a concern for HCPs during busy clinics '*memory, attention and decision processes*'. Therefore, having prompts, feedback loops and audit trials would be useful tools to address the clinical team's referral rates, ensuring that patients are being offered exercise, this could also act as a prompt to HCPs. Whilst remembering to discuss exercise and make it a part of their consultation routine is very important. There are several beliefs that need to be addressed before considering forming routines within consultations. Ways for HCPs to achieve '*behaviour regulation*', were suggested in the form of feedback loops and audits. These techniques have been found to be successful in changing HCP behaviour in previous interventions (Ivers et al., 2012).

HCPs express a want and a need for training, particularly around behaviour change skills, a barrier previously highlighted (Keogh et al., 2017). As they believed that developing their '*skills*' in this area would allow them to support the patients with exercise. Husebø et al., (2013) carried out a systematic review which aimed to predict exercise adherence in cancer survivors and found that there is a need for HCPs to understand behaviour change. It is also important for HCPs to have the appropriate skills to be able to support cancer survivors and improve their beliefs around exercise to facilitate behaviour change.

The concept of exercise and the benefits for cancer survivors was considered a 'new area' that conflicts with previous evidence and care. A survey carried out by (Support, 2011) showed that one in ten doctors or nurses still believe it is important to recommend rest during treatment and recovery rather than exercise. Spellman et al., (2013) found similar findings amongst prostate cancer HCPs. There were perceptions that exercise might not benefit this patient group and that patients would not be motivated to access an exercise programme '*beliefs about consequences*'. This perception about the patients' motivation has

been previously explored in an interview study of HCPs experiences of exercise-referral schemes (Din, Moore, Murphy, Wilkinson, & Williams, 2015). HCPs commonly reported making assumptions based on the patient's appearance to whether they thought the patient would be motivated to exercise or not. This stigmatisation ultimately impacted whether they broached the subject of exercise with their patients.

Some HCPs did not perceive it as their role to discuss exercise with their patients '*social/professional role and identity*', which has been previously reported (Spellman et al., 2013). HCPs frequently reported their concerns around having the time during clinics to discuss exercise with their patients and concerns around the referrals process being complex and time-consuming, '*environmental context and resources*'. Blaming a lack of time is a commonly reported barrier from HCPs in previous research, however a survey found that only three in ten HCPs reported time as a barrier to discussing exercise (Support, 2011). Having support from the organisation to deliver an exercise referral service was recommended to bring about change within the department '*social influences*'. However, implementation research tells us that whilst having a department conducive to change is crucial, engagement needs to be from the HCPs as individuals (Grol & Grimshaw, 2003) and is therefore unlikely to be the only solution.

Finally, there were concerns around providing exercise professionals with information about the health of the patient to exercise were raised, particularly from the consultant urologists '*beliefs about capabilities*.' Feeling protective over their patients was an '*emotion*' reported by the nurses and nursing specialists. To my knowledge has not been previously acknowledged in research understanding HCPs views on exercise.

Following the identification of these barriers, a behavioural diagnosis was carried out (see Appendix L). Where the seven target behaviours were individually analysed, mapping key barriers identified from the TDF alongside the COM-B model. To change all the target behaviours in a complex intervention 'Capability, Opportunity and Motivation' all need to be considered. This process allowed us to understand what aspects need to change in a future complex intervention to increase HCPs providing exercise advice, exercise

recommendation, exercise support and exercise referral as part of standard prostate cancer care in line with NICE recommendations NG131 1.4.19.

5.9.1 Strengths

The MRC, BCW and TDF offer systematic approaches to intervention development and understanding what needs to change in order to change specific target behaviours. Previous research within this area has often been criticised for only focusing upon one specific health profession and not the whole clinical team (Yang et al., 2017). This research explored the views of varied HCPs within the prostate cancer clinical team, to ensure challenges across the whole team were captured.

The interview findings are in line with other previous research, when exploring the views of HCPs in regards to discussing exercise with patients or exercise referral schemes (Din et al., 2015; Karvinen et al., 2012; Spellman et al., 2013; Williams et al., 2015). Using the TDF as a framework, offered a focused approach to understanding in detail the barriers and facilitators of the target behaviours, previous approaches have not used the TDF to explore this area.

The TDF was originally developed to understand HCP behaviour regarding the issue of implementation of clinical recommendations (Michie et al., 2005). The major strengths of the TDF are its comprehensive approach to understanding behaviour and behaviour change and its ability to identify potential mediators of behaviour change (Francis et al., 2012). The TDF has been widely used to understand HCPs behaviour and behaviour change. To use the TDF as a framework for developing interview schedules to explore influences on HCPs behaviour and to use as an analytic framework is advised (Cane et al., 2012; Francis et al., 2012; Michie, van Stralen, et al., 2011).

Double-coding of ten of the interviews by two independent experienced researchers (LS and ES) strengthens this research and this is advised when using framework analysis in multi-disciplinary teams (Gale et al., 2013).

Specifically, when using the TDF as an analytical framework, it is important to have independent experienced researchers coding the data to improve rigour. Difficulties in being able to distinguish between the domains and having a full understanding of the domains without training is a criticism of the previous research having used the TDF without experience (Francis et al., 2012)

Therefore, having a health psychologist (LS) and experienced qualitative researcher (ES) double code the interviews are beneficial for this research. The overall coding was then also reviewed by another member of the research team (MA), an experienced health psychologist.

5.9.2 Limitations

The approach of the TDF suggests it aims to understand behaviour and the influences upon behaviour and that individuals could be able to verbalise these influences accurately, especially in regard to understanding automatic motivations. Whereas during the interviews, the participants would often talk about the behaviour of the patients, rather than the influences, specifically on their behaviour. Whilst this was picked up on in the interviews and attempts were made to try to bring the HCPs back to discussing their behaviour, it is an important limitation to note. Similarly, criticisms of using the TDF as an interview schedule have been that it is too restrictive and doesn't allow for discussion outside of these domains, such as the consideration of organisational aspects (Francis et al., 2012). Recent evidence has suggested qualitative work using the TDF as a framework uses inductive aspects to analyse qualitative data aiming to capture behavioural determinants as the TDF can be too rigid when applied deductively (McGowan et al., 2020). This approach was taken within this study to aim to reduce this issue.

As exercise is not yet integrated into the prostate cancer care pathway, questions were asked on the HCPs anticipated barriers to the new proposed target behaviours. Therefore, it must be acknowledged that other, more practical barriers may be present in providing exercise support or referral when delivered in practice. Due to this potential limitation when developing the HCPs intervention, we will work closely with clinical teams to optimise the intervention. Further to this, using interviews to understand habitual behaviour may not be appropriate.

For the analysis of these interviews, double coding of the transcripts was carried out, an inter-rater reliability tool such as Cohen's kappa would have been beneficial to use. This level of analysis was not carried out due to resources and time. This would have offered further methodological rigour to

this research as a potential risk of bias in the coding could have been minimised.

Another limitation of this study is that the interviews were carried out in 2015-2016. These interviews were reanalysed from July 2018 - Oct 2018. A lot of the barriers identified focus upon a lack of awareness of the NICE CG 1.4.19 and a lack of knowledge around 'exercise oncology'. However, as time moves on, these barriers may not be as common amongst the HCPs. Therefore, understanding the current practice of the HCPs and the NHS site in terms of these guidelines is important for the development of future intervention.

5.9.3 Impact for practice and research

The current long-term cancer plan aims for every person by 2021 to have access to personalised care (NHS England Long-term plan, 2019). An aspect of this personalised care is to support self-management, encouraging people to have the knowledge, skills and confidence to live well with their health condition and to also encourage individuals to manage their health through access of interventions to improve well-being. However, this research highlights the barriers around discussing self-management strategies such as exercise with patients. Developing an intervention to overcome these barriers, will aim to give the HCPs the capability, opportunity and motivation to discuss self-management strategies such as exercise and could be transferred to helping the HCPs achieve aspects of the current long-term cancer plan.

5.10 Conclusion

HCPs perceived several barriers to recommending exercise, providing exercise support and exercise referral for men with advanced prostate cancer on ADT. The TDF was viewed as appropriate to understand influences on HCPs behaviour in this population. Ten out of the fourteen domains of the TDF were identified as influencers on HCPs behaviour. These commonly included perceptions from the HCPs that patients would not be motivated to take part in exercise and apprehensions about whether they would be able to exercise (*beliefs about consequences*), lack of conviction about the NICE exercise recommendations and benefits of exercise for this patient group (*knowledge*), lack of ability to remember all the schemes on offer for patients (*memory, attention and decision processes*) and concerns regarding having the physical;

time during consultations to discuss exercise (*environmental context and resources*). Following a behavioural analysis, key areas for change will be fed into the intervention development, using the behaviour change wheel (Michie, van Stralen, et al., 2011) as a framework. The barriers identified will be addressed in a future complex intervention. Working closely with HCPs within their clinical teams during the intervention development phase will also allow for future, more practical barriers to be identified and addressed in the process that may not have been fully understood in the interviews.

5.11 Chapter summary

This chapter is the basis for the development of a complex intervention to support prostate cancer HCPs to recommend exercise, provide exercise support and exercise referral, all in line with NG131 1.4.19 recommendations. The next chapter identifies the behavioural content for the HCP intervention.

6) Chapter six: Translating evidence into a theory and evidence-based HCPs training package to address key barriers using the behaviour change wheel

6.1 Intervention development overview

Chapter five explores specific barriers and facilitators to understanding why the NICE NG131 1.4.19 recommendations do not reflect usual care and why exercise advice and support is not provided to men with prostate cancer on Androgen Deprivation Therapy (ADT). Changing HCPs behaviours to support the integration of these recommendations requires a complex intervention. The Medical Research Council (MRC) framework and Behaviour Change Wheel (BCW) were selected as intervention development frameworks, as they offer a systematic and comprehensive approach to intervention development. They are complementary, the BCW offers a practical guide to intervention development and builds on the current MRC guidance. This chapter will apply the next steps to intervention development, to identify appropriate behaviour change techniques and content, based on theory and real-world evidence.

6.2 Aims

To iteratively develop a prototype version of an evidence and theory-based intervention to support HCPs in recommending exercise, providing exercise support and referral in line with recent NICE recommendations.

6.2.1 Objectives

- To identify and select appropriate intervention functions.
- To identify and select appropriate behaviour change techniques (BCTs) for the intervention based on the latest evidence and appropriate theory.
- To identify the theoretical underpinning of the intervention.
- To propose the mode of delivery of the BCTs within the intervention.

6.3 Methods and procedures

6.3.1 The team

The core intervention development team was multi-disciplinary and included: Myself (RT), LS and MA (Health Psychologists), DR (Consultant Urologist) and ST (Professor of Primary care and public health).

6.3.2 BCW Step 5: Intervention functions

The BCW guide (Michie et al., 2014) was used to select the appropriate intervention functions for the 'Capability Opportunity and Motivation = Behaviour' model (COM-B) and TDF domains identified as needing to change. Affordability, practicability, effectiveness/cost-effectiveness, acceptability, side-effects/ safety, and equity (APEASE criteria) was considered throughout this process, (see Table 2.5).

6.3.3 MRC Stage 2: Identifying and developing theory and MRC

Stage 3: Modelling process and outcomes

To understand how change may occur, theory needs to be considered as this allows us understand why and when a behaviour does or does not occur (Michie et al., 2014). Following the identification of the seven target behaviours and behavioural analysis it was identified that changes in the TDF domains were required. The core intervention development team then decided the key domains relating to the target behaviours to target in the intervention.

The TDF acts a framework of domains, made up of thirty-three theories and eight-four constructs (Cane et al., 2012), which specifies different determinants or domains relating to behaviour change (Nilsen, 2015). These classic thirty-three psychological theories were reviewed to identify potentially appropriate theories for the use of this intervention. Other theories were considered outside of the thirty-three theories, due to the intervention development teams awareness and expertise. The review process involved searching for constructs within these theories relating to the TDF domains such as *knowledge*. Classic psychological theories were then selected if they were relevant to the domains targeted in this intervention.

Additionally, the literature around effective ways to encourage professional behaviour change was reviewed. The theoretical understanding of the intervention and proposed effects of intervention content on behaviour change were then mapped out. Logic models were developed for three of the identified target behaviours (see Table 5.2) to provide examples of the proposed mechanisms of change due to the complexities of the intervention.

6.3.4 BCW Step 7: Selecting behaviour change techniques

With decisions made by the core intervention development team, BCTs and their mode of delivery were selected. BCTs are active ingredients within an

intervention, designed to change behaviour (Michie, Ashford, et al., 2011), (see section 2.4.2, page 92). BCTs were selected from the behaviour change taxonomy (BCTTv1). Within this taxonomy, there are 93 different BCTs within 16 hierarchical clusters and are all numbered (Michie et al., 2013). The full list of BCTs from this taxonomy can be found at <https://www.bct-taxonomy.com/>. BCTs were carefully chosen from 1) Recent systematic reviews that have highlighted specific BCTs that have been shown to be effective when promoting professional behaviour change specifically in HCPs, 2) Selecting BCTs that are proposed by the theories the intervention is underpinned with. 3) Using the theory and techniques online tool (<https://theoryandtechniquetool.humanbehaviourchange.org/>), this identified a number of links between BCTs (n=74) and mechanisms of action (n=26) from published intervention literature (Carey et al., 2018). Once a list of potential BCTs were selected, the APEASE criteria was applied by the intervention development team (see Table 2.5).

In addition, to consulting the APEASE criteria (see Table 2.5), during the refinement and optimisation phase of the intervention development, specific BCTs were modified or removed following feedback from the participants of the rehearsal delivery and stakeholder workshop, as reported in chapter seven. The lack of the involvement of the target population in intervention development, is a criticism for the BCW approach (Janols & Lindgren, 2017), so ensuring that the target population were considered throughout this process is essential.

6.3.5 BCW Step 8: Mode of delivery

Considerations to the mode of delivery of the training overall and behavioural content is important and often neglected (see Chapter two) Mode of delivery of the intervention and its behavioural content was selected based on 1) The mode of delivery used in the professional behaviour change literature, 2) Suggestions from theories used within this intervention. The APEASE criteria was considered throughout (see Table 2.5).

6.4 Results

A complex intervention targeting secondary care prostate cancer care HCPs was developed. The results from this process are presented in the following of the MRC and BCW steps.

6.4.1 Step 5: Selecting intervention functions

The intervention functions selected for use within this intervention including the APEASE consideration are presented in Table 6.1 Six intervention functions were selected: Education, Training, Environmental restructuring, Enablement, Persuasion and Modelling.

Table 6.1: Intervention functions selected in the intervention development process and APEASE considerations

Target behaviours	Intervention functions included	Intervention functions considered and rejected using APEASE
1. Recommend exercise training at any point within the pathway	Education, Training, Environmental restructuring, Enablement, Persuasion, Modelling and Restriction	Restriction - not acceptable in cancer care setting, cannot restrict other competing behaviours.
2. Discuss barriers and facilitators around exercise training	Education, Training, Environmental restructuring, Enablement, Persuasion, Modelling and Restriction	Restriction - not acceptable in cancer care setting, cannot restrict other competing behaviours.
3. Make referral for exercising training	Education, Training, Environmental restructuring, Enablement, Persuasion, Modelling, Restriction, Coercion and Incentivisation	Restriction - not acceptable in cancer care setting, cannot restrict other competing behaviours. Coercion - not acceptable in cancer care setting. Incentivisation - not affordable or potentially sustainable
4. Provide patient with information pack and materials	Education, Training, Environmental restructuring, Enablement, Persuasion, Modelling and Restriction	Restriction - not acceptable in cancer care setting, cannot restrict other competing behaviours.
5. Recognise whether a patient is suitable for exercise	Education, Training, Environmental restructuring, Enablement, Persuasion, Modelling and Restriction	Restriction - not acceptable in cancer care setting, cannot restrict other competing behaviours.

6. Read and interpret exercise progress report	Education, Training, Environmental restructuring, Enablement, Persuasion, Modelling and Restriction	Restriction - not acceptable in cancer care setting, cannot restrict other competing behaviours.
7. Provide feedback to the patient on the exercise progress report	Education, Training, Environmental restructuring, Enablement, Persuasion, Modelling and Restriction	Restriction - not acceptable in cancer care setting, cannot restrict other competing behaviours.

6.4.2 MRC Stage 2: Identifying and developing theory

The core intervention development team identified key domains for the intervention to target, these are presented in Table 6.2. These are matched against the target behaviours (see Table 5.2). The key domains of the intervention were to a) improve knowledge b) increase confidence, c) change HCP beliefs, d) establish social norms, e) provide training in behavioural skills and f) change HCP belief of their perceived role. To aim to achieve these changes, classic psychological theories were drawn upon, the domains driven by the TDF targeted in this intervention were reflective of the theories selected, as presented in Table 6.2. These were the Social Cognitive Theory (Bandura, 1986), Social Learning Theory (Bandura & Walters, 1977), Theory of Planned Behaviour (Ajzen, 1991), the Necessity and Concerns framework (Horne et al., 2013) and Theories of Habit (Gardner & Rebar, 2019). Due to the complexity of the intervention and targeting change in seven behaviours, to use just one single classic psychological theories was not suitable for this intervention, therefore constructs and specific relations from more than one existing theory were used to underpin the intervention.

6.4.3 MRC Stage 3: Modelling process and outcomes

Logic models for three of the seven target behaviours (Table 5.2) were developed for the proposed intervention, suggesting the assumptions for the programme of work for each of these behaviours, see Appendix K. The above section compliments the logic model and provides more in-depth information.

6.4.4 Step 7: Selecting behaviour change techniques

Table 6.2 presents the selection of the BCTs for all of the seven behaviours, their link with theory and evidence and the application of the APEASE criteria (see Table 2.5). Initially 40 possible BCTs were identified from the literature and theory discussed above that may be beneficial for this intervention. Following the application of the APEASE criteria, 22 BCTs were identified for the use of the intervention including *problem solving* and *credible source*. BCTs were rejected due to not being acceptable, effective, and practical.

Table 6.2: Behaviour change techniques identified from theory and the literature for intervention development

Intervention domains to address	BCTs (Ones in bold, were considered and accepted using APEASE)	Evidence and theory base	BCTS considered and rejected using APEASE
<p><i>Skills</i></p> <ul style="list-style-type: none"> Need skills to make the exercise referral (TB3) Needs skills to access the progress report (TB6) <p><i>Cognitive/Interpersonal skills</i></p> <ul style="list-style-type: none"> Need to have the skills to recommend exercise and support in a supportive way (TB1, 2 & 7) 	<p>1.1 – Goal setting (behaviour)</p> <p>2.2 - Feedback on behaviour</p> <p>2.3 – Self-monitoring of behaviour</p> <p>2.7 – Feedback on outcomes of behaviour</p> <p>3.1 – Social support (unspecified)</p> <p>4.1 – Instruction to perform behaviour</p> <p>6.1 – Demonstration of behaviour</p> <p>8.1 – Behavioural practice/rehearsal</p> <p>8.7 – Graded tasks</p> <p>9.1 – Credible source</p> <p>10.1 – Material incentive (behaviour)</p> <p>10.8 – Incentive (outcome)</p> <p>10.10 – Reward (outcome)</p> <p>15.4 – Self-talk</p>	<p>Feedback on behaviour and outcomes of behaviour has been found to be effective in HCP interventions (Ivers et al., 2012; Johnson & May, 2015) as well as financial incentives (Flodgren, Eccles, et al., 2011), this also draws upon the Social Cognitive Theory (Bandura, 1986) and Social Learning Theory (Bandura & Walters, 1977), when learning a new skill self-monitoring, goal-setting, feedback, support from others, rewards and self-talk are important. Also, the use of modelling and demonstration with practice and rehearsal in a positive environment.</p>	<p>1.1 – Goal setting (behaviour), does not meet APEASE criteria as this would not be <i>acceptable</i> in this context.</p> <p>1.6 – Discrepancy between current behaviour and goal, does not meet APEASE criteria as this would not be <i>acceptable</i> in this context.</p> <p>1.8 – Behavioural contract, does not meet APEASE criteria as this would not be <i>acceptable</i> or <i>practical</i> in this context.</p> <p>3.2 – Social support (specified), does not meet APEASE criteria as this would not be <i>practical</i> in this context.</p> <p>4.2 – Information about antecedents, does not meet APEASE criteria as this would not be <i>effective</i> in this context.</p>
<i>Knowledge</i>	4.1 – Instruction to perform behaviour	Improving knowledge with education is necessary for change, but needs to be	

<ul style="list-style-type: none"> • Need the knowledge of the benefits of exercise and awareness of the evidence-based recommendations (TB1) • Need the knowledge of the behaviour change skills needed to provide exercise support by all members of the clinical team (TB2 & 6) • Need the knowledge of whether a patient is suitable for exercise or not (TB5) • Need the knowledge of the patient materials to hand out to patients (TB4) • Need to have an awareness of the processes for exercise referral and the progress report. (TB3 & 6) 	<p>5.1 - Information about health consequences</p> <p>5.3 – Information about social and environment consequences</p>	<p>used alongside other intervention components (Grimshaw et al., 2001). Presenting this information in an interactive way is important as stated in the Social Cognitive Theory (Bandura, 1986). Also, the necessity and concerns framework (Horne et al., 2013), which highlights if people have higher necessity beliefs and lower concerns beliefs about the behaviour, they are more likely to carry out that behaviour.</p>	<p>5.2 - Salience of consequences, does not meet APEASE criteria as this would not be <i>acceptable</i> in this context.</p> <p>5.5 – Anticipated regret, does not meet APEASE criteria as this would not be <i>acceptable</i> in this context.</p> <p>6.2 – Social comparison, does not meet APEASE criteria as this would not be <i>acceptable</i> in this context.</p> <p>7.5 – Remove adverse stimulus, does not meet APEASE criteria as this would not be <i>acceptable</i> or <i>practical</i> in this context.</p>
<p><i>Memory, attention, and decision processes</i></p> <ul style="list-style-type: none"> • Need to remember to discuss exercise and provide exercise support to patients. (TB1, 2 & 7) • Need to remember to give the information packs to patients. (TB4) • Need to remember to access the progress report prior to consultation with patient. (TB6) 	<p>7.1 – Prompts and cues</p> <p>11.3 – Conserving mental resources</p> <p>12.5 - Adding objects into the environment</p>	<p>Using reminders and adding objects into the environment may be beneficial for prompting the HCPs. Links between these BCTs and memory has been identified (Carey et al., 2018).</p>	<p>8.7 – Graded tasks, does not meet APEASE criteria as this would not be <i>acceptable</i> in this context.</p> <p>10.1 – Material incentive, does not meet APEASE criteria as this would not be <i>acceptable</i> or <i>effective</i> in this context.</p>

Behavioural regulation <ul style="list-style-type: none"> Need to develop routines and habits to discuss exercise with patients (All behaviours) Need for monitoring of this to be in place (All behaviours) 	1.1 – Goal setting (behaviour) 1.4 – Action planning 1.6 – Discrepancy between current behaviour and goal 1.8 – Behavioural contract 2.3 – Self-monitoring of behaviour 3.1 – Social support (unspecified) 4.2 – Information about antecedents 10.1 – Material incentive (behaviour) 10.8 – Incentive (outcome) 10.10 – Reward (outcome) 15.4 – Self-talk	Self-regulation is needed when behaviours are not habitual. To achieve self-regulation, the Social Cognitive Theory (Bandura, 1986) suggests the use of self-monitoring behaviour, goal setting, feedback, support from others, rewards and self-talk are important.	10.4 – Social reward, does not meet APEASE criteria as this would not be <i>acceptable</i> in this context. 10.8 – Incentive (outcome) does not meet APEASE criteria as this would not be <i>acceptable</i> or <i>effective</i> in this context. 10.10 – Reward (outcome) does not meet APEASE criteria as this would not be <i>acceptable</i> or <i>effective</i> in this context. 11.3 – Conserving mental resources, does not meet APEASE criteria as this would not be <i>acceptable</i> or <i>practical</i> in this context.
Social/Professional role and identity <ul style="list-style-type: none"> Need to perceive exercise recommendation, referral and support to be perceived as part of their role (All behaviours) 	3.1 – Social support (unspecified) 3.2 – Social support 6.2 – Social comparison 6.3 – Information about others' approval 9.1 – Credible source 10.4 – Social reward	Providing appropriate 'role-models' as highlighted in the Social cognitive theory (Bandura, 1982) may change beliefs around role. Additionally, the theory of planned behaviour highlights the role of normative and subjective norms on behaviour. This theory states an individual needs to feel the behaviour in question is approved by peers or others (normative) and that peers and others would perform this behaviour (subjective) (Ajzen, 1991)	12.1 - Restructuring the physical environment, does not meet APEASE criteria as this would not be <i>acceptable</i> in this context. 12.2 - Restructuring the social environment, does not meet APEASE criteria as this would not be <i>acceptable</i> in this context
Beliefs about capabilities	1.2 – Problem solving 4.1 – Instruction to perform behaviour	Social cognitive theory (Bandura, 1982), drawing upon established ways to increase self-efficacy (mastery of	

<ul style="list-style-type: none"> Need to improve confidence in recognising if patients are eligible for exercise (TB5) 	6.1 – Demonstration of behaviour 8.1 – Behavioural practice/rehearsal 9.1 – Credible source 11.2 - Reduce negative emotions 15.1 - Verbal persuasion 15.3 – Focus on past success 15.4 – Self-talk	experience, vicarious experience, verbal persuasion and improving emotional and physical states).	12.3 -Avoidance/reducing exposure to cues for the behaviour, does not meet APEASE criteria as this would not be <i>acceptable</i> in this context 15.4 – Self-talk, does not meet APEASE criteria as it is not likely to be <i>acceptable</i> or <i>effective</i> in this context.
<i>Beliefs about consequences</i> <ul style="list-style-type: none"> Need to believe exercise is beneficial for this patient group (All behaviours) Need to believe patients will want to take part in exercise (All behaviours) Need to believe exercise is an important part of patient's care (All behaviours) Need to improve trust in exercise professionals (TB1,2,3,4) 	5.1 - Information about health consequences 5.2 - Salience of consequences 5.5 – Anticipated regret 5.6 – Information about emotional consequences 9.2 - Pros and cons 9.3 – Comparative imaging of future outcomes	Theory of planned behaviour (Ajzen, 1991) was drawn upon with a focus of how to change beliefs by providing information about the behaviour and the consequences of the behaviour.	
<i>Emotion</i> <ul style="list-style-type: none"> Need to feel positive about making an exercise referral (TB4) 	11.2 – Reduce negative emotions	Ensuring the HCPs are in a good emotional state when attempting a new behaviour is important as highlighted in the Social cognitive theory (Bandura, 1986).	

<p><i>Social influences</i></p> <ul style="list-style-type: none"> • Need to maintain a good relationship with the patient when discussing exercise (TB1,2 &6) • Need to perceive colleagues are providing the same support to patients (All behaviours) • Need to have support from the organisation regarding change that is necessary (All behaviours) 	<p>3.1 – Social support (unspecified) 3.2 – Social support 6.2 – Social comparison 6.3 – Information about others’ approval 9.1 – Credible source 10.4 – Social reward</p>	<p>The use of role-models is stipulated in the Social cognitive theory (Bandura, 1986) as people are more likely to follow guidance given to them by people they trust (Bandura, 1986). The theory of planned behaviour (Ajzen, 1991) describes an individual’s perceptions of whether important others think they should perform a behaviour, combined with their motivation to comply with others’ beliefs. The use of opinion leaders has also been found to be effective in professional behaviour change (Johnson & May, 2015).</p>	
<p><i>Environmental context and resources</i></p> <ul style="list-style-type: none"> • More time needed for in-depth discussions around exercise (All behaviours) • Access to an exercise referral scheme (All behaviours) • Need to have access to all resources for patients (TB4) 	<p>7.1 – Prompts and cues 7.5 – Remove adverse stimulus 8.3 – Habit formation 12.1 - Restructuring the physical environment 12.2 - Restructuring the social environment 12.3 -Avoidance/reducing exposure to cues for the behaviour 12.5 - Adding objects into the environment</p>	<p>Changes to the environment and the use of prompts can result in changes to habitual behaviour according to the habit theory (Gardner & Rebar, 2019), repeated the new desired behaviour in this environment, should aid to form new routines or habits.</p>	

Key:

- TB1 - Recommend exercise training at any point within the pathway
- TB2 - Discuss barriers and facilitators around exercise training, provide support using BCTs
- TB3 - Make referral for exercising training
- TB4 - Provide patient with information pack and materials
- TB5 - Recognise whether a patient is suitable for exercise
- TB6 - Read and interpret exercise progress report
- TB7 - Provide feedback to the patient on the exercise progress report

6.4.5 Step 8: Mode of delivery

The intervention is to be delivered face to face to ensure engagement with HCPs, the delivery of the training package will be further refinement with the input of stakeholders, this is presented in Chapter seven. The mode of delivery of the intervention also encompasses how individual BCTs are delivered. Details of the delivery of the behavioural content is highlighted in Table 6.3.

6.5 Version ‘one’ of the healthcare professional training package

An interactive, skills-based half-day training package was developed. This included six modules, categorised into two levels of training (level one and level two) and the ongoing provision of a self-monitoring tool and other intervention characteristics. An overview of Level one and level two is provided in line with the TIDieR framework (Hoffmann et al., 2014) in Table 6.4. An overview of the behavioural content of all six modules and the continued intervention support is presented in Table 6.3. The training also aimed to teach HCPs eight key BCTs which have been shown to be effective and relevant for exercise behaviour change in cancer survivors, see Chapter three and when used in health behaviour change conversations, see Table 6.5 as specified in line with BCTTv1 taxonomy (Michie et al., 2013). Several other BCTs were identified as important for exercise behaviour change in cancer survivors and more specifically in men with prostate cancer, such as *action planning*, *setting of graded tasks* and *instruction of how to perform behaviour*. However, these are best to be delivered by an exercise professional rather than an HCP. As exercise professionals will see patients more frequently (twice a week) and be responsible for providing the exercise prescription alongside in-depth behavioural support. Therefore, it is important to note that the development of the patient intervention and exercise professional intervention have been developed separately to the HCP intervention in greater detail than what is reported in this thesis.

It was decided there would be two levels of training (level one and level two). Level one covers information on behaviours one and five, see Table 5.2 and level two covers information on behaviours two, three, four, six and seven, see Table 5.2. HCPs would be asked to attend either level one or both level one and

two depending upon their role, as the behaviours they would be asked to deliver would be dependent upon their role.

Two manuals were also produced as part of the intervention, one for the facilitators and one for the HCPs to refer to following the training for further support.

Table 6.3: Version one of the HCP training package including BCTs and Mode of delivery

Modules	BCTs	Mode of delivery
1) Overview of the project	1.2 – Problem solving 3.1 – Social support (Unspecified) 5.1 – Information about health consequences 5.3 – Information about social and environmental consequences 5.6 – Information about emotional consequences 9.1 – Credible source	<i>HCP training package:</i> <ul style="list-style-type: none"> • Introductions. • Use of an importance ruler to assess HCP perceptions on exercise. • Information presented about the project, NICE recommendations, patient experiences with exercise. • Video of professor of exercise oncology talking about the importance of exercise • Discussion about the common barriers reported from HCPs around not discussing exercise. • Information presented as written text
2) Prostate cancer and exercise – the evidence	3.1 - Social support (Unspecified) 5.1 – Information about health consequences 5.3 – Information about social and environmental consequences 5.6 – Information about emotional consequences 6.3 – Information about others' approval 9.1 – Credible source 11.2 – Reduce negative emotions	<i>HCP training package:</i> <ul style="list-style-type: none"> • Information presented about the evidence base for exercise in prostate cancer. • Information presented via videos, written text, handouts of scientific papers and links to further reading.

<p>3) Discussing exercise as a healthcare professional</p>	<p>1.2– Problem solving 1.4– Action planning 3.1 – Social support (unspecified) 4.1 – Instruction on how to perform the behaviour 5.1 – Information about health consequences 5.3 – Information about social and environmental consequences 5.6 – Information about emotional consequences 6.1 – Demonstration of behaviour 6.3 – Information about others’ approval 7.1 – Prompts/cues 8.3 – Habit formation 9.1 – Credible source 9.2 – Pros and cons 9.3 – Comparative imagining of future outcomes 12.5 – Adding objects to the environment 15.1 – Verbal persuasion about capability 15.3 – Focus on past success</p>	<ul style="list-style-type: none"> • Discussion around pros and cons of discussing lifestyle factors with this patient group and problem-solving task. • Information on the teachable moment, on new roles for HCPs and procedures. • Demonstrations of discussions of exercise with patients. • Information presented as patient vignettes, written text, prompts for clinic use and links to further reading.
<p>4) Skills for supporting people with exercise</p>	<p>2.2 – Feedback on behaviour 3.1 – Social support (unspecified) 4.1 – Instruction on how to perform the behaviour 5.1 – Information about health consequences 5.3 – Information about social and environmental consequences 5.6 – Information about emotional consequences 6.1 – Demonstration of behaviour 8.1 – Behavioural practice/rehearsal 12.5 – Adding objects to the environment 15.1 – Verbal persuasion about capability 15.3 – Focus on past success</p>	<ul style="list-style-type: none"> • Information about behaviour change and behaviour change theory. • Introduction to techniques to support behaviour change in this patient group. • Some role-play elements of how to support patients with exercise. • Reflections on previous experiences. • Information presented as patient vignettes, diagrams demonstrations, written text, prompts for clinic use and links to further reading.

		<ul style="list-style-type: none"> • Patient materials handed out for HCPs to give to patients.
5) The role of exercise professionals	3.1 – Social support (unspecified) 5.1 – Information about health consequences 5.3 – Information about social and environmental consequences 5.6 – Information about emotional consequences 6.3 – Information about other approval 9.1 – Credible source	<ul style="list-style-type: none"> • Discussion of opinions and experience of exercise referral schemes. • Information about Nuffield Health, services they provide and their exercise professionals. • Information presented via diagrams, videos and written text.
6) The exercise referral pathway and communication pathway	1.2 – Problem solving 2.2 – Feedback on behaviour 3.1 – Social support (unspecified) 4.1 – Instruction on how to perform the behaviour 5.1 – Information about health consequences 5.3 – Information about social and environmental consequences 5.6 – Information about emotional consequences 7.1 – Prompts/cues 8.1 – Behavioural practice/rehearsal 8.3 – Habit formation	<ul style="list-style-type: none"> • Overview of the processes for referrals and communication. • Information provided via demonstrations, written text and prompts for clinic use.
Intervention support outside of the training	2.3 – Self-monitoring of behaviour 2.7 – Feedback on outcome(s) of behaviour	<ul style="list-style-type: none"> • The use of a screening log to self-monitor behaviour and feedback on behaviour such as referrals via email or telephone.

Table 6.4: Version one of the intervention reported in line with TIDieR framework (Hoffmann et al., 2014)

Name	HCP training package
Why	HCPs do not routinely discuss exercise with men with prostate cancer on ADT and report several barriers as to why. Therefore, a training package is required to support HCPs in recommending exercise, providing behavioural support and exercise in line with recent NICE recommendations NG131 1.4.19. See section 5.1, page 179, for more detailed rationale.
What	<p>Module one: An overview of the project</p> <p>This module aims to introduce the facilitators to the clinical team, give an overview of the training package and an overview of the project. NICE NG131 1.4.19 recommendations will be introduced here.</p> <p>Module two: Prostate cancer and exercise – the evidence base</p> <p>This module will give an overview of the benefits of exercise for men with prostate cancer on Androgen Deprivation therapy.</p> <p>Module three: Discussion exercise as a healthcare professional</p> <p>This module will identify clinical roles within the team to aid the implementation of the NICE recommendations. How to discuss exercise and lifestyle with this patient group will also be introduced. Common assumptions made by HCPs about patients' capabilities to exercise will aimed to addressed.</p> <p>Module four: Skills to supporting people with exercise</p> <p>This module will provide HCPs with the appropriate skills in terms of behaviour change techniques to use to</p>

	<p>support this patient group with exercise. Role-play and group tasks will be included within this module.</p> <p>Module five: The role of exercise professionals</p> <p>This module will give an overview of the roles and experience of exercise professionals working with this patient group. It will aim to overcome some of the apprehensions HCPs have about working with exercise professionals.</p> <p>Module six: The exercise referral pathway and communication pathway</p> <p>This module will provide HCPs with the information of how to make referrals for exercise, what information to hand out to patients and how secure communication will take place with Nuffield Health and the NHS.</p> <p>HCP manual will also be given out at the training to support HCPs.</p>
Who provided	Researcher/health psychologist
How	Face to face in small groups
Where	On site at the hospital or at a university
When and how much?	Half day training once
Tailoring	HCPs receive either level one or both level one and two of the training packages depending upon their role.
Modifications	Face to face, to be delivered on NHS site or locally to NHS site.
How well	Process measures, acceptability and fidelity will be measured, see Chapter eight.

Table 6.5: BCTs taught in training package to HCPs

Behaviour Change Technique	Evidence and theory base
1.2 Problem solving	Identified in Chapter three as a useful technique for cancer survivors in the promotion of exercise (Turner et al., 2018).
3.1 Social Support (unspecified)	Identified in a systematic review discussed in Chapter three as helpful for improving exercise behaviour in men with prostate cancer (Hallward et al., 2020) and has been shown to be effective and relevant in conversations about lifestyle change (NICE, 2014).
5.1 Information about health consequences	Aimed at helping the patient group to change their beliefs about exercise. As highlighted in the Theory of Planned Behaviour regarding the importance of providing information about the behaviour and the consequences of the behaviour for changing beliefs. (Ajzen, 1991).
5.3 Information about social and environmental consequences	
5.6 Information about emotional consequences	
6.3 Information about others' approval	The concept of teachable moment highlights the importance of HCPs advocating exercise at the point of diagnosis (Demark-Wahnefried et al., 2005).
9.2 Pros and Cons	Aimed at helping the patient group to change their beliefs about exercise, as highlighted in the Theory of Planned Behaviour (Ajzen, 1991).
15.1 Verbal persuasion about capability	Verbal persuasion alongside other techniques delivered to the patients may help to improve self-efficacy as highlighted in the Social cognitive theory (Bandura, 1982).

6.6 Discussion

This chapter describes the process of a systematic and comprehensive method to intervention development using the MRC and BCW as complementary approaches. A half-day, face to face, interactive and skills-based training package for secondary care prostate cancer care HCPs was developed. This training package is designed to support HCPs who see men with prostate cancer specifically on ADT to provide exercise recommendation, behavioural support, and an exercise referral all in line with recent NICE recommendations NG131 1.4.19.

The intervention developed is complex and multifaceted, including six intervention functions (education, persuasion, training, modelling, environmental restructuring, and enablement). These intervention functions were selected based on the BCW guide (Michie et al., 2014). This guide was easy and clear to use for the selection of the intervention functions. According to the guide, all the intervention functions were to be considered for this intervention, however, when applying the APEASE criteria it was decided restriction and coercion would not be selected due to it not being acceptable to use coercion or restriction within a cancer care setting. Incentivisation was not selected due to not having the resources, despite there being potential benefit of incentivisation in HCP behaviour, as discussed in Chapter one (Flodgren, Eccles, et al., 2011). However, the use of the intervention functions, seemed to be unnecessary and an additional step with little benefit. All behavioural content was selected based on relevant theories or 'real-world' evidence, which had been identified as being effective to make changes to the TDF domains identified in Chapter five. Behavioural content was not selected based on the intervention functions used in this intervention. Intervention functions were not used following their selection, except for reporting, which is important but due to the complexities of the intervention, reporting the six intervention functions does not tell readers about the intervention, further detail around the BCTs and mode of delivery is required to understand what was developed. If I were to develop this intervention again, using the steps highlighted in this chapter and the previous chapter (Chapter five) without using intervention functions, I do not believe the intervention would have been developed differently.

The BCW and MRC guidance offers a systematic and comprehensive approach to intervention development that is accessible to all researchers. The systematic BCW approach to intervention development has been criticised by some health psychologists (Ogden, 2016). It has been suggested the BCW poses health psychologists as technicians rather than professionals, taking the opportunity away from health psychologists to make decisions about intervention development. However, I would disagree with this argument. As whilst the BCW may appear to be a guide for intervention development, an in-depth understanding of the underlying psychological processes and theory is required to enable the selection of appropriate and potentially effective BCTs. Whilst this work was carried out, it is not clearly stated how to do so, or that it is required (De Silva et al., 2014; Hansen et al., 2017). To tackle this issue, I had to revert to 'traditional' approaches to theory selection. Classic psychological theories were reviewed, the review process involved searching for constructs within these theories relating to the TDF domains such as *knowledge*. Classic theories were then selected if they were relevant to the domains targeted in this intervention. This review process was not systematic, which is a limitation of this approach. Aspects of theories were selected to underpin this intervention, these were the Social Cognitive Theory (Bandura, 1986), Social Learning Theory (Bandura & Walters, 1977), Theory of Planned Behaviour (Ajzen, 1991), the Necessity and Concerns framework (Horne et al., 2013) and Theories of Habit (Gardner & Rebar, 2019). Due to the complexity of the intervention and targeting change in seven behaviours, constructs and specific relations from more than one existing theory were used to underpin the intervention and the domains driven by the TDF targeted in this intervention were reflective of the theories selected. One of the challenges with linking theory and intervention content is common within health psychology and behavioural science. Whilst Predictive theories offer an insight to how behaviour may occur or change, they often do not give clear instructions on how to change behaviour (Carey et al., 2018). The Social Cognitive Theory (Bandura, 1986) is an exception as it offers clear examples of techniques to use to influence behavioural determinants such as self-efficacy. Whereas other theories such as Theory of Planned Behaviour (Ajzen, 1991) do not offer clear guidance and focus more on prediction of behaviour. Further research is required to map theoretical constructs derived from theories onto effective intervention content (Hagger & Weed, 2019). The

logic models (see Appendix K) were a useful way of presenting the proposed mechanisms of change, however, due to the complexities of the intervention, it was not possible to develop an overall logic model, whilst maintaining key information. Logic models have been criticised for being ‘inadequate’ in describing complex intervention (Mills, Lawton, & Sheard, 2019). Therefore, mapping the key behaviours individually seemed most appropriate.

In addition to theory, BCTs were also selected based on real-world evidence, where BCTs had been found to be effective in HCP behaviour change, as presented in Chapter one. Understanding what techniques have been used, with what effects and in what ‘real-world’ contexts is an essential step to developing an intervention. Theories are useful tools for recommending what techniques may work, however, evidence which tests these theories in a real-world context is critical, especially for this intervention, which will be implemented into a complex healthcare setting. Furthermore, the work by Carey et al., (2018) was important in the selection of behavioural content. This tool (theory and techniques tool) allowed for us to identify the mechanisms of action, which were our theoretical constructs and identify BCTs that were likely to be effective to change behaviour. The tool was developed to make behavioural science research more accessible. An important consideration whilst using the theory and techniques tool alongside the BCW is that BCTs which are linked to the intervention functions in the guide as ‘most used’, differ greatly in comparison to the evidence-based theory and techniques tool. At this point, a decision was made to not use the BCW guidance to select behavioural content due to the guide not providing sufficient evidence of effectiveness of behavioural content.

Following the selection of intervention functions, 22 BCTs were selected such as *demonstration of behaviour* and *credible source* and training HCPs to deliver BCTs to support patients such as *problem solving* and *verbal persuasion about capability* (see Table 6.3). The intervention aimed to make changes to the identified TDF domains by the specified 22 BCTs but more specifically aimed to a) improve knowledge using techniques such as *information about health consequences*, b) increase confidence using techniques such as *behavioural practice/rehearsal*, c) change HCP beliefs using techniques such as *information about health consequences*, d) establish social norms using techniques such as

credible source, e) provide training in behavioural skills using techniques such as *feedback on behaviour* and f) change HCP belief of their perceived role using techniques such as *social support*.

In regards to the number of BCTs delivered within an intervention in relation to effectiveness, there isn't a general consensus of whether a single-component vs multifaceted interventions for professional behaviour change are more effective to change HCP behaviour is inconsistent (Squires et al., 2014). The number of BCTs (22) included within this present intervention is high, due the complexities of the intervention and there being several HCP barriers to tackle for several different target behaviours. However, implementing such an intervention may be problematic in the future due to the potential cost to implement and its complexities, which may be difficult to sustain over time, especially if a health psychologist/ behavioural scientist is required to deliver the training. Previous attempts of interventions aiming to increase lifestyle advice from HCPs who work with cancer survivors have often been less complex. For example, Webb and colleagues (2016) developed an intervention using the BCW to support nurses to discuss physical activity more frequently with cancer survivors. The intervention is yet to be fully evaluated, however changes in beliefs were present (Webb, Hall, et al., 2016). The training developed an hour-long session which delivered five BCTs, which is a vast difference in comparison this developed intervention. However, the intervention is aiming to achieve only one behaviour change in one profession 'to provide advice on exercise', whereas the current intervention is aiming to change seven behaviours in multiple professions (see Table 5.2). This intervention key principle was focused upon gaining workplace support, hoping for HCPs to act as role-models in the delivery of the intervention using *credible sources*. Furthermore, the selection of BCTs was guided using the BCW guide. The BCW guide offers BCTs that are 'most used' within certain intervention functions, but this does not mean they are effective and more specifically, effective in HCP behaviour change. BCTs needs to be selected based on theoretical recommendations and real-world behaviour change contexts in which they have been used and been shown to be effective. This is a big gap within the BCW guidance and could explain why this intervention is only applies a few BCTs.

6.6.1 Strengths

Combining the BCW, MRC and TDF approaches to intervention development offers a comprehensive and systematic approach. Firstly, identifying the theoretical assumptions for the proposed intervention is strength of combining the BCW and MRC approach. This allows for a developed understanding of the theoretical assumptions and intervention components. This can aid an evaluation of the intervention and help with replication of the intervention.

Secondly, the BCW approach allows for researchers to consider all the possible intervention options and to systematically select these. This is important as often interventions are developed using the '*it seemed like a good idea at the time*' (ISLAGIATT) principle rather than having a theoretical basis, which can potentially limit the effectiveness of an intervention (Michie et al., 2014).

Thirdly, as the BCW and MRC guidelines were followed and decision-making processes were documented throughout, based on evidence where applicable using the APEASE criteria. This is an important strength of the approaches followed as often interventions are developed and key aspects go underreported, which is an issue for future research and understand what may or may not work in specific contexts.

6.6.2 Limitations

As reported by other researchers (Sinnott et al., 2015; Webb, Foster, et al., 2016), the BCW process is time-consuming and resource intensive. The intervention development process within this thesis took around 12 months to complete without refinement and optimisation, which is reported in chapter seven. However, this does allow for a comprehensive approach and provides for a good basis for the evaluation of the programme. As this process allowed for clear mapping of the theoretical assumptions, intervention components and proposed outcomes.

Whilst, the intervention development team was multi-disciplinary, involving HCPs and clinical teams in the development process from the beginning would have been advantageous (Bull et al., 2019; Janols & Lindgren, 2017). Examples of work, where the BCW intervention development process has involved intervention users such as clinical teams in partnership with academics have been found to be helpful in improving self-efficacy and giving HCPs the tools to help change practice (Bull et al., 2019). Not involving HCPs so far in the

intervention development is a limitation to the study as details of the workforce culture, context, and practicalities of delivering the training package could have been missed. This could have implications for the intervention, as there may be problems with implementation and further barriers from HCPs. For example, new models of care that come from the top-down have been highlighted as the cause and consequence of a poor workforce culture amongst clinical teams (Bull et al., 2018). Due to this issue and the importance of involving intervention users within the development process, the next stages of the intervention development will be to refine and optimise the intervention with HCPs, this is reported in Chapter seven.

6.7 Conclusion

By using the MRC, BCW and TDF as complementary frameworks an intervention to support HCPs to recommend exercise, provide exercise support and exercise referrals for men with prostate cancer was developed. The training was in the form of a half-day, interactive and skills-based package, that included six intervention functions and 22 BCTs. The MRC and BCW offer comprehensive and systematic approaches to intervention development, despite them being time-consuming, this effort is important to develop an intervention as potentially effective as possible. However, further refinement is required using key stakeholders.

6.8 Chapter summary

A first version HCP training package was developed using the MRC, BCW and TDF complementary frameworks. The next chapter explores the further refinement and optimisation of the training package using key stakeholders' input.

7) Chapter seven: Iterative refinement and optimisation of the intervention: Rehearsal delivery to one clinical team and using stakeholder workshops to gain feedback

7.1 Background

Following the development of the first version of the healthcare professional (HCP) intervention, further refinements are required to ensure the intervention is user-friendly, acceptable to HCPs and potentially effective. A limitation of the Behaviour Change Wheel (BCW) is the lack of consideration for the involvement of stakeholders within intervention development (Janols & Lindgren, 2017). However, the Medical Research Council (MRC) suggests key stakeholders should be involved in the design process of interventions (Craig et al., 2008). Additionally, more recent guidance suggests the importance of involving key stakeholders in the development of complex interventions (O'Cathain et al., 2019). Stakeholders can be defined as *“A person or organisation who has something to gain or lose as a result of the outcomes of a project, programme or process.”* (Hovland, 2005, p. 8). Effective stakeholder engagement in research and implementation is important for several reasons as follows; It allows to bring a lived-experience perspective to the research, encourages support from stakeholder workshops for the research and allows for stakeholders to have an input into the research that can ultimately affect their care or practice (Greenhalgh et al., 2019). There are several different ways to involve stakeholders in the development process; these can range from co-design to one-off meetings. Additionally, stakeholders' views may be gained from interviews, focus groups and or surveys. There is no general consensus of how stakeholders should be involved within research and this can often lead to tokenistic efforts, which should be avoided (Mitton, Smith, Peacock, Evoy, & Abelson, 2009). Within the context of this thesis, it was aimed to engage with HCPs within the prostate cancer clinical team and wider stakeholders such as patients and exercise professionals.

7.2 Aim

To optimise and refine the developed training package for prostate cancer HCPs using key stakeholders.

7.3 Objectives

Step 1

- To deliver our first iteration of our "in development" intervention training with a team of prostate cancer HCPs.

Step 2

- To obtain written and /or oral feedback via focus groups from HCPs on the designed intervention.

Step 3

- To deliver one stakeholder workshop involving key stakeholders (e.g. patients, NHS staff and community exercise professionals).

Step 4

- To obtain oral feedback and collect data from stakeholder workshop to further refine the intervention.

7.4 Methods

7.4.1 The team

The intervention refinement team was multi-disciplinary and included: Myself (RT), Qualitative expert (ES), Health psychologists (MA & LS) Research Fellow (SR), Professor and Consultant Urologist (DR), Professor of Cancer Research (LB), Professor of primary care and public health (ST) and Clinical professor and consultant physiotherapist (DM).

7.4.2 Overview of methodology

Qualitative research methods were used within this study and methods involved incorporating intervention users and key stakeholders for feedback to refine and optimise the intervention. The intervention development refinement process was iterative, this is presented in Figure 7.1.

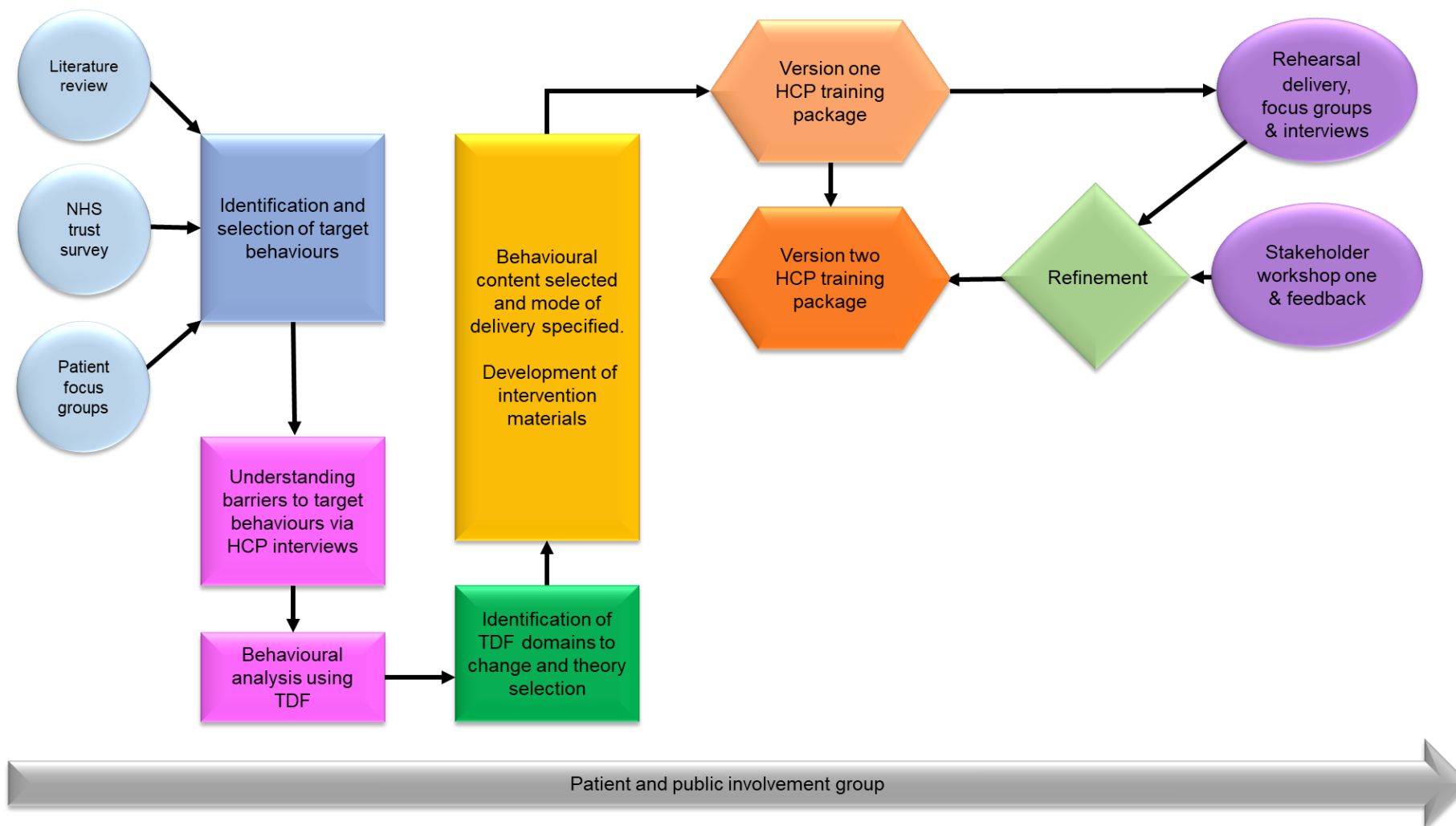


Figure 7.1: Overview of the development and refinement of the intervention

7.4.3 Ethics and data storage

Ethical review was granted 23rd October 2018 by North West - Liverpool East Research Ethics Committee REC reference: 18/NW/0738 / IRAS project ID: 254343. A non-substantial amendment was submitted and approved 11th December 2018 to allow for the training to take place on university premise rather than hospital grounds and to increase the number of HCPs for recruitment. All data is securely stored on a secure drive at Sheffield Teaching Hospitals (STH), with only the research team having access to. All hard copies of transcripts are stored in a site file securely on STH premises.

7.4.4 Study design

Step one

The training package was delivered to one clinical team, face to face from an NHS trust in North England. This was termed a 'rehearsal delivery'.

Step two

Focus groups and interviews were carried out directly after the delivery of the training package, which informed the intervention refinement.

Step three

The intervention was further refined and optimised using a full-day workshop with key stakeholders.

Step four

Field notes were collected from working group discussions with stakeholders at the stakeholder workshop and used to inform the intervention.

7.4.5 Topic guide design

It is important to note these topic guides were developed as part of the wider STAMINA programme, see Figure 0.2. They were used to evaluate the exercise professional and patient intervention also. The topic guides were developed by ES and had previously been developed as part of the wider project grant application.

Step two

The working group schedule was semi-structured with open-ended questions and prompts to allow for participants to express their views (see Appendix J).

This topic guide was based on (Kirkpatrick, 1977). Kirkpatrick (1977) argues there are four processes to evaluate training programmes. These are reaction; learning; behaviour and results. Reaction is concerned with understanding how participants feel about the training programme. Learning is to what extent the attendees have learnt something new such as skills. Behaviour is concerned with what extent their behaviour has changed due to the training. Finally, results are to what extent the training has affected outcomes. The topic guide was based on the concept's reaction and learning.

Some example questions are as follows:

How confident do you feel in being able to use these skills as part of the STAMINA intervention/ in routine practice?

- *What would increase your confidence?*

Step four

The focus group schedule was semi-structured with open-ended questions and prompts to allow for participants to express their views (see Appendix M). This topic guide was based on the Normalisation Process Theory (NPT) (Murray et al., 2010). As discussed in Table 2.1, The NPT is a framework for developing, evaluating and implementing complex interventions (Murray et al., 2010). The NPT differs to the BCW as it considers factors around implementation of new practice (May et al., 2015), considering more sociological factors to explain and understand social processes of new practice. The topic guide aimed to explore all four constructs of the NPT (coherence, cognitive participation, collective action, and reflective monitoring) concerning the HCP intervention. The NPT allowed questions to be explored around the wider context of the potential implementation of the intervention.

Some example questions are as follows:

How feasible is the delivery of the intervention?

- *Opinions on the mode of delivery of intervention?*
- *Opinions on the duration of intervention?*

7.4.6 Sampling

Purposive sampling was used in this study.

Steps one and two

NHS HCPs from one prostate cancer care team including Consultant Urologists, Consultant/Specialist nurses and staff nurses were invited to attend the training sessions. As discussed in chapter five, these HCPs are predominantly involved in the patient's care.

Step three and four

Stakeholders including participants who took part in Step one and two, patients and their partners/carers, health psychologists, exercise specialists, oncologists/urologists, specialist nurses, commissioners and relevant third sector organisations were invited to participate in the stakeholder workshops.

7.4.7 Recruitment

Steps one and two

The project was presented to the Urology Academic Directorate by the Chief Investigator of STAMINA, DR, (Senior Consultant Urologist within the directorate and Urology department). The Urology Academic Directorate was pleased to support the project and allow for 6-10 relevant HCPs to be released from clinical duties for half a day or for sessions to be delivered in the evening or weekends.

Following this, the project was presented at the nurse routine meetings and urology breakfast meetings by RT, to gain interest from HCPs. Additionally, an email was circulated to the entire Urology department from the Chief Investigator of STAMINA (DR) to again obtain interest and support for the study. Participant information sheets (see Appendix N) were handed out at these meetings or sent via email to potential participants if interest was expressed. Possible participants were given at least 24 hours to consider the participant information sheet and ask any further questions before agreeing to take part. If a participant wished to take part, informed consent was taken before the clinical team training (see Appendix O). Once consent and/or expressions of interest were given, the operations manager from the Urology department was asked which dates would suit the department to run the sessions. Two dates were given, and participants were asked to choose a date to attend. Due to staff sickness, an additional two sessions were offered and taken up.

Step three and four

Participants were identified via contacts who had expressed an interest in the programme via the previous NIHR programme development grant, existing clinical and professional networks, research participant representative networks, national charity representatives and our patient and public involvement group. Potential stakeholders were sent a participant information sheet (see Appendix P) via post or electronically. They had a minimum of 24 hours to consider the information sheet and ask any questions about the research.

7.4.8 Data collection

Step one

Four rehearsal training sessions were carried out between January 2019 and February 2019. The sessions were carried out face to face and lasted on average between 2.5 hours and 3.5 hours. The sessions were delivered by RT and at least one co-facilitator (SR and/or LS). The sessions were videoed, and audio recorded using a video-recorder and Dictaphone with the focus upon the lead facilitator (RT). The training was delivered as presented in Chapter six with six topic areas, including level one and level two.

Step two

The focus groups were carried out face to face directly after Step one. The sessions were audio-recorded using a Dictaphone. The focus groups were run by independent researchers (SR and LS) to mitigate bias from the intervention deliverer (RT) and for participants to feel comfortable in providing honest feedback without the intervention deliverer present. Field notes were also collected from the participants as they were encouraged to comment on any intervention materials.

Step three

One full day stakeholder workshop was held in February 2019. The presentations by the research team were video recorded using a video-recorder.

Step four

Field notes from observations, informal discussions and the working groups were taken throughout the stakeholder workshop by the research team and facilitators (RT, SR, LB, ST, and ES). Researcher field notes were written into a

word document individually; these were then collated and combined into one-word document. This document was then circulated to all the stakeholder attendees to ask for any further comments or clarification. A deadline of two weeks was given for stakeholders to comment.

7.4.9 Procedures

Steps one and two

Participants were asked to attend up to half a day of training at Collegiate Campus, Sheffield Hallam University (SHU). Due to staff sickness, winter bed pressures and clinical commitments, it was not possible to run two training and feedback sessions. Four sessions of the training and feedback sessions were run, between January 2019 and February 2019. At this point in the programme, no exercise referral pathways had been 'initiated' as part of the wider study, so the training aimed to deliver core components of the proposed programme and gather feedback on future referral pathway to be implemented at a later stage of the research.

Step three and four

Stakeholders were asked to attend up to one full day of the workshop. The stakeholder workshop was delivered at a local hotel. Stakeholders were sent an agenda before attending the event and asked to contact the research team if they had any further questions.

When stakeholders arrived, they were welcomed by members of the research team. All stakeholders had received a participant information sheet and informed consent (see Appendix Q) was given upon arrival. Stakeholders were allocated specific tables to ensure professions were mixed amongst the group. Each table had around 8-10 participants plus a facilitator on.

The workshop itself commenced with an introduction to the project and overview of the aim of the workshop led by a facilitator and co-applicant of the wider project, DM.

Specifically, the HCP intervention session was delivered in the following format:

A 30-minute presentation by RT, this covered background, rationale, intervention development process and overview of content, format, and delivery. At the end of the presentation, 'key uncertainties' were posed to the stakeholders to discuss in their groups. These key uncertainties were:

- What is the optimal duration of the training packages?
 - *is it too long, too short, just right?*
- How can the intervention be operationalised in the NHS?
 - *the notice period, previous training experiences, online vs face-face*
- How can we develop trust in the new integrated pathway?
 - *HCP trust of exercise professionals, communication*
- Any other ideas?

Following this, a 20-minute table discussion was delivered on each table by an independent member of the research team (LB, SR, ES & ST). A further 10 minutes were then allocated for the tables to feedback to the group. Field notes were taken throughout this process on each table.

7.4.10 Facilitators

Stakeholders were on four tables, with a facilitator from the research team on each table (RT, SR, LB, ST and ES). Facilitators were given an instruction pack before the stakeholder workshop. The main responsibilities of the facilitators were to facilitate the focus groups after each presentation, make notes and write the key points on the flipchart paper.

7.4.11 Data analysis

Step one and three

The training sessions audio-recordings were transcribed. The video-recordings from both the training sessions (step one) and the stakeholder workshop (step three) were used for personal reflection about the delivery of the intervention by RT.

Step two and four

For step two, the focus groups audio-recordings were transcribed. Inductive thematic analysis was carried out to analyse the focus groups transcripts. For step four, field notes were taken and written up into one-word document, these were analysed thematically.

NVivo software version 11. was used to aid analysis during both step two and three. Thematic analysis offers a flexible approach to qualitative analysis (Braun & Clarke, 2006). Braun and Clarke (2006) outline key stages to thematic analysis; these were followed for this analysis. The five steps were as follows:

1. Familiarisation of the data

The researchers initially familiarised themselves with the data by listening to the audiotapes and re-reading the transcripts. During the familiarisation stage, the researchers listed any key ideas, thoughts, and recurrent themes, to gain an understanding, depth, and diversity of the data.

2. Generating initial codes

Following on the familiarisation of the data, all the transcripts were initially coded. Once all the transcripts were coded by RT, the two researchers independently coded the same transcripts (LS & SR). This coding was then compared, face to face. Discussions were had about the coding and if there were any disagreements, these were resolved by a discussion with a senior qualitative researcher (ES).

3. Searching for themes

Once the transcripts were coded, the codes were then organised into potential themes. If it was not clear where codes sat within a theme, a theme named 'miscellaneous' was introduced. It was important at this stage, not to lose any of the codes identified in stage two.

4. Reviewing the themes

Codes within identified themes were re-read to ensure there was a coherent pattern within the themes. A discussion with independent researchers (LS and SR) was had at this point, to understand if there were any disagreements regarding the themes. Any disagreements were resolved in a discussion with a senior qualitative researcher (ES).

5. Defining and naming themes

This aspect of analysis entailed identifying the 'meaning' of each theme and/or sub-theme. Names of themes were given, ensuring the names aimed to give the reader an understanding of exactly what the theme entails. Due to the purpose of this thematic analysis being to understand potential refinements to the intervention, key themes were identified; key aspects of the feedback were highlighted, rather than reducing them down into sub-theme headings.

Intervention refinement

Once key themes were highlighted, these themes were considered in relation to the intervention. Key themes were presented to the intervention development

team at a meeting (RT, SR, LS, ST, DR, LB), it was then considered if a change to the intervention was necessary in relation to each key theme. This was judged using the APEASE criteria, see Table 2.5 for definitions. These were later discussed in further detail with MA and LS and the APEASE criteria was considered and applied by RT, with discussions with MA and LS where appropriate.

7.5 Results

7.5.1 Step one and two

7.5.1.1 Participants

The participants were working in diverse roles representing different disciplines within a prostate cancer clinical team. Two Consultant Urologists, four Clinical Nurse Specialists (CNS's) and two staff nurses attended the rehearsal delivery and focus groups or interview over four sessions.

7.5.1.2 Feedback from delivery of version one of the clinical team training

Table 7.1 presents the data gained from the focus groups and interviews following the delivery of version one of the clinical team training. Table 7.1 also presents whether changes are necessary, which were judged using the APEASE criteria (see Table 2.5) to the intervention following the specific feedback and the impact this may have on the intervention. Summary of key points from Table 7.1 is presented in Section 7.5.3.

Table 7.1: Feedback from delivery of version one of the clinical team training and the impact upon the intervention

Key theme	Feedback	Example quote	Is a change necessary? Does it meet the APEASE criteria?	Impact upon intervention
Content of the training package	The content of the training package was found to be suitable for all healthcare professions	<i>"It was delivered brilliantly; the slides were really clear. Yeah, it was a nice level, we learned things from other trials." FG3</i>	N/A	The programme was found to be enjoyable.
Changes to the content of the training package	1. Using patient case studies and patient scenarios to work with was suggested to help engage the HCPs.	<i>"You want us to tell clinicians, patients, if we can picture what we're prescribing in talking to them, then we're much more animated, much more bought into it, rather than come and have an exercise package, which to me could be anything basically." FG3</i>	Yes, meets APEASE criteria.	Patient case studies and scenarios will be used throughout the training sessions in several different modules.
	2. To include more task-orientated activities	<i>"So we're task orientated, but if we don't have an outlet or an</i>	Yes, meets APEASE criteria.	The inclusion of task-orientated activities will be used throughout the

		<i>outcome that improves it, we tend to ignore it, which is probably a bad thing, it's probably, but when you have 12 minutes." FG3</i>		training sessions in several different modules. It is anticipated that there will be several group work tasks, particularly in level two of the training package.
	3. To pose exercise as a treatment alongside treatment, so this could fit into their 'usual conversations' with patients and would not add too much time.	<i>"It's subtleness, that is so much quicker than going you need to have ADT, and then on top of that I'd like to have exercise, and this is why. Whereas if they just get, if we just package it as you're for ADT and exercise, just like you've got ADT and radiotherapy, ADT and chemotherapy. They just then process on, and they find out about both of those things." FG3</i>	Yes, meets APEASE criteria.	The training will encourage exercise to be recommended as a treatment component alongside their ADT, this will work for the level one training and the role of the consultant urologist. However, to discuss exercise quickly would not be optimal for the role of the keyworker as we are aiming to train the keyworkers to discuss barriers and facilitators with patients.
	4. There were concerns over the motivations of Nuffield health's involvement in the study. Further information about	<i>"Is it that somebody in Nuffield Health has a thing about cancer care, or is it just that as a company they feel it's important to get involved in</i>	Yes, meets APEASE criteria.	A clear message of the reasons for Nuffield Health's involvement in the overall STAMINA programme will be presented in the training package. This will involve videos of personal trainers

	Nuffield health would help alleviate some of these concerns.	<i>something other than just corporate, the corporate world? Or is there a corporate thing at the back of it all that they're thinking after 12 weeks, 12 months, that patient then potentially could become a member? So, for the free year that we give them, we might end up with five years membership. I'd like to think it isn't that." FG4</i>		from Nuffield Health but also videos of more senior managers of Nuffield Health discussing.
	5. A simple message that is focused, needs to be conveyed to the HCPs about what is expected of them and what is required for the study. HCPs express they are used to change within the NHS, they just need clear direction of what has changed.	<i>"Because the classic NHS, which is the environment we're working in all the time, is we want you to do something different. This is what we want you to do. So we're quite open at having our pathways turned upside down overnight by someone telling us to do something different, so we don't have a problem with that.</i>	Yes, meets APEASE criteria.	A clear message of the HCP's roles will be presented in both level one and level two training package. This will be referred to throughout the training, to ensure HCPs are clear about their new roles.

		<i>We just want to know what we've got to do basically." FG3</i>		
	6. An understanding of the communication pathway was suggested to be very important for the HCPs. Having a contact person would be helpful to signpost the patients to if they have any questions the HCPs are unable to answer.	<i>"A clear communication pathway between us, the gym, yourselves, needs to be I think clearly marked – because you know that a patient's always going to ask you a question that you did not expect, so a contact person." FG4</i>	Yes, meets APEASE criteria.	The communication pathway will be highlighted in the training package. Ensuring that both teams understand who to contact and how to contact them.
	7. There were mixed opinions on including role play within the training session, as some found it 'intimidating', whereas others enjoyed taking part in role play activities as part of training.	<i>"Yeah, especially if it's in front of your colleagues (role play), particularly for example XXX was here or something, it is quite intimidating. It doesn't make it very easy." FG1</i> <i>"So yeah, I get very much in it. I get that for some people roleplay, they get nervous about being up in front of people. But I personally think it</i>	Yes, meets APEASE criteria.	Whilst there was concerns about role play, using role play is a useful tool for skill-based learning. Therefore, the training will include aspects of role play. It will be important to ensure the environment will be comfortable for the individuals taking part.

		<i>adds a bit of fun to it. And I think once everyone's up there, and you're doing it and you're laughing, or you're just going through it, I think it makes it a little bit easier." FG2</i>		
Whole team training vs individual profession training	There were mixed views over having the training delivered to the whole clinical team, as there were concerns that having senior colleagues present would be 'intimidating' for less senior colleagues.	<i>"They might feel a bit inadequate or a bit intimidated. Not all of them but some of them might. I think as well, I mean we're clinical nurse specialists, and that was news to us. I think for a staff nurse in terms of the NICE guidance, but I think for a staff nurse that would be even more of a, they'd probably feel quite lacking in knowledge." FG1</i>	Yes, meets APEASE criteria.	Rather than tailoring the training to each healthcare profession, the intervention should focus upon developing an intervention that aims to overcome the barriers identified previously. The intervention should be offered to any member of the clinical team who sees men with advanced prostate cancer on androgen deprivation therapy.
	However, it was thought that having everyone present would be beneficial in generating discussions.	<i>"Without a doubt, I think the more people there are, and the more conversation there is, the better the feedback would be." FG1</i>	Yes, meets APEASE criteria.	

Intervention providers	Having an exercise professional attend the training was suggested to help alleviate any worries or concerns regarding the delivery of the exercise programme.	<i>"I think that would be useful if there was a PT here, so that we can, because these patients are going to have predisposed ideas about running on a treadmill and stuff like that. And it would be nice to be able to say well actually no, this is how it starts, and this is what they get you to do first. So, I think having a PT here would be useful."</i> FG4	No, does not meet APEASE, as this approach is not practical.	Whilst having an exercise professional present at the training may be of benefit, this would not be practical. Therefore, the intervention will have to compromise to include videos of exercise professionals discussing key points and helping to alleviate some of the worries and concerns HCPs may have.
Duration of training package	The training was posed as being too long and would be difficult to have HCPs to attend a longer training session.	<i>"It was good. If I'm honest it's too slow and too long for busy people over here. But you want, as urologists you've got two basically, so if you want to get more people."</i> FG3	Yes, meets APEASE criteria.	Finding the balance between training not being too disruptive to clinical practice but also long enough to engage the HCPs is crucial. Therefore, a Level one introductory session (60 minutes) will be offered for all the clinical team and a Level two advanced (2.5 hours) will be offered to all the clinical team but essential for the keyworkers (usually the role of a clinical nurse specialist).
	However, it was perceived that if training was reduced, people would not engage.	<i>"Yeah, 20 minutes long, you won't have people on board."</i> FG1	Yes, meets APEASE criteria.	

Mode of delivery: Face to face vs online training	Face to face training was preferred over online training as questions can be asked face to face. It was also stated online training tends to get left until the last minute.	<i>"I'm a bit old school, I like face-to-face things, but that's because I've always got questions. I've always got to ask questions." FG2</i> <i>"Whenever we get anything online, bearing in mind the number of emails we get every day, it tends to get left. A bit like when we do mandatory training, we leave it until when you have to do it." FG1</i>	Yes, meets APEASE criteria.	The training will ideally be delivered face-to-face for interactive skills-based learning.
Mode of delivery: Train the trainer's approach	As there was an understanding amongst the HCP that it may be difficult to train all the clinical team, using approaches such as train the trainers was recommended.	<i>"Rather than trying to train the whole department, have you thought about training just one or two and asking them to disseminate it?" FG4</i>	No, does not meet APEASE, as this approach is not practical.	Using the train the trainer's approach would allow for dissemination of the training throughout the department and be convenient and possibly cost-effective. To ensure that the training is disseminated correctly and maintained fidelity, the trainers would need to be monitored which would not be practical in this instance; therefore, a train the trainer's approach will not be used.

Behaviour change techniques	The use of prompts and cues was suggested to help remind HCPs to discuss exercise with their patients.	<i>"I think just again a little bit further down the line if you could maybe create things for prompts for certain people to go off I think that would be really good." FG2</i>	Yes, meets APEASE criteria.	Including prompts around the clinic to remind HCPs to discuss exercise with their patients will be used in the intervention as suggested.
Practicalities of HCPs attending the training	Difficulties were identified in being able to release HCPs, particularly staff nurses, was discussed.	<i>"I think like I said before, from a band 5 perspective I think you're going to find that really difficult. I don't think we can afford that amount of time out of clinical duties for one trial. From a research nurse point of view that's fine, but from a clinical staff nurse, band 5 point of view I don't think we can be spared, especially with winter pressures at the moment." FG4</i>	Yes, meets APEASE criteria.	Difficulties in HCPs attending the training sessions were discussed due to the pressures of the NHS. Therefore, possibly offering the following alternatives may help to resolve some of these issues. <ol style="list-style-type: none"> 1. Offer at least 6-8 weeks' notice for the clinical team. 2. Ensure senior managers and clinicians are bought into the concept and support the project.
Barriers to the intervention	1. There were concerns that there would not be engagement from the whole team, and this would be a barrier in integrating	<i>"And it needs engagement from all of them, and that is one of our biggest barriers. We have this all the time. And it would be really interesting to</i>	Yes, meets APEASE criteria.	All HCPs involved in the care of men with advanced prostate cancer will be invited to attend the training package. Approval will be sought from the department for all the relevant HCPs to

	exercise into the prostate cancer care pathway (social influences)	<i>be a fly on the wall next week when you see consultants, just to see what their take is on it, because I think it will be very different." FG1</i>		attend; this will aim to encourage the whole team to be involved.
	2. Some HCPs felt torn between quality of life outcomes and survival outcomes within the NHS, as they generally felt curing and focusing upon survival was their main role. As the HCPs see and treat very diverse patient groups and tended to have concerns over younger patients with poor life expectancy than concerns around sexual dysfunction for example of an older prostate cancer patient. (Social/Professional role and identity)	<i>"In a lot of our life we are trying to cure cancer by, if you want to be emotive disfiguring people, taking out their organs, giving them stomas, making them incontinent. And day in day out we are dealing with people dying of cancer, failing operations, major surgery. So when someone says oh I've lost my sex life, that isn't a big pressure to us, because we're thinking well I understand that's a big issue to you, but this guy's 38 and he's got metastatic bladder cancer and he's got a six month old child. That's the thing that I'm stressed about, not the fact</i>	Yes, meets APEASE criteria.	This concern is unlikely to be addressed in the training package. However, there needs to be an awareness of this barrier. The training package will allow for discussions around barriers, encouraging the HCPs to be open and honest. This will hopefully highlight that offering an exercise programme and recommending exercise is a small task, which can really offer something positive to this patient group.

		<i>that the 75-year-old guy's erections aren't as good." FG3</i>		
	3. There was acknowledgement that assumptions are commonly made regarding patients' ability to exercise and the HCPs stated they needed to be aware of this when discussing exercise with their patients. (Beliefs about consequences)	<i>"And I think that the thing for us is not to bring our judgement to the table. Because I think we will be surprised I'm sure by the ones who we probably think will definitely take it up who choose not to, and the ones who you think would be least likely who end up going." FG1</i>	Yes, meets APEASE criteria.	This aspect already included in the proposed training package.
	4. It was anticipated that HCPs who may not exercise themselves may struggle to bring up exercise to their patients. (Beliefs about consequences)	<i>"I think it's really difficult as a HCP to talk about lifestyle when you perhaps yourself aren't maybe complying with the advice that you're giving. And I think for patients that is often a big thing." FG1</i>	Yes, meets APEASE criteria.	Addressing this barrier in the training is beneficial as it important to iterate that the intervention is about providing support to patients around exercise. The exercise support provided will have an influence upon the patient regardless of the HCPs own exercise behaviour. The training will also aim to increase the HCP's confidence in providing exercise support.

7.5.2 Step three and four

7.5.2.1 Participants

Twenty-eight stakeholders attended the stakeholder workshop. The demographics of these stakeholders are presented in Table 7.2.

Table 7.2: Demographics of stakeholder workshop attendees

Organisation/Profession	Role	Number attended
Nuffield Health	Physiologist	1
	Personal trainers	3
	Fitness managers	2
	General manager	1
	Clinic manager	1
	Medical director	1
Local CCG	Project manager	1
	Lead nurse for cancer	1
	Quality improvement manager	1
Healthcare professionals	Consultant urologist	1
	Clinical Oncologist	1
	Consultant nurse	1
Academics	Health psychologist	1
	Sport and exercise medicine	1
	Health economist	1
Public and patient involvement group	n/a	8
Local charity	Exercise professional	1
Cancer alliance	Project manager	1
	Total	28

7.5.2.2 Feedback from stakeholder workshop one

Table 7.3 presented the data collected from the stakeholder workshop. Table 7.3 also presents whether changes are necessary to the intervention following the specific feedback and the impact this may have on the intervention.

Summary of key points from Table 7.3 is presented in Section 7.5.3.

Table 7.3: Feedback from stakeholder workshop one and the impact upon the intervention

Key themes	Overview	Feedback	Is a change necessary? Does it meet the APEASE criteria?	Impact upon intervention
Duration of training package	There were differences in opinion on the duration of training; needs to be long enough to cover everything but also not too time-consuming for the HCPs.	The training packages (Level 1 and 2) are a reasonable length given that staff must only attend training once.	Yes, meets APEASE criteria.	Concerns around the duration of the training package were mixed. However, a significant point that was highlighted which stated the training may not be perceived as important if it is not very long in duration. Finding a balance of having an in-depth training session combined with something that is practical to deliver in the NHS is important; therefore, the Level one and Level two training will be offered as half day training. Level one training will be for an hour for those who are only able or
		Concerns that there will be a lot of information to take in such as on the topic of behaviour change, should the training be a whole day?		
		Two hours did not seem long enough for the training and may be perceived as 'not important' enough.		
		It was suggested to amalgamate levels 1 and 2 in to one 3-hour training slot. The rationale behind this was how much 'buy-in' are you realistically going to get from HCPs who only have 60 mins to spare?		

				required to attend the Level one training.
Delivery of training package	The training needs to be delivered at a convenient time such as part of a routine meeting and organised with a lot of notice, not at evenings or weekends.	The time of day that training is arranged is important- must be during core hours i.e., not in the evenings/ weekends	Yes, meets APEASE criteria.	Delivering training during core hours has been challenging from the previous experience of Step 1 and 2. However, training will only be offered during core times as this is most practical and acceptable to the HCPs that will be attending the training.
		Training should be delivered at a convenient time such as the local directorate where there is likely spare capacity- days where there are directorate meetings were suggested or in MDT however time slots need to be pre-identified as MDT will need to be extra-long (suggestion to deliver training before discussing usual MDT agenda e.g. patients).	Yes, meets APEASE criteria.	Understanding when routine meeting will take place in the department would be useful, so the training could take place before, during or after the routine meeting. Contact will be made with the operational team at each NHS site the intervention will be delivered at to get an understanding when it may be best to deliver the intervention.

	Training should be delivered face to face and offered online as a back-up if the HCP is unable to attend.	Face-face training is more advantageous compared to online training. Staff can ask questions and discussion can be generated. Face to face training for second part of training is imperative.	No Does not meet APEASE, it is out of the scope of this thesis to develop an online training programme, with face to face training being the preferred option.	Training will be offered face to face. Potentially future work should focus upon the development of an online training programme.
		There must be a second mode of delivery- an e-learning option. Online training should be a backup to face to face training sessions rather than a primary mode of training delivery.	No Does not meet APEASE, it is out of the scope of this thesis to develop an online training programme, with face to face training being the preferred option.	
	Training site delivery	It was suggested training for the HCPs should be delivered at a Nuffield Health site.	No Does not meet the APEASE criteria, as it is not practical	Delivering the training to HCPs at a Nuffield site would not be practical, as training may happen in the middle of the day or between clinics, so taking the

				HCPs off NHS site would be inconvenient.
	Patient involvement in training	Having patients attend the training sessions was also suggested to help enhance the patient's voice throughout the training.	No Does not meet the APEASE criteria, as it is not practical	Having patients attend the HCP training would not be practical, as the aim is to deliver two training sessions per NHS site and having a patient present at all training session would be burdensome for the patient.
Content of training package	There were many suggestions around what should be included in the training packages.	To include more patient stories and working on patient case studies throughout the training.	Yes, meets APEASE criteria.	Patient stories and case studies will be used throughout the training as suggested.
		To ensure the training covers communication skills and behaviour change in relation to the patient's behaviour around exercise.	Yes, meets APEASE criteria.	Role play is already included in the proposed training plan.
		To allow for structured discussion after all modules and to focus upon action planning as a team	Yes, meets APEASE criteria.	Allowing time after sections of the training was suggested to allow for discussion and time to action plan, this will be incorporated into the training.
		For the training to include key logistic information; referral pathway,	Yes, meets APEASE criteria.	Already included in the proposed training plan.

		communication points, inclusion/exclusion criteria.		
		For the training to highlight the high-quality evidence around exercise and prostate cancer.	Yes, meets APEASE criteria.	Already included in the proposed training plan.
		The focus on roles should be included from level one and highlighting the importance of roles.	Yes, meets APEASE criteria.	Highlighting clinical roles from level one will be included, it will then be emphasised that further training will be delivered in level two around how to fulfil the new required roles.
		Roles play activities should be included, but also video footage of good conversations.	Yes, meets APEASE criteria.	Already included in the proposed training plan.
		It might be helpful (to build trust in Nuffield Health as an external provider) to show NHS HCPs a video (or equivalent) the rigorous training that Nuffield Health exercise professionals go through.	Yes, meets APEASE criteria.	A video will be included in the training package around the training exercise professionals will undergo to be employed by Nuffield health. Subsequently, information will be presented regarding the training that the exercise professionals will undergo to be part of STAMINA.

		To cover other topics such as diet, but this would be focused specifically on whose role it is to discuss diet	Yes, meets APEASE criteria.	The topic of diet will not be covered in the training package; however, HCPs will be provided with patient materials that include diet and lifestyle.
Assessment of training	Having some form of assessment throughout the training was suggested.	In face to face training, provide a scenario and staff members work in small groups to solve problems (e.g. what they would do in that instance). This should be interactive and generate discussions. Each group should have a different, contrasting scenario and then feedback to the entire group. This can be made more challenging by adding further problems to the scenario once solved. These can then be assessed.	Yes, meets APEASE criteria.	Role play scenarios and group tasks will be used within the training package. However, these will not be assessed due to practicalities, but feedback will be given.
Who should the training be aimed at?	There were different opinions on who the training should be offered	Level one training should be offered to all the secondary care clinical team.	Yes, meets APEASE criteria.	Level one training will be offered to all the clinical team who initiate ADT and support men with prostate cancer on ADT.

	to and whether it should be offered in the community as well as secondary care.	GPs and community staff may see the patients in the community and therefore they may need training.	No Does not meet APEASE criteria as it is not practical.	Due to the future trial being a cluster randomised trial, training the community staff may increase the risk of contamination and this needs to be considered. Our investigative work on the pathway states that most men with prostate cancer at trust one and two are followed up in secondary care by their keyworker, so targeting secondary care HCPs only is appropriate.
Releasing HCPs	Releasing HCPs to attend the training session was suggested to be potentially problematic due to NHS pressures. Different strategies to ensure HCPs will be likely to attend were suggested.	Six weeks is the very minimum notice period for staff release. Period of notice should ideally be eight weeks minimum, but twelve weeks is more suitable.	Yes, meets APEASE criteria.	12-8 weeks' notice will be given to HCPs to attend the training.
		It is crucial to get line managers on board with the STAMINA programme. They are the ones responsible for releasing staff (e.g. clinical lead, director, operational lead ward manager and matron).	Yes, meets APEASE criteria.	Clinical leads, directors and operations managers will be targeted as part of setting up each NHS site to ensure support is approved by all. It will also be advised for the clinical

				leads or principle investigators of each site to encourage HCPs to attend the training.
Repetition of the sessions	How many training sessions should be offered per trust was discussed and what approaches may be helpful to ensure everyone receives the necessary training.	Only offering two dates of training per large trust/teams may not be enough. More dates may need to be offered to ensure the relevant team is training	No Does not meet APEASE criteria as it is not practical.	Only two dates will be offered per NHS site due to resources and practicalities.
		The dates offered should be on different days/ times (be flexible) as a lot of staff will work part time and therefore work on different days	Yes, meets APEASE criteria.	Flexible dates and times will be offered to the HCPs that are approved by the department and acceptable to the HCPs.
		Using a train, the trainers approach may be beneficial to help with difficulties of releasing staff e.g. only the lead nurse attends then trains others within the team	No Does not meet APEASE criteria as it is not practical or likely to be effective.	Whilst train the trainers approach has it benefits, to maintain fidelity this approach will not be adopted at this stage.
Methods to increase NHS trust in Nuffield Health.	Trust between the HCPs and exercise professionals has been highlighted as barrier and there were suggestions on how to improve trust.	HCPs and exercise professionals to meet before a referral pathway is in place.	Yes, meets APEASE criteria.	HCPs and Nuffield Health will meet prior to the referrals being made. This will occur at the site initiation visit.
		To endorse and highlight the quality of Nuffield Health as a unique operator of exercise/health facilities to NHS teams to help build trust in the new pathway.	Yes, meets APEASE criteria.	To ensure that the HCPs have trust within the exercise professionals, information will be presented throughout the

				training package on Nuffield health qualities, the experience of the exercise professionals and the training they undergo.
Any other practical barriers	Making training mandatory can 'annoy' HCPs as they are given a lot to do.		Yes, meets APEASE criteria.	Training will not be made mandatory but will be encouraged for HCPs to attend by their department.

7.5.3 Summary of results and version two of the training package

Following the feedback gained from steps one, two, three and four. Revisions were made to the training package. A summary of the feedback and potential changes are as follows:

1. **Content:** More patient case studies and task-based exercises were suggested. They suggested to include more information about Nuffield Health and the role of exercise professionals. Some HCPs wished for a representative from Nuffield Health and a patient to attend the training, but this was assessed as not being practical.
2. **Key roles:** Key roles/behaviours of the HCPs within the project should be highlighted from the outset and referred to throughout the training. The use of infographics will also be given to HCPs to have during clinics.
3. **HCPs to target:** There were mixed views around which HCPs should attend the training, it was decided the training will be offered to any HCP who sees men with advanced prostate cancer on ADT.
4. **Mode of delivery:** A face to face training package will be offered but it was suggested for future work that an online training package could be offered. Two dates per NHS site for training will be offered, delivered during working hours. Furthermore, a train the trainer approach was suggested, this will not be adopted due to not being practical and there were also concerns over maintaining fidelity of the intervention.
5. **Engagement:** There were concerns that the whole clinical team may not engage due to other priorities. Potential solutions are to offer at least 8-12 weeks' notice for the clinical team. Ensure senior managers and clinicians are bought into the concept from the start of the project and willing to support the clinical team attendance. Training will not be made mandatory, as we would be unable to achieve this operationally with the hospitals, but all HCPs will be encouraged to attend.
6. **Duration:** There were concerns a half-day training package was possibly too long, but it was also argued that anything shorter might lead to a lack of engagement and perceived lack of importance. The

half-day training package will continue to be split into level one aimed at the whole clinical team and level two accessible for the whole clinical team but targeted at key workers.

7. **Behaviour change techniques:** The use of *1.2 prompts and cues* in clinics to support HCPs and remind them was suggested. Also, to use *1.4 action planning* as a team was suggested. These BCTs are already included in the intervention, but the mode of delivery will be altered to suit the preferences of the HCPs.
8. **Support:** Additional intervention support was included following the half-day training of further *1.2 prompts and cues*, *2.7 feedback on recruitment behaviour*, and behavioural checklists that the HCPs could follow when meeting with patients. Whilst these BCTs are already included in the intervention, the mode of delivery will be altered to suit the preferences of the HCPs. Additionally, changes to module six, to include more information about behavioural support at follow-up was included and therefore this is to be repeated between 8-12 weeks. Specifically, including *8.1 Behavioural practice/rehearsal* and *2.2 feedback on behaviour*. This ongoing support, whilst is resource-intensive, is likely to be necessary, however, whether this is practical in the future needs to be considered at this point.

Optimised and refined versions of the training package (version two) in presented in Table 7.4. Additions to the training package are highlighted in **bold** and aspects that have been removed as written in **red** and in *italics*. The updated TIDieR checklist is reported in Table 7.5.

Training slides and materials were produced as part of the intervention. Additionally, two manuals were produced as part of the intervention, one for the facilitators and one for the HCPs to refer to following the training for further support.

Table 7.4: Version two of the HCP training package including BCTs and Mode of delivery

Modules	BCTs (additions are in bold)	Mode of delivery (removals are in <i>italics</i> and red)
1. Overview of the project	1.2 – Problem solving 3.1 – Social support (Unspecified) 5.1 – Information about health consequences 5.3 – Information about social and environmental consequences 5.6 – Information about emotional consequences 7.1 – Prompts/cues 9.1 – Credible source 12.5 – Adding objects to the environment	<i>HCP training package:</i> <ul style="list-style-type: none"> • Introductions. • Use of an importance ruler to assess HCP perceptions on exercise. • Information presented about the project, NICE recommendations, patient experiences with exercise and proposed new HCP roles. • Information presented as patient vignettes, videos, written text, prompts for clinic use and links to further reading. • Problem solving task in relation to new HCP roles such as providing exercise referrals. • <i>Video of professor of exercise oncology talking about the importance of exercise</i> • <i>Discussion about the common barriers reported from HCPs around not discussing exercise.</i>
2. Prostate cancer and exercise – the evidence	3.1 - Social support (Unspecified) 5.1 – Information about health consequences	<i>HCP training package:</i> <ul style="list-style-type: none"> • Information presented about the evidence base for exercise in prostate cancer.

	<p>5.3 – Information about social and environmental consequences</p> <p>5.6 – Information about emotional consequences</p> <p>6.3 – Information about others’ approval</p> <p>9.1 – Credible source</p> <p>11.2 – Reduce negative emotions</p>	<ul style="list-style-type: none"> • Information presented via videos, written text, patient case studies, handouts of scientific papers and links to further reading. • Case study task in relation to reducing assumptions about patient’s suitability for exercise.
<p>3. Discussing exercise as a healthcare professional</p>	<p>1.3– Problem solving</p> <p>1.4 – Action planning</p> <p>3.1 – Social support (unspecified)</p> <p>4.1 – Instruction on how to perform the behaviour</p> <p>5.1 – Information about health consequences</p> <p>5.3 – Information about social and environmental consequences</p> <p>5.6 – Information about emotional consequences</p> <p>6.1 – Demonstration of behaviour</p> <p>6.3 – Information about others’ approval</p> <p>7.1 – Prompts/cues</p> <p>8.3 – Habit formation</p> <p>9.1 – Credible source</p> <p>9.2 – Pros and cons</p> <p>9.3 – Comparative imagining of future outcomes</p> <p>12.5 – Adding objects to the environment</p> <p>15.1 – Verbal persuasion about capability</p> <p>15.3 – Focus on past success</p>	<ul style="list-style-type: none"> • Discussion around pros and cons of discussing lifestyle factors with this patient group and problem-solving task. • Information on the teachable moment, patient views of HCPs discussing lifestyle, on new roles for HCPs and procedures. • Demonstrations of discussions of exercise with patients. • Information presented as patient vignettes, videos, written text, prompts for clinic use and links to further reading. • Action planning task as a team.

4. Skills for supporting people with exercise	2.2 – Feedback on behaviour 3.1 – Social support (unspecified) 4.1 – Instruction on how to perform the behaviour 5.1 – Information about health consequences 5.3 – Information about social and environmental consequences 5.6 – Information about emotional consequences 6.1 – Demonstration of behaviour 8.1 – Behavioural practice/rehearsal 12.5 – Adding objects to the environment 15.1 – Verbal persuasion about capability 15.3 – Focus on past success	<ul style="list-style-type: none"> • Information about behaviour change and behaviour change theory, introduction to techniques to support behaviour change in this patient group and demonstration of these. • Overview of all the specific BCTs, providing instruction and demonstrations how to deliver them. • Opportunity for role play and feedback tasks in relation to techniques. • Reflections on previous experiences. • Information presented as patient vignettes, diagrams demonstrations, written text, prompts for clinic use and links to further reading.
5. The role of exercise professionals	3.1 – Social support (unspecified) 5.1 – Information about health consequences 5.3 – Information about social and environmental consequences 5.6 – Information about emotional consequences 6.3 – Information about other approval 9.1 – Credible source	<ul style="list-style-type: none"> • Discussion of opinions and experience of exercise referral schemes. • Information about Nuffield Health, services they provide and their exercise professionals. • Information about the exercise prescription for patients and their views. • Information presented via diagrams, videos, and written text.
6. The exercise referral pathway and	1.2 – Problem solving 2.2 – Feedback on behaviour 3.1 – Social support (unspecified)	<ul style="list-style-type: none"> • Overview of the processes for referrals and communication.

communication pathway	4.1 – Instruction on how to perform the behaviour 5.1 – Information about health consequences 5.3 – Information about social and environmental consequences 5.6 – Information about emotional consequences 7.1 – Prompts/cues 8.1 – Behavioural practice/rehearsal 8.3 – Habit formation	<ul style="list-style-type: none"> • Information provided via demonstrations, written text and prompts for clinic use. • Discussion around providing support at follow-up with information provided by written text and patient vignettes. • Opportunity for role play and feedback tasks in relation to techniques.
Intervention support outside of the training	2.2 – Feedback on behaviour 2.3 – Self-monitoring of behaviour 2.7 – Feedback on outcome(s) of behaviour 8.3 – Habit formation 7.1 – Prompts/cues 12.5 – Adding objects to the environment	<ul style="list-style-type: none"> • The use of prompts within clinics, feedback on behaviour such as referrals via email or telephone and the use of a screening log to self-monitor behaviour

Table 7.5: Version two of the intervention reported in line with TIDieR framework (Hoffmann et al., 2014)

Name	HCP training package
Why	HCPs do not routinely discuss exercise with men with prostate cancer on ADT and report several barriers as to why. Therefore, a training package is required to support HCPs in recommending exercise, providing behavioural support and exercise in line with recent NICE recommendations NG131 1.4.19. See section 5.1, page 179, for more detailed rationale.
What	<p>Module one: An overview of the project</p> <p>This module aims to introduce the facilitators to the clinical team, give an overview of the training package and an overview of the project. NICE NG131 1.4.19 recommendations will be introduced here.</p> <p>Module two: Prostate cancer and exercise – the evidence base</p> <p>This module will give an overview of the benefits of exercise for men with prostate cancer on Androgen Deprivation therapy.</p> <p>Module three: Discussion exercise as a healthcare professional</p> <p>This module will identify clinical roles within the team to aid the implementation of the NICE recommendations. How to discuss exercise and lifestyle with this patient group will also be introduced. Common assumptions made by HCPs about patients' capabilities to exercise will aimed to addressed.</p> <p>Module four: Skills to supporting people with exercise</p> <p>This module will provide HCPs with the appropriate skills in terms of behaviour change techniques to use to support this patient group with exercise. Role-play and group tasks will be included within this module.</p> <p>Module five: The role of exercise professionals</p>

	<p>This module will give an overview of the roles and experience of exercise professionals working with this patient group. It will aim to overcome some of the apprehensions HCPs have about working with exercise professionals.</p> <p>Module six: The exercise referral pathway and communication pathway</p> <p>This module will provide HCPs with the information of how to make referrals for exercise, what information to hand out to patients and how secure communication will take place with Nuffield health and the NHS. Further support is provided in role-play exercises.</p> <p>Support outside of the training</p> <p>The use of prompts within clinics, feedback on behaviour such as referrals via email or telephone and the use of a screening log to self-monitor behaviour.</p> <p>HCP manual will also be given out at the training to support HCPs.</p>
Who provided	Researcher/health psychologist
How	Face to face in small groups
Where	On site at the hospital or at a university building
When and how much?	Half day training with follow-up between 8-12 weeks
Tailoring	HCPs receive either level one or both level one and two of the training packages depending upon their role.
Modifications	Face to face, to be delivered on NHS site or locally to NHS site.
How well	Process measures, acceptability and fidelity will be measured.

7.6 Discussion

Key stakeholders were involved in the process of refining and optimising the in-development HCP training package. Key themes raised by stakeholders to be considered for intervention development from this process were identified. These were generally related to content, duration, and mode of delivery. The feedback also highlighted potential challenges to the delivery of the training package and ensuring the engagement of the relevant HCPs. The engagement of key stakeholders in the intervention development process is a strength of this research and is advocated within the development of complex interventions (Janols & Lindgren, 2017).

The intervention development team were multi-disciplinary and were involved in the decision-making process for the refinement of the intervention, this was valuable for the development of the intervention. Using the APEASE criteria (see Table 2.5) was a valuable tool for making decisions on changes to the intervention. Expertise was required to make these decisions and is important as the decisions made need to be based on evidence, if possible. Making these subjective judgements seems somewhat odd within this systematic and scientific framework, which other intervention developers have experienced (Sinnott et al., 2015). However, on reflection, it would have been beneficial to have the clinical teams and stakeholders involved in these decision-making processes and using APEASE alongside the intervention development team. We could have benefitted from their perspectives on what they thought was acceptable, for example, and considered this alongside the evidence.

Refining the intervention using stakeholder involvement, is something that is rarely reported in interventions that have used the MRC and or BCW guidance. However, it is something that is advised by O’Cathain and colleagues (2019) in the recent intervention development guidance. Often decisions were easily made amongst the team, for example the use of ‘real-world’ applications such as patient case studies and using interactive tasks within HCP training was suggested and to include a varied range of BCTs such as prompts and cues. This was a change that could be easily implemented. Other suggestions and decisions were more difficult such as delivering the training online or offering an online approach as well as face to face. This involved gaining an understanding of the benefits of online training vs face to face training, so this was a time-

consuming decision to make. It was identified that whilst online training can offer a flexible and potentially a more cost-effective approach to learning, self-discipline and time is needed to ensure the training is completed in the first instance. This decision was based upon several factors; it was anticipated that it would be difficult to engage in an interactive training programme online for half a day, therefore a face to face training programme was suggested. A half a day intervention was selected due to the content within the intervention requiring a half day delivery. Additionally, to ensure that the training package was not too time-consuming for HCPs to attend and resource intensive for future implementation. Whilst, some research suggests little difference of effectiveness of imparting behaviour skills between online training and face to face training (Sinclair, Kable, Levett-Jones, & Booth, 2016). An integrative literature review on online training to support HCPs to provide self-management strategies in patients highlighted that few online learning approaches were interactive or allowed time for reflection or used 'real-world' examples, which is problematic when learning behavioural support skills (Lawn, Zhi, & Morello, 2017). As the training includes skills-training, delivering this face to face was suggested to be most suitable. Finally, using a face to face training model, the management team can be approached to allow for the dedicated time for the clinical team to attend training. An online interactive training package for HCPs to improve self-management in patients was only accessed by half of the intervention group due to time and organisational constraints (Sassen et al., 2014). Additionally, as discussed above, the want for task-based exercises from HCPs would not be achievable using traditional online training. In this instance, a face to face approach was adopted, but it was suggested future work should explore the concept of developing online training as a blended learning approach, with key knowledge elements being taught ahead of time online.

There is a lack of clarity of how mode of delivery is defined (Dombrowski et al., 2016). Therefore, the mode of delivery of the behavioural content is often neglected but has been suggested to be an active ingredient in interventions, a behavioural intervention could be delivered in many ways, impacting upon effectiveness (Dombrowski et al., 2016). The mode of delivery of the intervention was decided between the intervention development team drawing on expertise and experience, however, the BCW guide lacks clear guidance on

how to make decisions on the intervention components and how to then document this. There were sometimes different perspectives of how the behavioural content should be delivered amongst the intervention development team and expertise of how to deliver such behavioural content successfully was required. Additionally, there is a lack of reporting mode of delivery of BCTs, which could influence effectiveness. For example the 'spirit' of motivational interviewing which relates to the interpersonal style of the person delivering the motivational interviewing and can include empathy and rolling with resistance (Rollnick, Butler, Kinnnersley, Gregory, & Mash, 2010), may be often used when delivering BCTs within an intervention (Hagger & Hardcastle, 2014). Some motivational interviewing techniques are documented in BCT taxonomies (Michie et al., 2013), the interpersonal style that may aid behaviour change aren't included (Hagger & Hardcastle, 2014). Ongoing research as part of the human behaviour change project aims to bridge this gap, with the development of a behaviour change mode of delivery ontology (Michie et al., 2017). This project aims to provide a clear, usable, and reliable classification system to specify the mode of delivery of behaviour change interventions, including single BCTs. This ongoing work is necessary due to the ambiguity and underreporting of behaviour change interventions mode of delivery. Furthermore, during the refinement stage of the intervention, a tool developed by (Pearson, Byrne-Davis, Bull, & Hart, 2018) to provide practice-related examples of 43 BCTs was published. This was in the form of cards for the 43 BCTs, named 'cards for change'. They provide trainers or educators who wish to use BCTs within their training practical examples of how to deliver the BCTs. They also include key information whether the BCTs would be delivered well online or face to face. Following the publication of these, these were then incorporated into the training to help with specifying the mode of delivery. These cards were a helpful resource when selecting the mode of delivery for the interventions' behavioural content.

Whilst engaging stakeholders was beneficial, the process of involving stakeholders within the intervention development process was challenging. HCPs needed a minimum of 6-8 weeks' notice to attend a rehearsal delivery or stakeholder workshop and this needed to be approved by the operational team. Clinical duties often needed to be rescheduled to allow for clinical teams to

attend, which is problematic. Additionally, in cancer care, HCPs are often approached about numerous studies, new evidence-based recommendations and new technologies (Agbassi, Messersmith, McNair, & Brouwers, 2014; Dizon et al., 2016), therefore it is likely there are competing demands. Research has also highlighted when change is implemented in new models of care from the top-down, it can cause and be a consequence of a poor workforce culture (Bull et al., 2018). It was considered important to engage HCPs in the recruitment process by attending routine meetings, getting to know the clinical teams, and presenting our work to them. This process helped us to understand the future problems with recruitment and delivering training in healthcare. It was beneficial for engaging HCPs within the intervention development process and should be considered vital when carrying out similar research.

7.6.1 Strengths

Involving stakeholders in intervention refinement is advocating by recent guidance (O'Cathain et al., 2019), but is not clearly outlined within the BCW guidance. Therefore, seeking additional guidance to include stakeholders in the development of the intervention, is a strength of this research. As this intervention is being developed alongside a patient intervention and exercise professional intervention, it is beneficial to include other stakeholders within the refinement process such as patients and not limit this to just HCPs.

7.6.2 Limitations

Due to time and resource issues within the trust, the rehearsal deliveries had to be delivered over four different dates with different members of the clinical team. Ideally, the training would have been delivered to all relevant HCPs at one-time point. These issues need to be addressed moving forward into the delivery of the refined training package, by engagement the management teams and allowing for at least 6-8 weeks' notice.

To capture feedback in a group context, especially when working with clinical teams is useful. However, within this study, the focus group participants were already a part of an already formed group, in terms of their clinical team. While this can encourage people to be more open and share their views, it may also emphasise a power-dynamic, where more junior HCPs may not feel they can share their views in the presence of a senior colleague. However,

understanding this dynamic from these groups is essential in the intervention development process.

The topic guides used to collect the interview and focus group data were developed as part of the previous grant application, (see the wider context of this thesis, page 21) with limited scope for change. Whilst using the Kirkpatrick (1977) training evaluation framework and the NPT (Murray et al., 2010) had their specific advantages, using the 'capability', 'opportunity', 'motivation' = behaviour (COM-B) model or for even further detail the theoretical domains framework (TDF) may have been more appropriate for several reasons. Firstly, using the COM-B model (Michie, van Stralen, et al., 2011) or TDF (Cane et al., 2012) firstly fits within the theoretical frameworks used within this study, therefore, this fits with the rationale of why these frameworks were selected initially, as discussed in more detail in Chapter two. Secondly, the COM-B model offers a comprehensive model to understanding behaviour in any context (Michie, van Stralen, et al., 2011) and the TDF offers an even more in-depth understanding of behaviour, as a framework (Cane et al., 2012). Whilst the NPT offers a framework for understanding and evaluating the processes by which complex interventions are embedded (Murray et al., 2010) and organisational factors about implementation are important to consider. The COM-B model/TDF would also aim to capture these issues and additionally. The Kirkpatrick (1977) training evaluation framework clarifies individuals' views on the training package, using the COM-B model/TDF alongside this would have been advantageous. As whilst the intervention needs to be acceptable and user friendly, the main aim is to target and change behavioural determinants, which hopefully would lead to behaviour change. On reflection, not including the COM-B model or TDF during this refinement phase is a limitation to this work.

7.7 Conclusion

Complex intervention development is not a linear process and often continuous refinement is necessary. Involving stakeholders such as patients and HCPs in this process is advantageous. Stakeholders can help identify potential challenges with the intervention and make further suggestions on how to optimise the intervention. Involving stakeholders will hopefully be beneficial in gaining 'buy-in' from clinical teams. Changes were made to the training package to reflect the feedback including adding more patient case studies and providing

a clearer understanding of what behaviours were being targeted for change. These were mainly to the content and mode of delivery. Further considerations were given to the processes in which to engage HCPs within the training.

7.8 Chapter summary

The first version of the developed intervention was delivered to one clinical team, to gain feedback and offer suggestions for refinement. This feedback was captured in focus groups and interviews. Additionally, a stakeholder workshop was carried out to capture further feedback on the intervention. The intervention was appropriately refined and optimised. The next chapter discusses how the developed training package was delivered and evaluated at two NHS sites.

8) Chapter eight: Delivery and evaluation of the healthcare professional training package in a real-world setting

8.1 Background

A complex intervention has been developed to support healthcare professionals (HCPs) in providing exercise recommendation, referral, and exercise support to men with prostate cancer on Androgen Deprivation Therapy (ADT) in line with NG131 1.4.19 recommendations. Following the refinement and optimisation of the HCP training package, this study will aim to deliver the training package in a real-world setting in two sites and evaluate the intervention.

The primary outcome of this research is to understand if the intervention produced change in the seven target HCP behaviours (see Table 5.2). Whilst this is a preliminary evaluation and effectiveness of the training package on HCP behaviour cannot be established, it is an essential step for intervention development (Craig et al., 2008). It is also important to understand effects on the HCP behavioural determinants. For example, whether the intervention improved self-efficacy. Without assessing behavioural determinants alongside behavioural outcomes, we cannot understand how the proposed mechanisms of change work or do not work, which is essential for further developing and refining the intervention (Chisholm et al., 2020).

Assessment of the fidelity of the delivery of the target behaviours and the quality of delivery is recommended and should be an integral part of intervention development and implementation (Borrelli, 2011). Treatment fidelity is the *"ongoing assessment, monitoring and enhancement of the reliability and internal validity of a study"* (Borrelli, 2011, p. 52), see Chapter two. In 2004, the National Behaviour Change Consortium (NIH-BCC) developed a fidelity framework that incorporated five areas: design of the study, training providers, delivery of treatment, receipt of treatment and enactment of treatment (Bellg et al., 2004), see Table 2.6 for definitions. As well as assessing the delivery of intended intervention content, assessing communication skills is useful as delivery quality can influence the effectiveness of an intervention (Bellg et al., 2004; Hagger & Hardcastle, 2014). For example, the 'spirit' of motivational interviewing which relates to the interpersonal style of the person delivering the

motivational interviewing and can include empathy and rolling with resistance (Rollnick et al., 2010), may be used when delivering BCTs within an intervention and can have a positive impact on effectiveness (Hagger & Hardcastle, 2014).

Physical activity interventions, delivered by HCPs often lack fidelity assessments (Williams et al., 2020). To understand whether these HCP behaviours have been adopted by clinical teams, we need to have detailed information and understanding of how interventions were delivered as planned and to what level of quality, as it is hard to fully understand whether the intervention is effective and how to revise the intervention, if this information is not captured (Walton et al., 2019).

The above measures and concepts are important in understanding if an intervention is effective and if so why. However, if an intervention is not acceptable to the intervention user, they might not engage with it despite it being successful or not. Therefore, acceptability is an important concept to consider in intervention design, delivery and evaluation and is advocated by MRC (Craig et al., 2008). Sekhon et al., (2017) proposes acceptability is made up of seven constructs; affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness, and self-efficacy, see Chapter two and Table 2.7.

8.1.1 Wider context of the study

This thesis sits within a wider project STAMINA, see page 21. Interventions for exercise professionals from Nuffield Health (NH) and for men with prostate cancer on ADT have been developed separately. Due to the complexities of the interventions, the intervention needed to be delivered as a whole, as a STAMINA feasibility study. This was part of the intervention development process for the wider project STAMINA. However, for the purposes of this thesis this chapter specifically focuses upon the delivery of the HCP training package. HCP behaviour is then measured as an outcome of this intervention alongside other outcomes such as acceptability. Whilst the findings from this thesis will help to refine the future intervention and research processes for STAMINA and

will be reported on, it is not the primary concern of this programme of doctoral research.

The aims of this study were 1) To deliver training package to two NHS clinical teams at two NHS sites, 2) To carry out an evaluation of the intervention.

8.2 Objectives

1. To deliver the training package to two prostate cancer clinical teams from two NHS secondary care sites.
2. To assess HCP behavioural outcomes following the training programme.
3. To assess the fidelity of HCP enactment of treatment skills delivered to patients.
4. To assess HCP behavioural determinants pre, post and at follow up of the training programme.
5. To assess the acceptability of the intervention.
6. To assess the necessary changes to the intervention and research processes for the future trial.

8.3 Methods

8.3.1 Team

The core intervention development team was multi-disciplinary and included: Myself (RT), LS and MA (Health Psychologists), DR (Consultant Urologist), LB (Professor of Cancer Research), SR (Research Fellow), DG (Consultant nurse), ST (Professor of Primary care and public health), ES (Qualitative expert) and JD (research assistant).

8.3.2 Study design

Delivery of training package

The HCP training package was delivered to two NHS clinical teams at two NHS hospitals.

Evaluation

A non-randomised observational study was used to evaluate the intervention. Multiple methods were used including behavioural assessments, questionnaires, and interviews, these are discussed in further detail in section 8.3.7.

8.3.3 Intervention

The training package developed for HCPs was based on evidence and theory. The intervention was a half-day, interactive and skills-based training package, with six varied modules with follow up between 8-12 weeks as reported in Table 7.4 was delivered to HCPs. The TIDieR framework for the training package is found in Table 7.5. Two manuals were produced as part of the intervention, one for the facilitators and one for the HCPs to refer to following the training for further support.

The training aimed to teach HCPs to deliver seven target behaviours, see Table 5.2, including exercise recommendation and discussing barriers and facilitators to exercise. HCPs were taught to use eight BCTs to aid any discussions around exercise and use where applicable, see Table 8.1. Further detail of these BCTs is provided in Table 6.5, as specified in line with BCTTv1 taxonomy (Michie et al., 2013). Training providers were mentored by experienced health psychologist and all had previous experience of providing training and group facilitation.

Table 8.1: BCTs taught to HCPs in training package

Behaviour Change Technique
1.2 Problem solving
3.1 Social Support (unspecified)
5.1 Information about health consequences
5.3 Information about social and environmental consequences
5.6 Information about emotional consequences
6.3 Information about others' approval
9.2 Pros and Cons
15.1 Verbal persuasion about capability

8.3.4 Sampling

Purposive sampling was used in this study, an approach in which participants are selected as they have specific characteristics or features that will allow for appropriate exploration of a specific phenomenon (Bryman, 2012). The study aimed to identify and recruit HCPs working within the two NHS sites specifically within the advanced prostate cancer care pathway. There are typically six varied professionals involved within the care pathway: Consultant urologist, clinical nurse specialists (CNS), medical oncologists, clinical oncologists, General Practitioners (GPs), staff nurses and practice nurses. However, in this thesis due to pragmatic reasons, HCPs were only be sampled from secondary care due to practicalities and risk of contamination for the future trial, so GPs and practice nurses were not included.

The following inclusion and exclusion criteria were applied:

Inclusion criteria

- Involved in diagnosis and/or treatment and or follow-up of men with prostate cancer on ADT.
- Able and willing to receive training.
- Based at a site with enough men started on long-term ADT to achieve recruitment target within timelines.

Exclusion criteria

- No active involvement in the management of men with prostate cancer on long term ADT.
- Not based at a site with enough men started on long-term ADT to achieve recruitment target within timelines.
- Inability to read or speak English.

8.3.5 Recruitment

The lead researcher (RT) attended several routine urology meetings at both hospitals to raise the profile of the study and approached potential HCPs to take part between March 2019 and April 2019. This involved providing an overview of the project and the importance of training the prostate cancer clinical team. Participants who were potentially interested were sent a participant information sheet via email (see Appendix R). The operations and management team, as well as the potential participants were informed that HCPs needed to attend half-day training with follow up at 12 weeks. Potential suitable dates were provided for the HCP training to take place. Dates for the HCP training were organised with at least eight to twelve weeks of notice.

8.3.6 Ethics and data storage

Ethical review was granted on 18th February 2019 by North West - Liverpool East Research Ethics Committee for this study. REC reference: ID: 253778. All data is securely stored on a secure drive at Sheffield Teaching Hospitals (STH), with only the research team having access. All hard copies of transcripts are stored in a site file securely on STH premises. Trial registration number: ISRCTN15691664.

Several amendments were submitted throughout the course of the study as follows:

1. Non-substantial amendment 1 accepted 7th May 2019, to add a questionnaire based on the Theoretical Domains Framework (TDF) to be administered pre, post and at 12 weeks following training.

2. Non-substantial amendment 2 accepted 29th May 2019, to change the logos on the participant facing materials.
3. Substantial amendment 1 to the protocol REC reference: 19/NW/0025, accepted 16th August 2019, to make audio-recordings of consultations optional.

8.3.7 Outcomes and measures

An overview of the data collected to evaluate this intervention are presented in Table 8.2.

Table 8.2: Overview of evaluation methods

Research method or data source	Data type	Participants	Data collected	Purpose of the information	Timing of data collected
19 item questionnaires based on the TDF domains	Quantitative	Healthcare professionals who received the training.	To assess changes in HCPs beliefs (if any)	Assess behavioural determinants	Pre training, post training and at 6-8 weeks follow up.
Audio-recordings of consultations	Qualitative	Healthcare professionals who received the training and patients with prostate cancer on ADT seen as part of usual care clinics.	Assessment of whether HCPs recommended exercise to patients (Target behaviour 1) and explored barriers to exercise (Target behaviour 2)	Assessment of behaviour and Fidelity assessment (enactment of treatment)	In all consultations following training until 10 patients per site had been referred for exercise (as part of the wider study).
Screening logs	Quantitative	Healthcare professionals who received the training.	Number of suitable patients approached and recommended exercise, assessed via screening logs (Target behaviours 1 and 5)	Assessment of behaviour	From training until 10 patients per site had been referred for exercise (as part of the wider study).
Number of referrals for exercise	Quantitative	Healthcare professionals who received the training.	Number of patients referred (Target behaviour 3)	Assessment of behaviour	From training until 10 patients per site had been referred for exercise (as part of the wider study).

Patient self-report telephone conversation	Quantitative	Patients who have been referred for exercise by a trained healthcare professional	Number of patients who received an information pack and materials (Target behaviour 4)	Assessment of behaviour	From training until 10 patients per site had been referred for exercise (as part of the wider study).
Completed progress report	Quantitative	Healthcare professionals who received the training.	Number of HCPs who discussed the progress report with patients and completed it (Targets behaviour 6 & 7)	Assessment of behaviour	Until the end of the intervention follow-up.
Evaluation form	Quantitative and qualitative	Healthcare professionals who received the training.	To understand if the training could be improved in anyway and whether the format, delivery and content were suitable.	Acceptability	Directly following training.
Semi-structured interviews	Qualitative	Healthcare professionals who received the training.	To understand HCP views on delivering the target behaviours to patients and understand if the training was acceptable.	Acceptability	8-12 weeks following training.
Field notes	Qualitative	Healthcare professionals who received the training.	To highlight any key issues during the intervention period.	Acceptability	Until the end of the intervention follow-up.

8.3.7.1 Behavioural outcomes and fidelity assessments

The effectiveness of the intervention on the behaviour change of the HCPs in relation to the seven target behaviours (see Table 5.2) was evaluated using several assessments as documented in Table 8.2.

These methods are now discussed in turn, in relation to each target behaviour:

1. Recommend exercise training at any point within the pathway and 2. Discuss barriers and facilitators around exercise training, provide support using BCTs

HCPs recorded all usual care consultations with patients who were recognised as eligible for exercise. This was predominantly aimed at key workers as they are mainly responsible for this patients' groups care, see Chapter five. All HCPs were provided with Dictaphones from the research team and a standard operating procedure with instructions, which were stored securely on site.

Fidelity of enactment of treatment skills was assessed to understand the if the intervention delivered to patients by HCPs was delivered as intended, specifically in relation to target behaviours 1 and 2. A fidelity checklist was developed to analyse the audio-recordings captured in clinics informed by Borrelli (2011) and Borrelli et al., (2005), see Appendix V. The fidelity checklist reviewed several different aspects as follows:

The checklist coded whether target behaviours one and two had been carried out on a scale of 0-2, (0 = No, 1 = Partially, 2 = Yes). The quality of the delivery of these behaviours was then assessed on a scale of 0-2. A single example of the checklist in relation to target behaviour one is reported in Table 8.3.

As the training package aimed to equip HCPs to use a varied set of BCTs (N = 8, see Table 8.1), if required to help support patients with exercise. The checklist coded whether these BCTs had been delivered, whether the BCT was applicable and the quality of BCTs delivered. A single example of the checklist in relation to problem solving is reported in Table 8.4.

Table 8.3: A single example of fidelity checklist assessing one behaviour and the quality of delivery of the behaviour

Behaviours	Adherence to the content (0 = No, 1 = Partially, 2 = Yes)	Quality of content	Quality of content
Recommend exercise training as treatment component		0 1 2	0 = Poor, little discussion 1 = Limited discussion around the benefits of exercise 2 = Good discussion on the different benefits of exercise as a treatment component

Table 8.4: A single example of fidelity checklist assessing delivery and quality of behaviour change techniques

Behaviour change techniques	Applicable or not? (Yes or No)	Adherence to the content (0 = No, 1 = Partially, 2 = Yes)	Quality of the content	Quality key
<i>1.2 Problem solving</i>		0 1 2	0 1 2	<p>0 =Poor, attempting to problem solve for the patient and or problems identified but no solutions made.</p> <p>1 = Prompting the patient to problem solve, but limited support for the patient to come up with solutions.</p> <p>2 = Good interaction, supporting the patient to identify barriers themselves and come up with solutions. Led by patient, reflected by healthcare professional</p>

3. Make referral for exercising training

HCPs were asked to make a referral for exercise training, this was done via email using NHS.net, containing the relevant information. The number of referrals from HCPs was then monitored and recorded in an excel spreadsheet through receipt of email. Information on the number referred was cross-checked with the screening log and recorded in an excel spreadsheet.

4. Provide patient with information pack and materials

HCPs were trained to provide the relevant information packs and materials to patients at the point of exercise referral. These information packs and materials were developed as part of the wider project and included information on the benefits of lifestyle change, what to expect at Nuffield Health (NH) and behavioural support. Once patients were referred, our research team contacted the patients to organise a baseline assessment. Patients were asked whether they had received the appropriate information packs and materials, and this was recorded on an excel spreadsheet.

5. Recognise whether a patient is suitable for exercise

HCPs were asked to complete the screening log for all patients who were on ADT and potentially suitable for exercise. Information was extracted from the screening log as to how many patients were suitable for exercise, how many were approached and how many were referred.

6. Read, interpret exercise progress report and 7. Provide feedback to the patient on the exercise progress report

HCPs received a progress report after the patient had completed 12 weeks of supervised exercise from the NH personal trainers. This progress report was to be discussed with the patients in usual follow-up care clinics, completed by the HCP and returned to NH and research team. Copies of the completed progress report were stored, and the number of progress reports sent to HCPs and received back from HCPs were monitored.

8.3.7.2 Behavioural determinants

Changes in HCP behavioural determinants were assessed as stated in Table 8.2. pre, post and 12-weeks following the training delivery.

Pre, post and 12-week follow-up questionnaire

This questionnaire was based on the TDF. At the time of the development of the TDF questionnaire, there was no identified validated TDF questionnaire known. Therefore, a TDF questionnaire was developed specifically for this intervention (see Appendix S). The TDF questionnaire was developed using the behaviour change wheel (BCW) guide (Michie, van Stralen, et al., 2011) and findings from our HCP interview study reported in Chapter five. *Knowledge, beliefs about consequences* and *social influences* domains required more than one question, due to HCPs commonly holding several different beliefs that fell within one domain. A questionnaire based on all the TDF domains to understand clinicians perspectives on exercise in patients with cancer (Nadler et al., 2019) and generic TDF questionnaire developed by (Huijg, Gebhardt, Crone, Dusseldorp, & Presseau, 2014) also guided the development of the questionnaire. A five-point Likert scale was used as the scoring for questionnaire as Likert scales assess attitude on a continuum scale such as from strongly disagree to strongly agree and produces ordinal data (Likert, 1932).

The TDF questionnaire included 19 items, across all domains and took around 10-15 minutes to complete. Examples of some of the items were as follows:

1. *Exercise in line with the NICE CG175 1.4.19 recommendations will be beneficial for men with advanced prostate cancer on ADT (Beliefs about consequences).*
2. *Fellow healthcare professionals expect that I should be discussing exercise in all consultations with men with advanced prostate cancer on ADT (Social influences).*

Participants were asked to complete the TDF questionnaire at three-time points; pre training, directly following the training and at six to eight weeks later. Questionnaires were administered in person pre and post training. At six to eight weeks, all HCPs who attended the training were sent a link to the questionnaire via Qualtrics (www.qualtrics.com) to complete. Each HCP had a unique identifier number, to ensure all questionnaires could be matched up to the correct individual. Data was collected from May 2019 until September 2019.

8.3.7.3 Acceptability of the intervention

Acceptability was measured via semi-structured interviews and an evaluation form following the training session.

Acceptability interviews

HCPs who had been trained and been involved in the overall intervention were approached and invited to take part in a qualitative interview.

The semi-structured topic guide was based on the acceptability framework developed by (Sekhon et al., 2017), see Appendix T.

Examples of the semi-structured interview questions are as follows:

- *Do you believe this sort of programme can be helpful to men in with prostate cancer?*
- *What did it involve in terms of time/ opportunity/ effort to train to, and then deliver, the programme?*

Interviews took place face to face at NHS sites, between 8-12 weeks post training by an independent researcher (ES) and research assistant (JD), to minimise bias. The interviews took place 6-10 weeks post training as it was important to ensure the HCPs had had time to see potentially eligible patients to discuss exercise etc. Interviews were conducted either face-to-face (7) or by telephone (28) and lasted between 20 and 50 minutes. They were audio-recorded using a Dictaphone.

Evaluation form

An evaluation form was developed to be administered directly following the training, (see Appendix U). The evaluation form was developed to understand if participants felt comfortable during training, felt they had adequate breaks and thought the training could be improved in any way.

The evaluation form comprised of 17 questions and took around 5-10 minutes to complete, this was administered directly following the training. The questions were open-ended questions and Likert scale questions. Examples of some of the questions were as follows:

Q1. What is the main overall message you gained from today's session?

Q6. How useful was module 3: The role of the clinical team

1	2	3	4	5
Not at all useful	A little useful	Somewhat useful	Mainly useful	Extremely useful

Q16. Were you happy with the venue for the session?

Field notes

As the lead researcher (RT) delivered the training, attended several routine meetings, met with the clinical teams at 12 weeks and was contacted by the clinical team via email and telephone for additional support. Notes were kept from these meetings and visits and were recorded in an intervention log using excel.

8.3.8 Data analysis

8.3.8.1 Behavioural outcomes and fidelity assessments

Process data to assess all behaviours was analysed by collecting numerical data and summarising where necessary.

The following steps were taken to analyse the audio-recordings assessing enactment of treatment using the fidelity checklist:

- 1) 5 initial audio-recordings were listened to by two independent researchers (RT and SR) and were coded using the fidelity checklist (Appendix V).

- 2) The transcripts were coded for the relevant behaviours, the quality of the delivery of these behaviours, BCTs (where applicable) and quality of BCTs, where applicable.
- 3) Independent researchers met to discuss the coding to understand whether there were discrepancies between coding. If discrepancies were present, the researchers would discuss reasons why, discrepancies generally highlighted issues with coding instructions, so these were amended to be more detailed.
- 4) The rest of the audio-recordings were coded by the same two independent researchers.
- 5) Results of the coding were inputted into excel and scores were generated into percentage scores for each item on the checklist. An overall average score for each independent researcher for the behaviours, quality of behaviours, BCTs delivered, quality of BCT delivery and an overall was then generated for each independent researcher, see Appendix V.

Levels of fidelity were reported in line with the literature (Borrelli et al., 2005; Toomey, Matthews, & Hurley, 2017) as: 80-100% adherence interpreted as 'high fidelity', 51%–79% as 'moderate' and 0%–50% as 'low' fidelity.

BCTs were advocated to be used when patients felt ambivalent or resistant to exercise, so they were not always applicable. This was managed by a discussion with LS, who has extensive experience in the coding of BCTs and appropriate use.

8.3.8.2 Behavioural determinants

Pre, post and 12-week follow-up questionnaire

Means and standard deviations were calculated for each TDF domain and plotted in a graph at pre, post and follow-up for both sites. Where there was more than one question per domain (*knowledge, beliefs about consequences and social influences*), these were analysed together, with a mean and standard deviation calculated for the overall domain.

No further statistical analysis was carried out due to the study not being significantly powered due to low number of participants.

Questions 4, 12, 16 were reversed, so for these questions, scores were reversed prior to analysis.

8.3.8.3 Acceptability of the intervention

Acceptability interviews

The interview audio-recordings were transcribed. Inductive thematic analysis was carried out to analyse the interview transcripts. NVivo software version 11. was used to aid analysis. Braun and Clarke (2006) outline key stages to thematic analysis; these were followed for this analysis. These five stages are outlined in chapter seven, section 7.4.11, page 249.

Evaluation form

Feedback from the evaluation forms was collated, qualitative data was summarised and averages from the Likert scale questions were generated.

Field notes

The field notes were summarised and written up into a word document into key themes.

8.3.8.4 Intervention and research process refinement

Once key themes from the above collected data were highlighted, these themes were considered in relation to the intervention. Key themes were presented to the intervention development team at a meeting (RT, SR, LS & ST), it was then considered if these a change to the intervention was necessary in relation to each key theme. This was judged using the APEASE criteria, see Table 2.5 for definitions as advocated by the BCW (Michie et al., 2014).

8.4 Results

8.4.1 Recruitment

23 HCPs (10 HCPs from trust one and 13 HCPs from trust two) were approached to take part in the intervention. These HCPs were identified as having a key role in the care of men with prostate cancer on ADT. 17 of these HCPs (8 from trust one and 9 from trust two) agreed to take part in the

intervention. Reasons for HCPs not taking part in the intervention were due to a lack of engagement (n=3) and a lack of time (n=3).

8.4.2 Participants

17 HCPs (8 from trust one and 9 from trust two) working in diverse roles representing different disciplines within the advanced prostate cancer care pathway received the intervention, see Table 8.5.

Table 8.5: Demographics of healthcare professionals who attended the training

Trust	Profession	Number attended
Trust one	Consultant Urologist	4
	Oncologist	1
	Clinical Nurse Specialist (Keyworker)	1
	Support worker	1
	Urological radiographer	1
Trust two	Consultant Urologist	4
	Clinical Nurse Specialist (Keyworker)	5
	Total	17

8.4.3 Behavioural outcomes and fidelity assessments

1. Recommend exercise training at any point within the pathway and 2. Discuss barriers and facilitators around exercise training, provide support using BCTs

38 patients were approached about exercise as documented in the screening log. 26 audio-recordings of initial consultations with 22 patients were completed at both trusts. 15 consultations with 13 patients were completed at trust one and 12 audio-recordings of 9 patients were completed at trust two. Unfortunately, audio-recordings from trust two were not completed correctly, as the audio-recordings provided a summary from the HCP of the consultation, not the actual conversation with the patient. Therefore, these could not be coded or used in the fidelity analysis. Fidelity scores are reported in Table 8.6.

Table 8.6: Fidelity scores for consultation audio-recordings

Initial consultation (n=15 consultations with 13 patients) from trust one	1st coder	2nd coder	Level of adherence
Behaviour score	83%	83%	Moderate fidelity
Quality of behaviour score	76%	75%	Moderate fidelity

3. Make referral for exercising training, 4. Provide patient with information pack and materials and 5. Recognise whether a patient is suitable for exercise

28 suitable patients were referred, all with the relevant patient materials.

6. Read, interpret exercise progress report and 7. Provide feedback to the patient on the exercise progress report

18 out of 28 patients completed 12-weeks exercise programme. Not all patients completed 12 weeks of exercise due to 1 withdrawing and 9 becoming ineligible due to changes in treatment. A progress report was generated for the ones who completed the 12-week exercise programme. Only 5 out of 18 patients were followed up in care with trained HCPs, therefore only 5 completed progress reports were sent back to the study team.

8.4.4 Behavioural determinants

17 TDF questionnaires were completed pre-training, 16 TDF questionnaires were completed post-training and 12 TDF questionnaires were completed at 6-8 weeks follow, see Figure 8.1 (chart) and Table 8.7 (key).

Improvements were made when comparing pre-training to post-training in all the TDF domains. These improvements continued at follow-up in intentions, goals and environmental context and resources, memory attention and decision

processes and emotion. However, the rest of the domains had sustained improvements from pre-training.

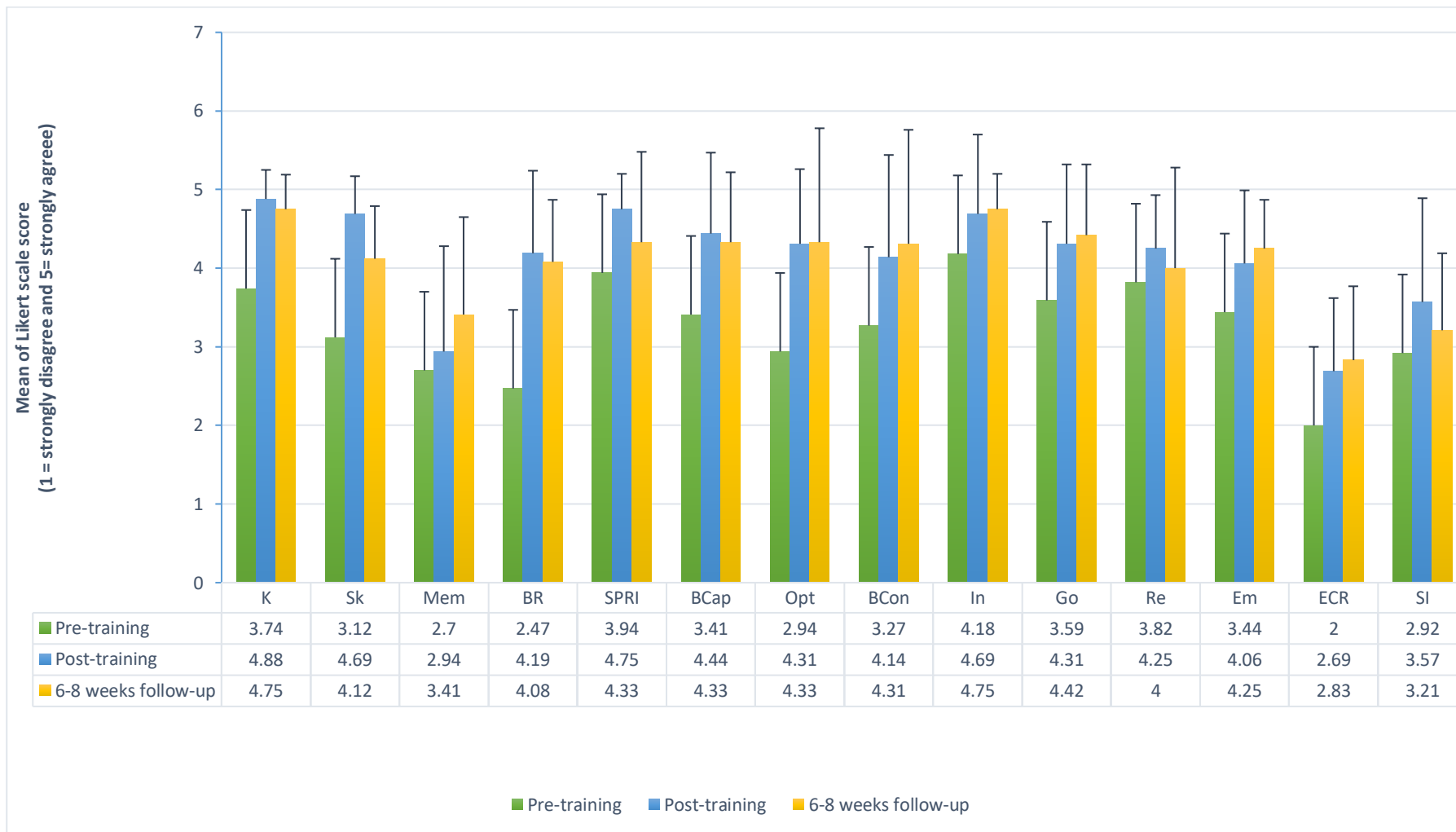


Figure 8.1: Pre, post and follow-up TDF questionnaire results

Table 8.7: Key for TDF questionnaire chart

Chart key	Full TDF domain name
K	Knowledge
Sk	Skills
Mem	Memory, Attention and Decision Processes
BR	Behavioural Regulation
SPRI	Social/ Professional Role and Identity
BCap	Beliefs about Capabilities
Opt	Optimism
BCon	Beliefs about Consequences
In	Intentions
Go	Goals
Re	Reinforcement
Em	Emotion
ECR	Environmental Context and Resources
SI	Social Influences

8.4.5 Acceptability of the intervention

Acceptability interviews

Five HCPs across both trusts took part in an interview following the delivery of the intervention, these were consultant urologists (3) and CNS's (2). Table 8.8 presents data gained from acceptability interviews. Table 8.7 also presents whether changes are necessary, which were judged using the APEASE criteria (see Table 2.5) to the intervention following the specific feedback and the impact this may have on the intervention.

Evaluation form

16 out of 17 HCPs completed an evaluation form following the delivery of the training. 69% of HCPs suggested the training should be a combination of face to face and online learning, with the rest suggesting a face to face training programme is preferred. 75% of the HCPs found the training extremely useful and 25% mainly useful. Qualitative data captured is presented in Table 8.8, with discussion around potential changes to the intervention and applying the APEASE criteria.

Field notes

Field notes captured throughout the process are presented in Table 8.8. Potential changes to consider for the future intervention are also discussed, applying the APEASE criteria.

Table 8.8: Intervention changes to consider from the qualitative data collected from the study

Overall theme	Feedback source	Example quote or relevance	Changes to consider	Is a change necessary? Does it meet the APEASE criteria?
Practicalities	Acceptability interviews	<i>"I wonder if perhaps some of it doesn't have to be face-to-face. You maybe could have a bit more of a blended approach and have some e-learning and some face-to-face. Certainly, because I think it was all afternoon and that felt like quite long."</i> URO3	Face to face training is the preferred method following feedback from the evaluation forms; however, it is important to consider an online training programme. Future work needs to consider online training.	Yes, future work will consider an online training/blended training approach. Potentially with educational aspects being put online but ensuring the behavioural aspects to be delivered face to face.
	Field notes	HCPs were concerned about the additional time the	Issues around an increase in time will be tackled in the future training programme. Focusing on	Yes, include more action planning within the training as a team

		consultations were taking with their patients.	how to bring in the conversation of exercise without it taking up too much time.	and individually throughout the training.
		HCPs wanted support to be present on the day of going live for recruitment.	Support can be provided via telephone, email or zoom. However, it is not practical to be able to support clinical teams in person the day of recruitment going live.	Yes, support will be provided up to six months via telephone, email or zoom.
Training content	Evaluation form		To include example photos/videos of the exercise's patients will be doing.	Yes, an example exercise prescription will be included within the training and additional photos/videos of patients exercising.

	Acceptability interviews/Evaluation form/Field notes	<i>"I think it would have been really helpful to have had some sort of a video example of what that conversation should look like. What you're expecting from our conversations, rather than us trying to work it out for ourselves, if that makes sense."</i> CNS1	To include video examples of the different roles of the key in the training.	Yes, video examples will be included within the training on the different HCPs behaviours.
	Field notes	HCPs requested a prompt sheet on how to support patients around exercise	Further prompt sheets will be developed to use in practice. These could also feed into assessments of fidelity.	Yes, prompt sheets in the form of a behavioural checklist will be made to be used within clinics.
Training recipients	Evaluation form		To educate wider urology team that are not oncology.	No, this is not practical at this stage. However, ultimately when implemented in the future the more

				people who are aware of guidance the better.
	Field notes	Oncology and urologist colleagues attended all the training at Trust one; however, senior members of the clinical teams often put pressure on the CNS team to deliver the majority of the behaviours required for the intervention.	To develop the training further to split it into clear modules rather than level one and two and tailor the intervention to the appropriate HCPs. Ensuring the training modules, they receive are targeted at them and they do not attend training modules which may not be relevant to them.	Yes, HCPs will attend training relevant for them.
Positive experiences	Acceptability interviews	<i>"I thought it was very good. Because rather than being just dropped in at the deep end and dealing with it, it was nice to have a formal overview of what it entails, what the evidence is of the NICE guidelines and the</i>	The training programme was thought to provide enough relevant information and was found to be enjoyable.	N/A

		<p><i>funding associated with it."</i></p> <p>URO4</p>		
		<p><i>"So, I think having a programme from the hospital encouraging exercise and being motivator that I think is very useful. Even other treatments, you know, if someone had surgery or someone was to undergo radiotherapy, you need to motivate those patients and to continue because ultimately you want them to continue their quality of life and improve the way of life. So, I think it's a good opportunity."</i></p> <p>URO4</p>	<p>Emphasising that exercise is something beneficial and positive to offer patients was important.</p>	<p>No, but this message needs to be consistent throughout the training.</p>
Wider support	Acceptability interviews	<p><i>"But finding time when you can be away from clinical activity to embark on that is actually quite</i></p>	<p>Support for HCPs to take part in the training from management is required. Engaging the</p>	<p>Yes, engaging the operations management team is</p>

		<i>a challenge in itself. So that was an element that was supported thankfully. We had support from our management team, which made that possible." CNS1</i>	management team in the programme from the start will be an approach to continue with.	essential before approaching the clinical teams to attend training.
Concerns about the exercise professionals	Acceptability interviews	<i>"No, as long as the professionals involved, you know, consider, so for example patients who've got metastatic disease, they just need to be happy to deal with those patients and obviously not push them too far because they can be at an increased risk of fracture; but as long as they're used to dealing with that kind of cohort of patients, yeah no concerns." URO3</i>	Further efforts within the training are needed to provide information and reassurance of the exercise professional's ability to work safely with this population. For the HCPs and exercise professionals to meet prior to opening the site to recruitment would be beneficial.	Yes, HCPs and exercise professionals will meet at the site initiation visit however this will not be part of the training package due to practicalities.

Delivery concerns	Acceptability interviews	<i>"You're trying to make sure that we're all doing exactly the same thing, that's quite difficult to manage."</i> CNS1	Ensure there is time within the training for the team to discuss how everything will work in practice and to ensure the whole team is trained where possible.	Yes, extra time will be added for the team to action plan.
	Fidelity assessments	HCPs are generally not asking the patient if they have any barriers or concerns about the exercise programme.	Yes, more emphasis of this behaviour needs to be included within the training. Infographics need to be updated to reflect this and videos of HCP examples should be used.	Yes, more emphasis on this is required on asking patients about their barriers to exercise, in the same way they will ask patients if they have any concerns about treatment.
		HCPs need to provide more information on the benefits of exercise.	Yes, more emphasis of this is needed in the training. Infographics need to be updated to reflect this and videos of HCP examples should be used.	Yes, more emphasis on this is required.

Research processes	Evaluation form	Questions were asked regarding trial relation information that was required.	To include more research information upfront about the study, such as inclusion/exclusion criteria and recruitment numbers.	Yes, this will be covered in the sit initiation visit but also module one, will introduce some of the trial specific information as this training will be the first point of contact for the clinical teams.
	Acceptability interviews	<i>"That was quite difficult. We felt as a team, and we did speak to the STAMINA team about this, but we felt that it wasn't appropriate to record the entire conversation, because we don't record consultations as a standard practice now."</i> CNS1	Research processes such as keeping a screening log and audio-recording their consultations were barriers to the delivering intervention aspects of the programme.	Yes, research processes will be streamlined if possible, such as making audio-recordings optional or exploring other ways to assess fidelity. This will be covered in the site initiation visit.

	Field notes	The site initiation visit ran by the research team was delivered prior to training of the HCPs. This was problematic as HCPs started to have conversations with patients about the research rather than exercise.	To ensure the site initiation visit is always delivered after the HCP training.	Yes, ensure timing of site initiation visit is well placed and to be considered for the future research.
		HCPs were concerned about whether patients were eligible as not all the patient notes included information about their treatment due to patients being under care at different trusts	The eligibility criteria for patients was altered to include all men with prostate cancer on ADT at any point, not just newly diagnosed.	Yes, ensure this is reflected in new prompts etc. that will be used in clinics.

8.4.6 Intervention and research process refinement

Intervention refinement

Following the above outcomes of the study, a summary of possible changes to inform the future training package are documented below:

1. **Content of the training:** HCPs suggested more videos of HCPs delivering specified behaviours were included, so it would be clear exactly what is expected from the conversations with patients. HCPs also suggested we include more information about an example exercise prescription for patients, so HCPs could provide patients with this information. There was also a suggestion to include more information about the research aspects around patient recruitment. However, this will have to be delivered by the research team separately, to keep the research and intervention distinct.
2. **Levels within the training:** At present the training package is separated into six modules, module six is repeated between 8-12 weeks. The idea for this was for HCPs to attend modules one, two and three and then for key workers (HCPs who are predominantly involved in this patients' group care) to attend modules four, five and six as well. As each 'level' was role specific. HCPs suggested that HCPs attend modules relevant for them and their role, rather than split it into different levels. Cancer care is complex and often delivered across different trusts and hospitals, (see Chapter five), so assigning HCPs modules rather than whole levels may aid efficiency of delivery of the training.
3. **Mode of delivery:** Face to face delivery was preferred but it was suggested to investigate delivering some elements online where possible. Some modules which focus upon education specifically could be developed online. However, the importance of the training needs to be maintained and specific time needs to be allocated from operations managers for HCPs to complete the training online.
4. **Engagement of HCPs:** To continue to ensure senior managers, operational teams and clinicians are bought into the concept from the start of the project and willing to support the clinical team attendance

was suggested. This approach was successful in allocating HCPs time to attend the training and helping with engagement. This approach is recommended for future similar research.

5. **Establishing trust:** Further efforts are required to reassure the HCPs of the capability of personal trainers to support this patient group safely. Ideally HCPs and exercise professionals could meet beforehand and develop a professional relationship. This was previously suggested in the refinement stage of the intervention, reported in Chapter seven, but was not viewed as practical. However, this could be facilitated on an online platform.
6. **Behaviour change techniques:** HCPs suggested using action planning for the whole clinical team to be present throughout the training. Whilst there are elements of this, adding more time for HCPs to do this would be beneficial. Using techniques such as problem solving more frequently throughout the training around how to support HCPs to deliver the required behaviours in the clinics time was suggested. Additionally, using behavioural prompt sheets or checklists during consultations was suggested, so HCPs could cross check the delivery of the behaviours until the consultations discussions around exercise became a routine.
7. **Support for HCPs:** HCPs wanted support on the days following the training to help set up the clinics with prompts and be on hand to help answer any queries. This would not be feasible, however, providing virtual support for up to six months via telephone or email would be recommended for the future intervention. Additionally, there is already a follow-up visit between 8-12 weeks, where further support can be provided.

Research process refinement

Following the above outcomes of the study, a summary of possible changes to inform the future research processes are documented below:

Audio-recordings of consultations to assess enactment of treatment skills and target behaviour 1 and 2

The audio-recordings during consultations between HCP and patients did not seem feasible or acceptable. There were concerns completing these audio-

recordings as HCPs did not feel comfortable recording the whole consultation with patients, so when recordings were made they were often a summary of what had been discussed previously with the patient and we were unable to capture what had been discussed in real-time. It is important to note that no patients declined the audio-recordings and it was HCP perceptions that patients would feel uncomfortable rather than the patient's actual perceptions. Due to HCPs not feeling comfortable completing the audio-recordings and it was hindering delivery of the intervention, they were made optional by the research team, which was approved as a substantial amendment to the protocol REC reference: 19/NW/0025, 16th August 2019. Using audio-recordings to capture fidelity data needs to be reassessed, with more emphasis on making HCPs feel confident in carrying out this research task, or alternative fidelity measures need to be explored.

Capturing process data appeared feasible however, completion of the screening log at one of the sites was problematic as the HCPs kept forgetting to complete the screening log. However, a system was put in place by the research team to request copies of the screening log every week, to prompt HCPs to complete the screening logs on time.

Fidelity checklist to assess enactment of treatment skills and target behaviour 1 and 2

The fidelity checklist developed for the purpose of this study was easy to use, however time-consuming to code. High interrater agreement was observed between the two coders, see Table 8.6. Coding whether BCTs were applicable or not was a more difficult task and required expertise on BCT coding and understanding where some BCTs may be helpful. However, most patients were not ambivalent or resistant to the idea of exercise when it was introduced by their HCP. Further testing of this checklist is required in a larger sample, as we were unable to code the audio-recordings from trust two.

Pre, post, and follow-up questionnaire to assess behavioural determinants

The pre, post and follow up questionnaire based on the TDF appeared to be feasible, it took around 10-15 minutes to complete and those of which were completed did not have any missing data. There was a drop-out rate for completion of 6% for the post-training questionnaire and a further 29% drop out

rate for the follow-up questionnaire. Since the delivery and evaluation of this training package, a validated questionnaire based on the COM-B ‘capability, opportunity motivation’ = ‘behaviour’ model has been developed (Keyworth, Epton, Goldthorpe, Calam, & Armitage, 2020). The use of this new questionnaire could be explored for the future randomised cluster trial, as the questionnaire is validated and has been assessed for reliability. Furthermore, the questionnaire has been tested with samples of HCPs and has been shown to be acceptable.

Acceptability interview topic guide

The topic guide for the acceptability interviews was based on acceptability framework developed by Sekhon and colleagues (2017), as discussed in Section 8.1, offering an opportunity to understand acceptability in a deeper sense. However, this framework was difficult to use to analyse these interviews. Interpreting some of the seven constructs (see Table 2.7) was challenging and data was captured from these interviews that were outside of acceptability framework. *Affective attitude* and *Intervention coherence* were useful constructs to explore the HCP’s overall perceptions of the interventions, however, often the HCPs would talk about the patient experience rather than their own. *Burden* was also helpful in exploring the effort and requirements it took to participate in the intervention. However, this seemed to overlap with *Opportunity costs*. *Perceived effectiveness* and *Self-efficacy* seemed useful constructs to assess, however, they seemed to overlap with behaviour change models and theory. Interpreting the construct of *Ethicality* proved the most challenging as it considers individual value systems and it overlaps with other constructs of acceptability. Therefore, an inductive thematic analysis was the approach taken for analysis, rather than using the acceptability framework as a guide. Consequently, the use of this topic guide, based on acceptability framework developed by Sekhon and colleagues (2017), in the future cluster randomised trial to assess acceptability would not be advised, as changes to the topic guide would be necessary due to the issues discussed above.

Evaluation form

The evaluation form appeared to be feasible as it took around 5-10 minutes to complete, there was no missing data and was completed by 94% of HCPs as required. It helped to capture useful data on the training venue and overall

perception of the training programme. These would be recommended for the future cluster randomised trial.

8.5 Discussion

A theory and evidence-based HCP training package was delivered to two prostate cancer care clinical teams at two NHS sites. Overall, the intervention data suggested improvements in the TDF domains, which subsequently led to delivery in the seven identified target behaviours (see Table 5.2). HCPs recommended exercise and discussed barriers to exercise with 38 patients, 28 were referred with all the relevant information packs and all patients who were seen at follow-up by trained HCPs had a discussion about exercise informed by their progress report.

Whilst the effectiveness of this training package is yet to be established and further research is required to support this finding further, the delivery of HCP behaviour and behavioural determinants following the training and at follow-up are promising. Delivery of the seven target behaviours in a real-world setting was the primary aim for this developed intervention and the results from the available data are suggestive of change. Some of the behaviours (Behaviour one and two, see Table 5.2), whilst all delivered, differed in terms of delivery. From the audio-recordings that were taken (15 consultations with 13 patients were completed at trust one). There was a lack of exploring if patients had any concerns or barriers to exercise and more information about the benefits of exercise could have been provided. However, it is important to note that this was always provided but could have been expanded upon. This highlights the importance of measuring fidelity and highlights the need for further intervention support where necessary.

The TDF questionnaire demonstrated trends towards positive changes in behavioural determinants across all the domains alongside behavioural changes. The training package consisted of 22 BCTs which aimed to specifically make changes to the ten domains identified as influential to HCP behaviour in Chapter five. There was a focus within the training of group discussions, group tasks, use of case studies and practice and rehearsal of new skills. Presenting the information in different ways to encourage learning and engagement; the use of *Action Planning* helped the HCPs to focus as a team and as individuals on how they were going to approach patients around

exercise and improved *Behavioural Regulation*. Techniques such as *Problem solving* were then included to promote discussions around how to overcome barriers such as time constraints when having these conversations. The use of *Credible Source* videos and case studies of senior HCPs and patients and *Information about health consequences* were helpful in creating positive beliefs of exercise and improving *Knowledge* which increased following the training, as previously identified (Johnson & May, 2015). Changes in *beliefs* and positive *emotions* increased at follow-up, which might have been due to positive patient feedback in clinics. Providing *Demonstration of behaviour and instruction of behaviour* using these *credible sources* were helpful in teaching new skills and further examples of these were requested. Additionally, using *Behaviour practice/rehearsal* with *Feedback* throughout the training to promote the learning of new behavioural skills and BCTs was a key tool used. The use of the cards for change were important as the BCTs being taught to HCPs were given out to HCPs alongside role-play tasks to promote the key points for using these BCTS (Pearson et al., 2018). Changes in beliefs around *skills* increased following training but dropped at follow-up. This is probably due to lack of repetition of using the key skills, repeating *Behaviour practice/rehearsal* with *Feedback* at the follow-up module between 8-12 weeks is critical for skill acquisition. *Memory, attention, and decision processes* increased following training and increased again at follow-up. The use of *Prompts and cues* and *Adding objects to the environment* were utilised in clinics and will have probably contributed to this. The acceptability data highlighted the want for further *Prompts and cues* within clinics due to them being useful. Furthermore, the supportive and friendly environment and using techniques such as providing *Social support* and *reducing negative emotions* that did not induce fear and aimed to create a partnership were beneficial in engaging HCPs and creating positive working relationships, which is important for change (Bull et al., 2018). Positive beliefs on *Social influences* and *Social/Professional role and identity* increased following the training probably due to this, however, these seemed to change at follow-up. This was probably due to the level of support provided decreasing and some HCPs from the clinical team did not access the training, which could have negative implications on trained HCPs beliefs on *Social influences* and *Social/Professional role and identity*. Whilst pragmatically, not all HCPs can be trained due to the complexity of the pathways, providing some

written information on the importance of exercise could be beneficial. Changes in beliefs regarding *Optimism, Goals, Reinforcement, and Intention* were shown, however, these were not targeted in the intervention specifically. Due to overlaps in the TDF (McGowan et al., 2020) and complexities of the intervention, it likely the BCTs influences other domains. The use of *Action planning* and *Problem-solving* activities likely increased *Intention* to perform behaviour.

Ten domains were identified as influential to HCP behaviour in Chapter five, in the development of the questionnaire some of the domains required more than one question. For example, four questions were included for the *Beliefs about consequences* domain as identified in chapter five; HCPs commonly held several different beliefs about recommending and supporting exercise in this patient group. At the time, there were no validated TDF questions and limited examples within the literature of something suitable. Nadler et al., (2019) developed a questionnaire for clinicians to understand their perspective on exercise for cancer survivors. However, it only included certain domains, as the authors agreed *Social Influences, Optimism, Goals, Reinforcement, and Emotion*, were less relevant to changing HCPs behaviour and therefore not included in the questionnaire. Our research contradicts with this, finding *Social Influences* and *Emotion* to be important determinants of behaviour, especially within clinical teams.

The fidelity assessments of enactment of treatment skills, when carried out correctly, provided an excellent insight into assessing HCP behaviour and behaviour change skills. However, assessing fidelity via audio-recordings of consultations created a barrier to the delivery of the intervention itself, as previously found (Hrisos et al., 2009). There were differences between the two sites regarding the audio-recordings, this could indicate there were different factors at play, in addition to issues with acceptability. There was a perception at trust two for the team to be giving the same information and support, which could have played into the issues of the audio-recordings. Using audio-recordings to assess clinical behaviour is the current gold standard; future research needs to understand other ways to assess fidelity without obstructing the intervention as the barriers to the fidelity assessments suggest they were not acceptable to HCPs. Ensuring measures of fidelity as acceptable and

practical is an important aspect of fidelity (Walton et al., 2017). A recent online questionnaire identified that a lack of knowledge and understanding of fidelity assessments was a barrier to engaging in assessments within complex healthcare interventions (McGee, Lorencatto, Matvienko-Sikar, & Toomey, 2018). A lack of time, resource, and a lack of training within this area were also reported as barriers. Finally, a lack of acceptability and practicality of fidelity assessments was highlighted as a barrier to engagement in assessments. These identified barriers are likely mirror the barriers within this thesis concerning the engagement of audio-recordings. This is hardly surprising as little work had gone into how to understand ways to engage HCPs in research processes. The research then becomes the barrier to the engagement of the intervention, not the addressed barriers identified in the previous intervention development work. This seems to be overlooked within the literature and maybe a reason for why fidelity assessments are few and far between in complex interventions (Walton et al., 2017). Recent work has aimed to integrate behavioural strategies to improve fidelity of delivery and engagement within a complex intervention in dementia (Walton et al., 2020). These strategies included providing clear instruction, time to practice activity, provide regular telephone support and provide a session summary document. Furthermore, Williams et al., (2020) used a range of techniques to encourage providers to record intervention sessions for fidelity assessments using text messages, emails, support visits and gift vouchers. However, the impact of this was not monitored. Further work on to develop strategies to aid the delivery fidelity assessments and research processes to be carried out by HCPs during interventions is required.

Recruitment of HCPs from both clinical teams was challenging, however, the help of the operations management team was beneficial in freeing up time for HCPs to attend. There was a lack of engagement in some of the HCPs, due to capacity, this will be anticipated in other future larger sites and is often common within this type of research (Riis, Jensen, Maindal, Bro, & Jensen, 2016). This became problematic when patients were receiving follow-up with untrained HCPs as we were unable to track or record those conversations during consultations, there was a risk that the untrained HCPs may not advocate exercise and even dismiss it creating patient barriers as discussed in chapter

one. This is an important issue to consider for the future implementation of this training package. However, due to the complexity of the cancer care pathways, it is quite difficult to follow a patient's care. Pragmatically, it was not possible to train both the urology and oncology clinical team at each trust, as often oncology teams sit at a different trust as stated in chapter five. This needs to be considered for the future intervention and despite an online training package not being the preferred mode of delivery; it may need to be explored.

Acceptability was assessed via interviews with HCPs who had received the training package and been a part of the intervention, post-training evaluation form and field notes taken throughout the process. The interviews, evaluation forms and field notes identified several barriers with the research processes, which were also identified in the fidelity assessments. Concerning the acceptability of the training package and the HCPs delivering the intervention a few barriers were identified by the HCPs. These were typically around time in clinics to discuss exercise and ensuring the whole team were consistent in their messages. These barriers were identified in previous research in chapter one (Huijg et al., 2015; Karvinen et al., 2012). There was a further want for videos of HCPs delivering specific behaviours within the training and prompt sheets to support delivery within clinics. However, the acceptability framework developed by Sekhon and colleagues (2017) whilst offering an opportunity to understand acceptability in a deeper sense, was difficult to use to analyse these interviews. Interpreting some of the seven constructs was challenging and data was captured from these interviews that were outside of the acceptability framework. It would be recommended that this topic guide is changed for the use within the future cluster randomised trial. Whilst acceptability is important to assess, perhaps using an open-ended questionnaire specifically to assess these constructs may be better suited. With follow-up interviews based on the TDF or COM-B model, as these frameworks and models fit within this programme of research.

8.5.1 Strengths

This research aimed to assess several outcomes that are important for the future refinement and optimisation of complex interventions (Craig et al., 2008). A strength of this research is the comprehensive assessment of behaviour, behavioural determinants, acceptability, and fidelity using multi-methodologies.

The comprehensive assessment has allowed for an overall understanding of what has worked and what has not worked so well. For example, capturing the data at different points within the intervention has helped us to understand further the complexities of the cancer care pathway especially at follow-up and how to think about how to address this in the future intervention. Additionally, as there were issues with the audio-recording fidelity assessments, we were able to capture other aspects of fidelity to measure clinical behaviour in-directly. However, it is important to note that this was the first phase of development of the fidelity measures and further refinement will take place prior to the future trial.

8.5.2 Limitations

This was a preliminary evaluation of the training package, with several limitations. The primary limitation of this research is that the effect of the intervention is yet to be established. As the intervention was not delivered in a randomised control trial setting with a comparison to a control group. However, the study aimed to assess delivery of target behaviours, behavioural determinants, acceptability, and fidelity in several ways for the further refinement and optimisation of the intervention to ensure the intervention has the best possible chance of being effective in the future consistent with the process outlined in the MRC framework for intervention development. Furthermore, there is important learning for the field of behavioural science from the process of developing the intervention as documented in the previous Chapters.

There was further opportunity within this study to assess other aspects of treatment fidelity such as assessing treatment delivery by video-filming training and coding the training against the developed manuals or providing regular training for training facilitators to ensure skills are maintained. As well-trained facilitators are less likely to diverge from the treatment (Borrelli, 2011), but due to resources and time, we were unable to achieve this. These areas need to be considered in the future, as this will add methodological rigour to the research and intervention itself. Using the framework to guide fidelity assessment as developed by the NIH-BCC (Bellg et al., 2004) helped to enhance fidelity when developing the training package and understand ways in which to assess fidelity. Using the approach suggested by Walton et al., (2019) in the future to

develop a fidelity guideline would be recommended as this approach provides recommendations on how to develop measures of fidelity for complex health interventions, focusing on engagement, with consideration around implementation. It also focuses upon involving stakeholders for feedback in developing checklists. This approach also appears to be very structured and clear, in comparison to the NIH-BCC approach (Bellg et al., 2004), which offers suggestions for assessing fidelity rather than how to develop fidelity assessment checklists.

8.5.3 Implications for further research

The training package following further refinements will be piloted before a randomised cluster definitive trial. Further research will continue to refine the intervention and aim to address some of the barriers still present. Whilst issues such as time and resource are likely to not change, the focus needs to be on action planning and what can be done in the normal consultations.

Changes to some of the research assessments and tools are required as discussed above and additional areas of fidelity should be measured regarding the delivery of the HCP training package. Strategies to engage HCPs in research should be utilised and incorporated into future research.

This training package was delivered face to face. Suggestions were made during the rehearsal delivery and stakeholder workshop as presented in chapter seven regarding an online training package, however, due to practical reasons, this was not pursued. Therefore, future research should focus upon the development of online training to support the face to face training. Some aspects of the current training package are unlikely to be appropriate on a traditional online platform such as the behavioural aspect; however, aspects relating to information provision might be appropriate.

8.5.4 Implications for future practice

Further work needs to be done to ingrate research into clinical practice, to ultimately make it more accessible in everyday practice. In the intervention development process, an immense amount of work goes into understanding how to change clinical behaviour, in this case how to encourage HCPs to recommend and support exercise. However, it often appears that little work goes into how to understand ways to engage HCPs in research processes,

research then becomes the barrier to engagement, not the addressed barriers identified in the previous intervention development work.

8.6 Conclusion

The theory and evidence-based training package was found to be acceptable to HCPs. There were some positive trends in behavioural determinants and HCPs delivered the seven target behaviours. There were, however, a few issues with the fidelity assessments and research processes, which need to be refined. Further refinements and optimisation of the HCP training package are required before delivering as part of a randomised cluster definitive trial.

9) Chapter nine: Discussion and conclusions

The body of research within this thesis aimed to develop a theory and evidence-based training package for healthcare professionals (HCPs) to recommend exercise, provide exercise support and make an exercise referral in line with NICE recommendations (NG131 1.4.19), specifically for men with prostate cancer on Androgen Deprivation Therapy (ADT). This has made an original contribution to knowledge as these recommendations are not currently being implemented in usual care (Bourke et al., 2018) and this training package is the first to offer a way to integrate exercise into the prostate cancer care pathway.

The Medical Research Council (MRC) (Craig et al., 2008) and Behaviour Change Wheel (BCW) (Michie et al., 2014) guidance was used to develop an intervention for HCPs to support the delivery of the NICE recommendations. The following steps were taken. The first half of the thesis (Chapters one, three and four) aimed to understand what strategies influenced cancer survivors exercise behaviour (systematic review) and what the present exercise clinical recommendations in cancer were available for HCP use (rapid review). The second half of the thesis (chapters two, five, six, seven and eight) explored the HCP role in supporting exercise, specifically in men with prostate cancer on Androgen Deprivation Therapy (ADT) and identified target behaviours to change to support delivery of NICE NG131 1.4.19 recommendations. A behavioural analysis was carried out on the seven identified target behaviours, to understand key barriers to change using the Theoretical Domains Framework (TDF) (Chapter five). Theory was then drawn upon to develop the intervention, identifying intervention functions, behavioural content, and mode of delivery (Chapter six). The intervention was refined and optimised with the involvement of HCPs (Chapter seven). The developed intervention was delivered in a non-randomised observational study, assessing behaviour, behavioural determinants, fidelity, and acceptability of the intervention (Chapter eight).

This chapter will draw upon the previous chapters to summarise the key findings of the thesis. The strengths and weaknesses of the methodologies applied are discussed, alongside key reflections. The implications for practice and future research are also explored.

9.1 Principle key findings

9.1.1 Supporting cancer survivors with the uptake of exercise

The earlier work in this thesis aimed to understand what strategies influenced cancer survivors exercise and what the present exercise clinical recommendations were available for HCP use. There are several key learning points from this work.

Strategies to support cancer survivors with exercise

The side-effects of cancer treatment are debilitating, more specifically in men with prostate cancer on ADT. ADT causes significant side-effects including cancer-related fatigue (CRF) (Walker et al., 2013), increase in weight gain (Braunstein et al., 2014) sexual dysfunction (Ng et al., 2012), increased cardiovascular morbidity and mortality (Bourke et al., 2012) and increase risk of type 2 diabetes (Wang et al., 2016); all resulting in a reduced health-related quality of life (HRQoL) (Cheung et al., 2017; Dacal et al., 2006). There is accumulating evidence including epidemiological studies, randomised control trials (RCTs) and systematic reviews (see Chapter one) that have found engaging in exercise after a diagnosis can have a protective effect against cancer reoccurrence, alleviating some of these treatment effects and mortality (Cormie et al., 2017). However, exercise levels are low amongst cancer survivors with patients reporting several barriers (Clifford et al., 2018; DoH, 2012). Including a lack of exercise recommendation or support from HCPs within the cancer care pathway (Duncan. et al., 2017). There are several evidence-based strategies to promote and support exercise behaviour in cancer survivors, as found in Chapter three. These include providing supervised exercise programmes, commonly used behaviour change techniques (BCTs) such as *setting graded tasks*, *action planning*, *problem-solving* and *instruction on how to perform the behaviour* and HCPs promoting and supporting exercise, which supports the literature in this area (Finne et al., 2018; Grimmer et al., 2019), see Chapter three.

The identification of these BCTs and strategies to support exercise within cancer survivors has implications for both research and practice. Firstly, these findings should be translated into practice. HCPs are in a prime position to deliver some of these BCTs, as presented in this training package, see Table 6.5 and provide behavioural support as part of usual care, see Table 5.2.

Additionally, exercise professionals are well placed to provide some of these strategies such as supervised exercise, *instruction on how to perform the behaviour* and *setting graded tasks*. Further analysis should be carried out to understand possible associated effectiveness of BCTs, strategies or potential combinations in relation to associated effectiveness to promote exercise behaviour in cancer survivors.

Secondly, future exercise trials should incorporate these strategies into the design and report these clearly using BCT taxonomies such as BCTTv1 taxonomy (Michie et al., 2013) and intervention description frameworks such as TIDieR (Hoffmann et al., 2014). Exercise oncology is a rapidly expanding area and trials need to be designed based on previous 'real-world' evidence to lead to the development of further recommendations and guidelines for other cancers aside from breast and prostate cancer. Without clear reporting, there may be further research waste within this field (Ioannidis et al., 2014), see Chapter three.

Role of behavioural science in exercise oncology research

There are many studies within the field of exercise oncology, as highlighted in Chapter three, that aim to improve exercise behaviour in cancer survivors. Exercise physiologists and professionals working with health psychologists and behavioural scientists may lead to a more effective solution to encourage cancer survivors and other clinical populations to increase their exercise. Within the literature, there is an established difference between the physiological outcome-based studies delivered in a lab and more behavioural exercise cohort studies delivered in real-world settings (Bluethmann et al., 2015). The difference between the two is the physiological outcome based studies focus on understanding the effects of exercise in a very controlled setting and whilst these types of studies are important for establishing effectiveness of exercise, there can be difficulty with replicating or implementing these studies in 'real-world'. For example, aspects such as one to one supervision with a personal trainer in a gym as part of an exercise intervention, may not be achievable or affordable. On the other hand, interventions that have been delivered in a real-world setting which focus on people getting active and have more of a behavioural focus such as improving exercise behaviour may not have the same level of control as in a lab based study and are therefore sometimes are

dismissed within the field of exercise oncology. This issue was highlighted in Chapter three, where the Cochrane methodology assessment of the risk of bias applied strict criteria. Further efforts are needed to focus on behavioural outcomes as well as physiological outcomes within these studies. Additionally, for interventions involving exercise behaviour change need to include multi-disciplinary (MDT) teams such as HCPs, health psychologists, exercise physiologists and patient representatives, so important physiological outcomes can be assessed alongside understanding how to encourage to changes in exercise behaviour. This would then aim to improve the implementation of exercise research or exercise recommendations into real world practice.

Exercise recommendation alone is not sufficient for behaviour change

Chapter four reviewed and appraised the current clinical exercise recommendations for cancer survivors. Twenty-eight clinical exercise recommendations in the top four most common cancers in the Western world for HCPs to follow were identified. Recommendations were predominantly present in breast and prostate cancer and were rarely specified behaviourally, rarely explained why exercise should be offered, and often were very vague potentially leading to implementation issues (Michie & Lester, 2005). These recommendations highlighted one of the reasons why there is inconsistent advice and provision in exercise for cancer survivors. Whilst these recommendations are a starting point to increase knowledge and awareness of the need to promote exercise in treatment, multiple complex behaviours are required from the HCPs to implement such recommendations and support cancer survivors with exercise. Chapter five identified additional behaviours for HCPs (Table 5.2) and included discussing barriers to exercise and recognising patients who were suitable for exercise. Cardiac Rehabilitation (CR) provides an example for the need to specify additional behaviours to support the delivery of exercise recommendations. When CR was rolled out Nationally and intervention fidelity was not maintained, effectiveness and cost-effectiveness was compromised (Doherty & Lewin, 2012). Furthermore, the context of the delivery of CR in an exercise lab-based setting, is extremely different to the delivery of the programme into various healthcare settings (e.g. GP practices or hospitals) and was not considered fully (Doherty & Lewin, 2012). Following this, NICE

published many detailed recommendations on how to deliver CR, what information and support to provide and how to deliver CR and lifestyle support (NICE, 2013a). This has led to an increase in attendance and adherence to CR, improvements in cost-effectiveness of CR (Shields et al., 2018) and improvements in its effectiveness (BHF, 2018). Recommendations for exercise in cancer care should learn from the mistakes of CR and offer more detailed and structured approaches of what is required when implementing such recommendations. This thesis offers an original contribution to knowledge, highlighting the key target behaviours required to implement the NICE recommendations NG131 1.4.19 and whilst further research is required, key learning can be taken from this approach and applied to other cancers and conditions where exercise should be offered as part of care.

9.1.2 Developing complex behavioural interventions for professional behaviour change

This thesis developed a training package for HCPs to provide exercise recommendation, exercise support and exercise referral in line with NG131 1.4.19 recommendations for men with prostate cancer on ADT. More specifically, focusing on delivering seven new target behaviours (see Table 5.2) to support patients. There are several key learning points from the development of this intervention, these will now be discussed in this section.

Using the BCW and MRC guidance

The approach to intervention development was systematic and comprehensive, using the BCW (Michie et al., 2014) and MRC guidance (Craig et al., 2008). This thesis provides a good example of how to develop complex interventions for HCPs and highlights the complexities of this process. The reporting of the development of this complex intervention through its iterations has been transparent and aims to contribute knowledge to the field of intervention development, as other researchers can observe the rigour needed to develop theory and evidence-based interventions. The actual process of intervention development is an extremely lengthy and non-linear process which has previously been reported (Sinnott et al., 2015; Webb, Foster, et al., 2016). It took 12 months, from analysing the HCP interviews (Chapter five), to developing the first version of the intervention. The refinement and optimisation of the intervention took a further 6 months. However, despite this approach

being time-consuming, this time was important to ensure the intervention was developed to be as effective as possible, to avoid research waste (Ioannidis et al., 2014). The time required should not be viewed as a disadvantage to developing complex intervention; however, researchers should be aware of what is required. Researchers should be aware that adopting 'traditional' intervention development approaches, such as developing interventions based on classic psychological theories without a consideration of the barriers to target behaviours (Chapter two), whilst may be substantially quicker, are not able to encapsulate the complexities required. In addition, intervention development can be expensive. For example, holding the rehearsal deliveries and stakeholder workshops within this research was costly, due to costs such as venue hire and research resources, therefore not always achievable in other projects with a limited budget.

Within the field of complex intervention development there are fundamental issues. Traditionally complex interventions have been developed without methodological rigour (Hoddinott, 2015) and the use of theory (Michie, van Stralen, et al., 2011). Intervention development frameworks such as the BCW and MRC have been developed to tackle these issues. However, individual frameworks still have their limitations (O'Cathain et al., 2019). These typically include a lack of detail of how to undertake each step of intervention development and a lack of emphasis on involving intervention users in the development (see Chapter six and seven). One key issue with this is the selection of BCTs critical for effective intervention. The guide suggests which BCTs map to which intervention functions, but these are not evidence-based or context-specific. Therefore, a review of the evidence and theory as suggested by the MRC guidance was needed to understand what BCTs might be effective or not, this is reported in more detail in Chapter six.

Involving multi-disciplinary teams and stakeholders in the process of development

The intervention development team were multi-disciplinary (e.g. academic HCPs, health psychologists and exercise physiologists) and were involved in the decision-making process for the refinement of the intervention. This was valuable for the development of the intervention. The APEASE criteria (see Table 2.5) was a useful tool for making intervention development decisions,

however, expertise from the team was required to make these decisions, and the differences in expertise across the team most likely influenced the decisions made. This expertise of the intervention team is important as the decisions made need to be based on evidence. However, making these subjective judgements seems somewhat odd within this systematic and scientific framework, and has been commented on by other intervention developers (Sinnott et al., 2015).

Refining the intervention using HCP stakeholder involvement, is something that is rarely reported in interventions that have used the MRC and or BCW guidance. However, it is something that is advised by O’Cathain and colleagues (2019) in the recent intervention development framework. Complex interventions are being designed by researchers, but it is the HCPs who must deliver the intervention. HCPs will have more of an understanding of the local characteristics of the complex system, in which they work. Therefore, working closely with the HCPs from the start of the process was a strength of this research. Furthermore, engaging HCPs may aid to develop good relationships and rapport between the research team and HCPs. As research has highlighted when change is implemented in new models of care from the top-down, it can cause and be a consequence of a poor workforce culture (Bull et al., 2018), should be avoided. The approach of co-design and participatory research may have been beneficial here. Co-design and participatory research goes beyond user-involvement and aims to develop intervention by bringing together intervention users by intervention users having a consultant or advisory role (Sánchez de la Guía, Puyuelo Cazorla, & de-Miguel-Molina, 2017). This approach means that solutions are produced with an understanding of the local context in which the intervention is to be implemented in. Using this approach for the development of this intervention would have been of benefit to ensure HCP engagement and ensuring the research was acceptable from the inception. However, it could have been challenging to ensure HCPs were committed to being involved for the full period of time and were able to give up a substantial amount of time.

The use of theory in the development of the intervention

The BCW and MRC guidance highlight the importance of theory in developing intervention, but neither offer guidance on how to select and apply appropriate

theories (De Silva et al., 2014), which adds to the fundamental issue of interventions being developed without theory (Prestwich, Webb, & Conner, 2015). To tackle this issue, classic psychological theories were drawn upon, the domains driven by the TDF targeted in this intervention were reflective of the theories selected, as presented in Table 6.2, see Chapter six. These were the Social Cognitive Theory (Bandura, 1986), Social Learning Theory (Bandura & Walters, 1977), Theory of Planned Behaviour (Ajzen, 1991), the Necessity and Concerns framework (Horne et al., 2013) and Theories of Habit (Gardner & Rebar, 2019). Due to the complexity of the intervention and targeting change in seven behaviours, to use just one single classic psychological theories was not suitable for this intervention, therefore constructs and specific relations from more than one existing theory were used to underpin the intervention. The TDF helped bridge the gap between what needed to change and identifying theory. As the TDF clearly presents the constructs in which the domains are made up of, derived from theory (Cane et al., 2012). Whilst there are efforts by the Human Behaviour Change Project to link theory to BCTs (Michie et al., 2017), this methodology is not yet available. This methodology will aid the development of interventions based on theories as it will allow researchers to search for theoretical constructs identified for change and theories will presented that are linked to this specific construct.

Defining behavioural content for the intervention

The final consideration is whilst the behaviour change technique taxonomy (BCTTv1) (Michie et al., 2013) provides a common language for researchers, when selecting and delivering the BCTs for the intervention, it was thought there is a need to further elaborate upon the 93 BCTs (Michie et al., 2013). For example, the 'spirit' of motivational interviewing which relates to the interpersonal style of the person delivering the motivational interviewing (Rollnick et al., 2010), may be often used when delivering BCTs within an intervention (Hagger & Hardcastle, 2014). Whilst some motivational interviewing techniques are documented in BCT taxonomies (Michie et al., 2013), the interpersonal style that may aid behaviour change is not included (Hagger & Hardcastle, 2014). Including these techniques in a taxonomy would be beneficial. Further to this, some of the BCTs included in the taxonomy, such as *goal setting*, could be delivered in several ways. Goals could be set for the

individual, as reported in Chapter three, the exercise interventions often set a programme goal of 150 minutes of aerobic exercise per week. However, goals could be set by the individual, which is likely to aid autonomous motivation. These differences need to be specified, as it may be likely that BCTs used in a way that promote autonomy may be an additional aspect of behaviour change interventions to consider (Hagger & Hardcastle, 2014). Recently, there have been efforts to try to consider the mode of delivery of BCTs for intervention developers and educators. Pearson and colleagues (2018) developed a tool called 'Cards for Change' which are used to train HCPs, they specify BCTs and provide different mode of deliveries. Whilst this tool is yet to be evaluated, using such tools can provide educators with examples of how to deliver BCTs specifically within HCP training is useful.

9.1.3 Delivery and evaluation of the complex intervention

The training was a half-day interactive, skills-based package and consisted of six modules, with module six being repeated between 8-12 weeks. The training package was delivered and evaluated in two NHS sites with two clinical teams, see Chapter eight. HCPs beliefs in line with TDF domains changed and the seven target behaviours that were assessed were delivered. The training was found to be acceptable and fidelity was assessed. Key learning points are now discussed.

Core components of the training package

The key domains of the intervention were to a) improve knowledge b) increase confidence, c) change HCP beliefs, d) establish social norms, e) provide training in behavioural skills and f) change HCP belief of their perceived role. Due to the results of the evaluation (see Chapter eight), it can be indicated the above domains were targeted and this led to the delivery of the seven target behaviours. Improving knowledge was a key aim of the intervention, this was achieved by presenting *information on the health consequences of behaviour*. As the Necessity Concerns Framework states if people have higher necessity beliefs and lower concerns beliefs about the behaviour, they are more likely to carry out the behaviour (Horne et al., 2013). Using education alongside other intervention components has previously found to be effective in HCP behaviour change (Johnson & May, 2015). The information was interactive and presented in different formats. Ensuring HCPs had confidence in delivery of all the new

skills was important. Using techniques such as *demonstrations, behavioural practice/rehearsal* and *verbal encouragement* helped to build confidence. The training itself was delivered in a friendly manner, with a supportive atmosphere. HCP beliefs were challenged by *information on health consequences* as discussed above, but also using other techniques such as *pros and cons* and the use of local opinion leaders and *credible sources*, which have been found to be effective in HCP behaviour change in previous studies (Johnson & May, 2015). Furthermore, using patient case studies and videos of the benefits of exercise were useful during the training. Asking HCPs to reflect on the future positive outcomes of exercise and how important they deemed exercise for this patient group was a good discussion point to start the training. The whole clinical team who saw men with prostate cancer on ADT were invited to the training, which has previously been suggested to be important for influencing social opportunity (Tomasone et al., 2020). HCPs were taught to deliver eight key BCTs, see Table 6.5. Role play exercises were used to teach HCPs new behavioural skills, using techniques such as *demonstrations, behavioural practice/rehearsal* and *verbal encouragement*. Role play exercises originally caused issues in the rehearsal deliveries (see Chapter seven) as there were mixed opinions on the use of role play, however, these exercises worked well in the delivery of the training. One of the most predominant barriers to discussing exercise with patients was HCPs not perceiving it as part of their role, see Chapter one. HCPs roles were discussed from the start of the training and throughout. BCTs such as *problem solving*, and *action planning* were useful in creating plans about which HCPs would be responsible for certain elements. Additionally, using patient videos as *credible sources* stating the importance of HCPs discussing exercise with them were used. Several *prompts and cues* were used during the training and for HCPs to put in their clinics, they were further requested during the intervention delivery period. The use of prompts and cues aimed to remind HCPs during consultations to discuss exercise and the steps required for referrals. Links between these BCTs and memory has been identified (Carey et al., 2018). *Action planning* and *problem solving* as a team was requested following the rehearsal deliveries (see Chapter seven) and was used throughout the training and may have helped with *Behavioural regulation*.

Future delivery of the training package

Delivery of a multi-faceted intervention, including 22 BCTs was complex and requires a large amount of effort to deliver. Whilst training delivery fidelity was not assessed, see Section 9.3 (limitations) developing manuals for facilitators was critical in attempting to maintain fidelity. At present a behavioural scientist/health psychologist would be required to deliver the training, but this could be costly and approaches such as 'train the trainers' might have to be considered. Which would involve training fewer HCPs to deliver the training to their colleagues. Whilst this has its advantages such as reducing the cost of implementation; it has its disadvantages such as concerns around maintaining fidelity of the intervention. A key consideration for this training package is balancing the essential components of the intervention, which led to HCP delivery of behaviours and were acceptable to HCPs with considering how this could be rolled out into future additional sites.

Evaluation of the training package

The evaluation aimed to evaluate delivery of the seven behaviours (see Table 5.2), changes to behavioural determinants such as *social influences*, fidelity of the delivery of some of the seven behaviours and acceptability of the intervention. The evaluation was pragmatic and does have its limitations.

Acceptability data was captured in several ways. There were issues with the use of the Acceptability framework developed by Sekhon and colleagues (2017), see Chapter eight, however, HCPs viewed the training package as acceptable and the delivery of the seven target behaviours acceptable.

Acceptability is critical to assess to ensure intervention users are likely to engage with an intervention (Sekhon et al., 2017). Capturing information about recruitment indicates whether the training package was acceptable or not. 6/23 HCPs from the clinical teams did not attend the training due to a lack of engagement (n=3) and a lack of time (n=3). Approaches to engage HCPs could be to meet virtually or face to face prior to discuss the research, provide informative and clear information about the research within the participant information sheets and gain the support of senior clinicians and management.

Assessing behaviour and behavioural determinants alongside each other was a strength, see Chapter eight. Behaviour was assessed using observation, collection of process data and patient recall. Having direct observational data of

these behaviours would have been a more methodological sound approach and is viewed as the gold standard (Hrisos et al., 2009). However, maintaining the balance between high quality data collection and limiting being intrusive is difficult. The data necessary to be captured for this research took place in clinical consultations between HCPs and men with prostate cancer on ADT. To have a trained observer to sit in these consultations would potentially provoke an ethical issue, due to the nature of the conversation between the HCP and patient, especially at the point of diagnosis. Additionally, direct observation may be costly if a trained observer is required. Further work is required to find acceptable research measures for HCPs, this is discussed in more detail in section 9.1.4. Furthermore, treatment fidelity could have been assessed in further detail and this would have been of benefit to the research. This is specifically discussed in the methodological limitations of the study in Section 9.3.

The behavioural determinants were assessed pre, post and between 8-12 weeks following training using the questionnaire based on the TDF. Assessing determinants directly following training was a strength of the research, as it reduces issues with recall. However, this could explain why changes in some beliefs reduced at 8-12 weeks as intentions may have been high directly following training, but these changed when HCPs were delivering the behaviours in their role. The TDF offered an extensive framework that captured multiple determinants of behaviour and has been used throughout this thesis. The TDF questionnaire aimed to understand barriers to specific behaviours, so it is not applicable to other settings, but gaining this level of depth and detail about possible changes to behavioural determinants was necessary for this study, see Chapter eight.

9.1.4 Integrating research into clinical practice and strategies to aid the evaluation of fidelity in complex interventions

Engaging clinicians in this research has been challenging and other research suggests barriers to research from HCPs include as time and a lack of confidence (Heiwe et al., 2011). Key learning points from this process are now discussed.

Challenges of engaging HCPs within research

A large amount of effort went into understanding barriers to HCPs providing exercise recommendation, support and referral and developing a complex intervention to address these barriers. However, research also requires HCPs to adopt new behaviours such as to complete a screening log or carry out audio-recordings. These seem to be implemented without any behavioural support or consideration and impacted upon the intervention delivery and assessments of fidelity. Whilst it is important to make the distinction between the intervention itself and the research and operational elements required, strategies could be implemented to aid the delivery of research processes.

Research processes such as screening logs or fidelity assessments need to be acceptable to HCPs (Walton et al., 2017). Working with HCPs and clinical teams on research measures and trialling them beforehand is important. This would be expected within health services research when implementing measures to patients, as they would be trialled beforehand with patients or a patient and public involvement group. Therefore, this learning should be applied when working with professionals. The future cluster randomised trial needs to carry out further work in testing the acceptability of some of these research measures and monitoring the use of them, as suggested in Chapter eight.

Strategies to improve engagement in research processes

HCPs need behavioural support in how to complete and engage with research processes such as fidelity assessments. It would be advised that this support is delivered separately to the intervention, at a site initiation visit for instance. Understanding possible barriers to engaging in research processes would be the first step. Whilst there is a dearth of literature in this area, there is some evidence to suggest reasons for lack of engagement is a shortage of time, resources, lack of knowledge and skills, low confidence and a limited support to deliver research activities (Heiwe et al., 2011; Roll et al., 2013; Syme & Stiles, 2012). After identifying barriers to engagement, behavioural support could be established. Walton et al., (2020) and Williams et al., (2020) provided examples of strategies to enhance engagement with fidelity assessments, see Chapter eight.

For this intervention techniques such as *behavioural practice/rehearsal* and *Feedback on behaviour* could be used to help practice using Dictaphones

during consultations. Using *prompts and cues* within clinics to remind healthcare professionals to carry out certain activities and provide *social support* via telephone or email may be helpful. Additionally, providing examples of senior HCPs completing research activities as a *credible source*. Within this research, prompts and standard operating procedures, were provided within the manuals to the HCPs regarding research activities, to provide further support. However, more behavioural support for the individual HCPs would have been advantageous and is recommended.

9.2 Methodological strengths

The intervention was developed systematically and comprehensively, it is based on the current evidence and theory; the MRC (Craig et al., 2008) and BCW (Michie et al., 2014) frameworks were used. This is a strength of this thesis; a further strength is the involvement of the clinical team and key stakeholders in the development of the HCP training package.

Working as part of a large MDT to develop this intervention was a strength and included expertise from health psychologists, methodologists, academic HCPs, exercise oncology and health services researchers. Intervention development was aided by expert input from several experts from different disciplines being on the research team. This expertise is required when making decisions during the development phase of complex interventions, as discussed earlier in this Chapter.

Context is important for implementation and this is reflected in several theories, models, and frameworks (Nilsen, 2015). The process of understanding the determinants of identified behaviours within the specified context, whilst lengthy, is critical for developing a potentially effective intervention. Understanding the different contexts at both NHS trusts where the intervention was delivered is a strength of this research. Cancer care pathways are complex and differed between sites, see Chapter five. Therefore, the intervention took this into account and ensured the relevant HCPs were trained, depending upon their role. Furthermore, using the TDF to understand these barriers is a strength (Michie, van Stralen, et al., 2011). The TDF was specifically designed to understand barriers from HCPs regarding the implementation of guidelines. Once the key domains that were found to influence behaviour were identified, existing theories were drawn upon to understand the proposed mechanisms of

change, see Chapter six. The TDF helped bridge the gap between what needed to change and identifying theory.

The intervention development process has always considered the implementation of the intervention in the 'real-world', a step that is advocated by O'Cathain and colleagues (2019). Realistic approaches have been taken throughout the development and using the APEASE criteria as part of the BCW process has been helpful concerning this. For example, HCPs suggested further dates for training to be offered, to ensure the whole team was trained as discussed in Chapter seven, but this would not be feasible or practical in the 'real-world', so a decision was made to ensure only two dates of training were offered per site.

The training package is behaviour specific, which is common in interventions aiming to change HCP behaviour (Bull & Dale, 2020). Whilst this could be viewed as a limitation, there are multiple behaviours required to implement such recommendations. These behaviours have been clearly defined as part of this research and future work should focus on the delivery of these behaviours in other clinical populations, which is a strength of this research.

Highlighting the clinical exercise recommendations in the top four most common cancers, see Chapter four, is a strength of this research. Often exercise trials follow generic cancer exercise guidelines but these have been criticised for having a one size fits all approach (Segal et al., 2017b). There is a lack of awareness of the clinical exercise recommendations, even in the field of exercise oncology and this review highlights these recommendations clearly. Future research should focus upon the implementation of other clinical exercise recommendations for other cancers.

9.3 Methodological limitations

The primary limitation of this body of research is that the effect of the intervention is yet to be tested. Changes to HCP behaviour and behavioural determinants were shown and acceptability and fidelity measures of the intervention were assessed, but it cannot be implied that there is effectiveness of the training package on HCP behaviour change as it has not been delivered in a randomised control trial (RCT) setting. However, some important findings have been identified that will feed into the main randomised cluster trial, where

effectiveness will be measured. This thesis sits in a wider programme of work, to have the opportunity to refine and optimise the intervention multiple times is crucial to ensure the intervention is as effective as can be, see page 21.

Suggestions for the future randomised cluster trial are presented in Section 9.6.2.

There was further opportunity within this study to assess other aspects of treatment fidelity, see Chapter eight. Treatment delivery could have been assessed by video-filming training and coding the training against the developed manuals, but due to resources and time, we were unable to achieve this. Furthermore, training providers could have been provided with training to maintain skills and ensure all training providers were delivering similar content. While the use of the same trainers and facilitators manuals helped alleviate this issue, this should be considered if the training were to be rolled out and delivered by several providers. These areas need to be considered in the future, as this will add methodological rigour to the research and intervention itself.

Throughout this research, I have been involved in all aspects of the process, that has led me to developing the intervention, delivering the intervention, and evaluating it. I have also been involved in engaging NHS sites and recruiting participants. Whilst this has allowed me to learn several new skills, in an ideal world, I would have not been involved in the evaluation of the intervention, as this should have been ideally delivered by an independent researcher, to mitigate bias. Furthermore, I was involved in obtaining local research governance at each NHS, this role was extremely valuable. However, this was a difficult task, as obtaining local research governance was a lengthy process and there were often delays but I still had to try and engage HCPs in the future research whilst this process was ongoing. Once local research governance was given, 30 days were given to recruit and consent participants into the study. This was problematic as HCPs needed at least 6-8 weeks' notice to be involved in the training or other research activities. I felt there was often a conflict between being an intervention developer and being a researcher.

9.4 Implications for research

Key findings from this thesis have identified that can inform future complex behavioural interventions and behaviour change research:

To ensure complex behavioural interventions are developed using comprehensive and systematic intervention development frameworks.

Chapter two (specifically Table 2.1) highlights intervention development frameworks available to researchers, these should be considered when developing a complex intervention. These frameworks aid the development process, provide replicable and transparent methodologies that are systematic and structured. Recent guidance from O’Cathain and colleagues (2019), reviewed all published approaches to intervention development such as the BCW and MRC guidance and developed an overall guide to intervention development, including key aspects from published approaches such as including stakeholders and drawing upon theory. Whilst the approach taken in this thesis has carried out most of these steps to intervention development, this body of work drew on several different frameworks and sources to achieve this, as this approach was not available at the time.

To ensure interventions are based on theory and evidence and this is well-reported.

There are many issues with the use of theory to develop and test complex behaviour change interventions. Prestwich and colleagues (2015) highlight the key issues of the use of theory in interventions that this thesis has also highlighted. These are as follows: 1) There is often little use of theory or it is poorly reported and 2) There is often an issue with selecting appropriate theories for interventions. In a review of physical activity and diet interventions, it was found that all of the studies reported a ‘theory-based’ intervention but did not identify theoretical constructs that were targeted or why this theory or BCTs were included (Prestwich et al., 2014). This was also identified in Chapter three and has been observed in other areas of behaviour change interventions reviewed in this thesis. This problem is likely to be due to intervention development frameworks not being clear about how to apply theory to intervention design. The approach taken in this thesis, although it was systematic, would be recommended to ensure the intervention is theory based, (see Section 6.3.2., page 215). It is important to note that there is further efforts taking this forward to think BCTs to theory and make information such as ‘what

will work compared to what, in which context' more accessible (Michie et al., 2017).

To assess behavioural determinants alongside behavioural outcomes

Behavioural determinants such as *social influences* were assessed using a questionnaire based on the TDF, see Appendix S, as well as behavioural outcomes. Whilst effectiveness of the training package cannot be assumed, as the intervention is yet to be tested, assessing behaviour determinants can tell us why or why not interventions may work.

To ensure studies report their interventions using the TIDieR framework (Hoffmann et al., 2014) or GUIDED framework (Duncan et al., 2020).

A lack of clear reporting in intervention papers is a fundamental issue and can contribute to research waste (Hoffmann et al., 2014). This was highlighted in the systematic review in Chapter three and has been observed in other areas of behaviour change interventions reviewed in this thesis. Using frameworks such as TIDieR (Hoffmann et al., 2014) and a more recent guideline; GUIDED framework (Duncan et al., 2020) to report interventions and development processes. The GUIDED framework, whilst not used in this thesis due to it being very recent, focuses on encouraging researchers to report the whole process of intervention development. Whereas TIDieR framework encourages researchers to document the intervention. It is suggested these are complementary to each other (Duncan et al., 2020).

To ensure BCTs are reported using taxonomies within studies and additional techniques that are not included within the BCT taxonomies to be documented within study reporting.

BCTs taxonomies provide researchers with a shared language to report behavioural content (Michie et al., 2013), however, these taxonomies do not appear to be used by researchers in other fields, as found in Chapter three. Using these taxonomies are recommended, so an understanding can be gained of what BCTs are used in effective and non-effective interventions.

To ensure stakeholders and intervention users such as clinical teams are engaged and involved throughout the intervention development process.

Effective stakeholder engagement in research and implementation is important for several reasons (see Chapter seven). Whilst it can be challenging to engage HCPs in research, it should be encouraged from the inception of the research, where possible, as this is likely to have a better outcome in engagement and acceptance.

To assess the acceptability of research processes

As this research highlighted significant problems with assessing fidelity using audio-recordings to assess clinical behaviour. This obstructed the delivery of the intervention to patients as HCPs did not feel comfortable. Ensuring research measures and processes are acceptable to intervention users is important to assess potential barriers to engagement with these. By engaging HCPs in these research assessments these problems could have been identified earlier and addressed.

9.5 Implications for practice

HCPs are the gateway to an exercise referral and can help support patients with exercise. However, there appears to be a lack of consistent behaviour change training in exercise promotion and support for HCPs in cancer within the NHS (Bull & Dale, 2020). There is also desire from HCPs for this training (Bourke et al., 2018) and training should be offered to HCPs who are responsible for providing behavioural support (NICE, 2014). Despite there being no current provision, it would be advised that clear roles of HCPs are defined in providing exercise recommendation and support and to also work together as a clinical team to provide consistent advice to patients.

Whilst this training package is to be further refined and tested following findings from Chapter eight and further delivery in future NHS sites. If found to be effective, this training package could be delivered within the NHS to support the integration of NICE recommendations NG131 1.4.19 and potentially the integration of exercise across other cancers, where an evidence-base is present. Further to this, the NHS 'recovery package' aims to support self-management in patients with cancer, but it is unclear if this is being delivered nationally (NCSI, 2013). This training could ultimately support the

implementation of this aspect of care. HCPs report barriers to discussing lifestyle with cancer survivors and this training aims to overcome these barriers and provide support to HCPs.

HCPs should also consider working in partnership with external providers to deliver exercise provision, as NHS exercise provision is limited and extremely varied (Bourke et al., 2018). Ensuring the HCPs have a mutual trust with the exercise professionals providing the exercise is critical, as this is a common barrier as identified in Chapter five.

Further efforts should be made to incorporate NHS HCPs into research, as these individuals are aware of the context in which the research is being delivered and have a greater understanding of potential barriers and solutions to change. By embedding a research culture into healthcare and involving HCPs in research practices will also aid engagement when delivering research activities within trusts. Whilst there will be good examples of research embedded in clinical care, this research identified more work is required to support HCPs with developing and delivering research.

9.6 Future work and refinements to the training package

Since the development of the HCP training package was delivered and evaluated at two NHS sites in the North of England, see Chapter eight. The HCP training package was further refined following the outcomes of this work and delivered to a third prostate cancer care clinical team at a third NHS site in the South West of England. Following this, the same measures were measured as reported in Chapter eight and a further stakeholder workshop was delivered, following the same methodology as reported in Chapter seven. Following these findings, further refinements, and optimisation of the HCP training package, it will then be tested in a large randomised cluster trial. This will form my post-doctoral work. Key considerations for the future trial and the impact of the current Coronavirus pandemic are discussed below.

9.6.1 Impact of the coronavirus pandemic

Coronavirus is an infectious respiratory disease, that started following an outbreak in China and is a global pandemic (WHO, 2020). Clinical studies have shown individuals with Coronavirus show symptoms of a fever, loss of smell and taste, cough, sore throat, myalgia and fatigue and can cause death (Guan

et al., 2020; Huang et al., 2020). There is currently no vaccine for the prevention of the illness, however, research is being rapidly conducted and shared. The impact of coronavirus has led to changes in policy, healthcare, the economy, and our everyday lives, with lockdown measures being issued across the world to minimise the spread of infections and minimise the burden on our healthcare systems (Iacobucci, 2020).

Considering the recent coronavirus pandemic, there is likely to be several impacts upon this research, the generalisability of this research and future work. The long-term impact of coronavirus men with prostate cancer is unknown, however, research has suggested this patient group may appear to be partially protected from coronavirus due to the effect of ADT on the body (Patel et al., 2020), which is to be further explored. It can be anticipated that there will be significant changes to the delivery of healthcare and the management of all patients such as lack of face to face contact and changes to treatment pathways. Furthermore, it is likely these changes will impact upon HCP beliefs and patients' beliefs with regards to exercise as a treatment component for men on ADT.

The first consideration for the future of this research is whether the beliefs held by HCPs and patients about exercise the same as identified in this thesis and other prior research. It is likely that there are new barriers around delivering exercise recommendation, support, and referral from HCPs in relation to the coronavirus pandemic. The second consideration is the delivery of the HCP training package, would the mode of delivery need to change. It is unsure whether NHS trusts will have the capacity for a face to face training package delivery and whether it would be deemed 'safe' for researchers to train on NHS premises. Online delivery of the interactive training package needs to be explored and whether this would be acceptable to HCPs and NHS trusts. The third consideration is whether usual care for this patient group be the same as before. NICE amongst other guidelines have issued several new recommendations around the delivery of cancer care due to the impact of Coronavirus. For example, NICE have published guidance on the delivery of systemic anticancer treatments which may impact upon patient care (NICE, 2020). Furthermore, care may not be delivered in a face to face setting rather in a virtual setting and the key HCPs who deliver this care may be different from

those previously identified in Chapter five. Therefore, it will need to be identified if there are any significant changes to the pathway that could impact the delivery of the proposed intervention will need to be identified. The fourth and final consideration is how the pandemic might impact men with prostate cancer on ADT. Due to individuals self-isolating, and or shielding, there may be significant impact upon their physical and psychological health. In addition, to the effects cancer and cancer treatment is having upon their bodies already. Physical functioning deteriorates following a cancer diagnosis and is linked with mortality (Brown et al., 2015; Pandya et al., 2019). A prolonged stay at home may exacerbate this and also lead to weight gain, social isolation and reduced physical activity (Lippi, Henry, Bovo, & Sanchis-Gomar, 2020), leading to poorer outcomes.

Overall, it is likely this pandemic will influence this research, patients and the healthcare system, research in this field, and our future work. Whilst these are some of the key considerations of this research due to the coronavirus, there may be further considerations to consider that emerge over the coming months due to the ever-changing context.

9.6.2 Future suggestions for the trial

This thesis focus was the development of a complex HCP intervention. This intervention will be refined further and delivered as part of a large cluster randomised trial as discussed in the wider context of this thesis section on page 21. Following on from the work in this thesis, the training package was delivered to an additional site in the South-West of England. The training package was successful in the delivery of target behaviours behaviour and indicating positive trends in behavioural determinants. Intervention development has no clear end points, but it would be of benefit for furtherer refinement to the training package following the findings of the study. Refinements would be in line with suggestions made following delivery of the HCP training package (see Chapter eight) such as inclusions of video examples of HCPs delivering specific behaviours and changes to the research processes in which key data is collected need to be explored. Further work is required to test the effectiveness of the training package in a randomised control setting as planned and understand how long these changes are sustained.

9.7 Conclusions

This thesis makes an original contribution to knowledge through the development of an evidence and theory-based training package for HCPs to provide exercise recommendation, referral, and support for men with prostate cancer on ADT, all in line with NICE recommendations NG131 1.4.19. This training package was guided by the BCW and MRC intervention development frameworks, drew on theory and evidence and offers further learning of how to develop complex interventions using stakeholder's involvement. Furthermore, this training package led to HCP delivery of the seven target behaviours and positive trends in behavioural determinants were identified to influence HCP behaviour. The training package was found to be acceptable, however, there were issues with the acceptability of the fidelity assessments used.

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Appendices

Appendix A: Search strategies for systematic review

1. CENTRAL search strategy

CENTRAL 2018 update search

#1 MeSH descriptor Neoplasms explode all trees

#2 (cancer* or tumor* or tumour* or neoplas* or malignan* or carcinoma* or adenocarcinoma* or choriocarcinoma* or leukemia* or leukaemia* or metastat* or sarcoma* or teratoma*)

#3 (#1 OR #2)

#4 MeSH descriptor Exercise explode all trees

#5 MeSH descriptor Exercise Movement Techniques explode all trees

#6 MeSH descriptor Exercise Therapy explode all trees

#7 MeSH descriptor Physical Fitness, this term only

#8 (physical* adj5 (fit* or activ*))

#9 (exercis* or aerobic* or resistance* or strength* or walk* or endurance* or lifestyle* or behav*)

#10 (#4 OR #5 OR #6 OR #7 OR #8 OR #9)

#11 #3 and #10

#12 MeSH descriptor: [Health Behavior] explode all trees

#13 MeSH descriptor: [Risk Reduction Behavior] this term only

#14 ((promot* or motivat* or advis* or encourag* or assist* or develop* or stimulat* or help* or support* or organis* or aid* or assist* or endors* or prompt* or driv* or inspire* or lead* or inspir* or further* or advocat* or recommend* or endorse* or foster* or champion*) near/5 (exercis* or aerobic* or resistance* or strength* or walk* or endurance*))

#15 #12 or #13 or #14

#16 #11 and #15

CENTRAL 2012 search

- #1 MeSH descriptor Neoplasms explode all trees
- #2 (cancer* or tumor* or tumour* or neoplas* or malignan* or carcinoma* or adenocarcinoma* or choriocarcinoma* or leukemia* or leukaemia* or metastat* or sarcoma* or teratoma*)
- #3 (#1 OR #2)
- #4 MeSH descriptor Exercise explode all trees
- #5 MeSH descriptor Exercise Movement Techniques explode all trees
- #6 MeSH descriptor Exercise Therapy explode all trees
- #7 MeSH descriptor Physical Fitness, this term only
- #8 (physical* adj5 (fit* or activ*))
- #9 (exercis* or aerobic* or resistance* or strength* or walk* or endurance*)
- #10 (#4 OR #5 OR #6 OR #7 OR #8 OR #9)
- #11 MeSH descriptor Patient Education as Topic, this term only
- #12 (educat* or inform* or teach* or supervis* or communicat* or leaflet*)
- #13 MeSH descriptor Survivors, this term only
- #14 survivor*
- #15 MeSH descriptor Behavior Therapy explode all trees
- #16 (behaviour* or behavior* or cognit* or CBT)
- #17 MeSH descriptor Motivation explode all trees
- #18 MeSH descriptor Interview, Psychological, this term only
- #19 (motivat* or interview*)
- #20 (#11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19)
- #21 (#3 AND #10 AND #20)

2. MEDLINE search strategy

MEDLINE 2018 update search

- 1. exp Neoplasms/
- 2. (cancer* or tumor* or tumour* or neoplas* or malignan* or carcinoma* or adenocarcinoma* or choriocarcinoma* or leukemia* or leukaemia* or metastat* or sarcoma* or teratoma*).ti,ab.
- 3. 1 or 2
- 4. exp Exercise/
- 5. exp Exercise Movement Techniques/
- 6. exp Exercise Therapy/
- 7. Physical Fitness/
- 8. (physical* adj5 (fit* or activ*)).ti,ab.
- 9. (exercis* or aerobic* or resistance* or strength* or walk* or endurance* or lifestyle* or behave*).mp.

10. 4 or 5 or 6 or 7 or 8 or 9

11. 3 and 10

12. exp Health Behavior/

13. risk reduction behavior/

14. ((promot* or motivat* or advis* or encourag* or assist* or develop* or
stimulat* or help* or support* or organis* or aid* or assist* or endors* or prompt*
or driv* or inspire* or lead* or inspir* or further* or advocat* or recommend* or
endorse* or foster* or champion*) adj5 (exercis* or aerobic* or resistance* or
strength* or walk* or endurance*)).ti,ab.

15. 12 or 13 or 14

16. 11 and 15

17. randomized controlled trial.pt.

18. controlled clinical trial.pt.

19. randomized.ab.

20. placebo.ab.

21. clinical trials as topic.sh.

22. randomly.ab.

23. trial.ti.

24. 17 or 18 or 19 or 20 or 21 or 22 or 23

25. (animals not (humans and animals)).sh.

26. 24 not 25

27. 16 and 26

key:

mp=title, abstract, original title, name of substance word, subject heading word,
protocol supplementary concept, rare disease supplementary concept, unique
identifier

pt=publication type

ab=abstract

ti=title

sh=subject heading

MEDLINE 2012 search

1. exp Neoplasms/
2. (cancer* or tumor* or tumour* or neoplas* or malignan* or carcinoma* or adenocarcinoma* or choriocarcinoma* or leukemia* or leukaemia* or metastat* or sarcoma* or teratoma*).mp.
3. 1 or 2
4. exp Exercise/
5. exp Exercise Movement Techniques/
6. exp Exercise Therapy/
7. Physical Fitness/
8. (physical* adj5 (fit* or activ*)).mp.
9. (exercis* or aerobic* or resistance* or strength* or walk* or endurance*).mp.
10. 4 or 5 or 6 or 7 or 8 or 9
11. Patient Education as Topic/
12. Patient education handout/
13. (educat* or inform* or teach* or supervis* or communicat* or leaflet*).mp.
14. Survivors/ or survivor*.mp.
15. exp Behavior Therapy/
16. (behaviour* or behavior* or cognit* or CBT).mp.
17. exp Motivation/
18. Interview, Psychological/
19. (motivat* or interview*).mp.
20. 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
21. 3 and 10 and 20
22. randomized controlled trial.pt.
23. controlled clinical trial.pt.
24. randomized.ab.
25. placebo.ab.
26. clinical trials as topic.sh.
27. randomly.ab.
28. trial.ti.
29. 22 or 23 or 24 or 25 or 26 or 27 or 28
30. 21 and 29
31. exp animals/ not humans.sh.
32. 30 not 31

key:

mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier

pt=publication type

ab=abstract

ti=title

sh=subject heading

3 EMBASE search strategy

EMBASE 2018 update search

1. exp neoplasm/
2. (cancer* or tumor* or tumour* or neoplas* or malignan* or carcinoma* or adenocarcinoma* or choriocarcinoma* or leukemia* or leukaemia* or metastat* or sarcoma* or teratoma*).ti,ab.
3. 1 or 2
4. exp exercise/
5. exp kinesiotherapy/
6. fitness/
7. (physical* adj5 (fit* or activ*)).ti,ab.
8. (exercis* or aerobic* or resistance* or strength* or walk* or endurance* or lifestyle* or behav*).mp.
9. 4 or 5 or 6 or 7 or 8
10. 3 and 9
11. exp health behavior/
12. risk reduction/
13. ((promot* or motivat* or advis* or encourag* or assist* or develop* or stimulat* or help* or support* or organis* or aid* or assist* or endors* or prompt* or driv* or inspire* or lead* or inspir* or further* or advocat* or recommend* or endorse* or foster* or champion*) adj5 (exercis* or aerobic* or resistance* or strength* or walk* or endurance*)).ti,ab.
14. 11 or 12 or 13
15. 10 and 14
16. crossover procedure/
17. double-blind procedure/
18. randomized controlled trial/
19. single-blind procedure/
20. random*.mp.
21. factorial*.mp.

22. (crossover* or cross over* or cross-over*).mp.
23. placebo*.mp.
24. (double* adj blind*).mp.
25. (singl* adj blind*).mp.
26. assign*.mp.
27. allocat*.mp.
28. volunteer*.mp.
29. 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28
30. 15 and 29
31. (exp animal/ or nonhuman/ or exp animal experiment/) not human/
32. 30 not 31

key:

[mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]

EMBASE 2012 search

- 1 exp neoplasm/
- 2 (cancer* or tumor* or tumour* or neoplas* or malignan* or carcinoma* or adenocarcinoma* or choriocarcinoma* or leukemia* or leukaemia* or metastat* or sarcoma* or teratoma*).mp.
- 3 1 or 2
- 4 exp exercise/
- 5 exp kinesiotherapy/
- 6 fitness/
- 7 (physical* adj5 (fit* or activ*)).mp.
- 8 (exercis* or aerobic* or resistance* or strength* or walk* or endurance*).mp.
- 9 4 or 5 or 6 or 7 or 8
- 10 patient education/
- 11 (educat* or inform* or teach* or supervis* or communicat* or leaflet*).mp.
- 12 survivor/ or survivor*.mp.
- 13 behavior therapy/
- 14 cognitive therapy/
- 15 (behaviour* or behavior* or cognit* or CBT).mp.
- 16 motivation/
- 17 interview/
- 18 (motivat* or interview*).mp.
- 19 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18
- 20 3 and 9 and 19

21 crossover procedure/
 22 double-blind procedure/
 23 randomized controlled trial/
 24 single-blind procedure/
 25 random*.mp.
 26 factorial*.mp.
 27 (crossover* or cross over* or cross-over*).mp.
 28 placebo*.mp.
 29 (double* adj blind*).mp.
 30 (singl* adj blind*).mp.
 31 assign*.mp.
 32 allocat*.mp.
 33 volunteer*.mp.
 34 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33
 35 20 and 34
 36 (exp animal/ or nonhuman/ or exp animal experiment/) not human/
 37 35 not 36

key:

[mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]

4 AMED search strategy

Amed Ovid 2018 update search

1 exp neoplasms/

 2 (cancer* or tumor* or tumour* or neoplas* or malignan* or carcinoma* or adenocarcinoma* or choriocarcinoma* or leukemia* or leukaemia* or metastat* or sarcoma* or teratoma*).mp.

 3 1 or 2

 4 exp exercise/

 5 exp exercise therapy/

 6 physical fitness/

 7 (physical* adj5 (fit* or activ*)).mp.

 8 (exercis* or aerobic* or resistance* or strength* or walk* or endurance* or lifestyle* or behav*).mp.

 9 4 or 5 or 6 or 7 or 8

 10 exp Health behavior/

11 ((promot* or motivat* or advis* or encourag* or assist* or develop* or
stimulat* or help* or support* or organis* or aid* or assist* or endors* or prompt*
or driv* or inspire* or lead* or inspir* or further* or advocat* or recommend* or
endorse* or foster* or champion*) adj5 (exercis* or aerobic* or resistance* or
strength* or walk* or endurance*)).ti,ab.

12 10 or 11

13 3 and 9 and 12

key:

mp=abstract, heading words, title

Amed Ovid 2012 search

1 exp neoplasms/

2 (cancer* or tumor* or tumour* or neoplas* or malignan* or carcinoma* or
adenocarcinoma* or choriocarcinoma* or leukemia* or leukaemia* or metastat*
or sarcoma* or teratoma*).mp.

3 1 or 2

4 exp exercise/

5 exp exercise therapy/

6 physical fitness/

7 (physical* adj5 (fit* or activ*)).mp.

8 (exercis* or aerobic* or resistance* or strength* or walk* or endurance*).mp.

9 4 or 5 or 6 or 7 or 8

10 exp patient education/

11 (educat* or inform* or teach* or supervis* or communicat* or leaflet*).mp.

12 survivors/ or survivor*.mp.

13 exp behavior therapy/

14 (behaviour* or behavior* or cognit* or CBT).mp.

15 exp motivation/

16 interviews/

17 (motivat* or interview*).mp.

18 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17

19 3 and 9 and 18

key:

mp=abstract, heading words, title

5 CINAHL search strategy

CINAHL 2018 update search

1 exp NEOPLASMS/

2 (cancer* OR tumor* OR tumour* OR neoplas* OR malignan* OR carcinoma*
OR adenocarcinoma* OR choriocarcinoma* OR leukemia* OR leukaemia* OR
metastat* OR sarcoma* OR teratoma*).af

3 1 OR 2

4 exp EXERCISE/

5 exp THERAPEUTIC EXERCISE/

6 exp PHYSICAL FITNESS/

7 (physical* AND (fit* OR activ*)).af

8 (exercis* OR aerobic* OR resistance* OR strength* OR walk* OR endurance*
or lifestyle* or behave*).af

9 4 OR 5 OR 6 OR 7 OR 8

10 3 and 9

11 exp BEHAVIOR THERAPY/

12. (risk reduction*) AND (behav*)

13 ((promot* or motivat* or advis* or encourag* or assist* or develop* or
stimulat* or help* or support* or organis* or aid* or assist* or endors* or prompt*
or driv* or inspire* or lead* or inspir* or further* or advocat* or recommend* or
endorse* or foster* or champion*) adj5 (exercis* or aerobic* or resistance* or
strength* or walk* or endurance*)).ti,ab.

14 11 or 12 or 13

15 10 AND 14

16 Randomized controlled trials

17 Randomised controlled trials

18 16 or 17

19 15 AND 18

key

af=any field

CINAHL 2012 search

1 exp NEOPLASMS/

2 (cancer* OR tumor* OR tumour* OR neoplas* OR malignan* OR carcinoma*
OR adenocarcinoma* OR choriocarcinoma* OR leukemia* OR leukaemia* OR
metastat* OR sarcoma* OR teratoma*).af

3 1 OR 2

4 exp EXERCISE/

5 exp THERAPEUTIC EXERCISE/

6 exp PHYSICAL FITNESS/

7 (physical* AND (fit* OR activ*)).af
 8 (exercis* OR aerobic* OR resistance* OR strength* OR walk* OR endurance*).af
 9 4 OR 5 OR 6 OR 7 OR 8
 10 exp PATIENT EDUCATION/
 11 (educat* OR inform* OR teach* OR supervis* OR communicat* OR leaflet*).af
 12 CANCER SURVIVORS/
 13 survivor*.af
 14 exp BEHAVIOR THERAPY/
 15 (behaviour* OR behavior* OR cognit* OR CBT).af
 16 exp MOTIVATION/
 17 MOTIVATIONAL INTERVIEWING/
 18 (motivat* OR interview*).af
 19 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17 OR 18
 20 3 AND 9 AND 19
 21 RANDOMIZED CONTROLLED TRIALS/
 22 20 and 21

6 PsycINFO search strategy

PsycINFO 2018 update search

1 neoplasms.af

 2 ((cancer* OR tumor* OR tumour* OR neoplas* OR malignan* OR carcinoma* OR adenocarcinoma* OR choriocarcinoma* OR leukemia* OR leukaemia* OR metastat* OR sarcoma* OR teratoma*)).ti,ab

 3 exercise.af

 4 (physical AND fitness).af

 5 ((physical* adj5 (fit* OR activ*))).ti,ab

 6 ((exercis* OR aerobic* OR resistance* OR strength* OR walk* OR endurance* OR lifestyle* OR behave*)).af

 7 1 OR 2

 8 3 OR 4 OR 5 OR 6

 9 (health AND behaviour).af

 10 (risk AND reduction AND behaviour).af

 11 (((promot* OR motivat* OR advis* OR encourag* OR assist* OR develop* OR stimulat* OR help* OR support* OR organis* OR aid* OR assist* OR endors* OR prompt* OR driv* OR inspire* OR lead* OR inspir* OR further* OR advocat* OR recommend* OR endorse* OR foster* OR champion*) adj5

(exercis* OR aerobic* OR resistance* OR strength* OR walk* OR endurance*))) .ti,ab

12 9 OR 10 OR 11

13 7 AND 8 AND 12

PsycINFO Ovid 2012 search

1 exp neoplasms/

2 (cancer* or tumor* or tumour* or neoplas* or malignan* or carcinoma* or adenocarcinoma* or choriocarcinoma* or leukemia* or leukaemia* or metastat* or sarcoma* or teratoma*).mp.

3 1 or 2

4 exp exercise/

5 physical fitness/

6 (physical* adj5 (fit* or activ*)).mp.

7 (exercis* or aerobic* or resistance* or strength* or walk* or endurance*).mp.

8 4 or 5 or 6 or 7

9 client education/

10 (educat* or inform* or teach* or supervis* or communicat* or leaflet*).mp.

11 survivors/ or survivor*.mp.

12 exp cognitive behavior therapy/

13 exp behavior therapy/

14 (behaviour* or behavior* or cognit* or CBT).mp.

15 exp motivation/

16 motivational interviewing/

17 (motivat* or interview*).mp.

18 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17

19 3 and 8 and 18

20 clinical trials/

21 (random* or trial* or group* or placebo*).mp. mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures

22 20 or 21

23 19 and 22

key:

[mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]

7 PEDro search strategy

PEDro 2012 search

- Title and abstract: "cancer"
- Therapy: fitness training (selected)
- Sub discipline: oncology (selected)
- Method: clinical trial (selected)

8 SPORTS DISCUS search strategy (EBSCO host)

Sports discus update 2018 search

1. TX cancer* OR tumor* OR tumour* OR neoplas* OR malignan* OR carcinoma* OR adenocarcinoma* OR choriocarcinoma* OR leukemia* OR leukaemia* OR metastat* OR sarcoma* OR teratoma* (26,616)
2. TX randomi*ed controlled trial (12,682)
3. (TX randomi*ed controlled trial) AND (S4 AND S5) (636)
4. Limiters - Published Date: 20120101-20171231 (411)

Appendix B: Risk of bias domains and definitions

Risk of bias domains	Definition of domains
Sequence generation (method of randomisation)	Low risk of bias (e.g. participants assigned to treatments on basis of a computer-generated random sequence or a table of random numbers)
	High risk of bias (e.g. participants assigned to treatments on basis of date of birth, clinic ID number or surname, or no attempt to randomly assign participants)
	Unclear risk of bias (e.g. not reported, information not available)
Allocation concealment (selection bias)	Low risk of bias (e.g. when the allocation sequence could not be foretold)
	High risk of bias (e.g. allocation sequence could be foretold by participants, investigators or treatment providers)
	Unclear risk of bias (e.g. not reported)
Blinding (masking) of participants and personnel (detection bias)	Low risk of bias, if participants and personnel were adequately blinded
	High risk of bias, if participants were not blinded to the intervention that the participant received
	Unclear risk of bias, if this was not reported or was unclear
Blinding (masking) of outcome assessors (detection bias)	Low risk of bias, if outcome assessors were adequately blinded
	High risk of bias, if outcome assessors were not blinded to the intervention that the participant received
	Unclear risk of bias, if this was not reported or was unclear
Incomplete outcome data	Low risk of bias, if fewer than 20% of participants were lost to follow-up and reasons for loss to follow-up were similar in both treatment arms
	High risk of bias, if more than 20% of participants were lost to follow-up or reasons for loss to follow-up differed between treatment arms
	Unclear risk of bias, if the loss to follow-up was not reported
Selective outcome reporting	Low risk of bias (e.g. review reports all outcomes specified in the protocol)
	High risk of bias (e.g. if it is suspected that outcomes have been selectively reported)

	Unclear risk of bias (e.g. if it is unclear whether outcomes were selectively reported)
Other sources of bias	Low risk of bias, if no other source of bias is suspected and the trial appears to be methodologically sound
	High risk of bias, if it is suspected that the trial was prone to an additional bias
	Unclear risk of bias, if uncertainty exists about whether an additional bias may have been present

Appendix C: Rapid review searches

Searches

NICE evidence database searches

Filtered by Guidance tab

1. Breast cancer (n= 905)
2. Prostate cancer (n= 671)
3. Lung cancer (n=1057)
4. Colorectal cancer (n= 572)

TRIP database searches

Filtered by Guidelines tab

1. Breast cancer (n= 617)
2. Prostate cancer (n= 246)
3. Lung cancer (n=500)
4. Colorectal cancer (n= 284)

National Guideline Clearing house

1. Breast cancer (n= 146)
2. Prostate cancer (n= 70)
3. Lung cancer (n=162)
4. Colorectal cancer (n= 77)

International guideline library

Filtered by Guidelines tab and English language tab

1. Breast cancer (n= 51)
2. Prostate cancer (n= 23)
3. Lung cancer (n=46)
4. Colorectal cancer (n= 20)

BMJ Best practice

1. Prostate cancer (n=26)
2. Breast cancer (n= 28)
3. Lung cancer (n= 11)
4. Colorectal cancer (n= 26)

Total

- Prostate (n=1036)
- Breast (n=1747)
- Lung (n= 1776)
- Colorectal (n= 979)

191 guideline panels identified.

Appendix D: Identified relevant guideline panels

Guideline panels	Abbreviation	Cancer(s) covered in guideline	Country/ Continent	Website searched
American College of Chest Physicians	CHEST	Lung	USA	http://www.chestnet.org/
American College of Gastroenterology	ACG	Colorectal	USA	https://gi.org/
American College of Physicians	ACP	All	USA	https://www.acponline.org/
American Gastroenterology Association	AGA	Colorectal	USA	http://www.gastro.org/guidelines
American Society of Clinical Oncology	ASCO	All	USA	https://www.asco.org/
American Urological Association	AUA	Prostate	USA	http://www.auanet.org/guidelines
Australian Cancer Network	ACN	All	Australia	http://www.cancer.org.au/health-professionals/clinical-guidelines/
British Association of Urological Surgeons	BAUS	Prostate	UK	https://www.baus.org.uk/
British Society of Gastroenterology	BSG	Colorectal	UK	https://www.bsg.org.uk/site-search.html?q=cancer
British Thoracic society	BTS	Lung	UK	https://www.brit-thoracic.org.uk/

Canadian Clinical Practice	CCP	All	Canada	https://www.cma.ca/En/Pages/clinical-practice-guidelines.asp
Canadian Urological Association	CUA	Prostate	Canada	https://www.cua.org/en
Cancer care Ontario	CCO	All	Canada	https://www.cancercareontario.ca/en/guidelines-advice
Cancer Control Alberta	CCA	All	Canada	https://www.albertahealthservices.ca/info/cancerguidelines.aspx
Cancer Australia	CA	All	Australia	https://canceraustralia.gov.au/clinical-best-practice/cancer-types
European Association of Urology	EAU	Prostate	Europe	http://uroweb.org/
European Respiratory Society	ERS	Lung	Europe	https://www.ersnet.org/
European Society for Medical Oncology	ESMO	All	Europe	http://www.esmo.org/Guidelines
Ministry of Health	MoH	All	New Zealand	http://www.health.govt.nz/
National Comprehensive Cancer Network	NCCN	All	USA	https://www.nccn.org/
National Health and Research Medical Council	NHRMC	All	Australia	https://www.nhmrc.gov.au/
National Institute of Clinical Excellence	NICE	All	UK	https://www.nice.org.uk/

Scottish Intercollegiate Guidelines Network	SIGN	All	Scottish	http://www.sign.ac.uk/
World Gastroenterology Organisation	WGO	Colorectal	World	http://www.worldgastroenterology.org/

Appendix E: Originally identified target behaviours

Target behaviour	Why is this behaviour important?	Who?		When? /How often?	Does this meet the APEASE criteria?
		Trust one	Trust two		
Recognise whether a patient is suitable for exercise	Many patients will be able to exercise with the correct supervision, however, there are some contraindications to exercise that need to be considered by the HCPs for the safety of the patients.	Any member of the clinical team	Any member of the clinical team	At any point within the pathway/ At any clinical visit	Yes
Recommend exercise training in line with NICE recommendations	NICE NG131 1.4.19 state all people with prostate cancer should be offered an	Any member of the clinical team	Any member of the clinical team	At any point within the pathway/ At any clinical visit	Yes

	exercise programme who are commencing or undergoing ADT.				
Discuss barriers and facilitators around exercise training	It is likely patients will need support around exercise training and evidence suggests this has beneficial effects on patients engagement in exercise.	Keyworker: CNS	Keyworker: CNS	At the point of an exercise referral/	Yes
Provide patient with information pack and materials	Patients have expressed a want for information packs and materials to be	Keyworker: CNS	Keyworker: CNS	At the point of an exercise referral/ Once when a referral is made	Yes

	given around exercise.				
Make referral for exercising training	NICE NG131 1.4.19 state all people with prostate cancer should be offered an exercise programme who are commencing or undergoing ADT.	Keyworker: CNS	Keyworker: CNS	At any point within the pathway/ Once when making a referral	Yes
Read and interpret an exercise progress report from exercise professionals	Feedback loops between the NHS and exercise professionals have been identified as important for patient support and feedback.	Consultant Urologist	Keyworker: CNS	Follow up appointment	Yes

Provide feedback to the patient on the exercise progress report	Feedback loops between the NHS and exercise professionals have been identified as important for patient support and feedback.	Consultant Urologist	Keyworker: CNS	Follow up appointment	Yes
Provide information to the exercise professionals on the health of the patient to exercise	If there are any contraindications to exercise that HCPs has identified, the exercise professional needs to be aware of these.	Consultant Urologist	Consultant Urologist	At the point of an exercise referral	No - Specialist HCPs such as Urologists or CNS are not best placed to provide exercise professionals with information on the health of the patient to exercise.
Provide an exercise	An exercise prescription would be given to the patient, in the same	Consultant Urologist	Consultant Urologist	At the point of an exercise referral	No - Exercise prescriptions should be offered by an appropriately trained person. HCPs are not

prescription to the patient	way, a prescription would be given for drugs.				necessarily trained to facilitate this. However, it is important that when the exercise is recommended it is recommended as a treatment component
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Appendix F: Semi-structured interview schedule for healthcare professionals based on theoretical domains framework

Semi-structured interview schedule

Introduction

Thank you for your time in taking part in this interview. We are interested in your perspective regarding roles, responsibilities and training needs associated with providing supervised exercise programmes for men with prostate cancer on ADT. By supervised exercise, we mean a structured programme of exercise training delivered and overseen by a professional.

We would like to audio record the interviews but these will be completely confidential and all data will be anonymised in transcription and analysis. Can you please confirm you have read, understood and signed the informed consent form and are happy to proceed?

Questions

- Can you tell me a little about your current role in the care pathway for men with prostate cancer on androgen deprivation therapy (ADT)?
- How do your patients cope with their cancer and ADT?
- What are the common adverse effects with this treatment, and which do you feel men find most bothersome?
- How would you say being on ADT for prostate cancer affects men's quality of life?
- Are you aware of any non-pharmacological treatment or any supportive programmes designed to improve quality of life for men on ADT?
- What do you know about the role of exercise in treating men with PC? (knowledge)
- Are you aware of any guidance? Can you tell me what the NICE recommendations are as you see them? (knowledge)

- How do you feel about behaviour change strategies like looking at worries and concerns and setting goals? Do you think they have a role in exercise programmes? (beliefs about consequences)

Current guidance recommends men with prostate cancer on ADT have access to supervised exercise which should include an exercise prescription as well as behavioural support such as goal setting and addressing worries and concerns.

- How do you feel about this:

- As part of standard NHS practice?

- Should this be separate from NHS care?

- What is your organisation already doing with regards to exercise for men with prostate cancer? (memory, attention, decision)
- Are you currently involved in setting goals with your patients and do you follow up on whether these are achieved or not?
- Are you aware of any exercise programmes for other patient groups? How beneficial do you think exercise/exercise programmes would be for your patients with prostate cancer?
- Who's role would you see it as to i) make referrals for exercise programmes ii) delivery of exercise? (social/professional role identity)

- Should this take place in primary/secondary care/community/outpatient settings (who specifically?)

**Probe* who should introduce idea to patient, delivering exercise (prescription & behaviour change elements), following up with patients the amount of exercise being done. If you do not see it as your role, can you elaborate as to why and who might be better placed?*

- Have you been involved in referral or delivery of exercise programmes to any other patient groups in the past?

Our research team are hoping to evaluate how a 12 week, or 12 month, supervised exercise programme could be delivered in the NHS for men on ADT. This will require professionals in your role to support this process. That might involve making referrals, delivering the exercise programme and providing specialised behaviour change support. How would you feel if one or more of these elements became part of your role? (social/professional role identity, emotion)

- What applicable skills do you think you currently have? Do you think you'd be able to new relevant learn skills (what training would that need) (skills)
 - Given training do you think you'd feel confident in doing this? (optimism)
 - How difficult or easy do you think it would be for you to do? (beliefs about capabilities)
 - Would it be something you'd like to do (all/part/none)? (goals)
 - Would it be compatible with how you see your role? (social/professional role identity)
 - How do you think your colleagues/seniors e.g. consultants/managers would respond, would this help or be a problem? (social influences)
 - Would there be capacity to support a 12 week or 12 month programme?
- What would help to facilitate capacity? (environmental context and resources)

- Given people were trained and happy to do this what barriers might there be to putting it in place from your point for view? Does this differ between a 12 week and 12 month commitment?(environmental context and resources)

- Practical/resource
 - From staff, patients, systems?
 - What do you think would happen if you did take this on? (for self/patients)
 - If this did become part of your role is there anything which would make it more likely you'd do it (incentives), what would these look like?
- (Reinforcement)
- Would there be systems that could help monitor if it's being done, make it easier? (Behavioural regulation)

If the exercise programme was put in place what do you think patients would think about it?

- Positive/negative reactions
- Barriers to attending,
- What would make them more likely to attend and maintain their involvement?

- Going back to training, if this was to take place, would you be able to undertake training sessions in your current role?
- What would be the best way to deliver the training?

**Probe* format, length, time of day, location, number of sessions, duration of sessions, practical element with supervision, including videoing?*

- Would you be prepared to do things like homework, keep a reflective journal?
- If we were to develop a training programme with a view to implementing an intervention would you be interested in taking part? (Intention)

- If not, why not?

Appendix G: Semi-structured interview schedule based on amendment

Semi-structured interview questions: based on 2015 STAMPEDE results

STAMPEDE trial data

- The standard of care for advanced hormone sensitive prostate cancer is long term-androgen deprivation therapy. How much do you agree with this statement?
- Recent data from the STAMPEDE and CHAARTED trial suggest there to be a survival benefit in initiating chemotherapy earlier in the hormone sensitive advanced PCa pathway. Do you feel the recent findings of the trials will change the standard of care, and to what extent?
[PROBE]
 - How might you change your own practice?

The HCPs role and current pathway for men with metastatic castrate resistant prostate cancer (mCRPC)

- What is your role within the care pathway for men whose cancer has relapsed (i.e. become castrate resistant)?
[PROBE]
 - Involved in the treatment of these men: How do you typically sequence treatment for men with mCRPC? [Chemotherapy first? 2nd line ADT first? Other?]
 - Will this change based on the STAMPEDE and CHAARTED trial data?
- For these men (mCRPC), what are the most common reasons that effect not only the initiation of 2nd line treatment but also the duration?
[PROBE]
 - Fitness - How might you assess these men for fitness to initiate 2nd line treatment and what specifically might you find that would prevent you in prescribing such treatment?
 - Impact on QoL - What specifically may result in a poorer QoL?
 - Clinician's advice - What specifically may influence the clinician?
- In your experience what do you consider to be the most important outcome for men with mCRPC?
- What supportive and/or palliative programmes for men with mCRPC do you know of?
[PROBE]
 - Would you refer routinely into such programmes and if so what factors might prompt you to?
 - Local / National?
 - In your opinion how successful have they been?

Muscle loss and cachexia in mCRPC

- In your experience, what adverse effects do you consider to have the most impact on men with mCRPC?
[PROBE]
 - Treatment specific?
 - Disease specific?
- What impact does muscle wastage have on these men?
[PROBE]
 - Do you consider it to be clinically important?

- What do you do currently to address muscle wastage in men with mCRPC?
[PROBE]
 - Do you consider the cause of muscle wastage? (do you distinguish between muscle wastage associated with ADT and inactivity or cachexia and sarcopenia) - is there any merit to that?
 - How do you assess?
 - What treatments might you implement?
 - How successful have you found these? Adverse effects?
 - What might prompt you to initiate such treatments?
 - Are there any barriers to addressing muscle wastage?
- Are there any specific therapies you might offer for a man with mCRPC with suspected cachexia or early onset cachexia? (different to treatment strategies for muscle wastage)
[PROBE]
 - What therapies?
 - How successful have you found these therapies?

Prostate cancer and exercise interventions

- What do you know about the role of exercise in treating men with PCa?
[PROBE]
 - Could you describe any guidance or recommendations you are aware of for these men?
- What is your organisation already doing with regards to exercise for men with prostate cancer on ADT?
- How beneficial do you think exercise/exercise programmes would be for your patients with mCRPC?
[PROBE]
 - Would you be prepared to directly advocate and be personally involved in exercise programmes for men in your clinics?
 - Where do you think exercise should fit in the treatment pathway for men with mCRPC? (Before initiation of chemotherapy/2nd line ADT, during or after?)
 - Are there any additional behavioural change strategies you feel might complement exercise programmes?
- Which health care professional do you feel should be responsible for referring and following up exercise interventions in men with mCRPC?
[PROMPT] Urologist/Oncologist/GP/other?
- What are the barriers you foresee for men with mCRPC in enrolling in a 12 week exercise programme?
[PROBE]
 - Practical/resource (Is there currently capacity?)
 - From staff, patients, systems?
 - Patient related personal barriers?

Novel pharmacological agents in combination with exercise

- How would you feel about allowing your patients take novel pharmaceutical agents with anabolic effects that might improve the response to exercise?
[PROBE]
 - Would you be concerned with androgenic effects? (Which ones and why?)
 - [Dependant on response] What anabolic agents do you have specific knowledge of to make you feel this way?

- If there was an evidence based intervention that clearly improved patient outcomes, do you think there is a place for such a combination of therapies in the NHS?

Our research team are hoping to evaluate how a 12 week supervised exercise programme, potentially in combination with a pharmaceutical agent to improve response, can be delivered in the NHS for men initiating 2nd line treatment for mCRPC. This will require professionals in your role to support this process.

- How would you feel about referring your mCRPC men to a study which would investigate:
 - a) An exercise intervention alone
 - b) An exercise intervention in combination with a SARM (describe if not known)
 - c) An exercise intervention in combination with an anabolic steroid
- Given what we have spoken about today, how would you move forward to improve outcomes in men with mCRPC?
[PROBE]
 - What would be the best approach?
 - Where should research be focussed?
- Is there anything else you would like to add?

Appendix H: Participant information for healthcare professional interviews



The
University
Of
Sheffield.

Sheffield Teaching Hospitals
NHS Foundation Trust



NHS
National Institute for
Health Research

PARTICIPANT INFORMATION SHEET: HEALTH PROFESSIONAL INTERVIEWS

Version 1.1 21/08/15

**Sustained exercise TrAining for Men with prostate caNcer on Androgen
deprivation:**

the STAMINA programme

We would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully.

What is the purpose of the study?

In July 2014, NICE published updated guidelines for the diagnosis and treatment of prostate cancer. This included a recommendation that men with prostate cancer on androgen deprivation therapy (ADT) should be offered 12 weeks of supervised resistance and aerobic exercise at least twice a week, to reduce fatigue and improve quality of life.

The aim of this study is to understand the perspectives of different health care professionals in primary and secondary care regarding their role in providing supervised exercise programmes as part of cancer care for men on ADT. This will be done using semi-structured interviews.

What are the possible benefits of taking part?

We cannot promise that taking part in this study will help you personally, but the information you provide will be very useful to the research team in terms of evaluating if exercise training can be part of improving cancer care in the NHS.

What are the possible disadvantages of taking part?

We will ask you to give up your time to take part in the interview. We hope not to take more than 40 minutes.

Why have I been invited to take part?

You have been invited to participate because of your role as a health professional and your expertise in cancer, exercise or primary care.

Do I have to take part?

It is up to you to decide whether or not to take part in this research. If you agree to be interviewed you will be asked to sign a consent form to show that you have read this information sheet and agreed to take part. You are free to withdraw from the study at any time, without giving a reason. Taking part in this study will not affect your legal rights.

What will happen to me if I take part?

If you decide to take part in the study, one of the research staff will ask you to let us know when we can visit you to perform the interview or tell us when you could be

interviewed over the phone. The discussion will last around 30-40 minutes and will take place at a time and date convenient to you.

The topics to be discussed will include your current role in treating or supporting men with prostate cancer on ADT and your perceptions of how their quality of life can be positively or negatively affected, as well as your views regarding the role of exercise within treatment and support.

You do not have to answer or comment on anything that you would prefer not to. You will be asked to agree to the discussion being audio recorded by signing the consent form.

What if I change my mind during the study?

You are free to withdraw from the study at any time.

Will my involvement in the study be kept confidential?

Yes. We will follow legal and ethical practice and all information about you will be handled in strict confidence.

We will transcribe the recordings of the interviews and will be writing up a report of the findings but we will not use your real name anywhere in the report. When we are analysing the data it will only be seen by the research team and it will be stored securely according to the Data Protection Act.

What will happen to the information from the study?

The results of the study will be used to develop research which will test if we can effectively deliver exercise training for men on ADT as a brand new supportive cancer therapy. The overall (and anonymised) results will be written up for publication in scientific journals, will be fed back to patient groups, charities and also be fed back to national bodies such as the National Cancer Research Institute. We will be able to provide you with the overall results on request. You can request a copy of your interview transcript and let us know if you would like to amend anything you said.

What action will be taken if the interviews find that the NICE guidelines are not being followed?

All the results from these interviews will be anonymised and fed back to the clinical team providing care for men with prostate cancer in your area. No specific action will be taken by the research team.

Who has reviewed this study?

This study has been reviewed by the South West – Cornwall and Plymouth Research Ethics committee.

Who is funding the study?

This study has been funded by the National Institute for Health Research.

Who has checked the ethical implications of this study?

The South West – Cornwall and Plymouth Research Ethics committee has reviewed and approved this study.

What if I have further questions or would like more information about the study?

If you would like more information about the study you are invited to contact:-

Dr Liam Bourke 5396	Project Supervisor	Tel: 0114 225
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Mr Derek Rosario 3223	Chief Investigator	Tel: 0114 271
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What happens if I have a complaint?

If you have any cause to complain about any aspect of the way in which you have been approached or treated during the course of this study, please contact the project supervisor Dr Liam Bourke 0114 2255396.

THANK YOU FOR TAKING THE TIME TO CONSIDER PARTICIPATING IN THIS STUDY

MR DEREK ROSARIO

STH18391 STAMINA WS2, PIS, v1.1, 21/08/15

Appendix I: Healthcare professional interview theoretical domains framework coding manual

Coding rules and suggestions

- Code data into TDF domains deductively where applicable.
- If uncertainty, code data into 'miscellaneous' and discuss this as a team.
- If necessary, code data into more than one domain.
- Where applicable, code data into one of three categories relating to 1) HCPs views on their behaviour as HCPs, 2) views on patients behaviour and 3) views on exercise professional behaviour.

Codes	Description taken from (Cane et al., 2012)	Constructs taken from (Cane et al., 2012)
Knowledge	An awareness of the existence of something.	<ul style="list-style-type: none">• Knowledge (including knowledge of condition /scientific rationale)• Procedural knowledge• Knowledge of task environment
Skills (Physical and cognitive interpersonal skills)	An ability or proficiency acquired through practice.	<ul style="list-style-type: none">• Skills• Skills development• Competence• Ability• Interpersonal skills

		<ul style="list-style-type: none"> • Practice • Skill assessment
Memory, attention and decision processes	The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives.	<ul style="list-style-type: none"> • Memory • Attention • Attention control • Decision making • Cognitive overload / tiredness
Behavioural regulation	Anything aimed at managing or changing objectively observed or measured actions.	<ul style="list-style-type: none"> • Self-monitoring • Breaking habit • Action planning
Social/professional role and identity	A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting.	<ul style="list-style-type: none"> • Professional identity • Professional role • Social identity • Identity • Professional boundaries • Professional confidence • Group identity • Leadership • Organisational commitment

Beliefs about capabilities	Acceptance of the truth, reality or validity about an ability, talent or facility that a person can put to a constructive use.	<ul style="list-style-type: none"> • Self-confidence • Perceived competence • Self-efficacy • Perceived behavioural control • Beliefs • Self-esteem • Empowerment • Professional confidence
Optimism	The confidence that things will happen for the best or that desired goal will be attained.	<ul style="list-style-type: none"> • Optimism • Pessimism • Unrealistic optimism • Identity
Beliefs about consequences	Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation.	<ul style="list-style-type: none"> • Beliefs • Outcome expectancies • Characteristics of outcome expectancies • Anticipated regret • Consequents
Intentions	A conscious decision to perform a behaviour or a resolve to act in a certain way.	<ul style="list-style-type: none"> • Stability of intentions • Stages of change model • Transtheoretical model and stages of change

Goals	Mental representations of outcomes or end states that an individual wants to achieve.	<ul style="list-style-type: none"> • Goals (distal / proximal) • Goal priority • Goal / target setting • Goals (autonomous / controlled) • Action planning • Implementation intention
Reinforcement	Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus.	<ul style="list-style-type: none"> • Rewards (proximal / distal, valued / not valued, probable / improbable) • Incentives • Punishment • Consequents • Reinforcement • Contingencies • Sanctions
Emotion	A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event.	<ul style="list-style-type: none"> • Fear • Anxiety • Affect • Stress • Depression • Positive / negative affect

		<ul style="list-style-type: none"> • Burn-out
Environmental context and resources	Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour.	<ul style="list-style-type: none"> • Environmental stressors • Resources / material resources • Organisational culture /climate • Salient events / critical incidents • Person x environment interaction • Barriers and facilitators
Social influences	Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours.	<ul style="list-style-type: none"> • Social pressure • Social norms • Group conformity • Social comparisons • Group norms • Social support • Power • Intergroup conflict • Alienation • Group identity • Modelling
Miscellaneous	This code is reserved for anything that cannot be coded but is important to consider in this analysis.	

Appendix J: Topic guide for healthcare professional rehearsal delivery

Topics to be include in group discussion following Two-hour basic HCP training (PCa care team training) on exercise and PCa care (work package 2i) (Based on Kirkpatrick 1977)

How do you feel about the training experience?

- Content - Was it understandable? Was it enjoyable?
- Delivery - Was it pitched at the correct level?
- Was the duration correct? Delivered by right personnel

Did participants feel they had learned something new from the training? What new skills/information do you feel you have learnt from the course?

- probe (different skills targeted)

Do you think there are other topics/skills that would have been useful to include in the training? Were there any aspects of the course which you didn't find helpful?

How confident do you feel in being able to use these skills as part of the STAMINA intervention/ in routine practice

- What would increase your confidence?

How motivated do you feel to deliver STAMINA within your team?

- Probe, all members of team
- Anything that could aid motivation

Do you see any barriers to using these skills in practice/ Are there any things which could make it easier?

How do you feel patients will respond to this new approach?

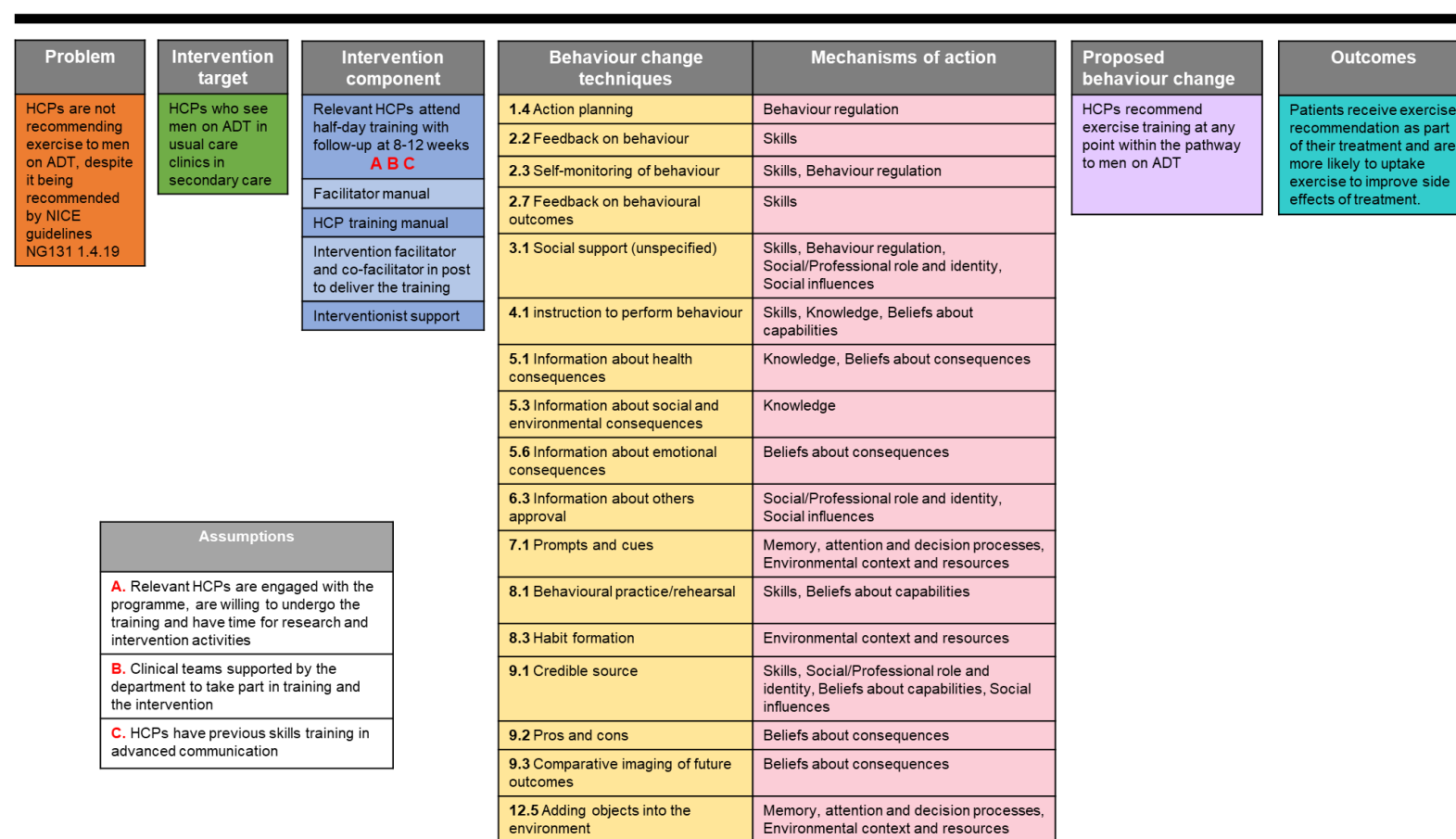
- Helpful?
- Acceptable to patients?

Would you recommend the course to others?

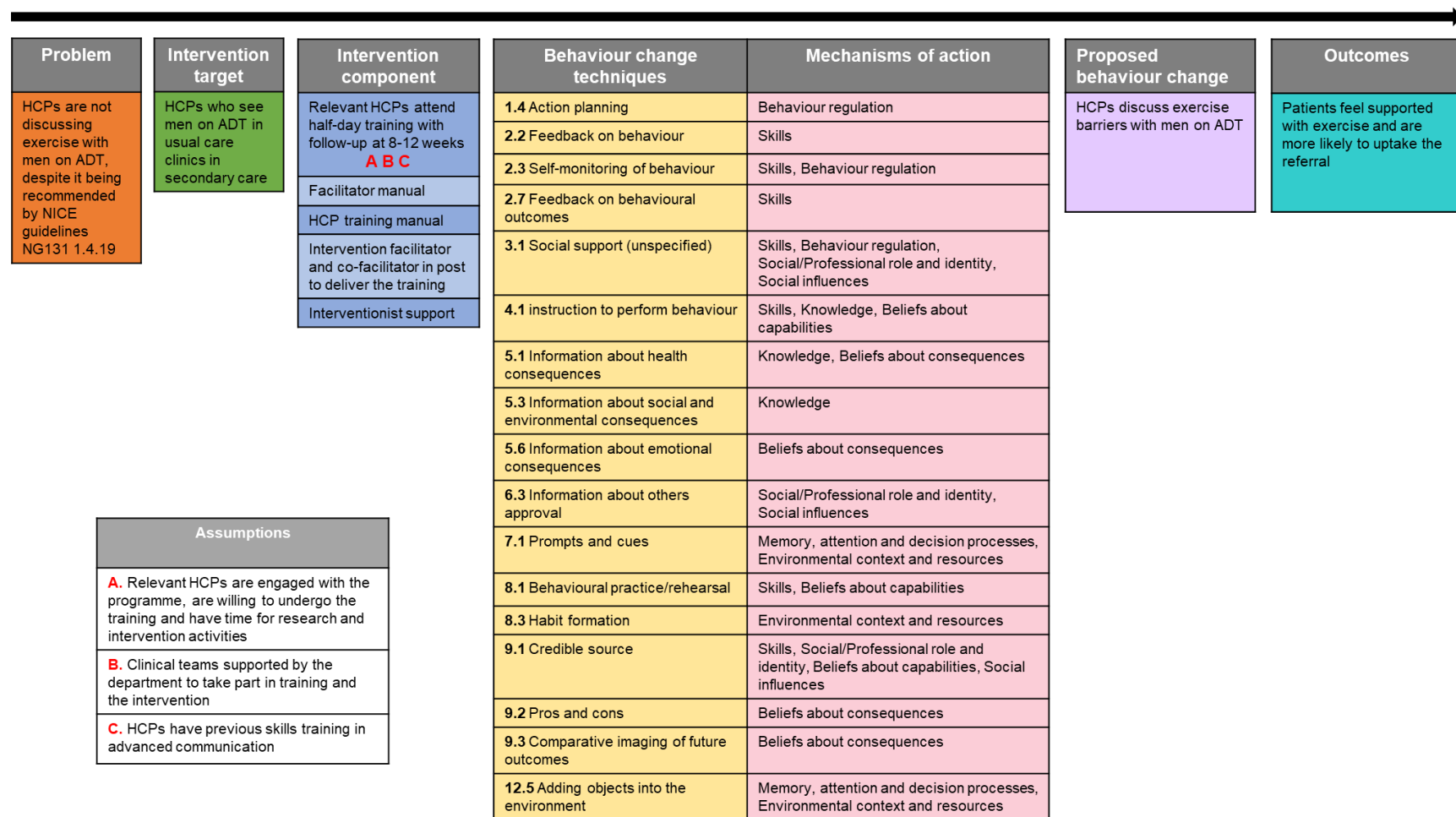
Reference

Kirkpatrick, D.L. (1977) „Evaluating training programs: Evidence vs proof“, Training and Development Journal, pp.9-12.

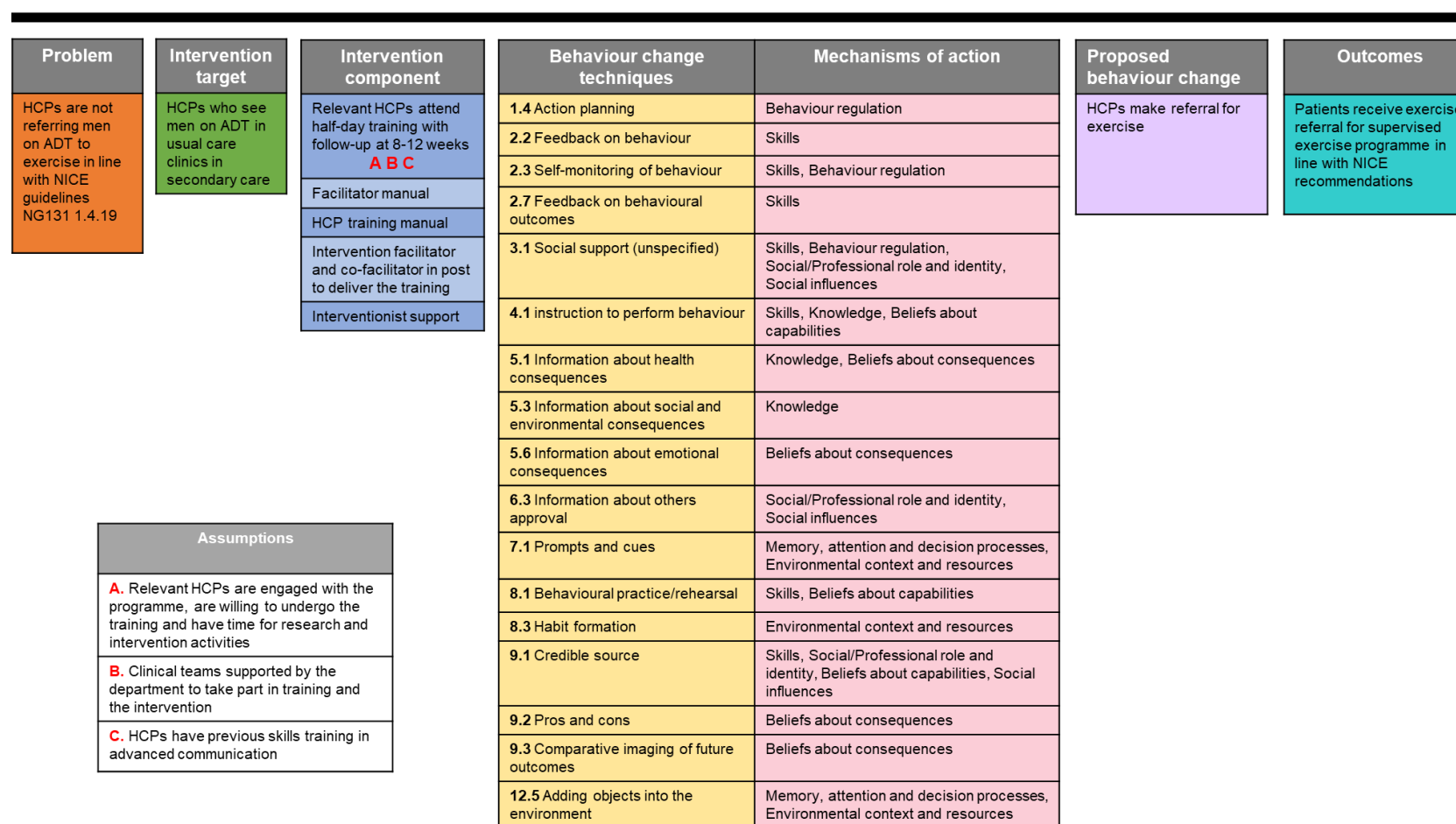
Appendix K: Exemplar logic models for the intervention



Logic model for target behaviour 1 (recommend exercise as a treatment component)



Logic model for target behaviour 2 (discuss barriers and facilitators to exercise)



Logic model for target behaviour 3 (make an exercise referral)

Appendix L: Behavioural diagnosis of the seven target behaviours

Behaviours	TDF domains	What is needed for change?	Is there a need for change?
1. Recommend exercise training at any point within the pathway, provide support using BCTs	Skills	Need behavioural support skills to support patients with exercise.	Yes
	Knowledge	Need the knowledge of the benefits of exercise and awareness of the evidence-based recommendations. Need the knowledge of the behaviour change skills needed to provide exercise support by all members of the clinical team.	Yes
	Memory, attention, and decision processes	Need to remember to discuss exercise and provide exercise support to patients.	Yes
	Behavioural regulation	Need to develop routines and habits to discuss exercise with patients. Need for monitoring of this to be in place.	Yes
	Social/Professional role and identity	Need to perceive exercise recommendation to be perceived as part of their role	Yes
	Beliefs about capabilities	Not identified in the interviews in relation to this target behaviour	No
	Beliefs about consequences	Need to believe exercise is beneficial for this patient group. Need to believe exercise is an important part of patient's care.	Yes
	Intentions	Not identified in the interviews	No
	Optimism	Not identified in the interviews	No
	Goals	Not identified in the interviews	No
	Reinforcement	Not identified in the interviews	No
	Emotion	Not identified in the interviews in relation to this target behaviour	No
	Social influences	Need to maintain a good relationship with the patient when discussing exercise.	Yes

		Need to perceive or observe colleagues are providing the same support to patients.	
		Need to have support from the organisation regarding change that is necessary.	
	Environmental context and resources	More time needed for in-depth discussions around exercise or to develop strategies to discuss exercise under time-pressures.	Yes
2. Discuss barriers and facilitators around exercise training, provide support using BCTs	Skills	Need behavioural support skills to support patients with exercise.	Yes
	Knowledge	Need the knowledge of the behaviour change skills needed to provide exercise support by all members of the clinical team.	Yes
	Memory, attention, and decision processes	Need to remember to discuss exercise and provide exercise support to patients.	Yes
	Behavioural regulation	Not identified in the interviews in relation to this target behaviour	No
	Social/Professional role and identity	Need to perceive discussing barriers and facilitators to exercise and providing behavioural support is part of their role.	Yes
	Beliefs about capabilities	Not identified in the interviews in relation to this target behaviour	No
	Beliefs about consequences	Need to understand the importance of providing behavioural support.	Yes
	Intentions	Not identified in the interviews	No
	Optimism	Not identified in the interviews	No
	Goals	Not identified in the interviews	No
	Reinforcement	Not identified in the interviews	No
	Emotion	Not identified in the interviews in relation to this target behaviour	No
	Social influences	Need to perceive or observe colleagues providing behavioural support	Yes
	Environmental context and resources	More time needed for in-depth discussions around exercise or to develop strategies to discuss exercise under time-pressures.	Yes
3. Make referral for exercising training	Skills	Need physical skills to make an exercise referral	Yes
	Knowledge	Need to have an awareness of the processes for exercise referral.	Yes

	Memory, attention, and decision processes	Need to remember to make an exercise referral. Need to believe patients will want to take part in exercise.	Yes
	Behavioural regulation	To monitor number of exercise referrals made by each HCP within a clinical team	Yes
	Social/Professional role and identity	For HCPs to perceive making an exercise referral is part of their role	No
	Beliefs about capabilities	Not identified in the interviews in relation to this target behaviour	No
	Beliefs about consequences	Need for HCPs to trust exercise professionals. Need to believe patients will want to take part in exercise.	Yes
	Intentions	Not identified in the interviews	No
	Optimism	Not identified in the interviews	No
	Goals	Not identified in the interviews	No
	Reinforcement	Not identified in the interviews	No
	Emotion	Need to have a positive view about referring patients to an exercise referral scheme	Yes
	Social influences	Not identified in the interviews in relation to this target behaviour	No
	Environmental context and resources	Need access to an exercise referral scheme. Exercise referral needs to be a simple process. More time needed for exercise referral or to develop strategies to carry out exercise referrals under time-pressures.	Yes
4. Provide patient with information pack and materials	Skills	Not identified in the interviews in relation to this target behaviour	No
	Knowledge	Need the knowledge of the patient materials to hand out to patients.	Yes
	Memory, attention, and decision processes	Need to remember to give the information packs to patients.	Yes
	Behavioural regulation	Not identified in the interviews in relation to this target behaviour	No

	Social/Professional role and identity	HCPs often give out patient materials to patients as part of their role	No
	Beliefs about capabilities	Not identified in the interviews in relation to this target behaviour	No
	Beliefs about consequences	Need to perceive the information for the patients as beneficial.	Yes
	Intentions	Not identified in the interviews	No
	Optimism	Not identified in the interviews	No
	Goals	Not identified in the interviews	No
	Reinforcement	Not identified in the interviews	No
	Emotion	Not identified in the interviews in relation to this target behaviour	No
	Social influences	Not identified in the interviews in relation to this target behaviour	No
	Environmental context and resources	Need to ensure the resources are available to give to patients	Yes
5. Recognise whether a patient is suitable for exercise	Skills	Not identified in the interviews in relation to this target behaviour	No
	Knowledge	Need the knowledge of whether a patient is suitable for exercise or not	Yes
	Memory, attention, and decision processes	Not identified in the interviews in relation to this target behaviour	No
	Behavioural regulation	Not identified in the interviews in relation to this target behaviour	No
	Social/Professional role and identity	Need to perceive it as part of their role to recognise patients are eligible to exercise	Yes
	Beliefs about capabilities	Need to improve confidence in recognising if patients are eligible for exercise	
	Beliefs about consequences	Not identified in the interviews in relation to this target behaviour	No
	Intentions	Not identified in the interviews	No
	Optimism	Not identified in the interviews	No
	Goals	Not identified in the interviews	No
	Reinforcement	Not identified in the interviews	No
	Emotion	Not identified in the interviews in relation to this target behaviour	No
	Social influences	Not identified in the interviews in relation to this target behaviour	No

	Environmental context and resources	Not identified in the interviews in relation to this target behaviour	No
6. Read and interpret exercise progress report	Skills	Need the skills to access the progress report	Yes
	Knowledge	Need to have an awareness of the processes for the progress report.	Yes
	Memory, attention, and decision processes	Need to remember to access the progress report prior to consultation with patient.	Yes
	Behavioural regulation	Not identified in the interviews in relation to this target behaviour	No
	Social/Professional role and identity	Interpreting and reading tests results is already part of HCP roles	No
	Beliefs about capabilities	HCPs already interpret and read test results as part of their role	No
	Beliefs about consequences	HCPs thought feedback on progress would be beneficial	No
	Intentions	Not identified in the interviews	No
	Optimism	Not identified in the interviews	No
	Goals	Not identified in the interviews	No
	Reinforcement	Not identified in the interviews	No
	Emotion	Not identified in the interviews in relation to this target behaviour	No
	Social influences	Not identified in the interviews in relation to this target behaviour	No
	Environmental context and resources	Need to have the time to access the report and read it prior to consultations	Yes
7. Provide feedback to the patient on the exercise progress report, provide support using BCTs	Skills	Need behavioural support skills to support patients with exercise.	Yes
	Knowledge	Need the knowledge of the behaviour change skills needed to provide exercise support by all members of the clinical team.	Yes
	Memory, attention, and decision processes	Need to remember to provide feedback and exercise support to patients.	Yes
	Behavioural regulation	Not identified in the interviews in relation to this target behaviour	No
	Social/Professional role and identity	Need to perceive discussing barriers and facilitators to exercise and providing behavioural support is part of their role.	Yes

	Beliefs about capabilities	Not identified in the interviews in relation to this target behaviour	No
	Beliefs about consequences	Need to understand the importance of providing behavioural support.	Yes
	Intentions	Not identified in the interviews	No
	Optimism	Not identified in the interviews	No
	Goals	Not identified in the interviews	No
	Reinforcement	Not identified in the interviews	No
	Emotion	Not identified in the interviews in relation to this target behaviour	No
	Social influences	Need to perceive or observe colleagues providing behavioural support	Yes
	Environmental context and resources	More time needed for in-depth discussions around exercise or to develop strategies to discuss exercise under time-pressures.	Yes

Appendix M: Topic guide for stakeholder workshop

Topic Guide for two workshops to discuss developing content of the STAMINA interventions for HCPs and the pathways of communication between HCPs and exercise professionals (work package 2iii) (Adapted from the TIDieR checklist, BMJ 2014 and Murray BMC Medicine 2010)

(Preamble will include presentation of proposed intervention under TIDieR Headings. Although all elements of the intervention will be described and open for comment the primary elements for comment are the HCP elements including HCP behaviours and communication pathways)

Opinions on the proposed content, format and structure of the intervention (HCP, patient and exercise professional elements and communication pathways) (Coherence)

Does the intervention have a clear purpose for all participants (HCPs in the MDT, exercise professional and study patient participants)?

How feasible is the delivery of the intervention?

- Opinions on the mode of delivery of intervention?
- Opinions on the duration of intervention?

Do participants believe the intervention will be put in place (cognitive participation/context)

- What would be peoples' motivations, barriers, capabilities to put in place?
- Does intervention fit with individuals' roles? Does the intervention fit with the overall organizational goals of the hospital team and the exercise professionals?

Do participants believe the intervention will bring benefits (and be perceived as advantageous) for patients, for staff and for organisations?

- How will benefits be recognised,
- Ways to facilitate this

How acceptable is the new HCP behaviour likely to be to patients (the ultimate recipients)?

How acceptable is the communication pathway likely to be to patients?

Opinions on the proposed pathways of communication between health care professional and exercise professionals

- What are the best ways of communicating between these two groups?
- What is feasible?
- How acceptable is this communication, to patients?

How might the fidelity of the intervention be promoted?

Will it be clear from the study what effects the intervention has had, will the team be aware of benefits?

Is there learning from related areas that could be helpful here e.g. cardiac rehabilitation.

References

Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ. 2014 Mar 7;348:g1687. doi: 10.1136/bmj.g1687.

Murray E, Treweek S, Pope C, MacFarlane A, Ballini L et al. Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. BMC Medicine 2010 8:63 <https://doi.org/10.1186/1741-7015-8-63>

Appendix N: Participant information sheet for healthcare professional rehearsal delivery and feedback session



Health care professionals training and feedback Participant information sheet

Supported exercise TrAining for Men with prostate caNcer on Androgen deprivation therapy - STAMINA.

We would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully.

What is the purpose of the study?

The purpose of this study is to assess the feasibility of integrating a behavioural support intervention centred on the promotion and adoption of exercise prescription into the prostate cancer care pathway.

The purpose of this specific aspect of this study is to deliver our developed evidence based training package to a clinical team to provide behavioural support for exercise behaviour in cancer survivors.

What are the possible benefits of taking part?

The information we get from this study will help us answer important questions to decide how we deliver the intervention in our planned clinical trial. This could help us provide care and support men with prostate cancer in the future.

What are the possible disadvantages of taking part?

We will ask you to give up your time to take part, we hope not to take more than up to a working day. We do not expect there will be any risk in taking part.

Why have I been invited to take part?

You have been invited to participate because of your role as a health care professional employed by NHS working within the prostate cancer care pathway.

Do I have to take part?

It is up to you to decide whether or not to take part in this research. If you agree you will be asked to sign a consent form to show that you have read this information sheet and agreed to take part. You are free to withdraw from the study at any time, without giving a reason. Taking part in this study will not affect your legal rights.

What will happen to me if I take part?

If you decide to take part in the study, a member of the research team will contact you to organise the date and time for you to attend the training. **These will take place at XXXXX.** The training will last around half a day. Your expenses for time (inconvenience allowance) and travel expenses you may incur as a result of participation in the study will be reimbursed. The training is for our research team to practise delivering the training to health care professionals, to inform the future clinical trial. Therefore, the focus will be on the trainers and not yourselves. You will be asked to agree to the training being video recorded by signing the consent form.

Directly after the training there will be an open discussion with you and your peers reflecting on content and delivery of the training, what worked and what could be done differently etc.

You do not have to answer or comment on anything that you would prefer not to. You will be invited to provide further feedback via email or verbally if desired post training. We will collect your contact details so we can let you know about the training and we will collect information about your role and experience working in cancer care.

Video-recordings and audio-recordings will also be transcribed and stored securely and confidentially, transferring of files will be carried out by an encrypted memory stick and transcription will take place by a recognised provider. Video recordings cannot be anonymised.

Under UK Data Protection laws Sheffield Hallam University (SHU) and Sheffield Teaching Hospitals Foundation Trust (STH) are joint the Data Controller (legally responsible for the data security) and are responsible for looking after your information and using it properly. STH is the sponsor for this study based in the United Kingdom. STH and SHU will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. If other researchers request data, all data will be anonymised.

You can find out more about how we use your information at <https://www.sheffieldclinicalresearch.org/>

STH and SHU will use your name and contact details to contact you about the research study. Individuals from STH, SHU and regulatory organisations may look at research records to check the accuracy of the research study. The only people in STH and SHU who will have access to information that identifies you will be people who need to contact you to or audit the data collection process.

What if I change my mind during the study?

You are free to withdraw from the study at any time, but due to the nature of the study we will keep the information that we have already collected and use this in the analyses.

Will my involvement in the study be kept confidential?

Yes. We will follow legal and ethical practice and all information about you will be handled in strict confidence.

Feedback will be recorded and summarised into a written document that will be provided to you and your peers for further comment and amendments before approval but we will not use your real name anywhere in the report. When we are analysing the data it will only be seen by the research team and it will be stored securely according to the Data Protection Act.

What will happen to the information from the study?

The feedback will be collated and used to further develop the training programme for exercise professionals and health care professionals to integrate exercise into the cancer care pathway by providing behavioural support and adapting to changes within the pathways. The overall (and anonymised) results will be written up for publication in scientific journals, will be fed back to patient groups, charities and health professional groups. We will be able to provide you with the overall results on request. If other researcher's request data, data will be anonymised.

Who is involved in this study?

This study is organised and run by Sheffield Hallam University and Sheffield Teaching Hospitals. This study is funded by the Department of Health (National Institute for Health Research) and has been reviewed by North west Liverpool central NHS Research Ethics Committee.

What if I have further questions or would like more information about the study?

If you would like more information about the study you are invited to contact the individuals below.

Name: Miss Rebecca R Turner

Address: J104, J floor, Royal Hallamshire hospital, Sheffield, S10 2JF
Email: rebecca.turner@shu.ac.uk/rebecca.turner@sth.nhs.uk
Phone: 0114 2252410

What happens if I have a complaint?

If you have any cause to complain about any aspect of the way in which you have been approached or treated during the course of this study, please contact

Prof Liam Bourke	Programme director	Email: l.bourke@shu.ac.uk
Prof Derek Rosario	Chief Investigator	Email: derek.rosario@sth.nhs.uk

THANK YOU FOR TAKING THE TIME TO CONSIDER PARTICIPATING IN THIS STUDY

Liam Bourke
Professor in Cancer Research, Sheffield Hallam University

STAMINA Programme Lead

Derek Rosario
Hon. Professor in Cancer Research, Sheffield Hallam University

Consultant Urologist,
Sheffield Teaching Hospitals

Chief Investigator STAMINA programme.

Appendix O: Healthcare professional consent form for rehearsal delivery and feedback



WP2 Health care professionals training and feedback consent form

Supported exercise TrAining for Men with prostate caNcer on Androgen deprivation therapy - STAMINA.

Please initial

1	I confirm that I have read and understood the information sheet <u>(Version X)</u> for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2	I understand that my participation is voluntary and that I am free to withdraw at any time.	
3	I understand if I withdraw, all data taken from my participation will be retained for analysis.	
4	I understand that the information I provide will be confidential and that my identity will not be used in any outputs from the research.	
5	I give permission for research personnel to retain my personal details only for the purposes of participation in the research study. I understand these details will not be passed on to third parties under any circumstances. I understand that my identifiable data will be kept securely by the trial co-ordinating centre (Sheffield Hallam University).	
6	I agree to the training being digitally audio and visually recorded. I understand that video recording cannot be anonymised.	

7	I agree that if I take part in a post-training feedback session they will be recorded and my anonymised responses may be used for research purposes and publication.	
8	I agree to take part in the above study.	

Name of participant (PRINT)	Date	Signature
Name of individual taking consent (PRINT)	Date	Signature

Researcher's contact details:

Name: Rebecca R Turner

Email: rebecca.turner@sth.nhs.uk / rebecca.turner@shu.ac.uk

Telephone: 0114 2252410

(1 copy for participant; 1 for the co-ordinating centre (SHU); original stored in Trial Master File)

Appendix P: Participant information sheet for stakeholder workshop



Stakeholder workshop: Participant Information Sheet

Supported exercise TrAining for Men with prostate caNcer on Androgen deprivation therapy - the STAMINA programme.

We would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully.

What is the purpose of the study?

The purpose of this study is to refine and develop our ideas for an evidence-based training package for exercise professionals and health care professionals to support exercise training in men diagnosed with prostate cancer on hormone therapy.

What are the possible benefits of taking part?

The information we get from this study will help us answer important questions to decide how we deliver the intervention in our planned clinical trial. This could help us provide care and support men with prostate cancer in the future.

What are the possible disadvantages of taking part?

We will ask you to give up your time to take part in a working group amongst peers. We hope not to take more than a day of your time. We can provide expenses for your participation.

We do not expect there will be any risk in taking part.

Why have I been invited to take part?

We are inviting a number of different individuals to take part in the stakeholder workshops: we really value the input from a range of different perspectives. Everyone participating will all have some experience of working within the prostate cancer care pathway, working with cancer survivors, living with cancer, being a relative or carer to a cancer survivor.

Do I have to take part?

It is up to you to decide whether or not to take part in this research. If you agree you will be asked to sign a consent form to show that you have read this information sheet and agreed to take part. You are free to withdraw from the study at any time, without giving a reason. Taking part in this study will not affect your legal rights. You will need to have employer permission to take part.

What will happen to me if I take part?

If you decide to take part in the study, a member of the research team will contact you to organise participation in two stakeholder workshops (around 6 months apart). These will take place on 28.02.2019 at Copthorne Hotel, Bramall Lane, Sheffield S2 4SU and

23.01.2019. This will be a full day event. Your expenses for time (inconvenience allowance) and travel expenses you may incur as a result of participation in the study will be reimbursed. We will ask for your input on a wide range of topics related to the proposed research design and delivery which includes things like intervention design, integration with NHS care pathways, research outcomes, communication between research participants in the NHS and our partner Nuffield Health.

You do not have to answer or comment on anything that you would prefer not to. There are no right or wrong answers; we are just interested in your opinion. We will collect your contact details and basic demographic details so we can let you know about the workshops and we will collect information about your role and experience working in cancer care.

What if I change my mind during the study?

You are free to withdraw from the study at any time, but due to the nature of the study we will keep the information that we have already collected and use this in the analyses.

Will my involvement in the study be kept confidential?

Yes. We will follow legal and ethical practice and all information about you will be handled in strict confidence.

Feedback that is provided in the workshops will be recorded via flipcharts and summarised into a written document that will be provided to you and your peers for further comment and amendments before approval but we will not use your real name anywhere in the report.

Under UK Data Protection laws Sheffield Hallam University (SHU) and Sheffield Teaching Hospitals Foundation Trust (STH) are joint the Data Controller (legally responsible for the data security) and are responsible for looking after your information and using it properly. STH is the sponsor for this study based in the United Kingdom. STH and SHU will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. If other researchers request data, all data will be anonymised.

You can find out more about how we use your information at <https://www.sheffieldclinicalresearch.org/>

STH and SHU will use your name and contact details to contact you about the research study. Individuals from STH, SHU and regulatory organisations may look at research records to check the accuracy of the research study. The only people in STH and SHU who will have access to information that identifies you will be people who need to contact you to or audit the data collection process.

What will happen to the information from the study?

The results of the study will be used to refine a training package for exercise professionals and health care professionals to integrate exercise into the cancer care pathway by providing behavioural support and adapting to changes within the pathways. The overall (and anonymised) results will be written up for publication in scientific journals, will be fed back to patient groups, charities and health professional groups. We will be able to provide you with the overall results on request. Additionally,

you will be provided with a document of the feedback from the working group for further comments etc. If other researcher's request data, data will be anonymised.

Who is involved in this study?

This study is organised and run by Sheffield Hallam University and Sheffield Teaching Hospitals. This study is funded by the Department of Health (National Institute for Health Research) and has been reviewed by North West Liverpool Central NHS Research Ethics Committee.

What if I have further questions or would like more information about the study?

If you would like more information about the study you are invited to contact the individuals below.

Rebecca R Turner	rebecca.turner@shu.ac.uk	0114 2252410
Sophie Reale	s.reale@shu.ac.uk	0114 2256310

What happens if I have a complaint?

If you have any cause to complain about any aspect of the way in which you have been approached or treated during the course of this study, please contact

Prof Liam Bourke	Programme director	Email: l.bourke@shu.ac.uk
Prof Derek Rosario	Chief Investigator	Email: derek.rosario@sth.nhs.uk

THANK YOU FOR TAKING THE TIME TO CONSIDER PARTICIPATING IN THIS STUDY

Liam Bourke
Professor in Cancer Research, Sheffield Hallam University

STAMINA Programme Lead

Derek Rosario
Hon. Professor in Cancer Research, Sheffield Hallam University

Consultant Urologist,
Sheffield Teaching Hospitals

Chief Investigator STAMINA programme.

Appendix Q: Stakeholder workshop consent form



Stakeholder's workshop consent form

Supported exercise TrAining for Men with prostate caNcer on Androgen deprivation therapy - STAMINA.

Please
initial

1	I confirm that I have read and understood the information sheet <u>(Version X)</u> for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2	I understand that my participation is voluntary and that I am free to withdraw at any time.	
3	I understand if I withdraw, all data taken from my participation will be retained for analysis.	
4	I understand that the information I provide will be confidential and that my identity will not be used in any outputs from the research.	
5	I give permission for research personnel to retain my personal details only for the purposes of participation in the research study. I understand these details will not be passed on to third parties under any circumstances. I understand that my identifiable data will be kept securely by the trial co-ordinating centre (Sheffield Hallam University).	
6	I agree that my anonymised data may be used for research purposes and publication.	
7	I agree to take part in the above study.	

Name of participant (PRINT)	Date	Signature
Name of individual taking consent (PRINT)	Date	Signature

Researcher's contact details:

Name Rebecca R Turner

Address Room Q302
Parkholme Building
Collegiate Campus
Sheffield
S10 2BP

Email rebecca.turner@shu.ac.uk rebecca.turner@sth.nhs.uk

Telephone 0114 2252410

(1 copy for participant; 1 for the co-ordinating centre (SHU); original stored in Trial Master File)

Appendix R: Intervention delivery participant information sheet



STAMINA - Supported exercise TrAining for Men with prostate caNcer on Androgen deprivation therapy.

Work Package 3 healthcare professional information sheet

We would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully.

What is the purpose of the study?

The purpose of this specific aspect of our programme of work is to test and evaluate our first version of our evidence-based exercise and behavioural support intervention. We are calling this first attempt a 'pre-pilot'. It will involve training health care professionals (HCPs) in endorsing, recommending and supporting the NICE CG 175 1.4.19 recommended supervised exercise training intervention.

The actual exercise training will be delivered and supervised by specifically STAMINA-trained exercise professionals (EPs) based at a Nuffield Health Gym partnered with your Department.

What are the possible benefits of taking part?

Unmet needs are a real problem in prostate cancer care, particularly for men on hormone therapy. Addressing these is often difficult and time-consuming. During this research project, you will receive information and training to help provide currently accepted best practice to help address some of these patient needs.

What are the possible disadvantages of taking part?

You will need to give up time for the training sessions and to provide the researchers with feedback. Your trust will be reimbursed for the time during which you take part in the research.

Why have I been invited to take part?

You have been identified as having a pivotal role in the clinical management of men with prostate cancer on hormone therapy. This includes your role at initial diagnosis, treatment and/or follow up of this patient group.

Do I have to take part?

It is up to you to decide whether or not to take part in this research.

What will happen to me if I take part?

If you decide to take part in the study, a member of the research team will contact you. We will be asking you to do three linked activities:

- You will be invited to attend a training session at your local NHS trust to learn new skills to enable you to deliver the intervention (training duration: up to a day).
- Recruit patients on ADT (around 8) from your NHS site and deliver your part of the intervention (referring the patient to Nuffield Health gym subsequently for their 12 weeks of exercise).

- Take part in an audio recorded interview after recruitment to let us know about your experience of being a part of our 'pre-pilot'.

These activities will take part sequentially over a maximum period of 12 months. Additionally, a possible audio recording of your consultation with a patient may be taken, this will be rated by the researchers using a validated checklist for behavioural components.

What if I change my mind during the study?

You are free to withdraw from the study (without giving reason for doing so) at any time up until the end of your involvement.

Will my involvement in the study be kept confidential?

Yes. We will follow legal and ethical practice and all information about you will be handled in strict confidence. Data that is recorded as part of this pre-pilot study will be anonymised and used to develop our ideas about how the final intervention will be designed.

Under UK Data Protection laws Sheffield Hallam University (SHU) and Sheffield Teaching Hospitals Foundation Trust (STH) are joint the Data Controller (legally responsible for the data security) and are responsible for looking after your information and using it properly. STH is the sponsor for this study based in the United Kingdom. STH and SHU will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. If other researchers request data, all data will anonymised.

You can find out more about how we use your information at
<https://www.sheffieldclinicalresearch.org/>

STH and SHU will use your name and contact details to contact you about the research study. Individuals from STH, SHU and regulatory organisations may look at research records to check the accuracy of the research study. The only people in STH and SHU who will have access to information that identifies you will be people who need to contact you to or audit the data collection process.

What will happen to the information from the study?

The results of the study will be used to refine a training package for HCPs and EPs to integrate exercise into the prostate cancer care pathway by providing behavioural support and adapting to changes within the pathways. The overall (and anonymised) results will be written up for publication in scientific journals, will be fed back to patient groups, charities and health professional groups. We will be able to provide you with the overall results on request. Additionally, you will be provided with a document of the feedback from the working group for further comments etc. If other researcher's request data, data will anonymised.

Who is involved in this study?

This study is organised and run by Sheffield Hallam University and Sheffield Teaching Hospitals. This study is funded by the Department of Health (National Institute for Health Research).

Who has reviewed this study?

The National Institute of Health Research (NIHR), the National Health Service ethical review system and the Health Regulation Authority.

Who has checked the ethical implications of this study?

This study has been reviewed by **NorthWest Liverpool East** NHS Research Ethics Committee.

What if I have further questions or would like more information about the study?

If you would like more information about the study you are invited to contact the individuals below.

insert TBA researcher contact details

What happens if I have a complaint?

If you have any cause to complain about any aspect of the way in which you have been approached or treated during the course of this study, please contact either of the study team leads:

Prof Liam Bourke
Prof Derek Rosario

Programme director
Chief Investigator

Email: l.bourke@shu.ac.uk
Email: derek.rosario@sth.nhs.uk

If you have concerns about the way the research is being conducted, please contact the study sponsor, Sheffield Teaching Hospitals via the STH Clinical Research & Innovation Office:

<https://www.sheffieldclinicalresearch.org/contact/>

Telephone no: 0114 226 5938

THANK YOU FOR TAKING THE TIME TO CONSIDER PARTICIPATING IN THIS STUDY

* Insert local PI*

Appendix S: Theoretical Domains Framework Questionnaire

Healthcare professionals Theoretical Domains Framework questionnaire

Identification code:

1. I am aware of the NICE CG175 1.4.19 recommendations for exercise for men with advanced prostate cancer on ADT.

1	2	3	4	5
Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree

2. I am aware of the benefits of exercise for men with advanced prostate cancer on ADT.

1	2	3	4	5
Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree

3. I have the skills to deliver exercise support and make an exercise referral in line with NICE CG175 1.4.19 recommendations to men with advanced prostate cancer on ADT.

1	2	3	4	5
Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree

4. Discussing exercise with men with advanced prostate cancer on ADT during consultations is something I often forget.

1	2	3	4	5
Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree

5. I have made a plan about how to deliver exercise and support referral and check that I have done so with all men with advanced prostate cancer on ADT.

1	2	3	4	5
Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree

6. I perceive it as part of my professional role to discuss exercise with my patients with advanced prostate cancer on ADT.

1	2	3	4	5
Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree

7. I feel confident that I can assess the suitability of men with advanced prostate cancer on ADT to exercise.

1	2	3	4	5
Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree

8. I feel confident that all men with advanced prostate cancer on ADT will receive exercise support and referral in line with NICE CG175 1.4.19 recommendations.

1	2	3	4	5
Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree

9. If I discuss exercise, provide exercise support and make an exercise referral for men with advanced prostate cancer on ADT they will take up the exercise programme.

1	2	3	4	5
Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree

10. Exercise in line with the NICE CG175 1.4.19 recommendations will be beneficial for men with advanced prostate cancer on ADT.

1	2	3	4	5
Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree

11. Men with advanced prostate cancer on ADT will be capable of taking part in supervised exercise in line with the NICE CG175 1.4.19 recommendations.

1	2	3	4	5
Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree

12. I'm not sure that exercise professionals will be able to support men with advanced prostate cancer on ADT through an exercise programme.

1	2	3	4	5
Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree

13. I intend to discuss exercise with all my patients who have advanced prostate cancer on ADT when I see them in clinic.

1	2	3	4	5
Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree

14. I want to deliver exercise support and referral as much as I want to deliver the other aspects of my role/tasks I need to deliver with men with advanced prostate cancer on ADT.

1	2	3	4	5
Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree

15. There will be positive benefits for me as a healthcare professional, if we deliver exercise support and referral in line with recommendations to all men I see in clinic with advanced prostate cancer on ADT.

1	2	3	4	5
Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree

16. I am anxious about delivering exercise support and referral in line with recommendations to men with advanced prostate cancer on ADT.

1	2	3	4	5
Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree

17. I have enough time and resources to be able to discuss exercise with all my patients with advanced prostate cancer on ADT during all consultations

1	2	3	4	5
Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree

18. Fellow healthcare professionals expect that I should be discussing exercise in all consultations with men with advanced prostate cancer on ADT.

1	2	3	4	5
Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree

19. Men with advanced prostate cancer on ADT expect that I should be discussing exercise in all consultations with men with advanced prostate cancer on ADT.

1	2	3	4	5
Strongly disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Strongly agree

Appendix T: Healthcare professional acceptability semi-structured interview schedule

Topic guide for interviews with members of the multidisciplinary clinical team caring for men who have received the exercise intervention in work package 3

- How did you find delivering the STAMINA Programme?
 - o Experience of delivering the STAMINA Programme
 - o Feelings about the STAMINA programme?
- What did delivering the STAMINA programme involve?
 - o What did it involve in terms of time/ opportunity/ effort to train to, and then deliver, the programme?
 - o Referral processes/eligibility criteria/screening log/audio recording/progress reporting/communications with EPs
- Do you believe this sort of programme can be helpful to men in with prostate cancer?
 - o In what way?
- If you believe the STAMINA programme is beneficial, how do you think it might work?
- Do you feel the role of delivering this programme is appropriate for members of the MDT?
 - o Do you have any concerns about this role?
- How does delivering the exercise support components of the programme fit in with your professional development?
- What do you think about the actual content of the STAMINA programme?
 - o a) The gym components
 - o b) How follow-up is embedded in the STAMINA programme?
 - o Could the STAMINA programme be improved? If so, how?
- How confident were you about delivering the STAMINA Programme?
 - o At the start?
 - o Now
- Do you have any concerns or worries about the STAMINA Programme?
 - o Probe the two components (a - b) mentioned above
- Did you feel that you have enough support to deliver the programme?
 - o Show the HCP the draft booklet and ask for comments
 - o Probe whether the table is useful, should it sit in the manual or appendices?
- Is there anything else you'd like to say about your experience of delivering the STAMINA Programme or about the programme in general?

References

Sekhon, M., Cartwright, M., & Francis, J. J. (2017). Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. *BMC Health Services Research*, 17(1), 88. doi:10.1186/s12913-017-2031-8

Appendix U: Evaluation form for intervention delivery

Job role:

Many thanks for attending our healthcare professional training session. We would value your comments and be very grateful if you would spend a few minutes completing this form. Please hand in the form before you leave.

Today's session

Q1. What is the main overall message you gained from today's session?

Q2. How useful did you find this session overall?

1	2	3	4	5
Not at all useful	A little useful	Somewhat useful	Mainly useful	Extremely useful

Q3. How useful was the overview given regarding STAMINA?

1	2	3	4	5
Not at all useful	A little useful	Somewhat useful	Mainly useful	Extremely useful

Q4. How useful was module 1: STAMINA overview

1	2	3	4	5
Not at all useful	A little useful	Somewhat useful	Mainly useful	Extremely useful

Q5. How useful was module 2: Advanced prostate cancer and exercise

1	2	3	4	5
Not at all useful	A little useful	Somewhat useful	Mainly useful	Extremely useful

Q6. How useful was module 3: The role of the clinical team

1	2	3	4	5
Not at all useful	A little useful	Somewhat useful	Mainly useful	Extremely useful

Q7. How useful was module 4: Skills to discussing exercise

1	2	3	4	5
Not at all useful	A little useful	Somewhat useful	Mainly useful	Extremely useful

Q8. How useful was module 5: The role of exercise professionals

1	2	3	4	5
Not at all useful	A little useful	Somewhat useful	Mainly useful	Extremely useful

Q9. How useful was module 6: Referral and communication pathway

1	2	3	4	5
Not at all useful	A little useful	Somewhat useful	Mainly useful	Extremely useful

Q10. What would you say were your main learning outcomes from the session?

Q11. What would you say was missing from the session?

Q12. Did you feel able to contribute throughout the session?

Q13. Do you think the session would be better delivered (please tick):

1. Online.
2. Combination of online and face to face.
3. Face to face.

Q14. How could we improve this session?

Q15. Would you recommend this session to your colleagues (please circle)?

YES or NO

Please can you explain your answer:

Q16. Were you happy with the venue for the session?

Q17. Were there adequate breaks during the session?

Any further comments:

Appendix V: Fidelity checklist

Fidelity checklist - healthcare professionals' initial consultation with patient

General instructions

There are three key aspects to this fidelity checklist:

- 1) Record fidelity of the necessary behaviours
- 2) Assess the quality of behaviours
- 3) Assess the quality of behaviour change techniques (if used)

Recording identifier	
-----------------------------	--

Behaviours	Adherence to the content (0 = No, 1 = Partially, 2 = Yes)	Quality of content	Quality of content
Provide information on the side-effects of ADT		0 1 2	0 = Little information given 1 = Limited information given, some key aspects missed 2 = Good information provided
Recommend exercise training as treatment component		0 1 2	0 = Poor, little discussion 1 = Limited discussion around the benefits of exercise 2 = Good discussion on the different benefits of exercise as a treatment component
Provide information about the research processes e.g. discussions about referral process		0 1 2	0 = Little information given 1 = Limited information given, some key aspects missed 2 = Good information provided
Provide information about the exercise referral scheme		0 1 2	0 = Little information given 1 = Limited information given, some key aspects missed 2 = Good information provided
Ask if there are any barriers to exercise training		0 1 2	0 = Poor, with closed questions 1 = Limited questions to explore barriers 2 = Good open questions

If applicable discuss any barriers and or facilitators to exercise training		0 1 2	0 = Poor, with a lack of focus on barriers and facilitators 1 = Limited discussion around barriers and facilitators, not patient led 2 = Good discussion around barriers and facilitators. Participant led approach.
	Total score =	Total score =	

Behaviour change techniques	Applicable or not? (Yes or No)	Adherence to the content (0 = No, 1 = Partially, 2 = Yes)	Quality of the content	Quality key
1.2 Problem solving		0 1 2	0 1 2	0 =Poor, attempting to problem solve for the patient and or problems identified but no solutions made. 1 = Prompting the patient to problem solve, but limited support for the patient to come up with solutions. 2 = Good interaction, supporting the patient to identify barriers themselves and come up with solutions. Led by patient, reflected by healthcare professional
9.2 Pros and cons		0 1 2	0 1 2	0 =Poor, attempting come up with pros and cons for the patient. 1 = Prompting the patient to come up with pros and cons, but limited support for the patient to come to a decisional balance 2 = Good interaction, supporting the patient to identify pros and cons and come to a decisional balance. Led by patient, reflected by healthcare professional
Outlining necessities and concerns		0 1 2	0 1 2	0 = Poor, concerns are highlighted with little discussion around the necessity beliefs. 1 = Limited necessity and concerns factors are discussed and is not patient led. 2 = Good discussion, both concerns and necessities are discussed.
15.1 Verbal persuasion about capability		0 1	0 1	0 = Poor, no persuasion is given 1 = Limited verbal persuasion is given 2 = Good verbal persuasion is given; focus is on the positive aspects the patient can achieve.

		2	2	
3.1 Providing social support		0	0	0 = Poor, little attention given to the support that could be provided or advised on. 1 = Social support examples are discussed briefly 2 = Social support examples are provided and discussed with the patient
		1	1	
		2	2	
6.3 Information about others' approval		0	0	0 = Poor, information given is fear-inducing 1 = Limited discussion around the clinical team's approval for the patient to exercise 2 = Good discussion, it is explained to the patient that the clinical team approve and reasons why. Patient understanding is checked.
		1	1	
		2	2	
5.1 ,5.3, 5.6 Information about consequences (health, emotional, social and environmental)		0	0	0 = Poor, information given is fear-inducing 1 = Limited information is provided 2 = Helpful information is provided, checking for patient understanding
		1	1	
		2	2	
		Total score =	Total score =	

Any other comments

	Scores	Overall fidelity % score
Behaviours scoring		
Quality of behaviours		
BCT delivery		
Quality of BCTs		
Overall score		