Embedding Multimodal Rehabilitation Within Routine Cancer Care in Sheffield—The Active Together Service Evaluation Protocol

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ABSTRACT

Background: Approximately three million people in the United Kingdom (UK) are currently living with or beyond cancer. People undergoing treatment for cancer are at risk of complications following treatment. Increasing evidence supports the role of rehabilitation (including prehabilitation) for enhancing psychological and physical wellbeing in cancer patients and improving outcomes. Active Together is an evidence-based, multimodal rehabilitation service for patients with cancer, providing support to help patients prepare for and recover from treatment. This paper presents the evaluation protocol for the Active Together service, aiming to determine its impact on patient-reported outcomes and clinical endpoints, as well as understand processes and mechanisms that influence its delivery and outcomes.

Methods: This evaluation comprises an outcome and process evaluation, with service implementation data integrated into the analysis of outcome measures. The outcome evaluation will assess changes in outcomes of patients that attend the service, and compare healthcare resource use against historical data. The process evaluation will use performance indicators, semi-structured interviews and focus groups to explore mechanisms of action and contextual factors influencing delivery and outcomes. Integrating psychological change mechanisms with outcome data might help to clarify complex causal pathways within the service.

Conclusions: Evidence to support the role of multimodal rehabilitation before, during and after cancer treatment is increasing. The translation of that evidence into practice is less advanced. Findings from this evaluation will contribute to our understanding of the real-world impact of cancer rehabilitation and strengthen the case for widespread adoption of rehabilitation into routine care for people with cancer.

BACKGROUND

Approximately three million people in the UK are currently living with or beyond cancer and this is predicted to rise to four million by 2030[1]. People undergoing treatment for cancer may experience, or be at risk of, adverse effects, particularly those who do not possess sufficient physiological resilience to tolerate treatment[2]. For example, most patients with cancer undergo surgical procedures and 30% of patients develop post-operative complications that delay discharge from hospital[3]. Complications during and following treatment inflate costs (longer hospital length of stay (LOS), more interventions and increased readmissions) and worsen patient experience[4]. Furthermore, surgical outcomes vary according to the operative procedure carried out and patient fitness[5]. This is unsurprising given the physiological and psychological strains resulting from cancer treatments[6], with high-risk groups (e.g., frail and unfit) particularly affected by treatment[4]. Cancer patients are also at risk of malnutrition prior to surgery, and this is related to physical and psychological outcomes[7]. Adverse effects associated with cancer and its treatment include cancer-related fatigue, anxiety, depression, peripheral neuropathy, weight changes, osteoporosis, lymphoedema, urinary and bowel problems, night sweats, hot flushes and difficulty with memory and concentration[8]. It is estimated that 78% of cancer survivors experienced one or more of these side-effects in the last 12 months, while 71% report at least one of these more than ten years after treatment[9].

Cancer is increasingly viewed as a long-term condition[10,11]. Advances in technology, improved cancer treatments, screening programmes, improved diagnostics and input from multidisciplinary teams have led to an increase in the number of people living for longer with cancer. However, not everyone is living well – one in four of those living with cancer (~500,000 people in the UK) face poor health and disability after treatment[12] and one in five may have unmet need[13]. Inequalities in treatment outcomes increase strain on the healthcare system and negatively impact the quality of life of those most in need, with individuals from the most deprived areas more likely to suffer from diseases linked to unhealthy lifestyle behaviours, such as cardiovascular disease, obesity and cancer[14]. Tackling these inequalities by improving the quality of and access to support for people with a cancer diagnosis,

especially those living in disadvantaged communities who do not typically access services, must be a health service priority[15].

Cancer rehabilitation (including prehabilitation) is a multimodal, multi-disciplinary approach that aims to improve outcomes and patient experiences of treatment, through the provision of physical activity, nutrition, and psychological support. Evidence in support of the role of multimodal interventions to improve psychological and physical wellbeing in cancer patients and reduce the negative impact of cancer related side-effects at all stages of cancer treatment is growing rapidly[16-19]. Support throughout the cancer treatment pathway has been shown to improve several modifiable risk factors (e.g., cardio-respiratory fitness, psychological wellbeing, nutritional status) before treatment, so that people are fitter[7,20], can tolerate acute treatment more effectively and recover well after treatment[21]. This promotes earlier discharge[22] and reduces treatment-related adverse effects[23]. There is also an opportunity to improve psycho-social support and patient experience, which is particularly important for patients who are already vulnerable and have pre-existing mental health difficulties.

Observational studies have linked insufficient physical activity[24] and poor nutrition[25] with disease-related outcomes such as cancer recurrence risk, death from cancer, and overall mortality. There is increasing evidence that physical activity, psychological state and nutrition are related to prognosis and survival after cancer[26]. Evidence now suggests that regular exercise before, during and after treatment decreases the severity of treatment-related adverse side effects and is associated with reduced risk of cancer recurrence, mortality and comorbid conditions[23,27,28]. Being more physically active after a cancer diagnosis is associated with a 21-35% lower risk of cancer recurrence, a 28-44% reduced risk of cancer-specific mortality and a 25-48% reduced risk of all-cause mortality for some cancers[23]. However, it is important to note that the recurrence and mortality evidence is limited due to the epidemiological nature of the literature, the few experimental trials that do assess recurrence and mortality are not statistically powered to detect an effect in those outcomes, there are inconsistencies in defining endpoints and the tools used to assess physical activity are often open to measurement error. There are likely broader impacts of cancer rehabilitation on the health system

such as optimising treatment, reducing hospital length of stay, reducing complications during and after treatment, which will have financial and broader societal benefits. The aim of this paper is to describe the mixed-methods evaluation of a multimodal rehabilitation service for people living with cancer – the Active Together service.

METHODS

The Active Together service

The Advanced Wellbeing Research Centre (AWRC) at Sheffield Hallam University (SHU), in partnership with Yorkshire Cancer Research (YCR) and Sheffield Teaching Hospitals National Health Service (NHS) Foundation Trust (STH) have implemented an evidence-based multimodal rehabilitation pathway for people living with cancer[29]. During the first three years, the Active Together service will focus on providing support for patients with lung, colorectal or upper gastrointestinal cancer, under the care of STH, who are being treated with curative intent. Since February 2022, patients over the age of 18 years who receive treatment in Sheffield are referred to Active Together for personalised physical activity, dietetic and psychological support based on a comprehensive needs assessment. Support spans the rehabilitation continuum, from preventive rehabilitation (prehabilitation) following diagnosis, maintenance rehabilitation during treatment, through to restorative and supportive rehabilitation after treatment. The service is being delivered and supported by a multidisciplinary team of staff including physiotherapists, dietitians, psychologists, specialist exercise professionals, administrative staff, and academics. For key challenges, insights and learnings from the first 12 months of the service, see the recent paper by Keen et al. [30].

The purpose of the Active Together service is to embed multimodal rehabilitation support, at all stages of the cancer treatment journey, within existing clinical pathways for people affected by cancer who are treated in Sheffield. Beyond the initial three years, the ambition is to expand the service delivery to include patients with other forms of cancer, and scale to other NHS trusts across Yorkshire and beyond. The service aims to improve clinical, and patient reported outcomes such as functional

capacity, psychological wellbeing, treatment-related side effects, tolerance to treatments, post-operative complications, and survival rates. For further information about the design of the Active Together service, see Humphreys et al.[29]. The level of physical activity, nutritional or psychological support offered to patients will be determined on an individual basis according to the results of an initial needs assessment. For the exercise prescription, the aim is to achieve 30 minutes of moderate intensity aerobic exercise three times per week and two sessions of resistance exercise twice per week. Each patient's starting point will depend on their current fitness and cancer/treatment related side effects when they enter the service.

The Active Together service evaluation

This protocol is reported according to the Transparent Reporting of Evaluations with Non-randomized Designs (TREND) guidelines[31].

The service evaluation protocol has been reviewed by the Health Research Authority (HRA) who concluded that formal NHS ethical approval was not required because no new or untested treatment is being offered and there is no experimentation being conducted with patients. The service evaluation has been approved by the Clinical Effectiveness Unit (CEU) at Sheffield Teaching Hospitals NHS Foundation Trust (Ref 11115 - 19/5/2022). Informed consent for anonymised data to be used in the service evaluation will be obtained from all patients prior to attending the service or during their initial assessment. Evaluation data will be processed in accordance with the 2018 data protection act.

The purpose of the evaluation is to determine the impact of a multimodal rehabilitation (including prehabilitation) service on patient outcomes, while also exploring service implementation, mechanisms of action and contextual factors that influence delivery and outcomes. Data relating to the implementation of the Active Together service will be integrated into the analysis of outcome effectiveness measures using a mixed-methods design, aligned to the latest guidance on developing

and evaluating complex interventions[32]. In addition, data on intermediate processes identified in the process evaluation might inform the inclusion of new outcome measures in future.

Outcome evaluation design

The primary aim of the outcome evaluation is to determine the impact of the Active Together service on physical outcomes, patient-reported outcomes and clinical endpoints, as well as determine benefits to the wider health system.

The outcome evaluation comprises both a single group, longitudinal design to determine the impact of the Active Together service on measured outcomes (physical and patient-reported) throughout the rehabilitation pathway, as well as a between group design (Active Together patients compared to non-Active Together patients) using hospital records data to assess the impact on secondary healthcare resource use and clinical endpoints. Both health resource usage and clinical endpoints data will be made available through a data sharing agreement with STH. There will be three overall patient groups to be compared with regard to hospital data: 1) patients that accept referral and attend the Active Together service, 2) patients that decline referral and do not attend the Active Together service, and 3) patients who received treatment for cancer between March 2017 and January 2022, prior to the launch of the Active Together service. These data will enable a comparison between patients that have received rehabilitation from the Active Together service and those who received standard care without rehabilitation.

Throughout the delivery of the Active Together service, patient outcomes will be measured at key time-points (Figure 1) and recorded digitally in an anonymised database. This dataset, in combination with health resource usage and clinical endpoint data will enable a pragmatic evaluation of the Active Together service.

Data collection timepoints

Patients will have outcome measures taken at an initial assessment at the AWRC (T1). The outcome measures collected at this initial assessment determine the frequency and intensity of support patients receive during the prehabilitation phase of the service, and provide a baseline for their physical, psychological, and nutritional state for the purposes of the evaluation. Outcome measures will be collected from patients at the end/beginning of each phase of the service pathway: post-prehabilitation (pre-treatment) (T2); post-maintenance rehabilitation (post-treatment) (T3), post-restorative rehabilitation (T4); post-supportive rehabilitation (T5) (Figure 1). In addition, patient reported outcomes, as well as health resource usage and clinical outcomes data (length of stay, readmission and 1-year survival) extracted from electronic patient records will be assessed at 12-months following treatment (T6).

FIGURE 1 HERE

Due to the complexity and individualised nature of cancer and its treatment, not all patients will proceed through the service pathway or these assessment points linearly. Instead, their service pathway will depend on the type of cancer treatment they receive, as demonstrated in Figure 2. In general, patients will be reassessed each time something changes in their treatment pathway.

FIGURE 2 HERE

The outcome measures that will be collected at each time point during the Active Together service are shown in Table 1 and described in more detail below.

TABLE 1 HERE

Outcome measures

Outcome data will be collected by service delivery staff via service delivery records, electronic patient records, questionnaires and physical measurement procedures. Training regarding data collection methods for service delivery staff will be provided to maximise consistency and reliability. Hospital data will be obtained from STH under a data sharing agreement. Primary and secondary outcomes are described below.

Primary outcomes

Aerobic capacity: the 6-minute walk test (6MWT) will be used to provide a proxy of patients' aerobic capacity. The 6MWT is a valid and reliable measure to estimate aerobic capacity in people with cancer [33]. Aerobic capacity was chosen as the primary outcome for several reasons; the 6MWT is widely used in the prehabilitation literature and therefore data can be compared and contrasted with other research and service evaluation; it is a prognostic factor for survival in some cancers[34]; it is associated with postoperative complication and length of stay[35]; and physical performance has been linked to survival and treatment-related complications in older adults with cancer[36,37].

Quality of life: will be assessed using the European Quality of Life Five Dimensions questionnaire (EQ-5D-5L) which has five domains focusing on mobility, self-care, usual activities, pain/discomfort and anxiety/depression, with one question per domain[38]. An additional visual analogue scale (VAS) question asks individuals to rate their current overall health on a scale ranging from 0 to 100.

Secondary outcomes

Lower limb strength and endurance: will be assessed using the 30 and 60-second sit-to-stand test. Patients will be encouraged to complete as many full sit-to-stand motions as possible within 60 seconds (the number of repetitions will also be recorded at 30-seconds)[39]. If a patient is unable to attend a face-to-face assessment (e.g., during isolation before chemotherapy/surgery) they will complete the 60-seconds sit-to-stand at home; the number of repetitions completed in the full 60 seconds will be used to assess the patient's tolerance to exercise in the absence of the 6MWT [40].

Upper limb strength: will be assessed using hand grip strength measured using a grip strength dynamometer to evaluate functional aspects of muscle strength, and to predict nutritional and general health status of patients[41,42].

Blood pressure and resting heart rate: will be measured using an automated digital sphygmomanometer according to the American Heart Association guidance, using the mean of two measured values[43].

Anthropometric proxies of nutritional status: body measures collected from patients will include body mass (kg), height (m), waist, and hip girth (cm), using International Society for the Advancement of Kinanthropometry (ISAK) procedures[44]. Body mass index (BMI) will be calculated as mass/height^2; waist-to-hip ratio (WHR) will be calculated as waist girth/hip girth.

Nutritional status: will be assessed using the modified Patient-Generated Subjective Global Assessment (mPG-SGA) questionnaire. The mPG-SGA is a validated nutritional assessment tool for cancer patients, which has been found to be easier to use than the original PG-SGA questionnaire and appears to have better predictive validity for survival[45].

Anxiety: will be assessed using the Generalised Anxiety Disorder questionnaires (GAD-7)[46].

Depression: will be assessed using the Patient Health Questionnaire (PHQ-9)[47].

Fatigue: the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue) will be used to assess self-reported fatigue levels of patients and its impact upon their daily activities and function [48].

Self-efficacy: will be measured using the Self-Efficacy for Exercise Scale (SEE) [49].

Physical activity: will be estimated using the exercise vital signs (EVS) tool, which is a valid proxy measure of the total minutes of physical activity patients perform each week [50].

Hospital data: hospital length of stay (LoS) will be measured as the total number of days an in-patient remains in hospital during a single admission event and is one of the major indicators for the consumption of hospital resources[51]. For the purposes of this evaluation, the number of standard ward

bed days as well as critical care bed days required for more advanced support and close monitoring, that patients require during their admission for surgery will be assessed. **Number of emergency department readmissions** will be assessed within 30 or 90 days of discharge. These outcomes are commonly used as a measure of patient outcomes following surgery, with increased numbers of readmissions contributing to higher costs to the health system. **One-year survival** following the end of treatment will be used as a clinical endpoint measure to determine the impact of the service on mortality.

Process evaluation design

The primary aim of the process evaluation is to understand what aspects of the service did or did not work and why, as well as contribute to the interpretation of the findings of the outcome evaluation. The design of the process evaluation is informed by the Medical Research Council (MRC) guidance on the process evaluation of complex interventions[32]. The MRC identify three essential features to understand the processes through which outcomes are achieved: context, implementation and mechanisms of impact. The application of this framework is described below, with the relationships between these functions of process evaluation shown in Figure 3.

FIGURE 3 HERE

The objectives of the process evaluation are to:

- Assess the reach and dose of the Active Together service delivery.
- Assess the treatment fidelity of the Active Together service to understand if the service was delivered as intended and whether any adaptations were made.
- Explore the experience of the Active Together service from the perspective of different stakeholders.

- Explore the presence of any theoretical mediators that explain changes in patient outcomes and clinical endpoints.

Reach and dose

Service performance indicators will be collected as part of the process evaluation to enable assessment of the reach and dose of the Active Together service. Performance indicators will include referral rates, uptake and adherence to the programme (number of sessions offered versus number of sessions attended), attrition rates of patients leaving the service early, signposting to other services and any documented adverse events. This information described in table 2 will be routinely collected and tracked by the service delivery team. In a subsample of Active Together patients, heart rate and rate of perceived exertion data will be captured to assess the intensity of the exercise being performed.

TABLE 2 HERE

Treatment fidelity

Treatment fidelity strategies will be assessed using adapted checklists created by the National Institute for Health-Behaviour Change Consortium (NIH-BCC)[52], and expanded further by Borelli[53]. The processes used in the Active Together service will be adapted to balance the realities of assessing treatment fidelity in the 'real world', as opposed to a controlled study environment. Table 3 provides definitions for each of the treatment fidelity components for this evaluation. Treatment fidelity will be assessed for each of the components described within the table (design, training and delivery).

TABLE 3 HERE

Perspectives of stakeholders

Semi-structured interviews and focus groups (face-to-face, telephone or Microsoft Teams) will explore the experiences of the Active Together service from different perspectives, including patients and professionals. We will recruit a diverse range of patients based on ethnicity, socioeconomic group, cancer diagnosis, age, outcomes and engagement with Active Together. Patients will be contacted once they have reached the end of the rehabilitation pathway, so they have experience of the whole service. Healthcare professionals across a range of clinical backgrounds and cancers as well as a range of staff delivering the service will be approached by the evaluation team to take part in an interview at various times during the evaluation. Patients and healthcare professionals will only take part in one interview. The researcher conducting the interviews will follow a pre-defined semi structured interview schedule to minimise potential bias (see supplementary materials). Interview topics for professionals will cover questions on opinions of the service, anticipated impact of Active Together, mechanisms for success and sustainability of the service. Interview topics for patients will cover service expectations, feedback and impact of the service. The data collected during the interviews/focus groups will also be used to capture emerging changes in the implementation of the service, as well as unanticipated or complex causal pathways which could inform new programme theory.

Qualitative samples will be large enough to ensure that most, or all the perceptions that might be important within the Active Together aims are uncovered, without being too large to reduce data, becoming repetitive and eventually superfluous.

Programme theory

The MRC guidance states that underpinning programme theory should be put in place to explain how a project or programme is understood to contribute to a chain of results that produce the intended or actual impact[32]. This includes seeing service development as a dynamic and iterative process which involves the input from key stakeholders using repeated cycles of development. Those responsible for the design, delivery and evaluation of the Active Together service, have developed programme theory

to describe 'the how' and 'the why' of the Active Together service (Table 4). This is based on learning from other complex system programmes and cancer rehabilitation services. This programme theory describes how the Active Together service is intended to deliver its outcomes and the conditions required to succeed. The programme theory also sets out the causal pathway between the context of the service, intermediate outcomes, and long-term goals and how these interact with contextual factors.

TABLE 4 HERE

Cancer rehabilitation programmes, such as Active Together, are complex in nature due to the interaction of multi-organisation and multi-level components, which could create some barriers to achieving the intended outcomes. During the Active Together programme theory development, logic models were used to communicate various parts of the programme theory (e.g., mechanisms by which the service will achieve its outcomes). Figure 4 is an example of the initial logic model, which will be tested and refined as the service is being delivered. Focus groups with the core Active Together delivery team will be carried out to explore how the service is progressing in relation to the initial logic model, which will help demonstrate theory of change. Topics within the focus group will include questions relating to the team vision, reviewing what is still applicable from the initial logic model and what has changed, barriers to delivery and anticipated delivery plans. Focus groups will take place on three occasions, every six-months. The programme theory and logic models will be refined and amended to reflect any changes.

FIGURE 4 HERE

Service refinement and monitoring

The Active Together team will closely monitor and detect significant deviations from the Active Together protocol[29], to prevent any issues from being widespread, and long-lasting. The framework recommended by the NIH-BCC will be embedded into the service from the outset to assess if the service is being delivered as intended[55].

As part of continuous service improvement, it is anticipated that Active Together will need to be refined and adapted, either based on data collected or the evolution of the programme theory. By engaging service users and other key stakeholders in service feedback loops, the feasibility and acceptability of the Active Together service will be improved iteratively over time. This refinement process will be a key feature of the Active Together service, ensuring that the service remains patient-focused and evidence based. Any time a significant change is made to the Active Together service delivery or evaluation protocol it will be documented, including the date of the change, exactly which elements of the service or evaluation have changed and the reason for the change. Any changes to the service design and delivery will be reported in subsequent reports and publications where relevant and evaluation data will be analysed and interpreted in light of any alterations.

Data analysis

Outcome evaluation analysis

Descriptive statistics will summarise the characteristics of patients that access the Active Together service and will be used to assess the diversity of patients from a socio-economic and ethnicity perspective. A one-way repeated measures (within-group) analysis of variance (ANOVA) will be used to determine both the statistical significance of changes in the mean value of patient outcome measures throughout the Active Together pathway and their clinical significance based on pre-defined thresholds where available. This analysis will be performed with all patients considered as a single group and within groups of patients stratified according to demographic characteristics and cancer tumour type, for example. In addition, a between-group ANOVA will enable comparative analysis of changes in these outcome measures throughout the service pathway between these patient sub-groups. Group-based trajectory modelling[56] will also be used to assess and visualise observed changes in patient outcome measures throughout the Active Together service. Predefined criteria will be applied to ensure patients are eligible for inclusion in the analysis, or how patients are divided into

sub-groups. For example, if patients have had a prehabilitation phase (time between initial assessment and start of treatment) lasting less than two weeks, they will be analysed separately from patients that received prehabilitation over a longer period. This is because a previous prehabilitation evidence and insight review recommended that two weeks is the minimum period within which it is feasible to intervene before acute treatment[57].

Economic evaluation of the Active Together service will centre on the value-based healthcare approach, including patient treatment outcomes and the impact on resources. Individual healthcare usage will be obtained retrospectively, thereby restricting the cost analysis to direct healthcare costs. Individual usage will then be scaled up to determine average and unit costs, based on the National Cost Collection Index 2019/20[58] and from Unit costs of Health and Social Care database[59]. A proxy measure of bed-day cost will be calculated as an average of the excess bed-day tariff for procedures carried out on patients. Critical care tariffs will be used for surgical patients to assess the impacts on critical care. To consider the impact of emergency readmission, a one-day excess bed day tariff will be used. It must be noted that this will not equate to actual cash releasing 'cost savings' but reflects impact on provider costs in terms of bed days and capacity. If this shows a positive outcome, it can be assumed that resources will be redirected and a net efficiency saving for the health system can be demonstrated.

Process evaluation analysis

Initially, analysis of quantitative process data will include descriptive statistics relating to questions such as fidelity, dose, and reach. Subsequently, quantitative process measures will be integrated with outcomes data to help understand how, for example, implementation variability of the service affects outcomes and theories arising from patient interview responses. By using qualitative data, it could be that patient motivation is supported by other mechanisms, such as social support from other patients. The integration of quantitative measures of psychological change mechanisms with outcome data may help to clarify complex causal pathways within the service. By doing so, it will be possible to

understand how the Active Together service works by testing theoretical mediators through which the service exerts its effects to determine whether the Active Together service leads directly to changes in measured patient outcomes, or whether the service changes some intermediary variable, such as self-efficacy, which in turn leads to changes in these outcomes. This combination of data from the quantitative outcome evaluation and the qualitative interview data from the process evaluation within a mixed-methods analysis will enable the findings of the two aspects of the evaluation to be linked together.

Verbatim transcription of interview and focus group recordings will be conducted by an external transcription company. These data will be examined using thematic analysis. The approach involves the development of an initial coding index based on the interview guide. The coding index will be implemented to organise the data into themes. The research team will thematically analyse the data[60] and identify key themes raised by patients and professionals regarding the Active Together service. At least one other experienced qualitative researcher will support the analysis to facilitate triangulation and rigour, exploring different interpretations of the data and minimising researcher bias. Each stage of analysis will build an increasingly nuanced understanding of important themes. Data analysis from all stages of the evaluation will be synthesised to form a 3D intervention logic model[61]. This model will outline a hypothesised theory of change[62]. This will inform subsequent recommendations for the future development of Active Together.

DISCUSSION

There is increasing evidence supporting the efficacy of rehabilitation (including prehabilitation) as an adjunct to cancer treatment[22,63-65]. While prospective trials comparing prehabilitation with standard care might yield evidence of comparative treatment effects in experimental measures, evaluation of large cohorts from real-world rehabilitation services can help understand wider clinical value. The evaluation of the Greater Manchester Prehab4Cancer service provides real-world evidence of the effectiveness of cancer prehabilitation for patients, providers and the wider healthcare system[66]. The

independent evaluation found there was a reduced demand on healthcare services throughout the cancer pathway, patients benefitted from health improvements prior to surgery and longer-term following post-operative rehabilitation, reduced ward and critical care bed days, and evidence of improved one year survival in colorectal and upper GI cancer patients. When considering the long-term commissioning and sustainability of rehabilitation services, the report concluded that bed days 'released' per Prehab4Cancer patient covered the cost of setting up and delivering the service for a year.

Despite the increasing scientific evidence of the benefits of cancer rehabilitation, the translation of evidence into practice is less advanced. Cancer rehabilitation is not currently routinely provided as part of standard NHS care. The Active Together service aims to test a model of multimodal rehabilitation embedded within existing cancer care pathways to address the gap in patient care. Findings from the evaluation of Active Together will contribute to the emerging evidence base of the real-world effectiveness of cancer rehabilitation and potentially strengthen the case for widespread uptake and adoption of rehabilitation for cancer patients. The results of this evaluation will provide valuable insight into service implementation and an understanding of impacts on both patient outcomes and the health economic landscape.

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Trial registration: This service evaluation was registered with the Clinical Effectiveness Unit at Sheffield Teaching Hospitals (Reference number 11115).

Ethics approval and consent to participate

All data collection methods and procedures detailed in this protocol will be carried out in accordance with the principles laid out in the Declaration of Helsinki. All procedures detailed in this service evaluation protocol have been reviewed by the Health Research Authority (HRA) who concluded that formal NHS ethical approval was not required because no new or untested treatment is being offered and there is no experimentation being conducted with patients. The service evaluation has been approved by the Clinical Effectiveness Unit (CEU) at Sheffield Teaching Hospitals NHS Foundation Trust (Ref 11115 - 19/5/2022). Informed consent for anonymised data to be used in the service evaluation is obtained from all patients prior to attending or during their initial assessment and data will be processed in accordance with GDPR.

Availability of data and materials

Not applicable. No datasets were generated or analysed for the purposes of this manuscript.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

AM, GF, CK, KP, GP and MT drafted the manuscript. AM, LH, GF and RC, with support from the Active Together clinical advisory group, designed the project. All authors read and approved the final manuscript for submission.

LIST OF ABBREVIATIONS

- **UK**: United Kingdom
- **LOS:** Length of stay
- **WHO:** World Health Organisation
- **AWRC:** Advanced Wellbeing Research Centre
- **SHU:** Sheffield Hallam University
- **YCR:** Yorkshire Cancer Research
- **STH:** Sheffield Teaching Hospitals NHS Foundation Trust

- **NHS:** National Health Service
- **6MWT:** 6-minute walk test
- **SEE:** Self-efficacy for exercise scale
- **EVS:** Exercise vital signs
- **mPG-SGA:** Modified patient-generated subjective global assessment
- **BMI:** Body mass index
- **SACT:** systemic anti-cancer therapy
- **CNS:** Clinical Nurse Specialist
- **HRA:** Health Research Authority
- **CEU:** Clinical Effectiveness Unit
- **EOT:** End of treatment
- **SES:** Socio-economic status
- **IMD:** Index of Multiple Deprivation
- **PAR-Q:** Physical Activity Readiness Questionnaire
- **FACIT-Fatigue:** Functional Assessment of Chronic Illness Therapy-Fatigue
- **PHQ:** Patient Health Questionnaire
- **GAD:** Generalised Anxiety Disorder
- **WHR:** Waist-to-hip ratio
- **ISAK:** International Society for the Advancement of Kinanthropometry
- **MRC:** Medical Research Council
- **NIH-BCC:** National Institute for Health-Behaviour Change Consortium
- **ANOVA:** Analysis of variance

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TABLES

Table 1. Schedule and details of outcome measures to be collected during Active Together service.

	Prehabilitation			Rehabilitation (Maintenance / Restorative / Supportive)			
Patient outcome	**T1: Pre-prehab**	**T2: Pre-treatment**	The type and duration of treatment will vary between participants	**T3: Post-treatment**	**T4: Post-restorative**	**T5: Post-supportive**	**T6: 12-month follow-up**
Eligibility	✓						
Cancer diagnosis (site, stage, etc.)	✓						
Socio-demographics (age, sex, ethnicity, postcode (IMD))	✓						
Medical history	✓						
Anthropometry (height, mass (BMI); waist and hip circumference (WHR))	✓	✓		✓	✓	✓	
Aerobic capacity (6MWT)	✓	✓		✓	✓	✓	
Hand grip strength (Dynamometer)	✓	✓		✓	✓	✓	
Leg strength/endurance (30 and 60s sit-to-stand test)	✓	✓		✓	✓	✓	
Blood pressure and resting HR (Sphygmomanometer)	✓	✓		✓	✓	✓	
Physical activity level (EVS)	✓	✓		✓	✓	✓	✓
Health-related quality of life (EQ-5D-5L)	✓	✓		✓	✓	✓	✓
Fatigue (FACIT-Fatigue)	✓	✓		✓	✓	✓	✓
Nutritional state (mPG-SGA)	✓	✓		✓	✓	✓	✓
Anxiety and depression (PHQ-9/GAD-7)	✓	✓		✓	✓	✓	✓
Self-efficacy (SEE)	✓	✓		✓	✓	✓	✓
Electronic patient record							✓

IMD: Index of Multiple Deprivation; BMI: body mass index; WHR: waist-to-hip ratio; 6MWT: six-minute walk test; HR: heart rate; EVS: exercise vital signs; FACIT-Fatigue: Functional Assessment of Chronic Illness Therapy-Fatigue; PHQ: Patient Health Questionnaire; GAD: Generalised Anxiety Disorder; SEE: Self-efficacy for exercise; mPG-SGA: modified patient-generated subjective global assessment.

Table 2. Service performance indicators.

Outcome	**Measurement method**
Referral into service	Service delivery records
Source of referral	Service delivery records
Uptake of the service (conversion ratio)	Service delivery records
Reasons for opt-out	Service delivery records
Reasons for leaving the service	Service delivery records
Attendance levels	Service delivery records
Attrition rates	Service delivery records
Stage of treatment (prehab, maintenance, rehab)	Service delivery records
Service completion rates	Service delivery records
Number of patients referred to support services (e.g., smoking cessation and complementary therapies)	Service delivery records
Adverse events associated with the service	Service delivery records
Participant satisfaction with the service	Questionnaire

Table 3. Treatment fidelity: what and how.

Treatment fidelity component	**Definition**	**How it will be delivered**
Design	The theoretical model and guidelines of the hypothesis that is being tested. It includes factors to consider when designing the study which can help in future to ensure replication.	• Documentation will be checked, and key members of the management team will be interviewed about the design of the service. • NIH-BCC checklists will be used to ensure that the design is compliant with the key fidelity components.
Training	To ensure that Active Together delivery staff receive adequate training prior to and during service delivery.	• Documentation will be checked, and key members of the management and delivery team will be asked about the training they received. • NIH-BCC checklists will be used to ensure that the training in compliant with the key fidelity components.
Delivery	To confirm that the Active Together content and quantity of the intervention are delivered as intended and that each session adheres to the intervention protocol.	• Delivery staff will be observed delivering sessions to patients. • NIH-BCC checklists will be used to ensure that the delivery is compliant with the key fidelity components.

Table 4. Active Together programme theory.

If	Then	Because
• Key professionals (non-clinical and clinical) come together to form an improvement team to address any changes to the service • The Active Together team will engage regularly with patients to gain patient feedback • The Active Together team and healthcare professionals from STH regularly review quality improvement approaches, and • All relevant stakeholders are updated and made aware of the project and improvement goals • Processes are fully transparent between the Active Together team and cancer clinical teams • There is an explicit common purpose or agenda and agreed direction of travel for the Active Together service • Commit to having ongoing dialogue with end users and recognise the need for iteration to find approaches that resonate with patients • There is a sense of trust across the system in what the Active Together team are trying to do (a sense of working for the greater good)	• A shared view of performance and service improvement gaps can be created • The Active Together team can work as a team to define and achieve service improvement goals • Basic quality improvement approaches can be employed to achieve the improvement goals • Stakeholders will be more engaged in the need for change and aware of how improvement will occur • Cross sector collaboration is more likely	• Improved joined up working can be achieved across the system • Improvements in Active Together service delivery in line with the recommended rehabilitation pathway can be achieved • Patients are most adequately prepared physically and psychologically for their cancer journey • Patient outcomes are improved in the long-term

FIGURES

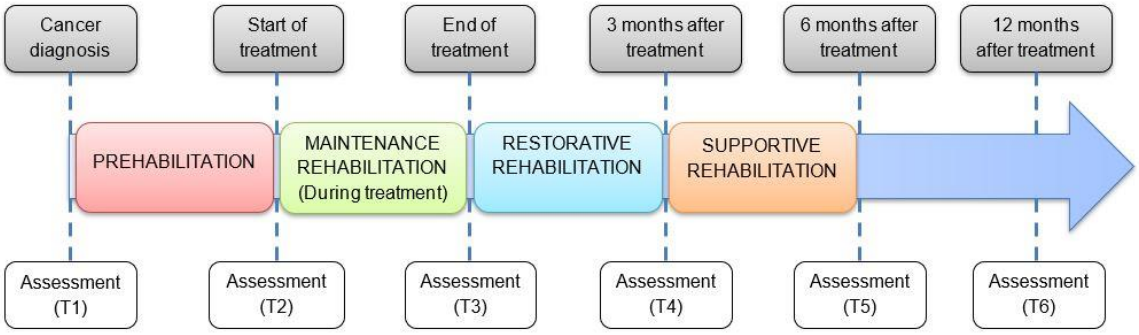


Figure 1. Phases of Active Together service pathway and assessment points.

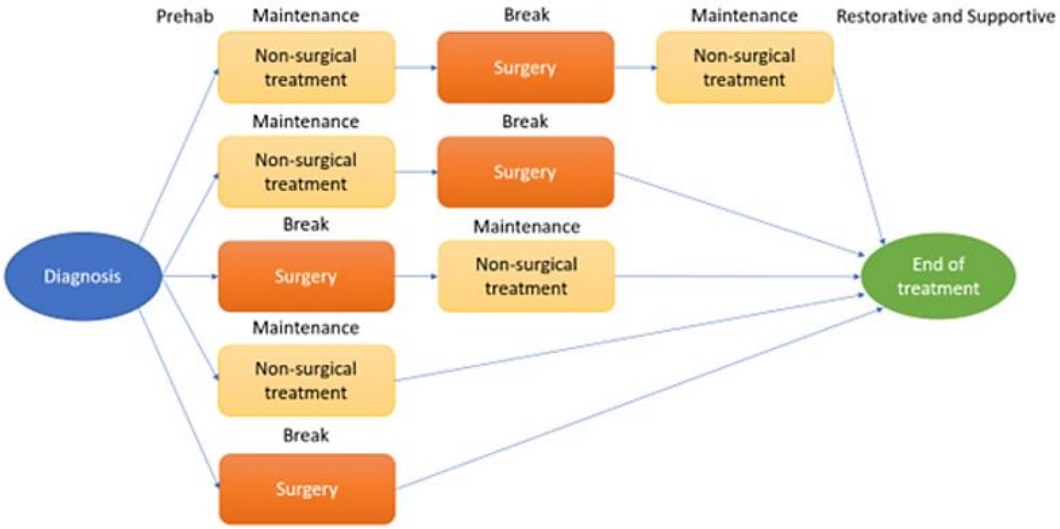


Figure 2. Examples of different treatment pathway scenarios.

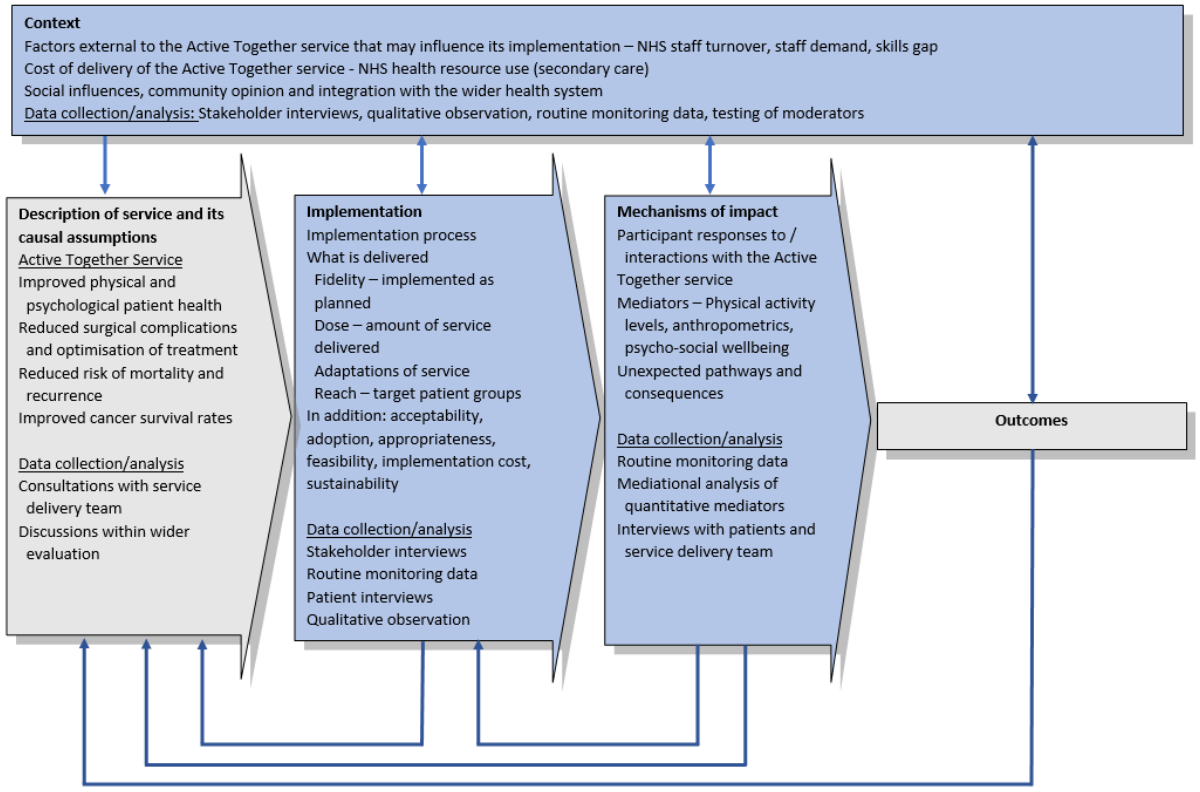
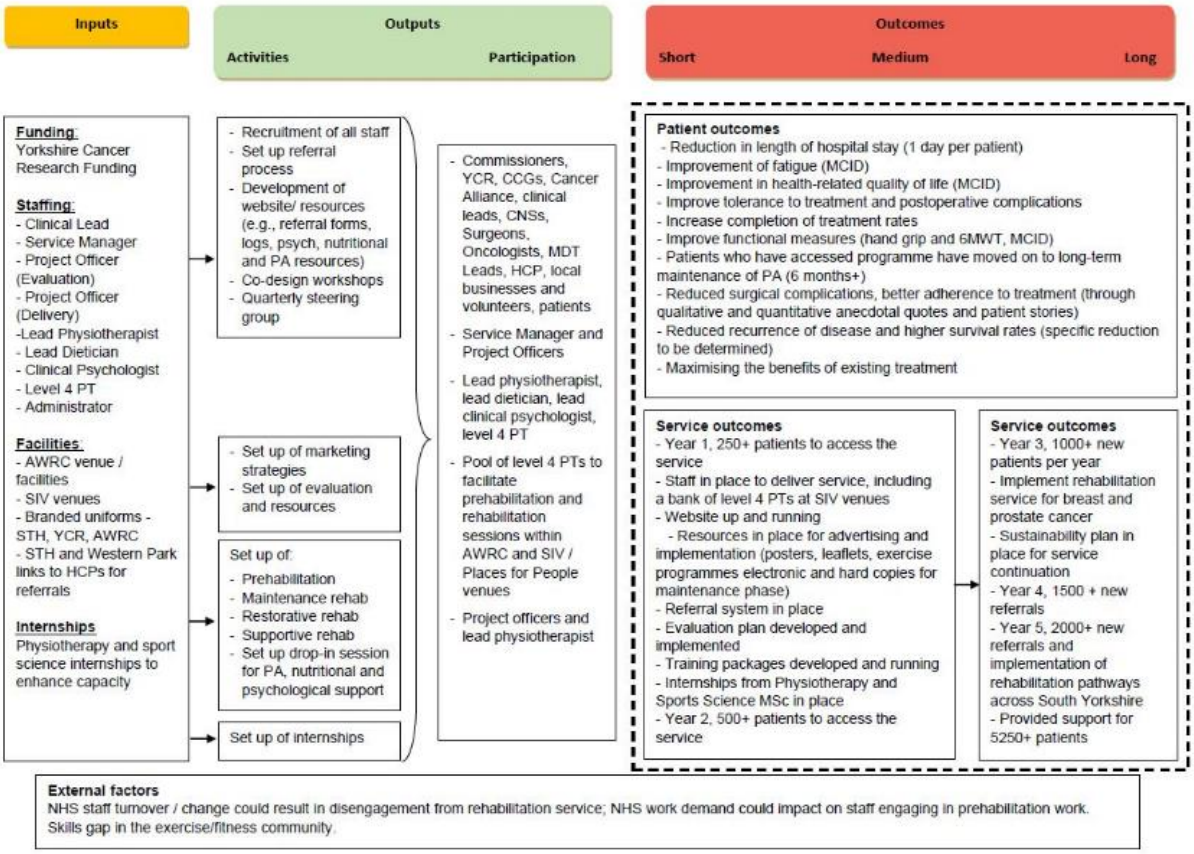


Figure 3. Description and relationships between the three dimensions of the process evaluation.



PT: physical trainer; AWRC: Advance Wellbeing Research Centre; SIV: Sheffield International Venues; STH: Sheffield Teaching Hospitals; YCR: Yorkshire Cancer Research; HCP: healthcare professionals; PA: physical activity; CCG: clinical commissioning group; CNS: clinical nurse specialist; MDT: multidisciplinary team; MCID: minimal clinically important difference.

Figure 4. Initial logic model for the Active Together service in Sheffield.