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Development of a web-based health and wellbeing programme to support people preparing for major surgery

Submission date 04/10/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 06/10/2021	**Overall study status** Ongoing	
Last Edited 10/12/2025	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
Supporting people to improve their health and wellbeing before surgery is known as prehabilitation. This may involve structured support to increase physical activity and fitness, stop smoking, reduce alcohol consumption, eat more healthily, sleep better or prepare psychologically for major surgery. Preparing patients for their operation in this way can improve outcomes. Support can be delivered in many ways. The aim of this study is to design and develop (stage 1) then road-test (stage 2) a web-based prehabilitation programme in partnership with patients and healthcare professionals.

Who can participate?
In stage 1 patients aged 18 and over who are preparing for or have recently undergone major surgery and healthcare professionals responsible for their care can take part. Stage 2 will involve patients aged 18 and over who are preparing for major surgery and healthcare professionals responsible for testing the programme developed in stage 1

What does the study involve?
Participants will be involved in a structured co-design process led by a multidisciplinary design team. Their views will be sought throughout on how best to design and develop the programme, aiming for a product that works well for patients and healthcare professionals. Participants will be invited to undertake a brief questionnaire, a structured interview and take part in a series of workshops to review the programme as it develops. This will be based on a theory for the development of health behaviour change interventions called the behaviour change wheel. People approaching major surgery will be invited to use the programme developed in stage 2, supervised by healthcare professional participants acting in a supervisory role. They will be asked to feedback on their experience of using the programme throughout.

What are the possible benefits and risks of participating?
Patient participants will need to giving up their time to attend and participate in group workshops. Patients may be experiencing a difficult journey toward or recovering from their operation. Discussing issues around this may be stressful or lead to anxiety for some. Patients

can speak to a team member if this is the case. They do not need to take part in every workshop or stay for the whole workshop if a particular topic is difficult for them. There is unlikely to be a direct benefit to patients. However, it is hoped that they will find the experience interesting, informative and that they benefit from the chance to interact with other patients who have had similar experiences to them. The information collected may also help develop a programme for patients in the future.
Healthcare professional participants will need to giving up their time to attend and participate. There may be no direct benefit to them individually but it is hoped that they will find the experience interesting, worthwhile and benefit from the chance to interact with patients and other like-minded staff members intending to build something new to benefit future patients. This is also an opportunity to contribute to service development and CPD requirements

Where is the study run from?
Teesside University and South Tees Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
July 2020 to December 2025

Who is funding the study?
1. Sport England (UK)
2. Macmillan Cancer Support (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
300425

ClinicalTrials.gov (NCT)
Nil known

Central Portfolio Management System (CPMS)
49967

Study information

Scientific Title
Systematic development and feasibility testing of a digitally facilitated, remotely supervised, multimodal prehabilitation intervention for patients approaching major surgery

Study objectives
The aim is to develop and feasibility test a multi behavioural health and wellbeing intervention to support patients preparing for major surgery and reduced perioperative risk. The intervention will be web-based and systematically co-designed with patients and healthcare professionals prior to feasibility testing in patients preparing for major surgical intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/09/2021, Preston Research Ethics Committee (Barlow House, 3rd Floor, HRA NRES Centre, Manchester, M1 3DZ, UK; +44 (0)207 104 8206; preston.rec@hra.nhs.uk), REC ref: 21/NW/0219

Study design

Non-randomized; Both; Design type: Treatment, Prevention, Process of Care, Education or Self-Management, Dietary, Psychological & Behavioural, Complex Intervention, Physical, Other, Qualitative

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients approaching major surgery

Interventions
Stage 1: Systematic development of the web-based multi behavioural prehabilitation programme
Stage 1 Timescale: 15 months
Stage 1 Participants:
A co-design group will be recruited to guide the design and development of the web-based programme. members will include patients who have recently undergone or are preparing for major surgery, healthcare professionals (HCPs) involved in the preparation of patients for surgery. The group will be supported by our multidisciplinary design team of clinicians, researchers (including exercise scientists, behaviour change specialists and health psychologists and a partner web developer experienced in the design of health behaviour change programmes for the national health service (NHS)
Stage 1 will involve three components and may involve a maximum of 110 patient and HCP participants. However, it is anticipated that the actual number will be far fewer as participants will be invited to undertake multiple components. Participants will be recruited at two NHS sites (South Tees Hospitals NHS Foundation Trust and York and Scarborough Hospitals NHS Teaching Hospitals).
Patient participants may also wish to involve a partner or companion. We recognise the value of their contribution to the process and supporting individuals undertaking the intervention. We will therefore also invite these individuals to consent for their contribution to be included in the analysis and contribute to the development of the programme.

Stage 1 Methods:
Stage 1 will use established methods for the development of behavioural interventions to improve health including the behaviour change wheel (BCW) and the theoretical domains framework (TDF). The programme will be developed in a stepwise approach drawing together input from several sources to create a programme optimised for feasibility testing in stage 2. An accompanying training resource for healthcare professionals supervising patients using the programme will be developed alongside, in addition to a draft framework for evaluating the programme during a future randomised controlled trial.

The development process will involve 3 components in stage 1:
1. Behavioural analysis self-evaluation (COM-B) questionnaires:
10-20 patients and 10-20 HCP participants will be invited to undertake the 10-15 minute COM-B behavioural self-evaluation questionnaire to establish the key factors supporting uptake and engagement with the web-based programme.

2. Semi-structured interviews:
10-20 patients and 10-20 HCP participants will be invited to undertake a 60-minute, audio-recorded, semi-structured interview with 1-2 members of the study design team. Interviews will focus on key drivers and barriers to behaviour change prior to major surgery and use of the programme, alongside the content of the programme and accompanying training resources. A topic guide will be drafted based on COM-B questionnaire results. A remote participation option using telephone or a secure video-conferencing platform (e.g. Zoom/Microsoft Teams) will be made available if required.

3. Co-design workshops:
Up to 25 patient and HCP participants in total will be invited to attend a series of co-design workshops, with options for face-to-face and remote participation, in line with current COVID-19 restrictions and precautions at both sites.
Some sessions will involve patients or HCP members only depending on the goal. Sessions will be attended and facilitated by study design team members.
Workshops will run for approximately 2 hours and focus on review of the programme as it develops allowing rapid feedback to the design team and stepwise modification in readiness for future sessions. Participants will be invited to attend up to 6 workshops but are not required to attend every session unless they wish to.
All sessions will be audio-recorded and transcribed for analysis. detailed notes will be taken by design team members to understand how and why key development decisions were made.
The workshop series content will cover a number of key development areas:
1. Messaging around health risk behaviours before surgery and how to present this
2. Methods for self-monitoring, feedback and support
3. Programme look, feel and user-friendliness

Stage 2: Feasibility testing of the programme with patients approaching major surgery at two National Health Service (NHS) centres
Stage 2 timescale: 8 months
Stage 2 participants:
40 patients preparing for major surgery at two NHS sites
2-3 healthcare professionals at each site to act as programme facilitators

Stage 2 methods:
Overview of the anticipated web-based prehabilitation programme:
The programme produced in stage 1 cannot be pre-empted. However, it is expected to have the following central features and functions.
1. The programme will be utilised for 4-8 weeks before surgery using digital devices (smartphone /iPad/desktop) owned by the patient.
2. Participants will be encouraged to 'login' several times per week to access support relevant to their individual health behaviours. It is anticipated that participants will access 2-3 areas of content simultaneously reflecting the tendency of health risk behaviours to cluster in individuals preparing for major surgery and the need to support patients fully in relatively short timeframes before surgery.
3. Programme content and support will be provided using audiovisual material including:
3.1. A structured exercise training programme to improve cardiorespiratory endurance, whole-body strength and training for the muscles of breathing.
This will be supported by home exercise equipment including resistance bands, an inspiratory muscle trainer and an integrated wearable (e.g. FitBit) device to guide the intensity of training and feedback other health data to the participant. Participants will download the relevant wearable application to their smartphones for linkage to the platform.
3.2. Smoking cessation support

3.3. Alcohol reduction support
3.4. Nutrition support
3.5. Support to improve sleep quantity and quality
3.6. Psychological wellbeing support
3.7. Educational content to improve readiness for surgery

4. Tools for personalised goal-setting, self-monitoring and problem-solving
5. Remote HCP feedback, oversight and support
Healthcare professionals will have a dedicated interface allowing an overview of all patient participants using the platform to allowing monitoring and remote feedback and support.
6. Messaging and communication features to interact with the facilitating healthcare professionals and other participants using the programme to allow patient and peer education alongside receipt of feedback, support and raising of issues and problems.

Participant study visits:
Visit 1- Baseline assessment (up to 120 minutes)
Following screening, recruitment and informed consent stage 2 patient participants will attend for their initial visit at the hospital site. They will be met by an HCP facilitator participant trained to supervise patients using the programme and at least one study team member.
After screening for any safety concerns against International criteria for clinical exercise testing and training. Participants will be guided through programme registration and introduced to the intervention

1. Platform registration and health risk behaviour assessment

Registration will involve a first login to the programme after the creation of a username and password. The registration process will incorporate:
1. Collection of key clinical and surgical information
2. Completion of several questionnaires related to health risk behaviours to identify relevant content and support for the programme to offer. These will be presented to the patient electronically, however paper examples are appended. Information collected will include:

Demographic information:
1. Name
2. Age
3. Gender
4. Preferred email and/or mobile phone number
5. Chronic health conditions

Surgical information:
1. Planned date
2. Specialty
3. Planned procedure
4. Chemoradiotherapy prior to surgery

Health risk behaviour questionnaires utilised will include:

Smoking:
1. Smoking status and history in pack-years
2. Fagerstrom score for nicotine dependence

Alcohol:
1. Units of alcohol per week
2. AUDIT-C tool (if consuming >14 units per week)

Exercise and activity
1. Duke Activity Status Index (DASI)
2. International physical activity questionnaire (IPAQ) short form

Nutrition
1. Dana Faber cancer institute eating habits questionnaire (modified for personal assessment domains only)

Psychological wellbeing
1. Hospital Anxiety and Depression Scale (HADS) for depression and anxiety

Sleep
1. Pittsburgh sleep quality index

Other
1. Quality of life EQ-5D-5L
2. Quality of life SF-36 v2
3. Patient Activation Measure (PAM)

2. Clinical assessment:
Participants will then undergo a clinical assessment with data inputted to the platform at a later date by facilitating HCPs and study team members:

Physical measurements:
1. Height
2. Weight
3. Resting Heart rate
4. Resting Blood pressure
5. Resting oxygen saturations
6. Non-invasive body composition assessment using bioimpedance
7. The patient-generated subjective global assessment (PG-SGA) of nutritional status

Exercise assessment:
1. 6-minute walk test
2. 30-second sit-to-stand test
3. Grip strength
4. Maximum inspiratory pressure measurement

3. Programme introduction:
Following registration and clinical assessment, participants will be introduced to the key programme features and provided with key instructions for safety, troubleshooting, question and queries and issued with exercise equipment to be used alongside the programme (resistance bands and inspiratory muscle trainer). Participants will then be able to access and use the programme as they wish in the subsequent weeks prior to their operation with oversight, support, prompting and check-ins by the supervising HCPs. Participants will otherwise engage normally with their routine preoperative care.

Visit 2 - Preoperative assessment (up to 90 minutes)
Visit 2 will mirror visit 1 and be scheduled immediately prior to surgery. Participants will return to the hospital site for a repeat health risk behaviour and clinical assessment to assess changes following the use of the programme. Participants will undergo surgery following this. Following surgery, they will have ongoing access to the programme which will provide rehabilitation support to aiming to support recovery.

Visit 3- 3 month postoperative assessment (up to 90 minutes)
Visit 3 will mirror visits 1 and 2 with a repeat of the health risk behaviour and clinical assessment aiming to assess the persistence of any changes following surgery.
Participant study involvement will end after the completion of visit 3 however they will be welcome to continue using the programme if they wish.

Semi-structured interview:
10-20 patient participants will be invited to undertake a postoperative semi-structured, audio-recorded interview with at least one member of the study team. This will be scheduled following surgery. Interviews will last up to 60 minutes and cover their experiences of using the programme. Participants will have a remote option using telephone or video-conferencing if required. A topic guide has been drafted and appended.

Healthcare professional participant diaries and semi-structured interview:
Participating HCP facilitators will be asked to diary their time and activity supporting the patient participants using the programme. This will facilitate an early-stage health economic analysis of intervention delivery. They will also be invited to undertake one semi-structured, audio-recorded interview with a study team member covering their experiences of supporting patients using the programme. A topic guide has been drafted and appended.

Intervention Type
Other

Primary outcome(s)
1. Intervention feasibility
2. Intervention acceptability to patients and HCPs
3. Intervention fidelity
Measured using a combination of qualitative participant feedback (semi-structured interviews) and programme usage data including e.g. logins, time spent and completion rates of programme components at exit from the study

Key secondary outcome(s))
Surgical data:
1. Alive at hospital discharge based on review of electronic records at hospital discharge
2. 30-day mortality measured based on review of electronic records at day postoperative day 30
3. 90-day mortality measured based on review of electronic records at postoperative day 90
4. Postoperative morbidity assessed using the Comprehensive complication Index (CCI) at hospital discharge
5. Days at home post-surgery (DAH30) measured based on review of electronic records at 3-month postoperative assessment
6. Length of hospital stay (days) based on review of electronic records at 3-month postoperative assessment
7. Length of critical care stay (days) based on review of electronic records at 3-month postoperative assessment

Behavioural risk factor assessment:

Smoking:
1. Smoking status (number of cigarettes) at baseline assessment, preoperative assessment and 3-month postoperative assessment
2. Nicotine dependence assessed using Fagerstrom score (if smokes) at baseline assessment

Alcohol:
1. Consumption (units of alcohol) at baseline assessment, preoperative assessment and 3-month postoperative assessment
2. Alcohol dependence assessed using AUDIT (if >14 units per week) at baseline assessment

Exercise and activity:
1. Functional capacity assessed using Duke Activity Status Index (DASI) at baseline assessment, preoperative assessment and 3-month postoperative assessment
2. Physical activity assessed using International Physical Activity Questionnaire (IPAQ) Short form at baseline assessment, pre-operative assessment and 3-month postoperative assessment
3. Risk or respiratory complications assessed using ARISCAT score at baseline assessment, pre-operative assessment and 3-month postoperative assessment

Nutrition:
1. Diet quality assessed using Dana Faber Cancer institute eating habits questionnaire (personal dietary assessment domains) at baseline assessment, pre-operative assessment and 3-month postoperative assessment
2. Nutritional status assessed using MUST at baseline assessment, preoperative assessment and 3-month postoperative assessment
3. Nutritional status assessed using PG-SGA at baseline assessment, preoperative assessment and 3-month postoperative assessment
4. HbA1C (record if routinely collected) at baseline assessment, preoperative assessment and 3-month postoperative assessment
5. CRP (record if routinely collected) at baseline assessment, preoperative assessment and 3-month postoperative assessment

Psychological health and wellbeing measured using the:
1. Hospital Anxiety and Depression Scale (HADS) Anxiety at baseline assessment, preoperative assessment and 3-month postoperative assessment
2. Hospital Anxiety and Depression Scale (HADS) Depression at baseline assessment, preoperative assessment and 3-month postoperative assessment

1. Sleep measured using the Pittsburgh Sleep Quality Index at baseline assessment, preoperative assessment and 3-month postoperative assessment

Other questionnaires:
1. Self-efficacy assessed using Patient Activation Measure (PAM) at baseline assessment, preoperative assessment and 3-month postoperative assessment
2. Quality of life assessed using EQ-5D-5L at baseline assessment, preoperative assessment and 3-month postoperative assessment
3. Quality of life assessed using SF-36 v2 at baseline assessment, preoperative as-assessment and 3-month postoperative assessment

Clinical assessment:

Physical observations:
1. Height (m) measured using the standard clinical technique at baseline assessment
2. Weight (kg) measured using the standard clinical technique at baseline assessment, preoperative assessment and 3-month postoperative assessment
3. Body Mass Index (BMI) measured using the standard calculation at baseline assessment, preoperative assessment and 3-month postoperative assessment
4. Resting heart rate measured using a pulse oximeter at baseline assessment, pre-operative assessment and 3-month postoperative assessment
5. Resting blood pressure (mmHg) measured using an automated DINAMAP device at baseline as-assessment, preoperative assessment and 3-month postoperative assessment
6. Resting oxygen saturations SPO_2 (%) measured using pulse oximetry at baseline assessment
7. Body composition measured using bioimpedence at baseline assessment, preoperative assessment and 3-month postoperative assessment

Functional capacity (exercise capacity) assessed using:
1. 6-minute walk test (m) at baseline assessment, preoperative assessment and 3-month postoperative assessment
2. 30-second sit-to-stand test (repetitions) at baseline assessment, preoperative assessment and 3-month postoperative assessment
3. Grip strength (kg) at baseline assessment, preoperative assessment and 3-month postoperative assessment
4. Maximum inspiratory pressure (cmH2O) at baseline assessment, preoperative assessment and 3-month postoperative assessment

Cardiopulmonary exercise test data if undertaken as part of routine care:
1. VO_2 peak (ml/min/kg/VO_2) measured using review of clinical records at baseline assessment, preoperative assessment
2. VO_2 AT (ml/min/kg/VO_2) measured using review of clinical records at baseline assessment, preoperative assessment

1. Physical activity measured using accelerometry data from the integrated wearable device continuously whilst participants are utilising the platform
2. Feasibility and usability of the integrated wearable device to guide the intensity of remotely-supervised exercise training and vital sign monitoring through the perioperative period. This will be assessed qualitatively using semi-structured interviews with participants and recording of biometric data continuously whilst participants are utilising the platform

Completion date
30/06/2026

Eligibility

Key inclusion criteria
Stage 1:
Patient participants:
1. Adult patients (≥18 years of age)
2. Within 3 months of having undergone major surgery or preparing for major surgery
3. Discharged from hospital to their own home

Healthcare professional participants:
1. Perioperative team members currently caring for patients approaching major surgical

intervention in the preoperative period.
2. Employed at South Tees Hospitals NHS Foundation Trust or York Hospital
3. A medical, nursing or allied healthcare professional background or a wider stakeholder in perioperative care e.g. an individual with management or commissioning responsibility for perioperative services.

Stage 2:
Patient participants:
1. Adult patients (aged >18 years) listed for a major surgical procedure.
2. A minimum of 4 weeks available prior to planned surgery.
3. ASA (American Society of Anaesthesiology) fitness for surgery grade >2
4. At least one health risk behaviour amenable to remotely supervised prehabilitation via the developed intervention.
5. Access to and willingness to utilise a smartphone and integrated wearable device.
6. Able to access and utilise the internet at home.

Healthcare professional participants:
1. Perioperative team members currently caring for patients approaching major surgical intervention in the preoperative period.
2. Employed at South Tees Hospitals NHS Foundation Trust or York Teaching hospital NHS Foundation Trust

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
40

Key exclusion criteria
Stage 1:
Patient participants:
1. Unable to provide informed written consent
2. Currently receiving end-of-life care
3. Unable to understand and communicate in written and spoken English

Stage 2:
Patient participants:
1. Unable to provide informed written consent
2. Pregnancy
3. History of severe mental illness requiring active investigation or treatment by mental health services or compromising the informed consent process
4. Unable to understand spoken and written English
5. Already undergoing prehabilitation or a preference for an alternative mode of support e.g. a face-to-face service
6. Safety concerns around remotely supervised exercise training based on American College of Sports Medicine (ACSM) criteria for clinical exercise testing and prescription

Date of first enrolment
15/10/2021

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
James Cook University Hospital
Marton Road
Middlesbrough
England
TS4 3BW

Study participating centre
York Hospital
Wigginton Road
York
England
YO31 8HE

Sponsor information

Organisation
South Tees Hospitals NHS Foundation Trust

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Government

Funder Name
Sport England

Funder Name
Macmillan Cancer Support

Alternative Name(s)
Macmillan, Society for the Prevention and Relief of Cancer, Cancer Relief Macmillan Fund, Macmillan Cancer Relief, MCS

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Pseudoanonymised participant data can be available with consent on request from the study sponsor (South Tees Hospitals NHS Foundation Trust). Please contact the Co-Chief Investigators intially for support with this request: Prof. Gerard Danjoux (gerard.danjoux@nhs.net) and Dr Leah Avery (Leah.avery@tees.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version 3.0	16/09/2021	05/10/2021	No	Yes

Participant information sheet	version 3.0	16/09/2021	05/10/2021	No	Yes
Protocol file	version 2.0	23/08/2021	05/10/2021	No	No