Digital prehabilitation for patients undergoing major elective surgery: a single-arm pilot study

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Protocol summary

Study Title	Digital prehabilitation for patients undergoing major elective surgery: a single-arm pilot study	
Short title	Digital prehabilitation for patients undergoing major elective surgery	
Study Design	Single-centre, single-arm, pilot study	
Study Participants	Patients aged ≥50 years that are scheduled for major elective surgery in ≥10 weeks	
Planned Sample Size	N = 34	
Intervention Duration	6 weeks	
	Objectives	**Outcome Measures**
Primary	Assess the feasibility of PreActiv's digital prehabilitation.	Recruitment rate, uptake rate, screen-pass rate, adherence, compliance, retention, safety, acceptability
Secondary	Assess the effect of PreActiv's digital prehabilitation on fitness and wellbeing outcomes in patients awaiting major elective surgery.	● Cardiorespiratory fitness ● Functional fitness ● Resting blood pressure and heart rate ● Self-reported physical activity level ● Quality of life ● Mood ● Economic impact ● Environmental impact
Intervention	Digital prehabilitation including aerobic, resistance, and breathing exercises that are tailored to the patient's mobility and fitness level.	
Dose	3 x 35-minute sessions per week.	

1. Background

The annual cost of surgical procedures within the National Health Service (NHS) in the UK is estimated at £9.5 billion (Abbott et al., 2017). The most recent estimation of surgical admissions to NHS hospitals between 2016-2019 – prior to disruptions caused by the Covid-19 pandemic – was 4,685,106 per year, of which 3,414,531 were defined as elective surgery scheduled with wait times ≥4 weeks (Dobbs et al., 2021). Elective surgeries are non-emergency surgeries that are planned in advance, which provides the opportunity for patient optimisation prior to surgery with the aim of improving postoperative outcomes. Increasingly, cardiopulmonary exercise testing (CPET) is being implemented preoperatively to stratify surgical risk based on cardiorespiratory fitness (Levett et al., 2018). Indeed, numerous trials demonstrate that higher preoperative cardiorespiratory fitness is associated with reduced postoperative morbidity and mortality following major surgery (Ozova et al., 2022, Moran et al., 2016, West et al., 2014, Prentis et al., 2012, Torchio et al., 2010, Wilson et al., 2010). Based on these findings, the use of 'formal prehabilitation pathways' to improve fitness was recommended in the Royal College of Anaesthetists (RCoA) Guidelines for the Provision of Anaesthetic Services (2021).

Prehabilitation is the process of preparing a patient for a medical intervention such as surgery. Effective prehabilitation programmes use surgery as a 'teachable moment' to introduce individualised, multi-modal lifestyle interventions with the aim of optimising modifiable risk factors for surgery, namely: physical activity, nutritional status, mental wellbeing, smoking status, alcohol intake, and pain management. Given the association between cardiorespiratory fitness and surgical outcomes, prehabilitation programmes are typically centred around exercise training. Evidence from systematic reviews demonstrates that prehabilitation interventions which include aerobic and/or resistance exercise training are effective at improving preoperative fitness and postoperative outcomes across a range of surgical populations (Clifford et al., 2023, Jain et al., 2023, Punnoose et al., 2023, McIsaac et al., 2022, Heger et al., 2020, Santa Mina et al., 2014). Specifically, measurements of cardiorespiratory fitness including $\dot{V}O_{2PEAK}$, 6-minute walk distance, and 1-minute sit-to-stand performance improve in response to prehabilitation (Bradley et al., 2023, Hall et al., 2022, West et al., 2015). Furthermore, prehabilitation has been shown to reduce postoperative complications, pain, length of hospital stay, and improve postoperative function, compared to usual care (Clifford et al., 2023, Punnoose et al., 2023, McIsaac et al., 2022, Moyer et al., 2017, Wang et al., 2016, Santa Mina et al., 2014).

In order to maximise the potential benefits from prehabilitation, including improved surgical outcomes and reduced costs to the NHS, accessibility is key. Commonly, prehabilitation is delivered via face-to-face sessions in hospital or community facilities. However, the most frequently reported barriers to engagement in prehabilitation programmes are lack of time and difficulty travelling to facilities on a regular basis (Gurunathan et al., 2023, van der Velde et al., 2023, Waterland et al., 2021). In addition to presenting a barrier to patients, face-to-face interventions are accompanied by high running costs to the healthcare provider, making the economic case for their implementation challenging (Barberan-Garcia et al., 2019). Furthermore, in-person interventions are vulnerable to disruption, e.g., during the Covid-19 pandemic, with the target population of surgical patients susceptible to infection. As such, home-based interventions may provide an alternative approach. Indeed, a systematic review of prehabilitation studies identified home-based programmes as a strategy to overcome commonly-reported barriers of lack of time when scheduling prehabilitation around work, medical appointments, and practical tasks, plus lack of transport and parking (van der Velde et al., 2023).

In prior studies, it has been shown that ~70% of patients would prefer to complete prehabilitation in their home (Gurunathan et al., 2023, Waterland et al., 2021). Furthermore, patients and/or their informal carers identify a tailored approach based on individual needs and preferences, access to resources, the ability to

monitor their progress, and motivation from achieving objective progressions as facilitators to engaging in prehabilitation (van der Velde et al., 2023, Agasi-Idenburg et al., 2020). Traditional paper handouts of exercises to perform at home may not provide scope for individually-tailored, progressive, and engaging exercise prescriptions, and have been shown to be inferior to digital home-based interventions (Lambert et al., 2017). Therefore, digital home-based prehabilitation interventions may overcome issues with face-to-face and traditional home-based interventions.

There has been a rapid uptake of digital appointments since the Covid-19 pandemic – known as 'telemedicine'. Such strategies have been applied to prehabilitation – known as 'teleprehabilitation'. Teleprehabilitation may involve remotely-supervised exercise sessions (e.g., via videoconferencing), which have been shown to be acceptable and effective for patients awaiting surgery (Parraguez et al., 2023, An et al., 2021, Doiron-Cadrin et al., 2020). Notably, teleprehabilitation was shown to be similarly effective as in-person supervised prehabilitation (Doiron-Cadrin et al., 2020) and unsupervised teleprehabilitation (An et al., 2021). The equivalence to unsupervised teleprehabilitation is relevant, as supervised teleprehabilitation brings a high personnel burden and cost. For example, a three-week teleprehabilitation intervention delivered prior to total knee arthroplasty involved twice-daily 30-minute sessions on five days each week, each supervised by a physical therapist (An et al., 2021).

Unsupervised teleprehabilitation involves providing patients with access to an online platform of prehabilitation resources, often supplemented with 'check-in' calls arranged weekly. Previous trials have demonstrated the acceptability and efficacy of unsupervised teleprehabilitation in onco-surgery (Drummond et al., 2022, Franssen et al., 2022, Wu et al., 2021, Piraux et al., 2020, Bruns et al., 2019), major elective surgery (van der Velde et al., 2022), lung transplant (Singer et al., 2018), and total joint arthroplasty (Chughtai et al., 2019). Only one trial, to our knowledge, has implemented unsupervised teleprehabilitation within the NHS in the UK (Wu et al., 2021). The four-week intervention included aerobic and resistance exercise, information on nutrition, and referral to smoking cessation, alcohol moderation, and psychological support services, plus weekly video calls (Wu et al., 2021). Whilst the resistance exercise training was delivered via exercise videos, no specific exercise prescription (i.e., frequency, intensity, time, type) was provided for aerobic exercise, and instead participants were advised to accumulate 150 minutes of moderate intensity aerobic activity per week (Wu et al., 2021). To improve cardiorespiratory fitness parameters associated with improved postoperative outcomes in the restricted preoperative time-frame, targeted exercise prescriptions such as high intensity interval training may be preferable (Weston et al., 2016). Furthermore, patients reported that they felt peer support was missing from the intervention (Wu et al., 2021). As such, there is space within the UK market for tailored, progressive, dynamic, evidence-based interventions that are aligned with patient preferences and are cost-effective for implementation within the NHS.

PreActiv's digital prehabilitation platform has been developed over the last two years by physicians, exercise physiologists, physiotherapists, software engineers, front-end developers, graphic designers, accessibility experts, and members of the public. PreActiv's digital prehabilitation platform provides tailored, progressive, dynamic, evidence-based prehabilitation to patients within their own home via their computer, smartphone, or tablet. Exercise prescriptions are tailored to the patient's mobility level and fitness level, which are assessed via in-platform questionnaires and functional assessments. Subsequently, patients are enrolled onto an easy-to-follow programme of vigorous intensity aerobic and resistance exercise, plus breathing exercises in three 35-minute sessions per week for six weeks. The programme is adapted iteratively based on the patient's fortnightly exercise test results, further tailoring the course to their needs and aiming to progress the intensity of the exercises over time. Within PreActiv's digital prehabilitation platform, patients are enrolled into a managed community forum of patients and healthcare professionals where they can post their achievements and questions. Alongside access to

PreActiv's digital platform, patients will be given educational materials that summarise the benefits of prehabilitation and how to realise them. At the end of the programme, patients are given a certificate and report which details their progress.

The novel provision of tailored, progressive, dynamic, evidence-based, and home-based prehabilitation via a digital platform requires evaluation for feasibility, prior to a larger study investigating the efficacy of PreActiv's digital prehabilitation platform to improve preoperative fitness and postoperative outcomes.

2. Aims

The primary aim of this study is to evaluate the feasibility of PreActiv's digital prehabilitation, prior to a future larger study investigating its efficacy. The following outcomes measures will be evaluated during the study:

- Recruitment rate (the proportion of patients invited that provide written informed consent)
- Uptake (the proportion of patients invited that are willing to be screened for eligibility)
- Screen-pass rate (the proportion of willing patients that pass screening for eligibility)
- Adherence (the proportion of exercise sessions offered that are attended)
- Compliance (the proportion of exercise sessions that are completed as prescribed)
- Retention (the proportion of patients that enrol into the study who complete follow-up measurements)
- Safety (the incidence and severity of adverse events)
- Acceptability (Likert scale and open-ended survey questions, posts in community forum)

The secondary aim is to assess the preliminary efficacy of PreActiv's digital prehabilitation by measuring pre- to post-intervention changes to:

- Cardiorespiratory fitness (VO_{2PEAK}, ventilatory threshold)
- Functional fitness (1-minute sit-to-stand test, 1-minute seated push-up test)
- Resting blood pressure and heart rate
- Self-reported physical activity level (International Physical Activity Questionnaire Short Form)
- Quality of life (EuroQoL EQ-5D-5L Scale)
- Mood (Hospital Anxiety and Depression Scale)

An exploratory aim is to evaluate the economic/environmental impact of PreActiv's digital prehabilitation:

- Cost per patient to deliver PreActiv's digital prehabilitation, with comparison to published costs for face-to-face and telemedicine prehabilitation programmes

- Environmental impact avoided by performing prehabilitation at home via PreActiv's digital prehabilitation compared to the estimated hypothetical emissions associated with participants travelling to the hospital three times per week for six weeks for face-to-face prehabilitation.

3. Study design

A single-arm pilot study conducted at the Royal United Hospitals Bath NHS Foundation Trust (RUH). All participants will be allocated to receive PreActiv's digital prehabilitation alongside usual care. Usual care at the RUH involves a digital preoperative assessment of surgical risk and relevant investigations such as electrocardiogram (ECG) and blood tests for all patients. For some patients, usual care may also include seeing an anaesthetist (depending on their risk factors) and seeing other allied healthcare professionals, e.g., dietician (depending on their individual requirements or the nature of the surgery). Prehabilitation is not standard of care at the RUH. Pre-intervention testing will be conducted in week 0 and post-intervention testing will be conducted in week 7.

4. Participant eligibility

The following inclusion criteria will define patients eligible for the study:

- Planned for major elective surgery ≥10 weeks from time of recruitment
    - Major or complex surgery examples in NICE guideline NG45 'Routine preoperative tests for elective surgery' provides appropriate examples that are relevant to the patient cohort at RUH. We have extrapolated from these examples a list of surgical procedures that qualify as major or complex surgery and are carried out at the RUH. This list is not exhaustive but provides a range of procedures that are applicable for example: laparotomy, joint replacement, total abdominal hysterectomy, nephrectomy, neck dissection, parotidectomy, endoscopic resection of prostate, thyroidectomy.
- Aged ≥50 years

Subgroups of patients will be excluded:

- Surgery scheduled in <10 weeks
- Any relative or absolute contraindications to undertake an exercise test as described by the American College of Sports Medicine (ACSM, 2022) and the American Heart Association (Fletcher et al., 2013)
- Unsuitable to increase physical activity level as determined by Physical Activity Readiness Questionnaire (PAR-Q)
- Uncontrolled or poorly-controlled lung condition, diabetes, or seizures
- Recent (<12 months) cardiovascular events needing hospital admission
- Ongoing infection or wound making this programme hazardous for the patient
- Unable to access technology required to use the PreActiv digital platform

- Currently meeting World Health Organisation (WHO) physical activity guidelines of 75-300 minutes of moderate to vigorous intensity physical activity per week, plus twice-weekly muscle strengthening activities
- Unable to understand explanations and/or provide informed consent
- Unable to understand written or spoken English, and without ongoing access to an interpreter
- Any condition and/or behaviour that would pose undue personal risk or introduce bias into the study
- Currently enrolled in another research trial

5. Study procedures

a. Sample size

A sample size of N = 34 has been selected, based on the primary aim of this pilot study to determine whether progression to a full-scale study is indicated, according to predefined progression criteria. Methodology for sample size estimation in external pilot studies published by Lewis et al. (2021) has been used to inform the sample size. A traffic light system (Avery et al., 2017) has been used to define progression criteria based on two key outcome measures - adherence and retention:

	Red *stop*	**Amber** *amend*	**Green** *go*
Adherence	0-50%	51-74%	75-100%
Retention	0-50%	51-74%	75-100%

Based on these progression criteria, and aiming to test the hypothesis that feasibility outcomes will not fall within the red zone (*stop*) based on the expectation of being in the green zone (*go*) with 90% power and one-sided alpha of 0.05, we need to consent N = 34 participants. As such, recruitment will cease once N = 34 participants have provided written informed consent.

b. Recruitment, screening & informed consent

Participants will be recruited from the preoperative assessment clinic at the RUH. Preoperative assessment clinic is delivered predominantly via a virtual clinic (‘MyPreOp’) at the RUH, whereby patients complete questionnaires and provide consent for surgery online. However, all patients awaiting major elective surgery are required to attend the RUH for a blood test as a minimum, with patients aged ≥65 years and/or those with systemic disease also required to attend for ECG, as per the NICE guidelines (NICE, 2016). Preoperative nurses will identify potentially eligible patients who are booked for a blood test and/or ECG appointment according to study inclusion criteria. Preoperative nurses will email (emailing patients is part of normal practice) the participant information sheet to potentially eligible patients a minimum of 48 hours prior to their appointment. A short period between provision of study information and follow-up by the research team is justified in the context of potentially short surgical pathways in the study population.

During their appointment, the patient will be asked by the preoperative nurse if they are interested in participating in the study. If they are interested, the patient will be introduced to a researcher who will be present in the preoperative clinic. For those patients who are not interested in being involved in the study, we are interested in capturing the reasons why for research reporting and to inform the design of a future RCT. We will explain to these patients that they do not need to give a reason as they are free to decline to answer, but that it would be really helpful if they could explain their reason for declining involvement, as this will contribute to research reporting and future study design of this project.

Patients who are interested in participating will be invited to stay after their appointment to complete the study screening and consent visit. This approach is anticipated to reduce patient burden by avoiding an additional trip to the RUH for the study. Patients may also contact the researchers directly upon receipt of the participant information sheet, or agree with the researcher in the preoperative assessment clinic, to arrange a separate visit for screening and informed consent if preferred.

Screening will be performed by a researcher - who is an RUH physician - against the inclusion/exclusion criteria via a bespoke health questionnaire completed by the patient (Appendix 1). The researcher will obtain verbal consent to access the patient's medical record to validate the information provided in the health questionnaire. Indeed, as many of the exclusion criteria relate to very specific medical diagnoses, screening medical records to verify patient-reported medical conditions is anticipated to be the most comprehensive screening process. Patients will be asked to provide written informed consent in the presence of the researcher once patient eligibility has been confirmed and any questions about the study have been answered. If the patient does not have adequate understanding of written or spoken English, the informed consent process will be facilitated by a professional translator via Language Line. However, subsequent interpreting during the study will need to be provided by a non-professional interpreter (e.g., family member) as per the exclusion criteria: "Unable to understand written or spoken English, and without ongoing access to an interpreter".

c. Intervention

Intervention tailoring

Upon commencement of the intervention, participants will complete in-programme mobility and fitness assessments for tailoring of their programmes.

[redacted]

A dynamic course will be created for each individual participant based on the data they have submitted. Indeed, an appropriate programme will be created for weeks 1 and 2 based on the initial baseline responses to the mobility questionnaire and performance in the fitness assessment. In week 2 and week 4, the fitness assessment will be repeated, and appropriate programmes will be allocated for weeks 3-4 and weeks 5-6, respectively.

The prehabilitation programmes are personalised to cater for differing mobility and fitness requirements and adapt on a fortnightly basis in line with the patient's progress. [redacted]

Exercise dose

All prehabilitation programmes consist of three ~35-minute sessions per week for a six-week period (Table 2). Rest days will be encouraged throughout the programme to facilitate recovery and reduce the likelihood of injury. Previous studies have found that six weeks of prehabilitation with three sessions per week improved 1-minute sit-to-stand test performance (Bradley et al., 2023), $\dot{V}O_{2PEAK}$ and ventilatory threshold (West et al., 2015). A multimodal approach to fitness will be taken, with each of the three sessions having an aerobic, resistance, and respiratory component, as recommended in the best practice guidelines for preoperative exercise (Tew et al., 2018).

Exercises will be performed in a vigorous-intensity circuit-training format utilising body-weight and light external resistance. Previous research has shown circuit training with body-weight and dumbbell exercises reduced postoperative outcomes and length of hospital stay following elective abdominal aortic aneurysm repair (Barakat et al., 2016).

The training sessions will commence with a 5-minute warm-up of dynamic mobility exercises performed at light intensity (rating of perceived exertion (RPE) 2-3/10 on a Borg CR10 scale) (Arney et al., 2019, Garber et al., 2011). Next, participants will complete aerobic exercise training for three sets of five exercises, where exercises are performed for 40 seconds followed by 20 seconds of passive rest, with a 50-second passive rest between sets. After completing aerobic exercise training, participants will be guided through resistance training for major muscle groups, utilising bodyweight and light external resistance (e.g., food tins, water bottles) for two sets of five exercises, where exercises are performed for 40 seconds followed by 20 seconds of passive rest, with a 50-second passive rest between sets. The target intensity for both aerobic and resistance exercise is vigorous-very vigorous, defined as RPE ≥5/10 on a Borg CR10 scale (Arney et al., 2019, Garber et al., 2011). Finally, participants will complete two respiratory muscle training exercises for a total of ~4 minutes.

The exercise prescription has been designed to achieve World Health Organisation physical activity guidelines for 75 minutes of vigorous intensity activity per week, whereby 25 minutes of vigorous intensity

exercise per session (excluding 'set rest') performed thrice weekly equals 75 minutes per week. Short 20-second rest intervals have been selected so recovery is incomplete between exercises resulting in sustained intensity across the entirety of the aerobic and resistance exercise sections. Such an approach is adapted from Tabata training and repeated sprint training principles, but utilising multi-modal exercises as compared with uni-modal cycling or running-based exercise typically used in Tabata/repeated sprint training.

Table 2. Summary of exercise prescription

	Number of exercises	Sets	Exercise interval	Exercise intensity (RPE /10)	Rest interval (seconds)	Set rest (seconds)
Warm-up	6	1	2-6 reps	2-3	-	-
Aerobic	5	3	40s	5-10	20	50
Resistance	5	2	40s	5-10	20	50
Respiratory	2	1	3 reps	-	5	30

Progression of the intervention

[redacted]

Monitoring of exercise intervention

Immediately after completing the aerobic exercise section, participants will be asked to report their overall RPE for aerobic exercise. The same process will be repeated immediately after the resistance exercise section. Participants will be asked to select the most appropriate score from 0-10 following the standardised prompt: "How much effort/exertion did you put into the workout? Where 0 would be no effort/exertion, and 10 would be the most effort/exertion you could possibly give."

Monitoring of participant engagement will also be conducted using the 'back-end' data from PreActiv's digital platform.

- **Adherence:** If participants have not performed a session in the past four days, a researcher will email them to remind them to log-in and complete their sessions. If there is no response to the

email after two days, a researcher will telephone the participant to explore reasons for low adherence and provide support to increase adherence.

- **Compliance:** If participants report an RPE <5 for aerobic and/or resistance exercise on two occasions, they will be telephoned by a researcher to assess why they have scored their RPE <5. If poor technique or lack of understanding is causing RPE <5, education on the importance of intensity and how to achieve higher intensities will be provided. If technique/understanding are not the issue, and the programme is too easy, the course would be adapted manually (in the future, the adaptation of the course would be partially automated).

Non-exercise intervention

General advice and information on services relating to alcohol consumption, smoking, and nutrition will be provided in the PreActiv eBook. Specific instruction or advice on alcohol, smoking, and nutrition is beyond the scope of this iteration of the PreActiv digital platform but will be included in subsequent versions.

A community forum will be provided within the PreActiv digital platform, which will allow people undergoing similar surgeries to share experiences, discuss queries, and seek support from peers. Participants will have access to the community forum throughout their prehabilitation programme, and for one month post-surgery, to allow participants to share comments about their surgery and recovery experience. All comments made in the community forum will be archived for later analysis in order to further refine and evaluate PreActiv's digital prehabilitation.

There will be a check-in session on a Monday with a member of the research team via the community forum so users can access health professional support. This support is included in the implementation plan and is part of the intervention.

d. Measurements

Primary outcome measurements will be collected throughout the study (week 0-7).

Feasibility

- Recruitment rate: the proportion of patients invited that provide written informed consent
- Uptake: the proportion of patients invited that are willing to be screened for eligibility
- Screen-pass rate: the proportion of willing patients that pass screening for eligibility
- Adherence: the proportion of exercise sessions offered that are attended, assessed based on the number of sessions completed on the PreActiv platform (note: subsequent exercise sessions only become available to participants once they have watched the previous video).
- Compliance: the proportion of exercise sessions that are completed as prescribed:
    - Exercise intensity: comparing the RPE reported by participants to the target RPE prescribed (i.e., RPE 5-10/10 is the target, so RPE 6/10 would be compliant but RPE 4/10 would be non-compliant). The proportion of aerobic and resistance sessions that are completed at the target intensity will be reported. It has been shown that an RPE score reported at the end of an exercise session is equivalent to the average RPE reported after each exercise (Day et al., 2004).

    - Exercise type: after each session, participants will respond to the question: “how much of the session could you complete?” with options: all / most / some / none. If they select any option other than “all”, they will be asked to identify any exercises included in their session that they couldn’t complete from a list. Any sessions where ≥1 exercise was not completed will be deemed non-compliant to the type of exercise prescribed. The proportion of sessions where all exercises are completed will be reported.

    - Duration: after each session, participants will respond to the question: “how much of the session could you complete?” with options: all / most / some / none. If they select any option other than “all”, they will be asked to identify any exercises included in their session that they couldn’t complete from a list. If they do not select any specific exercise, then we infer that participants were unable to perform the exercises for the required duration. Any sessions where most / some / none is reported with no specific exercise identified will be deemed non-compliant to duration. The proportion of sessions where exercises were performed for the target duration will be reported.

- Retention: the proportion of patients that enrol into the study who complete follow-up measurements

- Safety: the incidence and severity of adverse events reported during the weekly check-in session with a member of the research team, and via a free-text response box after each exercise session to be completed if the participant indicates that they could not perform all exercises.

- Acceptability (week 7 only): collected via a survey integrated within PreActiv’s prehabilitation platform containing a combination of Likert scale and open-response questions about participant experiences of using PreActiv’s digital prehabilitation (Appendix 2). Responses to the survey will be fully anonymised, meaning responses cannot be attributed to the participant by name or study ID. Additional feedback will be obtained from comments submitted by participants to the community forum throughout the intervention.

Secondary outcome measurements will be conducted at the University of Bath during week 0 (pre-intervention) and week 7 (post-intervention), with each visit lasting 1-hour:

Participant characteristics

- Baseline characteristics (week 0 only): age, sex, ethnicity, surgery type, comorbidities, medications, mobility, transport to hospital visits (Appendix 3).

Physical assessments

- Resting blood pressure and heart rate will be measured using an automated sphygmomanometer after 15 minutes of seated rest.

- Cardiorespiratory fitness: Cardiopulmonary exercise tests (CPET) will be performed using a ramp-incremental protocol on a cycle ergometer. Body mass, height, and resting blood pressure will be measured prior to commencing exercise. After a 3-minute low-intensity warm-up, participants will be instructed to maintain a consistent cadence of 50-70 rpm during a ramp protocol whereby the resistance against the pedals increases incrementally over time. The rate of the incremental ramp protocol will range from 5-30 watts/minute, based on participant’s ability, with the aim of achieving maximal exertion within 8-12 minutes. Participants will be encouraged to exercise to maximal exertion. Heart rate, blood pressure, oxygen saturation, and rating of

perceived exertion (RPE) rated from 0-10 will be monitored throughout. A 5-minute low intensity cool-down will be completed after the ramp protocol with monitoring of heart rate and blood pressure recovery. Measurements of VO_{2PEAK} and ventilatory threshold will be derived from CPETs.

- Functional fitness: 1-minute sit-to-stand test (for participants able to transition from seated to standing unsupported) or 1-minute seated push-up test (for participants unable, or requiring support, to transition from seated to standing).
    - 1-minute testing protocols have been selected to increase the emphasis on measuring endurance rather than muscular strength, due to the associations between cardiorespiratory fitness and surgical outcomes. The 1-minute sit-to-stand test has been shown to induce similar cardiorespiratory responses as cardiopulmonary exercise testing in COPD patients (Gephine et al., 2020), and has been implemented in prehabilitation trials (Bradley et al., 2023). The 1-minute seated push-up test is a relatively novel assessment, and has been shown to correlate with other functional fitness measures (Chokphukiao et al., 2023, Poncumhak et al., 2023).
- Self-report physical activity: Participants will complete the IPAQ short-form questionnaire to self-report days per week and minutes per day of vigorous intensity physical activity, moderate intensity physical activity, walking, and sitting. 'MET-hours' (MET = metabolic equivalent of task) per week will be calculated. This information will be compared to the WHO guidelines on physical activity and sedentary behaviour.

Psychological assessments

- Quality of life: Participants will complete the EQ-5D-5L to provide insights into mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.
- Mood: Participants will complete the Hospital Anxiety and Depression Score

Economic & environmental

- Cost per patient to deliver PreActiv's digital prehabilitation, with comparison to published costs for face-to-face and telemedicine prehabilitation programmes
- Environmental impact avoided by performing prehabilitation at home via PreActiv's digital prehabilitation compared to the estimated hypothetical emissions associated with participants travelling to the hospital three times per week for six weeks for face-to-face prehabilitation. Publicly-available carbon emissions data will be used for calculations.

e. Data analyses

The primary aim of this study is to test feasibility of the PreActiv's digital prehabilitation. Feasibility will be assessed by reporting proportions and comparing to predefined progression criteria (for adherence and retention). This pilot study is not adequately-powered to investigate the statistical significance of pre- to post-intervention changes to secondary outcome measures. As such, data analyses will be predominantly descriptive. Effect sizes will be reported to convey the magnitude of pre- to post-intervention changes to secondary outcomes.

6. Patient and public involvement (PPI)

We have undertaken two phases of PPI activities in the development of this study. Firstly, PreActiv's digital prehabilitation has been co-designed with N=30 members of the public aged 50-96 years over a two-year period. Whilst these contributors were not all awaiting major elective surgery, they are otherwise reflective of the demographic of participants for this study. We also wanted to represent the views of surgical patients in our PPI activities. As such, secondly, we conducted a series of 1:1 interviews with N = 4 aged 50-65 years patients awaiting major elective surgery at the RUH. These interviews involved discussions of the participant journey through the study, PreActiv's digital prehabilitation intervention, measurements of interest to participants, incentives for participation, and the participant information sheet. Examples of iterations to the study design and intervention based on PPI are summarised below:

PPI feedback	Changes implemented
PPI phase 1	
Originally, each exercise session was 60 minutes long, and users reported that was too long and that they couldn't find the time for three 60-minute sessions per week.	We have shortened each session to 35 minutes, which was deemed more accessible and achievable by users. The shorter sessions still meet our goal of achieving WHO physical activity guidelines for 75 minutes of vigorous intensity aerobic activity, plus two sessions of strength training, per week.
Users reported that having one continuous exercise video was hard to follow and it was unclear how hard they should be working in each section.	We have implemented separate exercise videos for each section - warm-up, aerobic, resistance, and breathing - with specific instructions on intensity and signs of exertion that are relevant to each section.
Users reported that when asked for their RPE score at the end of the whole session, they were inclined to report how they were feeling at that moment. As they had just completed the low-intensity breathing exercises, the RPE scores were lower than expected.	By splitting each of the sections into separate exercise videos, we were able to embed the RPE question directly after the aerobic and resistance exercise videos. Users then reported their RPE for each specific section directly after they had completed that section. As a result the RPE scores were higher and reflective of the effort/exertion experienced for that section.
We originally used a modified Borg RPE scale with descriptions beside each number based on breathlessness. The higher the score, the more breathless you were with 9-10 being: 'you are unable to talk and completely out of breath.' Users reported that the RPE scale we had originally used was difficult to understand as each level included two numbers (1-2, 3-4 etc) with no way to differentiate between them. Users also reported that defining exertion based on breathlessness was inappropriate, as they associated being breathless with being unfit, and therefore were	We have changed the wording accompanying our validated 0-10 Borg RPE scale to avoid mentioning breathlessness. The new phrasing is: "How much effort/exertion did you put into the workout? Where 0 would be no effort/exertion, and 10 would be the most effort/exertion you could possibly give." The resulting scores have been 7-9/10 using this scale, compared to 2-4/10 on the original scale. When combined with participants reporting that their heart rate was up and that they were sweaty, the new scale appears

more likely to rate their RPE lower, even though they reported that their heart rate was up and that they were sweaty.	better at capturing their exertion than the original scale.
Users reported that they were likely to follow the pace of the model in the exercise videos, even if they could exert themselves further and go faster. Users either stuck to the pace of the instructor or, if they weren't able to keep up, would go at a slower pace.	We have ensured the instructor's pace is set at an optimal speed during the exercise videos for the study. If this is too fast for some users, we are confident that they will self-regulate their speed, based on user feedback.
Users reported that they weren't always able to look at the video throughout the whole exercise (e.g., if they needed to be on the floor, or facing a wall), and therefore, they would miss out on visual encouragement or indications of how much time was left.	We have added in audible motivational phrases to try to get users to work hard throughout their exercises. For example, "keep going", "push yourself right to the end", "see if you can up your speed for the last 10 seconds". We have also added in a beep and a flashing countdown timer for the last 5 seconds, to help achieve maximal exertion and so that users are aware that the end of the exercise rep is nearing, even if they cannot see the screen.
Users reported that they didn't have time to hydrate between exercises as they didn't have water to hand.	Before a user begins a session, they are informed of the equipment they will need e.g. chair, weights. We have now added a glass of water icon and description to this area so users will be prepared.
PPI phase 2	
Some patients reported that they would like to meet the researcher at a time when they were already attending the hospital for a surgical appointment: "as your mind is on the surgery". However, others reported that: "people might feel stressed [after their surgical appointment] and just want to get out". Patients that preferred to stay for the screening and consent visit after their appointment raised that they would need to know the exact amount of time it would take, due to planning and paying for parking.	We will send the participant information sheet to patients ahead of a routine appointment, with the aim of conducting screening and consent visits after their appointment. This approach will reduce the time and travel burden for patients. We have explained in the participant information sheet that the screening visit will last 45 minutes, and will reimburse participants for 1 hour of extra parking. We will also have an option for patients to arrange a separate visit to the hospital for screening and consent if that is their preference.
When asked if two days' notice was enough time to decide whether they would like to take part in the study, patients reported that this was similar to the amount of notice they had for other appointments.	We will pursue a minimum two-day period between sending the participant information sheet and the patient's routine appointment where they will be asked if they are interested in taking part.
Patients were shown PreActiv's prehabilitation website and eBook. Patients reported: "I think it is	

a very good programme frankly" and they liked that the website was "extremely simple". Patients found the eBook "interesting, particularly Food Fit".	
When asked about attending the University of Bath for the measurement visit, patients reported that: "it is quite intimidating for people who haven't been there".	We need to use equipment at the University of Bath for the study measurements, and as such, it was not possible to change the venue. We will provide participants with a detailed map and directions to the car park. The researcher will meet them in the car park and walk with them to the laboratory. Patients will also be given a contact number for the researcher if they have any issues. This approach has been successful in previous research studies.
When asked about the benefits they would be hoping for if they took part in the intervention, patients reported that: "seeing fitness results improving during the programme" and "noticing an impact after surgery" were important to them.	We explained to patients that measuring postoperative outcomes was outside the scope of this feasibility study, but that such measures would be included in a future study. The platform involves repeated assessments of fitness every two weeks, where participants can see their results progress in their user profile.
When asked about incentives for taking part, patients reported: "a certificate of results would give a sense of achievement" and "money is not needed".	We will provide participants with a certificate of their progress during the intervention, plus a report of results from health, fitness, and wellbeing assessments performed at the University of Bath. We will provide money to cover the costs associated with taking part in the study.
When asked for their feedback on the participant information sheet, patients reported that it looked professional and was easy to understand, but that it was quite long and a summary would be helpful. Patient's proposed that they could talk to the researcher for more details.	We have included a two-page executive summary within the participant information sheet, which contains the most important information for patients to decide whether to take part. The researcher will talk through the details of the participant information sheet during the screening and consent visit.

7. Benefits of participating

Participants will be provided with bespoke feedback on their test results after completing the study period. This will include physical activity level, blood pressure, cardiorespiratory fitness, and functional fitness, with reference to population norms and recommended guidelines – and highlighting any changes that occur between baseline and follow-up measures. Participants will also be awarded a certificate highlighting their progress throughout the digital prehabilitation intervention, including sessions performed and in-platform fitness test results.

Participants will receive free access to PreActiv's digital prehabilitation for six weeks [redacted]

Participants will be reimbursed for their travel costs associated with taking part in the study, including parking costs, and fuel costs paid at 45p per mile for study visits. Payments will be made via BACS transfer.

8. Risks of participating

Risks of exercising: While exercise training provides long-term benefits that reduce the risk of adverse health events, the risk of acute injury and medical events is elevated whilst exercise is being performed. In particular, our exercise intervention is to be performed at vigorous to maximal exertion (i.e., a rating of perceived exertion 5-10/10), which increases the risk of adverse reactions if not appropriately prescribed. To mitigate these risks, all participants will be thoroughly screened for exercise contraindications as per in the inclusion/exclusion criteria, and people presenting with contraindications will be excluded from the study on safety grounds. Furthermore, the exercise prescription has been developed by physicians, physiotherapists, and clinical exercise physiologists, meaning the exercises that have been selected are deemed suitable for the population by a multidisciplinary team of experts. In addition, the exercise programme is tailored to the participants mobility and fitness level. The exercise videos embedded in the platform provide visual and verbal instructions for correct technique to reduce the risk of injury. Participants are also advised to separate their sessions with rest days to allow for recovery. As the risk of acute injury and medical events can be minimised, but not eliminated, participants will be provided with instructions for setting up a safe exercise space at home, and will be advised to stop exercising upon the onset of red-flag symptoms (e.g., pain, dizziness, light-headedness, feeling generally unwell) and to seek medical attention. Furthermore, there will be access to first aid and immediate life support (including defibrillator) during cardiopulmonary exercise testing.

Time burden: In planning this research, the team has made careful consideration of the time burden involved. Indeed, part of the rationale for this study is that lack of time is a commonly-reported barrier to engaging with prehabilitation. The intervention requires participants to perform three 35-minute sessions per week, for a total time commitment of 1-hour 45 minutes per week. Whilst this time commitment only represents approximately 1% of their week, we acknowledge that there are competing priorities during the preoperative period, including medical appointments, making preparations, and seeing family/friends. As such, our intervention has been designed to be performed within the participant's home, to avoid additional time required for travelling, and to provide flexibility with scheduling around other commitments. Our user testing revealed that 35 minutes was the optimum duration for sessions, so we modified our original 60-minute sessions to meet user preferences. We have also planned for the screening/consent visit to coincide with a time that the participant is already at the hospital for a blood test/ECG to reduce the number of visits required.

Digital exclusion: This risk is not possible to completely mitigate. There is a minimum requirement that patients will need to be able to access a website and register their details. We have created navigation videos to help with onboarding patients and to enable easy use of the platform. Patients are encouraged to select a champion, usually a friend or relative, to help with adherence and onboarding. Accessibility experts have been consulted and user interface and user experience (UI/UX) developers have focussed on accessibility, which has been central to the design to ensure ease of use.

Software bugs impact on usability: For example crashes, loss of data, or functionality errors. The involvement of an experienced lead developer and technical team will mitigate this risk by analysing user data every two weeks to identify bugs early.

Poor UI/UX: May reduce the accessibility of PreActiv's digital prehabilitation, particularly in this patient group who commonly have less digital experience, and often sensory impairments. The platform interface has been designed with accessibility as a priority, drawing on the experience of PreActiv's developers who have experience in UI/UX design that focuses on accessibility, and continuously engaging with user feedback to improve the UI/UX design.

Changes to the regulatory frameworks may occur: Including medical device standards and information governance. The platform is compliant with regulatory frameworks, and updates will be monitored closely by the research team to ensure continued compliance to regulatory requirements.

9. Data management

Manual files containing personal data (i.e., informed consent forms, health screening questionnaires) will be stored securely in the Clinical Trials Office at the Royal United Hospitals Bath NHS Foundation Trust.

Electronic files containing personal data (i.e., a password-protected Excel spreadsheet that links the study-specific anonymisation code to the participant's personal data) will be stored securely on an NHS computer.

Study data anonymised using a study-specific ID score will be stored securely in a locked filing cabinet at the University of Bath (manual files) or on a cloud-based platform (e.g., GoogleDrive) accessible via a password that will only be provided to members of the research team (electronic files). At the end of the trial, manual files will be transferred from the University of Bath to the Royal United Hospitals Bath NHS Foundation Trust.

With regards to study data stored within PreActiv's digital prehabilitation platform, data storage practices conform with GDPR and NHS data security guidelines. In-platform storage processes are as follows:

- Personal data supplied by the participant to enrol onto PreActiv's digital prehabilitation platform (first name, surname, email address) will be stored in a Relational Database Management System (RDBMS) called MYSQL. The MySQL Database is made up of tables of data with relational keys to associate data between them. All user data is held within this database and the majority is stored in plain text, JSON, and serialised array format. The database is hosted on non-public facing infrastructure (i.e., it cannot be accessed via a URL). However, the participant is able to access their own data, and PreActiv's tech lead is able to access all participant data, as described next.

- When data are accessed from the database, they are sent and received via an encryption method called SSL/TLS. SSL/TLS stands for secure sockets layer and transport layer security. It is a protocol or communication rule that allows computer systems to talk to each other on the internet safely. SSL/TLS certificates allow web browsers to identify and establish encrypted network connections to web sites using the SSL/TLS protocol.

- Participants can access their own data from the database via the application server (i.e., via PreActiv's digital prehabilitation platform on a web browser) using stored credentials over a secure TLS connection. This connection requires a username, password, and a private / public key pair-based authentication method, which is only known by the participant.

- PreActiv's tech lead can access all participant data via PHPMyAdmin, which is a web-based database management tool that developers can use to view, edit, and delete not only the data stored in the database, but the schema of the database itself. This is also transferred over a

secure TLS connection, and requires a username and a password and can only be accessed via token-based authentication directly obtained from the administrative dashboard of our web host. It is not publicly available and can not be viewed through a normal web address or a public IP address. PreActiv's tech lead will only use personal data to provide tech support to participants.

10. Definition of end of study

The end of the study will be the date of the last visit of the last participant.

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Appendix 1. Health questionnaire

PreActiv digital prehabilitation project

HEALTH SCREENING QUESTIONNAIRE

Chief investigator:	Dr Alec Snow	alec.snow@nhs.net
Researchers:	Dr Helen Sims	helen.sims@nhs.net
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It is important that volunteers participating in research studies are currently in good health to exercise. This is to ensure (i) their own continued well-being and (ii) to avoid the possibility of introducing bias into the study outcomes.

Please initial boxes:

1. Are you scheduled to have surgery in 10 weeks or more from today?
   Yes ☐ No ☐
2. Is the surgery you are scheduled for considered 'major surgery'? Please consult with your surgical team if you are unsure. Yes ☐ No ☐
3. Are you aged 50 years old or older? Yes ☐ No ☐

4. Are you able to understand written and spoken English, either independently, or with support from a family member or friend who can act as a translator throughout the study? Yes ☐ No ☐

5. As far as you are aware, **do you suffer** or **have you ever** suffered from:

   a) Any heart condition (e.g., heart attack, angina, arrhythmia, vessel disease, valve disease, heart failure, inflammation, aortic dissection, cardiomyopathy) Yes ☐ No ☐

   b) Blood pressure higher than 200/120 mmHg Yes ☐ No ☐

   c) Pulmonary embolism or infarct Yes ☐ No ☐

   d) Deep vein thrombosis Yes ☐ No ☐

   e) Stroke or transient ischaemic attack Yes ☐ No ☐

   f) Uncorrected medical conditions such as significant anaemia, important electrolyte imbalance, and hyperthyroidism Yes ☐ No ☐

   g) Mental or physical impairment limiting exercise Yes ☐ No ☐

6. As far as you are aware, **do you suffer** from any of the following conditions:

   a) Lung condition(s) Yes ☐ No ☐

      If yes, are your lung condition(s) well-controlled Yes ☐ No ☐

   b) Seizures Yes ☐ No ☐

      If yes, are your seizures well-controlled Yes ☐ No ☐

   c) Diabetes Yes ☐ No ☐

If yes, is your diabetes well-controlled Yes ☐ No ☐

d) Ongoing wound Yes ☐ No ☐

If yes, could the wound be made worse by exercise

Yes ☐ No ☐

e) Ongoing infection Yes ☐ No ☐

If yes, could the infection be made worse by exercise

Yes ☐ No ☐

7. Have you been hospitalised for a cardiovascular event within the past 12 months? Yes ☐ No ☐

8. The Physical Activity Readiness Questionnaire (PAR-Q) is a standard questionnaire used to identify risks that require consideration when increasing physical activity level. Please answer the following questions to the best of your knowledge:

   a) Has your doctor ever said that you have a heart condition, and should only do physical activity recommended by a doctor?

   Yes ☐ No ☐

   b) Do you feel pain in your chest when you do physical activity?

   Yes ☐ No ☐

   c) In the past month, have you had chest pain when you were not doing physical activity? Yes ☐ No ☐

   d) Do you lose your balance because of dizziness, or do you ever lose consciousness? Yes ☐ No ☐

e) Do you have a bone or joint problem (for example back, knee or hip) that could be made worse by a change to your physical activity?

Yes ☐ No ☐

f) Is your doctor currently prescribing drugs (for example water pills) for your blood pressure or heart condition? Yes ☐ No ☐

g) Do you know of any other reason that you should not do physical activity?

Yes ☐ No ☐

9. In the past week, did you perform:

a) Physical activities for a total of 2 hours and 30 minutes or more that made you breathe slightly harder than normal? Yes ☐ No ☐

b) Physical activities for a total of 1 hour 15 minutes or more that made you breathe much harder than normal? Yes ☐ No ☐

c) Muscle strengthening activities on two days or more? For example, lifting weights, using resistance bands, squats/push ups, heavy gardening

Yes ☐ No ☐

10. PreActiv's digital prehabilitation is delivered via a website that can be accessed on a computer, laptop, smart-phone, or tablet. Do you have access to any of these technologies to access PreActiv's digital prehabilitation?

Yes ☐ No ☐

11. Are you currently enrolled in any other research trials? Yes ☐ No ☐

If you have answered **YES** to **questions 5-11**, please provide details below (e.g., to confirm the problem was/is short-lived, insignificant or well controlled).

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Participant Name: _____

Participant Signature: _____

Date: _____

Participant ID: _____

Researcher Signature: _____

Date: _____

Thank you for your cooperation

Appendix 2. Feedback survey

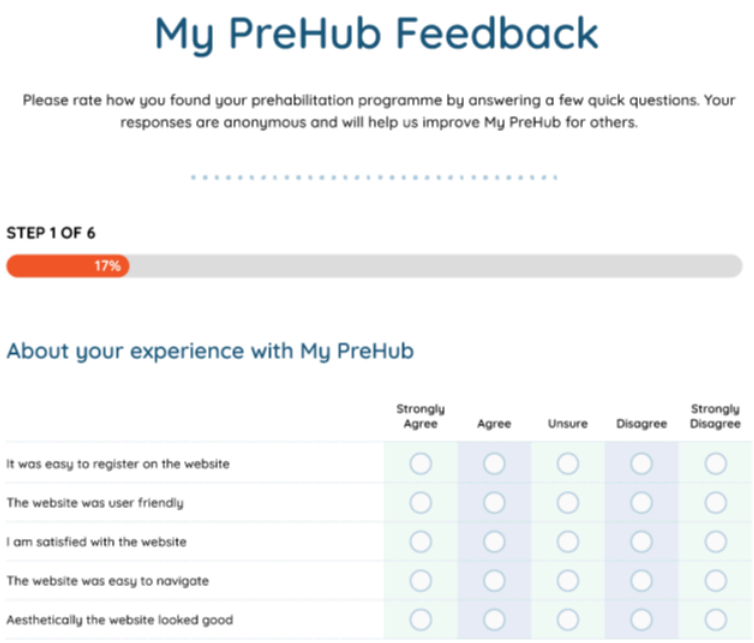
Please tick one box per question that best represents your experience of PreActiv's prehabilitation

1= Strongly agree, 2 = Agree, 3 = Unsure, 4 = Disagree, 5 = Strongly disagree

	1	2	3	4	5	N/A
Website						
It was easy to register on the website						
The website was user friendly						
I am satisfied with the website						
The website was easy to navigate						
Aesthetically the website looked good						
Exercise prescription						
The exercises in the programme felt appropriate for me						
The exercise videos were easy to follow						
The exercises were challenging						
The rating of perceived exertion scale (0-10) was easy to understand						
It was easy to complete the fitness test in the programme						
I felt motivated to follow the exercise videos						
I enjoyed doing exercises at home						
Booklet/eBook - 'A guide to prehabilitation'						
The booklet contained useful information						
I felt motivated to follow the guidance in the booklet						
I was happy to access the information as an eBook, instead of it being printed						
Support						

The community forum was a good source of support						
I received good tech support with using the platform *(if required)*						
I received good support from healthcare professionals through the platform						
Overall						
I would recommend the programme to a friend if they were having surgery						
I would continue to use the programme after the research ends						
I feel that the programme helped me to prepare for surgery						
Comments						
Please write any other comments or feedback here:						

The questions detailed above will be asked via PreActiv's website, to allow responses to be fully anonymised. An example screen displaying the questions is shown below:



Appendix 3. Baseline characteristics

Age (years)	*Please write here:*	
		Please tick one
Sex	Male	
	Female	
	Intersex	
		Please tick one
Ethnicity	White	
	Asian or Asian British	
	Black, Black British, Caribbean or African	
	Mixed or multiple ethnic groups	
	Other ethnic group	
Reason for surgery (diagnosis)	*Please list:*	
Surgery type	*Please list:*	
Medical conditions	*Please list:*	
Medications	*Please list:*	
		Please write yes or no
Mobility	Can you sit down and stand back up from a chair without pushing up on the arms of the chair, your legs, or a walking stick/frame?	

How do you typically travel to the RUH?	*Please write (e.g., car, bus, taxi, walk, cycle etc):*
How far is it from your home to the RUH?	*Please give your best estimate of the total distance from home to the RUH and from the RUH back to home:*
If you travel by car, please answer these questions	*What is the year of your car? (e.g., 2013)*
	What is the make of your car? (e.g., Ford):
	What is the model of your car? (e.g., Fiesta):
	What type of transmission does it have? (e.g., manual, automatic):
	What type of fuel does it use? (e.g., petrol, diesel, electric):
	Any further descriptions of the car? (e.g., engine size, turbo etc):