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Evaluating a digital prehabilitation tool in patients with colorectal surgery: protocol for a multisite randomised controlled trial

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ABSTRACT

Introduction Colorectal cancer is a leading cause of cancer mortality in the USA and occurs most frequently in older adults. These patients are at increased risk of adverse outcomes following major cancer surgery. While prehabilitation has been shown to mitigate this risk, multiple barriers to implementation remain. Our team created a digital tool co-designed with older adults that employs an algorithm to assess patient-specific geriatric vulnerabilities and generate personalised prehabilitation programmes before surgery.

Methods and analysis We have designed a multisite, unblinded randomised trial to be completed at three high-volume academic cancer centres located in California or Texas. Our study population is individuals aged 65 and older with planned colorectal cancer resection who are proficient in English and have home internet access. We aim to enroll 132 patients who will be randomised in a 2:1 ratio to receive the intervention (assistance from a home health coach and access to the web application (web app)) or control (usual care with written prehabilitation materials). Our primary outcome is patient engagement with prehabilitation activities.

Ethics and dissemination A properly executed, written, informed consent will be obtained from each subject prior to entering the subject into the trial. Information will be given in both oral and written form, and subjects may withdraw at any time from the study without effect on their medical care. The protocol and consent form have been approved by the Institutional Review Board (IRB) of each participating centre. We anticipate publication of results in a peer-reviewed journal.

Trial registration number NCT05520866.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The web app, PrehabPal, was iteratively designed with feedback from older adults, and its usability was previously confirmed through a pilot study of more than 200 older adults.
⇒ The patient-centred design of the web app and the inclusion of a human, dynamic health coach enables our study to mitigate challenges experienced by older adults when interacting with a digital platform that may otherwise limit utilisation.
⇒ Study activities include multiple modalities of surgical preparation, including advanced care planning and home preparation, ensuring older adults who are frail, not frail or have 1–2 components of frailty may still benefit from using the web app.
⇒ Study activities are entirely home-based, allowing participants who live in remote areas or who are on fixed incomes to complete prehabilitation without increased cost or transportation burden.
⇒ Current evidence is mixed regarding the efficacy of web applications to improve engagement and the efficacy of prehabilitation for preparation for colorectal cancer surgery, possibly limiting the impact of the intervention.

INTRODUCTION

Colorectal cancer is the third leading cause of cancer mortality in the United States and occurs most frequently in older adults.[1] While the primary management for non-metastatic colon cancer is colectomy, studies have shown that age 65 and older is associated with increased odds of adverse outcomes after surgery, including mortality, increased length of stay and discharge to a facility.[2 3] Mediators of this risk are multifactorial and include pre-existing functional or cognitive impairment, social isolation and malnutrition.[2] It is estimated that up to half of older adults who undergo surgery are considered frail, possessing multiple vulnerabilities.[4–6]

Preoperative optimisation and planning, including advanced care planning, delirium prevention, coordination of family support and multimodal preoperative rehabilitation (prehabilitation), have been shown to mitigate adverse surgical and functional outcomes in older adults, reduce complications and healthcare costs, and increase discharge to home rates and functional recovery.[2 5 7–9] In a randomised controlled trial of older patients with low preoperative aerobic fitness undergoing colorectal surgery, prehabilitation

increased aerobic fitness by approximately 10% and decreased the complication rate by 29.5%.[10] However, despite models illustrating programme cost-effectiveness and national guidelines recommending prehabilitation for older adults before colorectal surgery, uptake of these programmes has been slow for multiple reasons.[11–13]

First, studies have demonstrated that surgeons have a strong interest in prehabilitation programmes with one study reporting that 91% of surgeon respondents would be willing to delay surgery to optimise patients through prehabilitation—yet 33% report not knowing to whom to refer patients.[14] Second, multiple barriers to implementation exist, including direct and indirect costs to health systems and patients, a lack of financial reimbursement for these services, transportation costs for older adults who often possess a limited, fixed income and the multidisciplinary expertise required for these programmes.[15–18] Finally, while home-based prehabilitation tools, such as web apps, have demonstrated promise to decrease costs and increase accessibility of prehabilitation programmes, evidence has been mixed regarding their ability to increase adherence and reduce complication rates in the setting of colorectal surgery.[19–21]

We created a digital tool co-designed with older adults that employs an algorithm to assess patient geriatric vulnerabilities and generate a personalised prehabilitation programme before surgery. To evaluate the effectiveness of the digital tool in engaging older adults in prehabilitation as well as improving postoperative outcomes, we have designed a multicentre randomised trial that compares the web app with standard written surgery prehabilitation materials.

METHODS AND ANALYSIS

Intervention

Application development relied on expertise obtained from an in-person, multidisciplinary prehabilitation clinic for older patients at the University of California, San Francisco (UCSF). The clinic included pre-surgery recommendations targeting six domains: nutrition, physical fitness, home preparation, goals of care, advanced care planning and anxiety and was facilitated by a multidisciplinary team including a geriatrician, physical therapist, occupational therapist and dietician.[7] Recommendations from each of the six domains were translated into interactive digital content, and practitioners provided feedback and additional input when necessary to accommodate safety concerns with an exclusively remote programme. In addition to core content, an in-app health coaching portal was developed (figure 1). The application was co-designed with older adults and developed through an iterative process of testing, feedback and alterations to ensure it was optimised for an older user population. Finally, the web app, PrehabPal, was piloted among more than 200 UCSF surgical patients and underwent iterative development based on feedback from these older adults preparing for oncologic surgery.[22] In addition to examining rates of engagement among participants, we additionally confirmed the web app's suitability and usability through post-study satisfaction surveys.

On enrolment in the web app, patients complete a detailed intake survey which the web app algorithm uses to identify areas of vulnerability and create a customised nutrition, exercise, home preparation, goals of care, sleep and anxiety plan. Participants are instructed to log-in daily to log their exercises and review the next steps in their plan. For instance, exercise regimens may include a combination of aerobic workouts, such as walking, as well as strength exercises tailored to older adults, such as chair-based exercises, which promote strength training while decreasing the risk of injury. Nutrition recommendations include increasing protein intake and are adjusted according to patient comorbidities, such as diabetes, and home preparation guidance helps patients identify areas that require modification.

Participants are also paired with a virtual health coach who is available throughout the preoperative period to orient participants to the web app, answer questions, and help motivate individuals if their participation in the programme declines.

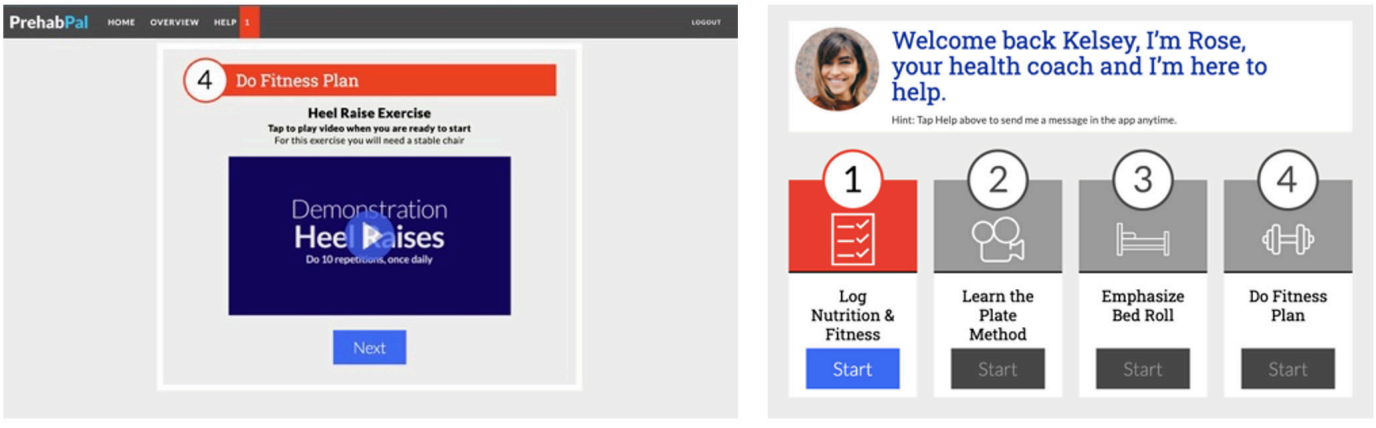

Figure 1 Screenshots of PrehabPal web portal. (1) Instructional exercise video and (2) homepage with coach information.

Study design and setting

The study is a multisite, prospective, unblinded randomised trial comparing patient engagement with prehabilitation via the PrehabPal web app to their engagement with written prehabilitation materials. The study will include patients aged 65 years and older who are planned to undergo colorectal cancer resection. The study will be conducted at three high-volume academic medical centres: the University of California, San Francisco Helen Diller Family Comprehensive Cancer Center (San Francisco, California, USA); MD Anderson Cancer Center (Houston, Texas, USA) and Stanford Healthcare (Palo Alto, California, USA).

A minimum of 44 eligible patients will be randomised at each study site (total 132) to digital prehabilitation or written instructions treatment groups. Patients will be enrolled for 7–21 days prior to surgery and followed for 8 weeks after surgery. The study period will span 30 months, with 24 months designated to subject recruitment and 6 months to allow for final subject follow-up.

The RCT is open to enrolment (ClinicalTrials.gov), we enrolled our first patient on 7 April 2023, and we anticipate the completion of enrolment by January 2026 and data collection by April 2026.

Study population

Eligibility criteria are patients aged 65 years or older at least 7 days prior to planned colorectal cancer resection, English language proficient, capable of providing informed consent and have home internet access. Patients with metastatic cancer or with a diagnosis of Alzheimer's Disease, dementia or other neurocognitive disorder will be excluded. No concomitant medications are prohibited. Usual care for all participants at each of the participating institutions includes Enhanced Recovery After Surgery pathways.

Study arms

Participants will be assigned at random to digital prehabilitation (intervention arm, Arm 1) or usual care with written prehabilitation materials (control arm, Arm 2) by a REDCap (Research Electronic Data Capture) randomisation module (figure 2). Participants assigned to the intervention arm of the study participate through a web-based application, PrehabPal, with the support of a motivational health coach who interacts with them through the web app. Content is centred around older adults and their individual vulnerabilities as patients are guided remotely through daily tasks centred around exercise, nutrition, anxiety reduction, sleep, home preparation, delirium prevention and advanced care planning prior to surgery.

Participants assigned to the control arm will receive written prehabilitation instructions on paper that provide equivalent content to the web app, including guidance on physical activity, diet, anxiety reduction and advanced care planning. Additionally, they will receive a paper diary to record their prehabilitation activities to measure patient engagement in each prehabilitation domain.

The PrehabPal digital prehabilitation tool content was co-created based on content created by clinicians in the UCSF Surgery Wellness Programme in collaboration with Ooney, a digital health company.[23] The written prehabilitation packet content was generated by the prehabilitation team in the UCSF Surgery Wellness Programme.

Randomisation assignment

A minimum of 44 eligible patients will be randomised at each study site to digital prehabilitation (intervention arm, Arm 1) or usual care with written materials (control arm, Arm 2) treatment groups in a 2:1 ratio using STATA-based computer-generated randomisation. This randomisation schema will be generated by the project's

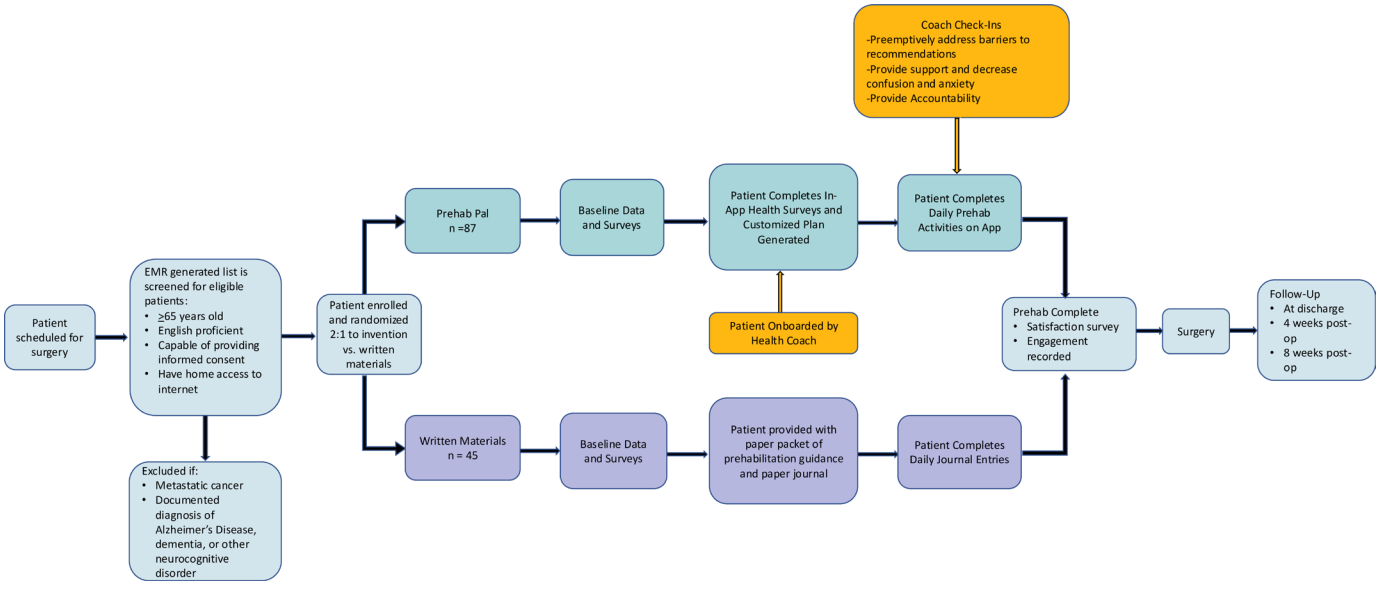

Figure 2 Schematic of participation in the study. (EMR = Electronic Medical Record)

statistician and recorded in the REDCap randomisation module. For each site, approximately 29 participants will be randomised to the PrehabPal web app and 15 to the written materials using a 2×3 factorial design.

Safety

The study protocol underwent a two-level peer review to assess the study feasibility and scientific merit at the University of California, San Francisco Helen Diller Family Comprehensive Cancer Center. The Gastrointestinal Protocol Review Committee reviewed the protocol first, gave feedback, and on approval recommended the protocol for review by the Full Protocol Committee. The Full Protocol Committee gave additional feedback, which was implemented, and V.1.4 (dated 22 December 2023) of the study protocol was approved. A properly executed, written, informed consent will be obtained from each subject prior to entering the subject into the trial (online supplemental appendix A). Information will be given in both oral and written form, and subjects may withdraw at any time from the study without effect on their medical care. The study protocol and consent form have been approved by Advarra the sIRB. Minor and serious adverse experiences regardless of causality will be reported to the IRB in accordance with the standard operating procedures and policies of the IRB/Independent Ethics Committee (IEC), and the investigator will keep the IRB informed as to the progress of the study. The investigator will obtain assurance of IRB/IEC compliance with regulations. Subjects will not be identified by name in the study database or on any study documents to be collected by the sponsor (or designee), but will be identified by a site number, subject number and initials. UCSF will act as the data coordinating centre as well as a participating site. UCSF has established a data monitoring plan to review data relating to safety and efficacy and to ensure the continued scientific validity and merit of the study.

This study involves minimal risks not materially greater than usual care. Some patients may feel overwhelmed by performing daily tasks and exercises in the days leading up to surgery. Others, however, may find it empowering. The knowledge gained in this study will facilitate effective dissemination of prehabilitation for all older adults preparing for surgery. These insights could benefit all older surgical patients.

Data collection

Chart review and patient interview

Study staff will use chart review at screening, enrolment and follow-up visits to obtain pertinent health information, including demographic information, baseline medical history and outcomes data. Screening and enrolment information will be confirmed with patients at the enrolment visit. Data will be stored in a UCSF-hosted REDCap database. The database will be partitioned by each site to maintain the confidentiality of site-specific participants. REDCap is a secure, web-based software platform designed to support data capture for research studies.[22 24] Available data from patients lost to follow-up will be analysed.

Patient questionnaires

At enrolment, study staff will determine frailty via the Edmonton Frailty Scale (EFS)—Acute Care version for virtual visits or the EFS—Bedside version for in office visits with the treating surgeon.[25–28] Patient-reported surveys will be administered using REDCap. Patient-reported measures (online supplemental appendix B) include:

- Demographic characteristics
- Technology use
- Functional status will be measured at enrolment, 4 weeks and 8 weeks postoperatively using the Short Form-36 v1.0 (SF-36) eight domains, and the calculated composite scores of the Physical Component Scale (PCS) and the Mental Component Scale (MCS) scores of the SF-36.[29–31 31–34] One or two days prior to surgery:
  - Patient-participant reported satisfaction with the PrehabPal web app and the paper-mode activities diary by REDCap.
  - Adverse event survey will be administered by telephone by the study staff.

PrehabPal website and patient log

Engagement will be measured as the proportion of available days before surgery engaged in prehabilitation activities. For the web app, this measure will be assessed directly as activities performed while logged in to PrehabPal. For the paper diary, this measure will be ascertained by the activities recorded in the patient logbook.

Outcome measures

Primary objective: to determine the engagement in digital prehabilitation among older adults

Patient engagement was chosen as the primary outcome of our study as it is of critical importance to assess the ability of our digital intervention to engage patients as compared with standard models of care and therefore fill a vital gap of accessible and available prehab platforms. To assess patient engagement, we will compare the proportion of days prior to surgery that patients engaged in prehabilitation in the intervention group with that of control arm with written materials group. Optimisation engagement is calculated as a proportion (#days engaged in activities/maximum #days eligible to optimise). Usual care with written materials participants will be prompted by the onsite clinical research coordinator to return their paper diary. Paper diary metrics will be entered into REDCap database for calculation of their optimisation engagement. For the PrehabPal web app intervention arm, the engagement metric will be calculated in the web app.

Secondary objective: to determine the impact of digital prehabilitation on surgical outcomes and functional recovery at 4 and 8 weeks postsurgery

Secondary outcomes are surgical outcome and functional recover at 4 and 8 weeks postsurgery. Surgical outcomes (operative complications and 30-day emergency department visit and readmission rate) will be determined via chart review 4 weeks postoperatively and classified using the Clavien-Dindo complications index.[25 35 36] Functional recovery will be measured at baseline (enrolment) 4 weeks and 8 weeks postsurgery using the SF-36 eight domains, and the calculated composite scores of the PCS and the MCS scores of the SF-36.[29–34]

Statistical considerations

Statistical power

In our pilot study, on average, half of the patients engaged with the PrehabPal web app in prehabilitation on >50% of the days before surgery. This is consistent with similar rates of moderate engagement reported with another web app for multimodal prehabilitation in patients receiving colorectal surgery.[19] Based on observation from clinical practice, we expect that 25% of patients in the control group will engage in prehabilitation on >50% of the days before surgery. As a result, we expect that patients who do not have digital prehab coaching will engage less frequently. With a sample size of 105 (70 in the intervention arm and 35 in the control arm), we will have 80% power to detect a difference of 25 percentage points in the primary endpoint using a χ^2 test with a one-sided type I error rate at 0.05. We plan to enrol and randomise 132 total subjects to allow for attrition.

Proposed statistical analysis

Analysis of primary endpoints

The χ^2 test will be used to compare the proportion of patients engaging in >50% of the prehabilitation activities before surgery between the intervention arm and the control arm. Multivariate logistic regressions will also be used to evaluate the intervention effect on engagement, controlling for covariates such as site, age, race, clinical characteristics and planned procedure. We may also include other factors that are not balanced between the sites. We will assess for differences in sample characteristics between sites by comparing means of continuous characteristics using analysis of variance and by comparing categorical characteristics using χ^2 tests. Available data from those lost to follow-up will be included with multiple imputation used for missing data, and an intention-to-treat analysis used.

Analysis of secondary/exploratory endpoints

All secondary endpoint analyses regression models will control for site, along with all covariates that were included in the secondary analysis of the primary endpoint. Binary or multinomial logistic, linear or quantile regression will be used, as appropriate, to compare secondary endpoints between the patients who received to PrehabPal web app programme and written materials. SF-36 scores, all eight domains scale scores and the PCS and MCS scores will be described in each study arm using graphs and summary statistics of each time point (baseline, 4 weeks and 8 weeks). Only measures at 8 weeks after surgery will be compared between the PrehabPal web app and written material arms using regression models.

Patient and public involvement

The PrehabPal web app was initially developed using a user-based design, where app developers conducted 10 feedback sessions with older adult patients. During these sessions, developers observed patients interacting with the web app and participants were asked to provide real-time feedback as they navigated through the app. These observations and feedback were then iteratively incorporated into a prototype that was piloted at our institution among more than 200 participants. After their participation in the pilot study, participants were invited to complete satisfaction surveys, and feedback from these surveys was incorporated into the final web app design used in this research study.

ETHICS AND DISSEMINATION

A properly executed, written, informed consent (online supplemental appendix A) will be obtained from each subject prior to entering the subject into the trial. Information will be given in both oral and written form, and subjects may withdraw at any time from the study without effect on their medical care. The study protocol and consent form have been approved by Advarra the sIRB (Advarra Pro00064862), as well as the IRB of each participating centre (UCSF (IRB #22-37253)), Stanford University, University of Texas MD Anderson Cancer Center). Serious adverse experiences regardless of causality will be reported to the IRB in accordance with the standard operating procedures and policies of the IRB/IEC, and the investigator will keep the IRB informed as to the progress of the study. The investigator will obtain assurance of IRB/IEC compliance with regulations. Subjects will not be identified by name in the study database or on any study documents to be collected by the sponsor (or designee), but will be identified by a site number, subject number and initials. The University of California, San Francisco Data Safety Monitoring Board has established a Data Monitoring Committee (DMC) to review data relating to safety and efficacy and to ensure the continued scientific validity and merit of the study. There will be no interim reviews conducted by the DMC for the purpose of monitoring study conduct and assessing patient safety.

A subject may be discontinued from study treatment at any time if the subject or the investigator feels that it is not in the subject's best interest to continue. If a subject is withdrawn from treatment due to an adverse event, the subject will be followed and treated by the Investigator until the abnormal parameter or symptom has resolved or stabilised.

This study involves minimal risks not materially greater than usual care. Some patients may feel overwhelmed by performing daily tasks and exercises in the days leading up to surgery. Others, however, may find it empowering. The knowledge gained in this study will facilitate effective dissemination of prehabilitation for all older adults preparing for surgery. These insights could benefit all older surgical patients.

EF is a co-creator of content for PrehabPal and a co-owner of Ooney.com. As such, a conflict of interest plan was developed by the conflict of interest Advisory Committee of the UCSF Office of Ethics and Compliance.

We anticipate publication of results in a peer-reviewed journal. Authorship will be based on the International Committee of Medical Journal Editors Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals

Contributors KO contributed to protocol development, manuscript writing, revision and approval. JB contributed to protocol development, protocol writing, protocol implementation, manuscript writing, revision and approval. CR contributed to protocol development, manuscript revision and approval. CK contributed to protocol development, protocol writing, protocol implementation, manuscript revision and approval. GJC contributed to protocol development, protocol writing, protocol implementation, manuscript revision and approval. EF contributed to conceptualisation of study design, protocol development, protocol drafting, manuscript writing, revision and approval. EF is responsible for the content as a guarantor.

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Competing interests EF is a co-creator of content for PrehabPal and a co-founder of Ooney INC. As such, a conflict of interest (COI) plan was developed by the Conflict-of-Interest Advisory Committee by the UCSF Office of Ethics and Compliance. All other authors declare no competing interests.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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