

**Feasibility of the Hip Instructional Prehabilitation Program for Enhanced
Recovery (HIPPER)**

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Research Protocol

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Background

Total hip replacements (THR) reduce joint pain and improve function in individuals with advanced osteoarthritis. In Canada, 49,503 THRs were performed in 2013-14, resulting in substantial health care costs [1]. The volume of THRs has grown by ~20% since 2009 [1]. Health promotion interventions, such as prehabilitation (pre-surgical education), are vital to optimising surgical outcomes, reducing hospitalisation costs, accelerating rehabilitation, and alleviating patient discomfort and pre-operative anxiety [2–7]. The evidence, however, is mixed, particularly regarding learning preferences and the delivery mode [7,8]. Education based on eHealth (e.g., online) principles offers considerable delivery flexibility while making learning interesting, interactive, and informative. Using a participatory action-based design focusing on user input, we created and refined online prehabilitation (prehab) education programming.

As a result, based on adult learning principles [9] and a user-centred approach [10], we developed HIPPER (Hip Instructional Prehabilitation Program for Enhanced Recovery), an interactive online (eHealth) pre-operative THR education program. Building on this work, and prior to conducting a definitive randomised controlled trial (RCT), we will conduct a 2-year tester-masked feasibility study to address design and HIPPER intervention fidelity.

Purpose: The goal of this research is to evaluate the feasibility indicators and clinical outcomes of the Hip Instructional Prehabilitation Program for Enhanced Recovery (HIPPER) (an eHealth approach for pre-surgical education) compared to traditional in-person group prehab.

Hypothesis: We anticipate that HIPPER will be as valuable as group webinar education in preparing a patient for THR. However, HIPPER, when compared to group webinar education, may reduce costs by freeing up clinical educator time and has improved feasibility indicators and clinical outcomes.

Objectives: The primary feasibility objectives are to assess: i) Process issues (e.g. subject recruitment, retention, perceived benefit); ii) Resource issues (e.g. treatment adherence, burden, incorporating a health utility index); iii) Management issues (e.g. subject processing, protocol administration) and iv) Treatment issues (e.g. safety, treatment effect). Secondary objectives are to evaluate the effect of HIPPER on primary and secondary clinical outcomes and obtain an estimate of treatment effect size.

Methods

Research Design: This study will conduct a 2-year masked feasibility RCT. Subjects will be randomly assigned to the HIPPER experimental group (n=20) or the control group, which will receive usual care (n=20).

Inclusion Criteria

- a) have advanced hip osteoarthritis
- b) are living in the greater Vancouver region;
- c) are aged 50 years or older;
- d) are scheduled to have a single THR in 12 weeks or later;
- e) have access to the internet

Exclusion Criteria

- a) cannot communicate and complete questionnaires in English;
- b) anticipate a health condition or procedure that contraindicates their THR surgery;
- c) are actively receiving physical therapy for their hip symptoms;
- d) have had a previous THR.

Recruitment: The Co-Investigators, who are also clinical educators (i.e., clinicians), will be assisting with the recruitment process. They will have a third-party admin assist by sending the initial contact letter with the education package to individuals in the OASIS program from the electronic medical record system. Should individuals be interested in participating, they will contact the researchers (i.e., research assistant; not the clinicians) at GF Strong. Participants will be recruited via advertisements sent to clinical networks and social media platforms (e.g., Twitter). In addition, VCHRI will be sent some information regarding our study to its employees. The information will be sent as an e-blast. They created a new document based on the formats that they use for this type of e-Blast.

Study Procedures: Upon successful screening/enrollment and baseline data collection, the study Coordinator will contact our statistician by telephone or email and obtain group assignment within 48 hours. Participants will be randomised to the experimental group (HIPPER, n=25) or the control group (n=25) using a 1:1 allocation ratio. The HIPPER experimental group will receive 12 interactive online modules (~20 minutes each), which permit self-paced progression that can be accessed from the participant's home or other location. HIPPER participants will receive an email or phone contact (participant preference) to provide them with access to the website portal, including the web address and simple instructions for accessing the website using the personalised, encrypted login information. The module formats include embedded videos, narrative PowerPoint presentations, and quizzes. Subjects will be encouraged to have a family member view HIPPER materials with them. The education consists of a comprehensive, structured library of materials covering exercise, equipment needs/setup, pain management, nutrition, and weight management.

We will remotely monitor online analytics (e.g., login frequency, module progression) and phone the participant within 2 weeks if no online activity is observed to promote adherence and troubleshoot potential technical issues.

To provide a comparable level of education, control subjects will receive 2 x 2-hour group webinars, as per current practice. These group sessions will cover similar content, with session 1 focusing on prehab material (e.g. exercise, nutrition) and session 2 focusing on pre-surgical content (e.g., home equipment, hip precautions).

Subjects will be able to have their questions addressed throughout the session. A central computerised randomization process will be designed by our statistician, with an undisclosed block size. Subject contact information will be forwarded to the appropriate group of testers. To address bias, subjects will be instructed not to discuss their program, and Testers will reinforce this point at each session. Baseline data (T1) will be collected online via our UBC Zoom accounts. Subsequent data will be collected at (T2) 7-10 days prior to surgery and (T3) 30 days post-surgery, which will occur in the subject's home (participants will fill out the questionnaires online, and there is no need for the researchers to meet them at home). These endpoints are strategic: collecting data 7-10 days prior to surgery captures the influence of our intervention on our primary clinical outcome of interest (anxiety) pre-surgery, while 30 days post-surgery reflects the optimal time window for self-report.

Sample Size: We will recruit 40 community-dwelling older adults from the greater Vancouver region. Our sample size enables us to assess our feasibility indicators with relative precision. For example, assuming a <10% refusal rate, we can be 95% confident that the estimate is within 9% of the true value [11]. Doubling the sample size (n=80) would only improve precision by 2 % points.

Statistical analyses: Subjects will be randomised in a 1:1 allocation ratio. A central computerised randomisation process will be designed, with an undisclosed block size. Data distribution will be evaluated using the one-sample Kolmogorov-Smirnov test. If data are normally distributed, means and standard deviations (continuous variables) and frequencies and proportions (categorical variables) will be used to summarise case mix and outcome variables within groups. Descriptive statistics will be used to assess online usage data (e.g. time spent using modules) to evaluate dose-response and adherence for the HIPPER group. A qualitative comparison of variable balance will be made, including the determination of prognostic importance [12].

Feasibility Indicators (process, resources, management, and treatment issues): The specific feasibility objectives will be treated as “successful” - indicating a sufficiently robust protocol (small or no modification required) or “revise” - if a substantive change is required prior to proceeding to a full RCT.

Clinical outcomes (physical function, anxiety, pain, satisfaction with education, and health-related quality of life): For all the outcomes (focusing on the primary end point of interest), the post-treatment scores will be compared in the HIPPER and control group using analysis of covariance (ANCOVA), controlling for baseline score as a covariate. Unequal cell sizes will be accommodated using Method 1, and diagnostic assessments will be conducted to evaluate model assumptions. Significance testing (p) and marginal means with 95% confidence intervals will be estimated under the alternative hypothesis that the HIPPER group is superior. Effect size (partial η^2) will be calculated as a ratio of the effect and the total sums of squares, with a 95% confidence interval. To preserve prognostic balance, the primary analysis will use intention-to-treat, but we will also consider per-protocol analyses as a secondary approach, given that one objective is to estimate the treatment effect. The focus on a single primary variable indicates we will not control for multiple comparisons, as the secondary outcomes are considered exploratory.

Variables/Outcome measures: Descriptive characteristics, including age, sex, marital status, education, comorbidities, and duration of osteoarthritis (OA), will be collected. We will also monitor for rehabilitation contacts (e.g. physical therapy visits) throughout the study.

Feasibility indicators for the process, resources, management, and treatment components will be assessed throughout and at the study end.

Clinical outcomes (physical function, anxiety, pain, satisfaction with education, and health-related quality of life) will be measured at 3 times. The following assessment scales will be used to collect the clinical outcomes: Hospital Anxiety and Depression Scale (HADS); 30-second chair sit-to-stand test; Physical Activity Scale for the Elderly (PASE); Self-Efficacy for Rehabilitation Outcome Scale (SER); Equipment Checklist; the EuroQol-5 Dimension, 5-level, System Usability Scale (SUS).

Primary Clinical Outcomes Scale

Hospital Anxiety and Depression Scale (HADS): The HADS is a validated 14-item tool that includes tension, Depression, worry and fear and has respondents indicate how they currently feel on a 4-point Likert scale [13]. Evaluation of the HADS among older adults with OA demonstrated good concordance with clinical diagnoses of depression, anxiety and sensitivity to change [14,15].

Secondary Clinical Outcomes Measures and Scales

Oxford Hip Score (OHS): A 12-item tool that assesses pain and function in patients undergoing hip replacement surgery. It demonstrates good construct validity and test-retest reliability in THR [16]. Participants will complete this measure at T1, T2, and T3.

Daily Activity Subscale of the Hip Disability and Osteoarthritis Outcome Score (HOOS): a patient-reported outcome measure (PROM) used to evaluate patients undergoing Total Hip Arthroplasty (THA). The HOOS questionnaire was built upon the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) – an instrument that also measures outcomes in osteoarthritis and following THA. Questions from the WOMAC (LK version 3.0) were used as the basis for the survey, and two additional dimensions were added: sport & recreation and hip-related quality of life [17]. In this study, we will use the Daily Activity Subscale of the HOOS, which has 17 items.

30-second chair-stand test: Functional lower limb strength and dynamic balance will be assessed by having subjects perform repeated sit-to-stands on a standard 43-46 cm straight-back chair with no armrests. This test will be excluded from the 30-day reassessment to allow subjects to adhere to the hip precautions. Excellent test-retest reliability has been reported in patients awaiting THR [18]. Participants will complete this measure at T1, T2, and T3. Participants will be recorded during this test to assess inter-observer reliability.

Physical Activity Scale for the Elderly (PASE): Patients are less physically active prior to THR and show minimal improvements in activity levels post-operatively. PASE is a 12-item tool developed for older adults to assess home, occupational and recreational activities in the previous 7 days [19]. It has moderate test-retest reliability in

hip OA and correlates well with other self-report activity measures [20]. Participants will complete this measure at T1, T2, and T3.

Self-Efficacy for Rehabilitation Outcome Scale (SER): A 12-item questionnaire that asks patients to rate their confidence on an 11-point Likert scale and yields 2 subscale scores: self-efficacy for rehabilitation therapy exercises and self-efficacy for overcoming barriers [21]. Overall reliability is excellent (ICC α 0.94) [22]. Participants will complete this measure at T1, T2, and T3.

Equipment Checklist: It is recommended that patients acquire equipment and mobility aids prior to THR to ensure their safety, support daily living activities, and adhere to surgical precautions post-operatively [23]. A comprehensive checklist of recommended equipment will be created based on current guidelines, clinical recommendations and our Patient Partners' input [23]. Participants will complete this measure at T1-T3

EuroQol-5 Dimension, 5-level: Health-related quality of life is a core outcome for hip OA, and the EQ-5D is a suggested measure. The EQ-5D is a brief questionnaire that assesses 5 health status domains and overall health state using a visual analogue scale [24]. In patients awaiting THR, the test-retest reliability of the newer 5-level tool was good (ICC=0.61-0.77), and convergent validity was strongly correlated with similar measures of pain and function [25]. A change of 0.10 represents a clinically important difference in the arthritis population [26]. Participants will complete this measure at T1, T2, and T3.

System Usability Scale: a 10-item questionnaire with five response options for respondents, ranging from "Strongly agree" to "Strongly disagree" [27]. Originally created by John Brooke in 1986, it allows us to evaluate a wide variety of products and services, including hardware, software, mobile devices, websites and applications. Some example items are "I think that I would like to use this system frequently," and "I needed to learn a lot of things before I could get going with this system." In this study, we replaced "the system" with "Hipper" to capture the opinion of participants regarding the usability of our eHealth program. Participants will complete this measure at T2 and T3.

Semi-structured Interview: Finally, Participants of the Hipper group will be invited to an optional semi-structured interview. The 45-60-minute audio-recorded semi-structured interviews will be conducted by the researchers with the experimental group participants at the end of the study (T3) to explore the experience and acceptability of the Hipper program. Using these semi-structured interviews, we will identify the advantages and disadvantages of Hipper and suggestions to improve the intervention and study protocols.

Time to Participate: Participants in the HIPPER (experimental group) will be asked to complete 10 modules. The total time to complete the modules is approximately 2 hours and 30 minutes.

Data collection sessions for the experiment group: Assessment measures will be collected at baseline (T1) and will take approximately 2 hours. Data collection at T2 (7-

10 days before surgery) will take approximately 90 minutes. Data collection at (T3) 30 will take approximately 60 minutes.

Participants in the experimental group will be asked to take part in an optional semi-structured interview lasting 45-60 minutes.

Time to Participate – Normal/Control Participants: Control participants will receive 2 x 2-hour webinars. Total = 4 hours of education sessions.

Data collection sessions for the control group: Assessment measures will be collected at baseline (T1) and will take approximately 2 hours. Data collection at T2 (7-10 days before surgery) will take approximately 90 minutes. Data collection at (T3) 30 will take approximately 60 minutes. Total time for participation: 4 hours (education sessions) + 6 hours (data collection sessions) = 10 hours

Known Study Risks/Harms: There are minimal risks associated with participating in the study. Participants in the experimental group will receive prehabilitation education, as in the control group, but through an online interactive platform. We do not expect the HIPPER prehabilitation education to lead to increased risk for the participants in the experimental group because it provides similar information to the existing system (usual care that the control group will receive).

Potential Benefits: There may be no direct benefit to participation in this study, but it may help prepare them for THR surgery. Participation in this study may contribute to future PT (Physical Therapy) educational practices by better understanding the needs and preferences of those with osteoarthritis. Effective online modules could offer the benefits of requiring less clinician contact and resources and of reducing travel demands, leading to both reduced direct health care costs and indirect costs (e.g., dependence on family).

Reimbursement/Remuneration: To compensate for their time, participants will receive \$50/ data collection session (T1-T3), for a total of \$150. Participants who participate in the semi-structured interview will receive \$25 as a token of appreciation.

Obtaining Consent: A member of the study team will explain the study and the informed consent to the participants and invite the subject to participate. Those interested in participating will complete the informed consent form independently and return it to the researcher. Participants will be asked to e-sign the consent forms and return them to the researcher before the T1 session, which will be held online via our

Using online tools (i.e. UBC REDCap or UBC Qualtrics) to collect data: All questionnaires will be entered into UBC REDCap/UBC Qualtrics, and all participants will be asked to complete the questionnaires online. At T1, all participants will be invited to a Zoom meeting and asked to complete the questionnaires via our online tool. A research assistant will be present in the Zoom meeting to help the participant become familiar with using the online tool and completing the questionnaires. If they do not have an email account to receive the questionnaires, an RA in our centre will create an account for them and teach them how to use email. At T2-T3, participants will receive a link to the questionnaires and be asked to complete them at home.

In addition to the self-reported measures, we ask participants to complete the 30-second Chair-Stand Test. At T1 and T2, an RA in our lab will contact them via Skype, FaceTime, or Zoom and ask them to do this test. Participants will be recorded during the 30-second chair sit-to-stand test. We will use the video recording function in Zoom and Skype (or the screen recording function if we use FaceTime). Participants will be notified when the recording starts and when it stops. The recordings will be saved on our lab mDrive.

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