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PROTOCOL

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The digital patient journey solution for patients undergoing elective hip and knee arthroplasty: Protocol for a pragmatic randomized controlled trial

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Abstract

Aim: To describe a randomized controlled trial (RCT) protocol that will evaluate the effectiveness of a digital patient journey (DPJ) solution in improving the outcomes of patients undergoing total hip and knee arthroplasty.

Background: There is an urgent need for novel technologies to ensure sustainability, improve patient experience, and empower patients in their own care by providing information, support, and control.

Design: A pragmatic RCT with two parallel arms.

Methods: The participants randomized assigned to the intervention arm (N = 33) will receive access to the DPJ solution. The participants in the control arm (N = 33) will receive conventional care, which is provided face to face by using paper-based methods. The group allocations will be blinded from the study nurse during the recruitment and baseline measures, as well as from the outcome assessors. Patients with total hip arthroplasty will be followed up for 8–12 weeks, whereas patients with total knee arthroplasty will be followed up for 6–8 weeks. The primary outcome is health-related quality of life, measured by the EuroQol EQ-5D-5L scale. Secondary outcomes include functional recovery, pain, patient experience, and self-efficacy. The first results are expected to be submitted for publication in 2020.

Impact: This study will provide information on the health effects and cost benefits of using the DPJ solution to support a patient's preparation for surgery and postdischarge surgical care. If the DPJ solution is found to be effective, its implementation into clinical practice could lead to further improvements in patient outcomes. If the DPJ solution is found to be cost effective for the hospital, it could be used to improve hospital resource efficiency.

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KEYWORDS
arthroplasty, digital patient journey solution, mobile health, nursing, randomized controlled trial

1 | INTRODUCTION

Globally, the demand and costs of primary lower-limb arthroplasty have increased significantly over the past decade. Only in the USA, for instance, the demand for total hip arthroplasty (THA) has almost doubled from 14.2–25.7 per 10,000 population (Wolford, Palso, & Bercovitz, 2015). Correspondingly, the demand for total knee arthroplasty (TKA) has doubled from 24.3–45.3 per 10,000 population in men and from 33.0–65.5 per 10,000 population in women (Williams, Wolford, & Bercovitz, 2015). At the same time, the mean length of stay (LOS) in hospital has shortened by 1 day (Williams et al., 2015; Wolford et al., 2015) due to accelerated discharge methodologies (Hansen, 2017; Lombardi et al., 2016).

These streamlined discharge methodologies, however, have not avoided criticism (Jansson, Harjumaa, Puhto, & Pikkarainen, 2019a): The current state of the elective primary lower-limb arthroplasty journey is not fully meeting the needs of healthcare professionals (Jansson, Harjumaa, Puhto, & Pikkarainen, 2019b) or of patients (Jansson, Harjumaa, Puhto, & Pikkarainen, 2020). Consequently, there is an urgent need for proactive care to increase patients' engagement in a pre-operative preparation to decrease pre-operative risk factors, which may potentially lead to complications or a prolonged LOS (Hansen, Bredtoft, & Larsen, 2012). In addition, patients need to be more involved in their postdischarge surgical care to manage their situation at home after discharge.

1.1 | Background

As the demand and costs of primary joint replacement will have increased worldwide by 2030 (Culliford et al., 2015), hospital-based healthcare resources will become limited. Only in Australia, for instance, the total cost of THA/TKA may be AUD 5.32 billion by 2030 (Ackerman et al., 2019). At the same time, there is an urgent need for novel technologies to ensure sustainability, improve the patient experience, and empower patients to be responsible for their own care by providing information, support, and control (Gunter et al., 2016; Jansson et al., 2019b).

While electronic health (eHealth) involves all aspects related to the application of information and communication technology (ICT) in healthcare provision, mobile health (mHealth) focuses on mobile devices and other wireless devices (WHO, 2011). The widespread deployment of mHealth technologies can help overcome some of the limitations faced by eHealth. In addition, modern mobile devices can include sensors, such as pedometers and accelerometers, that increase physical activity and other health outcomes.

With the provision of healthcare services decreasing, the use of mHealth opens up big opportunities to deploy systems and services in a cost-effective way. In fact, the deployment of mobile technologies has resulted in increased patient satisfaction (Chen, Chuang, Lin, Lin, & Chuang, 2017; Clari et al., 2015; Daniels et al., 2016; Goode et al., 2018) and it has reduced postdischarge health problems (Clari et al., 2015; Daniels et al., 2016; Timmers et al., 2019) and thus reduced healthcare consumption (Clari et al., 2015; Martinez-Rico, Lizaur-Utilla, Sebastia-Forcada, Vizcaya-Moreno, & Juan-Herrero, 2018; Timmers et al., 2019) without an increase in adverse events (Clari et al., 2015; Goode et al., 2018).

Despite the growing body of evidence, however, there is limited understanding of the effectiveness of the digital patient journey (DPJ) solutions used on a smart device that cover the whole patient journey (from home to hospital and back home). In addition, the effect of mHealth services and technologies on functional recovery in patients who have undergone THA/TKA is heterogenous and based on moderate- to low-quality evidence.

2 | THE STUDY

2.1 | Aims

The aim of this study is to design a detailed research protocol for the DPJ solution and evaluate its short-term effectiveness for patients undergoing elective THA/TKA. The primary outcome is to evaluate the effectiveness of the DPJ solution on health-related quality of life (QoL). The secondary trial aim is to evaluate the effectiveness of the DPJ solution on functional recovery, pain, patient experience, and self-efficacy. A cost–benefit analysis, including social project evaluation, will also be conducted from the hospital's and patients' perspectives. At the end, the user experience with the intervention will be evaluated.

2.2 | Objectives

To achieve the overall aim of the study, the following objectives are formulated:

- To evaluate health-related QoL using the EuroQol EQ-5D-5L scale.
- To determine the functional recovery using the Western Ontario and McMaster Universities Osteoarthritis (WOMAC), Oxford Hip Score (OHS), and the Oxford Knee Score (OKS).
- To evaluate the intensity of pain using the subscales of WOMAC and the OHS/OKS, as well as the Visual Analogue Scale (VAS).
- To assess the patient experience using three patient experience assessment scales.
- To evaluate self-efficacy regarding preparation for surgery and postdischarge surgical care, using a single-item measurement defined for

the purposes of the study and, regarding technology, using an adapted version of the healthcare technology self-efficacy (HTSE) scale.

- To explore a cost–benefit analysis using clinical data retrieved from medical records and patient-reported experience measures (PREMs).

2.3 | Hypothesis

The trial is designed to test the hypotheses at a 0.05 level of significance. To achieve the objectives of the study, the following hypothesis was formulated: *The posttest QoL, functional recovery, pain, patient experience, and self-efficacy among patients undergoing elective THA/TKA in the intervention arm will significantly improve compared with the control arm.*

2.4 | Trial design

A pragmatic randomized controlled trial (RCT) using a two-arm pre- and posttest design will be conducted (Figure 1). This protocol was prepared in accordance with the SPIRIT 2013 statement.

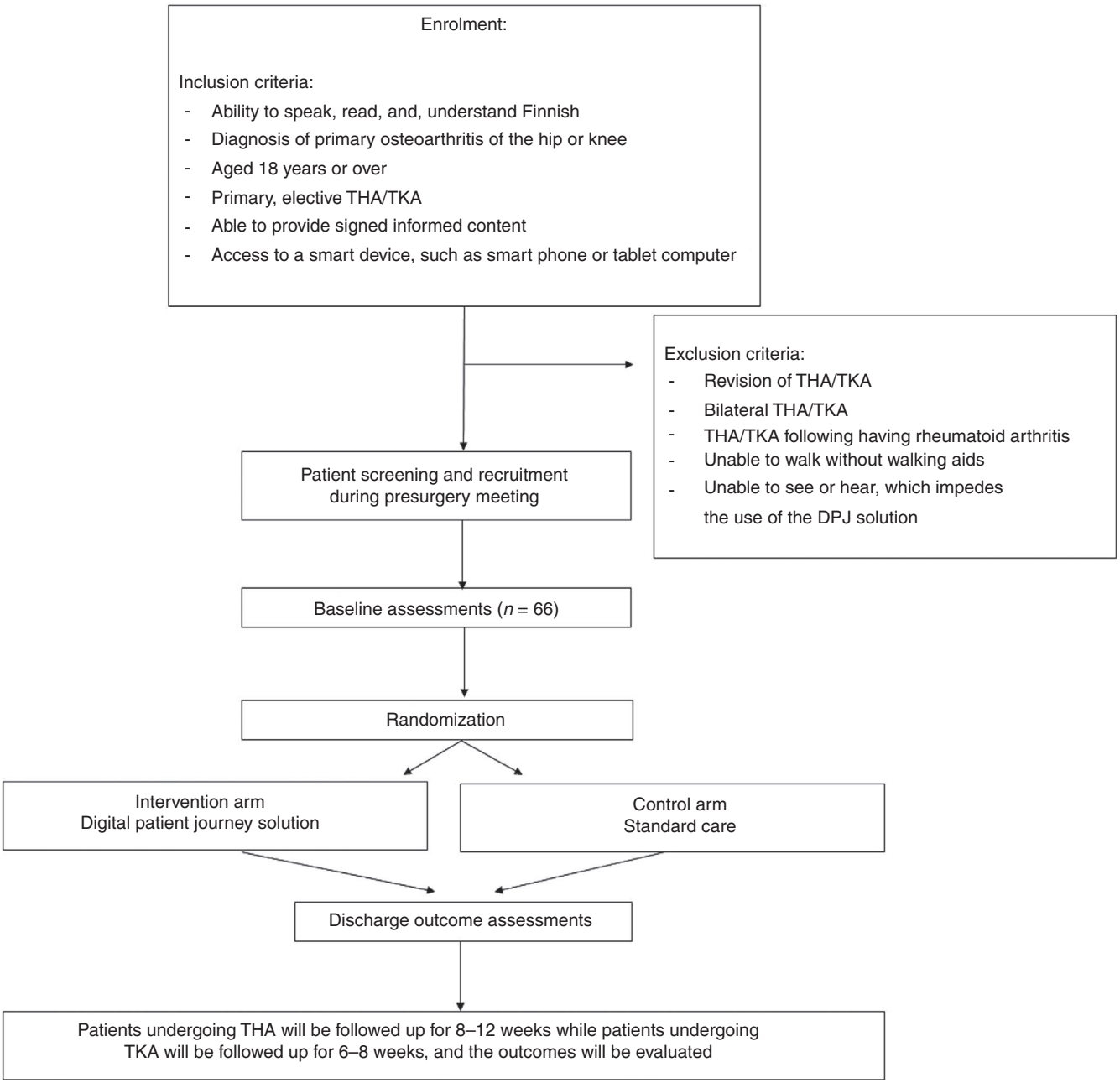

FIGURE 1 The enrolment, randomization, and follow-up of the study participants. THA, total hip arthroplasty; TKA, total knee arthroplasty

2.5 | Ethics and trial registration

The study has been reviewed and approved by ethical committee of North Ostrobothnia's hospital district in June 2019 (Ref no. 39/2019). The study will adhere to ethical standards founded on informed and voluntary consent. Written informed consent will be obtained from participants prior to inclusion in the study (Declaration of Helsinki, 2013). Participation is voluntary; participant withdrawal from the study will be respected without any disadvantage to or repercussions for the participant. The randomization of participants will ensure that all participants have an equitable chance of being allocated to either the intervention or control arms. The trial is registered prospectively at ClinicalTrials.gov (NCT04083326).

2.6 | Study setting and recruitment

This study will be conducted in a single joint-replacement centre in a 900-bed, tertiary-level university teaching hospital in northern Finland. In 2018, there were a total of 365 THAs and 361 TKAs performed in the hospital by nine orthopaedic surgeons. Patients undergoing a primary, elective THA/TKA will be invited to take part in the study. The patients will be screened and recruited during the usual presurgical visit by the study nurse. The participants will be recruited between September and December 2019. Once enrolled, the patients will be randomly assigned to either the intervention arm or the control arm.

2.6.1 | Inclusion criteria

The following inclusion criteria are formulated:

- 18 years or older.
- A diagnosis of primary osteoarthritis of the hip or knee (M16.0, M16.1, M17.0, and M17.1).
- Undergoing primary, elective THA/TKA.
- Access to a smart device, such as smart phone or tablet computer.
- Ability to speak, read, and understand Finnish.
- Able to give signed informed consent.

2.6.2 | Exclusion criteria

The following exclusion criteria are formulated:

- Undergoing a THA/TKA revision.
- A bilateral THA/TKA.
- THA/TKA following having rheumatoid arthritis.
- Inability to walk without walking aids.
- Unable to see or hear, which impedes the use of the DPJ solution.

2.7 | Sample size calculation

We aim to detect a difference of 0.24 points (standard deviation = 0.27) in the EQ-5D-5L scores, which is considered a clinically important difference (Bilbao et al., 2018; Conner-Spady, Marshall, Bohm, Dunbar, & Noseworthy, 2018). Setting an alpha level of 0.05 and power of 0.9, 56 patients (28 in each arm) would need to be recruited. As we furthermore predict a dropout rate of 15% that increases the number of enrolled patients to 66.

2.8 | Randomization and blinding

The participants will be randomized in permuted blocks of two and four, stratified by age (≤70 years old or >70 years old) and by whether or not they have had a prior joint replacement (*yes* or *no*) to either the intervention arm or the control arm in a 1:1 ratio. The allocation sequence is concealed from the study nurse using opaque and sealed envelopes until the baseline measures are completed. Due to the nature of the research, blinding will not be possible for either the participants or the healthcare team (excluding the orthopaedic surgeons). However, for the patients and for the study nurse, the group assignment will be masked during the recruitment until the baseline measures are completed. In addition, the group allocation will be masked from the outcome assessors.

Due to the nature of the intervention, the risk for contamination is minimal; the DPJ solution is tailored according to patients' individual timetable and individual needs and the journey can be accessed only with a personal activation code that each participant receives from the study nurse. In addition, the healthcare personnel is not specifically trained but all patients are treated as per usual. Therefore, we do not expect that control patients would benefit from obtaining information about the DPJ used in this study to the extent that it would affect their health-related QoL, or any other health outcome used in the study.

2.9 | The intervention

2.9.1 | The experimental intervention

The participants randomized in the intervention arm will receive the same information as the control arm plus have access to the closed DPJ solution, used on a smart device. The functionality of the DPJ solution is based on an existing mobile care coordination and patient engagement platform (BuddyCare, version 2.24.0) enhanced with messaging functionality and video calls (Near Real Connect, version 1.13 for Android, version 1.10 for iOS). The flow and content of the DPJ solution was developed in collaboration with the technology providers, the clinicians responsible for the THA/TKA journey, and the researchers. It started with a process mapping workshop to build a comprehensive understanding of the current patient journey

(Jansson et al., 2019a). The starting point for the journey was previous work done in lean transformation projects, which was then updated by the clinicians responsible for the organization of care. After the process mapping technology providers familiarized the clinicians and researchers with the current functionality of the technology, further development needs were identified by the research consortium and later through an interview study (Jansson et al., 2019a, 2019b, 2020).

Through the solution, the patient can familiarize himself or herself with the phases of care through a visual timeline representation of the journey, get information on how to prepare for surgery and postdischarge surgical care, receive reminders and notifications, fill in questionnaire forms, communicate with the care personnel via a messaging functionality and video calls, or search for information from frequently asked questions. The DPJ solution can be downloaded from the Google Play and App Store by anybody, but a personal activation code is required to enter the solution. The study participants will receive this code from the study nurse and the study nurse will also help to install the DPJ solution onto the participant's smart device if required.

The DPJ solution has three views: checklist, timeline, and menu views and the user can navigate between these views using the blue navigation panel at the bottom of the screen (Figure 2). *The timeline* is a visual timeline representation of the care pathway (the path) and is the main view. The timeline contains all the important tasks and instructions that are to be conducted before and after the surgery in chronological order. Tasks are marked with different colours based on their urgency using blue, green, orange, and pink colours. Tasks should be conducted if they are orange. Pink stands for urgent tasks, green tasks have been successfully conducted, and blue ones are upcoming. There is also a search functionality that can be used to search for any information along the timeline. *The checklist* contains the same information as the timeline, but the tasks are presented in a list format. It is also possible to navigate to a certain part of the timeline by selecting a task in the checklist. *The menu* contains all the information presented in the timeline, the forms presented in the timeline, a reporting tool for pain, a step-monitoring functionality, a messaging functionality, videos, information about the hospital, the contact information of the hospital, and user settings containing information disclosure.

FIGURE 2 The digital patient journey solution can be used during the whole care path [Colour figure can be viewed at wileyonlinelibrary.com]

The DPJ solution can be used during the whole care path. Its detailed content was developed and validated by the clinicians responsible for the THA/TKA journey. The technology providers supported the process by defining the required information and the clinicians provided the information in digital format; based on existing patient counselling materials. The DPJ solution contains all the relevant information about the operation, information videos and pictures, forms for anamnesis, anaesthesia, treatment follow-up, and reminders (e.g., when to start fasting and when to discontinue certain medication before the surgery). In addition, the DPJ solution gives instructions on how to get to the treatment unit and comprehensive guidance for wound care and rehabilitation at home after the operation. The patient solution does not run alone – the platform gives a web-based hospital dashboard for clinicians to manage the participants and their journey (e.g., to add new users, create personal activation codes, and add personalized events to the timeline, including pre-scheduled chat and video appointments). In our study, the dashboard will be used only by the study nurse.

2.9.2 | The control intervention

During the study period, a specialist assessment, conducted in conjunction with pre-operative surgical visits and patient education, will be performed on the same day. Traditionally pre- and postoperative information is provided face to face using paper-based methods. Patients will be admitted and mobilized on the day of the surgery and discharged 2–3 days after surgery using well-defined discharge criteria (Hansen, 2017). Follow-up will be conducted by a physiotherapist (if not contraindicated) 6–8 weeks postdischarge for patients who have undergone TKA and 8–12 weeks postdischarge for patients who have undergone THA.

2.10 | Data collection methods

Data will be collected by an independent study nurse who will be blinded during the recruitment and baseline measures. The outcome data will include: (a) paper-based questionnaires, (b) data collected by the DPJ solution, and (c) data from medical records. Repeated measures will be conducted pre- and postsurgery (Table 1). Patients who have undergone THA will be followed up for 8–12 weeks while patients who have undergone TKA will be followed up for 6–8 weeks and the outcomes will be evaluated. In addition, the patient experience and intensity of pain will be measured continuously through the journey using patient-reported outcome measures (PROMs) and PREMs. The patients in the digital journey arm will be asked to complete the relevant self-assessments through online questionnaires (excluding baseline measures); meanwhile, the patients in the conventional care arm will be asked to complete identical assessments by paper-based methods. The patients in the digital journey arm will get a push notification when the assessment is due, followed by reminders until the dedicated response time ends. A cost–benefit analysis will be conducted using clinical data retrieved from medical records and PROMs (Table 2).

2.11 | Outcomes and outcome measures

2.11.1 | Demographics

Age, gender, marital and work statuses, the level of education, height and weight, the number of comorbidities, the site of surgery, the number of previous prosthetic joints, previous surgical experience, and the use of pre-surgical walking aids and opioids will be considered. In addition, the use of ICT, the Internet, and smart phone applications for measuring physical activity during sports and exercise will be considered.

2.11.2 | Primary outcome

The EuroQol EQ-5D-5L assessment will be used in this study. It is a five-level, five-dimensional (i.e., the dimensions of mobility, self-care, usual activities, pain or discomfort, and anxiety or depression) conventionalized assessment tool, used to measure health-related QoL (Herdman et al., 2011). In addition, the tool includes a VAS whereupon participants are asked to rate their health on a scale from 0 (the worst health you can imagine) to 100 (the best health you can imagine). The instrument has been validated and can be delivered by paper format or digital format (Mulhern, O`Gorman, Rotherham, & Brazier, 2015).

2.11.3 | Secondary outcomes

The WOMAC is a disease-specific, self-administered health status instrument that assesses pain, stiffness, and function in patients with osteoarthritis (Bellamy, Buchanan, Goldsmith, Campbell, & Stitt, 1988). Pain is measured on a scale of 0–120 points, stiffness is measured from 0–8 points, and function is measured from 0–68 points. Higher scores indicate poorer statuses. The WOMAC is a globalized, PROM, available in 85 different language translations, and validated using Likert, numerical rating, and VAS formats. The Finnish version of the WOMAC has been validated among patients who have had elective THA/TKA due to primary osteoarthritis (Soininen, Paavolainen, Gronblad, & Kaapa, 2008). The WOMAC can be delivered by paper format or digital format (Bellamy et al., 2011).

The OHS and OKS are PROMs containing 12 questions about the activities of daily living, coordination, functional mobility, gait, negative affect, occupational performance, pain, seating, and sleep (Dawson, Fitzpatrick, Carr, & Murray, 1996). Each of the questions has five categories of response. Each question is scored from 1–5 (from the least difficult to the most difficult) yielding a total score of 12–60. The OHS and OKS can be delivered by paper format or digital format.

TABLE 1 The measures and measurement points per study arm

	Enrolment	Baseline	Study period						Close-out
Timepoint	After surgical decision making	Before the first intervention	Pre-operative surgical visits	Induction	The day before surgery	Discharge	Rehabilitation	Follow-up visit[a]	User experience
Enrolment									
Eligibility screen	X								
Informed consent	X								
Randomization		X							
Interventions									
Intervention			X	X	X	X	X	X	
Control									
Assessments[b]									
Demographics		X							
EQ-5D-5L		X						X	
WOMAC		X						X	
OHS/OKS[c]		X						X	
Patient experience (long)						X		X	
Patient experience (short)[d]			X	X	X	X		X	
Technological self-efficacy		X						X	
Self-efficacy regarding pre-operative preparation		X							
Self-efficacy regarding post-operative rehabilitation						X			
Self-efficacy during the rehabilitation[d]							X		
Application user experience[d]									X

Abbreviations: EQ-5D-5L, the EuroQol EQ-5D-5L scale; OHS, the Oxford Hip Score; OKS, the Oxford Knee Score; THA, total hip arthroplasty; TKA, total knee arthroplasty; WOMAC, the Western Ontario and McMaster Universities Index.

[a]The digital patient journey solution can be used during the whole care pathway. Follow-up will be conducted by a physiotherapist (if not contraindicated) 6–8 weeks postdischarge for patients who have undergone TKA and 8–12 weeks postdischarge for patients who have undergone THA.

[b]The patients in the digital journey arm will be asked to complete the relevant self-assessments through online questionnaires (excluding baseline measures); meanwhile, the patients in the conventional care arm will be asked to complete identical assessments by paper-based methods.

[c]The Oxford hip/knee score will be collected 6 weeks prior to surgery and 3 months after surgery from all patients by using the Omavointi service.

[d]Only for the intervention arm.

TABLE 2 A cost–benefit analysis will be conducted using clinical data retrieved from medical records and patient-reported experience measures

Phone calls from/to the patient pre-surgery	dd/mm/yyyy + reason (number [%]) per study arm
Number of pre-surgical outpatient visits	dd/mm/yyyy + reason (number [%]) per study arm
Pre-surgery consultation by anaesthetist (physical/paper consultation)	dd/mm/yyyy + reason (number [%]) per study arm
Cancellations, no-shows, or postponement of surgery (*yes/no*)	dd/mm/yyyy + reason (number [%]) per study arm
Nursing intensity during hospitalization (at the ward, in the operating theatre, and in the recovery room)	Rafaela/HOIq score/daily/patient per study arm PERIHOIq score/daily/patient per study arm
The patient is mobilized according to the programme (*yes/no*)	Number (%) per study arm
The patient is mobilized for elbows according to the programme (*yes/no*)	Number (%) per study arm
Length of hospital stay	Days per study arm
The total amount of pain killers	Total amount of pain killers/medicine/patient per study arm
Discharge within 2–3 postoperative days (*yes/no*)	Number (%) per study arm
The need for follow-up care (*yes/no*)	Number (%) per study arm
Phone calls from/to the patient and follow-up postsurgery (between discharge and the control/follow-up visit)	dd/mm/yyyy + reason (number [%]) per study arm
Cancellation, no-shows, or the postponement of the control/follow-up visit (*yes/no*)	dd/mm/yyyy + reason (number [%]) per study arm
An early (between discharge and the control/follow-up visit) complication	dd/mm/yyyy + reason (number [%]) per study arm If infection: germ, amount of antibiotics/medicine/patient per study arm
Need for revision (*yes/no*)	dd/mm/yyyy + reason (number [%]) per study arm
Other unplanned procedures (*yes/no*)	dd/mm/yyyy + reason (number [%]) per study arm
Readmissions to the hospital (*yes/no*)	dd/mm/yyyy + reason (number [%]) per study arm
Additional care (unplanned) due to complications (*yes/no*)	dd/mm/yyyy + reason (number [%]) per study arm
Additional care (planned) due to complications (*yes/no*)	dd/mm/yyyy + reason (number [%]) per study arm
Transportation costs and additional travel (time)	dd/mm/yyyy + reason (number [%]) per study arm, estimated price

The intensity of pain will be measured using the WOMAC, OHS/OKS, and the VAS formats, which together form a widely used method to measure the intensity of pain experienced by an individual (McCormack, Horne, & Sheather, 1988) that is valid and reliable (Williamson & Hoggart, 2005). The score range of the VAS is 0–100. A higher score indicates that the patient experienced more pain. The patient is asked to mark a point on the line they feel represents the degree of the pain they suffered. The distance between the left end of the line and the point marked by the patient represents the intensity of the pain they experienced. A VAS for pain will be delivered at 1st, 3rd, 7th, and 14th day after discharge for the intervention arm only.

The patient experience will be measured using the three patient experience assessment scales, which are formulated to assess: (a) care-related information, (b) the patient experience regarding a specific ward or part of the care path, and (c) the broad patient experience regarding the whole patient journey. The information-related patient experience will be investigated in connection with the DPJ solution info packages using two questions: (a) information understandability will be assessed on a 5-point Likert scale and (b) information

sufficiency will be assessed by using *yes–no* answer alternatives with an opportunity to elaborate a *no* answer with free text. The patient experience regarding hospital staff and operations on a specific ward or care-path part will be investigated with a short five-question questionnaire. Four statements will be answered on a 5-point Likert scale with answer alternatives from completely disagree to completely agree and one question will be an open question, intended for additional feedback. The questionnaire is compiled based on a howRwe questionnaire (Benson & Potts, 2014). The patient experience will be investigated more thoroughly at discharge and at a follow-up meeting.

The long patient experience questionnaire entails 18 questions: 17 statements will be answered on a 5-point Likert scale with answer alternatives from completely disagree to completely agree and there will be one open question, intended for additional feedback. The questionnaire is compiled based on the following questionnaires: 11 scale by Finnish institute for health and welfare (THL, 2018), the Nordic Patient Experience Questionnaire (Skudal et al., 2012), the Generic Short Patient Experience Questionnaire (Sjetne, Bjertnaes, Olsen, Iversen, & Bukholm, 2011), and the Picker Patient Experience Questionnaire (Jenkinson, Coulter, & Bruster, 2002). The patient experience instruments are formulated for this study and thus, they are not yet validated elsewhere.

The DPJ solution acceptance and user experience will also be investigated at the end of the study with regard to, for example, perceived usefulness, ease of use, ease of adoption, and trust. A 28-item questionnaire is drawn up for this study based on, for example, the Technology Acceptance Model for Mobile Services (Kaasinen, 2005). The first question on whether the solution was in regular use will be assessed by using *yes–no* answer alternatives with an opportunity to elaborate a *no* answer further by giving a reason for not using the solution. Twenty-three user experience-related questions are answered on a 5-point Likert scale. Three questions regarding user satisfaction and expected future use have answer scale from 0–10, with the higher number indicating higher satisfaction and the final open question about improvement ideas or other feedback is free text.

2.11.4 | Other pre-defined outcomes

A cost–benefit analysis will be conducted using clinical data retrieved from medical records and PREMs. Data to be collected from medical records are listed in Table 2. Additional methodology informed by the Global Reporting Initiative (GRI, 2015) will be used to measure the social benefits of the project from the clinician and patient perspectives (Annisette, Vesty, & Amslem, 2017; Vesty, Brooks, & Oliver, 2015). This measurement will capture the improved communication flows between the patient and the clinicians and ultimately it will enhance the reputational benefit of the healthcare provider. Provider time-based costs (e.g., the cost of: the average LOS, nursing intensity, pre- and postsurgery patient contact, readmission, and adverse events) and other resource consumption costs (e.g., the cost of: medication, physiotherapy interventions, and unused bed capacity), as well as patient time-based costs (e.g., the cost of: estimated transportation time and costs, additional travel, phone calls, fees, and the loss of income of both patient and family) will be calculated (Table 2).

Technological self-efficacy will be measured using a version of the HTSE instrument (Asimakopoulos, Asimakopoulos, & Spillers, 2017), adapted to the context of digital health services. The self-reported instrument consists of four items measured on a 5-point Likert-scale where a higher response indicates a higher perception of technological self-efficacy. The items have been translated to Finnish by the research team. The technological self-efficacy questionnaire will be administered to both the digital journey and conventional care arms as part of the baseline and follow-up visit measurements.

Self-efficacy regarding pre-operative preparation and post-operative rehabilitation will be measured by self-reported survey items developed for the purposes of this study. The items inquire about the patient's perceived self-efficacy to perform actions related to pre-operative preparations and postoperative rehabilitation. Both measurements contain one item each and are measured on a five-point Likert scale, where a higher response indicates a higher perception of pre-operative and postoperative self-efficacy, respectively. The pre-operative and postoperative self-efficacy survey items will be administered to both the digital journey and conventional care arms as part of the baseline and discharge measurements.

In addition, the postoperative rehabilitation survey items will be administered to the digital journey arm during the rehabilitation phase via the DPJ solution on postoperative weeks 1, 3, and 5. The self-reported postoperative rehabilitation measurement contains four items developed for the purposes of this study that inquire about the patient's perception of whether he or she will be able to walk longer distances as the rehabilitation process progresses. The items are measured using a 5-point Likert scale, where a higher response indicates a higher perception of self-efficacy regarding postoperative rehabilitation.

2.12 | Statistical methods

Data analysis will be performed according to the intention-to-treat (ITT) principle; patients will be analysed in the arms to which they will be randomly allocated, regardless of their exposure to the intervention. All outcomes will be analysed. Per protocol analyses are conducted secondarily to investigate the efficacy of the DPJ.

Descriptive statistics will be calculated and presented between the study arms. Quantitative variables will be described using mean and standard deviation or median and interquartile range as appropriate. Categorical variables will be described using frequency and percentage values. Differences between the arms will be analysed using statistical tests accounting for repeated measures design and the results will be presented with a 95% confidence interval and the corresponding *p*-value. Inference will be based on the effect and the 95% confidence interval together with the *p*-value. The outcome assessor will not be involved with the intervention or the assessment of patients.

Adherence to the intervention will be analysed separately and used in the efficacy analyses. Engagement with the DPJ will be measured through two adherence measures: pre-operative adherence and postoperative adherence. *Pre-operative adherence* encompasses the patient's interaction with the application prior to surgery, measured as the percentage of completed instructions sheets (seven in total) related to surgery preparation in the patients' timeline between enrolment and the date of the surgery. *Postoperative adherence* encompasses the patient's interaction with the application after the surgery, measured as the percentage of instruction and treatment sheets (eight in total) completed between discharge and the study's completion.

In addition to the defined adherence measures, the individual-level usage of the application will be investigated through the log files that give time-stamped information on any interaction with the application. These include open-ended items such as additional information provided by the user (e.g., steps counts and answers to different queries) and open-ended questions. The purpose of the usage analysis is descriptive and it aims to increase understanding of the effective usage patterns of the solution. Recommendations for usage intensity (e.g., daily or weekly) cannot be given for the participants because the usage is dependent on the active tasks in the timeline and usage activity varies during the journey.

2.13 | Data management and confidentiality

The study nurse will create a list of participants with study codes that are to be used in the pseudonymization of data and will store this list separately, protected by technical and organizational measures in a secure disc space provided by the hospital. Access to this disc space will only be allowed for the study nurse and the director of the research group. The study nurse will save the pseudonymized paper-based questionnaires in electronic form and subsequently move them to a secure study server provided by the hospital. The data collected by the DPJ solution will be stored in a secure cloud service in Europe and the company that will give the solution has signed a data processing agreement with the research partners who have joint controllership over the data. The data collected by the DPJ solution will be pseudonymized by the service-providing company and delivered to a secure study server provided by the hospital for monitoring and analysis by the limited group of researchers. The researchers will access the server using a virtual private network. Data from electronic health records will be collected and pseudonymized by the study nurse and stored on the secure study server provided by the hospital.

2.14 | Data monitoring

Any adverse events that may be reported will be documented and followed up by the corresponding author and reported to the ethical committee of North Ostrobothnia's hospital district.

2.15 | Validity and reliability

The study is designed to include pragmatic features, provided with the help of the PRECIS-2 tool, to enhance external validity (Loudon et al., 2015). The study will use valid and reliable measurement tools derived from the published literature to test primary and secondary outcomes. The DPJ solution was developed and validated by content experts and reviewed by institutional committees.

3 | DISCUSSION

This RCT will be the first study to evaluate the effectiveness of the DPJ solution that covers the whole patient journey (from home to hospital and back home) for patients undergoing elective THA/TKA. In addition, in this study it is possible to combine QoL, as a primary outcome, together with several secondary outcomes (e.g., pain, patient experience, and other pre-defined outcomes, such as cost–benefit evaluation). If the DPJ solution is found to be effective (in respect to the identified outcomes), the implementation into clinical practice could lead to the further improvements in patient outcomes. In addition, the findings revealed from the future RCTs will be used to support further research in the use of the DPJ solution for other surgical areas. If the DPJ solution is found to be cost effective for the hospital, its deployment will also support resource efficiency. However, some of the other value-added benefits of the DPJ solution, including the social benefit and flow on reputational effects for healthcare providers, are not necessarily captured in cash flow analysis (Annisette et al., 2017; Vesty et al., 2015). These need more careful consideration and are beyond the scope of this study.

3.1 | Limitations

There are some minor limitations to this protocol. First of all, this will be a single-centre study. However, this study will include pragmatic design to enhance the generalizability of the study findings (Ford & Norrie, 2016; Zuidgeest et al., 2017). Other limitations are discussed under the areas of the design and methodological limitations.

3.1.1 | Ascertainment bias

We acknowledge the increased risk for ascertainment bias due to the use of self-assessed research instruments and the lack of blinding. Ascertainment bias will be minimized by blinding the outcome assessors to the allocation status of the participants. However, masking the study arm will not be feasible given the participatory nature of the intervention.

3.1.2 | Selection bias

Selection bias has been minimized by using varying block sizes and concealing the allocation information until the patient has completed

the baseline assessment. Patients scheduled for a revision of THA/TKA or a bilateral THA/TKA, or those who have had a THA/TKA following rheumatoid arthritis will not be included in the trial as their treatment and outcomes are likely to be different from those receiving a primary elective THA/TKA.

3.1.3 | Self-reported data

Objective measures of function will not be included due to the difficulty of conducting these measures pre- and postoperatively, particularly with patients living in rural areas. However, electronic health records will be used as a part of the effectiveness evaluation as these data are routinely collected and they give objective measures of patient outcomes. It will not be possible to standardize baseline measurements. Furthermore, some of the instruments to be used are tailored for the purposes of this study and thus they are not validated.

3.1.4 | Participant attrition

This study will be a long-term intervention and some participants may not complete the study due to loss during follow-up, which would decrease the power of the study. Second, missing data may influence the results. To overcome this bias, a 15% attrition rate was included in the sample size calculation and an ITT analysis will be performed. Furthermore, participants in the digital journey arm will get push notification when the assessment is due, followed by reminders until the dedicated response time ends. In addition, discharging nurses and physiotherapists will remind patients during discharge and the follow-up visit, respectively.

4 | CONCLUSION

The current state of the elective THA/TKA journey does not fully meet the needs of healthcare professionals or patients. Although there are several studies evaluating impact showing mobile technologies have already resulted in increased patient satisfaction, it remains unclear what is the effectiveness (measured by QoL, pain, patient experience, and cost-efficiency outcomes) of mHealth interventions covering the whole patient journey (from home to hospital and back home). The aim of the designed study is to gain evidence from a heterogeneous patient population undergoing THA/TKA to inform current practices. This study will give necessary information about the effectiveness of the DPJ solution in the regional Finnish lower-limb joint replacement context.

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CONFLICT OF INTERESTS

No conflict of interest has been declared by the authors.

AUTHOR CONTRIBUTIONS

All authors have agreed on the final version and meet at least one of the following criteria (recommended by the ICMJE*): (a) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (b) drafting the article or revising it critically for important intellectual content. *http://www.icmje.org/recommendations/.

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