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Effect of a mHealth exercise intervention compared with supervised exercise therapy in osteoarthritis management: protocol of the DigiOA trial

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ABSTRACT

Introduction Soaring prevalence of hip and knee osteoarthritis (OA) inflicts high costs on the healthcare system. A further rise in the OA incidence is expected, generating increased demand of care potentially challenging accessibility and threatening to overwhelm the healthcare system. Innovative solutions that may improve accessibility to recommended OA care for patients in primary care and maintain healthcare sustainability are warranted. Digitalising home exercise therapy may be one such solution. The primary aim of this study is to evaluate the effectiveness of a mobile health app providing digitalised home exercises, compared with supervised exercise therapy in patients with OA. Second, we will evaluate the cost-efficiency of the intervention and explore potential differences in outcome and adherence to exercises in the experimental treatment group.

Methods and analysis A two-armed non-inferiority randomised controlled trial will be conducted. In total, 156 patients with hip and/or knee OA will be recruited from physiotherapy clinics in primary care in Norway. Following patient education, patients will be randomised to either 6 weeks of standard treatment (2 weekly sessions of supervised exercise therapy) or experimental treatment (home exercises via the Virtual Training (VT) app). Primary outcome is the proportion of Outcome Measures in Rheumatology-Osteoarthritis Research Society International (OMERACT-OARSI) responders at 6 weeks. Secondary outcomes include physical performance, patient-reported outcomes related to pain, fatigue, disease activity, physical function, mental health, health related quality of life, self-efficacy, utilisation of healthcare services and medication, digital competence and use of apps.

Ethics and dissemination Patients will sign an informed consent form before participating in the trial. Approval has been granted by the Regional Ethics Committee (201105) and Data Protection Officer at Diakonhjemmet Hospital (00221). Patient research partners will contribute in all parts of the study.

Trial registration number NCT04767854.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A strength of this study is the robust randomised controlled design evaluating effectiveness of digital exercise programmes in the treatment of osteoarthritis.
⇒ This study will provide knowledge on an individualised, innovative and sustainable treatment alternative for management of patients with OA in a primary care setting.
⇒ A limitation to the study is the lack of blinding.

INTRODUCTION

Background and rationale

Hip and knee osteoarthritis (OA) are of the most common joint diseases[1] leading to severe functional disability, comorbidity and reduced quality of life[2] as well as reduced health status and work productivity.[3] OA prevalence has increased over the last decades.[1] Increasing levels of obesity and longevity in the population are expected to spur a further rise to a point that may overwhelm healthcare services.[4 5] Both direct (eg, non-pharmacological and pharmacological treatment and surgery) and indirect (eg, productivity loss, sickness absence and disability benefits) costs of OA are substantial to the individual, employers and society in general.[6 7] No treatment has been shown to reverse the structural changes observed in joints with OA and therapies are primarily aimed at relieving symptoms and maintaining function.[8] International consensus recommends first-line treatment to consist of the core elements patient education, exercise and, if necessary, weight reduction.[9–11] To enhance compliance with the treatment recommendations, structured osteoarthritis management programmes (OAMPs) consisting of the core elements have been

introduced in different countries, such as the AktivA-programme in Norway, with beneficial effects on pain, physical function and quality of life.[12–14] The aim of OAMPs is to provide evidence-based treatment in a coordinated and structured setting, adapted to local context.[15] However, although considerable effort has been devoted to these programmes, previous research shows that the recommended core treatments are still underused and that the programmes do not reach essential parts of the patient population.[16 17] Research reports that only 41% of Swedish patients receiving hip replacement received structured education and exercise prior to surgery[12] and that merely 20% of patients seeking primary care for OA actually entered the Swedish OAMP version.[18] To close the highlighted gap between recommended core treatment and clinical practice, new solutions in the management of OA should be explored.

Development and evaluation of novel models of OAMPs has been called for.[15] Integrating the use of technology could be a solution to ensure effective management of the disease at a lower cost and with a potential to reach more patients.[19 20] Digital health solutions involving web applications, online platforms, telephone and video consultations have shown positive results in the management of OA.[21–26] Mobile health (mHealth) is a subset of digital health, involving the use mobile technologies and devices in healthcare, including mobile health applications.[27] The development of mobile health applications is progressing rapidly, with a potential to reach a large part of the OA patient population.[19 25] Among the developments are applications for generic digital exercise programmes, such as the Virtual Training (VT) application. Integrating mHealth applications for exercises in clinical practice could ensure access to essential elements in the recommended core treatment and have several benefits as opposed to face-to-face treatment.[28] Remotely supervised solutions available through mHealth is advantageous by increasing treatment accessibility and affordability seeing as it is not contingent on physical meetings.[29] This could reduce the barrier of travel time and time off from work and open up for more frequent exercise sessions, especially in rural areas.[28] Exercise could also be performed in the patient's preferred environment. In contrast to home exercises traditionally prescribed on paper, digital solutions offer the possibility of closer monitoring.[30] Transferring a proportion of the patient population from supervised exercise therapy session to remotely monitored home exercises could improve accessibility to physiotherapy for the subgroup of the patient population in need of physical meetings with the physiotherapist. Although we are aware of the potential beneficial effects, there is a lack of evidence regarding the effectiveness and cost-efficiency of mHealth technology usage in the management of OA.

Objectives

The primary aim of this study is to compare the effectiveness of a physiotherapy supervised generic mHealth application for exercise programmes (VT) with supervised exercise therapy (standard treatment) at physiotherapy clinics in primary care. A secondary aim is to analyse the cost-efficiency of the two interventions. Furthermore, we will explore exercise adherence and potential differences in characteristics of responders and non-responders in the experimental treatment group.

Hypothesis

Based on previous research, highlighting the potential beneficial effects of the use of mHealth in the treatment of musculoskeletal conditions, we hypothesise that the use of a generic exercise therapy mHealth application (VT) in treatment of patients with hip and/or knee OA in primary care is non-inferior to standard treatment measured by the proportion of Outcome Measures in Rheumatology-Osteoarthritis Research Society International (OMERACT-OARSI) responders (measuring change in pain, function and disease activity).[31] The use of the application is hypothesised to be more cost-efficient than standard treatment in a healthcare service perspective, with comparable exercise adherence.

METHODS AND ANALYSIS

Trial design

In this pragmatic two-armed non-inferiority randomised control trial, patients with hip or knee OA consulting a physiotherapist in primary healthcare will be invited to participate and randomised to either standard treatment or experimental treatment group. Exercise therapy has shown positive effects in improvement of pain and physical function in previous studies.[8] However, the scope of this trial is the mode of delivery of the therapy, hence a non-inferiority design is preferred. Similarly, other randomized controlled trials (RCTs) incorporating the use of digital solutions has shown non-inferior effects compared with exercise therapy.[21–23]

This protocol aligns with the Standard Protocol Items: Recommendations for Interventional Trials recommendations.[32]

Study setting

Physiotherapists at 10–15 outpatient physiotherapy clinics in primary care in Norway will participate in recruiting patients to the study. A fixed number of clinics has not been selected due to uncertainty in recruitment frequency of each clinic. The physiotherapists are experienced in management of OA and are, or will be, trained in a Norwegian OA management programme, AktivA.[14]

Patient recruitment

Enrolment of patients from the participating clinics was initiated in July 2021 and will continue until sample size is fulfilled, presumably by the end of 2022. Inclusion of patients is illustrated in figure 1.

Eligibility criteria

All patients fulfilling inclusion criteria are invited to participate in the study (table 1).

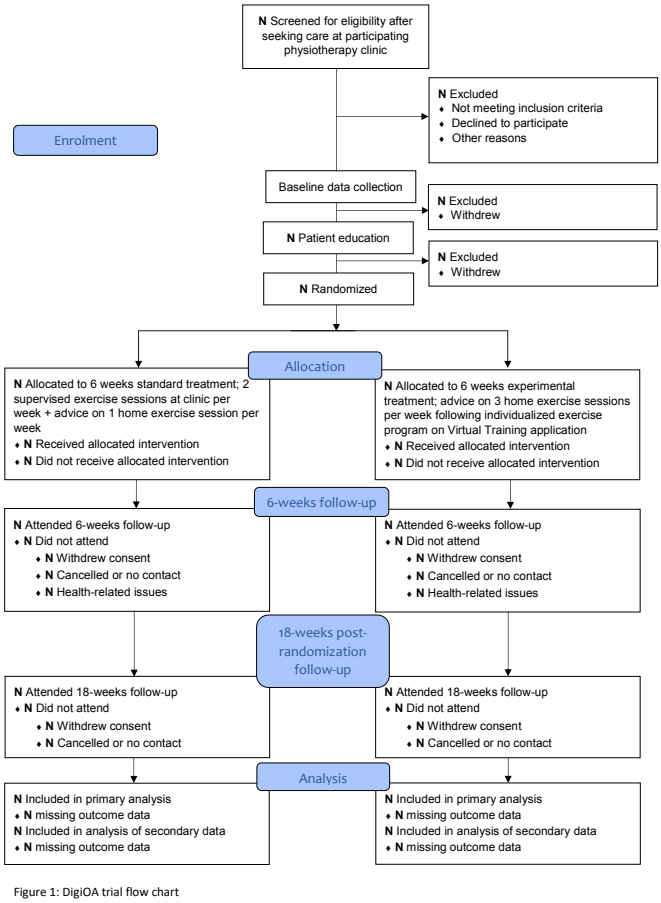

Figure 1: DigiOA trial flow chart

Figure 1 DigiOA trial flowchart.

Intervention

Patients receive information on the trial when they, on their own initiative, consult a physiotherapist for treatment of their condition. Written and verbal information will be provided to eligible patients by the physiotherapists. If willing to participate, the patients have to sign the informed consent form before completing the baseline questionnaire and participating in a 1–2 hours patient education session, commonly held within 1–4 weeks after enrolling to the study. The education session is according to AktivA and based on international guidelines.[9 14] The content of the patient education is information about, for example, disease progression, symptoms, treatment, exercise, self-care techniques and dietary information. The patient education will be provided either individually or as group sessions, based on each clinic's previous practice and preference. Following the education session, patients are randomised to either standard or experimental treatment.

Standard treatment: supervised exercise therapy

Patients allocated to standard treatment will participate in supervised exercise therapy sessions twice weekly for 6 weeks, a total of 12 sessions. Session content is based on an individually tailored exercise programme developed in a shared decision-making process between the physiotherapist and patient. The sessions are either one-to-one sessions with the physiotherapist, or a group setting with all patients performing their individually tailored supervised exercise programme. The sessions could have a duration from 30 to 60 min. Progression/adjustment of exercises is done by the physiotherapist during the supervised exercise therapy sessions. In addition to the supervised exercise therapy session, the patients will be motivated to perform a session of home exercise once a week, making it a total of 18 sessions.

Experimental treatment: digital exercise therapy

In the experimental treatment group, an individually tailored exercise programme is developed in a shared decision-making process between the patient and physiotherapist and made available for the patient in the VT mHealth app. The patient is advised to follow the exercise programme three times a week for 6 weeks, a total of 18 sessions. Length of sessions depends on extent of the exercise programme.

The exercise programme is delivered using the VT mobile health application, available for both IoS and Android. VT is a generic system for creating individually tailored digital exercise programmes, consisting of a web portal for the physiotherapist and an application for the patients. The exercise programmes are created based on a library of generic exercises in the web portal and made

Table 1 DigiOA inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
► 18 years old or older ► Activity-related hip and/or knee complaints ► Clinical signs and symptoms corresponding to hip and/or knee OA ► Access to smartphone or tablet ► Personal email address	► Neurological disorders ► Contraindication to physical activity ► Total hip or knee replacement in the actual joint(s) with no pain/complaints in the other hip or knee joint(s) ► Inflammatory rheumatic diseases (eg, rheumatoid arthritis, spondylarthrosis) ► Malignant illness or other major conditions (eg, unstable cardiovascular disorders or lung disease, dementia) that restrict the ability to adhere to the recommended treatment ► Not understanding the Norwegian language

OA, osteoarthritis.

available for the patients directly in the app. The patients will be guided through the exercise programme with text, audio and video instructions for each exercise. After each exercise, the patients will be asked to rate their effort on a Likert-scale, from 0 (very poor) to 5 (very good). After completing all exercises, patients will rate their pain on a numeric rating scale (NRS) from 0 (no pain) to 10 (worst possible pain).

The physiotherapist can monitor progression in the web portal. The average score on patient effort and pain at each session can be retrieved through the portal so that the physiotherapist can adjust the progression of the patient. The physiotherapists are advised to access the web portal once weekly to monitor progression. Should self-reported rating of effort fall below 60% or pain after completing all exercises ≥5 on a 0–10 NRS, the physiotherapist is instructed to contact the patient to adjust the exercise programme. Similarly, should self-reported rating of effort exceed 85%, the physiotherapist is instructed to contact the patient to ensure exercise progression. Failure to adhere to the recommended number of exercise sessions per week does not entail contact from the physiotherapist to the patient. There are no restrictions regarding patient contact with the physiotherapist during the intervention period for advice, support with the app and so on. These contacts could include physical sessions at the clinic, although it is advised by protocol to keep physical sessions at an instructional level.

During trial participation, patients may seek care by any healthcare professional for conditions that are not related to OA.

Outcome measures

Primary outcome in the RCT will be the proportion of responders according to the OMERACT-OARSI responder criteria at the end of the intervention (at the 6-week follow-up).[31] A patient is classified as a responder if one of the two following criteria is fulfilled:

1. High improvement in pain or function
   - ≥50% improvement+absolute change of≥20 in pain, OR
   - ≥50% improvement+absolute change of ≥20 in function.
2. Improvement in at least two of the three following:
   - ≥20% improvement+absolute change≥10 in pain.
   - ≥20% improvement+absolute change≥10 in function.
   - ≥20% improvement+absolute change≥1 in the patient's global assessment of disease activity.

We will derive improvement and absolute change in pain and function from the Hip disability and Osteoarthritis Outcome Score (HOOS) and Knee injury and Osteoarthritis Outcome Score (KOOS) subscales Pain and Function in daily living, which both subsumes the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) subscales Pain and Function questions.[33] Change in global assessment of disease activity will be derived from a 11-point NRS, ranging from 0 to 10.

Secondary outcome measures will include physical performance measure reported by the participating physiotherapists and patient-reported measures (table 2). Physical performance will be measured by the 30 s chair-stand test (30 CST). 30 CST is one of five OARSI recommended performance-based tests to assess physical function.[34] The test measures the number of chair stands over 30 s. The testing will be performed by each patient's treating physiotherapist.

Patient-reported outcome measures reported by all patients comprise fatigue, pain, global disease activity, patient specific and disease specific function, health related quality of life, mental health, social participation, self-efficacy and physical activity. Patients will report healthcare use by the number of consultations at general practitioner, medical specialist, physiotherapist in addition to the consultations related to participation in the study, manual therapist, chiropractor and alternative therapies. Furthermore, the number of referrals to X-ray, MRI, physiotherapy, healthy life centre and occupational therapy for assessment of living situation or aids will be reported. All reported use of healthcare services should be related to OA. OA-related medication use will be reported by name, dosage and administration. The general digital competence of the patients is examined by 19 items in the Health Literacy Population Survey 2019–2021 (HLS_{19}).[35]

Adherence to supervised exercise therapy at 6-week follow-up in the standard treatment group will be registered by the treating physiotherapist. Home-based exercise sessions in the standard treatment group will be self-reported at 6-week follow-up. Adherence in the experimental treatment group will be extracted from the VT web portal. Any additional consultations with physiotherapist from patients in experimental treating group will be registered by the physiotherapist. Adverse events will be self-reported by the patient.

In addition, patients in the experimental treatment group will evaluate specific domains regarding usability and satisfaction with the use of the app.

Demographic data regarding age, body weight, height, smoking status, education, employment, years living with disease and comorbidities are self-reported at baseline.

Data collection methods

All outcome measures, except 30 CST and adherence, will be collected through an encrypted web-based questionnaire, provided by Services for Sensitive Data (TSD) at the University of Oslo.

Patients will complete the electronic questionnaire at baseline, 6-week follow-up and 18-week postrandomisation. The physical performance test will be performed at baseline and 6-week follow-up.

Table 2 Primary and secondary outcomes

	Description of measurement scale	Time (weeks)
Primary outcome measure		
OMERACT-OARSI responder[31]	Computed binary score (yes/no) based on changes in self-reported pain, physical function and/or global disease activity	6
Measured secondary outcomes		
30CST[46]	Number of repetitions	0, 6
Patient-reported secondary outcome measures		
Fatigue	Average experience of fatigue last week, higher score indicates more fatigue. NRS 0–10	0, 6, 18
Pain	Average experience of pain last week, higher score indicates more pain. NRS 0–10	0, 6, 18
Global disease activity	Average experience of disease activity last week, higher score indicates more disease activity. NRS 0–10	0, 6, 18
PSFS[47]	Description of up to three difficult activities, difficulty rated on a 0–10 scale, higher number indicating more difficulties performing activity	0, 6, 18
Health-related quality of life (EQ-5D-5L)[48]	5 dimensions rated on a 5-point Likert scale. In addition, NRS 0–100 indicating experience of general health, higher number indicating better health	0, 6, 18
Mental health—HSCL-5[46]	5 items rated on 4-point Likert scale	0, 6, 18
Social activities—COOP/WONCA functional assessments charts[46]	Single chart from COOP/WONCA functional assessment charts regarding social activities, rated on a 5-point Likert scale	0, 6, 18
Function—K/HOOS[49 50]	5 dimensions with a total of 42/40 questions. Score of 0–100 on each dimension, higher number indicating no symptoms/problems	0, 6, 18
Self-efficacy—exercise self-efficacy[51]	4 dimensions rated on a 5-point Likert scale. Sum score 20–100, higher number indicating less barriers and greater self-efficacy	0, 6, 18
Self-efficacy—ASES[52]	2 dimensions rated on a 5-point Likert scale. Average score on each dimension calculated, higher score indicating higher self-efficacy	0, 6, 18
Physical activity—IPAQ-SF[53]	Amount of time (minutes per week/day) spent on sitting, walking and moderate and vigorous intensity physical activity the last week	0, 6, 18
General digital competence—HLS_{19}[35]	19 items on general digital competence from the Health Literacy Population Survey 2019–2021, rated on a 4-point Likert scale. Higher scores indicating higher digital competence	0
Healthcare and medication use	Number of consultations with healthcare personnel and referrals to healthcare professionals, healthy life centre, X-ray and MRI last 6/12 weeks	6, 18
Adherence to exercise	Number of supervised exercise sessions/number of performed exercise sessions in app	6
Adverse events	Description of adverse event(s), binary scores (yes/no) indicating need of extra medical supervision and missed one or several exercise sessions due to the adverse event(s)	6
Patient-reported secondary outcome measures—experimental treatment group only		

Continued

Table 2 Continued

	Description of measurement scale	Time (weeks)
Usability—SUS[54]	10 items rated on a 5-point Likert scale, higher score indicating higher usability	6
General usability of exercise app	NRS 0–10, higher score indicating higher usability	6
General satisfaction of exercise app	NRS 0–10, higher score indicating higher satisfaction	6

ASES, Arthritis Self-efficacy Scale; 30CST, 30-s chair-stand test; HLS_{19}, Health Literacy Population Survey 2019–2021; HSCL-5, Hopkins Symptom Checklist 5; IPAQ-SF, International Physical Activity Questionnaire-Short Form; K/HOOS, Knee Injury and Osteoarthritis Outcome Score/Hip disability and Osteoarthritis Outcome Score; NRS, Numeric Rating Scale; OMERACT-OARSI, Outcome Measures in Rheumatology-Osteoarthritis Research Society International; PSFS, Patient-specific Function Scale; SUS, System Usability Scale.

Sample size calculation

The number of OMERACT-OARSI responders in previous research of OA management varies widely. The proportion of responders varies from 25% to 83%,[36–38] hence, a conservative estimate in our trial would be 50% being classified as responders. No direct comparison of our study to other trials is to our knowledge available, increasing difficulty of specifying a non-inferior margin. However, a study evaluating the effect of a telerehabilitation intervention in postoperative rehabilitation after total hip replacement used the minimally clinically important difference on the subscales pain (24 (SD 22.8)), symptoms (23 (SD 14.9)) and quality of life (23 (26.3)) from HOOS to estimate the non-inferiority margin.[39] According to the developers of KOOS, a minimally clinically important change in knee OA is estimated to 8–10 points on a 0–100 scale, with a SD of 15 being applicable when estimating sample sizes.[33] Additionally, a blended physiotherapy and eHealth intervention estimated that when comparing effect sizes between a standard treatment group and experimental treatment group, a suitable non-inferiority margin could be 0.15.[21] With a conservative estimate in our study, considering a possible higher minimally clinically important change of patients with hip OA, a non-inferiority margin of 20% is chosen. Hence, with a non-inferiority margin of 20%, power of 80% and a 5% significance level, we need 78 patients in each group, 156 in total.

Allocation

A statistician at Diakonhjemmet Hospital will be in charge of the randomisation. Stratification based on location (hip or knee) will be performed to obtain balanced groups. Concealed, opaque envelopes prepared in advance will be used to allocate patients at each of the included physiotherapy clinics. Block randomisation of 10 at each clinic will be performed to ensure balance in treatment arms.

No information on the study is provided to patients until they contact one of the enrolled clinics with the intention to seek care. Blinding of participating patients and physiotherapists will not be possible due to the nature of the treatment modalities. The statistician conducting the analysis of the primary outcome will be blinded to group allocation.

Statistical analysis plan

The primary analysis will be conducted on an intention-to-treat basis by comparing the proportion of responders at 6 weeks according to the OMERACT-OARSI responder criteria in the standard treatment and experimental treatment groups using logistic regression analysis. Per-protocol analyses will also be conducted. Secondary, the same analyses will be performed 18-week postrandomisation. Differences in secondary outcomes will be assessed using t-tests or regression analyses. Associations between disease specific and other health related outcomes will be explored with correlation and regression analyses.

Cost-effectiveness will be evaluated in a healthcare service perspective, excluding societal costs like absenteeism costs, presenteeism costs and unpaid productivity costs, assessing the difference in healthcare and medication use and quality of life during 18-week postrandomisation follow-up, reporting the incremental cost-effectiveness ratio reflecting the between-group difference in incremental cost per adjusted life years. Between-group difference in adherence to exercise will be assessed using linear regression, while patient characteristics in the experimental treatment group will be assessed using logistic regression. Based on the magnitude and type of missing data, acknowledged methods for handling missing data will be used (eg, multiple imputation).

ETHICS AND DISSEMINATION

Research ethics approval and data management

This trial will be performed in compliance with the Helsinki Declaration. Approval has been granted by the Regional Ethics Committee (201105) and from the Data Protection Officer at Diakonhjemmet Hospital (00221). Any modifications to protocol will be reported to REK and the Data Protection Officer and clinicaltrials.gov. Participating patients must provide a signed informed consent form before entering the study.

Patient-related data at participating clinics will be stored at each clinic according to Norwegian law. Encrypted data from the questionnaires will be sent from nettskjema.no to a database administered by TSD, University of Oslo. This database fulfils the requirements of the Norwegian data protection authority and all storage of data will be according to current practice of law. All data files will be downloaded and stored in a secure research server at Diakonhjemmet Hospital with access restricted to project group members (LM, NØ, TM and ATT). All data shared with project group members are deidentified.

In the VT web portal, each physiotherapist only has access to the patients registered by themselves. Patients in the experimental treatment group are deidentified with a number when registered. Physiotherapists may identify the patients through a code list, enabling the possibility of monitoring and adjusting progression.

Risk of adverse events in the experimental treatment group is considered to be low, as home-exercises is frequently prescribed for patients with musculoskeletal conditions and few adverse events are described. All patients are insured by the Norwegian Patient Injury Act.

The results of this study will be submitted to international peer-reviewed journals as well as presented at international conferences within the research field of OA, rheumatology and health technology. We aim at including patient organisations in the dissemination of important results. A summary of the results will be provided to the patients in the study.

Patient and public involvement

The study is a collaboration between The Norwegian Council for Musculoskeletal Health, The National Advisory Unit on Rehabilitation in Rheumatology (NKRR) and participating physiotherapy clinics in primary care. The concept of the study is developed by physiotherapists and researchers at NKRR with previous clinical experience with the use of VT in other patient populations and with comprehensive knowledge and research experience in remote care of patient populations with rheumatic and musculoskeletal conditions. Two patient research partners, one with previous experience with the use of VT and one representative from a patient organisation, have been involved in discussing the project idea and application for funding. The partners will further participate in discussions of the results and dissemination strategy.

DISCUSSION

The use of OAMPs and exercise in the treatment of OA is still underused, despite vigorous efforts for implementation and strong evidence of beneficial effect.[5 15 16] This trial will contribute with knowledge regarding an innovative approach to OA management, through the integration of a digital intervention strategy. Previous studies have found the use of digital interventions in OA care and musculoskeletal physiotherapy to be potentially as effective as standard treatment.[25 40] If deemed to be non-inferior, further integration of digital exercise programmes in the treatment of patients with OA could fulfil the requirement of a personalised treatment approach, creating an option for greater empowerment of the patient.[41] The use of digital solutions may contribute to a sustainable healthcare system in the future. If found cost-efficient, the use of digital exercise programmes may be advocated as an alternative to physical consultations in the treatment of OA.[42] As the design of the mHealth application used in our study is generic, the results can support an implementation of digital exercise programmes in the treatment of other conditions where exercise therapy is recommended.

Strengths of the study are the randomised control design and the participation of healthcare services in the primary healthcare setting. Furthermore, our study is developed in close collaboration with patient research partners and fulfils The Norwegian Council of Musculoskeletal Health's focus on prevention and treatment of musculoskeletal conditions.[43]

There are some limitations to our study. Despite that all participating physiotherapists are trained in the same OAMP, differences between clinics may occur in implementation of the patient education session. Although the content is stringent, differences may arise as some clinics conducts the education as two sessions as well as both individual or group sessions.

The accomplishment of the advised sessions of the digital exercise programme is registered in the app. In addition, any additionally accomplishment of the exercise programme will be logged. Seeing as the patients are not restricted from participating in any other physical activity or other exercise programmes outside of the study, monitoring of physical activity may have provided further information regarding patient adherence. However, despite comprehensive monitoring by the app, we are not able to objectively monitor the physical activity level of the patients besides the accomplishment of the exercise programme, as we lack any wearable fitness trackers or exercise diary. Similarly, in the standard treatment group, the only information retrieved on adherence is the participation in the supervised exercise therapy sessions and the self-reporting of accomplishment of home exercise sessions. Any additional participation in physical activity or exercise programmes is not reported. The level of physical activity is reported by International Physical Activity Questionnaire; however, this has potential limitations, as self-reported physical activity could be biased.[44]

Increased knowledge and sound trials evaluating the use of digital interventions are sought for in musculoskeletal conditions.[40 45] This trial will add to the current knowledge on effectiveness of digital interventions and may provide knowledge that can be used in improving accessibility and quality in OA care.

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Contributors LM: study design, acquisition of data, drafting the article and final approval of the manuscript. NO, TM and ATT: study design, critical revision and final approval of the manuscript.

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Competing interests None declared.

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.

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