Statistical analysis plan

Section 1: Administrative information

Title and trial registration

Effect of a mHealth exercise intervention compared to supervised exercise therapy in osteoarthritis management – statistical analysis plan of the DigiOA-trial

Trial registration number: NCT04767854

SAP version

1.0 – 17.11.2023

Protocol version

Effect of a mHealth exercise intervention compared with supervised exercise therapy in osteoarthritis management: protocol of the DigiOA trial - PubMed (nih.gov) (1)

SAP revisions

Revision history	Justification for revision	Timing of revision

Roles and responsibility

Name	Role	Responsibility
Lars Martinsen	PhD-candidate	Drafting of SAP, final approval of document
Anne Therese Tveter	Project manager	Critical revision, final approval of document

Signatures

Lars Martinsen Anne Therese Tveter

Section 2: Introduction

Background and rationale

Hip and knee osteoarthritis (OA) are of the most common joint diseases (2) leading to severe functional disability, comorbidity and reduced quality of life (3), as well as reduced health status and work productivity (4). OA prevalence has increased over the last decades (2), and population obesity and longevity is expected to spur a further rise (5) to a point that may overwhelm health care services (6). Both direct (e.g. non-pharmacological and pharmacological treatment and surgery) and indirect (e.g. productivity loss, sickness absence and disability benefits) costs of OA are substantial (7) and infers considerable burden to the individual, employers and society in general (8). 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. 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 programs (OAMPs) consisting of the core elements have been introduced in different countries, such as the AktivA-program 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 programs, previous research shows that the recommended core treatments are still underutilized (16, 17) and that the programs do not reach essential parts of the patient population. 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. Digital health solutions involving web applications, online platforms, telephone- and video consultations have shown positive results in the management of OA (19-24). A subset of digital health, mHealth, involves the use mobile technologies and devices in health care, including mobile health applications. The development of mobile health applications is progressing rapidly, with a potential to reach a large part of the OA patient population (23, 25). Among the developments are applications for generic digital exercise programs, 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. Remotely supervised solutions available through mHealth is advantageous by increasing treatment accessibility and affordability seeing as it is not contingent on physical meetings. 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. 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. 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 osteoarthritis.

Objectives

The primary aim of this study is to compare the effectiveness of a physiotherapy supervised generic mHealth application for exercise programs (VT) with supervised exercise therapy (standard treatment) at physiotherapy clinics in primary care.

Secondary aims are to analyze the cost-efficiency of the two interventions, to explore exercise adherence, and analyze potential differences in characteristics of responders and non-responders in the experimental treatment group.

Hypothesis

1) 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 OMERACT-OARSI responders (measuring change in pain, function and disease activity)
2) Exercise therapy delivered through Virtual Training is more cost-efficient in a healthcare service perspective than supervised exercise therapy for patients with hip and/or knee OA
3) Patients with hip and/or knee OA using VT will be more adherent to exercises during the intervention period compared to patients receiving standard treatment
4) Patients with hip and/or knee OA using VT responding to treatment will be more adherent to exercises during the intervention period compared to non-responders
5) There are differences in patient and clinical characteristics between responders and non-responders in the experimental group

Section 3: Study Methods

Trial design

Pragmatic two-armed non-inferiority parallel group randomized controlled trial, with 1-1 allocation to either 6 weeks of physiotherapy supervised exercise therapy through the VT app or standard treatment at physiotherapy clinic.

Randomization

A digital randomization service is used to create a randomization list (26). 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 randomization of 10 at each clinic will be performed to ensure manageable treatment groups.

Sample size

A total of 156 patients will be recruited. Sample size calculation is described in Effect of a mHealth exercise intervention compared to supervised exercise therapy in osteoarthritis management: protocol of the DigiOA trial, by Martinsen et al. 2022 (1).

Framework

Non-inferiority hypothesis testing

Timing of final analysis

All outcomes are analyzed collectively.

Timing of outcome assessments

Baseline, 6 weeks follow-up and 18 weeks post-randomization

Section 4: Statistical Principles

Confidence intervals and *P* values

Level of statistical significance is set to 5%.

No adjustment for multiple testing will be conducted.

95% confidence intervals will be reported on all continuous variables.

Adherence and protocol deviations

Adherence are measured as a continuous variable and dichotomized into adherent or not adherent to the intervention.

Adherence in the experimental treatment group is defined as 2 exercise session per week over 6 weeks. Number of exercise sessions is extracted from the app. In the standard treatment group adherence is defined as participation in 12 supervised exercise session. Number of supervised exercise sessions is reported by the participating physiotherapists. Definition of adherence is based on recommendations from American College of Sports Medicine, stating that resistance or neuromotor exercise training should be performed 2-3 days pr. week (27).

Adherence to the intervention will be presented as total number of exercise sessions, as well as the number of exercise sessions per week.

To comply with the protocol, patients in both groups must participate in patient education prior to randomization.

A deviation from the protocol is defined as exercise sessions or use of app initiated before patient education is implemented.

Analysis populations

The primary analysis will be conducted as intention-to-treat.

Population included in per protocol analyzes are cases at 6 weeks follow up, adhering to the definition of adherence to protocol (2 exercise session per week over 6 weeks in experimental and standard treatment groups).

Section 5: Trial Population

Screening data

Number of eligible participants as defined by the physiotherapist will be shown in a flow chart.

Eligibility

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 e-mail 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 (e.g. rheumatoid arthritis, spondylarthrosis) • Malignant illness or other major conditions (e.g. unstable cardiovascular disorders or lung disease, dementia)

	that restrict the ability to adhere to the recommended treatment • Not understanding the Norwegian language

Recruitment

Physiotherapists at 10–15 outpatient physiotherapy clinics in primary care in Norway will participate in recruiting patients to the study. Patients with hip or knee OA consulting a physiotherapist at one of the clinics will be invited to participate. No information on the study is provided to the patient prior to consulting one of the physiotherapists. 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.

See figure 1 in Effect of a mHealth exercise intervention compared to supervised exercise therapy in osteoarthritis management: protocol of the DigiOA trial, by Martinsen et al. 2022 (1).

Withdrawal/follow-up

Withdrawal, including reason for withdrawal, will be reported at the time points baseline data collection, patient education, randomization/allocation, 6 weeks follow-up and 18 weeks post-randomization. Withdrawal will be presented as number of patients withdrawn at the time points.

Baseline characteristics

- Age
- Sex
- Height
- Weight
- BMI
- Marital status
- Education level
- Smoking status
- Employment status
- Most painful joint
- Other painful joints
- Symptom duration
- Level of disease activity
- Level of pain
- Level of fatigue
- Comorbidities
- Current pain medication use
- General digital competence

Continuous variables will be presented with mean and standard deviation, or median and interquartile range. Categorical variables will be presented with *n* and percentages. Baseline characteristics will be summarized independent of location of most painful joint and allocation.

Section 6: Analysis

Outcome definitions

Table 2: Primary and secondary outcomes		
	Description of measurement scale	Time (weeks)
Primary outcome measure		
OMERACT-OARSI responder (28)	Computed binary score (yes/no) based on changes in self-reported pain, physical function and/or global disease activity from baseline to 6 weeks.	6
Measured secondary outcomes		
30-s chair-stand test (30CST) (29)	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
Patient Specific Function Scale (PSFS) (30)	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) (31)	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 – Hopkins Symptom Checklist 5 (HSCL-5) (29)	5 items rated on 4-point Likert scale	0, 6, 18
Social activities – COOP/WONCA functional assessments charts (29)	Single chart from COOP/WONCA functional assessment charts regarding social activities, rated on a 5-point Likert scale	0, 6, 18
Function – Knee Injury and Osteoarthritis Outcome Score/Hip disability and Osteoarthritis Outcome Score (K/HOOS) (32, 33)	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 (34)	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 – Arthritis self-efficacy scale (ASES) (35)	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 – International Physical Activity Questionnaire-Short Form (IPAQ-SF) (36)	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 – Health Literacy Population Survey 2019-2021 (HLS_{19}) (37)	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
Health care and medication use	Number of consultations with health care personnel and referrals to health care professionals, healthy life center, 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
Patient reported secondary outcome measures - experimental treatment group only		
Usability – System Usability Scale (SUS) (38)	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

Analysis methods

The primary analysis will be conducted on an intention-to-treat basis by comparing the proportion of responders at 6 weeks follow-up according to the OMERACT-OARSI responder criteria in the experimental treatment group and the standard treatment group using logistic regression analysis. Secondary, per-protocol analysis including cases fulfilling definition of adherence will also be conducted. Non-inferiority margin is defined as 20%, as described in Effect of a mHealth exercise intervention compared to supervised exercise therapy in osteoarthritis management: protocol of the DigiOA trial, by Martinsen et al. 2022 (1).

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 health care and medication use and quality of life during 18 weeks post-randomization follow-up, reporting the incremental cost-effectiveness ratio (ICER) reflecting the between-group difference in incremental cost per adjusted life years (QALYs).

Between- and within-group difference in adherence to exercise will be assessed using linear and logistic regression.

Patient characteristics with regard to responders and non-responders in the intervention group will be assessed using logistic regression.

Primary outcome will be adjusted for self-reported pain, physical function and global disease activity.

Normal distribution of continuous variables will be checked using visual inspection of histograms and q-q plots. Categorical variables will be checked using frequency distribution. In case of few responders in each group, an amendment to this SAP will be published.

Sensitivity analysis will be conducted to differentiate between hip and knee osteoarthritis.

Dummy-versions of table 1 and 2 is presented below:

Table 1

	Mean (SD)	**Mean (SD)**
Characteristics	**Experimental treatment group**	**Standard treatment group**
Age, years		
Female, n (%)		
Height, cm		
Weight, kg		
BMI, kg/m^2		
Marital status, n (%) Living alone Living together		
Educational level, n (%) Primary school Upper secondary College/university, less than 4 years College/university, more than 4 years		
Smoking status (yes), n (%)		
Employment status, n (%) Employed, fulltime Employed, part time Sick leave, fulltime Sick leave, part time Retired Disability pension Rehabilitation benefit Homemaker Student		
Most painful joint, n (%) Right hip Left hip Right knee Left knee		
Other painful joints, n (%) Right hip Left hip Right knee Left knee Right ankle Left ankle Right hand/fingers Left hand/fingers Others		
Symptom duration, years		
Level of disease activity (NRS 0-10, 0=no disease activity)		
Level of pain (NRS 0-10, 0=no pain)		

Level of fatigue (NRS 0-10, 0=no fatigue)		
Comorbidities (yes), n (%)		
Current pain medication use (yes), n (%)		
General digital competence		

Table 2

	Experimental treatment group, 6 weeks	**Standard treatment group, 6 weeks**	**Experimental treatment vs standard treatment, 6 weeks (95% CI)**	***P***
OMERACT-OARSI responder, n (%)				
30-s chair-stand test (30 CST), mean (SD)				
Fatigue (NRS 0-10, 0=no fatigue), mean (SD)				
Pain (NRS 0-10, 0=no pain), mean (SD)				
Global disease activity (NRS 0-10, 0=no disease activity), mean (SD)				
Patient Specific Function Scale (PSFS) (NRS 0-10, 0=no problem), mean (SD)				
Knee Injury and Osteoarthritis Outcome Score/Hip disability and Osteoarthritis Outcome Score (K/HOOS) (0-100, 100=no problems), mean (SD) - Pain - Symptoms - ADL - Sports/rec - QoL				
International Physical Activity Questionnaire-Short Form (IPAQ-SF) (h/week), mean (SD) - Vigorous activity - Moderate activity - Walking - Sitting				

Missing data

Complete missing cases will not be imputed.

If missing items within a case, simple imputation (last observation carried forward) will be used. Sensitivity analyzes without imputed data will be conducted.

Additional analyses

Additional analyzes to this SAP may be conducted in conjunction with master thesis.

If the study of unknown causes is terminated prior to appropriate number of patients are included, an amendment to this SAP will be published prior to analyzes.

Harms

Adverse events are self-reported at 6 weeks follow-up. Adverse events are defined as one or multiple events as a result of participation in the study causing an injury or aggravation of complaints leading

to omitting an exercise session (minor adverse event), omitting multiple exercise sessions (moderate adverse event) or receiving additional healthcare due to the event (major adverse event). Adverse events will be analyzed using Chi-square test/Fisher's exact test reflecting distributions in the two groups and severity within a group.

Statistical software

Stata vers. 17.0 will be used as statistical software.

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