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Effect of an information- and self-management app for people with knee osteoarthritis

Submission date
22/10/2025

Recruitment status
Recruiting

Registration date
03/12/2025

Overall study status
Ongoing

Last Edited
18/11/2025

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
This study aims to investigate the effect of an information and self-management app for individuals with knee osteoarthritis, provided before a consultation in the specialist health service, on patients' level of knowledge and degree of shared decision-making during the consultation. The purpose of this study is to provide individuals with knee osteoarthritis access to information about osteoarthritis and recommended treatment before their consultation. The study will examine the effect of a newly developed app with an 8-week intervention consisting of videos that provide information about osteoarthritis and recommended treatment, as well as exercise instructions (the GENUS app).

Who can participate?
Participants aged >50 years and referred to surgical consultation at Diakonhjemmet Hospital due to knee osteoarthritis.

What does the study involve?
The goal is to investigate whether using the app increases patients' knowledge and thereby contributes to better shared decision-making during the consultation, compared to standard practice, which involves access to publicly available information during the waiting period before the consultation.
Data for the study will be collected through questionnaires (via the app and Nettskjema), interviews, and patient records at the start, after 8 weeks, and following the consultation (approximately 3–4 months later). Additional questionnaires will be sent out 1 and 2 years after the consultation. Participants in the app group will also answer some questions in the app after 4 weeks.

What are the possible benefits and risks of participating?
There are no apparent benefits for participants in the control group, but for the intervention group, they will get access to evidence-based information about knee osteoarthritis and recommended treatment options. They will be better educated before meeting for consultation with a healthcare provider in specialist healthcare. There are no apparent risks from being involved in participating in the study for either group. There may be some inconvenience in answering questionnaires multiple times before and after consultation.

Where is the study run from?
Diakonhjemmet Hospital, Norway.

When is the study starting and how long is it expected to run for?
October 2025 to December 2028

Who is funding the study?
The South-Eastern Regional Health Authority, Norway.

Who is the main contact?
Prof Anne Therese Tveter, a.t.tveter@medisin.uio.no

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Anne Therese Tveter

ORCID ID
https://orcid.org/0000-0003-1701-9835

Contact details
Diakonveien 12
Oslo
Norway
0370
+4791115550
a.t.tveter@medisin.uio.no

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
DS-00926

Study information

Scientific Title
Effect of an information- and self-management app for people with knee osteoarthritis (OA-AID)

Acronym
OA-AID

Study objectives
The primary aim of the trial is to assess if an information- and self-management app provided in the period between referral and consultation in specialist healthcare can improve knowledge about osteoarthritis and decision quality during consultation in patients with knee osteoarthritis.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/09/2025, REK KULMU (Committees for Clinical Trials of Medicines and Medical Devices) (University of Oslo, Oslo, 0313, Norway; +4722850383; rek-kulmu@medisin.uio.no), ref: 938916

Study design
Single-site parallel-group open-label randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Knee osteoarthritis

Interventions
A randomization list has been generated through SealedEnvelope (https://www.sealedenvelope.com/simple-randomiser/v1/lists). Participants will be randomized to either the intervention group or the control group.

The intervention group will get access to an information and self-management intervention delivered through the Genus app, including information videos, exercise videos, questionnaires, quizzes and feedback provided over 8 weeks between referral and consultation in specialist healthcare.

The control group will get information on where to access publicly available information about knee osteoarthritis in the waiting period between referral and consultation in specialist healthcare.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Genus app

Primary outcome(s)

1. Osteoarthritis and treatment options measured using the Knee OsteoArthritis Knowledge Scale (KOAKS), at baseline, 8 weeks and post consultation
2. The patient's uncertainty with treatment options will be measured using the Decisional Conflict Scale (DCS), post consultation

Key secondary outcome(s))

Secondary outcome measures are assessed post consultation:
1. Concordance between preferences and treatment decision, measured with one question from the Decision Conflict Scale (DSC)
2. Decisional quality, measured with section 3 (decision process scale) in the Decision Quality Index for Knee Osteoarthritis (K-DQI)
3. Level of shared decision-making, measured with the CollaboRATE questionnaire
4. Satisfaction with treatment choice, measured on a numeric rating scale (0–10, with a higher score indicating more satisfaction)

Other outcome measures:
5. Motivation for exercise, measured on a numeric rating scale from 0 to 10 with higher score indicating higher motivation, at baseline, 4 weeks (only intervention group), and 8 weeks
6. Motivation for surgery, measured on a numeric rating scale from 0 to 10 with higher score indicating higher motivation, at baseline, 4 weeks (only intervention group), and 8 weeks
7. Assessment of knee-related pain, measured with the Knee Injury and Osteoarthritis Outcome Score (pain section), at baseline, 4 weeks (only intervention group), 8 weeks, 1 and 2 years
8. Assessment of knee-related function, measured with the Knee Injury and Osteoarthritis Outcome Score (function section), at baseline, 4 weeks (only intervention group), 8 weeks, 1 and 2 years
9. Assessment of knee-related quality of life, measured with the Knee Injury and Osteoarthritis Outcome Score (quality of life section), at baseline, 4 weeks (only intervention group), 8 weeks, 1 and 2 years
10. Health-related quality of life, measured with EQ-5D-5L, and a Visual Analog Scale (VAS) from 0 to 100, with 100 indicating best health, at baseline, 1 and 2 years
11. Level of shared decision-making therapist, measured with 7 statements from the MAPPIN'SDM Therapist, post consultation
12. Preferred decision-making role, measured with the Control Preference Scale, post consultation
13. Illness perception, measured with the Brief Illness Perception Questionnaire (B-IPQ) at baseline and 8 weeks
14. Pain self-efficacy, measured with the Pain Self-Efficacy Questionnaire (PSEQ-2) at baseline and 8 weeks
15. Pain catastrophizing, measured with one question about concern about pain, measured on a 0 (not at all) to 4 (all the time) scale at baseline and 8 weeks
16. Pain intensity, measured with four questions from the Brief Pain Inventory, assessed on numeric rating scales from 0 (no pain) to 10 (worst possible pain) at baseline and 8 weeks
17. Pain intensity now, measured with one question about pain intensity now on a numeric rating scale from 0 (no pain) to 10 (worst possible pain) at baseline, 4 weeks (only intervention group), 8 weeks, 1 and 2 years
18. Disease activity, measured with a numeric rating scale from 0 (no disease activity) to 10 (worst disease activity) at baseline, 8 weeks, 1 and 2 years
19. Fatigue, measured on a numeric rating scale from 0 (no fatigue) to 10 (worst possible fatigue) at baseline, 8 weeks, 1 and 2 years
20. Importance of treatment options, measured with five questions from the Decision Quality Index for Knee Osteoarthritis (section 1). Assessed on numeric rating scales from 0 (not at all

important) to 10 (extremely important) at baseline and 8 weeks
21. Preferred treatment, measured with a question about whether they prefer surgery or non-surgical treatment at baseline and 8 weeks
22. Health literacy, measured with the HLS19-Q12 at baseline
23. Self-efficacy of digital solutions, measured with six questions about the self-efficacy of using different digital solutions (mobile phone, tablet, computer, apps, identification portal, helsenorge.no), assessed on a 6-point scale from never tried to manage very well at baseline
24. Previous treatment, assessment of previous treatment, answered with yes/no on questions related to previous physiotherapy treatment, previous osteoarthritis school at baseline
25. Health problems' impact on daily living, measured with one question from the Work Productivity and Activity Impairment questionnaire (WPAI) (question 6), answered on a numeric rating scale from 0 (no effect on daily activities) to 10 (completely prevented from doing daily activities) at baseline, 8 weeks, 1 and 2 years
26. Decision regret, measured with item 2 from the Decision Regret Scale, answered on a 5-point scale from totally agree to totally disagree post consultation
27. Use of pain medication, assessed with an open-ended question about the use of pain medication last three months (type and dosage) at baseline, 8 weeks, 1 and 2 years
28. Demographics, measured with questions about gender, age, education level, working status, smoking, living arrangements, socioeconomic status, and support at baseline
29. Anthropometrics, measured as self-reported height and weight at baseline
30. Joint-specific information, measured with questions about the most troublesome knee, duration of complaints, and other joints with complaints, at baseline
31. Exercise level, measured with one question about exercise level answered on a 5-point scale from do not exercise to exercise 3 or more times per week, at baseline, 8 weeks, 1 and 2 years
32. Comorbidities, measured with 15 questions about the presence of different diseases (yes /no), at baseline
33. Usability of the app, measured with System Usability Scale (SUS) comprising 10 statements answered on a 5-point scale from strongly disagree to strongly agree, converted to a 0–100 score with a higher score indicating better usability, at 8 weeks (only intervention group)
34. Satisfaction with the app, measured with two questions about the satisfaction with the information videos and exercise videos in the app, answered on numeric rating scales from 0 (not satisfied) to 10 (very satisfied), at 8 weeks (only the intervention group)
35. Suitability of the app, measured with two questions about the suitability of providing information and exercises through an app, answered on numeric rating scales from 0 (not suitable) to 10 (very suitable), at 8 weeks (only the intervention group)
36. Surgical treatment, measured with a question about whether the patient has undergone surgical treatment (yes/no) and for those answering yes, five questions about the improvement /satisfaction with the surgical treatment, on a 5-point scale from very satisfied to very dissatisfied, at 1 and 2 years
37. Healthcare costs and sick leave/disability benefits, measured using data collected from the register at 8 weeks, 1 and 2 years. Data will be collected from 1 year before inclusion

Completion date
31/12/2028

Eligibility

Key inclusion criteria
Men and women > 50 years referred to specialist healthcare for knee OA management

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Received joint replacement or are under consideration for revision in the referred joint
2. Have undergone joint replacement surgery in the opposite knee
3. Have uncontrolled serious comorbidities
4. Have cognitive deficits
5. Are seeking care for recent knee trauma conditions (less than 6 months after trauma) or mainly psoriatic/rheumatoid arthritis
6. Unable to understand Norwegian
7. Do not possess a smartphone

Date of first enrolment
24/10/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Norway

Study participating centre
Diakonhjemmet Hospital
Diakonveien 12
Oslo
Norway
0370

Sponsor information

Organisation
Diakonhjemmet Hospital

ROR
https://ror.org/02jvh3a15

Funder(s)

Funder type
Government

Funder Name
Helse Sør-Øst RHF

Alternative Name(s)
South-Eastern Norway Regional Health Authority, Southern and Eastern Norway Regional Health Authority, helsesorost, Helse Sør-Øst RHF, helse-sor-ost-rhf, HSØ RHF - South-Eastern Norway Regional Health Authority, sorost

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Norway

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes

Study website	Study website	11/11/2025	11/11/2025	No	Yes