Data collection to develop data driven algorithms for predicting the right advice at the right time in patients with hip and knee osteoarthritis: a cross-over study

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The primary objective of this study is to collect data to develop data-driven models to predict changes in physical functioning over time which will be used within the ArtroseCoach web application.

Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON57573

Source
ToetsingOnline

Brief title
e-cOAch cross-over study

Condition

- Joint disorders

Synonym
Degenerative joint disease of the hip or knee, hip or knee osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: NWO,Salut

Intervention

Keyword: artificial intelligence, e-health, Ostearthritis, self-management

Outcome measures

Primary outcome

The main outcome of the study is a dataset which allows us to create an

algorithm to predict the outcomes of physical functioning.

Secondary outcome

pain, participation, physical activity, weight, sleep quality

Study description

Background summary

Guidelines recommend a stepped-care strategy in patients with OA, starting with non-operative strategies. However, there is an underuse of these treatments. AI algorithms have the potential to provide just-in-time guidance, emphasizing the need for further development. Understanding data-driven factors predicting OA complaints is essential the development of future AI models.

Study objective

The primary objective of this study is to collect data to develop data-driven models to predict changes in physical functioning over time which will be used within the ArtroseCoach web application.

Study design

This study is a cross-over study. Participants are included for one year in their home setting.

Intervention

The app features an intuitive and user-friendly interface to ensure easy navigation. Clear and concise instructions guide users through the input process, making it accessible to a wide range of individuals. All content is

easy to understand at a B1 Level of Dutch. Different subgroups of patients (people with high and low digital health literacy) and HCPs tested the 1.0 prototype to ensure that the app technically works, is easy to use and relevant to patients with OA and HCPs. The content of the ArtroseCoach web application is based on national and international guidelines on hip or knee OA. Existing educational materials and questionnaires are used and rewritten in B1 level. Patients with hip and/ or knee OA as well as B1 language experts provided feedback on the content.
The content of the app consists of different follow-up actions with education about the disease, lifestyle advice (e.g. exercise program, weight management program, sleep program) and healthcare professionals.

1. Start program: Every participant starts with the start program. The topics of the start program are information about: the disease, how pain occurs in OA, symptoms of OA, what you can do about your symptoms yourself, the importance of exercise and healthy lifestyle and general information about OA medication. The content is provided through text, videos and assignments.
2. Physical activity program: This program aims to increase the knowledge and level of physical activity (PA) and to improve muscle strength and stability of the hip and/or knee in twelve weeks. The movement program consists of three parts: information, a graded activity program (BGA) and strength exercises. Firstly, the information entails the influence of movement on pain, why 150 minutes of MVPA is important, chronic pain and handling energy. This information is provided to any participant included in the movement program. Secondly, the BGA program incorporates a baseline test, goal setting, time-contingent PA objectives (i.e., on fixed time points) and notifications to promote PA. An essential feature of the BGA program is the positive reinforcement of gradual PA, despite the presence of pain. The gradual increase in activities changes the perception that PA is related to pain and reinforces confidence to improve PA performance. The BGA intervention can be delivered with or without an activity tracker. In this study, 200 participants receive an activity tracker Fitbit Inspire) which they can connect tto the ArtroseCoach web application. The patient starts with a seven-day baseline measurement. After those seven days, the following data is used: number of minutes of light physical activity (LPA) and moderate and vigorous-intensity physical activity (MVPA). The number of minutes of LPA and MVPA per week is seen as the baseline measurement. A personal goal is set for minutes of LPA and MVPA per week, aiming to surpass 150 minutes of MVPA per week after 12 weeks. The program will start at 75% of baseline measurement. Each week, the recommended amount of minutes MVPA is increased with ((personal goal - baseline) / number of weeks). Each day, the patient receives a positive reinforcement reminder of how far he/she is in reaching the week goal. Each week, the patient receives tailored feedback, based on the principles of graded activity.
Thirdly, exercises are provided through videos. The participant is encouraged to perform strength exercises twice a week for 20 minutes.
3. Sleep program: The sleep program aims to improve subjective sleep for people with clinical insomnia in 12 weeks. Insomnia is characterized by having trouble

falling asleep, staying asleep and waking up too early. The sleep program consists of three parts.
Firstly, there is a weekly educational theme about sleep or sleep hygiene. Sleep hygiene refers to a set of recommended behaviours a person can engage in throughout the day or before bedtime to promote good sleep. This includes abstinence from caffeine, alcohol, and nicotine late in the day, the practice of relaxation, regular exercise, regular sleep/wake times, modifying the environment (e.g., reducing impact of noise/light), no daytime napping, and minimal use of light-emitting devices (e.g., smartphones)14.
Secondly, participants are provided with mindful exercises (progressive muscle relaxation, mediation/ visualization). Mindfulness-based treatments are efficacious at reducing symptoms of insomnia and improving sleep quality.
Thirdly, participants are encouraged to adjust sleep behaviours through setting goals, tailored feedback and prompts.
4. Weight management program: The weight management program is designed to help participants adopting a healthier diet and achieving a healthier weight if needed. Based on Body Mass Index (BMI) (kg/m2), age, and ethical background it is determined whether participants have a healthy weight, under- or overweight, or extreme under- or overweight. For those with a healthy BMI it is mentioned that the weight management program can be used to receive advise for a healthy diet. Individuals who are under- or overweight are advised to work towards a healthier weight with support of the weight management program. While individuals who are extreme under- or overweight are recommended to seek professional assistance, but they are still able to utilize the weight management program.
Participants are provided with a target weight, which is set at five percent below their current weight, because this amount can reduce disability in people with knee osteoarthritis. They are then asked to complete the *Eetscore*, a short food frequency questionnaire evaluating diet quality across sixteen different food components. After completing the Eetscore, participants receive an overview with feedback for each food component, focusing on whether they consume an appropriate amount.
Throughout the program, six weeks are dedicated to providing tips for eating more or less from specific food components. Every week will focus on another food component. After participants received the feedback overview, participants are asked to select food components for which they want to receive tips. Most components can be addressed once, some can be addressed twice. The remaining six weeks focus on providing tips for weight loss. The twelve weeks alternate between focusing on food components and weight loss. Every day participants are provided a tip to aid them in their progress.
Additionally, on a weekly basis, participants receive informative texts covering different topics. Examples of topics include *the relation between weight and pain from OA* and *the significance of maintaining a healthy diet*.

Please see the protocol for an extensive description of the intervention

Study burden and risks

The risks for participants are expected to be negligible, since advices follow the current literature and guidelines and are focussed on selfmanagement and lifestyle. The burden of the data collection is relatively high, consisting questionnaires every two weeks during 12 months. Additionally a subset of participants will be asked to wear a wearable on their wrist during 12 months.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet the following criteria:

1. Have a hip or knee joint that, self-administered through a questionnaire, meets the National Institute for Health and Care Excellence clinical criteria for OA13:
a. Aged 45 years or over and;
b. Activity-related pain at the joint and;
c. Joint morning stiffness that lasts no longer than 30 minutes or no morning stiffness at the joint;
2. History of pain at the joint for at least 3 months;
3. Have access to a smartphone with internet connection and an email address;
4. Able to give informed consent and willing to commit to all study evaluation and assessment procedures
5. Able to read and understand texts in Dutch at B1 level.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. Self-reported systemic arthritis (e.g., rheumatoid arthritis, gout);
2. Scheduled for lower limb joint surgery within the next year;

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-04-2025
Enrollment:	600
Type:	Anticipated

Medical products/devices used

Generic name:	OsteoarthritisCoach web application
Registration:	No

Ethics review

Approved WMO Date:	21-05-2025
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL87119.041.24