BMJ Open

Effectiveness of the ARTHE-e app for exercise adherence in people with knee osteoarthritis: protocol for a randomised controlled trial

Mathilde Pelletier-Visa ,[1,2] Lech Dobija ,[1,2] Alexis Bonhomme,[1] Charlotte Lanhers,[1,3] Bruno Pereira ,[4] Emmanuel Coudeyre [1,2]

To cite: Pelletier-Visa M, Dobija L, Bonhomme A, *et al*. Effectiveness of the ARTHE-e app for exercise adherence in people with knee osteoarthritis: protocol for a randomised controlled trial. *BMJ Open* 2025;**15**:e088860. doi:10.1136/bmjopen-2024-088860

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (https://doi.org/10.1136/bmjopen-2024-088860).

Received 16 May 2024
Accepted 31 December 2024

For numbered affiliations see end of article.

Correspondence to
Mathilde Pelletier-Visa; mpelletiervisa@chu-clermontferrand.fr

ABSTRACT

Introduction Osteoarthritis, the most prevalent joint disease, poses a significant challenge due to its progressive nature and impact on the whole joint and periarticular structures. Although exercise is crucial for symptom improvement and progression slowdown, adherence to exercise programmes remains a concern. In response, we have developed a novel smartphone-based m-health application, ARTH-e, specifically designed to enhance adherence to adapted physical activity in individuals with knee osteoarthritis. We aim to perform a prospective,multicenter, randomized (1:1) controlled trial to compare the effectiveness of m-health application ARTH-e (intervention group) with standard care (control group) on exercise adherence in people with knee osteoarthritis. We hypothesise that adherence will be stronger among users of the ARTH-e application.

Methods and analysis We will recruit 120 participants from 5 hospitals in France. The participants will undergo a comprehensive assessment, including the Exercise Adherence Rating Scale (EARS) at 2, 4 and 6 months, Knee Injury and Osteoarthritis Outcome Score, Evaluation of the Perception of Physical Activity, Tampa Scale of Kinesiophobia, European Quality of Life 5 Dimensions and 3 Lines and a Visual Analogue Scale rating of pain at baseline and 6 months. Adherence will be monitored using a connected bracelet. The intervention group will use the ARTH-e application for 6 months, while the control group will follow stay-active advice from their physician. The primary outcome will be the difference between groups in the evolution of the EARS score at 6 months.

Ethics and dissemination The study has been approved by the medical ethics committee (Comité de Protection des Personnes) XI of Saint Germain en Laye (27 March 2024) (ID for ethics approval: 24.00330.000201). Eligible individuals will sign the informed consent form before enrolment. Study results will be reported in peer-reviewed publications and at scientific meetings.

Trial registration number NCT06359171.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ We will test a new application developed by healthcare professionals that integrates user feedback and current recommendations.
⇒ The impact of using the application on many aspects of knee osteoarthritis will be evaluated, from the body structures and function level to quality of life.
⇒ Adherence to exercises is measured in a declarative manner (questionnaire), however, step count and connection to the application will indirectly measure physical activity and use of the application, which are complementary to the construct of adherence to exercises.
⇒ Intervention addressed only to patients motivated to perform exercises.
⇒ Effects analysed only up to 6 months, with no assessment of long-term effects.

INTRODUCTION

Knee osteoarthritis (KOA) is a prevalent joint disease that particularly affects joints subjected to substantial mechanical stress, such as the spine, hip and knee. The condition affects the whole joint as well as the periarticular structures. This chronic condition increases in prevalence and severity with age and affects almost half of adults, some of whom will experience progressive disability, chronic pain and restricted mobility.[1] The socioeconomic impact is considerable because of the ageing population, resulting in rising public health costs.[2]

The treatment of KOA involves pharmacological and non-pharmacological approaches. The current emphasis is on non-pharmacological interventions, including regular physical activity, therapeutic education and weight management.[3 4] Despite advice from healthcare professionals, people with KOA often only engage in low levels of physical activity. Studies of the facilitators and barriers to performing physical activity highlight the importance of educating individuals about lifestyle modifications.[5]

Monitoring physical activity levels either quantitatively or qualitatively is challenging.

Motivation is strongly affected by misconceptions about physical activity[6] and kinesiophobia (fear of movement).[7] Addressing these issues is crucial for improving outcomes and managing knee OA effectively.

Today, connected objects, including smartphones, play a significant role in the daily lives of individuals, including seniors.[8] These devices serve as communication tools, aids for socialisation and are important sources of information. M-health applications are increasingly prevalent and are used as tools to provide assistance, information and support in various fields.[9] These applications can also provide education and adapt to the needs and progress of individuals, offering a motivating alternative to traditional paper handouts.[10] Studies on the use of smartphone applications in chronic pathologies, such as low back pain, support the development of these tools.[11]

Despite the widespread use of m-health applications, to our knowledge, only 11 randomised controlled studies have been published worldwide on their efficacy in terms of non-pharmacological management.[12–22] These studies used several criteria to assess exercise adherence, including the Exercise Adherence Rating Scale (EARS) questionnaire, the number of steps with a connected bracelet, analysis of app extracts and self-reported adherence. The authors included an average of 208 patients. Of the 11 studies selected, only 1 used the EARS questionnaire as the primary endpoint.[14]

We previously conducted a pilot study of the impact of the ARTH-e application consisting of self-management exercises for people with knee osteoarthritis (ClinicalTrials.gov: NCT04750304). The results showed a significant improvement in exercise adherence at 6 and 12 weeks of application use. We have since used the feedback from the participants in that study to develop an improved version of the ARTH-e app. The current study aims to investigate the effectiveness of the ARTH-e app (intervention group) and to compare it with standard care (control group) in terms of adherence to physical exercise in people with knee OA, using the EARS questionnaire at 6 months.

We hypothesize that adherence to physical exercise will be stronger in the group that uses the ARTH-e application (intervention group) than the group that does not (control group).

METHODS AND ANALYSIS

Study design and setting

We will conduct a multicenter (Clermont-Ferrand, Montpellier, Nantes and Puy-en-Velay), prospective, randomized controlled trial (1:1). Participants will be randomised into one of two groups: intervention or control. The assessor conducting the final study evaluation will be blinded to the participants' group allocation.

Participants in the control group will be given the app free of charge at the end of the study and those in the intervention group will be allowed to keep it. This protocol is reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials.[23] The study results will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement for non-pharmacological trials.[24 25] Interventions are detailed according to the TIDier checklist.[26] The provisional study schedule is presented in figure 1.

Participants

We will recruit, based on our sample size estimation described in below statistical considerations section, 120 participants aged between 40 and 85 years with symptomatic knee OA (according to European League Against

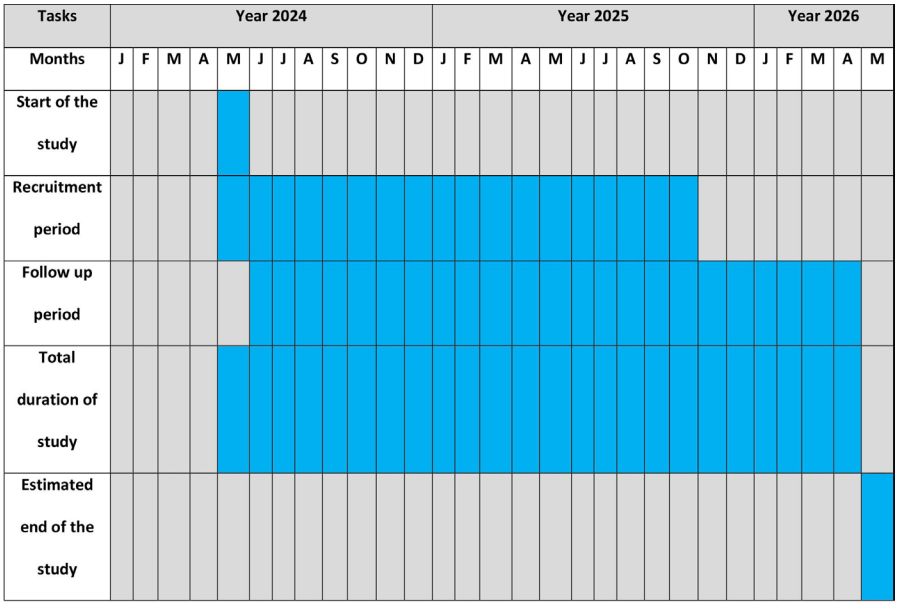

Figure 1 The provisional study schedule. The months of the year are indicated by their first letter. The blue shading indicates the months during which the corresponding tasks will be performed.

Table 1 Eligibility criteria

Inclusion criteria	► People aged between 40 and 85 years with uni or bilateral knee osteoarthritis according to the European League Against Rheumatism (EULAR) criteria and diagnosed prior to inclusion by a specialist or other physician. ► Owners of a smartphone or tablet running at least Android 5 or iOS 11. ► Able to give written consent to participate in the study. ► Beneficiary of a social security plan.
Exclusion criteria	► Pregnant women ► People under legal protection measures (guardianship, curatorship or court protection) ► People who have undergone knee surgery (total or partial prosthesis, tibial transposition surgery, arthrodesis) ► People with inflammatory rheumatism ► People with neurological sequelae ► Contraindications to physical activity for medical reasons ► People who have difficulty understanding French ► Refusal to participate ► People who have already participated in the ARTH-e 2 study or who are already included in a research protocol that could influence the current protocol

Rheumatism).[4] We chose the age range of 40–85 years to include early cases of KOA that often arise from trauma or structural abnormalities before 50, while capturing the peak prevalence of idiopathic OA between 60 and 70 years. Beyond 85, severe cartilage degeneration and comorbidities complicate symptom attribution solely to OA. Eligibility criteria for the study are shown in table 1. We will not recruit pregnant women, as some of the exercises in this study may not be suitable for them, and we aim to avoid incomplete participation due to childbirth.

Recruitment

Participants will be recruited from the Physical Medicine and Rehabilitation (PMR) departments of the Clermont-Ferrand, Nantes, and Montpellier University Hospitals and the rheumatology departments of Le Puy en Velay University Hospital, all in France. The department's Clinical Research Associate (CRA) will prescreen and schedule appointments for patients. Participants will be included in the consultations of each participating department. We will also use the press, the hospital's internal network and social networks to recruit.

Potentially eligible individuals will be informed about the study during a consultation with one of the investigators (physician). They will be given an information leaflet, and the investigator will answer any questions about the study. This consultation will occur at least 1 month before the inclusion visit to allow the individual to make an informed decision about their participation. To ensure the inclusion of the 120 planned participants, each participating centre should include two patients minimum per month for 18 months taking into account those lost to follow-up.

This study began on 14 May 2024 and is scheduled to end in January 2026.

Randomisation

Participants will be randomized (1:1) into one of two groups, intervention or control, during the consultation. Randomization will be performed by minimization, with stratification on center, level of education and retirement (yes/no). Randomization will be performed using Ennov Clinical software (V.8.2.50) by the CRA. Group allocation will be blinded to the second assessor (a physician investigator from the medical team) who will carry out the final study visit.

Procedures and schedule

The evaluations carried out at each visit are described in table 2. Adapted physical activity (APA) instructors, physiotherapists and physicians have been trained to study and carry out the various assessments for the management of patients with a KOA. Participants will attend an enrolment and allocation visit (V0) and a final visit (M6). The CRA will telephone them at 1 week, 2 months and 4 months.

Enrolment and allocation visit (V0)

The investigator will verify the inclusion and exclusion criteria and collect signed informed consent (online supplemental material).

Then, they will collect sociodemographic (age, sex, weight, height, education status and socioprofessional category) and medical data (history of KOA pain and treatments) delivered to the patient in paper form during the on-site visit. The investigator (medical team) will rate the Kellgren and Lawrence classification for assessing OA severity, evaluate knee flexion and extension using a goniometer, and the patient complete the questionnaires in paper form (Knee Injury and Osteoarthritis Outcome Score (KOOS), Evaluation of the Perception of Physical Activity (EPPA), Tampa Scale of Kinesiophobia (TSK), European Quality of Life 5 Dimensions and 3 Lines (EQ-5D-3L) and Visual Analogue Scale (VAS) for pain).

Then, an APA instructor will conduct the functional tests shown in table 2 after the participant performs a warm-up on a cycle ergometer (5 min, 30 W).

The CRA will give the participant a GARMIN wristband to monitor daily step count over the 6 months of the study (figure 2). They will assist the participant in downloading the GARMIN Connect application and ensure its correct functioning. Participants will be instructed to use the connected bracelet and the GARMIN application for a 1 week test phase and then throughout the 6-month study duration.

The CRA will then perform the randomisation and inform the participant of their group allocation.

Those allocated to the intervention group will then be assisted in downloading the ARTH-e app, and the

Table 2 Study schedule

	Study period					
	Enrolment	Randomisation	Post-randomisation			Closeout
Time point		V0	V0+7 days	V1	V2	V3
Enrolment						
Eligibility screen*	X					
Informed consent*	X					
Allocation†		X				
Intervention						
Control group				X	X	X
Intervention group			X	X	X	X
Clinical assessments						
Joint mobility*		X				X
Demographic questionnaire‡		X				
EARS‡				X	X	X
KOOS‡		X				X
EPPA‡		X				X
TSK‡		X				X
EQ-5D-3L‡		X				X
Pain‡		X				X
Functional tests§						
Chair stand test		X				X
Timed up and down stairs test		X				X
6 min Walk Test		X				X
Quadriceps isometric strength test		X				X
Other outcomes						
X-ray (KOA severity)	X		X	X	X	X
Number of steps				X	X	X
Application use (monthly extraction)				X	X	X

The table shows the interventions carried out during the study. Randomization took place on the day of inclusion. V1 represents the telephone call at 2 months. V2 is the telephone call at 4 months. V3 is the end-of-study visit. Concerning the application usage data, a monthly extraction is carried out.
*Performed by the physician.
†Performed by a clinical research associate.
‡Performed by the patient alone.
§Performed by adapted physical activity instructor.
EARS, Exercise Adherence Rating Scale; EPPA, Evaluation of the Perception of Physical Activity; EQ-5D-3L, European Quality of Life 5 Dimensions and 3 Lines; KOA, knee osteoarthritis; KOOS, Knee Injury and Osteoarthritis Outcome Score; TSK, Tampa Scale of Kinesiophobia.

APA instructor will show them how to use it. The APA instructor will address any difficulties with performing the exercises, suggest necessary alternatives and provide advice and reassurance.

Telephone calls at 1 week, 2 months (V1) and 4 months (V2)

After 1 week (V0+7 days), the CRA at each centre will contact the participant by telephone to collect the number of steps recorded on the connected bracelet.

At 2 and 4 months, the CRA will collect responses to the EARS questionnaire, pain levels and the average number of steps per day measured during the previous months by telephone. During the call, participants will connect to the GARMIN Connect application, click on steps, display the average number of steps per months and select the relevant months. The patient will record their average daily step count and report it to the CRA, as the CRA will not have access to the GARMIN application. The CRA will directly input all the data collected during the phone calls into Ennov Clinical.

Final visit (6 months)

During the final visit at 6 months (V3), the same outcomes as at the inclusion visit will be measured. The study investigator will be different from the one at the first visit, however, the same APA instructor, blinded to the randomisation group, will conduct the functional tests. The questionnaires completed at the inclusion visit (except for the demographic questionnaire) will be completed again, along with the EARS questionnaire.

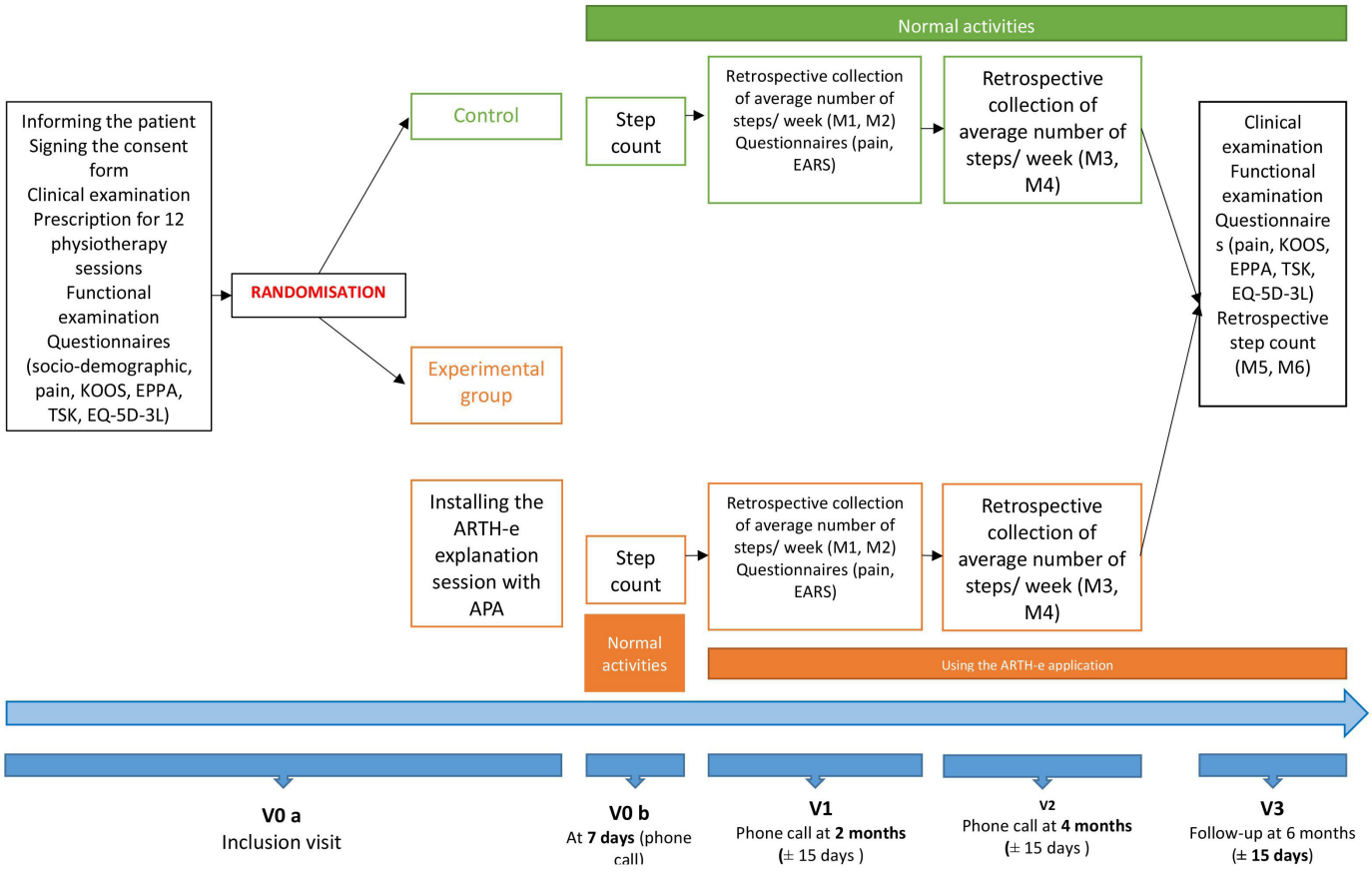

Figure 2 Study flow chart. APA, Adapted Physical Activity; CRA, Clinical Research Associate; EARS, Exercise Adherence Rating Scale; EPPA, Evaluation of the Perception of Physical Activity; EQ-5D-3L, European Quality of Life 5 Dimensions and 3 Lines; KOOS, Knee injury and Osteoarthritis Outcome Score; TSK, Tampa Scale of Kinesiophobia.

Participants will be allowed to keep the wristwatch at the end of the study if they wish. Data will be available on request from the corresponding author.

Interventions

All participants will receive a prescription for 12 physiotherapy sessions, which is standard practice in France and follows current recommendations.[27]

ARTH-e application

Participants allocated to the intervention group will download the ARTH-e application from the Google Play store or Apple App store on their smartphone and/or tablet. After downloading, participants will scan a QR code sent from the Clermont-Ferrand University Hospital to anonymise their data and create an account using their email address and a personal password.

The ARTH-e application features a user-friendly home screen with a dashboard, predefined exercises, a 'Did you know?' section with OA management advice, a shortcut to the current exercise programme, and true/false questions to test knowledge on the pathology. Each exercise programme is structured around five categories: a cardiovascular warm-up, a joint warm-up, muscle strengthening, neuromuscular control exercises (termed proprioception balance in the application) and stretching. As participants progress, three levels of difficulty are offered. The programmes in the application last between 25 and 30 min.

The application provides a written explanation and a professionally produced audio-visual demonstration for each exercise. Users can observe the correct technique, listen to the instructions and perform the exercise. The application also allows users to set a music soundtrack while performing the exercise programme and offers the ability to pause the video at any time.

The CRA will demonstrate the ARTH-e application to the intervention group participants and ensure they can use it correctly. They will instruct participants to use it for 6 months. If an issue with the app arises, patients are asked to contact the CRA directly so that we can resolve the problem with the development engineers, if necessary, within the same day to avoid impacting the progress of the study.

Control group

The control group will receive standard care, which in France[28] consists of an educational booklet that includes recommendations for physical exercises, such as strengthening, stretching and aerobic exercises. The booklet also provides information on knee anatomy, weight loss and both medical and non-medical treatments, including the use of braces and walking aids.

Primary outcome

The primary outcome will be the difference between groups in the evolution of the EARS score at 6 months. EARS score will be measured at 2, 4 and 6 months.

This questionnaire assesses adherence to home exercise programmes in people with chronic pathologies and has been validated in French. It comprises six items, and scoring is based on a 5-point Likert scale (from 0—'completely agree' to 4—'completely disagree'). This results in a score ranging from 0 to 24. A higher score indicates greater adherence.[29]

The EARS score will be compared between groups at each time point using a mixed model, taking into account the group, time and time×group interaction effects; therefore, the value of the score, not the change in the score, will be considered.

Secondary outcomes

The secondary outcomes include physical, psychological and economic evaluations.

1. Pain level[30]: Participants will rate their average level of pain over the last 3 days using a 10-point VAS (from 0—'no pain' to 10—'maximum conceivable pain') at inclusion, 2 months, 4 months and 6 months.
2. EPPA[5 31]: The EPPA questionnaire will be used to assess barriers and facilitators to physical activity. It has 24 items rated from 0—'strongly disagree' to 4—'strongly agree'. The total score ranges from 0—'poor perception of physical activity' to 100—'excellent perception of physical activity'. Responses will be collected at inclusion and 6 months. This questionnaire has been validated in patients with knee OA.[31]
3. Fears and Anxieties Related to Pain[30]: The TSK will be used to assess pain-related fear and anxiety. It consists of 17 statements rated from 1—'strongly disagree' to 4—'strongly agree'. The maximum score is 68 points, and a high score indicates a high level of kinesiophobia. Scores will be collected at inclusion and 6 months.
4. Patient-reported function[32]: The self-rated KOOS questionnaire will be used to assess difficulty performing various activities over the last 8 days. The maximum score is 68 (from 0—'no difficulty' to 4—'extreme difficulty'). The KOOS will be rated at inclusion and 6 months.
5. Quality of Life[33 34]: The EQ-5D-3L questionnaire will be used to assess mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Three levels of response are possible from 1—'no problem' to 3—'extreme problems'. The total score ranges from 5 to 15 points. The lower the score, the better the quality of life. This European quality of life scale includes questions known as the 'EQ-5D descriptive system', supplemented by a VAS known as the 'EQ-5D VAS'. The VAS consists of a 20 cm line graduated from 0 to 100, on which the person is asked to indicate how they rate their current state of health, 0 being the worst possible state and 100 being the best. Responses will be collected at inclusion and 6 months.
6. Joint Mobility: Knee flexion/extension will be measured using a goniometer at inclusion and 6 months.
7. Average Number of Steps[35]: The average number of steps taken during the previous months will be collected using the GARMIN-connected bracelet and reported by the participant during telephone calls at 2 months, 4 months and 6 months.
8. Functional tests at inclusion and 6 months:

a. 30 s Chair Stand Test[36]

This test assesses the number of times a person can stand up from a chair and sit down again in 30 s with their arms crossed over their chest. It will be performed from a 46 cm high chair. The number of complete sit-to-stand transfers will be recorded.

b. Timed up and down stairs test[37]

The participant will be asked to ascend a flight of 11 steps (height 13.5 cm), make a U-turn and descend again as quickly as possible while maintaining safety during the test (no loss of balance). The use of the handrail will be allowed, and the participants will be allowed to climb using a step-to or foot-over-foot pattern or any other method. Ascent and descent times will be measured separately using a stopwatch.

c. 6 min Walk Test[36]

This test measures walking endurance. It will be carried out in a 30 m corridor. The participant will be asked to complete as many corridor lengths as possible in 6 min. The total distance covered will be recorded.

d. Quadriceps isometric strength test[38]

Maximum isometric quadriceps force will be measured using a hand-held dynamometer (EasyForce, Meloq, Stockholm, Sweden). The participant will be seated on a plinth with their knees bent at 90° (verified with a goniometer). The dynamometer will be attached to the table and connected to a non-extensible strap around the distal part of the leg, 10 cm above the ankle joint. The participant will be asked to push their leg forward (isometric quadriceps contraction) for 5 s. The first three trials will be performed at submaximal effort, and then three maximum contractions will be recorded. The best result will be normalised to body mass (N/kg) and used in the analysis. A rest time of 30 s between repetitions will be applied.

9. Medicoeconomic analysis: The cost of medication consumption, the number of medical consultations and/or hospitalisations, the use of alternative therapies, and the number and cost of additional examinations and medical transport will be calculated.
10. Usage parameters of ARTH-E application: For the intervention group, the number of ARTH-E sessions performed and the pain levels during sessions will be extracted from the application production back office.

Statistical considerations

Sample size estimation

The main objective of this study is to investigate the effectiveness of the application compared with standard

management on the evolution of KOA patients' adherence to physical exercise using the EARS questionnaire. On the basis of data from a pilot study (NCT04750304), we can expect an effect size between the randomisation groups around 0.6, that is, a difference of 4.8 points (out of 24) with a standard deviation (SD) of 8, which seems relevant in terms of the minimum clinically relevant difference. For an intraclass correlation coefficient (due to repeated measurements for the same patient, at 2, 4 and 6 months) of 0.5 (estimated from NCT04750304), 51 patients per group are required to demonstrate 0.6 effect size difference, for a two-sided type I error equals 0.016 (correction due to multiple comparisons) and 90% statistical power. In order to take into account the lost to follow-up, it is proposed to include 60 patients per randomisation group.

Statistical analysis

All analyses will be performed according to a predefined statistical analysis plan, using the Stata software V.15.0 (StataCorp) before the breaking of the randomisation code, according to International Conference on Harmonisation-Good Clinical Practice guidelines.

The primary analysis will be conducted in the intention-to-treat population, which includes all randomised patients except those who withdraw consent for data use. We will also perform a per-protocol analysis on the primary outcome, that is, by removing from the analysis patients who will not be managed according to the randomisation group assigned.

Patients will be described and compared between randomisation groups according to the following variables: compliance with eligibility criteria, epidemiological characteristics, clinical characteristics and treatments. As according to the CONSORT 2010 statement, group differences in baseline variables will not be compared using significance testing unless specifically. A description of protocol deviations will also be provided.

The primary analysis will be performed using a mixed model taking into account the following fixed effects: group, time and the time×group interaction. More precisely, a linear mixed-effects model (constrained longitudinal data analysis) will be used. In this model, the variable to be explained (EARS score) includes both the values at inclusion and the postinclusion values, and the mean difference at inclusion between the groups is constrained to 0. This model makes it possible to calculate the changes between inclusion and each follow-up time (2, 4 and 6 months) while adjusting for the values at inclusion. As aforementioned, the difference between each group at each time is given by the interaction between time and randomisation arm. The normality of the residuals from these models will be studied using the Shapiro-Wilk test. The results will be expressed as regression coefficients, effect sizes and 95% confidence intervals. A sensitivity analysis will be carried out to study the attrition bias, that is, the quantity (level of attrition) and the nature (independence from the randomisation group) of the missing data. The primary analysis will be conducted on available data (ie, with missing), imputed data (first using multiple data imputation method and then, as sensitivity analysis, last observation carried forward method) and complete cases.

Adjusted analyses will be conducted only for the primary endpoint using multiple mixed linear regression to take into account covariates selected on the basis of the results of the univariate analysis and their clinical relevance: gender, level of education, retirement (yes/no), stage of OA and KOOS at inclusion. The centre will be considered as a random effect. A particular attention will be paid to the study of multicollinearity using Farrar and Glauber test and VIF indicator. The results will be expressed as regression coefficients, effect sizes and 95% confidence intervals.

Planned subgroup analyses will assess heterogeneity of the effect on the primary outcome measure in prespecified subgroups of patients defined according to level of education and retirement (yes/no). According to usual recommendations, the interactions between group randomisation and subgroups will be evaluated in regression models. The primary outcome will be evaluated in the subgroup analyses without adjustments for multiplicity.

The comparisons between randomisation groups will be carried out (1) in a similar way to that presented above for the primary endpoint for continuous endpoints and (2) by generalised linear model for categorical variables. For non-repeated endpoints, continuous variables will be compared with the use of the unpaired t-test or the Mann-Whitney U test when appropriate. Dichotomous secondary endpoints will be analysed using χ^2 or Fisher's exact test.

A two-sided $p<0.05$ will be considered for statistical significance of all analyses. Because of the potential for type 1 error due to multiple comparisons, findings from analyses of secondary endpoints will be interpreted as exploratory.

Patient and public involvement

None.

ETHICS AND DISSEMINATION

The study protocol has been approved by the medical ethics committee of Saint Germain en Laye (27 March 2024) (ID for ethics approval: 24.00330.000201) and the ANSM (Agence Nationale de Sécurité des Medicaments et des produits de santé—the French National Agency of Medicine and Health Products Safety). All the participants will provide written informed consent before participating. The study will be conducted in accordance with the Declaration of Helsinki.

Participants will be informed that they have the right to withdraw from the study at any time, in accordance with the Good Clinical Practice principles in the French regulatory framework. Additionally, premature withdrawal may occur due to intercurrent illness, death, a major

deviation from the protocol or if a participant is lost to follow-up. Any adverse events that occur during the study will be promptly reported to the principal investigator, ensuring appropriate actions are taken to address and mitigate potential risks to participants' health. Data confidentiality will be strictly respected, and precautions will be taken to protect the identity of participants.

Any modification to the protocol impacting conduct, participant benefits or safety will require formal approval of an amendment by CPP XI to maintain ethical standards.

Communicating our research findings will promote understanding and encourage sporting activity in knee OA. Our research team is committed to promoting open and transparent communication of our scientific results. The results of this study will be reported in peer-reviewed publications and at scientific meetings.

DISCUSSION

Following our previous study (ClinicalTrials.gov: NCT04750304), we have developed an application in collaboration with developers. In building this application, we initially based ourselves on the expectations of patients and healthcare professionals. The exercises were all described by the medical team of the Physical Medicine and Rehabilitation Department of the Clermont-Ferrand University Hospital. The ARTH-e application was then tested by patients, who provided us with suggestions for improving the version used in the ARTH-e 3 study.

The study should also provide further evidence of the benefits of exercise for knee OA.

Tracking participants' progress *via* regular follow-up and extracting data from the application will enable us to monitor the exercise sessions carried out and to be aware of any difficulties encountered. Adherence will also be evaluated quantitatively by a monthly extraction from the application's back office.

The outcome measures that will be used in this study have good metrological properties and are commonly used in people with knee OA. All the measures in this study cover several components of the International Classification of Functioning, Disability and Health, drawn up by the WHO, namely the organic functions and anatomical structures of individuals and the activities performed by individuals and the areas of life in which they participate.[39] We will perform these tests at enrolment and at the end of the study, enabling us to compare a gain/loss in mobility of the knee affected by OA. The secondary objectives of this study will also make it possible to determine whether the patient has gained in quality of life (EQ-5D-3L), thanks to the reduction in pain, a reduction in the score on the following self-questionnaires: EPPA, TSK and KOOS. This study will allow us to know if patients have gained joint mobility thanks to the goniometric measurement and if there is an increase in strength in functional tests.

The expected benefits for those taking part in the study are increased motivation for those in the intervention group who will use the application to carry out physical activity, greater autonomy in performing KOA-related exercises, increased joint mobility, increased muscle strength, reduced pain and improved quality of life.

The study may also be delayed if technical problems with the application arise during the study. We are working closely with Opénium (App engineering) to avoid this. During the intervention, if a problem occurs, the patients call us directly and we try, together with the Opénium company's development engineers, to solve the problem within the day so as not to impact on the progress of the study.

However, there are some limitations to this study. Exercise adherence is only analysed up to 6 months, so we will have no data for long-term effects. It would have been interesting to see the effects of this application after 1 or even 2 years of use. Exercise adherence will be measured declaratively (questionnaire), but the number of steps and connection to the app will indirectly measure physical activity and use of the app, which are complementary to the notion of exercise adherence. It should also be noted we will have a significant recruitment bias since only patients motivated to practice muscle strengthening will volunteer to take part. These are people who already engage in physical activity as part of their daily routine. We, therefore, run the risk of having a relatively active study population, which could limit the difference in outcomes between the groups.

Author affiliations
[1]Médecine Physique et de Réadaptation, Centre Hospitalier Universitaire de Clermont-Ferrand, Clermont-Ferrand, France
[2]Unité de Nutrition Humaine, INRAE, Université Clermont Auvergne, France, Clermont-Ferrand, France
[3]Neurodol, UMR 1017, Université Clermont Auvergne, France, Clermont Ferrand, France
[4]Direction de la Recherche Clinique et de l'Innovation, unité de Biostatistique CHU Clermont-Ferrand, Clermont-Ferrand, France, Clermont Ferrand, France

Contributors CL, EC, MP-V and LD contributed to the conception and design of the study. CL, EC, MP-V and LD contributed to the drafting of the original protocol. CL and MP-V contributed to the coordination of the study. MP-V is responsible for the acquisition of data. BP, EC and MP-V contributed to the design of the statistical analysis plan. CL, EC, MP-V and LD contributed to the drafting of the present protocol manuscript. CL was responsible for funding acquisition. CL, EC, MP-V and LD approved the final submitted manuscript. MP-V is the guarantor. The authors bear full responsibility for both the design and implementation of the study. They are also accountable for all aspects of study analysis, the creation and refinement of the manuscript and the ultimate content of the final document.

Funding This study received a grant from the Centre International de Recherche 3 I-site 2020-25, Université Clermont Auvergne, in May 2023, following a call for projects on connected health. To date, this funding amounts to €112 000. A contract was subsequently drawn up in partnership with Clermont Auvergne University and Clermont-Ferrand University Hospital. Award/grant number: NA.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iDs
Mathilde Pelletier-Visa http://orcid.org/0000-0002-4340-0069
Lech Dobija http://orcid.org/0000-0002-9021-5704
Bruno Pereira http://orcid.org/0000-0003-3778-7161
Emmanuel Coudeyre http://orcid.org/0000-0001-5753-2890

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