

BMJ Open Evaluating the effectiveness of an mHealth application to promote home-based exercise in adults aged 65 years and older: protocol for a randomised controlled trial

Kirsten Quadflieg , Jolien Robijns, Kim Daniels 

To cite: Quadflieg K, Robijns J, Daniels K. Evaluating the effectiveness of an mHealth application to promote home-based exercise in adults aged 65 years and older: protocol for a randomised controlled trial. *BMJ Open* 2025;**15**:e106629. doi:10.1136/bmjopen-2025-106629

► 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-2025-106629>).

Received 16 June 2025
Accepted 22 October 2025



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Centre of expertise in Care Innovation, Department of PXL—Healthcare, PXL University College, Hasselt, Belgium

Correspondence to

Dr Kirsten Quadflieg;
kirsten.quadflieg@pxl.be

ABSTRACT

Introduction With the global population ageing rapidly, older adults face increased risks of physical and cognitive decline. Despite the well-documented benefits of physical activity (PA), many older adults fail to meet PA guidelines. Mobile health (mHealth) apps offer promising tools to promote PA, but user engagement remains a challenge. In response, the MIA app was co-created with older adults using the Behavior Change Wheel framework to enhance usability, relevance and sustained engagement. A feasibility study showed promising results in usability and user satisfaction, supporting further evaluation. The goal of this study is to evaluate the effectiveness of MIA on PA promotion in older adults.

Methods and analysis A randomised controlled trial conducted in Belgium at a university college will assess the effectiveness of the MIA app in promoting PA in older adults. Participants will be randomly assigned in a 1:1 ratio to either the intervention group (MIA app use) or the control group (no use of MIA) for 8 weeks. The primary outcome is moderate-to-vigorous PA, measured via Garmin wearable devices. Secondary outcomes include self-reported measures (PA, well-being, user satisfaction), clinical assessments (physical and cognitive functioning) and time series assessments (daily steps). A total of 75 participants will be recruited to ensure sufficient power, accounting for dropout. Eligible participants must be ≥65 years, medically stable, have no significant cognitive or physical limitations, understand and speak Dutch and have access to a smartphone and/or computer. Exclusion criteria include an active lifestyle, participation in other exercise programmes or clinical trials, or any condition deemed by a healthcare professional to compromise safety or study validity.

Ethics and dissemination The study was approved by the UHasselt Medical Ethics Committee (B1152025000012) and complies with Belgian legislation on human research. Written informed consent will be obtained from all participants prior to enrolment. Data will be securely stored for up to 25 years. Results will be disseminated via peer-reviewed publications and conference presentations.

Trial registration number NCT06983574.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study will contribute to the growing evidence on the effectiveness of mobile health (mHealth) interventions to promote physical activity (PA) in older adults.
- ⇒ Findings will inform whether a co-created, theory-based mHealth app can support PA in ageing populations.
- ⇒ Some secondary outcomes rely on self-reported questionnaires, which are subject to recall and social desirability bias.
- ⇒ The study population is limited to medically stable older adults, which may affect the generalisability of the findings.

INTRODUCTION

The global ageing population is growing, with the number of individuals aged 65 years and older expected to more than double by 2050.¹ As individuals age, the risk of physical and cognitive disabilities increases, while chronic conditions and comorbidities become more common.² These age-related changes contribute to escalating demands on healthcare systems and social care services.

Promoting regular physical activity (PA) is a key public health strategy to support healthy ageing, with well-documented benefits for physical, cognitive and mental health in older adults.³ The WHO recommends specific PA guidelines for older adults, including aerobic activities, muscle-strengthening exercises and balance training.^{4 5} However, many older adults fail to meet these guidelines, underscoring the need for effective and scalable interventions that support long-term behavioural change.^{6 7}

To bridge this gap, innovative and sustainable interventions are needed. Mobile health (mHealth) applications offer a promising, cost-effective solution by providing

personalised guidance, tracking and encouragement for PA.^{8,9} With the widespread use of smartphones, mHealth applications present a practical channel to deliver PA interventions at scale and thus the promotion of PA in ageing populations. Thereby, offering convenient access to resources and progress feedback.^{10–12}

However, the real-world effectiveness of mHealth interventions remains uncertain. Recent systematic reviews and meta-analyses found only a limited amount of high quality randomised controlled trials (RCTs) evaluating the impact of mHealth apps on PA in older adults, highlighting a significant evidence gap and the need for robust trials in this demographic.^{10,11,13} Previous studies also suggest that mHealth interventions may have broader benefits beyond increasing PA. Improvements in physical functioning, including endurance, muscle strength and postural balance, are important as they relate directly to mobility, independence and fall risk in older adults.^{10,14,15} Similarly, cognitive function, perceived stress and sleep quality are key determinants of overall health and adherence to PA programmes.¹⁶

Moreover, real-world implementation is often hindered by low engagement and high attrition rates, frequently attributed to a lack of personalization and limited user involvement in the design process and challenges related to digital literacy. Involving end-users during the development process and grounding interventions in behaviour change theory may enhance usability, engagement and long-term adherence and can help overcome barriers, ensuring better outcomes in promoting long-term PA.^{17–20}

In response to these challenges, a collaborative co-creation process led to the development and refining of an mHealth app named MIA (More in Action). Briefly, this iterative process aimed to promote PA and cultivate a lifestyle centred around an active and healthy approach, of which complete details about the app and the development process are presented elsewhere.¹⁷ The app's content and design were crafted through co-creative workshops involving older adults, healthcare professionals and behavioural scientists. MIA is grounded in the Behavior Change Wheel (BCW),²¹ and uniquely integrates a smart algorithm that continuously adapts exercise recommendations based on user feedback after workouts. This iterative process ensured that the app met the needs of older adults while integrating behaviour change principles and is a key innovation of the app, distinguishing it from many other existing app solutions.¹⁷

Rather than moving directly to a full-scale trial, we first conducted a structured feasibility study involving 30 participants (mean age 70.3 years±4.8).²² Results demonstrated high usability and satisfaction, with participants engaging in over 580 workout sessions. The app received positive feedback, with a System Usability Scale (SUS) score of 77.4 and a Customer Satisfaction Score (CSAT) of 86.6%. The Net Promoter Score (NPS) was 33.34, indicating good customer loyalty. Qualitative feedback highlighted areas for improvement, including navigation, content relevance and social engagement

features. These findings informed minor design revisions.

Based on this feedback, the app was further refined, making it better suited to meet user needs. With these modifications, the app is now ready for testing in a larger sample to further evaluate its effectiveness in promoting sustained PA and healthy behaviours among older adults. The primary goal of this study is to prospectively evaluate the effectiveness of MIA, an mHealth application on PA levels among older adults in a real-world setting. In addition, the study aims to assess the impact of MIA on physical function, cognitive function and well-being.

METHODS AND ANALYSIS

Study design

The study is a two-arm, parallel-group RCT designed to evaluate the effectiveness of the MIA app in promoting PA among older adults. The trial will be conducted in Belgium at the PXL University of Applied Sciences. Participants will be randomly assigned in a 1:1 ratio to either the intervention group (MIA app) or the control group (usual activity) for a period of 8 weeks. The trial is registered on ClinicalTrials.gov (NCT06983574). The study is planned to begin participant recruitment in November 2025 and is expected to be completed by October 2027.

Primary and secondary outcomes

This RCT is designed to test the hypothesis that the use of the MIA app will lead to a significant increase in objectively measured moderate-to-vigorous physical activity (MVPA) among older adults compared with a control group maintaining usual activity levels. We further hypothesise that, compared with the control group, participants in the intervention group will demonstrate significant improvements in secondary outcomes such as in self-reported measures (PA, well-being, user satisfaction), clinical assessments (physical and cognitive functioning) and time series assessments (daily steps).

Study population

Participants who meet all of the following inclusion criteria are eligible for the study. Participants must be 65 years or older and medically stable. Any existing chronic illnesses, such as hypertension, diabetes or arthritis, must be effectively managed with medications. Participants should not be experiencing any recent or ongoing acute medical conditions, such as infections, recent surgeries or injuries, that could interfere with participation in the study. Participants must also understand and speak Dutch and have access to a smartphone and/or computer.

The presence of any one of the following exclusion criteria will lead to exclusion from the study. The trial targets insufficiently active individuals, those with an active lifestyle, defined as engaging in more than 150 min of objectively measured MVPA per week, will be excluded. Furthermore, enrolment in other exercise programmes or clinical trials that might interfere with study participation

or outcomes will lead to exclusion. Lastly, any condition or circumstance deemed by a healthcare professional to pose a risk to the participant's safety or the validity of the study will result in exclusion.

Recruitment

Participants will be recruited through organisations for older adults (such as the Senior University, the Hogeijf Service Center in the city of Hasselt, Happy Aging, Okra, etc.) as well as the retired former staff members of PXL University of Applied Sciences and Arts, and through general practitioners, friends and family of students and staff. Given the likelihood of recruiting participants from similar communities or social networks, there is a realistic risk of contamination between the intervention and control groups. To address this, participants will be explicitly instructed not to share access to or information about the MIA app with others. Recruitment will be carefully monitored and, where possible, organised in such a way that individuals from the same household, care unit or immediate social environment are not allocated to different study arms. The potential for contamination will also be evaluated in the process evaluation, and any observed instances will be documented and considered in the analysis and interpretation of study outcomes.

After receiving detailed information about the study and voluntarily signing the informed consent form (online supplemental appendix 1), participants will be eligible to take part in the study. This will be followed by a random allocation (1:1) of the participants to the experimental or control group. Participants will be allocated based on a block randomisation process, with a block size of 4 by using a computer-generated random number list prepared by a researcher who is not clinically involved in this trial. To account for heterogeneity in age and potential differences in health status, randomisation will be stratified by age category: 65–75 years, 76–85 years and 86–95 years. The allocation sequence will be generated by an independent researcher not involved in the enrolment or intervention.

Due to the nature of the intervention, blinding of participants and research staff is not feasible. To minimise potential bias, outcome assessments will be conducted

using objective measures where possible, such as wearable activity trackers for PA and standardised tests for physical and cognitive functioning. Predefined protocols and standardised procedures will be used throughout the study to ensure consistency in data collection and reduce the influence of subjective interpretation.

Study intervention

Experimental group

Participants in the experimental group will use the MIA app to engage in home-based workouts aimed at promoting PA. The app provides exercises lasting approximately 12–15 min each, which participants are encouraged to perform regularly to achieve a total of at least 150 min of MVPA per week. The intervention period spans 8 weeks, during which participants should follow the app's guidance to complete the recommended workouts and track their progress. Participants can also log any physical activities they perform outside the MIA app using the app's activity diary feature. Importantly, users are free to choose the frequency and timing of their sessions, in line with the app's autonomy-supportive philosophy. The app does not prescribe a fixed number of sessions per week but instead empowers users to structure their own routine as long as they work towards the 150 min weekly goal.

The MIA app is grounded in the BCW framework and integrates multiple behaviour change techniques, mapped onto the capability, opportunity, motivation - behaviour (COM-B) model of behaviour change. Key features are visualised in [table 1](#).

At onboarding, participants receive individualised instructions, both written and verbal, explaining the importance of regular PA for healthy ageing and how the MIA app supports this goal. They are encouraged to treat the workout sessions as a daily routine, much like taking medication, and are told that 'even small movements done consistently can significantly benefit your health'. Compliance is supported through encouraging in-app messages, reinforcement of streaks or milestones, and motivational tips that reinforce users' competence and effort.

Table 1 Key features of the behaviour change techniques used in the MIA app

Behaviour change technique	Implemented in the app
Tailored exercise programming	An adaptive algorithm continuously adjusts the difficulty, intensity and type of exercises based on users' feedback (eg, perceived exertion and completion rate) to ensure progression and safety.
Self-monitoring tools	Users can track their workouts and log additional physical activities via an in-app diary, supporting awareness and accountability.
Motivational prompts and feedback	The app delivers just-in-time reminders, congratulatory messages and motivational tips to encourage adherence.
Autonomy-supportive design	Users can select preferred activities, set personalised goals and view their progress through the progression monitor, enhancing engagement.
Social and emotional support	Social and emotional support.

Participation in the experimental group may involve minimal physical risk due to the exercise component of the intervention, such as muscle soreness, fatigue or, in rare cases, injury. To mitigate these risks, all exercises included in the MIA app are tailored for older adults and follow established safety protocols. Participants are advised to perform the exercises at their own pace and within their physical limits. Video instructions and clear guidance are provided to support safe execution. Furthermore, only medically stable participants will be enrolled, based on a thorough screening process. Participation may also be experienced as burdensome due to the 8-week duration of the intervention, multiple assessments and use of digital technology. To reduce this burden, the app is designed to be user-friendly and intuitive. Participants are given technical support if needed, and the assessments are scheduled as flexibly as possible to accommodate individual needs.

Control group

Participants in the control group will receive no intervention during the 8-week study period and will be instructed to maintain their usual PA, dietary habits and sleep routines. In this context, 'usual' refers to the absence of any structured PA guidance, behavioural intervention or digital health support, reflecting the typical lifestyle of community-dwelling older adults who are not currently engaged in a formal exercise programme. To reduce the risk of intervention contamination, control group participants will be asked not to initiate any new exercise programmes or structured PA interventions during the study period. However, they are not restricted from continuing

light or incidental PA as part of daily living, in line with real-world conditions. Control group participants will receive minimal contact from the research team during the 8-week period, limited to logistical communication (eg, reminders for assessment appointments). No motivational messaging, PA coaching or feedback on behaviour will be provided to avoid unintentionally influencing behaviour.

At the end of the 3-month follow-up period, control group participants will have the option to use the MIA app if they wish.

Assessments

Participants will be assessed at baseline, during the intervention, at week 8, and 3 months after the intervention period. Assessments include a combination of self-reported measures, clinical assessments and time series assessment. Detailed information can be found in [table 2](#).

General participant information

General (eg, age, gender, living situation, educational degree) and medical information (eg, chronic conditions, medication usage) will be collected through a short digital questionnaire. The Digital Health Readiness Questionnaire (DHRQ) will be used to assess the digital readiness of participants, which consisted of different domains, including usage, digital skills, digital literacy, health literacy and learnability. It consists of 20 items rated on a five-point Likert scale (strongly disagree to strongly agree), with higher scores indicating better digital readiness.²³

Table 2 Timing of assessments

	Screening	Baseline	During intervention	Postintervention	Follow-up
	1 week before baseline	Week 1	Week 1–8	Week 9	3 months postintervention
Inclusion/exclusion check	X				
Study information	X				
Informed consent	X				
Self-reported measures					
General participant information		X			
Self-reported physical activity		X		X	
Well-being		X		X	
User satisfaction*				X	
Clinical assessments					
Physical functioning		X		X	
Cognitive functioning		X		X	
Time series assessment					
Wearable for physical activity tracking		X	X	X	X
Usage metrics*			X		X
*Experimental group only.					

Assessment of primary outcome

MVPA will be assessed using a wearable activity tracker, the Garmin Vivosmart 5, which allows for continuous, 24/7 continuous monitoring of PA. This device captures comprehensive data on activity levels and enables detailed analysis of participants' PA patterns over time. The Garmin Vivosmart 5 was chosen for its demonstrated accuracy, high user acceptance and its capacity to provide unprocessed data specifically tailored for research purposes through the manufacturer's research platform portal.^{24 25}

Participants will be instructed to wear the tracker on the non-dominant wrist to reduce overestimation from dominant-hand movements. Participants will be asked to wear the device continuously during both waking and sleeping hours. During the onboarding process, each participant will receive a brief standardised training session. This session will explain the purpose of the device and emphasise the importance of consistent wear. It will also cover instructions on how to properly wear and charge the device. Participants will be informed about behaviours to avoid, such as tampering with data settings or unnecessarily removing the device. Additionally, they will be assured that their data will be used solely for research purposes. Devices will be checked for functionality, battery life and data syncing during in-person assessments or via remote support when needed.

Assessment of secondary outcomes

Physical functioning

Gait speed will be measured using the Six Minute Walking Test performed according to the European Respiratory Society (ERS)/American Thoracic Society (ATS).²⁶ The absolute distance walked in the test will be used for analysis and compared with normative values.²⁷

Isometric quadriceps force will be assessed using the Kinvent2016 (Kinvent, Montpellier, France) handheld dynamometer. Participants will be tested while sitting in an upright position. The assessor applies resistance and asks the participant to maximally contract the muscle against the resistance.²⁸ At least three maximal efforts will be performed and the test will be repeated until reproducible measurements (less than 10% variability) are obtained. The highest value will be used for analyses and compared with normative values.²⁹

Handgrip strength will be measured isometrically using the KForce Grip (Kinvent) while sitting in the upright position with the elbow flexed 90° and the wrist in a neutral position.³⁰ Three maximal efforts will be performed and repeated until reproducible measurements (less than 10% variability) are obtained. The highest value will be used for analysis and compared with normative values.³¹

Postural balance will be assessed using the Kinvent PLATES v3 (Kinvent).³² Participants will undergo a double leg balance test three times for 10s with eyes opened and eyes closed, followed by a single leg balance test consisting of three repetitions for each leg with eyes opened.

The Timed Up & Go test will be conducted to evaluate fall risk. Participants will be observed and timed as they stand up from an armchair, walk 3 m, turn around, walk back and sit down again.³³

The Sit and Reach test will assess the spinal flexibility and hamstring length/flexibility. Participants will be seated on the floor with their legs extended and feet placed flat against a sit-and-reach box. A measuring scale will be attached to the top of the box. With their hands placed on top of the other, participants will be instructed to reach forward towards their toes as far as possible. The distance reached will be recorded using the measuring scale. The highest value will be used for analysis.³⁴

Muscle power will be assessed by the 30s sit-to-stand (STS) muscle power test. Briefly, the subjects will perform as many STS repetitions as possible in 30s on a standardised armless chair from the sitting position, buttocks touching the chair, to the full standing position, with their arms crossed over the chest. Verbal encouragement will be given throughout the test. The participants will be allowed to try one to two times before the definitive measure is annotated.^{35 36}

Physical activity

Daily steps will be assessed using a wearable activity tracker, the Garmin Vivosmart 5.

The International Physical Activity Questionnaire—Short Form measures participants' PA levels over the past 7 days. Participants will be categorised as low-active, moderately active or highly active based on their scores.³⁷

The Exercise Self-Efficacy Scale measures participants' confidence in their ability to engage in regular PA. It also assesses their perceived ability to overcome barriers to exercise. It includes 10 items rated on a four-point Likert scale, with higher scores indicating greater self-efficacy.³⁸

The Behavioral Regulations in Exercise Questionnaire will be used to evaluate participants' motivations for engaging in PA. This scale examines a spectrum of motivational orientations, ranging from intrinsic (internal motivation) to extrinsic (external motivation) factors. It includes 24 items rated on a five-point Likert scale, with higher scores indicating stronger motivation.^{39 40}

The Physical Activity Enjoyment Scale is a self-reported questionnaire that will be used to measure an individual's enjoyment of PA. It consists of 18 items that assess positive and negative feelings associated with engaging in physical exercise. A higher score indicates greater enjoyment, while a lower score suggests less enjoyment.⁴¹

Cognitive functioning

The assessment of cognitive functioning will be conducted using the SWAY (SWAY Medical, Inc., Tulsa, OK, USA).⁴² The cognitive performance segment of the app encompasses three modules focusing on memory, reaction time and impulse control. Based on the results, participants will be classified into percentiles ranging from very low (<10%) to very high (>10%).

Well-being

The WHO Quality of Life (WHOQoL) questionnaire will measure the participants' quality of life across four domains: physical health, psychological well-being, social relationships and environmental factors. Raw scores from the WHOQoL were converted to a 0–100 scale. Higher scores in each domain indicate a better quality of life.⁴³

The Perceived Stress Scale will measure participants' perceived stress levels over the past month. Scores were classified into low stress (0–13), moderate stress (14–26) and high stress (greater than 26).⁴⁴

The Geriatric Sleep Questionnaire will collect information about participants' sleep patterns, including sleep quality, disturbances and overall sleep habits. It includes six items with five-point Likert-type responses covering sleep latency, difficulty falling asleep, night awakenings, early waking, the problem of early waking and overall sleep quality. Item scores are summed (Item 6 reversed), with higher scores indicating poorer sleep quality.⁴⁵

User satisfaction

Three questionnaires were chosen to provide a multi-dimensional evaluation of user satisfaction: SUS for usability, CSAT for immediate satisfaction and NPS for long-term loyalty and recommendation potential. These will be assessed in the experimental group only after the 8-week intervention period. Together, they allow for a comprehensive assessment of user-centred outcomes.

The SUS provides a standardised measure of usability through a 10-item questionnaire, with response options ranging from 'Strongly Agree' to 'Strongly Disagree.' A SUS score above 68 indicates above-average usability.⁴⁶

The CSAT quantifies overall satisfaction by asking users to rate their experience with the application on a predefined scale, typically ranging from 'Very Dissatisfied' to 'Very Satisfied'. This metric offers a direct insight into user contentment and perceived value.

The NPS assesses user loyalty by asking participants to rate their likelihood of recommending the application on a scale from 0 to 10. The NPS is calculated based on responses to the following question: 'On a scale from 0 to 10, how likely are you to recommend the MIA-app to a friend or peer?' Respondents are categorised as follows: Promoters (score 9–10); Passives (score 7–8); Detractors (score 0–6). The final NPS score is derived by subtracting the percentage of detractors from the percentage of promoters, providing a simple yet effective measure of user loyalty and referral potential.⁴⁷

Usage metrics

For the experimental group only, user engagement with the MIA app will be monitored through several automatically recorded metrics. These will include the frequency of app logins, the number of completed workouts and the total minutes of PA logged, encompassing both app-guided workouts and activities recorded in the in-app diary. Additionally, the usage frequency of specific app features such as the diary, progression monitor and

chatbot will be tracked. Adherence will also be assessed, with participants who achieve less than 70% of the prescribed 150 min/week MVPA being excluded from the final analysis.

Sample size

The sample size calculation was based on detecting a between-group difference in MVPA, measured in minutes per week, which is the primary outcome of this study. Based on data from a recent meta-analysis of mHealth interventions promoting PA in older adults,⁴⁸ an expected mean difference of 77 minutes/week was used as the anticipated effect size. A SD of 150 minutes/week was assumed, consistent with previous feasibility data from our own study population and comparable trials targeting insufficiently active older adults. Using these parameters, a two-tailed independent samples t-test was modelled with an alpha level of 0.05, a power of 0.80 and an effect size (Cohen's d) of 0.51, which was calculated as 77 divided by 150.

The required sample size was calculated using G*Power (V.3.1.9.7, Universität Düsseldorf), yielding 30 participants per group (60 total) to detect a statistically significant difference in MVPA between groups at postintervention. To account for an expected dropout rate of 20%–25%,^{49 50} a total of 75 participants will be recruited.

Data analysis plan

Statistical analyses will be performed in IMB SPSS statistics (V.29.0.2.0 (20)). The primary analysis will follow the intention to treat principle, including all participants as randomised, regardless of adherence to the intervention. A per protocol analysis will also be conducted as a sensitivity analysis, including only participants who complete the intervention as specified ($\geq 80\%$ data availability, no missing assessments). Descriptive statistics will summarise baseline characteristics. Normality of continuous data will be assessed using the Shapiro-Wilk test, and homoscedasticity will be evaluated using the Brown-Forsythe test. Continuous variables will be summarised as mean and SD or as median and IQR, depending on the distribution. Categorical variables will be presented as frequencies and percentages.

To assess the effect of the intervention over time, we will use linear mixed-effects models (LMM), which accommodate repeated measures and allow for inclusion of participants with partially missing data. These models will include group (intervention vs control), time (baseline, postintervention, follow-up) and group $\times$ time interaction as fixed effects, with participant ID as a random effect. If model assumptions are violated, generalised estimating equations or appropriate non-parametric alternatives will be used.

The primary outcome (MVPA in minutes/week) will be compared between groups over time using the LMM approach, adjusting for relevant covariates (eg, age, baseline MVPA, digital readiness). Secondary outcomes will be analysed similarly.

A sensitivity analysis will be performed to examine the robustness of the findings by excluding participants with low adherence, adjusting for baseline digital health readiness scores (DHRQ), and stratifying the results by age group (65–75, 76–85 and 86–95).

Wearable data cleaning procedures will follow standard protocols: a minimum wear time of 10 hours per day on at least 5 days per week will be required for inclusion in analyses.

Missing data will be assessed for patterns of randomness using Little's MCAR test. If data are missing at random, multiple imputation will be used to handle missing values for key outcomes. Complete case analysis will be conducted as a sensitivity check. All statistical tests will be two-tailed, and p -values < 0.05 will be considered statistically significant.

Patient and public involvement

Older adults were actively involved in the development of the MIA app through a collaborative, iterative co-creation process.²² The app's content and design were shaped in co-creative workshops, guided by the BCW framework. This approach ensured that the app addressed the needs, preferences and barriers experienced by older adults regarding PA. Their input directly influenced key elements such as usability, relevance of the content and motivational strategies.

ETHICS AND DISSEMINATION

The study was approved by the Medical Ethical Committee of UHasselt (B1152025000012). Substantial amendments will only be implemented after approval of the Medical Ethical Committee. This study will be carried out in compliance with the Belgian Law regulating research on humans ('Wet inzake experimenten op de menselijke persoon, Loi relative aux expérimentations sur la personne humaine', 7 May 2004). Accordingly, insurance is taken out to cover any damage the participants might sustain (Ethias nv 45.236.692). Trained researchers will obtain written informed consent from all participants prior to study enrolment. Participants will receive verbal and written information about the study's purpose, procedures, risks and benefits, with time for questions.

Appropriate technical and organisational measures are taken to protect the provided and collected personal data against destruction, loss, accidental alteration, damage, accidental or unlawful access, or any other unauthorised processing of personal data. All data will be pseudonymised to protect participant identity. Collected data will be stored digitally and securely on the internal servers of PXL University of Applied Sciences for the duration of the research and for up to 25 years after the project's completion. Study data can be accessed by KQ, JR and KD.

Results of the study will be submitted for publication in national/international peer-reviewed journals and for presentation at national/international conferences.

Contributors All authors contributed to the conception and design of the study protocol. KQ drafted the manuscript. All authors critically reviewed, revised and approved the final version of the manuscript. KQ is the guarantor of this work and takes responsibility for the integrity and accuracy of the study protocol.

Funding This work was supported by PXL University of Applied Sciences and Arts grant number 2/DWO/2022/HC/VL041.

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 and analysis section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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ORCID iDs

Kirsten Quadflieg <https://orcid.org/0000-0002-3905-3180>

Kim Daniels <https://orcid.org/0000-0002-4222-4518>

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