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Boosting enjoyment and social inclusion to increase physical activity and reduce sedentary behaviour among older adults: protocol of a feasibility study to test the JOIN4JOY approach in five European countries

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ABSTRACT

Introduction: Programmes for older people increasing Physical activity (PA) and reducing sedentary behavior (SB) traditionally focus on achieving functional and health improvements, while focusing on enjoyment and social inclusion could strengthen adherence and help reaching older people with social disadvantages. The aim is to assess the feasibility and acceptability of the the JOIN4JOY approach in PA programmes and its assessments tools.

Methods and analysis: A multicentric, pragmatic, pre-post feasibility study using mixed methods will be conducted. The intervention will consist of a PA programme boosting enjoyment and social inclusion, grounded on a co-creation process. Trainers will offer 1-hour weekly sessions of group-based, structured, supervised PA for three months. Participants will be encouraged to increase activity in daily living 144 older people will be recruited from the community and nursing homes in Spain, Denmark, Italy, Germany, and France. Additionally, participants and trainers will be invited to join virtual communities of practice to share their experiences across settings and countries.
Qualitative procedures will be used to explore the acceptability of the design via interviews and focus groups with participants and trainers. Quantitative methods will be used to assess uptake, adherence, retention, reach, satisfaction, enjoyment (PACES questionnaire), physical function (e.g., Short Physical Performance Battery), quality of life (EQ-5D-5L scale), perceived improvement (Patient Global Impression of Improvement scale-I), activities of daily living (Barthel index), sedentary behaviour and physical activity patterns (IPAQ+ and accelerometry). The degree and type of participation in virtual communities of practice will be also assessed.
SPSS software will be used for the analysis of quantitative variables with paired t-tests. Qualitative data will be analysed using reflective thematic analysis following Braun and Clarke, 2006.
Ethics and dissemination: A favourable report by the Research Ethics Committee of UVic-UCC (282/2023) was obtained on June 26th, 2023. Participation and withdrawal will be voluntary. Legal guardian written permission will be requested, when necessary. Dissemination will taget lay and professional audiences.
Trial registration number: ClinicalTrials.gov ID NCT06100835

Strengths and limitations of this study

► The JOIN4JOY PA programme is focused on enjoyment and social inclusion and its design is the result of a co-creation process conducted with professionals, students, older people living in the community and in nursing homes, family members and researchers in Spain, Germany, Denmark, Italy and France.

► This is a pragmatic study aimed at assessing the feasibility and acceptability of J4J intervention and evaluation design using mixed (qualitative and quantitative) methods.

► One of the main limitations of the study is the lack of control groups.

► Results and conclusions that derive from this feasibility study will inform the design of a future RTC.

INTRODUCTION

Background and rationale

The older adult population is experiencing the most rapid growth among all age groups[1]. As people age, they become more susceptible to physical and cognitive decline, chronic illnesses, and comorbidities[2]. This poses a challenge for managing the rising health and social care needs that come with an ageing population and increased disease burden. As a result, it is recommended to plan and implement sustainable preventive programmes to address these challenges[3].

Regular physical activity (PA) is known to have many health benefits and to help prevent negative health outcomes, such as functional limitations and disease[4]. Likewise, insufficient levels of PA have been consistently linked to poor health outcomes[4].

Furthermore, sedentary behaviour (SB), defined as any non-sleeping activity with a low energy expenditure (< 1.5 metabolic equivalent) performed while sitting, reclining or lying[5], has significantly increased over the past 30 years, and this trend is particularly evident as people age[6].

Insufficient PA and excessive SB are associated with social, physical and mental health-related issues: older individuals with lower levels of PA and those who spend more time sitting during their daily activities tend to self-report worse general health states than their more active and less sedentary counterparts[7]. However, a recent study found that older adults living in the community spend a significant (78.8%) portion of their waking hours engaging in SB, with only a small percentage of time spent in light-intensity (18.6%) and moderate-to-vigorous (2.6%) PA[8]. A similar pattern was observed in a study by Parry et al., conducted in 2019, which focused on nursing home (NH) residents. The study found that residents spent most (85%) of their time being sedentary, with only a small portion of time spent in light-intensity (14%) and moderate-to-vigorous (1%) PA[9].

It is widely known that engaging in regular PA is a highly effective non-pharmacological approach to prevent and manage non-communicable diseases and that more active individuals generally experience healthier ageing trajectories[10,11].

Currently, the WHO has launched ‘Promoting physical activity for older people: a toolkit for action’ emphasizing, among others, that enjoyable opportunities to conduct PA supports engagement of older people. Specifically, it mentions that PA groups, once adapted to the abilities of participants to ensure inclusivity, can be a source of enjoyment and building confidence, which are key to overcoming the barrier that PA is “not for them”. Thus, encouraging inactive older people to join PA programmes they would normally refuse. Moreover, WHO points out that the design of PA programmes should be informed by goals, needs and preferences of older people to increase its effectiveness. Accordingly, older people should be in the center of the decision-making process to reach a meaningful engagement. Furthermore, the WHO toolkit widens the possibilities of PA with the concept of “active recreation” comprising activities engaged in for the purpose of relaxation, health and well-being or enjoyment, with the primary activity requiring physical activity, which can include

for instance walking, Tai chi, hiking, social dancing. Last, but not least, the WHO highlights that group physical activity impacts also the social dimension of health, for example facilitating social relationships. In this line, several studies show how participating in organised group-based physical exercise programme effectively enhances social connections, leading to improvements in social relations [12, 13]

Despite current guidance, there has been very little focus on joy to promote healthy ageing and many PA and SB reduction programmes targeting older adults in community and NH are traditionally and overly focused on achieving health improvements[14,15]. Moreover, regardless of their ability to improve movement patterns and improve physical and cognitive outcomes, many programmes fail to maintain healthy behaviors over time[16]. Furthermore, those programmes struggle to reach those with low functional and cognitive abilities, as well as ethnical minorities and individuals from low socioeconomic backgrounds[17]. Therefore, a new frame is urgently required to promote PA for older adults contributing to life satisfaction, sense of purpose, and sense of role fulfilment by enhancing social connections and participation in activities that are joyful and meaningful[14,15].

In terms of behavior change, enjoyment is a strong motivator to adopt a new behavior. Specifically, anticipating a positive emotional outcomes of a future action has a significant influence on initiating and mantaining a new health-related behaviours[12]. Accordingly, emphasizing enjoyment, social inclusion and meaningfulness in PA may constitute a more effective approach in terms of behaviour change promotion and maintainance, than relying on traditional health-focused approaches.

A recent systematic review aimed at identifying components of enjoyable group-based PA interventions for older adults in the community included six studies designed to promote enjoyment and measuring enjoyment as outcome. The results showed that supportive trainers and peers created a shared positive experience where they built confidence and experienced courage and social support. [18]

Last, as already mentioned, the intervention strategy should involve tailoring activities to each individual's interests and preferences[18]. One of the processes that serves this aim is co-creation,[19] which consists of a process emerging from the participatory design paradigm which may impact health outcomes positively[20]. It shifts the design process from the traditional "top-down" health model to an inductive paradigm of shared leadership, enabling different stakeholders, including end-users, to take control over the content of the activities[21], and to be involved in their own health management and decision-making[22]. This process may help design PA programmes targeting the end-user's motivation to participate and enjoyment, while taking into account the context and feasibility to allow for sustainability.

Therefore, the JOIN4JOY European project, in a first stage, has co-created a programme that offers joyful and inclusive opportunities to become more physically active and reduce their time spent in SB for older people. The programme has been designed for two different settings: JOIN4JOY-Community (JOIN4JOY-C) and JOIN4JOY-Nursing Homes (JOIN4JOY-NH). The feasibility of this new model has not been previously evaluated.

Objectives

In this study, the research aim is to assess the feasibility of the intervention and the assessment tools and to explore staff and older peoples' acceptability of both. In parallel, we aim to refine recruitment, retention strategies and the delivery of the intervention, if necessary, and to provide data to estimate the parameters required to design a definitive RCT.

The specific objectives are:

1. To determine the degree of success of the programme applying the eligibility criteria, and in reaching the target population.

2. To assess participant uptake, adherence and retention.

3. To assess the feasibility of delivering the Join4Joy intervention for nursing home residents and community-dwelling older people in terms of fidelity to the intervention planned.

4. To explore older people's and staff acceptability of the Join4Joy intervention as well as the achieved levels satisfaction based on their programme experience.

5. To assess the feasibility and acceptability of the assessment tools.

6. To synthesize data to inform the sample size of a definitive trial.

METHODS

This protocol follows the updated MRC recommendations on the evaluation of complex intervention regarding feasibility studies[23], and it is also based on an adaptation of the Equator Guideline CONSORT 2010 statement[24]: extension to randomised pilot and feasibility trials.

Design

The JOIN4JOY PA programm will consist of a multicentric, pragmatic, feasibility study with a pre-post design. Programme assessment will follow a mixed-methods approach, with a combination of both quantitative and qualitative techniques.

Study setting

JOIN4JOY-C will be conducted in local, community-based facilities in Denmark, Italy and Spain. JOIN4JOY-NH will be conducted in NHs in Germany, France and Spain. Overall, the intervention will be tested in six intervention sites.
Two consecutive groups will be conducted, per site. Results from the first groups will inform the refinement of the second groups regarding recruitment, delivery and assessment tools.

Sample size

A specific sample size calculation based on a primary outcome measure has not been deemed necessary. A pragmatic sample size of at least 144 end-users, 72 users will be nursing home residents and 72 from the community, has been estimated. It is the result of two consecutive groups of 12 end-users, per each of the six intervention sites, and it has been considered as a

large enough sample to inform about the practicalities of recruitment, delivery and assessment.

Eligibility criteria

Participants eligible for inclusion in the study for the JOIN4JOY-C setting will be volunteers who meet the following criteria:

1. Being 65 years of age or above.
2. Living in the community.
3. Presenting no cognitive decline as per short form Mini-Mental State Examination (SMMSE)[25]
4. Not suffering from any reported or diagnosed health condition which would contraindicate physical exercise interventions.

Participants eligible for inclusion in the study for the JOIN4JOY-NH setting will be volunteers who meet the following criteria:

1. Being 65 years of age or above.
2. Living in a NH.
3. Having the ability to participate in group-based, structured PA.
4. Not sufferening from any reported or diagnosed health condition that contraindicates physical exercise interventions.
5. Absence of a severe dependence, in the form of severe (7 points in the Global Deterioration Scale of Reisberg[26] reported by professional caregivers) cognitive decline or severe mobility deficits, requiring being bed-bound.

In addition, to reach a target population with otherwise fewer opportunities to join PA programmes, inclusion priority will be given to:

a. older people who usually do not participate in PA programms.
b. participants with the highest access barriers, such as ethnic minorities or people from low socioeconomic backgrounds.
c. participants with reduced physical function (9 or less points in the Short Physical Performance Battery test)[27].

Recruitment procedures

Recruitment of participants will be as follows:

1. Participants will be selected among the settings at the premises of the participating organisations in Denmark, Italy and Spain for JOIN4JOY-C, and in Germany, France and Spain for JOIN4JOY-NH.
2. Healthcare and exercise professionals of the settings will be invited to participate, on a voluntary basis. The research team will conduct an informative session about the study aims, the recruitment and intervention stages.

3. The qualified staff in the institutions (e.g., NHs, community centres for older people) will be in charge of informing and recruiting participants through various channels, including leaflets, face-to-face information, brochures and posters in the community centres and local businesses.
4. Detailed participant information sheets explaining the programme and participation options in detail will be provided to the candidates. Each candidate will be asked to read and consider the information before signing the informed consent form. If unable to read, the form will be read and explained to them. Participants and legal guardians will have the opportunity to ask questions and receive answers about the programme. Legal guardians will be asked to sign the consent form for participants with cognitive impairment.
5. Throughout the intervention period, we will consistently prioritize and respect the voluntary participation of interested participants in every session, emphasizing their freedom of choice.

Intervention

The JOIN4JOY PA programme consists of an innovative, complex intervention based on a structured, group-based PA programme supervised by trained professionals, tailored to participants' needs, to include joyful components combined with self-management strategies to encourage behaviour change that expands beyond the sessions.

Participants will be offered one 1-hour session of structured, group-based, supervised PA, on a weekly basis, for 12 weeks. They will complementary be encouraged to hold more active lifestyles and engage in autonomous physical activity practice in their daily living. Group sessions will take place in the participant's nursing home or on the premises of collaborating community centres. Participants will be offered the possibility to join virtual communities of practice (VCoP) for additional social support and knowledge exchange. Local adjustments on top of this will be allowed as a means to encourage co-creation and participation processes. The phases of the JOIN4JOY PA programme are described in Figure 1 (below).

The design of the JOIN4JOY PA programme is the result of an extensive co-creation process conducted with professionals, researchers, policy makers, students, end-users and family members in the participating countries (i.e., Spain, Germany, Denmark, Italy, and France) between the end of 2022 and the beginning of 2023.
During the co-creation process, the JOIN4JOY team conducted several focus groups and in-depth interviews to gain insight on the needs and preferences of primary and secondary end-users of the programme. In JOIN4JOY-C, a total of 6 focus groups were consulted, involving 44 participants, of which 28 were end-users, 12 were professionals, 3 were policy makers and 1 was a student. For JOIN4JOY-NH, 54 participants (23 end-users, 17 professionals, 7 policy makers, 5 family members, and 2 students) were involved in 7 focus groups and 3 interviews. In parallel, opinions on education-related aspects were collected through 3 individualized interviews with experts of Academia, and 2 focus groups with 9 physical therapy and 5 sport

sciences students, respectively.

Overall, the co-creation process allowed the teams to identify various aspects related to PA, its access barriers and how to address them. Participants shared their experiences, discussing the challenges they faced in engaging in PA and identifying potential solutions. The inclusion of family members and students provided additional insights into the needs and expectations of older adults. The sessions also explored the concept of enjoyment, emphasizing the importance of incorporating elements that would make the programme fun and engaging for older adults. Participants also explored the ways to incorporate gamification elements to help motivate older adults' participation in PA. Their diverse perspectives allowed for a comprehensive exploration on the potential of the program. By discussing these ideas, the research team gained insight for the development of a JOIN4JOY PA programme framework that aims to maximise enjoyment and effectively promote behavioural change. Figure 1 (below) shows the phases of the JOIN4JOY PA programme.

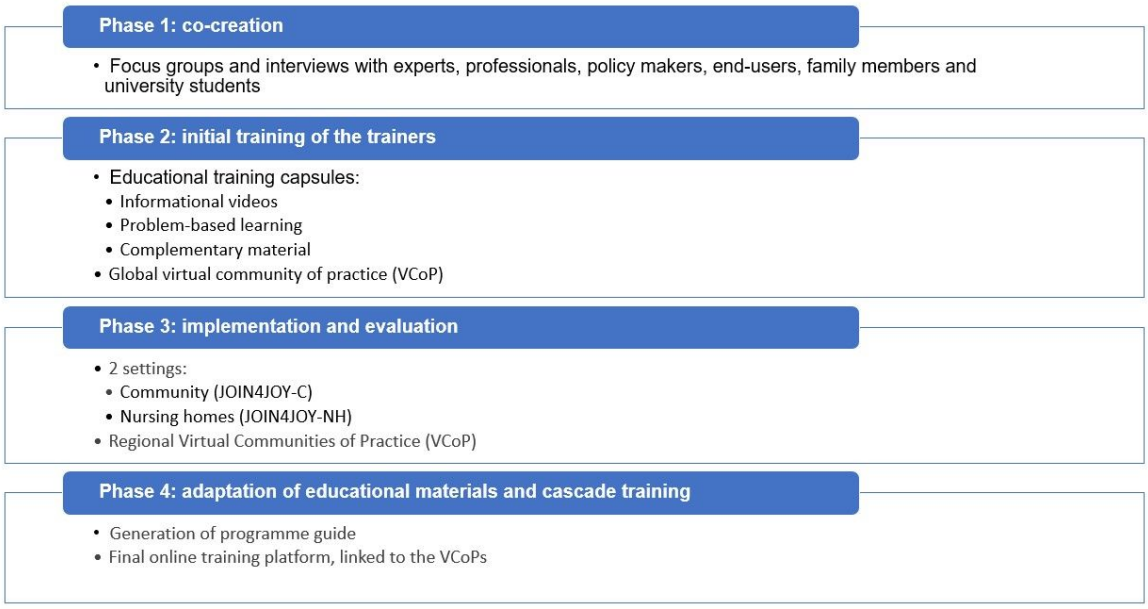

Figure 1. Phases of the JOIN4JOY PA programme.

Based on the results of the co-creation phase, a set of 9 core principles to the JOIN4JOY PA programme were established. Figure 2 shows the principles that emerged as key pillars for the programme.

Figure 2. The 9 core principles of the JOIN4JOY PA programme emerging from the co-creation phase.

These core principles serve as a foundation for the JOIN4JOY PA programme, ensuring that it is inclusive, tailored to individual needs, and focused on sustained engagement and well-being. Alongside, recommendations of potential activities and good practices were identified to be conducted to personalize the programme to the needs and preferences of the end users. Accordingly, the developed programme includes also a comprehensive list of different activities that trainers can choose from, implement and adapt as needed in their respective settings. These activities are designed to be flexible and person-centered, so that they can be customized to meet the unique needs and preferences of end-users. At the beginning of and during the programme, PA trainers are encouraged to review the activities with participants and select those that will be the most appropriate for the end-user's goals and interests and can be performed in their own facilities. This process will allow end-users to take an active role in their care and will ensure that the intervention will be tailored. The list of activities will serve as a starting point for trainers and will be further enriched during the project capturing further examples of practices.

PA trainers will be trained in a co-created educational course of 16 hours with theoretical and practical content that includes: a) Video-based, short capsules on physical activity, physical exercise and sedentary behaviour; the ageing process and its consequences; Join4Joy ground principles and framework for joyful and inclusive physical activity in older age; motivation and motivational interviewing; equity and social inclusion; introduction to behaviour change and self-management strategies; b) “Questions and answers” sessions to apply the theoretical contents to case studies, which will be specific of the local target population. Those trainers lacking previous academic education on PA will also be requested to follow additional capsules

on the basis of health-related physical fitness components and current guidelines on physical training for the older adult.

Undergraduate students of Physiotherapy and Sport Sciences from Spanish and Danish universities will also be invited to receive the training and will be offered placements and service-learning opportunities to take part in the delivery of the intervention, both in community and NH settings. By means of ad hoc questionnaires, participants' (including end-users, students and professionals) skills, knowledge and motivation towards behaviour change techniques, the JOIN4JOY educational training and ageing will be assessed. Complementarily, we will assess their satisfaction with the practice and skills acquisition in the intervention setting.

As a key component of the intervention, VCoPs will be developed for participant interaction, social connectiveness and knowledge exchange. At least one global VCoP in English language will be set up where trained professionals and students can interact to share their knowledge and practical experience implementing the programme, following their participation in the initial educational training. In each participating country, regional VCoPs in local language will be created for end-users to interact and share experience among themselves, with the support of moderators, during and after their participation in the PA programme intervention.

Patient and public involvement

End-users, family members, professionals, academics, policy makers, researchers and students were first involved in the co-creation of the intervention and the educational training in Autumn 2022 and Winter 2023. They will continue to be involved in the pilots to allow for an on-going optimization process. Their impression on acceptability of the intervention, including the burden and time required will be registered. Communication and dissemination activities will be undertaken in order to spread the JOIN4JOY PA programme. Recommendations on format and best channels for reaching the general public and similar target populations will be requested from the end-users.

Outcomes and assessment tools

Sociodemographic information such as sex, age, marital status or level of education, chronic conditions and unhealthy habits (smoking, alcohol) will be collected to characterize the sample. Other tools specific for JOIN4JOY-C and JOIN4JOY-NH are listed below.

Outcomes

The degree of sucess applying the elegibility criteria and the priority inclusion criteria will be quantitatively assessed with the sociodemographic data. This include reaching socially disadvantaged older population, i.e., people with traditionally reduced access to PA interventions such as individuals with low education, ethnic minorities, reduced mobility or low cognititve levels. Complementarily, recruitment staff and trainers will be interviewed qualitatively to explore the reasons for any deviation or sucess in this regard.

Assessment of participant uptake, adherence and retention will be measured by estimating recruitment rate (recruited vs informed individuals), adherence rate (number of sessions present vs absent) and retention (individuals completing the programme vs initially enroled). Additional collection of data will include reasons for non-attendance, number of and reasons

for drop-out, adverse events and degree of activity and interaction in the virtual communities of practice.

Feasibility of delivering the Join4Joy intervention will be assessed by considering the degree of fidelity comparing planned activities with actual implemented activities. A checklist will be developed to report on the conducted activities, session by session.

To test the acceptability of the programme for each of the settings, we will apply semi-structured interviews and focus groups based on the theoretical framework of acceptability (TFA)[28] defined by Sekhon et al., 2017. TFA describes acceptability as a multi-faceted construct which reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention. The TFA consists of seven constructs: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and self-efficacy.
For the qualitative procedures, a sample of diverse profiles of users and staff will be selected to explore their experiences and perceptions of the intervention.

Quantitatively, acceptability of the intervention will be determined assessing satisfaction of all involved actors (i.e., staff, students and older adults) measured via a 5-point-Likert-type scale [29] ranging from very satisfied to very unsatisfied.

Feasibility and acceptability of the assessment tools will be quantitatively assessed by analysing key outcome domains for completion rates, missing data, estimates, variances and 95% confidence intervals including physical function, quality of life, activities of daily living, lifestyle behaviours (including changes in SB and PA), self-reported health status and enjoyment assessed through questionnaires, functional tests and accelerometry. We will additionally ask qualitatively trainers and outcome assessors about their experience with the assessment tools. Together, these results shall constitute an indicator of adequacy of the assessment tools towards a definitive trial.

Measuring of key outcome domains will be carried out as follows:

a) Enjoyment will be assessed by asking participants to complete a Physical Activity Enjoyment Scale (PACES) – a questionnaire which measures what a person feels about the PA that they are doing[30].
b) Physical function will be assessed by using the Short Physical Performance Battery (SPPB) test before and after interventions. The scale consists of three different physical tests: gait speed, chair stand and balance tests[27]. Community settings will additionally collect data with the single leg stance test[31] and 2-Minute Walk Test[32].
c) Potential changes in quality of life and self-reported health status comparing this measure before and after interventions will be assessed by using the EUROQOL-5D scale, which assesses the quality of life in five different dimensions of daily living[33].
d) Perceived improvement after participating in the interventions will be assessed by using Patient Global Impression of Improvement (PGI-I) scale. The scale measures an improvement or a decline in clinical status[34].

e) PA and SB patterns will be measured using The Sedentary Behaviour Questionnaire (SBQ)[35] and the International Physical Activity Questionnaire-Short Form (IPAQ-SF)[36]. Complementary, some partners may use accelerometry-based measures with ActiGraph[37,38] devices and diaries of accelerometry.
f) Degree of awareness on sedentary behaviour and change techniques will be assessed with a yes/no question on perception of change.
g) Basic activities of daily living will be assessed in NH only by using the Barthel index, as modified by Shah[39] before and after implementation of the intervention.
h) The degree to which VCoPs fulfil objectives will be assesesed by means of the Sense of Community Index (SCI-2), which consists of 24 items and 4 domains: reinforcement of needs, membership, influence and shared emotional connection[40].

A synthesis of analysed data will be used to inform sample size, recruitment strategy, assesment and intervention methods of a definitive trial.

Data management

To ensure participant anonymisation, each participant in the programme will be allocated a distinctive study identification number that will be used in all paperwork and electronic databases. Electronic databases will be password-protected, while physical documents will be locked up. Informed consent forms will be kept separately from research data. The research team will have access to all data during and after the study, and the data will be available for monitoring as needed. All records will be kept for a minimum of five years.

Statistical methods

Quantitative data will be analysed descriptively and presented as means and standard deviations for continuous variables. When comparing the changes of the results of specific variables pre- and post-intervention either a t-test or a Rank-Wilcoxon test will be applied in accordance to the distribution of the data. Data analysis of variables will include estimates of change in activities of daily living, physical function, quality of life and SB. SPSS software platform (version 29.0) will be used for the analysis of the data. Qualitative data will be analysed using reflexive thematic analysis, following Braun and Clarke's (2006) steps[41].

Data monitoring

A data monitoring group will check upon the progress of the study and assess it at the beginning, during and after the intervention via online meetings. The data monitoring group will consist of the main researchers and other partners of the programme. The study will be open to audit as required.

Data sharing

Raw data supporting this article will be shared upon reasonable request, respecting legal and ethical considerations.

Harms

Serious adverse events are not expected during the study. However, should any adverse events occur, they will be recorded in databases, followed-up, and collected to ensure participant safety, monitor risks, and assess study acceptabilit. All of the study settings will have the necessary insurance policies to cover any harm that might be caused to participants during the time of the study.

Withdrawal from the study

Participants in the JOIN4JOY PA programme can discontinue to participate at any point in time, regardless of the reason. In order to maintain transparency and gather valuable feedback, we will kindly request that the participants provide us with the reason for discontinuation. This information is relevant for our records and programme analysis, as it helps us assess the acceptability of the programme and to make necessary adjustments.

ETHICS AND DISSEMINATION

Each partner will receive approval of the local ethical committee before start of the recruitment and intervention. All participants or their legal guardians will provide signed informed consent forms and will be free to withdraw from the intervention at any time. Moreover, informed consents will be signed between the JOIN4JOY partner members and the collaborating institutions, as well as with the participating older adults and students.

Results of the intervention will be disseminated through publication of scientific articles, presented at sport and health-related professional conferences and congresses, as well as presented in official JOIN4JOY website and social media.

REGULATORY APPROVAL

The Research Ethics Committee of the University of Vic (UVic-UCC) granted a favorable report (internal code nr. 233/2022), for the conduction of co-creation processes, on October 3rd, 2022. The intervention protocol described in this document received a favorable report by the same Committee, with internal code nr. 282/2023, on June 26th, 2023.
Trial registration number: https://clinicaltrials.gov/study/NCT06100835

STUDY STATUS

Recruitment at all sites is expected to start in November 2023 – January 2024.

Funding

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Competing interests None declared.

Patient and public involvement End-users, family members, professionals, academics, policy makers, researchers and students were involved in the design of the intervention and the design of the training to apply the intervention and will continue to be involved during the optimisation processes. The scientific and general public will be involved via dissemination and communication actions, throughout the development of the JOIN4JOY PA programme.

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Boosting enjoyment and social inclusion to increase physical activity and reduce sedentary behaviour among older adults: protocol for a feasibility study to test the JOIN4JOY approach in five European countries

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ABSTRACT

Introduction: Programmes for older people aimed at increasing physical activity (PA) and reducing sedentary behaviour (SB) traditionally focus on achieving functional and health improvements. Focusing on enjoyment and social inclusion could strengthen adherence and help reach older people with social disadvantages. The aim of this study is to assess the feasibility and acceptability of the JOIN4JOY approach in PA programmes and its assessments tools.

Methods and analysis: A multicentric, pragmatic, pre-post feasibility study using mixed methods will be conducted. The intervention will consist of a PA programme boosting enjoyment and social inclusion, grounded on a co-creation process. Trainers will offer 1-hour weekly sessions of group-based, structured, supervised PA for three months. Participants will be encouraged to increase activity in daily living. 144 older people will be recruited from the community and nursing homes in Spain, Denmark, Italy, Germany, and France. Additionally, participants and trainers will be invited to join virtual communities of practice to share their experiences across settings and countries. Qualitative procedures will be used to explore the acceptability of the design via interviews and focus groups with participants and trainers. Quantitative methods will be used to assess uptake, adherence, retention, reach, satisfaction, enjoyment (PACES questionnaire), physical function (e.g., Short Physical Performance Battery), quality of life (EQ-5D-5L scale), perceived improvement (Patient Global Impression of Improvement scale-I), activities of daily living (Barthel index), SB and PA patterns (IPAQ+ and accelerometery). The degree and type of participation in virtual communities of practice will be also assessed. SPSS software will be used for the analysis of quantitative variables with paired t-tests. Qualitative data will be analysed using reflective thematic analysis following Braun and Clarke, 2006.

Ethics and dissemination: A favourable report by the Research Ethics Committee of UVic-UCC (282/2023) was obtained on June 26th, 2023. Participation and withdrawal will be voluntary. Participants' (or their legal guardians', when necessary) written permission will be required. Results of the study will be disseminated through publication of scientific articles, presentation at sport and health-related professional conferences and congresses, and presentation via the JOIN4JOY website and social media.

Study registration: ClinicalTrials.gov, NCT06100835.

Strengths and limitations of this study

► The JOIN4JOY PA programme is focused on enjoyment and social inclusion and its design is the result of a co-creation process conducted with professionals, students, older people living in the community and nursing homes, family members and researchers in Spain, Germany, Denmark, Italy and France.

► This is a pragmatic study aimed at assessing the feasibility and acceptability of J4J intervention and evaluation design using mixed (qualitative and quantitative) methods.

► One of the main limitations of the study is the lack of control groups.

► Results and conclusions that derive from this feasibility study will inform the design of a future randomised controlled trial.

INTRODUCTION

Background and rationale

The older adult population is experiencing the most rapid growth among all age groups[1]. As people age, they become more susceptible to physical and cognitive decline, chronic illnesses, and comorbidities[2]. This poses a challenge for managing the rising health and social care needs that come with an ageing population and increased disease burden. As a result, it is recommended to plan and implement sustainable preventive programmes to address these challenges[3].

Regular physical activity (PA) is known to have many health benefits and to help prevent negative health outcomes, such as functional limitations and disease[4]. Likewise, insufficient levels of PA have been consistently linked to poor health outcomes[4].

Furthermore, sedentary behaviour (SB), defined as any non-sleeping activity with a low energy expenditure (< 1.5 metabolic equivalent) performed while sitting, reclining or lying[5], has significantly increased over the past 30 years, and this trend is particularly evident as people age[6].

Insufficient PA and excessive SB are associated with social, physical and mental health-related issues: older individuals with lower levels of PA and those who spend more time sitting during their daily activities tend to self-report worse general health states than their more active and less sedentary counterparts[7]. However, a recent study found that older adults living in the community spend a significant (78.8%) portion of their waking hours engaging in SB, with only a small percentage of time spent in light-intensity (18.6%) and moderate-to-vigorous (2.6%) PA[8]. A similar pattern was observed in a study by Parry et al., conducted in 2019, which focused on nursing home (NH) residents. The study found that residents spent most (85%) of their time being sedentary, with only a small portion of time spent in light-intensity (14%) and moderate-to-vigorous (1%) PA[9].

It is widely known that engaging in regular PA is a highly effective non-pharmacological approach to prevent and manage non-communicable diseases and that more active individuals generally experience healthier ageing trajectories[10,11].

Currently, the WHO has launched ‘Promoting physical activity for older people: a toolkit for action’ emphasizing, among others, that enjoyable opportunities to conduct PA supports engagement of older people. Specifically, it mentions that PA groups, once adapted to the abilities of participants to ensure inclusivity, can be a source of enjoyment and building confidence, which are key to overcoming the barrier that PA is “not for them”. Thus, encouraging inactive older people to join PA programmes they would normally refuse. Moreover, WHO points out that the design of PA programmes should be informed by goals, needs and preferences of older people to increase its effectiveness. Accordingly, older people should be in the centre of the decision-making process to reach a meaningful engagement. Furthermore, the WHO toolkit widens the possibilities of PA with the concept of “active recreation” comprising activities engaged in for the purpose of relaxation, health and well-being or enjoyment, with the primary activity requiring physical activity, which can include

for instance walking, Tai chi, hiking, social dancing. Last, but not least, the WHO highlights that group physical activity impacts also the social dimension of health, for example facilitating social relationships. In this line, several studies show how participating in organised group-based physical exercise programme effectively enhances social connections, leading to improvements in social relations [12, 13]

Despite current guidance, there has been very little focus on joy to promote healthy ageing and many PA and SB reduction programmes targeting older adults in community and NH are traditionally and overly focused on achieving health improvements[14,15]. Moreover, regardless of their ability to improve movement patterns and improve physical and cognitive outcomes, many programmes fail to maintain healthy behaviours over time[16]. Furthermore, those programmes struggle to reach those with low functional and cognitive abilities, as well as ethnical minorities and individuals from low socioeconomic backgrounds[17]. Therefore, a new frame is urgently required to promote PA for older adults contributing to life satisfaction, sense of purpose, and sense of role fulfilment by enhancing social connections and participation in activities that are joyful and meaningful[14,15].

In terms of behaviour change, enjoyment is a strong motivator to adopt a new behaviour. Specifically, anticipating a positive emotional outcome of a future action has a significant influence on initiating and maintaining a new health-related behaviours[12]. Accordingly, emphasizing enjoyment, social inclusion and meaningfulness in PA may constitute a more effective approach in terms of behaviour change promotion and maintenance, than relying on traditional health-focused approaches.

A recent systematic review aimed at identifying components of enjoyable group-based PA interventions for older adults in the community included six studies designed to promote enjoyment and measuring enjoyment as outcome. The results showed that supportive trainers and peers created a shared positive experience where they built confidence and experienced courage and social support. [18]

Last, as already mentioned, the intervention strategy should involve tailoring activities to each individual's interests and preferences[18]. One of the processes that serves this aim is co-creation,[19] which consists of a process emerging from the participatory design paradigm which may impact health outcomes positively[20]. It shifts the design process from the traditional "top-down" health model to an inductive paradigm of shared leadership, enabling different stakeholders, including end-users, to take control over the content of the activities[21], and to be involved in their own health management and decision-making[22]. This process may help design PA programmes targeting the end-user's motivation to participate and enjoyment, while taking into account the context and feasibility to allow for sustainability.

Therefore, the JOIN4JOY European project, in a first stage, has co-created a programme that offers joyful and inclusive opportunities to become more physically active and reduce their time spent in SB for older people. The programme has been designed for two different settings: JOIN4JOY-Community (JOIN4JOY-C) and JOIN4JOY-Nursing Homes (JOIN4JOY-NH). The feasibility of this new model has not been previously evaluated.

Objectives

In this study, the research aim is to assess the feasibility of the intervention and the assessment tools and to explore staff and older peoples' acceptability of both. In parallel, we aim to refine recruitment, retention strategies and the delivery of the intervention, if necessary, and to provide data to estimate the parameters required to design a definitive RCT.

The specific objectives are:

1. To determine the degree of success of the programme applying the eligibility criteria, and in reaching the target population.

2. To assess participant uptake, adherence and retention.

3. To assess the feasibility of delivering the Join4Joy intervention for nursing home residents and community-dwelling older people in terms of fidelity to the intervention planned.

4. To explore older people's and staff acceptability of the Join4Joy intervention as well as the achieved levels satisfaction based on their programme experience.

5. To assess the feasibility and acceptability of the assessment tools.

6. To synthesize data to inform the sample size of a definitive trial.

METHODS AND ANALYSIS

This protocol follows the updated MRC recommendations on the evaluation of complex intervention regarding feasibility studies[23], and it is also based on SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials)[24] and an adaptation of the Equator Guideline CONSORT 2010 statement[25]: extension to randomised pilot and feasibility trials.

Design

The JOIN4JOY PA programme will consist of a multicentric, pragmatic, feasibility study with a pre-post design. Programme assessment will follow a mixed-methods approach, with a combination of both quantitative and qualitative techniques.

Study setting

JOIN4JOY-C will be conducted in local, community-based facilities in Denmark, Italy and Spain. JOIN4JOY-NH will be conducted in NHs in Germany, France and Spain. Overall, the intervention will be tested in six intervention sites.
Two consecutive groups will be conducted, per site. Results from the first groups will inform the refinement of the second groups regarding recruitment, delivery and assessment tools.

Sample size

A specific sample size calculation based on a primary outcome measure has not been deemed necessary. A pragmatic sample size of at least 144 end-users, 72 users will be nursing home residents and 72 from the community, has been estimated. It is the result of two consecutive

groups of 12 end-users, per each of the six intervention sites, and it has been considered as a large enough sample to inform about the practicalities of recruitment, delivery and assessment.

Eligibility criteria

Participants eligible for inclusion in the study for the JOIN4JOY-C setting will be volunteers who meet the following criteria:

1. Being 65 years of age or above.
2. Living in the community.
3. Presenting no cognitive decline as per short form Mini-Mental State Examination (SMMSE)[26]
4. Not suffering from any reported or diagnosed health condition which would contraindicate physical exercise interventions.

Participants eligible for inclusion in the study for the JOIN4JOY-NH setting will be volunteers who meet the following criteria:

1. Being 65 years of age or above.
2. Living in a NH.
3. Having the ability to participate in group-based, structured PA.
4. Not suffering from any reported or diagnosed health condition that contraindicates physical exercise interventions.
5. Absence of a severe dependence, in the form of severe (7 points in the Global Deterioration Scale of Reisberg[27] reported by professional caregivers) cognitive decline or severe mobility deficits, requiring being bed-bound.

In addition, to reach a target population with otherwise fewer opportunities to join PA programmes, inclusion priority will be given to:

a. older people who usually do not participate in PA programmes.
b. participants with the highest access barriers, such as ethnic minorities or people from low socioeconomic backgrounds.
c. participants with reduced physical function (9 or less points in the Short Physical Performance Battery test)[28].

Recruitment procedures

Recruitment of participants will be as follows:

1. Participants will be selected among the settings at the premises of the participating organisations in Denmark, Italy and Spain for JOIN4JOY-C, and in Germany, France and Spain for JOIN4JOY-NH.
2. Healthcare and exercise professionals of the settings will be invited to participate, on a voluntary basis. The research team will conduct an informative session about the study aims, the recruitment and intervention stages.

3. The qualified staff in the institutions (e.g., NHs, community centres for older people) will be in charge of informing and recruiting participants through various channels, including leaflets, face-to-face information, brochures and posters in the community centres and local businesses.
4. Detailed participant information sheets explaining the programme and participation options in detail will be provided to the candidates. Each candidate will be asked to read and consider the information before signing the informed consent form. If unable to read, the form will be read and explained to them. Participants and legal guardians will have the opportunity to ask questions and receive answers about the programme. Legal guardians will be asked to sign the consent form for participants with cognitive impairment.
5. Throughout the intervention period, we will consistently prioritize and respect the voluntary participation of interested participants in every session, emphasizing their freedom of choice.

Intervention

The JOIN4JOY PA programme consists of an innovative, complex intervention based on a structured, group-based PA programme supervised by trained professionals, tailored to participants' needs, to include joyful components combined with self-management strategies to encourage behaviour change that expands beyond the sessions.

Participants will be offered one 1-hour session of structured, group-based, supervised PA, on a weekly basis, for 12 weeks. They will complementary be encouraged to hold more active lifestyles and engage in autonomous physical activity practice in their daily living. Group sessions will take place in the participant's nursing home or on the premises of collaborating community centres. Participants will be offered the possibility to join virtual communities of practice (VCoP) for additional social support and knowledge exchange. Local adjustments on top of this will be allowed as a means to encourage co-creation and participation processes. The phases of the JOIN4JOY PA programme are described in Figure 1.

The design of the JOIN4JOY PA programme is the result of an extensive co-creation process conducted with professionals, researchers, policy makers, students, end-users and family members in the participating countries (i.e., Spain, Germany, Denmark, Italy, and France) between the end of 2022 and the beginning of 2023.
During the co-creation process, the JOIN4JOY team conducted several focus groups and in-depth interviews to gain insight on the needs and preferences of primary and secondary end-users of the programme. In JOIN4JOY-C, a total of 6 focus groups were consulted, involving 44 participants, of which 28 were end-users, 12 were professionals, 3 were policy makers and 1 was a student. For JOIN4JOY-NH, 54 participants (23 end-users, 17 professionals, 7 policy makers, 5 family members, and 2 students) were involved in 7 focus groups and 3 interviews. In parallel, opinions on education-related aspects were collected through 3 individualized interviews with experts of Academia, and 2 focus groups with 9 physical therapy and 5 sport

sciences students, respectively.

Overall, the co-creation process allowed the teams to identify various aspects related to PA, its access barriers and how to address them. Participants shared their experiences, discussing the challenges they faced in engaging in PA and identifying potential solutions. The inclusion of family members and students provided additional insights into the needs and expectations of older adults. The sessions also explored the concept of enjoyment, emphasizing the importance of incorporating elements that would make the programme fun and engaging for older adults. Participants also explored the ways to incorporate gamification elements to help motivate older adults' participation in PA. Their diverse perspectives allowed for a comprehensive exploration of the programme's potential. By discussing these ideas, the research team gained insight for the development of a JOIN4JOY PA programme framework that aims to maximise enjoyment and effectively promote behavioural change. Figure 1 shows the phases of the JOIN4JOY PA programme.

Based on the results of the co-creation phase, a set of nine core principles to the JOIN4JOY PA programme were established. Figure 2 shows the principles that emerged as key pillars for the programme.

These core principles serve as a foundation for the JOIN4JOY PA programme, ensuring that it is inclusive, tailored to individual needs, and focused on sustained engagement and well-being. Alongside, recommendations of potential activities and good practices were identified to be conducted to personalize the programme to the needs and preferences of the end users. Accordingly, the developed programme includes also a comprehensive list of different activities that trainers can choose from, implement and adapt as needed in their respective settings. These activities are designed to be flexible and person-centred, so that they can be customized to meet the unique needs and preferences of end-users. At the beginning of and during the programme, PA trainers are encouraged to review the activities with participants and select those that will be the most appropriate for the end-user's goals and interests and can be performed in their own facilities. This process will allow end-users to take an active role in their care and will ensure that the intervention will be tailored. The list of activities will serve as a starting point for trainers and will be further enriched during the project capturing further examples of practices.

PA trainers will be trained in a co-created educational course of 16 hours with theoretical and practical content that includes: a) Video-based, short capsules on physical activity, physical exercise and sedentary behaviour; the ageing process and its consequences; Join4Joy ground principles and framework for joyful and inclusive physical activity in older age; motivation and motivational interviewing; equity and social inclusion; introduction to behaviour change and self-management strategies; b) "Questions and answers" sessions to apply the theoretical contents to case studies, which will be specific of the local target population. Those trainers lacking previous academic education on PA will also be requested to follow additional capsules on the basis of health-related physical fitness components and current guidelines on physical training for the older adult.

Undergraduate students of Physiotherapy and Sport Sciences from Spanish and Danish universities will also be invited to receive the training and will be offered placements and service-learning opportunities to take part in the delivery of the intervention, both in community and NH settings. By means of ad hoc questionnaires, participants' (including end-

users, students and professionals) skills, knowledge and motivation towards behaviour change techniques, the JOIN4JOY educational training and ageing will be assessed. Complementarily, we will assess their satisfaction with the practice and skills acquisition in the intervention setting.

As a key component of the intervention, VCoPs will be developed for participant interaction, social connectiveness and knowledge exchange. At least one global VCoP in English language will be set up where trained professionals and students can interact to share their knowledge and practical experience implementing the programme, following their participation in the initial educational training. In each participating country, regional VCoPs in local language will be created for end-users to interact and share experience among themselves, with the support of moderators, during and after their participation in the PA programme intervention.

Patient and public involvement

End-users, family members, professionals, academics, policy makers, researchers and students were first involved in the co-creation of the intervention and the educational training in Autumn 2022 and Winter 2023. They will continue to be involved in the pilots to allow for an on-going optimization process. Their impression on acceptability of the intervention, including the burden and time required will be registered. Communication and dissemination activities will be undertaken in order to spread the JOIN4JOY PA programme. Recommendations on format and best channels for reaching the general public and similar target populations will be requested from the end-users.

Outcomes and assessment tools

Sociodemographic information such as sex, age, marital status or level of education, chronic conditions and unhealthy habits (smoking, alcohol) will be collected to characterize the sample. Other tools specific for JOIN4JOY-C and JOIN4JOY-NH are listed below.

The degree of success applying the eligibility criteria and the priority inclusion criteria will be quantitatively assessed with the sociodemographic data. This include reaching socially disadvantaged older population, i.e., people with traditionally reduced access to PA interventions such as individuals with low education, ethnic minorities, reduced mobility or low cognitive levels. Complementarily, recruitment staff and trainers will be interviewed qualitatively to explore the reasons for any deviation or success in this regard.

Assessment of participant uptake, adherence and retention will be measured by estimating recruitment rate (recruited vs informed individuals), adherence rate (number of sessions present vs absent) and retention (individuals completing the programme vs initially enrolled). Additional collection of data will include reasons for non-attendance, number of and reasons for drop-out, adverse events and degree of activity and interaction in the virtual communities of practice.

Feasibility of delivering the Join4Joy intervention will be assessed by considering the degree of fidelity comparing planned activities with actual implemented activities. A checklist will be developed to report on the conducted activities, session by session.

To test the acceptability of the programme for each of the settings, we will apply semi-

structured interviews and focus groups based on the theoretical framework of acceptability (TFA)[29] defined by Sekhon et al., 2017. TFA describes acceptability as a multi-faceted construct which reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention. The TFA consists of seven constructs: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and self-efficacy.

For the qualitative procedures, a sample of diverse profiles of users and staff will be selected to explore their experiences and perceptions of the intervention.

Quantitatively, acceptability of the intervention will be determined assessing satisfaction of all involved actors (i.e., staff, students and older adults) measured via a 5-point-Likert-type scale [30] ranging from very satisfied to very unsatisfied.

Feasibility and acceptability of the assessment tools will be quantitatively assessed by analysing key outcome domains for completion rates, missing data, estimates, variances and 95% confidence intervals including physical function, quality of life, activities of daily living, lifestyle behaviours (including changes in SB and PA), self-reported health status and enjoyment assessed through questionnaires, functional tests and accelerometery. We will additionally ask qualitatively trainers and outcome assessors about their experience with the assessment tools. Together, these results shall constitute an indicator of adequacy of the assessment tools towards a definitive trial.

Measuring of key outcome domains will be carried out as follows:

a) Enjoyment will be assessed by asking participants to complete a Physical Activity Enjoyment Scale (PACES) – a questionnaire which measures what a person feels about the PA that they are doing[31].

b) Physical function will be assessed by using the Short Physical Performance Battery (SPPB) test before and after interventions. The scale consists of three different physical tests: gait speed, chair stand and balance tests[28]. Community settings will additionally collect data with the single leg stance test[32] and 2-Minute Walk Test[33].

c) Potential changes in quality of life and self-reported health status comparing this measure before and after interventions will be assessed by using the EUROQOL-5D scale, which assesses the quality of life in five different dimensions of daily living[34].

d) Perceived improvement after participating in the interventions will be assessed by using Patient Global Impression of Improvement (PGI-I) scale. The scale measures an improvement or a decline in clinical status[35].

e) PA and SB patterns will be measured using The Sedentary Behaviour Questionnaire (SBQ)[36] and the International Physical Activity Questionnaire-Short Form (IPAQ-SF)[37]. Complementary, some partners may use accelerometery-based measures with ActiGraph[38,39] devices and diaries of accelerometery.

f) Degree of awareness on sedentary behaviour and change techniques will be assessed with a yes/no question on perception of change.

g) Basic activities of daily living will be assessed in NH only by using the Barthel index, as modified by Shah[40] before and after implementation of the intervention.

h) The degree to which VCoPs fulfil objectives will be assessed by means of the Sense of Community Index (SCI-2), which consists of 24 items and 4 domains: reinforcement of needs, membership, influence and shared emotional connection[41].

A synthesis of analysed data will be used to inform sample size, recruitment strategy, assessment and intervention methods of a definitive trial.

Data management

To ensure participant anonymisation, each participant in the programme will be allocated a distinctive study identification number that will be used in all paperwork and electronic databases. Electronic databases will be password-protected, while physical documents will be locked up. Informed consent forms will be kept separately from research data. The research team will have access to all data during and after the study, and the data will be available for monitoring as needed. All records will be kept for a minimum of five years.

Data analysis methods

This study uses mixed methods research, thus combining qualitative and quantitative approaches in a single study, motivated by the need to address a complex research question. Accordingly, we will be able to provide a more comprehensive and nuanced understanding of our research topic involving a complex intervention aimed at impacting several interrelated human behaviours and subjective states (e.g. PA, SB, enjoyment, inclusion). Quantitative and qualitative results will be used complementarily to offer a richer and deeper data set that can capture the diversity and complexity of these research phenomena, thus increasing not only the trustworthiness, but also enhancing the interpretation and understanding of its results. However, it can also present several challenges. From the researchers' perspective, these challenges can range from the need for more time, resources, skills on both methodologies, or expertise to plan, implement, and report the research, to ethical, practical, or theoretical issues related to the sampling, data collection, data analysis, or data integration[42]. Moreover, while results obtained might be aligned, some results might reach different conclusions and specific aspects are only explored with one methodology. Thus, overall results will be more comprehensive than using one single methodology.

Quantitative data will be analysed descriptively and presented as means and standard deviations for continuous variables. When comparing the changes of the results of specific variables pre- and post-intervention either a t-test or a Rank-Wilcoxon test will be applied in accordance to the distribution of the data. Data analysis of variables will include estimates of change in activities of daily living, physical function, quality of life and SB. To measure the effect size of pre-test and post-test measurements for one group, Cohen's d will be calculated. This involves determining the mean difference between the pre-test and post-test scores and then dividing this by the standard deviation of the differences. This effect size provides a standardized measure of the intervention's impact, with values typically interpreted as small (0.2), medium (0.5), and large (0.8) effects, thus offering a clear indication of the magnitude

of change resulting from the intervention[43]. SPSS software platform (version 29.0) will be used for the analysis of the data.

Qualitative data will be derived from semi-structured interviews and focus groups with a diverse sample of participants, including users and staff. This approach will help explore their experiences and perceptions of the intervention in-depth. Qualitative information will be analysed using reflexive thematic analysis, following Braun and Clarke's (2006) steps[44]. Firstly, an edited transcription approach to the audio recorded interviews will be employed to facilitate smoother reading experience, comprehension and analysis by increasing accessibility and clarity of the information while retaining the essence and meaning of the original audio content. Listening to audio recordings and reading transcripts will be followed by rereading and making notes to become familiar with the data (phase 1). The next step will involve generating codes (phase 2). The software NVivo version 12 will be used to organise and manage the data. Once all transcripts are coded themes will be generated from the coded data by grouping together similar codes (phase 3). Initial themes will be reviewed and updated in an iterative process whereby themes may be expanded by incorporating more codes or collapsed by removing codes when they appear to have a better fit with other themes (phase 4). Critical discussion between the research team will occur to further refine the theoretical framework and to define and name the themes (phase 5). Once themes have been generated and purposeful selection of extracts have been finalised the write up of the report will commence (phase 6).

Data monitoring

A data monitoring group will check upon the progress of the study and assess it at the beginning, during and after the intervention via online meetings. The data monitoring group will consist of the main researchers and other partners of the programme. The study will be open to audit as required.

Data sharing

Raw data supporting this article will be shared upon reasonable request, respecting legal and ethical considerations.

Harms

Serious adverse events are not expected during the study. However, should any adverse events occur, they will be recorded in databases, followed-up, and collected to ensure participant safety, monitor risks, and assess study acceptability. All study settings will have the necessary insurance policies to cover any harm that might be caused to participants during the time of the study.

Withdrawal from the study

Participants in the JOIN4JOY PA programme can discontinue to participate at any point in time, regardless of the reason. In order to maintain transparency and gather valuable feedback,

we will kindly request that the participants provide us with the reason for discontinuation. This information is relevant for our records and programme analysis, as it helps us assess the acceptability of the programme and to make necessary adjustments.

ETHICS AND DISSEMINATION

The Research Ethics Committee of the University of Vic (UVic-UCC) granted a favorable report (internal code nr. 233/2022), for the conduction of co-creation processes, on October 3rd, 2022. The intervention protocol described in this document received a favorable report by the same Committee, with internal code nr. 282/2023, on June 26th, 2023. The study is registered at ClinicalTrials.gov (NCT06100835).

Each partner will receive approval of the local ethical committee before start of the recruitment and intervention. Any substantial modifications to the protocol will be promptly communicated to the ethics committee and regulatory authorities.
All participants or their legal guardians will provide signed informed consent forms (supplemental file) and will be free to withdraw from the intervention at any time. Moreover, informed consents will be signed between the JOIN4JOY partner members and the collaborating institutions, as well as with the participating older adults and students.

Results of the study will be disseminated through publication of scientific articles, presentation at sport and health-related professional conferences and congresses, and presentation via the JOIN4JOY website and social media.

Study status

Recruitment at all sites will be conducted between November 2023 and October 2024. The intervention phase will take place between December 2023 and January 2025. Data analysis will be performed between May 2024 and April 2025.

Contributors

LC-P and AF-V substantially and equally contributed to the conception and design of the work as well as the drafting and revising of the manuscript (including the proposal for the ethics committee); both also finally approved the version to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. JJ-R and MG-G contributed to the study conception and design of the work, writing and revising the work critically for important intellectual content; both also finally approved the version to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. EK contributed to the conception and design of the work as well as the drafting and revising of the manuscript (including the proposal for the ethics committee); she also finally approved the version to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. MR-M, AI, PC, MS, DD, GL, LB, DF, RC-P, EM-M, CP-M, SB-A, BR-V, JLS-C, AN-G and OS-N contributed to the conception and design of the work as well as the drafting and revising of the manuscript; they also finally approved the version to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Competing interests

None declared.

Patient consent for publication

Not applicable.

Provenance and peer review

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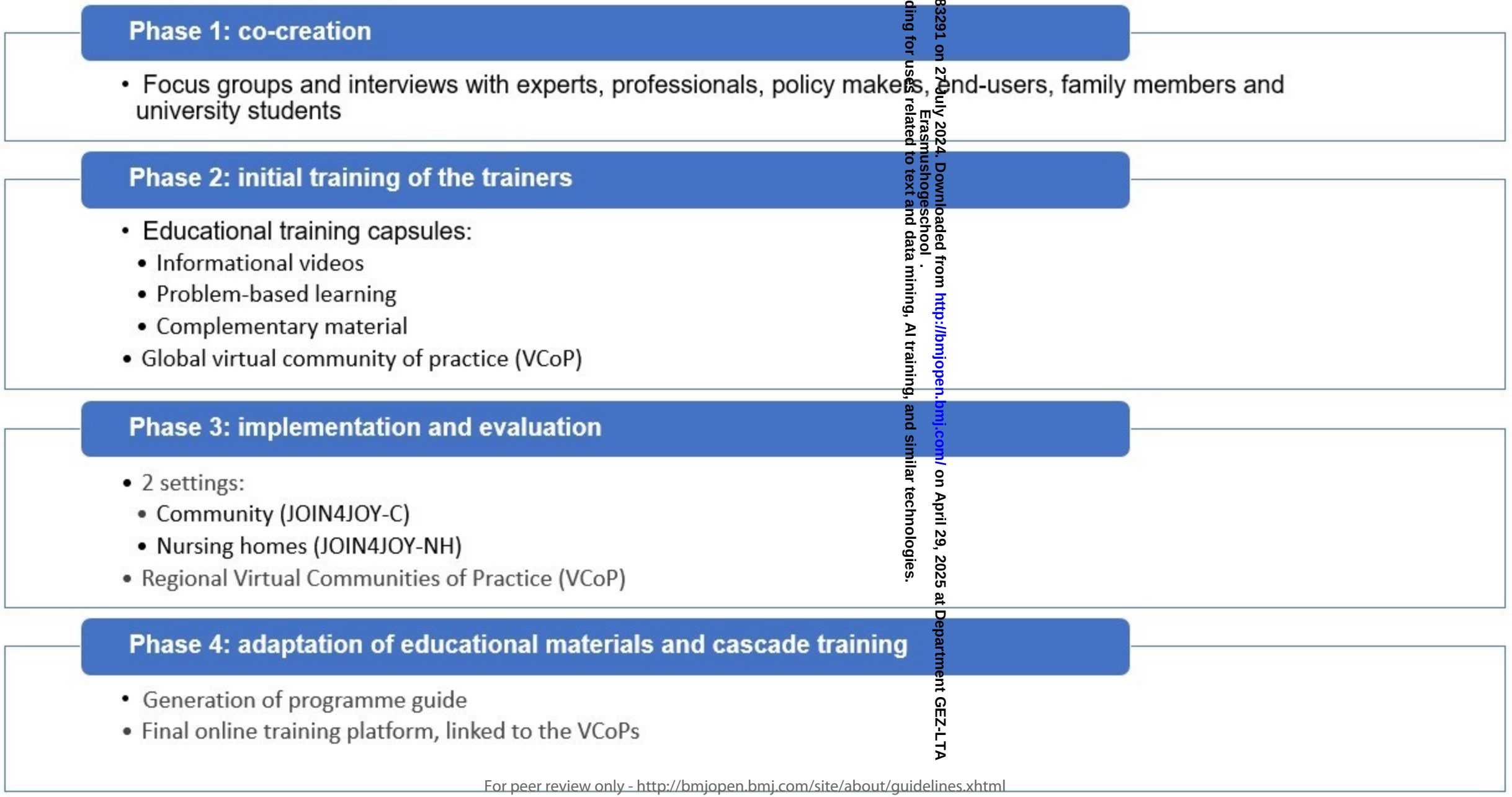
FIGURE LEGENDS

Figure 1. Phases of the JOIN4JOY PA programme

Figure 2. The nine core principles of the JOIN4JOY PA programme emerging from the co-creation phase



INFORMACIÓN PARA LOS USUARIOS

Título del Proyecto: Disfruta de la actividad física para combatir el sedentarismo y la inactividad entre gente mayor, desde una perspectiva inclusiva. Proyecto *Join4Joy*.

Estimado usuario:

Me llamo Dra. Laura Coll, y soy la investigadora responsable del proyecto con lema "únase para disfrutar". Se trata de un proyecto financiado por la Unión Europea, en el que participan cinco países diferentes, incluido el nuestro. Nuestro **propósito** es desarrollar actividades que fomenten una vida más saludable a través de disfrutar de la actividad física. Para ello hemos recogido información de más de 100 personas, que nos han compartido qué consideran ellos importante incluir. A continuación le explicamos en qué consiste por si desea unirse y participar. Al final del documento dispone de mis datos de contacto por si desea realizar cualquier consulta adicional.

En qué consistirá: Entre los meses de septiembre y diciembre 2023, nos reuniremos en la residencia 1 vez por semana para realizar un programa de actividades grupales, lideradas por un especialista. Además, se le propondrán otras actividades para que pueda usted realizar de manera independiente, o junto con alguna persona cercana, al menos otro día por semana.

Requisitos para participar: tener 65 años o más, no presentar deterioro cognitivo severo y poder participar en actividades grupales.

Participar en el estudio implica para usted:

1. Acudir a la actividad grupal [*especificar el día de la semana, hora de comienzo y hora de fin]*. También le propondremos que realice algo de movimiento, en uno o más de sus días libres.
2. Una cita inicial con el instructor para conocer sus preferencias.

Antes de comenzar, y también al terminar, le preguntaremos y haremos algunas valoraciones sencillas sobre su salud y hábitos de vida, de manera que podamos evaluar los efetos del programa. Al finalizar cada sesión le preguntaremos si le ha gustado y transcurridos los 3 meses es posible que le invitemos a una entrevista para conocer mejor su punto de vista.

Beneficios por participar: Es probable que participar ayude a que se sienta mejor física, mental y emocionalmente.

Riesgos y/o inconvenientes: Las actividades se adaptarán a su nivel de capacidad y no esperamos efectos adversos. No obstante, contamos con seguros y mecanismos adecuados para manejar cualquier imprevisto de salud, si sucediera.

Compensación económica: Actividad gratuita sin remuneración.

Confidencialidad y Almacenamiento de la Información: Sus datos personales se transformarán en código numérico (anonimización) para que la información no resulte identificable. El fichero original será custodiado en una base de datos científica, por nuestro centro coordinador en España, la Universidad de Vic. El acceso estará restringido, y será de uso exclusivo para los investigadores. Se respetarán en todo momento los derechos que establece la Ley orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales si el Reglamento general (UE) 2016/679, de 27 de abril de 2016 de protección de datos y normativa complementaria. Igualmente, se cumplirá con la regulación europea de datos personales (General Data Protection Regulation 2016/679/EC y sus enmiendas), así como a la directiva de privacidad en el sector de las comunicaciones electrónicas (E privacy directive 2002/58/EC). Para cualquier reclamación, podrá usted dirigirse al Delegado de Protección de Datos (DPD) de la UVic-UCC, máximo responsable en la universidad.

Si decide participar en el proyecto, usted se compromete a no revelar lo declarado por otras personas durante las entrevistas, y cumplir así con los debidos requisitos de confidencialidad en la investigación.

Derecho a negarse o retirarse: La participación es voluntaria. Si en algún momento quisiera retirarse, puede hacerlo sin compromiso. Solicitaremos una breve explicación para el registro documental, pero no tendrá ningún efecto negativo en la atención que usted reciba.

Datos del responsable:

Dra. Laura Coll Planas, PhD
Universidad de Vic, Universidad Central de Catalunya
Facultat de Ciéncies de la Salut i el Benestar.
C. Sagrada Família, 7. 08500 Vic.
Teléfonos: xxxxxxxxxxx
Correo electrónico: xxxxxxxxx

CONSENTIMIENTO INFORMADO PARA USUARIO FINAL

Yo, _____*(aquí el nombre de usted)*, mayor de edad, con Nº de identificación *nª*_____ , como usuario interesado o en su caso como familiar/asistente del usuario interesado D/Dª: _____*(nombre del usuario)*.

DECLARO QUE: He recibido información sobre el proyecto Join4Joy ("únase y disfrute"). Se me ha hecho entrega de un documento informativo, en el que se solicita mi participación. He podido entenderlo y aclarar las dudas que me hayan surgido durante su lectura.

Entiendo que el proyecto cumple con todos los requisitos de confidencialidad y protección de datos personales que conlleva el proyecto, y las garantías dadas en cumplimiento de la Ley orgánica 3/2018, de 5 de diciembre, de protección de datos Personales y garantía de los derechos digitales y el Reglamento general (UE) 2016/679, de 27 de abril de 2016, de protección de datos y normativa complementaria.

Mi colaboración en el proyecto es totalmente voluntaria y tengo derecho a retirarme en cualquier momento, sin que esto repercuta negativamente. En caso de retirada, tengo derecho a exigir que mis datos sean retirados del archivo del estudio. Así mismo, renuncio a cualquier beneficio económico, académico o de cualquier otra naturaleza que se pueda derivar del proyecto o de sus resultados.

Por todo ello, **DOY MI CONSENTIMIENTO A:**

1. Participar en el programa de actividad física del proyecto Join4Joy.

2. Que el equipo de investigación del proyecto Join4Joy y la Dra. Laura Coll Planas puedan gestionar mis datos y difundirlos resultados que el proyecto genere, de manera anonimizada.

3. Que el equipo del proyecto *Join4Joy* conserve todos los registros efectuados sobre mi persona con las garantías y los plazos legalmente previstos, y a falta de previsión legal, por el tiempo que fuera necesario para cumplir las funciones del proyecto para las que los datos fueran recaudados.

*[ciudad]*_____, el *[día]* ____ / *[mes]*____ / *[año]*_____

Firma del participante	Investigadora responsable	Asistente / Cuidador legal

CONSENTIMIENTO INFORMADO USUARIO -COPIA PARA INVESTIGADOR

Yo, _____***(aquí el nombre de usted)***, mayor de edad, con Nº de identificación *nª*_____ , como usuario interesado o en su caso como familiar/asistente del usuario interesado D/Dª: _____***(nombre del usuario)***.

DECLARO QUE: He recibido información sobre el proyecto Join4Joy ("únase y disfrute"). Se me ha hecho entrega de un documento informativo, en el que se solicita mi participación. He podido entenderlo y aclarar las dudas que me hayan surgido durante su lectura.

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*[ciudad]*_____, el *[día]* ____ / *[mes]*____ / *[año]*_____

Firma del participante	Investigadora responsable	Asistente / Cuidador legal

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1, lines 1-3
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 1, line 66
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	Page 15, lines 534-536
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 15, lines 528-533
	5b	Name and contact information for the trial sponsor	Page 15, lines 534-536
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Page 15, lines 537-538

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Pages 3-4, lines 69-148
	6b	Explanation for choice of comparators	N/A
Objectives	7	Specific objectives or hypotheses	Page 5, lines 150-165
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 5, lines 173-176
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 5, lines 178-183
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 6, lines 192-219
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Pages 7-10, lines 244-340
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Page 14, lines 498-503
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Page 11, lines 365-370

	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Pages 10-12, lines 353-424
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Page 7, lines 249-256
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 6, lines 185-191
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Pages 6-7, lines 221-242
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A

Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Pages 10-12, lines 353-421
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Page 11, lines 365-370
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 12, lines 426-432
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Pages 12-13, lines 434-479
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	N/A
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Pages 13-14, lines 481-485
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Pages 13-14, lines 481-485
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Page 14, lines 491-496
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Pages 13-14, lines 481-485

Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 14, lines 505-517
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Page 14, lines 512-514
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 6, lines 233-239
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 12, lines 426-432
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 15, line 540
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Page 1, lines 33-37
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	Page 14, lines 491-496
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 14, lines 518-520
	31b	Authorship eligibility guidelines and any intended use of professional writers	Page 15, lines 528-533
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Page 15, lines 548-552

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.