



University of Southern Denmark

**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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BMJ Open 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 assessment 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 twelve, 1-hour weekly sessions of structured, supervised, group-based PA. 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) and SB and PA patterns (IPAQ and accelerometry). The degree and type of participation in virtual communities of practice will also be assessed. SPSS software will be

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The Join4Joy PA approach focuses on enjoyment and social inclusion. 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 Join4Joy 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.

used for the analysis of quantitative variables. 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 26 June 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, presentations at sport and health-related professional conferences and congresses, as well as through social media and via the Join4Joy website.

Study registration ClinicalTrials.gov, [NCT06100835](https://clinicaltrials.gov/ct2/show/study/NCT06100835).

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 burden of disease. 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 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}

In 2023, the WHO has launched 'Promoting physical activity for older people: a toolkit for action' emphasising, 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 confidence building, which are key to overcoming the barrier that PA is 'not for them'. This could encourage inactive older people to join PA programmes, who 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 PA, which can include for instance walking, Tai Chi, hiking, social dancing. Last, but not least, the WHO highlights that group PA impacts also on the social dimension of health, for example facilitating social relationships. In this line, several studies have shown how participating in organised group-based physical exercise programmes 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 to them.^{14 15}

In terms of behavioural 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 new health-related behaviours.¹² Accordingly, emphasising enjoyment, social inclusion and meaningfulness in PA may constitute a more effective approach in terms of behavioural 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

An additional recommendation is that 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 It consists of a process emerging from the participatory design paradigm which may positively impact health outcomes.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.

Taking the above into consideration, the Join4Joy European project, in a first stage, has co-created a framework that offers older adults joyful and inclusive opportunities to become more physically active and reduce their time spent in SB. The project 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

This study aims to assess the feasibility of the intervention and its assessment tools, as well as to explore staff and older people's acceptability of both. It additionally aims to refine its strategies for recruitment, retention and intervention delivery, as well as to provide data to estimate the parameters required to design a definitive randomised controlled trial.

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 of satisfaction, based on their programme experience.
5. To assess the feasibility and acceptability of the assessment tools.
6. To synthesise 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 interventions 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 statement²⁵: extension to randomised pilot and feasibility trials.

Design

The Join4Joy PA project will consist of a multicentric, pragmatic, feasibility study with a pre-post design. Intervention 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 nursing home residents and 72 living in 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 (seven points in the Global Deterioration Scale of Reisberg²⁷ 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 (nine 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.
- 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.
 - 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.
 - 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.
 - Throughout the intervention period, we will consistently prioritise and respect the voluntary participation of interested participants in every session, emphasising their freedom of choice.

Intervention

The Join4Joy PA framework 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 behavioural 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 PA 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 (VCoPs) 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 project are described in [figure 1](#).

The design of the Join4Joy PA project 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 into 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, 28 of which were end-users, 12 were professionals, 3 were policy makers and one was a student. For Join4Joy-NH, 54 participants (23 end-users,

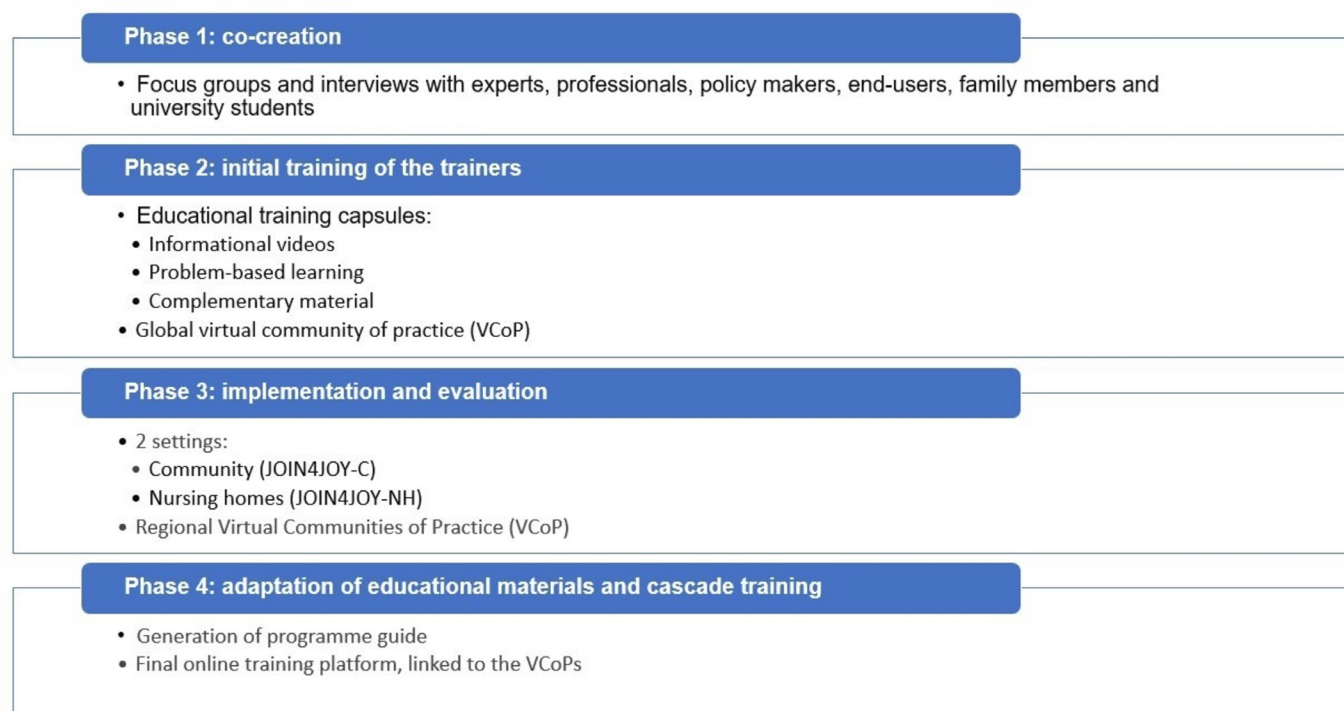


Figure 1 Phases of the Join4Joy PA programme.

17 professionals, 7 policy makers, 5 family members, and two students) were involved in seven focus groups and three interviews. In parallel, opinions on education-related aspects were collected through three individualised interviews with experts of Academia, and two focus groups with nine physical therapy and five 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, emphasising 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 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 framework, ensuring that it is inclusive, tailored to individual needs, and focused on sustained engagement and well-being. Alongside, recommendations for potential activities and good practices were identified to be conducted to personalise the programme to the needs and preferences of the end users. Accordingly, the developed programme also includes 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 customised to meet



Figure 2 The nine core principles of the Join4Joy PA programme emerging from the co-creation phase.

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 to select those that will be the most adequate 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 PA, physical exercise and sedentary behaviour; the ageing process and its consequences; Join4Joy ground principles and framework for joyful and inclusive PA 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, participant (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 exchange experiences 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 optimisation 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 approach. 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 characterise 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 includes reaching socially disadvantaged older population, that is, 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 adequate, 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 scale³⁰ 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 qualitatively ask 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 test³² and 2min 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-5L 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 the 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 accelerometry-based measures with ActiGraph³⁸ 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 before and after the intervention, in NH only, by using the Barthel index, as modified by Shah.⁴⁰
- 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 four 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 5 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 SD 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 SD of the differences. This effect size provides a standardised 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 First, 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). NVivo software, version 12, will be used to organise and manage the data. Once all transcripts have been coded, themes will be generated from the coded data by grouping similar codes together (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 on 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 on 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 favourable report (internal code nr. 233/2022) for the conduction of co-creation processes, on 3 October 2022. The intervention protocol described in this document received a favourable report by the same Committee, with internal code nr. 282/2023, on 26 June 2023. The study is registered at ClinicalTrials.gov (NCT06100835).

Each partner will receive approval of the local ethical committee before the 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 (online supplemental file 1) 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, training staff and involved students.

Results of the study will be disseminated through publication of scientific articles, presentation at sport and health-related professional conferences and congresses, dissemination on social media and via the Join4Joy website www.join4joy.eu.

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.

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Competing interests None declared.

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Patient consent for publication Consent obtained directly from patient(s).

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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 efectos 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.

Página 1 de 3 para el participante



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 Ciències de la Salut i el Benestar.

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Correo electrónico: xxxxxxxxxx



CONSENTIMIENTO INFORMADO PARA USUARIO FINAL

Yo, _____ (*aquí el nombre de usted*), mayor de edad, con N° de identificación n^a _____, como usuario interesado o en su caso como familiar/asistente del usuario interesado D/D^a: _____ (*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 N° de identificación n^a _____, como usuario interesado o en su caso como familiar/asistente del usuario interesado D/D^a: _____ (*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