

Research protocol - Ongoing Trial

A co-created intervention with care home residents and university students following a service-learning methodology to reduce sedentary behaviour: The GET READY project protocol

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Abstract

Background: There is a growing demand for long-term care settings. Care-home residents are a vulnerable group with high levels of physical dependency and cognitive impairment. Long-term care facilities need to adapt and offer more effective and sustainable interventions to address older residents' complex physical and mental health needs. Despite the increasing emphasis on patient and public involvement, marginalised groups such as care-home residents, can be overlooked when including people in the research process. The GET READY project aims to integrate service-learning methodology into Physical Therapy and Sport Sciences University degrees by offering students individual service opportunities with residential care homes, in order to co-create the best suited intervention with researchers, older adults of both genders (end-users) in care homes, health professionals, caregivers, relatives and policy makers. **Methods:** Stage 1 will integrate a service-learning methodology within a Physical Therapy module in Glasgow and Sport Sciences module in Barcelona, design two workshops for care home residents and one workshop for staff members, relatives and policy makers and conduct a co-creation procedure. Stage 2 will assess the feasibility, safety and preliminary effects of the co-created intervention in a group of 60 care home residents, within a two-armed pragmatic randomized clinical trial. **ClinicalTrials.gov Identifier:** NCT03505385.

Keywords: Co-creation, Care home residents, Physical activity, Sedentary behaviour, Service-learning methodology

Introduction

The number of older adults aged 65 or over in the population will increase significantly in the coming decades, with the proportion of those aged 80 years or above growing at a faster pace than any other age segment of the European Union's population¹. This increase is likely to be linked to a growing demand for long-term care, placing a significant strain on health care resources. Care-home residents are a vulnerable group with high levels of physical dependency², and with three-quarters having cognitive impairment³. This will require the adaptation of long-term care facilities' policies to offer more effective and sustainable interventions to address the complex physical and mental health needs of their residents⁴. It is well established that regular physical activity

(PA) limits the development and progression of chronic diseases and disabling conditions⁵. However, time spent in sedentary behaviour (SB) (defined as any waking behaviour

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characterized by an energy expenditure ≤ 1.5 Metabolic Equivalent Tasks while in a sitting or reclining posture)⁶ has increased substantially over the last three decades⁷ and increases with age⁸. SB has been gaining recognition as a risk factor, sometimes independent to PA status, for numerous health conditions⁵ including cardiovascular disease⁹, type II diabetes¹⁰, obesity¹¹, reduced mobility¹² and poor functional performance, which can cause falls and fractures¹³. There is a large body of evidence which has focused on PA-based interventions to improve physical function and prevent falls in institutionalized older adults¹⁴. A meta-analysis confirmed that PA programmes could improve activities of daily living in older people living in long-term care facilities although the characteristics of the best intervention remain unclear¹⁵. However, there is still a gap in knowledge on how to change the mind set and activities offered to older residents by 'gate-keeper' health professionals and how to make 'moving more often' normal in the residential setting. Despite the growing interest in SB research, there has been a lack of studies focused on reducing SB in institutionalized older adults.

Patient and public involvement (PPI) has developed into an integral part of research practice over the last 25 years. Despite the increasing emphasis on PPI, marginalised groups, such as care-home residents, can be overlooked when including people in the research process, although a recent systematic review showed that older care-home residents could be successfully involved¹⁶. It is thought that involving end-users in the development of solution-based interventions using key elements derived from participatory methodologies such as PPI may increase the likelihood of producing sustainable change¹⁷. Emergent from the participatory design paradigm is a process called co-creation¹⁸, which is hypothesised to have a strong and enduring impact on health outcomes¹⁹, and may be a promising strategy to address other complex health behaviours. To our knowledge, there is only one previous study involving community-dwelling older adults to co-create an intervention to reduce SB²⁰.

University degrees, such as Physical Therapy and Sport Sciences, need to have a practical approach rather than just be dominated by theory. Service learning is a teaching and learning strategy that involves students in community service, and integrates meaningful community service with instruction and reflection to enrich the learning experience, teach civic responsibility, and strengthen communities²¹. This project has the involvement of university students, care home residents (end-users), researchers, health professionals, care home staff, caregivers, family members and policy makers, enriching it with a distinctly multi-disciplinary and inter-sectorial nature.

The GET READY project aims to integrate service-learning methodology into Physical Therapy and Sport Sciences University degrees by offering students individual service opportunities with residential care homes²², in order to co-create the best suited intervention to reduce the SB of residents, with researchers, older adults of both genders

(end-users) in care homes, health professionals, caregivers, family members and policy makers. The project will use a Participatory Action Research (PAR) methodology²³ to support users to demand more responsive and integrated care programmes for chronic diseases, and to involve end-users in their health management and decision-making relevant to their own health²⁴. This will then be tested in both a feasibility study, to estimate important parameters needed to design the main study, and a pilot study, to test the integrity of the study protocol for a definitive future trial, and to determine the acceptability of the intervention within that context²⁵.

Materials and methods

The GET READY study will be divided into two stages. The first stage will focus on the integration of the service-learning methodology within a University degree, and the design of three workshops for the co-creation of an intervention to reduce sedentary behaviour and enhance physical activity in care home residents. The second stage will focus on the feasibility of the intervention co-created in the previous stage, and a pilot study to consider preliminary effectiveness.

Stage 1. Workshops and co-creation protocol

The present study is being conducted in Glasgow (Scotland) and Barcelona (Catalonia). A purposive sampling strategy will be used to identify a total of 5 to 6 residents living in two care homes in Glasgow and 5 to 6 residents living in two care homes in Barcelona. The total sample will include residents of both genders, with different physical and cognitive conditions, physical activity levels, and amount of time spent in sedentary behaviour. Questions about current levels of physical activity, sedentary behaviour, walking ability, physical and cognitive function, will be explored with the care home staff to enable purposive sampling to take place, after inviting all residents to participate. The study has been approved by the Ethics Committee of the School of Health and Life Sciences of Glasgow Caledonian University, and the Ethics Committee of the Faculty of Psychology, Education and Sport Sciences Blanquerna (Ramon Llull University). All participants (or legal representatives if applicable) will sign an informed consent prior to participation.

Health professionals at the care homes will provide clinical and demographic information: gender, date of birth, marital status, medical conditions, medication, timespan in the care home, PA levels assessed with the International Physical Activity Questionnaire, and proxy report of self-report hours of sedentary time a day. This data will allow description of the study population.

The service-learning methodology will be integrated within a current module in the Physical Therapy degree in Glasgow Caledonian University and in the Sport Sciences degree in Blanquerna, Ramon Llull University in Barcelona, adding content related to service-learning methodology and

successful experiences using service-learning methodology for undergraduate students, how to co-create a successful intervention, and tips on how to conduct a discussion group and foster positive group dynamics. A group of students will be involved in the design of two workshops (WS1 and WS2) for care home residents (as part of the module) including information regarding the health benefits of regular physical activity and reducing sedentary behaviour, barriers and motivators to be physically active and less sedentary, how to collect preferred strategies to be more physically active and less sedentary, as well as inform them about the importance of gathering end-users' opinion on how to design a "sit less move more" intervention for their daily living. Another group of students will design a workshop for staff members (WS3), relatives and policy makers to gather the same information.

Between WS1 and WS2, the care home residents will be asked to wear an ActivPAL™ monitor (PAL Technologies, Scotland), a valid "gold standard" method to measure postural sitting^{26,27}, that is feasible for use with high adherence rates (>90%) in older adults²⁸. The monitor can record the total time the residents spend sitting, standing and walking. However, at very slow walking speeds (e.g. <0.5 m/s), walking may not be identified²⁹, so we will use *time spent upright* (standing and walking) as our main outcome measure for physical activity, rather than differentiating between standing and walking³⁰. We will also document time spent sitting or reclining – *sedentary time*. The monitor will be waterproofed, and will be attached to the front of the thigh by a researcher. Participants will wear the monitor continually (including overnight) for nine days, and the activPAL™ monitor will be removed by the researcher at a second meeting. A graphical representation of sedentary behaviour data will be fed back to participants at the second workshop, to raise awareness of their sedentary time and their sedentary behaviour patterns, to enable identification of the best-suited strategy to modify this behaviour as it may be that certain times of the day are more appropriate for intervention.

WS1 aims to inform care home residents about the health-related benefits of being physically active and less sedentary, and to gather relevant information regarding their PA and SB patterns and willingness to change behaviour. WS2 aims to use the activPAL™ data to explore their preferences and goals to enhance changes within their daily routines. Both workshops will be conducted by the same three to four students that had designed them with the 5 to 6 residents, with researcher supervision. The workshop for staff members (WS3) will be conducted by the same students that had designed it and the following participants will be invited: two researchers, three health professionals working in the care home (e.g. physical therapist, nurse, occupational therapist, geriatrician), one caregiver, one family member, and one policy maker. WS3 will be aimed at identifying PA and SB patterns of care home residents, their perceived limitations to enhance movement

in care home residents, willingness to change and preferred strategies. WS1 and WS2 will last no more than 60 minutes each and WS3 will last for no more than 90 minutes. Each workshop will be audio-taped and/or video-recorded with participants' consent. Topics for all groups will include: (a) acceptability, feasibility and preferences for particular intervention components within their daily lives coherent with their daily routine (safety, engagement), (b) personal goals and action planning, (c) barriers and motivators for PA and SB reduction, and (d) information on what may help people to reduce the amount of time spent sitting in their daily lives within the care home environment. We will include important theoretical constructs towards successful behaviour change such as education, goal setting and action planning, prompts, and embedding PA and SB reduction in to the daily routine.

Stage 2. Feasibility and pilot study

In stage 2 of the GET READY project we will assess the feasibility, safety and preliminary effects of the intervention co-created in the previous stage in a group of care home residents from the same care homes. Once the aforementioned three workshops have been analysed, a first draft of the intervention will be designed, shown to the participants of the WS, and amended accordingly following their comments and preferences.

It is proposed that there are eight general areas of focus addressed by feasibility studies³¹: (a) *acceptability*, that looks at how the recipients, both targeted individuals and those involved in implementing programs, react to the intervention; (b) *demand*, that provides information on estimated use of selected intervention activities in a defined intervention population or setting; (c) *implementation*, that focuses on the extent, likelihood, and manner in which an intervention can be fully implemented as planned and proposed³²; (d) *practicality*, that explores the extent to which an intervention can be delivered when resources, time, commitment, or some combination thereof are constrained in some way; (e) *adaptation*, which focuses on changing program content or procedures, to be appropriate in new situations; (f) *integration*, that assesses the level of system change needed to integrate a new program or process into an existing infrastructure or program; (g) *expansion*, which examines the potential success of an already-successful intervention with a different population or in a different setting; and (h) *limited-efficacy testing*, as many feasibility studies are designed to test an intervention in a limited way. Such tests may be conducted in a convenience sample, with intermediate rather than final outcomes, with shorter follow-up periods, or with limited statistical power.

To assess intervention feasibility, we will record recruitment and retention through the programme. We will conduct qualitative interviews with participants, caregivers, family members and care home staff at the end of the programme and interviews will be recorded and transcribed

verbatim. Caregivers will be interviewed separately or together with the participant, depending on their preference. We will select for interview participants with low- and high-adherence. We will also seek to interview a sample of participants who discontinue the intervention. Using Thematic Analysis³³, we will elicit participants' views on acceptability of the intervention and research procedures. Participant perspectives of their behaviour changes will be reported separately.

We will use mixed methods to assess the intervention feasibility and we will conduct a pilot study with stop and go decision points of a two armed pragmatic randomized clinical trial to assess the effectiveness of the co-created intervention on reducing SB and increasing PA, in care home residents. This complex intervention co-created with care home residents and conducted by university students will be compared to usual care, conducted by health professionals working in the residential care homes.

Participants of the feasibility and pilot studies

Both countries will recruit approximately 30 care home residents from 2 homes (the duration of the intervention can't be anticipated as it depends on the co-creation process). Participants will be randomised to a PA group (usual care) or to the GET READY co-created intervention, in a cluster randomized pilot study. Eligible participants will be aged over 70 years willing to participate. Exclusion criteria will include comorbidity preventing participation (e.g. severe breathlessness, pain, or severe neurological disease), severe cognitive impairment, life expectancy of less than one year, being unable to rise out of a chair with help of one person, or being unlikely to undertake the intervention. Individual participants will discontinue participation if: they withdraw consent or no longer wish to take part; the health professional overseeing their care decides the participant is no longer able to take part; otherwise at the discretion of the investigator (e.g. risk to safety of staff). We will collect outcome data from those who withdraw, if they are willing.

Randomisation

The two care homes will be randomised after baseline measures, using an independent and secure, web-based randomisation procedure. The randomisation system will be maintained by a statistician independent of the analysis and research teams to ensure blinding of allocation and analysis.

Data collection

Measures will be assessed at baseline and end of intervention. Recruitment, retention and adherence rates will be used to assess feasibility³⁴ and, alongside effect size, will be used to refine the sample size required for a future definitive trial. The acceptability of the intervention will be assessed using two approaches: 1) all participants (or their caregivers in the case of cognitive impairment) will be asked to rate their level of satisfaction with the intervention on a 5-point Likert-type scale, as used in a previous PA

intervention³⁵; 2) a group of participants will be convened to explore their views of how the programme can be improved.

Primary outcome: Sedentary behaviour as total sitting time, breaks in sitting time and the α ratio (ratio among breaks and transitions), as measured by the gold standard activPAL™ monitor (PAL Technologies, Scotland)²⁹.

Secondary outcomes: (a) physical activity as time spent upright (same device)²⁹, (b) physical function: 5-chair rise test and gait speed³⁶. And anticipated secondary outcomes will include: activities of daily living; adherence; self-rated health and health-related quality of life; anxiety and depressive symptoms; social network; physical activity self-regulation or self-efficacy for exercise; fatigability; fear of falling; cognition and executive function. This list may vary following discussion with residents and care home staff about meaningful patient centred outcomes and considering participant and carer burden.

Data analysis

For efficacy analysis, descriptive statistics (e.g. means, medians, proportions, standard deviations and ranges) of baseline demographic and health status data will be calculated for both trial arms. We will compare changes in primary and secondary outcomes between the two trial arms, using an analysis of covariance to adjust for the baseline score and stratifying variables. Intervention effects will be represented by point estimates (95% confidence intervals). Statistical analysis will be performed to look at power for future sample size estimates.

For qualitative analysis of the workshops (stage 1), transcripts will be analysed using Thematic Analysis³³ with embedded constant comparative method. Analysis will be facilitated by the use of text management software (NVivo). Two researchers will be involved in the analysis to ensure reliability of interpretation and coding. Rigour will be ensured in a number of ways. Firstly, the constant comparative method relies on the researcher seeking disconfirming evidence for developing theory. This ensures transcripts are not analysed selectively, and that the totality of the dataset is consistent with the reported findings. Secondly, two members of the research team with qualitative research experience will meet regularly with the researcher to discuss emerging codes and categories, the interpretation of key texts and potential new lines of enquiry. Finally, towards the end of the analysis, once concepts, properties and dimensions have been formulated; two independent researchers will examine transcripts and assign established codes. A comparison of coding will be carried out to assess agreement between coders.

Discussion

This is, to our knowledge, the first study involving University students using a service-learning methodology in care home settings to co-create an intervention with care home residents aimed at decreasing sedentary

behaviour and increasing physical activity levels.

The co-creators aim to develop an intervention which is tailored to end-users' preferences and is congruent with their daily life. Physical activity and sedentary behaviour are ubiquitous throughout the day³⁷, and recommendations show that interventions need to modify the daily routine^{38,39} and be integrated within older adult's everyday activities, to be able to achieve sustainable changes in behaviour. Breaking up of sedentary behaviour, through standing up approximately once an hour, without any change in total sitting time or activity levels, have been shown to improve physical function over a 10 week period in residents of sheltered housing⁴⁰. However, this involved the use of a vibrating prompt and considerable time in motivational interviewing, which may not be possible in the care home setting.

There is a pressing need for interventions to increase activity and enhance independence among care home residents. This is to enable people to 'move more and sit less', live better lives, and to mitigate the increasing burden on health and social care of care home residents-related dependency. Fall-related injury and activity restriction are often responsible for deterioration in quality of life in care-home residents.

Care homes are unique research settings and care-home residents need specific consideration in relation to how they may be involved in research. A recent systematic review identified multiple barriers to and facilitators of involving residents as PPI members grouped under: social factors, skills, resources, care-home organisational factors and the organisation of the research¹⁶. These factors will be anticipated in the present project during the workshop.

Curricula of health professionals should comprise lecture-based and experiential training on population medicine, health promotion/disease prevention and social determinants of health⁴¹. PPI and service-learning are unique approaches to train Physical Therapy and Sport Science students how to provide patient care from a population perspective. Service-learning is a structured experience that combines community service with specific learning objectives, preparation and reflection through community-academic partnerships⁴². Studies demonstrate that, with appropriate supervision, student involvement not only maintains or improves patient satisfaction outcomes, but can contribute to improving patient safety and health outcomes^{43,44}.

The main objectives of the GET READY project are wider than improving quality of life and physical function in residents, as we aim to raise awareness, knowledge, skills and passion of graduates entering the workforce, and to lead to a change in culture of professionals working with this frail and co-morbid population. The GET READY intervention will be conducted in Glasgow and Barcelona, with the end point being a culturally and gender wide sustainable program ready to be tested in a RCT in different locations around Europe in a future research proposal.

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