

BMJ Open Promoting physical activity in vulnerable adults 'at risk' of homelessness: a randomised controlled trial protocol

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To cite: Stringer C, Loosemore M, Moller E, *et al.* Promoting physical activity in vulnerable adults 'at risk' of homelessness: a randomised controlled trial protocol. *BMJ Open* 2019;**9**:e026466. doi:10.1136/bmjopen-2018-026466

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2018-026466>).

Received 3 September 2018
Revised 13 February 2019
Accepted 21 February 2019



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ABSTRACT

Introduction People who are homeless, or at risk of homelessness, have substantially poorer health. Sustained and regular participation in physical activity is beneficial for both mental and physical health. Limited data suggest that levels of physical activity in the homeless and those at risk of homelessness are low, and access to community-based exercise is limited or non-existent for this population. Nonetheless, exercise programmes for the homeless could provide a feasible and scalable intervention for providing beneficial effects on physical and mental health in this population. The primary aim of this study is to evaluate the impact of a group exercise intervention on activity levels in people who are homeless or at risk of homelessness in central London, UK. The secondary aim is to evaluate the impact of the intervention on mental and physical health outcomes.

Method and analysis A 2-arm, individually randomised controlled trial in people who are homeless and those vulnerable and at risk of homelessness in central London, UK. Participants will be recruited through a London-based homeless charity, Single Homeless Project. Following baseline assessments and allocation to intervention (exercise classes) or control (usual care), participants will be followed up at 3, 6, 9 and 12 months. The primary outcomes will be change in objective physical activity. The secondary outcomes will include change in fitness assessments and mental health parameters. Changes in drug use and alcohol dependency will also be explored.

Ethics and dissemination Ethical approval to process and analyse data and disseminate findings was obtained through the Anglia Ruskin University Department of Sport and Exercise Sciences Research Ethics Committee. Results of this study will be disseminated through peer-reviewed publications and scientific presentations.

INTRODUCTION

A homeless person is an individual without permanent housing who may live on the streets; stay in a shelter, mission, single room occupancy facilities, abandoned building or vehicle; or in any other unstable or non-permanent situation.¹ In the UK, there were 271 000

Strengths and limitations of this study

- Approximately 800 participants will be recruited into the programme (400=intervention and 400=controls) which will make this the largest evaluation of its kind to date.
- Clear strengths of this evaluation include objective measurements of physical activity (Actigraph accelerometers) and health parameters.
- The intervention is being carried out on a large homeless population with multiple mental and physical health complications, including a high prevalence of drug and/or alcohol dependency, it is possible adherence to exercise session and/or protocol will be challenging.
- Multiple strategies are being adopted to prevent dropout. For example, incentives provided throughout the study (passes to visit the zoo) and exercise session reminders sent via text messages.
- The programme is conducted in real-world settings which is important for evidencing research translation; however, there is less control of the intervention conditions making it difficult to infer what aspects of the intervention may lead to physical activity improvements.

'local authority homelessness case actions' in 2015/2016, a rise of 32% since 2009/2010.² Being homeless, or at risk of homelessness, is detrimental to health.³ People living in damp, cold, or overcrowded housing experience greater physical risks to health, and strains on mental health occur through insecurity and personal debt.⁴ Thomson *et al*⁵ carried out a systematic review on housing improvements for health and found that compared with the general population, those who are homeless or at risk of homelessness were at increased risk of respiratory conditions, depression, anxiety and excess winter mortality. Importantly, homelessness, and risk of, is associated with premature mortality; with the single

homeless having an average age at death of just 47 years, 30 years lower than that for the general population.⁶ While it is essential that interventions are developed to prevent and manage homelessness, there is also a pressing need for interventions to improve mental and physical health outcomes in those who are currently homeless or at risk of homelessness.

Sustained and regular participation in physical activity is not only associated with healthy ageing but can also help delay, prevent, or manage many non-communicable diseases including those relating to physical (eg, cardiorespiratory)⁷ and mental health (eg, anxiety and depression).^{8,9} On the other hand, excessive sedentary time (ie, sitting or lying when awake) is detrimental to both physical and mental health, independent of physical activity.¹⁰ Despite this, data on the amount of physical activity among the homeless and correlates of are scarce. In a Danish study, approximately 70% of the homeless reported no participation in any form of exercise.¹¹ To date, no data exist on levels and patterns of sedentary time in the homeless. Gregg and Bedard¹² carried out a study (n=18) to describe the physical activity experiences and perceived benefits of and barriers to physical activity participation among patrons of a homeless shelter. The study concluded that preliminary evidence suggests that patrons of homeless shelters appear to be open to physical activity experiences and that benefits may go beyond improving physical fitness levels. Promoting physical activity may alleviate some of the physical and mental health issues experienced in the homeless. Indeed, recent research has suggested that group exercise classes can improve mental well-being and social inclusion among the homeless.¹³

Despite this clear rationale, only a handful of interventions have been carried out that have attempted to promote physical activity in the homeless.¹⁴ One study examined the extent to which 12 weeks of street soccer training affected the physical fitness and cardiovascular health profiles of homeless men (n=55). The study concluded that the exercise intensity is high during street soccer and regular street soccer training can be used as an effective activity to promote physical fitness and cardiovascular health status for homeless men.¹⁵ However, this study focused on homeless men only and did not monitor overall physical activity or sedentary behaviour. In addition to 'academic' interventions there are existing initiatives to promote physical activity among the homeless. One such initiative is known as the Skid Row Running Club. The Skid Row Running Club was founded in 2012 to provide a running programme for the Skid Row Community of Los Angeles and to involve the larger community in supporting its participants in overcoming alcohol and drug abuse and achieving positive life goals. However, to date no evaluation to assess the effectiveness of this initiative has been conducted.

In the UK, one population group who are at particular risk of poor health are the single homeless. The single homeless are people who are homeless but do not meet

the 'priority need' criteria to be housed by their local authority under UK law and essentially have no permanent home. Under the 1996 UK Housing Act, local authorities have a statutory duty to find accommodation for households deemed to be homeless, eligible and in 'priority need'. Most commonly, 'priority need' applies to adults with dependent children. If an individual who is homeless does not have a dependent or a spouse, then they are categorised as single homeless. Given the substantially poorer health of homeless people, the potential for physical activity to improve health outcomes and the absence of robust trials evaluating physical activity, we set out to conduct the first study in this area. Specifically, the present paper describes the protocol of an intervention funded by Sport England to promote physical activity via a charity 'The Single Homeless Project (SHP)' to the single homeless (≥ 55 years old) in central London, UK.

AIMS

The primary aim of the present project is to evaluate a group-based exercise intervention among 800 individuals (400=control and 400=intervention) classified as 'single homeless' (≥ 55 years old) in central London, UK, to increase levels of overall physical activity. The secondary aim is to evaluate the impact of the intervention on mental and physical health parameters.

Setting

SHP operates across more than 24 London boroughs and works with individuals to tackle the underlying causes of homelessness, such as poor mental health or drug and alcohol dependency. SHP has 40 years of expertise and a London-wide reach that works with 7000 people every year. Importantly, their work restores hope to people who might otherwise feel forgotten, left behind or written off, providing crucial footholds in their recovery journey from which they can go on to build independent and fulfilling lives. People with multiple and complex needs may experience several overlapping problems simultaneously, such as mental ill health, homelessness, drug and alcohol addiction, offending and family breakdown. The majority of SHP service users have multiple and complex needs. SHP secured funding from Sport England to implement an exercise intervention that aims to improve mental and physical health among the charities service users. The exercise intervention described below has been designed by charity service users, area experts, physiotherapists, clinicians and academics.

METHOD AND ANALYSES

The present evaluation will use a randomised controlled trial design. Baseline data collection will take place when participants enter the study and follow-up every 3 months thereafter for 12 months. The duration of the entire study will be 36 months. Participants will be randomised by the programme co-ordinator (using simple random

sampling) as they enter the study to either the control (usual care) or the intervention group (exercise classes) at baseline and prior to consent. Owing to the risks and complexities when working with this sample (eg, certain participants must not be mixed owing to potential exploitation and violence) concealed allocation will not take place. The unit of randomisation will be the participant. Participants in the intervention group will undergo one exercise session a week.

Recruitment

Participants will be service users of SHP who are 55 years and above. SHP staff at hostels will ask service users if they would like to take part in a study pertaining to their health and well-being. During this time verbal consent will be taken from service users to allow hostel staff to pass on service users' mobile numbers (if they own a mobile) to the exercise programme co-ordinator (an individual employed by the charity to implement the intervention). Service users will then be contacted by the co-ordinator to see if they have any further questions. After screening (described below) randomisation will take place and group (intervention/control) or one-to-one meetings will be held between potential participants and the exercise co-ordinator. During this time potential participants will be given further information (dependent on if in intervention or control group) about the programme and any questions will be answered. At this point written informed consent will be taken in the areas of data collection, media and behaviour. An information sheet and code of conduct will be given to participants before signing informed consent. Participants will be asked if they have any questions and will be told they can withdraw from the programme at any point without giving reason and no adverse action will be taken as a result of this. Referrals into the study can also be made from other departments within SHP. This will be done when service users express an interest to SHP staff in improving their health, diet, or fitness.

Participants and inclusion/exclusion criteria

All potential participants will be screened before being included in the project by the programme lead. Potential participants will be screened utilising a six-question survey to measure vulnerability [In the last year have you used any of SHP services?/In the last year have you received help from a charity or crisis centre?/In the last year have you been homeless (including living in a hostel, sofa surfing)?/In the last year have you ever been at risk of homelessness?/Do you have any physical or mental illnesses?/Do you have any disabilities? (response options yes or no)]. Potential participants will receive one score for a 'yes' answer to each question with a higher score representing a higher level of vulnerability. Each SHP service user has an online profile on the SHP database. The profile outlines the service users risks and their risk category, that is, high risk, medium risk and so on. It further identifies risks such as if a service user would have

to come to an all-male group, if a service user requires two members of staff to be present at all time, if a service user is a risk to themselves due to mental illness (eg, self-harm), or a risk to others due to financial exploitation (eg, theft, subsequent sexual transaction) and so on. Owing to the complex needs of this sample and the risk they pose to themselves, each other, and programme staff it is not possible or safe to employ a strict inclusion/exclusion criterion. The programme lead will consider the aforementioned information and the vulnerability score for appropriateness of each potential participant to take part in in the programme before a participant is recruited into the study.

A medical history will be carried out. SHP service users have their medical history stored in an online database. It contains information on the service users' medical conditions based on their general practitioners' records and service user self-report, such as diabetes and so on, but also on health behaviours such as drug use and an approximate amount they were taking at the time of the medical history being carried out. An exercise risk stratification screening tool (a system which categorises risk to partake in exercise)¹⁶ is then applied to the information contained in the potential participants database and if the potential participants are deemed moderate/high risk they are informed to consult a medical professional for advice on whether it is safe to partake in an exercise programme (if randomised into the intervention arm).

Physical activity levels over the previous week will be assessed using three survey items. Those potential participants who are classed as active, defined as meeting the government physical activity recommendation of 30 min of moderate to vigorous physical activity of five or more days of the week, will not be included in the study.

Finally, all participants in the intervention arm will be screened using the Physical Activity Readiness Questionnaire^{17 18} prior to starting the exercise programme and are advised to inform their general practitioner about their plans to engage in regular physical activity.

Intervention

Exercise sessions will run across four London boroughs (there will be one exercise centre per borough) during the first 9 months during which time the intervention and its delivery will be précised, if no substantial changes are made then this data may be used in the main analyses, after which the programme will be run across all SHP's London boroughs. Sessions will be set up using SHP spaces, or space that has been donated to the charity referred to as exercise centres. For each participant the intervention will last 12 months and will consist of one group exercise session a week at each centre.

All exercise sessions will be run by qualified fitness instructors or sport coaches and when possible overseen by the programme lead. All sessions will be designed to cater for the participants needs after conversations between participants and programme lead at the start and throughout the intervention. Conversations will be

unstructured and participant-led; the programme lead will however, focus specifically on what exercises are being enjoyed and what exercises the participants would like to try. Therefore, each group exercise session delivered at each of the 24 centres (one centre per borough) may differ (between centres and between weeks). However, each participant will always attend the same centre and there will be only one type of exercise class on at each centre each week. Examples of exercise classes to be run include: yoga, tai chi, aerobics, dance and self-defence/boxing. Each session will last approximately 2 hours and will consist of the following:

An initial 30 min during which participants arrive have refreshments and socialise.

A physical activity session lasting a minimum of 30 min. Lunch.

Each centre will host approximately 15–25 participants in each exercise class, and two instructors/coaches. During the initial 30 min, participants will have the chance to talk about any new injuries/illnesses that may have occurred, be told about the session and discuss any worries or fears that they have with either the programme lead or fitness instructor/coach. The time set aside for lunch following the physical activity will be used in multiple ways over the 12-month programme. It may consist of guest speakers, educational speakers, or a client-led activity. It will also be a time during which participants can reflect on sessions and feedback what they felt worked well and what they would like to see changed in the next session. Through doing this it allows the sessions to remain participant centred. In addition, feedback forms on different components of the programme will be completed by participants at 6 months.

Control group

All participants in the control group will complete all evaluation measures at each time point. Control participants will be given a participant information sheet and will be required to complete informed consent prior to collecting any measurements.

Strategies to promote attendance

To ensure attendance to exercise classes a system called Textmagic (<https://www.textmagic.com/>) will be used to send intervention participants a text reminder about sessions. Sessions will be based around participants wants and needs; participants will be asked at the start and throughout what type of activities they would like to do, with a participant-led style being adopted.

Participants in the intervention arm will be provided with incentives throughout the programme. Donations from private corporate organisations in the areas of trainers and tracksuits will be given out at the start of the programme to help them feel more equipped and confident to undertake the programme. Participants in the intervention and control groups will receive free and discounted tickets (eg, theatre shows, London Zoo and days away) throughout the programme these are activities

that our participants have expressed an interest in doing and enjoy. If a participant attends every session for 2 months (intervention), or two data collection sessions (control), they will receive a free ticket to the zoo, theatre shows, or days away.

Evaluation

All evaluation measurements will be taken at baseline and at 3-month intervals over the period of 12 months.

Free-living physical activity

Levels of free-living physical activity will be assessed using the Actigraph accelerometer (GT3X) at each data collection point. The Actigraph accelerometer is a valid and reliable tool to monitor free-living physical activity and its validity and reliability has been shown in multiple populations.¹⁹ The Actigraph GT3X is worn on a belt around the waist with the device itself positioned above the right hip either over or under clothing. We will employ a sampling frequency of 30 Hz. Service users will be asked to wear the device during waking hours every day for seven consecutive days, but not during water-based activities or sleep.

Mental health

Mental health status will be measured using a survey containing The Depression Anxiety Stress Scale-21 (DASS-21) questionnaire and five questions that measure mental well-being and management of own health problems. The DASS-21 questionnaire has been shown to be a valid and reliable tool to measure levels of depression, anxiety and stress in multiple populations.²⁰

An increase in social connection may also lead to an improvement in mental health. Indeed, the present intervention through physical activity may increase social connection the present evaluation will therefore measure levels of social connection at each data collection point through a widely-used self-report measure of social isolation (eg, see reference 21). This scale measures social isolation by assigning one point if the respondent is unmarried/not cohabiting, has less than monthly contact (including face-to-face, telephone, or written/e-mail contact) with each of children, other family members, and friends, and if they do not participate in organisations such as social clubs or residents' groups, religious groups, or committees.

The instructor, coach or programme leader will read questions to participants in a private room in the centre. The questionnaire will be administered in this way to ensure participants understand each individual question and the scoring process for each answer. A large proportion of SHP service users cannot read and can find wording of questions confusing potentially resulting in answers ranked incorrectly. Reading the questions to the participants and discussing confusion should minimise this risk.

Fitness assessments

A series of fitness assessments will be carried out, following Standard Operating Procedure Forms, on all

participants taking part in the study. Fitness assessments will be carried out to measure aspects of general fitness (strength, flexibility, cardiovascular): participants will be asked to perform the hand-held dynamometer test to assess grip strength (muscle function), the peak flow test to assess lung function (a measurement of how quickly one can blow air out of their lungs) and the sit-and-reach (or adapted sit-and-reach) test to assess flexibility. Participants' weight and body composition will be measured using the Tanita SC-330 Body Composition Analyser (Tanita, Illinois, USA) and height will be measured using the Leicester Height Measure, from which body mass index (BMI) will be calculated in kg/m^2 . Waist-to-hip ratio will also be recorded (waist measurement divided by hip measurement) and resting heart rate and blood pressure monitored using an Omron m2 Basic Upper Arm Blood Pressure monitor. These tests have been extensively used in previous studies^{22–25} and have shown good validity and reliability.^{26–28}

Medical history

Participants undergo medical screenings at multiple times when under the care of SHP. We will access these to evaluate any changes in chronic medical conditions (mental and physical), illicit drug and alcohol misuse, and hospital admissions between data collection points.

Volunteers

Over the course of the programme approximately 100 volunteers will be recruited to help run the programme. Volunteers will be recruited through adverts on multiple websites; SHP website, team London's website, Islington volunteer website, through SHP's corporate partners, and on social media. Volunteers will complete roles in the following areas: aid in the running of sessions, aid in evaluation, office work, talks on health topics and help on activities carried out away from the hubs.

ANALYSIS

Outcome

The primary outcome for this study will be change in average daily time spent in sedentary time, light physical activity and moderate-to-vigorous physical activity (MVPA) as recorded by the Actigraph accelerometer. Other secondary outcomes collected using participant questionnaires and objective measures include: (1) change in peak flow, sit-and-reach, grip strength and BMI/WHR/body composition; (2) change in DASS-21 and mental health outcomes and (3) change in medical history.

Actigraph processing

Raw data files will be extracted from each Actigraph device and processed using bespoke software (Actilife) to quantify a range of features that will directly contribute to the determination of active and sedentary time. Data files will be reintegrated to a 60s epoch and non-wear time defined as 60min of consecutive zeros, allowing for

2 min of non-zero interruptions. All participants with at least 1 day with at least 500min of measured monitor wear time between 07:00 and midnight will be included. This will allow for a high level of inclusion in our analyses and we have used this criteria previously in other populations.²⁹ Total physical activity will be expressed as total counts, including sedentary minutes, divided by measured time per day (counts/min, cpm). Time spent sedentary will be defined as all minutes showing less than 100 cpm and MVPA time as minutes showing more than 2600 cpm. These are cut points that have been previously used and recommended.^{30,31} It may be that in our trial the participants will not follow wear protocol, for example, if there is an adverse event in a hostel or an increase in localised drug use. Such adverse events could result in Actigraphs worn for 1 or 2 days. It is therefore important to be inclusive with collected data.

Sample size

Approximately 800 participants will be recruited into the study (400=intervention and 400=controls) which will make this the largest study of its kind to date. Previous studies have found a significant difference following exercise interventions in the outcomes that we are interested in using much smaller samples (eg, see reference 32 33). Moreover, based on a sample size of 800 participants and an alpha of 0.05, we will have 80.6% power to detect small effects ($f=0.10$) and 100% power to detect medium ($f=0.25$) and large ($f=0.40$) effects in our primary outcome, change in time spent in physical activity.

Statistical analyses

A full data analysis plan will be developed and published prior to completion of data collection. Baseline characteristics will be reported by each arm using descriptive statistics. Repeated measures analyses will be used to analyse the baseline, 3-month, 6-month, 9-month and 12-month data. Missing data will be explored to see if they are missing at random, and various sensitivity analyses performed after making different assumptions about the missing data. Exploratory subgroup analyses will be carried out to examine intervention interactions with gender, age, illness and so on.

Patient and public involvement

The SHP have been involved and led on most aspect of this project including, idea conception, acquisition of funding, delivery of the intervention and evaluation (academic partners will lead on the processing of data, analyses, and dissemination). Every 2 months a steering group is held including representatives from SHP, the evaluation team and service users.

Ethical consideration and dissemination

Explicit written informed consent will be sought by SHP from all study participants. All participants will be informed that they have the right to withdraw from the programme at any point without giving reason.

The results of this evaluation will be disseminated to academic audiences through presentations at national and international conferences in physical activity, public health and homelessness and through peer-reviewed publications in relevant journals. Results will be disseminated to the public, policy makers, and other charities through seminars and press releases co-ordinated through the Anglia Ruskin University Press Office and SHP Communication Team.

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Acknowledgements We thank The Single Homeless Project for facilitating this important work and the charity service users who have formed part of our steering group.

Contributors LS, CS, ML and EM conceived the study idea and designed the study protocol. LS drafted the protocol. CS, ML, EM, SJ, GFL-S, JF, JJ, BS, DV and LS critically reviewed the protocol and provided extensive comments. CS, ML, EM, SJ, GFL-S, JF, JJ, BS, DV and LS approved the final version of the manuscript.

Funding This work was funded by Sport England Active Ageing Project.

Competing interests None declared.

Patient consent for publication Obtained.

Ethics approval Ethical approval to process and analyse data and disseminate findings was granted by the Anglia Ruskin University Faculty of Science and Technology research ethics committee.

Provenance and peer review Not commissioned; externally peer reviewed.

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