STUDY PROTOCOL

REVISED A study to explore the role of a low threshold, fitness focussed physical rehabilitation intervention with protein supplementation to target physical function and frailty in people with problematic substance use and homelessness: protocol for a single-arm pre-post intervention study.

[version 2; peer review: 2 approved]

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Abstract

Background

People who are homeless are more likely to experience poor mental health and addiction as well as suffering from non-communicable diseases. There is evidence of frailty and accelerated physical ageing among people experiencing homelessness. Appropriate physical rehabilitation and nutritional supplementation strategies can stabilise or reverse frailty and general physical decline, but it is not known how this type of intervention would work in practice in this population.

Aim

To evaluate the feasibility and pre-post intervention impact of a low threshold physical rehabilitation intervention with protein supplementation to target physical functioning and frailty in people with problematic substance use who are experiencing homelessness.

Open Peer Review

Approval Status ✓ ✓

	1	2
version 2 (revision) 29 Oct 2024	✓ view	✓ view
version 1 25 Apr 2023	? view	? view

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Any reports and responses or comments on the article can be found at the end of the article.

Methods

The intervention will consist of a 12-week low threshold rehabilitation programme with protein supplementation. Participants will be service users of the Ballyfermot Advance Project, a day services centre for people with addiction issues and experiencing homelessness. Primary outcomes will be feasibility including numbers recruited, retention of participants and adherence to the exercise intervention and protein supplement. Any adverse events will be recorded. Secondary outcomes will be strength and muscular mass, physical performance and lower extremity physical function, pain, frailty and nutritional status.

Discussion

An immediate impact may be simply a distraction from difficult circumstances and potentially an improvement of physical health of participants, which can be a conduit for the emergence of other positive behaviours and recovery. Longer term, this study will generate preliminary data on which to inform the design of a definitive randomised controlled trial of physical rehabilitation and protein supplementation, if indicated.

Ethics and dissemination

Ethical approval was granted by the Faculty of Health Sciences Research Ethics Committee in TCD. Study findings will be disseminated through publication into an international peer-reviewed journal and presented at national and international conferences.

Keywords
Inclusion health, addiction, homelessness, exercise, nutritional supplementation

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REVISED **Amendments from Version 1**

This revised manuscript is intended to provide more clarity to the protocol presented. In response to the reviewer comments we have made a minor amendment to the title and aims. We have provided additional background in the introduction. The main amendment is to the methodology section which provides greater detail of the intervention and the outcome measures utilised and there is a minor revision in the analysis section. We have adressed the small number of grammar and punctuation issues. It is hoped that this version has provided the reader with more clarity and enhanced the quality of this manuscript.

Any further responses from the reviewers can be found at the end of the article

Introduction

Inclusion health is an approach which aims to prevent and address health and social inequalities of vulnerable people such as those who are homeless[1]. The collision of disease risk factors with poverty, constant stressors and social exclusion in people experiencing homelessness has demonstrated a markedly elevated rate of non-communicable diseases[2]. Related to non-communicable diseases and a complex interaction of other factors such as addiction and accidental death, socially excluded populations have a mortality rate that is almost eight times higher than the average for men, and nearly 12 times higher for women[3]. The median age of death among people experiencing homelessness[4] in Dublin, Ireland is staggeringly low among females at 38 years and 44 years among men[5].

Accelerated ageing and earlier geriatric conditions such as falls, poor strength and mobility problems are common in people experiencing homelessness[6,7]. A single centre, cross-sectional study, which applied a broad test battery of physical functioning tests to people experiencing homelessness who were admitted for inpatient care, demonstrated that despite a low median age of 45 years, 83% of participants had mobility problems and 70% were frail or pre-frail[5].

As frailty, a complex multidimensional state of physiological vulnerability[8] and pre-frailty, its prodromal stage[9], is normally a concept associated with ageing[10] - the concept of frailty in younger populations can be contentious. Nonetheless, frailty has been identified in younger populations across a number of settings[11,12] and it is recognised that those living in areas of greater deprivation experience the earlier onset of illness and associated disability[13,14]. A high prevalence of frailty has been identified in people experiencing homelessness[6,15–20]. Poorer physical health and frailty means people experiencing homelessness have fewer options for moving to independent housing due to accessibility issues which reinforces the cycle of entrenched homelessness, rough sleeping and dependence on long-term hostel accommodation[21]. The challenge is to bridge the implementation gap and provide innovative solutions to key challenges faced by people in long term homelessness. Improvements in physical health will not solve all complex challenges, it is nonetheless a sensible solution focussed target which can be a positive focus from which there can be a ripple effect in terms of outcomes.

Key drivers of physical frailty are poor nutritional intake[22] and sedentary behaviour. Food insecurity is extremely prevalent among people experiencing homelessness[23] and may contribute to frailty. It is possible that protein supplementation after exercise may optimise protein synthesis rates[24] and help stabilise frailty and physical de-conditioning[25]. This has been successfully demonstrated in frail older people[26]. Furthermore, in illicit drug users, exercise can increase the abstinence rate and can reduce withdrawal and anxiety symptoms[27].

There is a dearth of research exploring physical activity and nutritional interventions in this population. Kendzor *et al.*, 2017 investigated the effects of a diet and exercise intervention in homeless adults[28], in a randomised controlled trial. This study, however, did not provide a structured, supervised exercise programme. The intervention involved the provision of educational newsletters, healthy snacks and pedometers with advice on physical activity. This study is the first of its kind which will provide a structured exercise and nutritional intervention in this population.

Aim and objectives

The overall aim of this study is to test the feasibility and pre-post intervention impact of a low threshold physical rehabilitation programme with dietary supplementation to target frailty and poor physical functioning in people who are homeless.

Objectives:

1. To evaluate recruitment, retention and adherence to the physical rehabilitation and protein supplementation programme.

2. To examine baseline and pre-post intervention change in measures of physical, nutritional and frailty status, and self-reported pain.

3. To ascertain perceptions of unmet physical health needs, exercise habits and how an exercise intervention should ideally be designed to meet the needs of this cohort with lived experience of homelessness and active addiction issues.

Methods

Design and study setting

This single arm feasibility study is taking place in a surburban area od Dublin with high levels of deprivation. The study will commence in October 2022 and will finish in March 2023. The Ballyfermot Advance Project provides a five-day a week meal service, as well as drug and alcohol related services for people with active addiction issues, the majority of whom experience homelessness. A dedicated exercise room in a nearby community centre has been allocated for the duration of the intervention period. This study has received

ethical approval from the Faculty of Health Sciences REC at Trinity College Dublin (Ethical Approval Reference Number: 211202.

Sample selection, recruitment and eligibility screen

A gatekeeper in Ballyfermot Advance has been appointed as the study liaison. The gatekeeper will distribute the Participation Information Leaflet (PIL) and consent form in advance of the study. Staff members with a knowledge of eligible clients who access services in Ballyfermot Advance will inform them of the study and supply them with study related information. Study information leaflets in plain English will be available throughout the centre. Once referred, and the potential participants present to the exercise room, the dedicated research physiotherapist, FK, will do an initial eligibility screen at the point of enrolment to ensure potential participants meet the eligibility criteria.

Obtaining consent

All potential participants will be provided with a PIL and an exercise information leaflet detailing the purpose of the data collection, the exercise intervention, potential risks and benefits and data protection rights. Due to the expected high levels of functional illiteracy, the research physiotherapist will read the study related information where applicable and will be available to answer any study related queries. Where possible there will be a seven-day gap between receipt of the PIL and obtaining consent to allow potential participations time to consider participation. Due to the anticipated fluctuation in interest levels however, and other competing priorities related to mood, motivation and active addiction issues, flexibility has been built into the consent process. This means that clients who express an interest in the programme and willingness to participate the same day as first receiving the study information can be consented and commence the programme at a time suited to them. This method was successfully employed previously in a cross-sectional study conducted with patients experiencing homelessness in St. James's Hospital[6].

Once the research physiotherapist is satisfied that the potential participant has read (or has been read to) and fully understands the PIL, they will proceed to obtain written informed consent. Obtaining consent will take place at the first interaction with the participant prior to commencement of testing. The written consent informs participants that they are permitted to withdraw from the study at any time. Participants are given their own copy of this consent form and PIL, signed by themselves and the research physiotherapist. The research physiotherapist will be accompanied by a second research assistant.

Inclusion and exclusion criteria

The aim of the study is to be as pragmatic and low threshold as possible. This means that minimal constraints are put in place to access the intervention. In order to be as pragmatic as possible in terms of inclusion criteria, all clients (>18 years) accessing services in Ballyfermot Advance who consent to study participation can be included in this study. Only participants with problematic behavioural issues, including confusion or extreme agitation, or have major physical problems, (medical or orthopaedic) which would preclude ability to safely participate in the exercise class will be excluded from study participation. Participants with a confirmed pregnancy will also be excluded as physical functioning/performance tests scores in advanced stages of pregnancy may vary from baseline values[29].

In the design of this study, we were cognisant of the likely complex needs of many participants as complex childhood trauma has been commonly experienced by people who experience homelessness and substance misuse problems. Using a Trauma Informed approach to care[30] and based on experience from a previous Inclusion Health undergraduate clinical placement[31], the following were incorporated in the approach to assessment and follow up with participants; (i) empathy, (ii) consistency, (iii) understanding, and (iv) flexibility.

Intervention

The intervention will consist of three exercise opportunities, including a twice weekly, 12-week exercise programme with nutritional supplementation. The intervention will be fully supervised and delivered by two research physiotherapists. Group exercise classes or one-to one sessions will be delivered depending on participant preference. Participants will be advised of a schedule of class times, including gender specific classes and will be allocated to a specific class based on their preference. An alternate class will be offered if participants cannot attend at their scheduled time. A 'Park Walk' will also be scheduled one day per week. This will be a 30-minute self-paced walk of low intensity led by the research assistant involved in this programme. This is to build up exercise frequency during the week and is building in a habit which it is hoped can be continued by participants beyond the life cycle of the project. Flexibility in programme commencement and completion dates will be provided to enable the 12-week intervention to be completed within a 15-week period of time.

The PAR-Q[32], a pre-screening questionnaire, will be conducted with participants prior to commencement of the exercise classes. The research physiotherapist will, with permission, write to the participants General Practitioner (GP) to advise them of their intention to take part in the programme and to clarify that it is safe for them to proceed with the exercise intervention. If the individual does not have a GP, the research physiotherapist will discuss this individual case with a specialist consultant in Inclusion Health based in St. James's Hospital, Dublin. The case will be outlined in broad terms, without revealing any personal details of the participant, solely as a sounding board as to whether it would be suitable for the participant to attend or not.

The exercise intervention will focus on general fitness and will include resistance, aerobic and functional exercises, with in-built flexibility based on individual participants' needs. The exercise component will be based on 'core' exercises (Table 1)

Table 1. Exercise Circuit.

Core exercise	Initial Intensity	Progression/Adaptations*
Sit to stand/squats/lunges	2 sets 10–15 reps	3 sets of 15 reps use of weights/ball
Elbow Bends	2 sets 10–15 reps	3 sets of 15 reps weights
Step-ups	2 sets 10–15 reps	3 sets of 15 reps height of step; weights
Arm elevations	2 sets 10–15 reps	3 sets of 15 reps weights
'Penguin waddle'-hip abduction	2 sets 10–15 reps	3 sets of 15 reps With additional upper limb abduction and elevation; movement with 360° turns
Scapular retractions	2 sets 10–15 reps	3 sets of 15 reps weights
Aerobic activity	2 mins	3 mins ladders, hurdles, skipping ropes, jumping jacks dance, game with cones/balls
Balance	4–5 mins	5 mins Tandem; single leg stance, upper limb and trunk movements; weights and ball work

Adaptations: exercises individualised and progressed for each participant by research physiotherapist

which will be adjusted to increase or decrease difficulty based on the results of the initial assessment and ability of participants, as judged by the research physiotherapist. Each session, of approximately 20 minutes duration, will commence with a warm-up and stretch of the major muscles and will end with cool-down and stretch.

A low-specification pedometer will be supplied to encourage increasing daily step count and goal setting will be discussed with participants. This is to build a scientifically sound psychological framework into the intervention to encourage motivation to partake in physical activity.

The intensity of the workout will be managed by using the Borg Perceived Rate of Exertion (RPE) scale[33] where participants will be advised to exercise at a rate of between 11 and 13 on the PRE scale, i.e. where they find the exercise somewhere between 'fairly light' to 'somewhat hard', where they find it hard to have a conversation but can comfortably continue to exercise.

To promote post-exercise muscle protein synthesis[24], a nutritional supplement (200ml pre-prepared 'protein shake' Fresubin, https://www.fresubin.com/) which consists of 20g of protein will be offered to all participants immediately post exercise in the exercise room.

In an attempt to build sustainability beyond the life cycle of the project, participants will also be educated about exercise and available local resources where possible. Participants will be invited and encouraged to return three times weekly to continue with the exercise intervention.

Adherence

The service provided will be low threshold to facilitate adherence and compliance. The research physiotherapists will make every effort to be flexible and accommodating to participants in terms of their attendances to the exercise classes and the Park Walk. Adherence to the programme will be measured by the uptake, compliance and number of repeat visits to the drop-in programme. Demographic information will include biological sex and current homeless status.

Demographic details collected

Demographic details, including age, and named GP of participants will be collected. A letter will be sent to each GP to inform them of study participation. Questions around current addiction status will be guided by Section 1 of the Treatment Outcome Profile[27]. As the research physiotherapist will not have access to participant medical/social records, senior staff of Ballyfermot Advance Project will provide pertinent medical/addiction/social information relating to the participants if required.

Outcomes

Primary outcomes

The following feasibility outcomes will be recorded; numbers recruited, retention of participants including number of repeat visits and adherence. Any adverse events will also b threshold to facilitate its feasibility.

Recruitment and retention

The numbers recruited and frequency of attendances will be recorded. Participants will be encouraged to attend all sessions if possible. Drop out will also be recorded.

Adherence

The research physiotherapists will make every effort to be flexible and accommodating to participants in terms of their attendances and adherence to the programme. Adherence will be measured by the adherence to the exercise programme and the protein supplement.

e recorded. The service provided will be low threshold to facilitate its feasibility

Secondary outcomes

1. Strength and muscular mass: Muscular strength will be estimated[34,35] by using a Digital Hand Dynamometer in a sitting position while the hand is unsupported with the elbow at 90° flexion and the underarm and wrist in neutral. Two measurements will be inputted as part of the SHARE-FI frailty instrument[36] and values will also be compared to normative reference values established by Steiber[37].

Mid-calf circumference girth will be evaluated as this measure correlates with appendicular muscular mass[38]. This will be measured using a flexible tape measure at the level of the largest circumference of the calf. Higher scores indicate higher levels of muscular mass. The cut-off value for moderately and severely low calf circumference is 34 cm and 32 cm in males, and 33 cm and 31 cm in females[39].

Mid-arm muscle circumference reflects both muscle mass and caloric and protein adequacy, and may be used to signify malnutrition or wasting[40]. This test has been recommended for use in physical testing of those experiencing homelessness[41] due to the high prevalence of lower limb swelling[42]. The maximum upper arm muscular mass will be measured using a flexible tape measure. Results will be compared to global reference values[43].

2. Physical performance and lower extremity physical function:

This will be measured using the following physical performance measures:

(i) The 10m Walk Test (10MWT). This test measures walking speed and functional mobility and is recorded in m/s. Gait speed is calculated as total distance/time[44].

(ii) The 2minute Walk Test (2MWT). This test of self-paced walking ability and functional capacity assesses a participants' ability to walk unassisted over a 15m distance, as fast as possible, for two minutes. Rest breaks are permitted and the distance covered is measured[45].

(iii) The Chair Stand Test (CST). This test of lower limb strength and endurance measures the total number of sit to stand repetitions a participant can perform in 30 seconds[46].

(iv) The Single Leg Stance Test (SLS). This test of balance is performed on each leg. The participant is timed standing unassisted on one leg, with eyes open and hands placed on the hips[47].

3. Pain: Each participant will be questioned whether they are experiencing any pain and will be questioned about its location and duration. Severity of pain will be assessed using the Numerical Rating Scale (NRS). The NRS is a unidimensional measure of pain intensity from 0–10, with 0 being zero pain and 10 the worst pain imaginable[48].

4. Frailty: This will be assessed in two ways; using the Clinical Frailty Scale (CFS)[49] and the SHARE-FI[36]. This scale is assessed by the tester and each point on the scale is correlated with a description of frailty along with a visual chart to aid the tester in classifying frailty from 1 (very fit) to 9 (terminally ill). Higher scores indicate higher levels of frailty. The SHARE-FI is a valid tool to measure the level of frailty in individuals aged ≥50 years[36]. It consists of quick questions related of the following variables; exhaustion, loss of appetite, walking difficulties and low physical activity. Answers are entered into a freely available web calculator to generate a frailty score and a frailty category of non-frail, pre-frail and frail is generated.

5. Nutritional status will be assessed by using the Mini-nutritional assessment (MNA) score[50]. The MNA assesses the risk for malnutrition. In particular, the short form of the MNA (MNA-SF)[51] is a screening tool consisting of six questions on food intake, weight loss, mobility, psychological stress, or acute disease, the presence of dementia or depression, and body mass index (BMI). The maximum score for this part is equal to 14. A score equal to or higher than 12 indicates that the subject under study has an acceptable nutritional status thus excluding malnutrition and/or malnutrition risk, meanwhile, a score ≤ 11 implicates to proceed with the complete version of the MNA (MNA-LF)[51]. As this test has not been validated for this population, the terminology of two of the questions of the MNA (regarding acuity of illness and psychological stress) have been slightly modified for the purposes of this study, ie "Have you recently been sick or in hospital?" and "Have you problems with concentration or memory?"

6. Body Mass Index (BMI). Height and weight will be measured and the following formula will be applied to generate BMI; kg/m^2.

7. Self-report:

Short-Form 12 (SF-12)[52]. The SF-12 is a self-report measure of health used across age, disease and treatment groups. It uses eight domains including physical and social activities, pain, mental health, emotional health, vitality and general health perceptions to measure health. The participant completes a 12 question survey which is scored by the researcher. The minimum possible score is 12 and the maximum possible score is 48. Lower scores indicate better health. To ascertain perceptions of unmet physical health needs & rehabilitation/exercise preferences, open-ended questions will be used regarding

(i) concerns with current physical health, (ii) exercise history (iii) current concerns/priorities of the participant and (iv) the final questions asks "do you have someone who looks out for you?". This information will be transcribed by the research physiotherapist and repeated back to the participant to verify accuracy. It will not be audio-recorded.

*Reliability and validity of secondary outcomes measures have been confirmed (see *Extended data*, Supplementary Figure).

Data collection and management

Data will be collected pre- and post-intervention for those who complete the programme, by the research physiotherapist.

Analytic plan

Our study is very much feasibility focussed and not hypothesis driven so formal power calculations are not directly applicable. Prospectively, potential participants that meet the study eligibility criteria will be invited to participate. Descriptive statistics will summarise participant demographics and feasibility measures such as attendance rates. Nominal or ordinal variables will be reported as frequencies and percentages. Continuous variables will be summarised as mean and standard deviation if normally distributed and median and interquartile range if non-normally distributed. Results will be compared to evaluate change over time from initial to final intervention. Normally distributed data will be compared from initial to final recorded time-points using paired t-tests and non-normally distributed data via the Wilcoxin-sign rank test. As participants will be heterogeneous, data will be sub-stratified and participants will be grouped meaningfully. Free text responses from subjective questions will be reported and organised into topic areas.

Funding

This has been funded by Trinity College Dublin and the Ballyfermot Advance Project.

Dissemination plans

Conference presentations and publications in peer-reviewed journals will be one method of dissemination. Results will also be presented to the key stakeholders including people with lived experience and the funders of this study.

Study status

Recruitment and data collection will commence on October 3rd 2022 and will be completed by March 2023.

Discussion

This protocol describes a novel and pragmatic, low threshold intervention which aims to address the known poor physical health condition of people experiencing homelessness and problematic substance use. Given this is such a novel area there is no comparator group. This study will nevertheless increase knowledge, understanding and awareness of the physical health needs of this population and facilitate a better understanding of unmet need, thus assisting in shaping future physical rehabilitation services to suit these complex and transient needs. It is hoped that this study will provide preliminary data to optimise the intervention and inform the design of a definitive randomised controlled trial, where applicable. An immediate impact may be an improvement in physical health of participants, which can be a conduit for the emergence of other positive behaviours and recovery. Overall, this research will address an intractable global societal challenge, have wide impact and improve the quality of life, health and well-being of some of our most vulnerable citizens.

Data availability

Data from this study will be available in open access form.

Underlying data

No data are associated with this article.

Extended data

OSF: A study to explore the role of a low threshold, fitness focussed physical rehabilitation intervention with protein supplementation to target physical function and frailty in people who experience homelessness and addiction: protocol for a single-arm feasibility pre-post intervention study. https://doi.org/10.17605/OSF.IO/3AG9B[53].

The project contains the following extended data:

- Supplementary Figure.docx

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http://www.doi.org/10.17605/OSF.IO/3AG9B

Open Peer Review

Current Peer Review Status: ✔ ✔

Version 2

Reviewer Report 19 November 2024

https://doi.org/10.21956/hrbopenres.15384.r42998

✔ **Catriona Connell**
University of Stirling, Stirling, Scotland, UK

Thank you for the detailed responses to my review. The amended manuscript reads clearly, and I look forward to seeing results. There a couple minor editing issues (outcomes section has a cut and paste error) but otherwise there is sufficient detail here for reviewers of the results to follow any study changes.

Well done for sticking with this commitment to open science despite such a long wait to find reviewers.

Competing Interests: I work at The Salvation Army Centre for Addiction Services and Research, which receives some funds from The Salvation Army. The Salvation Army is a charity that provides homelessness and addiction services internationally. Whilst this has no bearing on my review, it may be perceived as a potential conflict of interest.

Reviewer Expertise: Applied health research in inclusion health (particularly justice, substance use, homelessness, mental health)

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 06 November 2024

https://doi.org/10.21956/hrbopenres.15384.r42997

JUAN TORTOSA-MARTÍNEZ
University of Alicante, Alicante, Spain

The authors have clarified nicely the points raised in my first revision.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Exercise for the health and quality of life of special populations

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 02 September 2024

https://doi.org/10.21956/hrbopenres.14958.r41844

?

Catriona Connell
University of Stirling, Stirling, Scotland, UK

Thank you for the opportunity to review this protocol for a 'low threshold fitness focused physical rehabilitation intervention with protein supplementation to target physical function and frailty in people with problematic substance use and homelessness'. It is positive to see intervention research by allied health professionals in this field.

I note that this protocol was published online and peer reviewed initially over a year ago, and that the dates of the study were such that even at that point the study should have concluded. As such providing comments now will be of no utility for designing the study, but I hope may assist in reporting the results.
Results of a similar study were published as a conference abstract in 2022, although it appears the intervention may have been developed. This prior study should be referenced and the adaptations to the intervention made clear.

A note on language. The authors use different terminology for substance use, including problematic substance use, illicit drug users, and addiction. It would be useful to select one term or make clear if these refer to different concepts. In some areas the term 'people who use drugs/alcohol' is preferred, or people with problematic use of drugs/alcohol/substances.

Abstract:
The aim of the study is to establish feasibility and preliminary efficacy, both need to be clearly

defined given the use of the term efficacy tends to be associated with more robust designs (e.g., controlled study with comparator group).

Introduction:
First sentence has an unnecessary comma after approach. Can you support the argument that homelessness/inclusion health is attracting more attention (in what sense, research, practice, policy, all?). Would also be useful to outline what homelessness is (i.e. are you considering rooflessness, or people living in temporary/unsuitable accommodation, sofa-surfing etc).
Paragraph 2-3 discuss pre-frailty and frailty. It would be useful to explain what these conditions are/look like for non-expert readers.
Paragraph 3 - Is there evidence to support the claim that physical disability this limits accommodation options and reinforces severe and multiple disadvantage (this would seem obvious but would be good to support this more clearly). This should be fewer options rather than less. Authors describe the challenge as being the implementation gap, but there isn't a clear account and evidence that there are a range of effective interventions not being implemented.
Please define 'medium- to long-term homelessness'. Final sentence is a bit long. Consider shorter clearer sentences.
Paragraph 4 – reference needed for statement that frailty is driven by poor nutrition.

Aims and objectives
As above re term 'preliminary efficacy'.
In objectives the term adherence is used for the first time. This is slightly different to feasibility as stated in your aim and abstract. Consistency of language needed here and in what you are considering. Objective 2 could be more explicit – to examine change in measures of … Objective 3, examining perceptions of unmet need, is not clearly reflected in the aims and abstract and needs a rationale. I agree with reviewer one that it would be (have been) useful to include qualitative process-type evaluation approaches to collecting and analysing this data, taking perceptions of participants, service providers and funders.
Methods
This is described as a single arm feasibility cohort study. 'Cohort' is not the correct terminology for your design, which is used in longitudinal observational studies rather than intervention studies like yours. Feasibility study is adequate.
As a feasibility study, you need to be explicit in advance in what would be the determining factor of feasibility. Is it that the intervention is feasible to deliver in practice, or is it that you need to know whether an RCT is feasible, or both. E.g., do you need to be able to recruit XX over a certain period of time, what proportion of drop out can you accommodate, what is considered sufficient adherence to gain a dose of the intervention and thus how much do people need to come etc…
Such specificity may be challenging at your stage of intervention development but it is still good practice to define what results you consider would indicate feasibility. Obviously this is no use now the study is concluded, but you can consider these in your main manuscript in the discussion of whether a full RCT is feasible.
You are very explicit about the study site (I am not sure what Dublin 10 is?) and should be careful that this does not risk identifying participants, this depends largely on how many people may have been using the service during the study. However, you have ethical approval so assume you have justified this.
Consenting process looks appropriate. At this point recruitment, consenting and I assume measures are all done by the person providing the intervention (I think, although who conducts the measures is unclear) and therefore it would be useful to note the limitations of this in

introducing bias. Inclusion and exclusion, how will you ascertain 'acute problematic behavioural issues" and what does this mean. Given you are working with people who use alcohol/drugs, it will be vital that there is ongoing attention to capacity. This is vital at the consenting stage but doesn't mean someone needs to be completely excluded. You mention trauma informed care and your adaptation of these. I am not sure who these are for and what 'communication skills are very important' means. It would be useful to expand on how this related to physical rehabilitation, particularly where there may be physical contact with participants.

Intervention

You need to have a much clearer articulation of the intervention components, and the hypothesised mechanisms of change. Using the TiDIER checklist (https://www.bmj.com/content/348/bmj.g1687) and presenting an intervention logic model will be helpful. It is a little unclear at present what each persons 'dose' would be. Is it one group and one park walk? Additional steps and goals? Three times weekly?

The PARQ- should be conducted with rather than on participants? In contacting the GP this is a good idea for obtaining information about contraindications, however, what if the person does not consent/a response is not forthcoming. This may be something that needs to be adapted to optimise feasibility.

Adherence (see above comment) – uptake, is that people recruited who actually engage, or the proportion of eligible day service clients who take up the intervention? What indicated compliance.

Demographics included here but should be all together.

Outcomes

Retention – useful to track dop out and point of drop out. Would also be vital to know how much prompting and support is required to facilitate attendance at the off site location.

I can't comment in detail on the physical outcome measures but just note that will need to add details of any known reliability and validity data where appropriate

IN terms of unmet need and wider input on feasibility, barriers and facilitators and intervention revisions and planning, a qualitative approach with a wider participant base would be helpful.

Data collection and management

No detail of who is collecting the data at what points. Analytical plan is light and could be more robust in explaining which tests will be used for each outcome depending on the type of data it produces. As there is no detail of the anticipated sample size, or of how the GLM will be constructed this is difficult to comment on. GLM is the first mention of timepoints, is there an interim measure or only pre-post?

Dissemination

It may be beneficial to consider dissemination beyond academic audiences, particularly to gain input from practitioners, policymakers and people experiencing homelessness and problematic substance use on issues relating to intervention optimisation and delivery in 'real world' practice.

Additional recommendations

When reporting your study, you should use CONSORT- extension for feasibility and pilot studies and include this as a supplementary file. See the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) website (www.equator-network.org/), and this article for some additional guidance [1].

References

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Is the rationale for, and objectives of, the study clearly described?
Partly

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: The Salvation Army Centre for Addiction Services and Research, University of Stirling, receives funds from The Salvation Army which part support my salary. The Salvation Army had no involvement in completing this peer review.

Reviewer Expertise: Applied health research in inclusion health (particularly justice, substance use, homelessness, mental health)

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 26 Sep 2024

Fiona Kennedy

Dear Dr. Connell,
Thank you very much for your feedback and the opportunity to revise this manuscript. Please see responses to each point raised. We feel the review process has significantly improved the quality of this protocol and very much hope this now meets the criteria for approval.
Best Wishes,
Fiona Kennedy and co-authors

Comment 1: Results of a similar study were published as a conference abstract in 2022, although it appears the intervention may have been developed. This prior study should be referenced and the adaptations to the intervention made clear.
Response: Thank you for this point. I believe this conference abstract you are referring to related to this and a previous linked study which was presented just after this protocol was submitted. It has been since published as a full paper:
(the LEAP I trial, doi: 10.1371/journal.pone.0301926).

Comment 2: A note on language. The authors use different terminology for substance use, including problematic substance use, illicit drug users, and addiction. It would be useful to select one term or make clear if these refer to different concepts. In some areas the term

'people who use drugs/alcohol' is preferred, or people with problematic use of drugs/alcohol/substances.
Response: Thank you. This has been amended and terminology is consistent throughout.
Amendment: 'A study to explore the role of a low threshold, fitness focussed physical rehabilitation intervention with protein supplementation to target physical function and frailty in people who experience homelessness and addiction'.

Abstract:
Comment 3: The aim of the study is to establish feasibility and preliminary efficacy, both need to be clearly defined given the use of the term efficacy tends to be associated with more robust designs (e.g., controlled study with comparator group).
Response: This has been amended to establish feasibility and 'pre-post intervention impact', as per further discussion with study collaborators since submitting the protocol and has been used for reporting of the results. This is reflected in the title, in comment 2 above and is also explained in the abstract and main article.
Amendment: 'the aim of this study is to test the feasibility and pre-post intervention impact'.

Introduction:
Comment 4. First sentence has an unnecessary comma after approach.
Response: Amended, thank you.

Comment 5. Can you support the argument that homelessness/inclusion health is attracting more attention (in what sense, research, practice, policy, all?).
Response: Upon reflection it was felt that this sentence lacked specificity and has since been removed.

Comment 6: Would also be useful to outline what homelessness is (i.e. are you considering rooflessness, or people living in temporary/unsuitable accommodation, sofa-surfing etc).
Response: Yes, the European Typology of Homelessness and Housing definition was used. European Typology of Homelessness and Housing Exclusion https://www.feantsa.org/download/en-16822651433655843804.pdf (line 57, reference 4)

Comment 7: Paragraph 2-3 discuss pre-frailty and frailty. It would be useful to explain what these 5. conditions are/look like for non-expert readers.
Response: **Frailty and pre-frailty are now defined.**
Amendment: Frailty 'a complex multidimensional state of physiological vulnerability' and pre-frailty its 'prodromal stage'.

Comment 8: Paragraph 3 - Is there evidence to support the claim that physical disability limits accommodation options and reinforces severe and multiple disadvantage (this would seem obvious but would be good to support this more clearly). This should be fewer options rather than less.
Response: Have referenced a report which outlines the difficulties of exiting homelessness when living with a disability (reference 21: Homelessness and disability

in the UK Report. Centre for Homelessness Impact. 2023. Accessed October 2024. https://cdn.prod.website-files.com/59f07e67422cdf0001904c14/645a76da097c6dad33fcc423_CHI-disabilities-homelessness23.pdf). Amended to 'fewer options'.

Comment 9. Authors describe the challenge as being the implementation gap, but there isn't a clear account and evidence that there are a range of effective interventions not being implemented.
Response: The authors are referring to the need to implement new or 'innovative' strategies (in addition to existing interventions) to target physical disability/function as a way to help people who are faced with the aforementioned challenges.

Comment 10. Please define 'medium- to long-term homelessness'.
Response: Long term homelessness is defined by many as chronic homelessness or those who have been in sheltered accommodation for a prolonged period. For the purpose of this section, this has been amended to long term homelessness.

Comment 11: Final sentence is a bit long. Consider shorter clearer sentences.
Response: Amended.
Amendment: 'Improvements in physical health will not solve all of the complex challenges faced by this population, it is nonetheless a sensible and positive solution focussed target which may have a ripple effect'.

Comment 12: Paragraph 4 – reference needed for statement that frailty is driven by poor nutrition.
Response: Amended.
Amendment: Reference no 22 : Pérez-Zepeda MU, Castrejón-Pérez RC, Wynne-Bannister E, García-Peña C. Frailty and food insecurity in older adults. Public Health Nutr. 2016;19(15):2844-9.

Aims and objectives
Comment 13: As above re term 'preliminary efficacy'.
Response: Amended to 'pre-post intervention impact'.

Comment 14: In objectives the term adherence is used for the first time. This is slightly different to feasibility as stated in your aim and abstract. Consistency of language needed here and in what you are considering.
Response: Apologies, adherence was used in the objectives to breakdown how feasibility was measured (ie. recruitment, retention and adherence). For improved clarity, this has been amended.
Amendment: 'To evaluate recruitment, retention and adherence to the physical rehabilitation and protein supplementation programme'.

Comment 15: Objective 2 could be more explicit – to examine change in measures of …
Response: Amended

Comment 16: Objective 3, examining perceptions of unmet need, is not clearly reflected in

the aims and abstract and needs a rationale. I agree with reviewer one that it would be (have been) useful to include qualitative process-type evaluation approaches to collecting and analysing this data, taking perceptions of participants, service providers and funders.
Response: Thank you for this comment. Since the protocol was written, a further amendment was made to ethics to include exit surveys, which we did. This is also part of the reason we amended the title of the study to 'impact' rather than efficacy/effectiveness.

Methods
Comment 17: This is described as a single arm feasibility cohort study. 'Cohort' is not the correct terminology for your design, which is used in longitudinal observational studies rather than intervention studies like yours. Feasibility study is adequate.
Response: Thank you for this comment. Amended.

Comment 18: As a feasibility study, you need to be explicit in advance in what would be the determining factor of feasibility. Is it that the intervention is feasible to deliver in practice, or is it that you need to know whether an RCT is feasible, or both. E.g., do you need to be able to recruit XX over a certain period of time, what proportion of drop out can you accommodate, what is considered sufficient adherence to gain a dose of the intervention and thus how much do people need to come etc... Such specificity may be challenging at your stage of intervention development but it is still good practice to define what results you consider would indicate feasibility. Obviously, this is no use now the study is concluded, but you can consider these in your main manuscript in the discussion of whether a full RCT is feasible.
Response: Thank you for this valuable point. As this type of study is so novel, it did not specifically define what results would define feasibility, rather it evaluated the feasibility of how this intervention would work in practice, therefore explored recruitment, retention and adherence to the programme, as stated in the aims and objectives.

Comment 19: You are very explicit about the study site (I am not sure what Dublin 10 is?) and should be careful that this does not risk identifying participants, this depends largely on how many people may have been using the service during the study. However, you have ethical approval so assume you have justified this.
Response: Amended this description.
Amendment: 'taking place in a suburban area of Dublin with high levels of deprivation'.

Comment 20: Consenting process looks appropriate. At this point recruitment, consenting and I assume measures are all done by the person providing the intervention (I think, although who conducts the measures is unclear) and therefore it would be useful to note the limitations of this in introducing bias.
Response: Yes recruitment, consent and measures were conducted by the person providing the intervention but also with a research physiotherapist and often a member of staff from the centre present. This has now been acknowledged this as a limitation in the discussion, thank you.
Amendment: 'A further limitation of this study is the same personnel conducting both

evaluation and the intervention, which may introduce bias'.

Comment 21: Inclusion and exclusion, how will you ascertain 'acute problematic behavioural issues" and what does this mean. Given you are working with people who use alcohol/drugs, it will be vital that there is ongoing attention to capacity. This is vital at the consenting stage but doesn't mean someone needs to be completely excluded.
Response: This comment intended to highlight that if a person's behaviour was problematic (ie. putting themselves, class participants or the researcher at risk), they would then be excluded. We used the term 'acute problematic behavioural issues' as it was considered a dynamic process and needed to be assessed at the initial consent stage and also at each interaction given the potential fluctuating presentation of participants. This has been amended.
Amendment: 'Participants with problematic behavioural issues, including confusion or extreme agitation or who have major physical problems (medical or orthopaedic), which would preclude ability to safely participate in the exercise class will be excluded from study participation. Assessment of behaviour will be a dynamic process and conducted at each interaction due to possible fluctuating presentations'

Comment 22: You mention trauma informed care and your adaptation of these. I am not sure who these are for and what 'communication skills are very important' means. It would be useful to expand on how this related to physical rehabilitation, particularly where there may be physical contact with participants.
Response: Thank you for this point. This section has been amended.
Amendment: 'Using a Trauma Informed approach to care[29] and based on experience from a previous Inclusion Health undergraduate clinical placement[30], the following were incorporated in the approach to assessment and follow up with participants; (i) empathy, (ii) consistency (iii) understanding and (iv) flexibility'.

Intervention
Comment 23: You need to have a much clearer articulation of the intervention components, and the hypothesised mechanisms of change. Using the TiDIER checklist (https://www.bmj.com/content/348/bmj.g1687) and presenting an intervention logic model will be helpful.
Response: Thank you. The Tidier checklist has since been used for the full study write-up.

Comment 24: It is a little unclear at present what each persons 'dose' would be. Is it one group and one park walk? Additional steps and goals? Three times weekly?
Response: Apologies for the lack of clarity. Amended.
Amendment: 'The intervention will consist of three exercise opportunities, including a twice weekly, 12-week exercise class with nutritional supplementation' and A 'Park Walk' will also be scheduled one day per week'.

Comment 25. The PAR-Q-should be conducted with rather than on participants?
Response: Amended

Comment 26. In contacting the GP this is a good idea for obtaining information about

contraindications, however, what if the person does not consent/a response is not forthcoming. This may be something that needs to be adapted to optimise feasibility.
Response: Thank you for this point. Considering this study involved an exercise intervention in a population who experience chronic medical conditions, and who also exercise minimally and have exercise- risk factors, (identified by the PAR-Q), it was deemed necessary to get medical consent from a medical practitioner. This was discussed and agreed with one of the study collaborators, a consultant in Inclusion Health. This was outlined in the consent form.

Comment 27. Adherence (see above comment) – uptake, is that people recruited who actually engage, or the proportion of eligible day service clients who take up the intervention?
Response: Apologies for the lack of clarity. Adherence refers to those who adhered to the exercise programme and the protein supplement, consistent with a preceding study (the LEAP I trial, doi: 10.1371/journal.pone.0301926). **and this line has been amended.**
What indicated compliance. 'Compliance' removed to avoid confusion. The section on primary outcomes has been amended.
Amendment: **'The following feasibility outcomes will be recorded; numbers recruited, retention of participants including number of repeat visits and adherence. Any adverse events will also be recorded.**
Recruitment and retention:The numbers recruited and frequency of attendances will be recorded. Participants will be encouraged to attend all sessions if possible. Drop out will also be recorded.
Adherence:The research physiotherapists will make every effort to be flexible and accommodating to participants in terms of their attendances and adherence to the programme. Adherence will be measured by the adherence to the exercise programme and the protein supplement.

Outcomes
Comment 28: Retention – useful to track drop out and point of drop out. Would also be vital to know how much prompting and support is required to facilitate attendance at the off-site location.
Response: Thank you for this point. This was intended and was included in the write-up when this study was completed and has been brought forward to a follow-up study.
Amendment: 'Recruitment and retention: The numbers recruited, and the frequency of attendances will be recorded. Participants will be encouraged to attend all sessions if possible. Drop out will also be recorded'.

Comment 29. I can't comment in detail on the physical outcome measures but just note that will need to add details of any known reliability and validity data where appropriate.
Response: A supplementary figure will be included to provide detail of validity and reliability of outcome measures.

Comment 30: In terms of unmet need and wider input on feasibility, barriers and facilitators and intervention revisions and planning, a qualitative approach with a wider participant base would be helpful.

Response: Thank you for this point and as per point above, a subsequent ethical amendment was made, related to permission to add a qualitative element to this study which has taken place and will be reported in the results.

Data collection and management
Comment 31: No detail of who is collecting the data at what points. Analytical plan is light and could be more robust in explaining which tests will be used for each outcome depending on the type of data it produces.
Response: More detail has been added to the analytical plan (see point 31).
Amendment: "Data will be collected pre and post intervention for those who complete the programme, by the research physiotherapist".

Comment 32: As there is no detail of the anticipated sample size, or of how the GLM will be constructed this is difficult to comment on. GLM is the first mention of timepoints, is there an interim measure or only pre-post?
Response: This has now been amended to reflect the pre-post intervention design of this study.
Amendment: 'Results will be compared to evaluate change over time from initial to final intervention. Normally distributed data will be compared from initial to final recorded time-points using paired t-tests and non-normally distributed data via the Wilcoxin-sign rank test'.

Dissemination
Comment 33: It may be beneficial to consider dissemination beyond academic audiences, particularly to gain input from practitioners, policymakers and people experiencing homelessness and problematic substance use on issues relating to intervention optimisation and delivery in 'real world' practice.
Response: Thank you for this important point and this has been done since the study completed.
Amendment: 'Results will also be presented to the key stakeholders including people with lived experience and also the funders of this study'.

Additional recommendations
Comment 34: When reporting your study, you should use CONSORT- extension for feasibility and pilot studies and include this as a supplementary file. See the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) website (www.equator-network.org/), and this article for some additional guidance [1].
Response: Thank you for this advice which we will take on board.

Competing Interests: No competing interests were disclosed.

Reviewer Report 18 July 2023

https://doi.org/10.21956/hrbopenres.14958.r34949

?

JUAN TORTOSA-MARTÍNEZ
University of Alicante, Alicante, Spain

The present manuscript is a protocol for a feasibility study about a physical rehabilitation program with protein supplementation in people with problematic substance use and homelessness. The topic of health inclusion is very relevant and deserves more intervention programs and further research. The potential value of this program for the quality of life of this population should be recognized.

The manuscript is well drafted but it requires some minor changes. The introduction section flows well although there should be information about previous exercise and nutrition programs for this population. This would help to understand better the choices made in the design of the program and identify the gaps in the literature. This would be the main required change.

In the methods section, it is stated that “The study will commence in October 2022 and will finish in March 2023.” This means that the protocol is being reviewed after the study has finished. This is unfortunate, as any comments or suggestions made by reviewers will not be considered for the intervention itself. It is also strange to see that it has been published in April 2023 and read that the study “will” commence in October 2022. However, this can´t be changed now.

The exercise program includes most information regarding the FIIT principles. The length, frequency and intensity of the program are reported but the duration of the sessions (other than the park walks) are not. Although it is stated that the exercises “will be adjusted to increase or decrease difficulty based on the results of the initial assessment and ability of participants, as judged by the research physiotherapist”, the sessions need more detail about the initial number of repetitions and sets of the strength and balance exercises, rest periods, and the specific duration of the aerobic exercises. In this regard, it would be advisable to plan a progression in the volume and/or intensity.

In the sessions, I am not sure if the exercises will be performed in the order presented in Table 1 or if it is just a list of exercises included. The order is important when mixing aerobic, strength and balance exercises in the same session and should be clarified. If the order is as presented in the table, I don´t think performing balance training the last is the best option. I would also include at least one exercise that targets the core muscles although perhaps there is some core muscle training in the “upper limb and trunk movements; weights and ball work” but I can´t tell with the limited description available.

Please add the aforementioned details about the exercise program so it can be replicated.

The primary outcomes are numbers recruited, retention of participants by number of repeat visits and adverse events. I think this information could be complemented with qualitative data gathered from the points of views of all participants in the program (eg. interviews), the ones that completed the program but also the ones that dropped the program. Understanding the reasons

why people dropped the program or why they stayed (adherence) is of special interest to analyse feasibility and improve the design of future programs. This information could be triangulated with the opinions of the physiotherapists (e.g. research diary) and perhaps from staff members of the Ballyfermot Advance (e.g. interviews). It would certainly help to achieve objective 3 of the study "To ascertain perceptions of unmet physical health needs, exercise habits and how an exercise intervention should ideally be designed to meet the needs of this cohort with lived experience of homelessness and active addiction issues."

The secondary outcomes are strength and muscular mass; physical performance and lower extremity physical function; pain; frailty; nutritional status; BMI; and the SF-12. I would have included the Timed Up and Go Test as it is one of the most widely used tests for physical performance and is also a measure of dynamic balance (the included Single Leg Stance measures static balance). Again, these secondary outcomes would complement nicely with a qualitative perspective, especially about the perceived benefits of the program, and would contribute to objective 3 of the study. As stated in the abstract, "an immediate impact may be simply a distraction from difficult circumstances", or there is an increase is self-esteem, or perhaps some other unexpected psychological or social benefits. Without asking participants about their perception, these types of benefits may be ignored when they can be of great relevance for the quality of life of a population with mental health problems and social exclusion. The information could be triangulated just the same way as with the main outcome. However, as it seems as the study already took place it may not be changed now but could be considered for future studies.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Exercise for the health and quality of life of special populations

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 26 Sep 2024

Fiona Kennedy

Dear Dr. Tortosa-Martínez,

Many thanks for your feedback and the opportunity to revise this manuscript. Apologies for the delay while awaiting a second review. Please see responses to each point raised. We very much hope the revised manuscript now meets the criteria for approval.
Best Wishes,
Fiona Kennedy and co-authors

Comment 1: The manuscript is well drafted, but it requires some minor changes. The introduction section flows well although there should be information about previous exercise and nutrition programs for this population. This would help to understand better the choices made in the design of the program and identify the gaps in the literature. This would be the main required change.
Response: **Thank you for this comment. Amendment will be made to reflect this gap in the literature. Most of the literature on physical activity/exercise interventions targeting this populations are multi-modal interventions and do not specifically focus on exercise and nutrition. To our knowledge, this is the first study, based on a pilot study, which provided an exercise and nutritional intervention in this population.**
Amendment: **'There is a dearth of research exploring physical activity and nutritional interventions in this population. Kendzor et al, 2017 investigated the effects of a diet and exercise intervention in homeless adults in a randomised controlled trial. This study, however, did not provide a structured, supervised exercise programme. The intervention involved the provision of educational newsletters, healthy snacks, and pedometers with advice on physical activity. This study is the first of its kind which will provide a structured exercise and nutritional intervention in this population'.**

Comment 2: In the methods section, it is stated that "The study will commence in October 2022 and will finish in March 2023." This means that the protocol is being reviewed after the study has finished. This is unfortunate, as any comments or suggestions made by reviewers will not be considered for the intervention itself. It is also strange to see that it has been published in April 2023 and read that the study "will" commence in October 2022. However, this can´t be changed now.
Response: **Thank you for your comment. This study was submitted for publication in advance of completion of the programme, however, due to the difficulty of initially getting reviewers, inevitable and protracted delays occurred. We feel revising the protocol is still a worthwhile endeavour to increase its quality.**

Comment 3: The exercise program includes most information regarding the FITT principles. The length, frequency and intensity of the program are reported but the duration of the sessions (other than the park walks) are not. Although it is stated that the exercises "will be adjusted to increase or decrease difficulty based on the results of the initial assessment and ability of participants, as judged by the research physiotherapist", the sessions need more detail about the initial number of repetitions and sets of the strength and balance exercises, rest periods, and the specific duration of the aerobic exercises. In this regard, it would be advisable to plan a progression in the volume and/or intensity.
Response: Apologies for this omission in the programme design. The target duration of the exercise circuit was approximately 20 minutes, based on learning from a pilot study in a similar cohort. For the initial session the target for each exercise was 2 sets of 10-15 repetitions with a rest period between sets, building to 3 sets of 15 repetitions

and following this using weights or resistance bands for progression of strength. The aerobic activity was timed and commenced with a minimum of 2 minutes and progressed weekly. More detail is provided in Table 1 in the manuscript.
Amendment: **'Each session, initially of approximate 20 minutes duration, will commence with a warm-up and stretch of the major muscles and will end with cool-down and stretch'**

Comment 4: In the sessions, I am not sure if the exercises will be performed in the order presented in Table 1 or if it is just a list of exercises included. The order is important when mixing aerobic, strength and balance exercises in the same session and should be clarified. If the order is as presented in the table, I don´t think performing balance training the last is the best option. I would also include at least one exercise that targets the core muscles although perhaps there is some core muscle training in the "upper limb and trunk movements; weights and ball work" but I can´t tell with the limited description available. Please add the aforementioned details about the exercise program so it can be replicated.
Response: Apologies for this lack of clarity. The exercise intervention was a circuit class. Each participant started with a different exercise. Upper limb and lower limb exercises were not performed consecutively to facilitate rest and recovery for muscle groups. Aerobic, balance and core exercises were part of this circuit and dependent on where the participant commenced.
Amendment: see Table 1 (manuscript).

Comment 5: The primary outcomes are numbers recruited, retention of participants by number of repeat visits and adverse events. I think this information could be complemented with qualitative data gathered from the points of views of all participants in the program (eg. interviews), the ones that completed the program but also the ones that dropped the program. Understanding the reasons why people dropped the program or why they stayed (adherence) is of special interest to analyse feasibility and improve the design of future programs. This information could be triangulated with the opinions of the physiotherapists (e.g. research diary) and perhaps from staff members of the Ballyfermot Advance (e.g. interviews). It would certainly help to achieve objective 3 of the study "To ascertain perceptions of unmet physical health needs, exercise habits and how an exercise intervention should ideally be designed to meet the needs of this cohort with lived experience of homelessness and active addiction issues."
Response: Thank you for this important point. This idea for a more in-depth qualitative analysis to ascertain the perspective of participants regarding dropping out/adhering to the programme emerged early in the programme and an ethics amendment was approved to conduct an exit survey upon completion of the programme to get perspectives from participants who attended and those who did not return. This will be reflected in the results paper.

Comment 6: The secondary outcomes are strength and muscular mass; physical performance and lower extremity physical function; pain; frailty; nutritional status; BMI; and the SF-12. I would have included the Timed Up and Go Test as it is one of the most widely used tests for physical performance and is also a measure of dynamic balance (the included Single Leg Stance measures static balance). Again, these secondary outcomes would

complement nicely with a qualitative perspective, especially about the perceived benefits of the program, and would contribute to objective 3 of the study. As stated in the abstract, “an immediate impact may be simply a distraction from difficult circumstances”, or there is an increase is self-esteem, or perhaps some other unexpected psychological or social benefits. Without asking participants about their perception, these types of benefits may be ignored when they can be of great relevance for the quality of life of a population with mental health problems and social exclusion. The information could be triangulated just the same way as with the main outcome. However, as it seems as the study already took place it may not be changed now but could be considered for future studies.
Response: **Thank you for your insightful comment. In a previous pilot study, the Short Physical Performance Battery (which includes a chair stand test, a short gait speed test, similar to the TUG, and a balance assessment) was utilised and a ceiling effect was observed in participants who had higher physical functioning. For this reason, we amended the test battery to include a more challenging assessment of balance (SLS), lower limb strength (30 second Chair Stand Test) and gait (10m Walk Test and 2 Min Walk Test).**

Competing Interests: No competing interests were disclosed.