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Research Protocol

Feasibility of engaging older adults living with multiple long-term conditions, frailty, and a recent deterioration in health in a study of lifestyle: protocol for the LiLL-OPM study

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Abstract

Community-dwelling older adults living with multiple long-term conditions (MLTC), frailty and a recent deterioration in health are underserved by research. This results in a limited evidence base for their care, including the potential benefits of lifestyle interventions such as structured exercise. The aims of the LiLL-OPM (Lifestyle in Later Life - Older People's Medicine) study are to determine if it is feasible to carry out a research project with these patients, describe their health and lifestyle, their attitudes to engaging in exercise and their experiences of taking part in the research. Older adults who are attending an Older People's Medicine Day Unit service in Newcastle, UK, and their informal carers will be invited to take part. The study will use mixed methods with semi-structured interviews and a health and lifestyle questionnaire, carried out in a way that is most convenient to participants, including in their own homes and with a flexible schedule of study visits. The findings from the feasibility study will provide invaluable data on how to design research, including the most suitable approaches to recruitment and data collection. This will improve the inclusion in research of older adults living with MLTC, frailty and a recent deterioration in health.

Keywords: Feasibility study, Frailty, Lifestyle, Multimorbidity, Multiple long-term conditions

Introduction

Increases in healthy life expectancy are not keeping pace with the average life expectancy, such that today's older people may face more time spent in poor health, including living with the ageing syndromes of multiple long-term conditions (MLTC, also known as multimorbidity)[1,2] and frailty[3,4]. These syndromes are complex and are associated with a range of consequences including a deterioration in health[5]. Indeed, older people living with MLTC and frailty account for a substantial and growing proportion of acute encounters in primary[6] and secondary care[7,8].

Living with MLTC is typically defined as the presence of two or more long-term health conditions (sometimes defined as lasting 12 months or longer)[9], whereby one is not necessarily more dominant than the other(s)[10,11]. Over half of older people aged 65+ in the United Kingdom live with MLTC[1,6]. The prevalence of MLTC is recognised to increase with age and social deprivation, and MLTC is more common in women[12]. A range of factors may lead to older people

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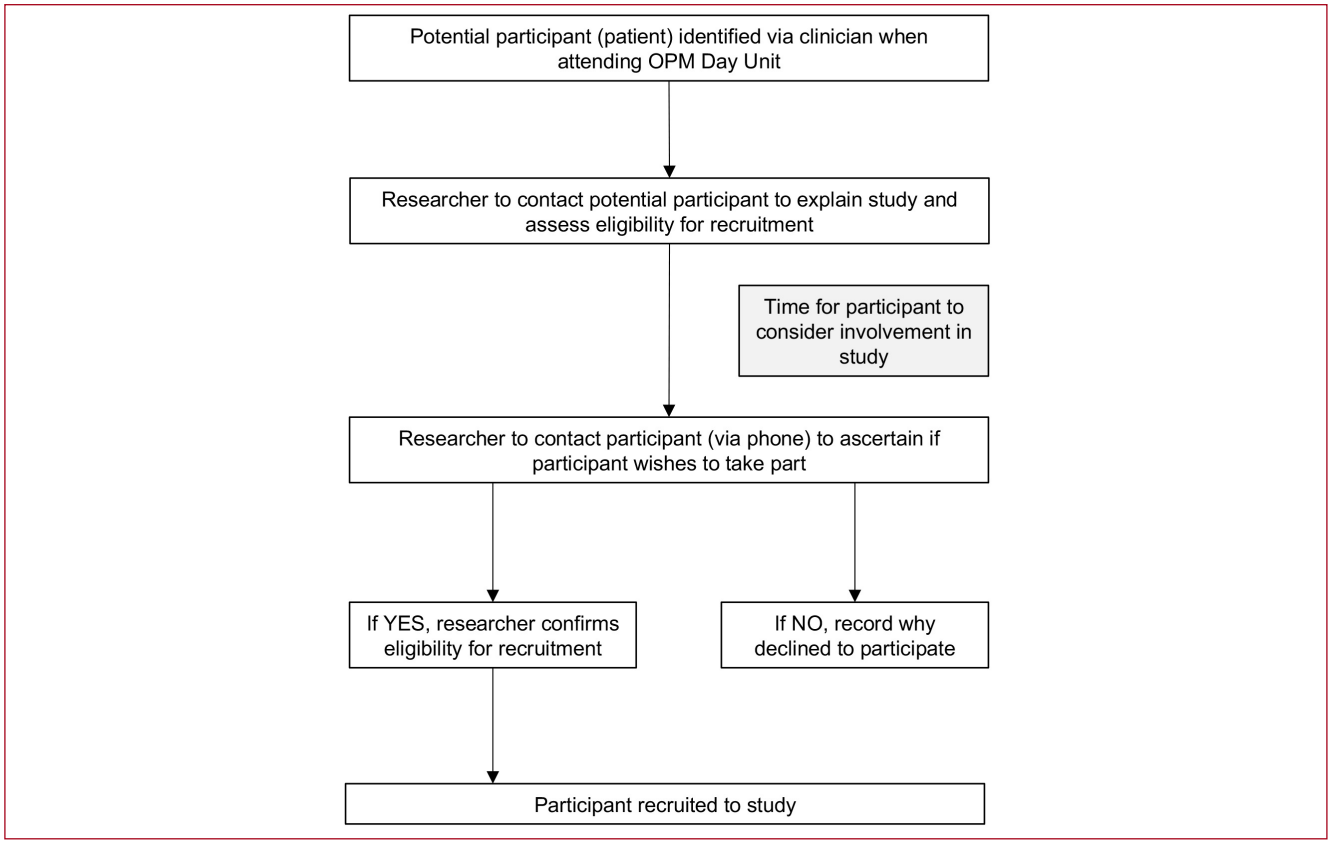

Figure 1. Participant (patient) recruitment process *(OPM, Older People's Medicine).*

living with MLTC being underserved by research, including the effect of study exclusion criteria, pre-existing time commitments including clinic appointments related to MLTC, and difficulty with travelling to study appointments[13–15].

Frailty is a progressive long-term condition characterised by an increased vulnerability to stressors due to impairments in multiple physiological systems leading to reduced homeostatic reserve and resilience[5,16]. A range of approaches have been taken to define frailty, including the frailty phenotype, based on the presence of three or more of the following criteria: unintentional weight loss, self-reported exhaustion, weakness (low grip strength), slow walking speed and low physical activity[17]. The prevalence of frailty gradually increases with age, and occurs more frequently in women[18]. Frailty and MLTC frequently co-occur[19], hence living with frailty may lead to individuals being underserved by research for the same reasons as living with MLTC. Additional barriers to taking part in research for people living with frailty include fatigue, the presence of physical, cognitive and sensory impairments, as well as overall poor health[15,20].

Older people living with MLTC and frailty are more likely to experience a deterioration in their health (for instance an increased risk of death or hospital admission) than individuals without these syndromes[5]. Carrying out research in this context is challenging. For example, clinicians acting as gatekeepers into clinical research studies might consider that research represents too great a burden[21,22]. Many studies are designed with multiple exclusion criteria that may exclude those with MLTC. Higher rates of dropout, death and adverse events may also make clinicians reluctant to enrol older people living with frailty and MLTC. Indeed, few studies have investigated if it is feasible to carry out research with older people living with frailty and a recent deterioration in their health[23].

We have described reasons why older people living with MLTC, frailty and a recent deterioration in health have been underserved by research. For example, our understanding of lifestyle factors that are known influences on health, such as physical activity, diet, smoking and alcohol consumption, is limited in older age[24]. Higher levels of physical activity in particular have been associated with improved physical function[25] and reduced risk of incident disability in older people[26]. Structured exercise represents a sub-set of physical activity which is planned and repetitive and aims to improve or maintain physical fitness[27]. Although recognised

Patients	
1	A semi-structured interview to understand how to design research, including approaches to recruitment and data collection.
2	A quantitative health and lifestyle assessment (refer to Table 2 for more information).
3	A semi-structured interview to explore participants' experiences of physical activity/exercise and their attitudes to engaging in these behaviours.
4	A semi-structured interview to understand their experiences of taking part in the research.
Informal carers	
1	A semi-structured interview to explore how to include older adults in research and explore carers' experience of taking part in the research.

Table 1. Study assessments.

to be beneficial for people living with MLTC[28], the most effective and acceptable form of structured exercise for older adults remains unknown[29,30].

The above knowledge gaps have motivated us to develop the Lifestyle in Later Life in Older People's Medicine (LiLL-OPM) Study, with the aims as shown below.

Methods

Study aims

The LiLL-OPM Study aims to:

1) Determine if it is feasible and acceptable to carry out a research project with older adults living at home with the complexity of MLTC, frailty and a recent deterioration in health. Views will be sought from older adults and their informal carers (relative or friend).
2) Describe the health and lifestyle of these older adults (demographic information, marital status and living arrangements, health, medication, social support, physical activity, dietary assessment, smoking and alcohol, disability and formal care).
3) Determine their attitudes to being physically active and engaging in exercise.
4) Understand participants' (older adults and their carers) experience of taking part in the research.

Study design

This is a mixed methods study incorporating a combination of semi-structured interviews and a health and lifestyle questionnaire involving older adults living with MLTC, frailty and a recent deterioration in health.

Eligibility criteria

The study aims to recruit older adults with capacity to consent to the study, who are living in their own home, who live with MLTC and frailty and who have experienced a recent deterioration in health, such that a healthcare professional (usually their General Practitioner) has referred them to our Older People's Medicine (OPM) Day Unit. There are no specific age criteria for inclusion in the study, although patients attending the OPM clinic are typically aged over 65 years. There is no upper age limit for inclusion. Any older adult who the OPM clinician feels it would be inappropriate to approach and those who are unable to provide informed consent will be excluded. Informal carers of these older adults (i.e., relative or friend, not a paid or professional carer) will also be invited to participate.

Recruitment of participants

Older adults attending an Older People's Medicine Day Unit service in Newcastle Hospitals, England will be invited to take part in the study. The model of care of older adults within the Day Unit involves Comprehensive Geriatric Assessment (CGA), including medical, functional, mental health, social and environmental dimensions[31], with an interdisciplinary approach. The Day Unit therefore provides an opportunity to identify and recruit older adults living with MLTC and frailty who have experienced a recent decline in their health. Clinicians within the Day Hospital service will identify potential participants (older adults) for the study, who meet the inclusion criteria above. Potential participants (and carers) will be provided with a brief explanation of the study and a participant information pack, including a participant information sheet. Details of potential participants will be provided to the research team who will contact them to discuss the study. Participants will have the opportunity to ask questions and be given time to consider their participation. Figure 1 summarises the patient recruitment process.

Consent procedure

Written informed consent will be obtained by a trained member of the research team and will be completed either face-to-face (where possible) or using postal consent. Capacity to consent will be assessed using an established consent pathway and checked throughout the active research phase (prior to each study assessment). Participants will be made aware they have the right to withdraw at any time, with the data gathered used up to the point of withdrawal. For those who lose capacity and do not recover during the research process, they will be withdrawn from the study. We

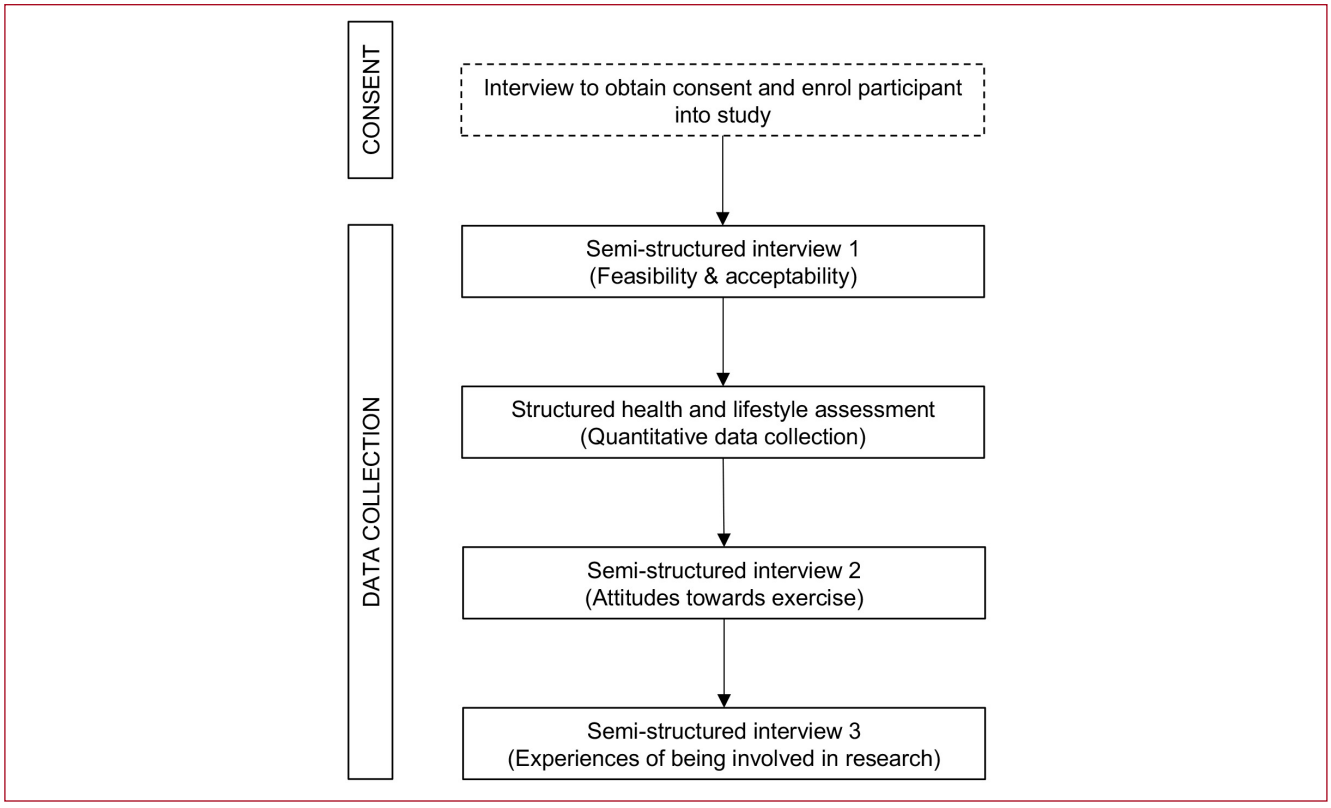

Figure 2. Data collection pathway (Participants).

will seek consent to use research data collected to the point where capacity is lost.

Data collection

Table 1 provides a summary of the study assessments. Older patients will be invited to take part in a maximum of four assessments and informal carers will be invited to take part in an optional separate semi-structured interview. To determine the feasibility and acceptability of the study, the number of older adults approached who agree or decline to participate or withdraw from the study (with reasons captured) will be collected and analysed. If clinically relevant results or new issues are identified during the study, the research team will notify the clinical team after seeking consent from the participant to do so. All participants will be assigned a unique identifier and all identifiable data will be kept separate from the study dataset. Interviewees will be assigned a pseudonym. To reduce burden, it is envisaged that the study assessments will take place in participants' homes or via video-link/telephone and last on average thirty minutes. Participants will have the option to suspend the assessments and re-schedule appointments at their convenience. Study assessments will be flexible to accommodate different days, times and frequencies to suit participants. Individual assessments can be broken down, or combined, depending on what the participant finds most convenient. We will maintain regular contact with the participants throughout the study, and post-completion to facilitate participant involvement, feedback of results and the ability to offer further research opportunities. Figure 2 summarises the data collection pathway.

Semi-structured interviews

The first semi-structured interview aims to understand how to approach and involve older adults in research, including gathering information on approaches to recruitment and data collection procedures. For example, '*we sometimes find it difficult to reach older adults living at home to invite them to take part in research. In your opinion how should we look to reach more older adults in the future to ask them to take part in research?*' and '*what would be the reasons that would prevent you from taking part in research and how can we help you overcome these?*'. The second semi-structured interview aims to explore older adults' attitudes towards engaging in exercise, for example '*how would you feel about becoming more active than you are now?*' and '*what may prevent you from becoming more active?*'. The third interview will explore the participants (patients and/or their carers) experiences of taking part in the research, for example '*can you tell me what you liked/disliked about the study?*' The interview findings

Topic	Tools used
Demographic information	
Marital status and living arrangements	
Health and function	Fried frailty score[17]
SARC-F score[33]	
36 domains of the eFI[34]	
GDS-4[35]	
Medication	
Social support	LSNS-6[36]
Physical activity	RAPA[37]
Wrist-worn tri-axial accelerometry (ActivInsights Ltd, Cambridge, UK)	
Dietary assessment including appetite	SNAQ[38]
FFQ[39]	
Smoking and alcohol	
Disability	Modified Barthel ADL index[40]
Formal care	

SARC-F: Strength, Assistance, Rise, Climb – Falls questionnaire. Simplified Questionnaire to Rapidly Diagnose Sarcopenia; eFI: electronic Frailty Index; FFQ: Food Frequency Questionnaire; GDS: Geriatric Depression Scale; LSNS: Lubben Social Network Scale; RAPA: Rapid Assessment of Physical Activity; SNAQ: Short Nutritional Appetite Questionnaire; ADL: Activities of Daily Living.

Table 2. Health and lifestyle assessment data.

will be used to guide the design of future research that meets the needs of older adults and their carers. All semi-structured interviews will involve the use of open-ended questions (Table S1) and will be audio-recorded.

Health and lifestyle assessment

In a separate structured interview to describe the lifestyle of the older participants, a questionnaire will be completed covering the following topics: demographic information, marital status and living arrangements, health, medication, social support, physical activity, dietary assessment, smoking and alcohol, disability, and formal care. Participants will be asked if they are willing to wear a wrist-worn tri-axial accelerometer (GENEActiv® Original, ActivInsights Ltd, Cambridge, UK) for a period of 7 days to provide an objective assessment of physical activity. Table 2 provides a summary of the data collected and tools used in the health and lifestyle assessment.

Data analysis

The qualitative interviews will be analysed using thematic analysis[32]. Thematic analysis is an accessible and theoretically flexible approach, providing a rich and detailed account of data. An inductive approach will be utilised meaning emergent themes will be grounded in the data. The researcher will familiarise themselves with the data by reading and re-reading the interview transcripts whilst identify interesting aspects with the use of forming initial codes. This will involve highlighting text (words and short segments of the data), that will represent meaning and patterns within the data. Once codes are established, they will be collated into potential themes and supported with relevant quotations. All final themes will be reviewed and defined.

As this is a feasibility study the quantitative data collected will be analysed using simple descriptive statistics, and we will therefore not perform a sample size calculation. Using these descriptive statistics, we will characterise the health and lifestyle of the older adults. Summary variables will be produced, such as those for the different definitions of sarcopenia and frailty.

Discussion

This protocol describes the design of a mixed methods study utilising semi-structured interviews and a health and lifestyle assessment to identify the feasibility of conducting research with older adults living with MLTC, frailty and a recent deterioration in health.

The findings will provide valuable information on how to design research, including the most suitable approaches to recruitment and data collection methods. We anticipate that data gathered from the health and lifestyle questionnaire and

the exercise interview will guide the future development of physical activity and/or structured exercise interventions. We envisage identification of potential barriers to participation, allowing us to provide recommendations on strategies that will increase the amount of research carried out with older adults living with MLTC, frailty and a recent deterioration in health.

Ethics approval

This study has been granted ethical approval from London – Harrow Research Ethics Committee [Approval number 20/LO/1243]. All participants will provide written informed consent.

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Authors' contributions

AAS conceived the idea for the study. All authors were involved in the design and/or conduct of the study. CH, LD and RD drafted the manuscript. All authors critically revised and approved the final manuscript.

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Supplemental Table

Table S1. Semi-structured interview questions.

Interview 1
1. Can you describe your experience of health research that you have been asked to take part in, in the past?
2 What are the reasons that you would like to be involved in research?
3. As researchers we sometimes find it difficult to reach older adults living at home to ask them to be involved in research. In your opinion how should we look to reach more older adults in the future to ask them to take part in research?
4 When inviting older adults to take part in research, who do you think should make the initial approach to discuss the study?
5. If you were to take part in research, where would be the most appropriate place to be seen by the researcher and why?
6. How confident do you feel when you are asked to attend a hospital appointment and who currently supports you when you attend a hospital appointment?
7 Can you describe your physical health, and how these currently may affect you in attending hospital appointments?
8. What would be the reasons that would stop you from taking part in research?
9. How important is it to you that we involve a relative or carer when making decisions about you being involved in research?
10. What would make you more likely to take part in research?
11. In what ways could we encourage others like yourself to be involved in research?
12. What support could we think about putting in place to help others to take part in research?
13. Can you describe your experience of using digital technology, for example an iPad, laptop or mobile phone device?
Harry has agreed to take part in the research and is asked to use digital technology for example, an iPad, laptop or mobile phone device to read the information about the study and to read and electronically sign the consent form.
14. How would you feel about being asked to use digital technology for reading information about the study? - including advantages/disadvantages?
15. Do you feel that you would be able to use digital devices independently or would you require support?
16. How could we encourage/support you in using digital technology in the future/what might make it easier for you?
Harry has signed the consent form and is ready for his first research visit. During this visit Harry is asked questions about his diet and exercise, and he is asked to complete physical performance tests for example, Harry is assessed on his walking speed and grip strength, as well as taking part in other tests.
17. How would you feel if you were Harry?
18. How do you feel about Harry being asked to complete physical performance tests?
19. What should the researcher consider as being important to Harry?
Interview 2
1. Thinking of a typical day is there anything that you do that you would consider to be physical activity?
2. How important is being physically active to you?
3. What do you think the benefits are of being physically active?
4. How about any disadvantages of physical activity?
5. Currently, what might prevent you from doing more physical activity?
6. Currently, what might encourage you to do more physical activity?
7. What does the term 'exercise' mean to you?
8. How important is exercise to you? Why?
9. What do you do now if anything that could be considered exercise?
10. Can you describe what exercise you have done in the past?
11. How would you feel about becoming more active than you are now? Why?
12. Is there anyone in your life such as family or friends who encourage you to be active or discourage you?
13. If you were to take part in exercise, what would you like to see as the main benefits for you personally?
14. If you were going to start engaging in an exercise programme (or think about starting) what type of exercise would you think of?
15. Have you ever been told to do more exercise by a doctor?
16. How would you feel if another professional like a physiotherapist was to advise you to exercise?
17. Do you see any potential for using technology in the future to support you being more active?
18. Have you heard of resistance exercise?
Resistance exercise (or strength training) is exercise which typically involves your muscles lifting or pulling or pushing against an external weight or resistance. It often takes place in a gym and can involve lifting weights, working on machines or using elastic resistance bands
19. Can you tell me what your thoughts are on resistance exercise?
20. Do you know of any positive effects of resistance exercise?
21. How would you feel about doing this kind of exercise?

Table S1. *(Cont. from previous page).*

22. If you wouldn't want to do this type of exercise, why not?
23. How could we encourage and support you to engage in this type of exercise? What would make you feel more comfortable about doing it? Individual vs. group
24. How would you feel about taking part in this kind of exercise programme (i.e., resistance exercise programme) at home?
25. How would you feel about taking part in an exercise programme in the hospital?
26. How would you feel about taking part in an exercise programme in the community (leisure centre)?
27. If you had a preference for at home, in hospital or in the community where would you prefer to do the exercise?
28. Would you prefer to participate in group with others like yourself or individual exercise sessions? Why?
29. What would be the best time of day for you to exercise?
30. If you were going to do some exercise, would you prefer to do it in your own time? Or how would you feel about attending sessions with others like yourself?
31. How often do you think you could do some exercise (how many times per week and for how long?)

Interview 3

1. What were your initial thoughts when you found out about the LiLL-OPM study that you kindly are taking part in?
2. When you received the invite to take part – what were the reasons you decided to take part?
3. Who have you spoken to about the study?
4. How did you decide that you wanted to take part?
5. What are the advantages of taking part in this study?
6. What are the disadvantages?
7. What were your fears/concerns about taking part in this study?
8. How has your health impacted on your participation in this study?
9. What is your overall impression of the study?
10. What aspects do you like/dislike?
11. What would your thoughts be if you were asked to participate again in research in the future?
12. How do you feel about your contribution to the research?
13. What you like to discuss anything else/do you have any more thoughts about the study that I have missed?