

Review Article

Why are older adults living with the complexity of multiple long-term conditions, frailty and a recent deterioration in health under-served by research?

A narrative synthesis review of the literature

Lorelle Dismore^{1,2,3}, Christopher Hurst^{1,2}, Antoneta Granic^{1,2}, Ellen Tullo^{1,2,3}, Miles D. Witham^{1,2,4}, Richard M. Dodds^{1,2,4}, Avan A. Sayer^{1,2,4}, Sian M. Robinson^{1,2}

¹AGE Research Group, Translational and Clinical Research Institute, Faculty of Medical Sciences, Newcastle University, Newcastle, UK;

²NIHR Newcastle Biomedical Research Centre, Newcastle University and Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle upon Tyne, UK;

³Northumbria Healthcare NHS Foundation Trust, North Tyneside Hospital, Rake Lane, North Shields, Tyne & Wear, UK;

⁴Older People's Medicine Department, Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle upon Tyne, UK

Abstract

Older adults living with the complexity of multiple long-term conditions (MLTC), frailty and a recent deterioration in health are under-served by research. As a result, current treatment guidelines are often based on data from studies of younger and less frail participants, and often single disease focused. The aims of this review were (i) to identify why older adults living with the complexity of MLTC, frailty and a recent deterioration in health are under-served by research and (ii) to identify strategies for increasing their recruitment and retention. Although a range of factors have been suggested to affect the participation of older adults with MLTC and frailty in research, this review shows that much less is known about the inclusion of older adults living with the complexity of MLTC, frailty and a recent deterioration in health. Researchers should focus on strategies that minimise participation burden for these patients, maintaining an adaptive and flexible approach, to increase their recruitment and retention. Future research should include qualitative interviews to provide further insights into how best to design and conduct research to suit the needs of this population group.

Keywords: Frailty, Multiple long-term conditions, Older people, Recent deterioration in health, Under-served by research

Introduction

Population ageing is a global phenomenon, with every country experiencing growth in the number and proportion of older adults¹. In the United Kingdom (UK) there are nearly 12 million people aged 65 and above, projected to increase by a further 8.6 million by 2066, accounting for 26% of the total population². On average, older men now spend 2.4 years and women spend three years with substantial care needs³. There is potential for community-based programs and services to better support older adults to prevent the need for potentially avoidable and costly acute care episodes⁴, and appropriate and efficient health and social care provision⁵. The National Institute for Health and Care Research (NIHR) in the UK

recognises the need for the provision of interventions and support through evidence-based practice to promote healthy

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Corresponding author: Sian M. Robinson, NIHR Newcastle Biomedical Research Centre, 3rd Floor Biomedical Research Building, Campus for Ageing and Vitality, Newcastle upon Tyne NE4 5PL, United Kingdom

E-mail: Sian.Robinson@newcastle.ac.uk

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ageing⁶, defined by the World Health Organisation as the process of developing and maintaining the functional ability that enables wellbeing in older age⁷. However, older people in the UK are under-served by research despite of their high utilisation of healthcare and disease burden^{8,9}, limiting the evidence available to policymakers. Research for older people living with frailty has been transformed over recent years thanks to investment by the NIHR^{8,9} but there remain sub-sets of older people for example, those living with the complexity of multiple long-term conditions (MLTCs), frailty and a recent deterioration in health (identified as an illness episode requiring interaction with healthcare services) who historically have not been recruited into research and remain underserved by it.

The very old (aged ≥ 85 years) are the fastest growing age group of older adults², with the likelihood of MLTC and frailty increasing with age; older adults continue to live longer and spend more time in poor health^{3,5}. Frailty is defined as a clinical state of older adults with increased vulnerability, resulting from age-related declines in physiologic reserve and function across multiple organ systems, whereby the ability to cope with every day or acute stressors is compromised¹⁰. MLTC (also known as multimorbidity) is defined as the presence of two or more long-term conditions and is most common in those aged 65 and above¹¹. MLTC and frailty may coexist¹² exacerbating disability and functional decline^{13,14}. Older adults who experience MLTC and frailty are therefore at risk for more adverse outcomes and more likely to experience a deterioration in health that requires interaction with healthcare services such as specialist referral and/or hospital admission¹⁴⁻¹⁷. Paradoxically, older people with a recent deterioration in health are often not included in clinical research despite being at a point in their illness trajectory where they are most likely to interact with health service, thus need the evidence provided by clinical research studies. The potential for higher rates of drop out of these patients from research studies, arising from acute episodes of illness together with the unpredictability of their illness trajectories and greater mortality risk, may make clinicians reluctant to include them. As a result, health and social care interventions are often based on data from studies involving primarily younger, healthier participants with lower levels of disability^{18,19}, and are often single disease focused²⁰. Some study protocols require 'stable' illness without recent changes in medications, and the burden of frequent healthcare contacts and burden of symptoms when health is deteriorating may act as a disincentive for participation. Findings in stable older people may not necessarily apply in those with a recent health deterioration, where mechanisms of illness may differ (e.g., the presence of acute inflammatory response), factors providing resilience to decompensation may be lost (e.g., due to poor food and fluid intake, physical deconditioning) and background medications may be changing.

There remains a need to improve the reach of research to

include all older adults, including under-served groups such as those in poorer health and with complex needs²¹. However, the recruitment of this sizeable but hard to reach group in research is challenging²². Knowledge of the reasons why this group is under-served in research will help overcome these challenges and will inform specific strategies for partnering with vulnerable groups in healthcare research²³.

Previous reviews have explored barriers to and strategies for the recruitment and retention of older adults in clinical research^{24,25} and some have paid attention to the challenges in engaging older adults with frailty^{23,26,27}. Less is known about those older adults living with MLTC and with a recent deterioration in health.

The aims of this narrative review were (i) to identify why older adults living with the complexity of MLTC, frailty and a recent deterioration in health are under-served by research and (ii) to identify strategies for increasing recruitment and retention of this under-served group.

Materials and Methods

This review is separated into four sections. A literature review with a narrative synthesis was performed to describe systematic reviews, non-systematic reviews, and research with older adults with: i) frailty, ii) MLTC and iii) older adults with a recent deterioration in health to identify reasons why they are under-served by research. We chose a narrative review to enable exploration of the literature on older adults living with the complexity of MLTC, frailty and a recent deterioration in health, and its critical analysis²⁸. To inform this narrative review, we used systematic search methods to identify studies, using Medline (without date restrictions) and Google Scholar up to December 2022. The search terms were ('old age', or 'older adults', or elderly or 'older people'), or geriatric*, (frail or 'frailty'), (co-morbid*, or multimorbid*), 'long term conditions', deterioration in health', 'deteriorating health', 'change* in health status' 'functional decline', inclusion, include*, engage*, recruit*, and represent*. Finally, we summarise strategies to increase recruitment and retention of older adults with MLTC, frailty and a recent deterioration in health.

Findings

Reasons older adults living with frailty are under-served by research

One systematic review conducted in 2014 by Provencher and colleagues²⁶ identified the challenges pertaining to recruitment and retention of frail older adults in research studies. Lack of perceived benefit, distrust of research staff, poor health and mobility problems were identified as common challenges. Challenges were also noted in relation to research procedures including difficulties in understanding and reading the consent form and older adults found the length and number of sessions and assessments demanding or intrusive.

Table 1. Why are older adults living with the complexity of MLTC, frailty with a recent deterioration in health under-served by research?

Frailty	MLTC	MLTC, Frailty and Recent Deterioration in Health
<p><u>Personal reasons</u></p> <ul style="list-style-type: none"> • Lack of perceived benefit • Distrust of research staff • Lack of confidence to make a decision <p><u>Health reasons</u></p> <ul style="list-style-type: none"> • Poor health and mobility problems • Communication problems/cognitive impairment • Disability • Fatigue <p><u>Research procedures</u></p> <ul style="list-style-type: none"> • Difficult to understand and read the consent form/information leaflets • Time consuming/demanding/intrusive • Travel requirements <p><u>Other</u></p> <ul style="list-style-type: none"> • Stereotypical assumptions about ageing; viewed as vulnerable and difficult to locate 	<p><u>Personal reasons</u></p> <ul style="list-style-type: none"> • Routines (i.e., caring for grandchildren) <p><u>Health reasons</u></p> <ul style="list-style-type: none"> • Complex needs; physical, psychological and social performance • Intrusive problems; pain, incontinence, falls, pressure ulcers and delirium • Fatigue, shortness of breath, limited mobility and anxiety • Medical reasons and health-related commitments (i.e., medical appointments) <p><u>Research procedures</u></p> <ul style="list-style-type: none"> • Travel and transport issues • Research outcomes less predictable and increased risk of adverse events • Time requirements 	<p><u>Paucity of research</u>: one study conducted by Bone et al., successfully recruited 90 older adults with frailty and a recent deterioration in health</p>
Strategies for increasing recruitment and retention of these under-served groups.		
Recruitment	Retention	Other
<ul style="list-style-type: none"> • Take time to explain the research fully and use simple language, involve relatives and friends to help/support the older adult to make a decision • Short consent form using large print • Educational materials • Gifts/financial compensation/reimbursement of costs incurred • Establish a trustworthy relationship • Use General Practitioners as a credible source • Ensure communication aids are working • Use suitable facilities • Mitigate unique challenges before starting recruitment • Avoid certain times of approaching participants 	<ul style="list-style-type: none"> • Offer a flexible approach and adaptation to study procedures including home-based assessments • Avoid the use of time-consuming questionnaires • Divide tasks into smaller sections and allow for breaks • Consider data collection and intervention delivered by telephone • Maintain regular contact with participants • Ensure research and clinical staff have excellent social skills • Provide feedback on participants performance and share study results • Consider outcome measures as physical, psychologically and socially acceptable 	<ul style="list-style-type: none"> • Use patient and public involvement • Include carers of participants and consider carer respite • Consider tools and resources within the Innovations in Clinical Trial Design and Delivery for the Under-served framework and roadmap (INCLUDE)

Other literature reviews highlight the challenges of engaging older adults in research in general, with consideration of the specific issues pertaining to older adults with frailty. For example, sensory communication problems and cognitive impairment may produce barriers towards the inclusion of frail older people in clinical trials²⁷. Older adults with frailty are more likely to experience disability compared to non-frail individuals contributing to difficulties in travelling to research facilities independently^{5,27}. They may need to be accompanied by a carer and require transport, resulting in a need for additional time, money and planning²⁷. Disability and difficulties in organising and travelling result in the care

of patients becoming increasingly complex - their need for healthcare services increases while their ability to navigate the healthcare system without help decreases¹⁴.

Frailty increases the risk of experiencing fatigue - older adults may prioritise their energy expenditure for activities of daily living in preference to spending limited reserves of energy on a research project²⁹. Research therefore needs to consider the participant's energy and time required to complete study procedures³⁰. Time constraints have been recognised as a barrier from the participant's and researcher's perspective, in both non-clinical and clinical trials in older adults^{31,32}. For example, recruiting community-

dwelling frail older people into a qualitative study to explore advice about exercise at the time of geriatric consultation proved difficult, due to the presence of severe medical conditions resulting in participants feeling too fatigued to be interviewed, and declining participation³³. Being in poor health may also serve as a barrier in retaining frail older adults in research; in one case, five older adults with health-related conditions participated in four advisory group meetings over a period of six months, but by the time of the final meeting one member had died and two members were unable to attend because of illness³⁴.

Harris & Dyson (2001) documented their experiences of recruiting older adults living with frailty into a randomised controlled trial (RCT) to evaluate the clinical outcomes and cost of transfer to a nursing-led inpatient unit research³⁵. They described the process as complex, with elements of the research process presenting barriers to recruitment and retention, such as the process of obtaining valid informed consent. This was due to problems with the accessibility of information including font size and reading level of patient information leaflets, and the participants reporting difficulties in hearing verbal information. In addition to the process of obtaining informed consent, the research process involved an assessment of a patient's understanding of the project, and older adults with frailty were more likely to experience some loss of cognitive agility or confidence to make an autonomous decision. Ethics committees and researchers have a duty of care to consider whether the benefits-burden ratio is justified and to what extent research extends beyond the risks of usual care. This is even more important when addressing research with frail older adults due to obligations to minimise harms from aggressive, or futile, interventions³⁰.

There are stereotypical assumptions about ageing with those aged 75 and over, who are frail, considered more difficult to locate and to interview²⁹. Older adults living with frailty may be viewed as potentially vulnerable which may act as a barrier to conducting research with this population^{27,36}. Labelling a patient as frail may be viewed negatively and healthcare professionals and researchers need to be aware of the unintended consequences of the construct³⁷. Yet older adults living with frailty view themselves as a group who are able to make unique contributions to research, often participating for altruistic reasons and older, more vulnerable adults may decide to take part in research for social reasons, due to being something they value in their everyday lives^{38,39}. In the Newcastle 85+ study, older adults showed subjectively high levels health and functional ability despite significant levels of disease and impairment⁴⁰. Older adults considered pre-frail participating in a nurse-supported pedometer-based walking intervention were more likely than non-participants to have a limiting longstanding illness and were less likely to report being active or walking fast³¹. However, the most physically limited or unwell opted out of a physical activity intervention, meaning that conclusions drawn from research trials in this area do not generalise to individuals with

function-limited health conditions⁴¹. RCTs are considered by some to be the gold standard for medical research; however, they are hard to perform with older adults. Recruitment and selection of patients is difficult as older adults may be judged as lacking capacity to consent to participate, and outcome measures may be burdensome or insufficiently responsive to changes in functional performance and quality of life⁴².

In summary, the reasons why older adults living with frailty are under-served by research are personal reasons; lack of perceived benefit and distrust of research staff, health reasons; mobility and communication problems, disability and fatigue and issues with the research procedures; time consuming and travel requirements (Table 1).

Reasons older adults living with MLTC are under-served by research

Similarly, to frail older adults, older adults living with MLTC have had limited involvement as research participants²³. A reason for exclusion may be due to the heterogeneity of the older study populations; multimorbidity and co-existent treatments make outcomes less predictable and increase the risk of adverse events²⁷. Studies often exclude people with comorbidities for a homogenous population, to reduce the risk of adverse events and to reduce the risk of dropout/withdrawal due to illness, death, etc; therefore, research doesn't reflect real-world populations⁴³. The high prevalence of MLTC may result in impaired physical, psychological and social performance⁴⁴, resulting in complex needs of older people with MLTC and researchers must be aware of the physical health factors that may impact on their research participation. For example, multimorbidity increases the risk of experiencing intrusive problems such as pain, incontinence, falls, pressure ulcers and delirium⁴⁵, with restrictions in daily routines through fatigue, shortness of breath, limited mobility and anxiety⁴⁶.

Reasons for non-participation in one rehabilitation programme for people with multimorbidity included distance to travel, transport, medical reasons (i.e., self-reported other medical issues, current hospital admission and medical appointments), doing enough exercise at home, work commitments, caring for grandchildren and time required to complete the programme⁴⁷. Another study investigating home telemonitoring application also noted time required to complete the study was a reason for non-participation in multimorbid patients⁴⁸. More recently, Biegus and colleagues reported that 30% of multimorbid older patients who were identified as eligible to participate in an RCT could not be invited to take part. Reasons for not being able to invite the remaining patients included having moved out of the area or into nursing homes or some of the participants had died before they could be contacted, others could not be reached⁴⁹.

To obtain more detailed insights older adults were interviewed to uncover the key factors associated with their participation into a clinical trial for the self-management of

multimorbidity. Reasons for their participation were altruism, a hope of health gains including psychosocial support, or that they took part on the recommendations of their doctor⁴⁰. As an illustration of the burden of MLTC on capacity to participate in research, 31 patients with multimorbidity were invited to take part in a semi-structured interview that sought to identify and describe threats to patient safety in primary care, of whom two did not wish to participate and three patients felt it would be too much to take part in the interview because of other health-related commitments⁵⁰.

In summary, the reasons why older adults living with MLTC are under-served by research are similar to those observed in older adults living with frailty including personal and health related reasons and issues with research procedures.

Older Adults with a Recent Deterioration in Health

One mixed methods study was identified that recruited frail older adults with a recent acute healthcare utilisation⁵¹. Participants were identified by clinical staff from inpatient, outpatient and an acute community service. Patients were eligible if they had a recent acute episode for example, emergency department or an ambulance call with or without a visit from the ambulance crew in the previous six months to indicate deteriorating health. The authors acknowledged that they successfully recruited a group of patients often neglected in research studies because of serious illness, unstable presentation and the accompanying ethical and practical challenges. They recruited 90 participants who predominantly had serious illness other than cancer, for whom there is limited evidence available. In summary, there is a lack of evidence about the inclusion of older adults in research who are living with MLTC and frailty and who have experienced a recent deterioration in health.

Identification of strategies for increasing recruitment and retention of these under-served groups

Strategies to Improve Recruitment

Several strategies have been suggested to increase the recruitment of older adults with frailty in research, such as taking time to explain the goal of the study using simple language²⁶. Older people appreciate having sufficient time to reflect on and decide about participation. They may wish the researcher to discuss the project with their relatives or trusted friends so that they could help/support decision-making³⁵. Other strategies include the use of a short consent form with large print, provision of educational materials, gifts/financial compensation, and establishing a rapport or partnership with research staff²⁶. General practitioners are viewed as credible sources to provide information to older adults with multimorbidity, and a personal expression of interest and request for participation was viewed as being more powerful than a generic letter⁴⁰. Studies could therefore consider the use of multiple recruitment methods²¹.

Researchers should ensure communication aids (such as portable hearing devices) are working along with facilities that are suitable for frail older people to use, and guarantee reimbursement for any costs incurred²⁷. Older adults with mobility limitations have previously described barriers to protocol adherence included inconvenience such as high frequency and time-consuming visits, and challenges of transportation, parking and accessibility⁵². Providing transportation and free parking increased the participation of vulnerable older adults aged 70 years or older in an 18-month prospective study⁵³. Recruitment plans must therefore consider the characteristics of the target population and develop a tailored approach, identifying and proactively planning ways to mitigating unique challenges before starting recruitment⁵⁴. For example, Harris & Dyson (2001) reported difficulties recruiting frail older adults into an RCT and noted times to avoid approaching participants that included mealtimes, immediately after physiotherapy, after a painful dressing change and immediately after an untoward incident (e.g., a fall). However, there is little rigorous empirical evidence to underpin any of these approaches⁵⁵.

Strategies to Improve Retention

Strategies could focus on improving research processes with older adults living with MLTC, frailty and a recent deterioration in health whilst minimising participation burden for this population. In older adults in general, adaptation of standard study procedures might make participation less burdensome and reduce attrition¹⁸. For example, data collection methods could avoid the use of time-consuming questionnaires (keeping assessments shorter than 75 minutes)^{30,53} and divide tasks into smaller sections, allowing for breaks in between¹⁸. Researchers could offer home-based assessment and flexibility in approach and scheduling opportunities, including time and place of study and extended hours^{18,26,53,56}. Older adults are receptive to data collection and intervention delivery by telephone⁵²; for example, in the Newcastle 85+ Study, the use of tablet laptops to capture data did not place any additional burden on participants or create a barrier to dialogue and interaction between the researcher and participant⁵⁶. Maintaining regular contact with older adults with multimorbidity, and research and clinical staff with excellent social skills, aided retention of older adults with multimorbidity in an RCT³⁹. This is important because frail older adults' perceptions of researchers may be based on first impressions of them as people and professionals³⁵. Participants should also be provided with timely and regular feedback on their performance as well as overall study results²⁶.

Consideration should be given to the outcome measures selected for studies to ensure physical and psychological/social acceptability⁴². For example, some older adults were intimidated by the use of modern, sophisticated, technical equipment (multi frequency impedance measurements)⁴⁵. Impractical outcome measures of pain, functionality and self-

reported adherence in a pilot study to test prioritising multi-medication in multimorbidity in general practices were found to be unfeasible due to frequent missing values, an incorrect manual or potentially invalid results⁵⁷. Piloting studies with new research instruments is therefore recommended to reduce burden associated with the research and to prevent high attrition⁴². However, strategies to improve retention are not supported by high-certainty evidence⁵⁸.

Strategies to Increase Engagement in Research in Older Adults with Frailty

Ethics research committees are in a strong position to influence research practice and to reduce age discrimination⁵⁹. Loosening exclusion criteria may increase recruitment efficiency, however widening eligibility and the inclusion of older adults with frailty may increase attrition⁴². The Interventions on Frailty Group developed recommendations to screen, recruit, evaluate and retain older adults with frailty in clinical trials⁶⁰. This included eligibility screening that is a multistage process, to quickly exclude those who are too well and those who are too sick, because they have already developed the outcome or because they are unlikely to respond to treatment. Inclusion criteria should target those most likely to benefit, be meaningful to clinicians and reflect advancements in the frailty research area. An integral part of the study design includes disability outcome measures that are self-reported, objective and proxy; several strategies can improve the reliability, validity, and comparability of disability measures over time and avoid loss of study outcomes. Consideration should be given to strategies that may improve retention and compliance as well as monitoring their effectiveness. Estimation of cost and sample size should anticipate high dropout rates and interference by competing outcomes⁶⁰. Using routinely collected data is one important way to reduce burden and the use of composite outcomes to enable the inclusion of participants data to ameliorate the effect of high loss to follow up due to death and illness⁶¹. A family-centric model of care emphasising the role of family caregivers is particularly relevant to engaging and empowering older adults living with frailty²³. Family and caregivers may play a role in the decision-making process for their relative, with many participants preferring to discuss the research with family or friends⁶². Support systems can facilitate or hinder research participation^{29,63}, with some support systems i.e., families holding the belief that their relative is too ill to participate³⁰. Successful involvement of older adults aged 85+ included protected time for researchers to engage with family and other key gatekeepers⁵⁶. It has been suggested that involving the carers of groups traditionally labelled as 'hard to reach' in research may facilitate the recruitment and retention of older adults in research^{26,64}. Consideration of respite of carers and identification of caregiving needs are therefore also important when involving carers as partners in research⁶⁵. There is a role for carers to support the

consent process, and research teams need to ensure that the questions and concerns of carers are addressed alongside those of participants, given the impact that carers may have on the decisions and actions of participants. However, caregivers may be marginally competent themselves too⁴² for example, living with disability.

Strategies to Increase Engagement in Research in older adults with MLTC

We identified two recently published articles that described the engagement of older adults with MLTC as patient research partners⁶⁶ and their caregivers⁶⁵. Challenges and lessons included actively finding patient partners who reflected the diversity of older adults with MLTC, developing strong working relationships with patient partners and researchers, using flexible approaches for engaging patients, and securing adequate resources to enable meaningful engagement⁶⁶. It is important to clarify roles and responsibilities; adopt a flexible patient-centred approach to involvement; respect research partners as colleagues and acknowledge contributions; identify and address barriers to engagement such as caregiving support and transportation; provide initial and ongoing training about research; and facilitate continued dialogue and feedback to clarify roles and manage expectations⁶⁵. However, the articles focused on patients as co-investigators as opposed to older adults as research participants.

Patient and Public Involvement in Research

One approach to proactively plan research and reduce the barriers and challenges, is the use of patient and public involvement and engagement (PPIE) in research. Public involvement in research is, research being carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them, and can be used for the purpose of planning research and to understand priorities of service users⁶⁷. For example, Jokstad and colleagues³⁴ reflected on the processes and outcomes associated with advisory group-researcher collaboration from a person-centered perspective. Feedback was sought from older adults with health-related conditions on study information sheets, study design and an interview guide. Input from the older adults contributed to the improvement of the language in the study information sheet, making it more suitable for the intended target group. Improvements were also made to the study design and development of the interview guide³⁴. The use of PPIE has benefits for both older adults and researchers⁶⁸ and enables to lend agency to vulnerable groups. The benefits to older people in being involved in health research included increased knowledge, awareness and confidence and meeting others in similar situations empowered older people to become active in their community regarding decision/policies which affected them⁶⁹. Involving older adults with health-related conditions as an advisory group may help

increase the quality and relevance of a research³⁴. Schilling and Gerhardus (2017)⁷⁰ identified studies that included older adults with age-related conditions congruent with the specific research topics and suggested that involvement of older people in research design and conduct is feasible. They identified strategies to enhance effective involvement comprises a thoughtful choice of location, use of visualisation and accessible communication, building good relationships and flexible approaches⁷⁰.

The NIHR Clinical Research Network identified the need to understand and overcome the lack of representativeness of trial populations. The 'Innovations in Clinical Trial Design and Delivery for the Under-served' (INCLUDE) project developed a framework and a roadmap that provides a strategic level overview of potential points for intervention including guidance and initiatives to improve inclusion of under-served groups across the life course of⁷¹. A selection of tools and resources are available (nih.ac.uk/include/home/the-framework) to guide funders, researchers and delivery teams in helping deliver inclusive research, as well as examples of good practice (NIHR, INCLUDE). However, there is a lack of empirical evidence to guide choices on effective strategies to improve recruitment and retention of older adults in trials and other studies. One way to fill gaps in evidence is to run Studies Within a Trial, or Studies within a Trial (SWAT)⁷².

Discussion

The inclusion of older adults in research can be challenging. This review identified a range of factors that may lead to the exclusion of older adults living with MLTC and frailty. Observing some of the issues experienced by this group offers insights into the complex needs of this population. Factors were identified pertaining to personal and health related reasons as well as challenges with research procedures. For example, elements of the research process such as, consent and data collection methods such as number of visits, cause barriers to recruitment and retention. Researchers should focus on strategies that minimise participation burden for these patients, maintaining an adaptive and flexible approach, to increase their recruitment and retention. Addressing the specific needs of under-served groups within the older population provides a better understanding of how to mitigate barriers to research participation. This will enable teams to refine research processes that specifically meet the needs of under-served groups to increase recruitment and retention. This may have further importance due to the Covid-19 pandemic, where older adults were disproportionately at greater risk of morbidity and mortality⁷³, and of being under-served in Covid-19 research; key issues to consider when designing Covid-19 studies have been recommended⁷⁴.

Furthermore, it is important to identify subgroups of older adults living with MLTC and frailty who are at particular risk of being underserved by research such as those with a recent deterioration in health. Only one study was identified

that included older adults living with frailty with a recent deterioration in health. There is a growing healthcare need of older adults who are deconditioning. Older adults who are hospitalised are at risk of decline and developing new health problems, with a further increase in older adults attending healthcare appointments due to Covid-19 and social restrictions; this is becoming acutely important and is worse now than pre-pandemic. It is therefore important to identify this group of older adults to increase their participation in research interventions to improve their health outcomes. Maximising research participation to ensure generalisability of findings is important to understand the most appropriate and efficient treatment methods for improving health outcomes in this population²¹. Ultimately, this will inform best practice in the clinical management of the growing older population⁷⁵.

Researchers and ethics committees have to consider the ethical balance of research interventions, for example improving muscle strength in this population might carry potential risks and ethical issues may arise in inviting them to participate in experimental research. However, we don't have information on the balance of benefits versus risks in these populations⁷⁶. Specifically, older adults with MLTC, frailty and a recent deterioration in health may be invited to receive interventions that are not of benefit to them, or they may be denied interventions that would be of benefit. Both situations disadvantage this vulnerable group. Ethics committees and researchers have a duty of care to consider whether the benefits-burden ratio is justified and to what extent research extends beyond the risk of usual care.

An important consideration is how to reach older adults who are living at home with MLTC, frailty and deteriorating health to include them in research. Bone et al., (2021) successfully recruited 90 older adults living with frailty and a recent acute healthcare utilisation; a group who predominantly had serious illness other than cancer, for whom there is limited evidence available⁴⁶. This study provides evidence that this group is willing to participate in research.

Limitations of this review include the lack of identified research specific to understanding the views of older adults with MLTC, frailty and a recent deterioration in health. Only one study was identified.

In conclusion, research is needed with careful consideration of the challenges and barriers of including older adults living with the complexity of MLTC, frailty and a recent deterioration in health as well as identification of the strategies that may increase their inclusion in research. When designing studies, researchers should consider embedding not only PPIE but also qualitative research to investigate barriers and drivers of research participation and to capture the views of those declining participation. Qualitative interviews would provide useful insights into how best to design and conduct research from the participant's perspective to suit the needs of this population.

Authors' contributions

All authors conceived the idea for the review. LD conducted the systematic searches and synthesised the literature. LD and RD drafted the manuscript. All authors critically revised and approved the final manuscript.

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