

RESEARCH PAPER

Including older people in health and social care research: best practice recommendations based on the INCLUDE framework

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Abstract

Background: Older people are often explicitly or implicitly excluded from research, in particular clinical trials. This means that study findings may not be applicable to them, or that older people may not be offered treatments due to an absence of evidence.

Aims: The aim of this work was to develop recommendations to guide all research relevant to older people.

Methods: A diverse stakeholder group identified barriers and solutions to including older people in research. In parallel, a rapid literature review of published papers was undertaken to identify existing papers on the inclusion of older people in research. The findings were synthesised and mapped onto a socio-ecological model. From the synthesis we identified themes that were developed into initial recommendations that were iteratively refined with the stakeholder group.

Results: A range of individual, interpersonal, organisational, community and policy factors impact on the inclusion of older people in research. A total of 14 recommendations were developed such as removing upper age limits and comorbidity exclusions, involving older people, advocates and health and social care professionals with expertise in ageing in designing the research, and considering flexible or alternative approaches to data collection to maximise opportunities for participation. We also developed four questions that may guide those developing, reviewing and funding research that is inclusive of older people.

Conclusion: Our recommendations provide up to date, practical advice on ways to improve the inclusion of older people in health and care research.

Keywords: inclusion, recommendations, socio-ecological model, older people

Key Points

- Individual, interpersonal, organisational, community and policy factors impact on the inclusion of older people in research.
- Researchers, reviewers and funders should consider engagement, inclusive study design, adequate resources and communication.
- Our 14 recommendations offer practical guidance on ways to improve the inclusion of older people in research.

Introduction

Evidence from health and social care research helps members of the public, patients, practitioners, commissioners and policy makers make decisions about treatment, care and services. However, those recruited into studies, in particular, randomised controlled trials (RCTs), frequently do not represent the population affected by the condition of interest [1, 2]. This impacts people on several levels. Firstly, an inequity in opportunities to participate in and benefit from research. Secondly, arbitrary exclusion (direct or indirect) based on a characteristic such as age is a form of discrimination. Thirdly, study findings may not apply to the breadth of people with a condition, and finally, therapies may not be offered due to absence of evidence or may be ineffective or unsafe. In order to address the lack of representativeness of populations recruited to research studies, the National Institute for Health and Care Research (NIHR) Innovations in Clinical Trials Design and Delivery for the Underserved (INCLUDE) project sought to address the barriers to the inclusion of under-served groups in health and care research [1]. Although there is no single definition for ‘under-served group’, commonly people in such groups have lower rates of inclusion than would be seen in the population of interest, they may engage or respond differently to interventions, or they have a high health and care burden unmatched by the amount of research conducted in that field. Factors to consider in under-served groups include, but are not limited to, demographics (e.g. age, ethnicity, sexual orientation, gender identity), socioeconomic factors (e.g. carers, digitally excluded), health status (e.g. multiple health conditions, hearing impaired) or living circumstances (e.g. care home, homeless).

Heterogeneity is a hallmark of ageing, and older people constitute a broad group, from the robust and healthy through to those with severe frailty and dependency. Older people and those with multiple long terms conditions or frailty are the highest users of health and care resources [3]. Older people are frequently excluded in many areas of healthcare research, through restrictions in upper age limits [4–7], the presence of comorbidities [6, 7] and cognitive impairment [5]. In 2011, McMurdo and colleagues published good practice guidance on improving recruitment of older people to research [8]. They made recommendations on planning and logistic considerations in different

settings, recruiting those with impaired capacity and those from ethnic minorities. Nonetheless the problem remains with evidence from a recent review finding that a third of COVID-19 trials had upper age limits that were unjustified, despite COVID-19 disproportionately affecting older people [9].

New recommendations on the inclusion of older people in research are needed for several reasons. Firstly, our understanding of under-served groups and how to improve inclusion has evolved in the last decade. For some older people, several factors may impact their inclusion in research and this intersectionality is important (Figure 1). Secondly, the clinical research landscape has evolved with new opportunities and challenges (e.g. digital outcomes, virtual trials) that warrant consideration. Finally, previous recommendations focused on those working in ageing research thus there is an opportunity to refine and extend previous guidance to a broader audience including other specialities.

The aim of our work was to develop system-level principles to guide all research relevant to older people. The objective was to identify factors that impacted the inclusion of older people in research through stakeholder engagement and evidence synthesis. This paper presents the NIHR INCLUDE Older People best practice recommendations.

Developing the INCLUDE older people best practice recommendations

The INCLUDE Older People project began in January 2021 and continued until September 2022. A diverse stakeholder group was established including multi-disciplinary health and care professionals representing geriatrics, general practice, nursing, physiotherapy and psychiatry, charity representatives (Age UK) and those with expertise in health and care research design and delivery (NIHR Clinical Research Network (CRN), Clinical Trials Units, Patient and Public Involvement), and ethics committee membership. The group also included three older people with experience of being involved in research. To maximise their engagement, alongside the stakeholder meetings, one of the academic team met with them separately to discuss key aspects of the work including barriers and solutions to including older people in research and the proposed theory of change model. Whilst the work focused on how to improve participation of older

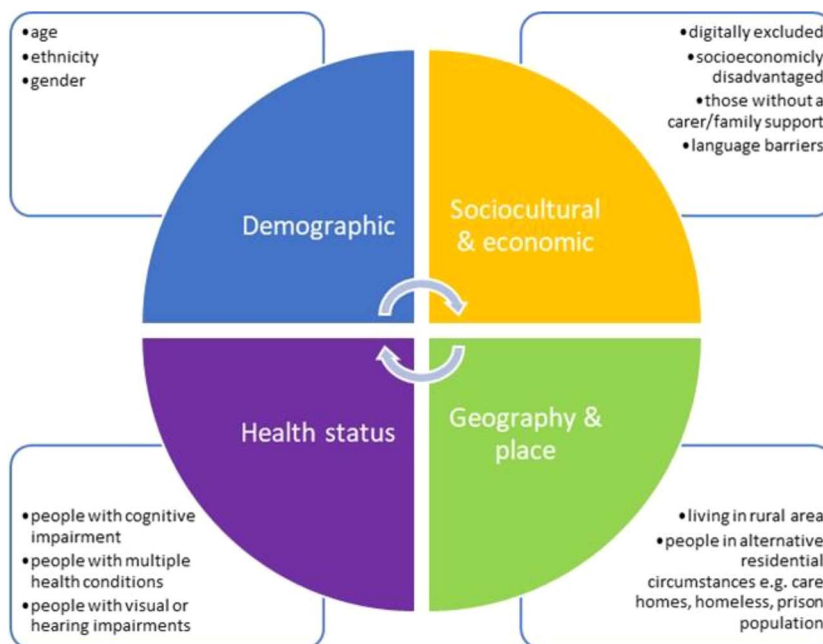


Figure 1. Intersectionality of factors that may impact on the inclusion of older people in research.

people in research, we also considered principles that may aid retention.

1. A multi-disciplinary core group (Goodwin, Quinn and Witham) met online in January 2021 and identified key stakeholders needed. The NIHR INCLUDE roadmap (Figure 2) as an initial guide [13] to prompt discussion. Areas for particular focus were non-hospital and non-NHS settings, as well as intersectionality with other under-served groups. This group met throughout the project to synthesise discussions and contributions and to lead development of the recommendations.
2. An initial online stakeholder meeting was held (April 2021). The group discussed and agreed that:
 - a. emphasis of recommendations should be on study design and ethics. Regulatory issues would be considered but would not be a primary focus
 - b. cross-speciality research that is relevant to older people should be considered, not just 'ageing' research
 - c. Tools were needed to help researchers or signpost them to existing resources e.g. www.capacityconsent.com or www.trialforge.org
3. Prior to the next online meeting (June 2021), stakeholders were invited to identify barriers and solutions to including older people in research at key stages of the INCLUDE roadmap [13] and add to a Google Jamboard (real-time digital whiteboard). At the meeting, two parallel groups further discussed factors around inclusion and developed a Theory of Change model (Figure 3) to describe *inputs* (what was needed), *activities* (what needed to be done), *outputs* (what we planned to produce) and *outcomes* in order to achieve *impact*.

4. In parallel, we conducted a broad rapid scoping search for published English language literature on inclusion of older people in research (March 2022). The aim was to supplement stakeholder activities and provide an overview of relevant literature in this area such as key barriers to including older people in research and potential strategies to improve recruitment and retention. PubMed (Medline), Google Scholar, ScienceDirect and the *Age and Ageing* journal were searched. We included 'older adults', 'elderly', 'recruitment', 'retention', 'inclusion' and 'research' as search terms using Boolean operators AND and OR.
5. We conducted the initial synthesis of findings from the literature review with outputs from the stakeholder discussions. Issues relating to the inclusion of older people in research are multi-faceted and complex, thus requiring a systems-level approach. We therefore mapped findings from the review and stakeholder discussions onto a socio-ecological model (SEM) [14]. The SEM (Figure 4) enables mapping of multi-level and interacting factors to help understand how micro, meso and macro-level factors influence the research ecosystem. This approach has been used to better understand recruitment and retention in trials of health interventions [15–17]. From the descriptive synthesis we identified themes that were developed into initial recommendations.
6. Initial recommendations were presented to the NIHR CRN Ageing National Speciality Group (June 2022) and shared with the stakeholder group (July 2022). Both groups provided feedback and recommendations were revised accordingly.

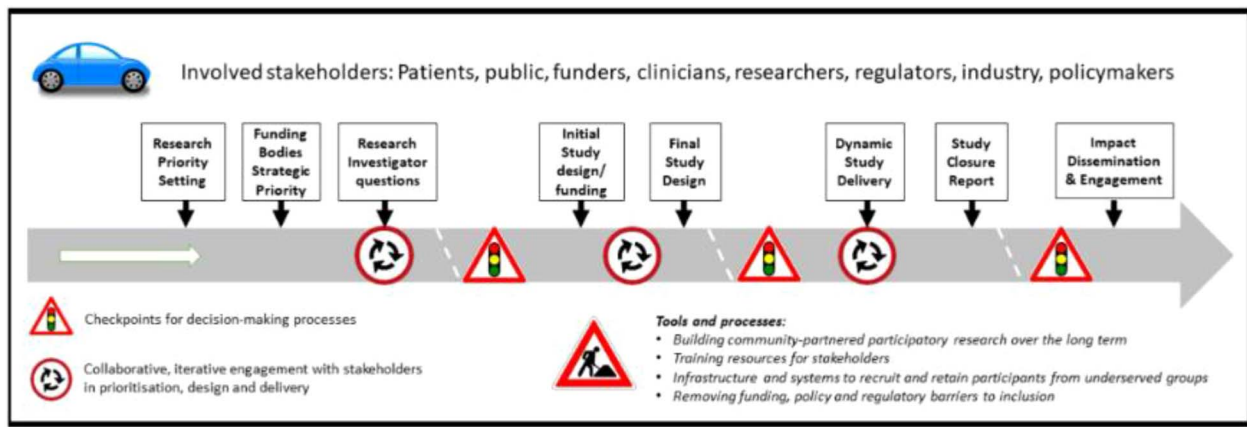


Figure 2. NIHR INCLUDE Roadmap (reproduced from Witham et al. [13] under CC-BY-4.0 licence).

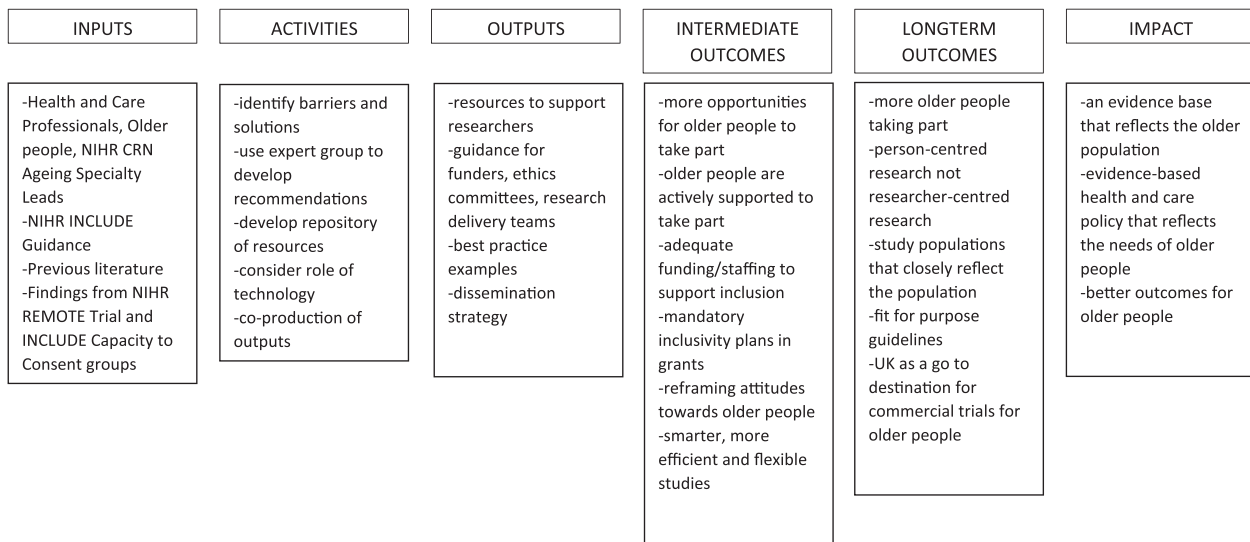


Figure 3. Theory of Change for improving the inclusion of older people in research.

7. Revised recommendations were shared with the groups described above (September–October 2022) along with a list of questions to assist researchers, reviewers and funders.

Results

A total of 14 recommendations are presented within the SEM and summarised in Table 1. Below we provide rationale for each recommendation with supporting evidence. Examples of good practice and relevant resources are in Appendix 1.

Individual factors

Recommendation 1A: Studies should not have upper age limits in inclusion criteria

Some studies still explicitly exclude participants based on chronological age [4, 7]. This approach is ageist and hence a morally indefensible form of discrimination. The heterogeneity of health and function in old age makes

chronological age a weak proxy for other factors (e.g. multimorbidity, mobility) that may be more relevant to study design.

Recommendation 1B: Studies should be designed to be inclusive of those with cognitive impairment

Informed consent is a core tenet of research participation. However, blanket exclusion of those with cognitive impairment is discriminatory [18, 19]. The Mental Capacity Act (2005) makes adequate provision for alternative means of participation using consultees [20]. Decisions about capacity to consent need to be taken on an individual basis, and such cut-offs impose a false dichotomy on the concept of capacity for research participation.

Recommendation 1C: Studies should not have comorbidity exclusions (except where there is an intervention contraindication)

Blanket exclusions because of comorbidity not only directly discriminate against participants with multiple

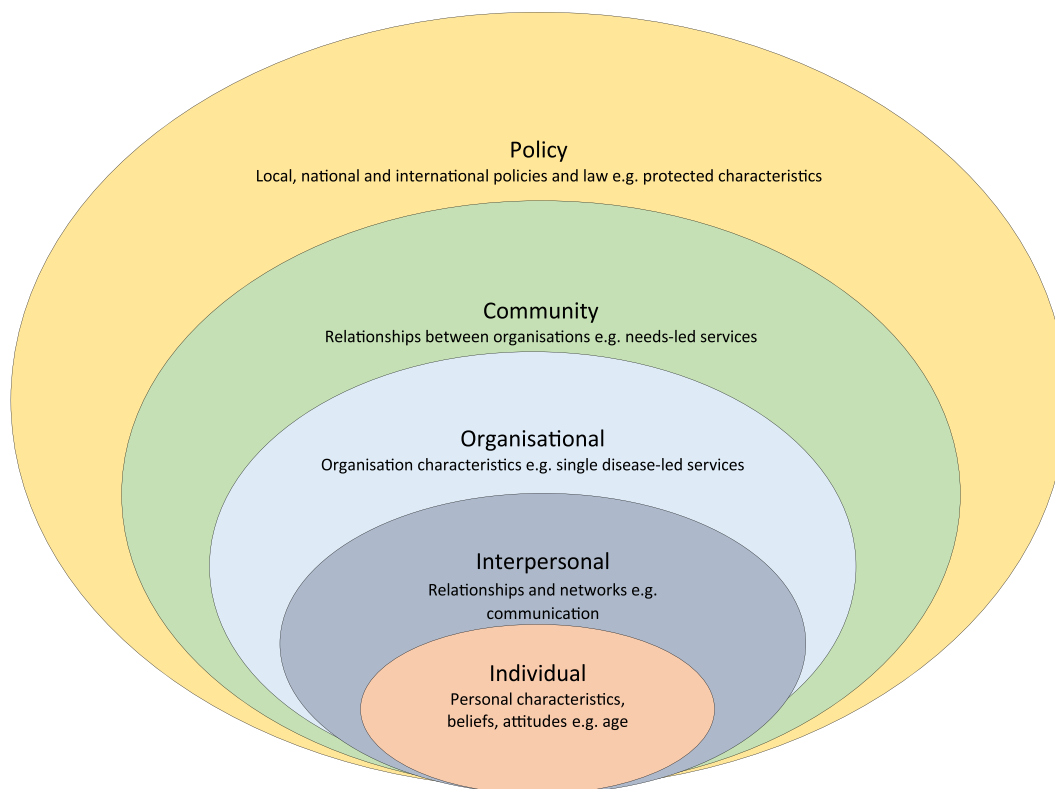


Figure 4. SEM representing the multi-level factors that may impact on the inclusion of older people in research.

Table 1. Summary of best practice recommendations for including older people in research.

SEM Factor	Recommendation
1. Individual factors	1a. Studies should not have upper age limits in inclusion criteria 1b. Studies should be designed to be inclusive of those with cognitive impairment 1c. Studies should not have comorbidity exclusions (except where there is an intervention contraindication) 1d. Use of clear explanations of why research is relevant to older people’s health and wellbeing
2. Interpersonal factors	2a. Advocates and peers should be involved in designing research that meets the needs of older people 2b. Health and social care professionals with expertise in ageing should be involved in designing research that meets the needs of older people 2c. Communication about research should be tailored to the needs of older people 2d. All older people who meet the eligibility criteria should be offered the opportunity to participate in research 2e. Consider the involvement of carers or family members and the impact involvement can have on them and the older person
3. Organisational factors	3a. Those commissioning, funding and approving research should ensure the inclusion of older people and intersectional factors, such as demographics and health status, have been considered 3b. Those commissioning, funding and approving research should include older people and those with expertise in ageing
4. Community factors	4a. Researchers should consider different and flexible approaches to promote accessibility of the research e.g. financial support to attend research centres or offering home visits for data collection 4b. Support, or alternatives should be offered to digital data collection and interventions
5. Policy factors	5a. Policymakers should consider the impact of policies on health inequalities in research participation

conditions but constitute covert age discrimination [7]. Many older people who are the target treatment population for an intervention will have multiple conditions, and excluding such patients risks the production of biased, unrepresentative research and therefore misleading results. This remains the case even for early phase studies where ‘clean designs’ to minimise heterogeneity may be sought.

Recommendation 1D: Use of clear explanations of why research is relevant to older people’s health and wellbeing

Research should be designed to maximise engagement of the entire population of interest. Some older people may have low interest due to a lack of perceived benefits or relevance of a study to themselves [18].

Some older people may have misconceptions about research, leading to distrust and unwillingness to engage.

The issue of trust in health care providers and researchers has been highlighted particularly amongst older people from ethnic minority groups [15]. Engagement with people with varying cultural backgrounds who speak different languages presents further challenges which must be surmounted.

Interpersonal factors

Recommendation 2A: Advocates and peers should be involved in designing research that meets the needs of older people

Personal characteristics may impact on individuals' perceived and actual ability to take part in research such as general poor health, multiple long-term conditions, fatigue or mobility issues [24, 29, 31]. This means older people may believe they are not able to take part or may have to withdraw from the study. Others may be reluctant to commit to taking part in research due to other priorities e.g. family responsibilities [7, 17].

Recommendation 2B: Health and social care professionals with expertise in ageing should be involved in designing research that meets the needs of older people

Some researchers lack knowledge and understanding of ageing and involving older people in research resulting in inflexible study protocols that don't accommodate age-related issues [32]. This can result in a general apprehension about recruiting older adults due to a higher likelihood of adverse events and attrition [24, 27].

Recommendation 2C: Communication about research should be tailored to the needs of older people

How research is communicated can have a significant impact on engagement [25, 27, 31]. Some may have difficulty reading and understanding promotional materials to take part in research.

Recommendation 2D: All older people who meet the eligibility criteria should be offered the opportunity to participate in research

Gatekeeping by those involved in recruiting older people can occur based on a misconception that older adults are vulnerable, due to e.g. comorbidities or a lack of mental capacity, and therefore, need to be protected from research [8]. It is important that all those eligible to take part in research be offered the opportunity to make an informed decision themselves. Researchers/clinicians should facilitate access to research and not inhibit it.

Recommendation 2E: Consider the involvement of carers or family members and the impact involvement can have on them and the older person

Lack of support from carers or family members can influence the decision to participate [25–27] and involvement in research can be an additional carer burden. Building a rapport with carers and family members may be important

to aid recruitment and retention [8, 26, 33]. For individuals with cognitive impairment, involving carers can aid consent processes, and provide reassurance and encouragement [27, 32, 33].

Organisational factors

Recommendation 3A: Those commissioning, funding or approving research should ensure the inclusion of older people and intersectional factors such as demographics and health status have been considered

Research tends to focus on individual condition processes due to fears that the effects of ageing would impair the ability to report on effects related to a single condition [32]. This focus on single condition at the expense of those living with multiple long-term conditions has resulted in research and guidelines that do not reflect the patients seen in clinical practice.

Recommendation 3B: Those commissioning, funding and approving research should include older people and those with expertise in ageing

Research funders, ethics committees, regulators, sponsors and Research and Development departments may have an overly risk averse approach to involving older people in research that fails to recognise the autonomy of older people [37]. There may also be apprehension to allow inclusion of those who are considered vulnerable. Reviewers and decision makers may lack an understanding of ageing, older people and those living with multiple long-term conditions resulting in ill-informed decision making.

Community factors

Recommendation 4A: Researchers should consider different and flexible approaches to promote accessibility of the research e.g. financial support to attend research centres or offering home visits for data collection

The inaccessibility of research facilities due to the need to travel long distances and/or a lack of available transport are significant barriers to older people taking part in research, especially for those with reduced mobility or fatigue [24, 25, 27] or where costs are prohibitive [25, 27].

Recommendation 4B: Support, or alternatives should be offered for digital data collection and interventions

Whilst there is increasing interest in remote research delivery that may be beneficial for some e.g. those with mobility impairment, caution must be taken not to exacerbate inequalities through digital exclusion [38]. Some may not have access to suitable equipment, or the internet [38]. Older people with equipment may be hesitant due to lack confidence to use it or privacy concerns. Remote trial delivery requires infrastructure and resources [39] and whilst NIHR have an ambition to work towards hybrid and fully remote

trials, consideration should be given to those who may be excluded.

Policy factors

Recommendation 5A: Policymakers should consider the impact of policies on health inequalities in research participation

Policy decisions, such as NHS England's Internet First [40] and Digital First Primary Care [41], are biased towards those who are digitally enabled. However, older people, and those with disabilities, whose first language is not English, on lower incomes and living in rural areas are considered more likely to be digitally excluded [42]. These types of healthcare directives can lead to unintended consequences and risk worsening of health inequalities,

The following questions may guide those developing, reviewing and funding research that is inclusive of older people:

1. *Engagement:* Are representative older people, their family members, advocates and those with experience of working with older people involved in designing the research?
2. *Inclusive study design:* Has consideration been given to **where** the research takes place, **how** researchers interact with older people and family members and **what** happens during interactions to maximise the accessibility of research to older people and family members? This may involve piloting study procedures to ensure they are feasible and acceptable.
3. *Resources:* Have adequate infrastructure and financial resources been costed into funding applications to maximise participation, minimise withdrawals and ensure recruitment targets are met? There is a need to recognise that studies involving older people and family members may require additional resources, such as staff time and travel to conduct face-to-face recruitment and data collection at the person's home.
4. *Communication:* Have a range of approaches to communicating with older people and family members about research been considered in terms of promoting the study, recruitment, data collection and dissemination.

Discussion

The exclusion of older people in research relevant to their health and care is not a new problem [43, 44]. The aim of our project was to develop best practice recommendations to promote the inclusion of older people in research. These were developed iteratively by identifying barriers and potential solutions in collaboration with a diverse group of stakeholders and from existing

evidence. We identified 14 recommendations and four questions for researchers, reviewers and funders to consider: engagement; inclusive study design; adequate resources; communication.

Whilst there are many well established public and patient involvement and engagement (PPIE) groups they tend to be white, middle-class, have background in health or research [45], and are already research active. Older people are the most heterogeneous of any age group [46] with a broad range of intersectional characteristics. Gaining wider perspectives from e.g. communities and community groups would give greater insight into what is important to them and how to overcome some of the perceived barriers. It is a myth that older people and those with complex needs are too risky to include in research. They can and should contribute to identifying important research questions, priority setting, designing studies, participation in studies and disseminating findings [47, 48]. Troya and colleagues evaluated the impact of PPIE in the development of research on self-harm amongst older adults highlighting both the added value PPIE can bring alongside challenges such as support, training and ongoing communication that requires both time and resources [49].

Our findings align with those of the recently developed frameworks for promoting inclusion of people from ethnic minority groups [11, 12] and those with impaired capacity to consent [10, 22]. These frameworks consider four questions that should be asked by those developing RCTs: (i) who should trial apply to; (ii) are these groups likely to respond in different ways; (iii) will intervention make it harder for some to engage and (iv) will the study design make it harder for some to engage? There are some similarities to the key considerations we identified through the literature and stakeholders.

Whilst involving and engaging with older people living with complex needs can be logistically challenging efforts should be made to design research to be more inclusive. For example, a trial of home-based extended rehabilitation for older people living with frailty follow-up data collection is postal with the option for in-person data collection at the person's home if needed [47]. Whilst having a more person-centred approach to recruitment, data collection and intervention delivery is clearly of benefit to the individual, this will come at a cost, both in staff time and resource [11, 50].

Communication about research needs to take place before, during and after a study. In the USA, the National Institute on Ageing has developed a toolkit and resources to encourage older people to take part in research addressing concerns and worries that older people may have [23]. Researchers need to identify a range of different communication strategies that incorporate people's preferences, cultural and communication needs. The push towards supporting everyone to be digitally included [41] may create barriers and can threaten some peoples' autonomy. We must ensure that those that don't want to or are unable to engage are offered alternatives.

Strengths and limitations of our work

Whilst we conducted a rapid search for existing publications on the inclusion of older people in research, the search strategy may not have been fully comprehensive, and we may have missed relevant studies, which could have been addressed by having broader search terms and by searching the Applied Social Sciences Index and Abstracts database. This said, by integrating the perspectives of a range of key stakeholders involved in research including public representatives, health and care professionals, charity representatives, academics and those involved in reviewing, funding and delivering research, we were able to identify different barriers and solutions that were not apparent in the peer reviewed publications.

Implications for research and practice

Our recommendations are new and simple to understand and provide practical guidance on ways to improve the inclusion of older people in health and care research. We next need to consider how best to implement change, in particular amongst those who are not specialists in conducting research with older people e.g. through the co-development of resources and training, and evaluate its impact on improving inclusion of older people in health and care research.

Conclusion

We have identified a range of factors that impact on the inclusion of older people in research and made recommendations of how these can be addressed in the future to ensure research findings are relevant to them.

Supplementary Data: Supplementary data mentioned in the text are available to subscribers in *Age and Ageing* online.

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