Improving recruitment of older people to research through good practice

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Abstract

There is widespread evidence both of the exclusion of older people from clinical research, and of under-recruitment to clinical trials. This review and opinion piece provides practical advice to assist researchers both to adopt realistic, achievable recruitment rates and to increase the number of older people taking part in research. It analyses 14 consecutive recently published trials, providing the number needed to be screened to recruit one older participant (around 3:1), numbers excluded (up to 49%), drop out rates (5–37%) and whether the planned power was achieved. The value of planning and logistics are outlined, and approaches to optimising recruitment in hospital, primary care and care home settings are discussed, together with the challenges of involving older adults with mental incapacity and those from minority groups in research. The increasingly important task of engaging older members of the public and older patients in research is also discussed. Increasing the participation of older people in research will improve the generalisability of research findings and inform best practice in the clinical management of the growing older population.

Keywords: recruitment, clinical trials, efficiency, older, elderly

Introduction

The welcome recent increase in life expectancy has resulted in the enlargement within each chronic disease of a frail, older group of patients who often have multiple co-morbidities in addition to their predominant disease. Despite the fact that older people are, quite rightly, ‘the core business of the NHS’ [1] there is widespread evidence that older people are being excluded from clinical research, including trials in cancer, cardiovascular diseases and even...
The reasons for exclusion of older people from research include investigator apprehension about the impact of enrolling participants with co-morbidities and multiple medications on drop out rates and adverse events, and a misplaced view of older people as ‘vulnerable’ and in need of protection from research. Older people with chronic disease may, not unreasonably, be reluctant to commit to clinical trials. It is also possible that some researchers are simply unsure how to go about involving and retaining older people in research.

Under-recruiting trials are bad for patients, bad for science and bad for the economy. A review of major funded UK trials found that less than one-third recruited their original target within the time originally specified [4]. Table 1 records our analysis of consecutive randomised controlled trials published in this journal over an 18-month period. It is disappointing to note that there are only 14 papers. Topics for trials varied widely but falls prevention was the most common subject to be investigated (four trials). Methods of recruitment were diverse, ranging from adverts in newspapers to cluster studies of primary care organisations. While most studies (12) in this series did achieve their stated recruitment target, nearly three participants needed to be screened on average for every subject included. Exclusion rates were very variable, being as low as 3.4% and as high as 49%. Likewise refusal rates were as high as 54% but more typically around 12–15%. Although the precise factors affecting recruitment were not clear from most papers, the trial by Azad et al. [5] clearly highlights ‘(patient) frailty and limited resources’. Drop out rates in this series ranged from 5 to 37%. More specifically drop out rates at 1 year for the two community-based falls prevention studies were 12 and 14%, and for the two falls studies in nursing homes were 19 and 37% (see Table 1). Of note the paper by Harris et al. [6, 7] was a randomised controlled trial of optimising recruitment into a community study of physical activity. The authors found that telephone contact significantly increased recruitment by about 10% more than simply sending a questionnaire through the post. Overall the studies demonstrate the diverse nature of research in older adults and the challenges posed by different types of trial and their settings.

Realistic targets and effective recruitment methods will benefit researchers, funders and, ultimately, older people. The purpose of this paper is to examine best practice on how to effectively recruit older people to clinical research, including planning, recruitment in specific settings, involving hard to target groups and engaging older people in research. The paper cites the evidence where it exists and offers a critical appraisal of how commonly experienced difficulties may be resolved.

Planning and logistic considerations

Successful recruitment starts at the planning stage. Piloting with a representative sample of older adults is essential to ensure that instructions, forms, questionnaires and measurement instruments are legible and appropriate for people who may have visual or other sensory impairments. Particular attention to the time needed to complete different assessments allows appropriate breaks to be factored-in during assessment procedures.

The physical environment in which research is conducted needs to be appropriate for older participants who may have mobility or balance impairments. Reduced mobility combined with the inability to continue driving can make accessing research institutions difficult, and transport is a recognised barrier to recruitment [8]. Provision of free-taxi transport to and from study centres is often appreciated, and needs to be costed into grant proposals. Adequate provision of ramps, lifts, wheelchair access and appropriate toilet facilities for people with mobility impairments need to be readily available.

Appointments for older research participants may need to be arranged around fixed home carer visits or meal provision times. It can be helpful to confirm appointments made by telephone in writing, and to follow-up with a reminder telephone call the day before to confirm transport arrangements, venue and time, and to check that the appointment is still convenient. Older people will vary as to how much they want to involve family and/or carers, but engaging with carers may be helpful in circumventing communication problems. If older people bring accompanying persons or carers to research appointments, it is important to consider their needs as well when organising the logistics of appointments. Attention to the practicalities of research should support recruitment and reduce attrition rates.

Recruiting in acute hospital care and rehabilitation units

The first day or two of an admission are often busy and tiring, and acute illness can make it difficult to concentrate on the researchers’ information sheets and consent forms. The attitudes of staff providing patient care are critical; they must have confidence in the research team, believe that the study topic is relevant and important to their patients and that the treatment or intervention has a reasonable chance of benefiting their patients [9]. The researcher needs to build a relationship with the clinical team ensuring everyone is aware of good research practice and highlighting eligibility criteria for the type of patient that each study is recruiting. Potential benefits to patients, carers and/or professionals should be emphasised as this will make the study more ‘real’ to colleagues.

Taking time to establish a good relationship with ward staff can pay dividends in ensuring the process of recruiting becomes a usual, rather than an exceptional ward activity. Research posters and leaflets in public areas make patients...
<table>
<thead>
<tr>
<th>Reference</th>
<th>Topic</th>
<th>Setting and type of trial</th>
<th>n needed to recruit</th>
<th>n, screened</th>
<th>n, recruited</th>
<th>n, excluded</th>
<th>n, refusing</th>
<th>Period of follow-up</th>
<th>Dropout</th>
<th>Power achieved?</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Randomised trials</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Perry et al. (2008) [20]</td>
<td>Activity levels</td>
<td>Residential care, cluster</td>
<td>124</td>
<td>208</td>
<td>149</td>
<td>33 (15.8%)</td>
<td>26 (12.5%)</td>
<td>6 month</td>
<td>20 (13.4%), 13 died, 11 transferred, 1 withdrew</td>
<td>Yes</td>
<td>Results likely contaminated by cross over between clusters</td>
</tr>
<tr>
<td>Azad et al. (2008) [5]</td>
<td>Heart failure clinic</td>
<td>Outpatients, single blinded</td>
<td>200</td>
<td>Not stated</td>
<td>91</td>
<td>Not stated</td>
<td>Not stated</td>
<td>6 month</td>
<td>7 (7.7%), not stated</td>
<td>No</td>
<td>Poor recruitment due to frailty and ‘limited resources’</td>
</tr>
<tr>
<td>Harran et al. (2008) [21]</td>
<td>Health risk appraisal</td>
<td>Primary care, self-report</td>
<td>2,053</td>
<td>5,982</td>
<td>2,503</td>
<td>884 (14.7%)</td>
<td>1,959 (33%)</td>
<td>1 year</td>
<td>648 (25.8%), did not return forms</td>
<td>Yes</td>
<td>Large-scale questionnaire intervention</td>
</tr>
<tr>
<td>Croty et al. (2008) [22]</td>
<td>Home versus day hospital post-hospital stay</td>
<td>Community, single blinded</td>
<td>150</td>
<td>301</td>
<td>229</td>
<td>34 (11.3%), mainly travel reasons</td>
<td>38 (12.6%)</td>
<td>6 month</td>
<td>11 (4.8%), 4 died, 7 withdrew</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Harris et al. (2008) [6]</td>
<td>Methods of increasing study recruitment</td>
<td>Postal and telephone, unblinded</td>
<td>560</td>
<td>1,529, available to recruit from</td>
<td>560, selected at random</td>
<td>273, multiple problems</td>
<td>N/A</td>
<td>Single-time point study</td>
<td>N/A</td>
<td>Slightly under, power</td>
<td>240 (43%) were recruited into the main study</td>
</tr>
<tr>
<td>Spice et al. (2009) [23]</td>
<td>Falls</td>
<td>General practices/secondary care, cluster</td>
<td>450</td>
<td>728</td>
<td>516</td>
<td>212 (29%), multiple reasons</td>
<td>110 (15%)</td>
<td>1 year</td>
<td>75 (14%), 38 died, 26 withdrew, 1 ineligible</td>
<td>Yes</td>
<td>Trial of setting/style of care</td>
</tr>
<tr>
<td>Moseley et al. (2009) [24]</td>
<td>Increased exercise after hip fracture</td>
<td>Rehab units and home, single blinded</td>
<td>160</td>
<td>404</td>
<td>160</td>
<td>397 (49%), multiple reasons, e.g. cognitive impairment</td>
<td>47 (11.6%)</td>
<td>16 weeks</td>
<td>10 (6.2%), 7 died, 3 withdrew</td>
<td>Yes</td>
<td>No differences shown with higher exercise levels</td>
</tr>
<tr>
<td>Gleason et al. (2009) [25]</td>
<td>Soy supplement</td>
<td>Community, double blind placebo</td>
<td>Not stated</td>
<td>34, unclear</td>
<td>31</td>
<td>3, not free of illness or cognitive problems</td>
<td>N/A</td>
<td>1</td>
<td>1</td>
<td>Yes</td>
<td>Presumably healthy volunteers perhaps from a panel?</td>
</tr>
<tr>
<td>Neyens et al. (2009) [26]</td>
<td>Falls</td>
<td>Nursing homes, cluster</td>
<td>360</td>
<td>518</td>
<td>518</td>
<td>29 in intervention arm (12.6%) no reasons—all controls included</td>
<td>20 in intervention arm (8%)</td>
<td>1 year</td>
<td>192 (37%), no reasons</td>
<td>Yes</td>
<td>Intention to treat; may be select group of homes participated as 34 out of 119 homes agreed and 12 selected</td>
</tr>
<tr>
<td>Meyer et al. (2009) [27]</td>
<td>Falls</td>
<td>Nursing homes, cluster</td>
<td>1,080</td>
<td>1,972</td>
<td>1,125</td>
<td>847 (43%) as no falls</td>
<td>20 nursing homes refused</td>
<td>1 year</td>
<td>218 (19%), 190 died, 28 moved</td>
<td>Yes</td>
<td>Intervention was a risk assessment tool for falls—all residents included automatically so no individual refusals</td>
</tr>
<tr>
<td>Ciaschini et al. (2009) [28]</td>
<td>Falls</td>
<td>Community, not blind, one centre</td>
<td>200</td>
<td>590</td>
<td>201</td>
<td>73 (12%), not at risk of falls</td>
<td>316 (54%)</td>
<td>1 year</td>
<td>25 (12%)</td>
<td>No</td>
<td>Adverts and direct clinician referral</td>
</tr>
<tr>
<td>Forster et al. (2009) [29]</td>
<td>Post-stroke support</td>
<td>Community, single blinded, two centres</td>
<td>487</td>
<td>265</td>
<td>163 (33.5%), not disabled</td>
<td>59</td>
<td>6 month</td>
<td>23 (8.7%), 16 died, 7 withdrew</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salonen et al. (2010) [30]</td>
<td>Medicine, reduction post-stroke support</td>
<td>Community, not blind, one centre</td>
<td>Not specific</td>
<td>612</td>
<td>391</td>
<td>21 (3.4%), multiple reasons</td>
<td>All agreed through adverts in a single town</td>
<td>1 year</td>
<td>61 (10.3%)</td>
<td>Yes</td>
<td>Recruited by adverts so selective population: one time counselling to reduce sedatives</td>
</tr>
<tr>
<td>Boxer et al. (2010) [31]</td>
<td>Drug treatment for sarcopenia</td>
<td>Community, double blinded, placebo</td>
<td>Not made clear</td>
<td>728 responses then 725 screened</td>
<td>99</td>
<td>329 (45%), not frail or normal DHEA levels</td>
<td>47 1st wave, 23 2nd wave, =70 total</td>
<td>6 months</td>
<td>12</td>
<td>Yes</td>
<td>Recruited by mailing</td>
</tr>
</tbody>
</table>

Excluded from search—meta-analyses, systematic reviews, observational studies and studies based on previous randomised trials.

Cox et al. (2008) [32] was excluded as it was cluster randomised to the level of primary care organisation and was too complex to describe in the table; O’Reilly et al (2008) [33] was a cost evaluation of a previously reported RCT and full details were not included in this paper; Horgan et al. (2009) [34] excluded as not a trial.
and visitors aware that the unit is research active and that they will be approached about studies. Patients will then view research as part of the normal hospital routine. It is essential to invest time explaining the studies, providing written material where appropriate, and recognising that older patients may wish to take into account the opinions of others before arriving at a decision. It is important to emphasise that participation (or non-participation) will not affect other aspects of their care or delay their discharge or disadvantage the participant in any way. People recruited in an acute setting may be discharged before the study activities are completed; therefore, it is important to be able to follow the patient to a rehabilitation setting or into their own home.

Recruiting in primary care

Working with general practitioners (GPs) provides researchers with superb opportunities to efficiently identify potentially eligible study participants and to disseminate and share research findings. Interested practices can search their computerised databases by age, sex, medication and diagnosis.

Primary Care Research Networks (PCRN) exist in the UK to increase the amount of research relevant to patient care carried out in primary care settings. The network should be approached prior to applying for funding to establish the feasibility of the project in primary care, the level of reimbursement for participating practices, and to agree the level of PCRN involvement. This may include circulating brief details of the study with inclusion/exclusion criteria to practices in the area and searching practice databases for suitable patients. The GPs can screen potentially eligible patients and remove the names of individuals that it would not be appropriate to contact; for example, the recently bereaved. The PCRN coordinator then sends letters of invitation to participate in the study to these patients, on practice-headed notepaper, signed by the GP and accompanied by the study Information Leaflet. Patients wishing to learn more about the research reply using a pre-paid envelope which is passed to the researcher, protecting patient confidentiality. This approach to potential research participants from their GP is associated with high recruitment rates [10]; the ratio of patients approached to patients enrolled has been found to be considerably better than targeting the general population from census or electoral registers [11].

Recruiting in care homes

There is considerable overlap in health needs between nursing and residential care and a high prevalence of cognitive impairment, co-morbidity and polypharmacy. Most residents are female and over 85 years old, with a life expectancy of less than two and a half years. Older people can be recruited to studies through directly approaching individual care homes/care home organisations (details of individual care homes and recent inspection reports can be located on line through the Care Quality Commission [12] or through GP practices with the support of the PCRN to identify their patients who are living in care homes.

Close attention to the following will assist recruitment:

- Culture and organisation of the care home. This will affect the number and level of explanations required about the study and could include head office of care home chains, care home managers, relatives and friends, staff members and residents’ groups. Researchers should discuss how care home staff view their role in the research, for example, as gatekeepers deciding who can be asked to participate or do they introduce the study to all residents? The former can lead to selection bias. Staged recruitment processes are preferable to allow sufficient time to establish relationships with health professionals, care workers and relatives, and to understand their priorities, concerns, goals of care and everyday routines.
- The research is being done in the residents’ home even if they do not individually consent to participate. Posters and explanatory leaflets with photos of the researchers are helpful for a population with high levels of cognitive impairment.
- It is important before commencing recruitment that researchers secure social care governance through the relevant local authority [13].
- Level of disruption that participation in research will cause to the care home. If involvement in research will take staff away from their caring duties then it is important to offer remuneration to ensure there is not a detrimental effect on the residents. Staff turnover is an issue in care homes and it helps to have a senior care worker who agrees to act as link person for the home for research studies.

Recruiting adults with mental incapacity

Older people with mental incapacity need to be protected from coercion through involvement in research, yet must be able to benefit from the advances brought about from research and so should not be excluded from it. Typical processes used to safeguard research participants require informed consent to be given, and these processes often require considerable amounts of cognitive and executive ability. Lack of mental capacity may be one of the reasons why many older and frailer people are not recruited into clinical drug trials [14]. The Mental Capacity Act 2007 provides helpful advice to describe when such research is deemed ethical and the steps needed to do so in the most ethical means possible. The Act requires that a person should be considered to have capacity to consent unless proved otherwise; capacity to consent is context specific and depends on the complexity of the decision.

It is necessary for all clinical research to be approved by an independent research ethics committee (REC), and in the UK there are specific RECs that consider applications concerning vulnerable patients, including those who may
lack mental capacity. The REC considers whether the research needs to be undertaken in people without capacity or whether it can be done perfectly well in people who have capacity; for example, research into a product for ageing skin. The REC also considers whether there is a reasonable balance of risk and benefits and if the risks have been minimised. It can be acceptable for permission to be given for people lacking mental capacity to be recruited to a research study involving a potentially hazardous intervention, as long as the potential benefits appear to be of a similar magnitude. Committees should therefore be informed in detail about the major and minor hazards and burdens entailed in every aspect of a research study. The REC has to decide whether it is reasonable for people to be recruited into studies without their full informed consent, and has to balance the need to develop scientific knowledge with the protection of vulnerable people. Researchers may find it helpful to discuss matters such as these with representatives of patient and user groups to help formulate these arguments and to find ways of reducing risk or burden.

Arrangements need to be made for the possibility that the participant regains capacity, and to allow them or a consultant to withdraw them from the study, in line with similar rights afforded to people with capacity. During periods of acute illness delirium or other conditions may temporarily impair patients’ capacity to consent to participate in research. However when the clinical condition improves they may regain the ability their capacity to consent. It is essential that research staff are fully trained in assessing capacity, and that there are clear processes to oversee their conduct and for complex or difficult decisions to be reviewed by senior staff, and for independent adjudication to be available in the event of uncertainty.

Recruiting people from minority ethnic groups

The percentage of people from black and ethnic minorities (BEM) living in the UK is increasing; the 2001 UK population census showed that 7.9% of the population belonged to an ethnic minority. The disease profile in this population is different from the Caucasian population and the representation of older people from an ethnic minority in clinical trials is poor. Some views in the literature suggest that black patients may be less willing to engage in research [15]. The choice of research topic should address and acknowledge the interest and diversity of the group. This can be achieved through meaningful involvement of potential research participants in the planning stages of the research in focus group meetings. The use of interpreters, involving key figures from the community, using culturally appropriate language in research advertisements and targeting the local GPs in areas with a high population of BEM groups are all useful approaches. Ensuring adequate follow-up of recruited patients through weekly contact in the form of personalised reminders such as ‘missing a letter’ is often helpful in maximising retention [15].

The researcher should develop links with key research centres experienced in working with older people from BEM such as PRIAE (Policy Research Institute on Ageing and Ethnicity). A successful example has been the use of indigenous health workers to recruit from an ethnic minority [16].

Older patient and public involvement

Broadening patient and public involvement (PPI) in research is now an established goal of science policy in the UK [17]. PPI is increasingly required by research funders and there is growing experience of PPI in the research community. The Department of Health is further seeking to strengthen PPI through a project called The Way Forward.

The National Institute of Health Research (NIHR) states that ‘PPI means that people are active partners in the research process by, for example, advising on a research project, assisting in the design of a project, or in carrying out the research, rather than being the “subjects” of research’. A hierarchy of three levels of PPI is now recognised—consultation, collaboration and user control (see Box 1) and higher levels of PPI are encouraged including designing questionnaires and topic guides, conducting interviews and focus groups, reviewing transcripts and contributing to interpretation and preparing patient information.

Box 1. The hierarchy of PPI

- Consultation: when you consult people who use services about research, you ask them for their views and use these views to inform your decision-making. For example, you might hold one-off meetings with people who use services to ask them for their views on a research proposal. You will not necessarily adopt those people’s views, but you may be influenced by them.
- Collaboration: collaboration involves active, on-going partnership with members of the public in the R&D process. For example, people who use services might take part in a steering committee for a research project, or collaborate with researchers to design, undertake and/or disseminate the results of a research project.
- User control: user-controlled research might be broadly interpreted as research where the focus of power, initiative and subsequent decision making is with service users rather than with the professional researchers. It does not mean that service users undertake every stage of the research, or that ‘professional’ researchers are necessarily excluded from the process altogether.
Box 2. Enhancing recruitment through PPI

Recruitment will be more effective if the following are enhanced by PPI:

1. the relevance of the research project to potential recruits;
2. the quality of information resources used for consent and participation;
3. the acceptability of methodology such as questionnaires, interview schedules and focus group guides;
4. the appropriateness of the research project outcomes;
5. the opportunities for peer recruitment, including hard to reach populations.

Enhanced PPI can help with recruitment. INVOLVE, a national advisory group on public involvement in research, suggests actions which may assist in recruitment, at all stages from design to peer encouragement [18]. Advice and training is accessible through regional Research Design Services, the Comprehensive Local Research Networks (CLRN) of the national Comprehensive Clinical Research Network (CCRN) and the INVOLVE ‘People in Research’ website which provides additional resources for patients and members of the public to assist participation in research. Box 2 summarises how PPI can help with recruitment. Researchers may find it helpful to contact established organisations such as Age UK, which is highly experienced in providing guidance and support on the involvement of older people in research, and has led the user involvement work package in the EC funded FUTURAGE project which will set the standards for user involvement in EC programmes for the next 10–15 years.

Conclusions

The European charter for older people in clinical trials (PREDICT) was launched in 2009 [19]. Following a rigorous consultation process funded by the European Union, this set out what older people should be able to expect in relation to clinical trials. The charter covers right of access, prevention of discrimination, practicality and safety. Involving older participants in research will inform best practice in the clinical management of our growing older population. Avoiding arbitrary upper age limits in protocols will make trial findings more generalisable, increase the pool of potential participants, improve recruitment rates and make for better science. This article has laid out practical guidance for researchers, specifying best practice approaches to the planning and conduct of clinical studies in both inpatient and community settings which will enhance recruitment and improve retention. The greatest burden of ill health falls on the older population—it is time that research activity reflected this.

Key points

- Older people are often excluded from research and researchers are often over-optimistic in estimating recruitment rates.
- Maximising effective communication, involvement of carers, use of research networks, overcoming potential problems with access and transport improve recruitment and retention.
- Recruiting under-studied groups of older people including those in care homes and those with mental incapacity is possible but requires particular planning and expertise.

Acknowledgements

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Additional resources

Primary Care Networks.
http://www.sspc.ac.uk/spcrn/.

Department of Health (2008a) Guidance on nominating a consultee for research involving adults who lack capacity to consent Issued by the Secretary of State and the Welsh Ministers in accordance with section 32(3) of the Mental Capacity Act 2005 www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_083131.

Conflicts of interest

None declared.

Patient and public involvement

www.peopleinresearch.org/.
www.invo.org.uk/Whatextenttoinvolvepublic.asp.

Social Care Research Ethics Committee

www.screc.org.uk.

References


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