

Improving recruitment of older people to research through good practice

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Introduction

The welcome population health gains of the past few decades have produced a number of important changes. First, the increase in life expectancy has resulted in a shift in the age distribution of many diseases of later life. Second, the population burden of disability has risen as a result of the longevity. This 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. This is true for trials in cancer, cardiovascular diseases and even for some diseases of old age like Parkinson’s disease². The lack of fit between participants in clinical trials and users of healthcare in the real world raises serious concerns regarding equity of care³.

The reasons for the 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. It is also possible that some researchers are simply unsure how to go about involving and retaining older people in research.

Equitable and efficient recruitment matters. 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 specified⁴. Our own analysis of 14 consecutive recent randomised trials in older people published in this journal shows that up to three times the target number of participants needed to be screened to recruit one participant, that only 9/14 (64%) of trials achieved the pre-specified power, and that drop out rates varied between 3% and 37% (Table 1). 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, cite the evidence where it exists and offer a critical appraisal of how commonly experienced difficulties may be resolved.

Recruiting in acute hospital care and rehabilitation units

There is plenty to cope with during a hospital admission without also having to manage decisions about whether to participate in research. 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 forms. During this period, delirium may supervene and temporarily relieve a frail older person of their capacity to consent to participate in research. Accordingly researchers and clinical staff

responsible for identifying potential recruits need to take these factors into account when designing recruitment strategies targeting patients in acute hospital care or rehabilitation units.

The attitudes of the clinicians providing the patient care is critical; the attending physicians 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 patients⁵. The attributes of the researcher are also important. Recruiters with strategies to overcome the challenges of communicating effectively with people with poor vision and hearing impairment are needed. Providing information in sufficiently large font and in simple format without losing the content is necessary. The researcher needs to build a relationship with the clinical team ensuring everyone is aware of good clinical practice and the studies that are open for recruitment, highlighting eligibility criteria so everyone in the multidisciplinary team is aware of the type of patients that each study is recruiting. Any potential benefits to patients, carers and/or professionals should be emphasised as this will make the study more meaningful and 'real' to colleagues.

It helps if the research and clinical staff understand each other's interests and routines. Taking time to establish a good relationship with the ward staff can pay dividends in ensuring that suitable patients are identified and ensuring the process of recruiting becomes a usual, rather than an exceptional ward activity. Research posters and leaflets in public areas ensure that patients and visitors are aware that the unit is research active and that they will be approached about studies. Patients may then view the researchers as part of the normal hospital routine, especially if the ward information mentions research activities.

Recruiting older patients in inpatient and rehabilitation settings takes time, patience and flexibility. 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. Spending extra time finding out about their life story and current situation is always of interest, and may help potential participants to feel valued and more likely to get involved in the research. It is important to emphasise that participation (or non participation) will not affect other aspects of their care or delay their discharge. People recruited in an acute setting may be discharged before the study activities are completed, therefore it's important to be able to follow the patient on transfer of care to a rehabilitation setting or into their own homes.

Successful recruitment often requires several strategies. Patients are more likely to participate if they consider the research to be important and perceive that they will have the time to participate. They need to trust the research process and be sure they won't be uncomfortable or disadvantaged if they take part. Challenges relating to recruitment of people who lack capacity are dealt with later

in this article, but it is worth remembering that when the clinical condition improves, people who had previously been unable to provide consent to participation in research may regain the ability to do so as confusion secondary to acute illness settles.

Recruiting in Primary Care

Primary Care Research Networks exist in both Scotland and England. Their purpose is to increase the amount of research relevant to patient care carried out in the primary care settings. Given the central role of Primary Care in the NHS and the computerised disease databases held by practices, collaboration with PCRNs provides researchers with superb opportunities to efficiently identify eligible study participants in cooperation with primary care colleagues. 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. When ready to begin recruitment, the PCRN circulates brief details of the study with inclusion/exclusion criteria to research active practices in the area. The PCRN coordinator then visits practices which have elected to contribute to search their databases for patients matching the age and condition criteria required. A list of potentially eligible patients is generated which is screened by the general practitioner, and the names of individuals that it would not be appropriate to contact, for example those with a recent bereavement, are removed. The PCRN coordinator then sends letters of invitation to participate in the study to these patients. The letter is on practice-headed notepaper, signed by the general practitioner and accompanied by the study Information Leaflet. Patients wishing to learn more about the research reply using a pre-paid envelope either to the practice, or to the PCRN offices. Only at this point are replies passed to the researcher. Thus patient confidentiality is protected, and researchers receive only the details of patients who have expressed an interest in finding out more about the study. The first approach to potential research participants comes from their primary care physician - a familiar and trusted figure. Such approaches may be associated with high recruitment rates⁶; the ratio of patients approached to patients enrolled has been found to be considerably higher than targeting the general population from census or electoral registers⁷.

<http://www.sspc.ac.uk/spcrn/>

<http://www.ukcrn.org.uk/index/networks/primarycare.html>

Recruiting in care homes

Care homes is the generic term for long term care settings that offer on site nursing support and/or personal support (residential). There is considerable overlap in health needs between nursing and residential care and 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(<http://www.cqc.org.uk/>)) and or through GP practices with the support of Primary Care Research Network (PCRN) to identify their patients who are living in care home. Close attention to the following will assist recruitment:

- Culture and organisation of the care home. This will affect the number and level of explanations about the study that will need to be completed. This could include, head office of care home chains, care home managers, relatives and friends, staff members and residents' groups. Researchers should discuss how care homes staff see their role in the research For example, do staff see themselves as the 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
- NB Before commencing recruitment in addition to formal ethical review need to secure social care governance through the relevant local authority.
www.dh.gov.uk/en/Aboutus/Researchanddevelopment/AtoZ/Researchgovernance/index.htm
- 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.
- Securing consent: This is very time consuming and resource intensive. The Mental Capacity Act 2005 (Department of Constitutional Affairs, 2005) requires that a person should be considered to have the capacity to consent unless proved otherwise; capacity to consent is context specific and depends on the complexity of the decision. Assessment of capacity can involve the resident's GP and care home staff involved in providing care. It cannot be

assumed that a diagnosis of dementia will be formally recorded in care notes. Consent can be **on-going process**, repeated at each encounter, to ensure continued consent and maximise the opportunities for participation. Oral consent should be witnessed and documented. Where a person no longer has the capacity to give consent, a consultee has to be identified who, based on their knowledge of the person, could provide an opinion as to whether the older person would have consented to participate if they had capacity. This can be difficult in a care home and involve care home staff in contacting relatives on the researcher's behalf. A personal consultee could be: a family member, carer or friend, an attorney acting under a Lasting Power of Attorney (LPA), a court appointed deputy (Court of Protection), provided that they had a relationship with, or personal knowledge of, the person lacking capacity before their appointment as deputy. The personal consultee **must not be** someone who is caring for the person who lacks capacity or is interested in their welfare in a professional capacity or for remuneration. This would therefore exclude a care worker, or a care home manager. However, it could include the team manager of the person's social worker or an Admiral Nurse who had contact with the care home.

Useful resource: 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_0831

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Recruiting adults with mental incapacity

Older people with mental incapacity need to be protected from coercion through involvement in research, yet such people 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 many reasons why many older and frailer people are not recruited into clinical drug trials⁸. So what can be done when a potential research participant does not have capacity to do give informed consent?

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. Although

precise processes and legalities will differ from country to country, its overall principles should be applicable elsewhere.

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 should be consulted to consider applications concerning vulnerable patients, which includes those who may lack mental capacity. The first thing a REC needs to consider is whether there is a good case that 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 can probably be done in older people with mental capacity and it would be reasonable to extrapolate the results of most such studies to people with mental health conditions. People with mental without mental capacity should not be invited to be involved in research simply because they are there.

Overall, the next issue that a REC needs to consider is whether there is a reasonable balance of risk and benefits and that 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, so long as the potential benefits appear to be of a similar magnitude. Committees need to be informed in detail about the major and minor hazards and burdens entailed in every aspect of a research study to make this decision. The REC has to decide whether it is reasonable for people to be recruited into studies without their full informed consent, and has to judge 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.

If a REC decides that there is a good case to do the research and that vulnerable patients need to be included, the next step is to establish what processes should be followed to recruit them and assure their interests and wishes are best considered. It is advised that if a potential participant does not have mental capacity that a “consultee” is sought, and that the information pertaining to the study is discussed with the consultee. Ideally a “personal consultee” should be sought, who has an existing relationship with the person who lacks capacity, and who can advise the researcher about that person’s participation in the project. Where no such consultee is available, a “nominated consultee” should be sought. In certain occasions, this can be the consultant in charge, so long as that consultant is not involved in

any way in the research and hence that there are no conflicts of interest. A full set of trial documentation such as information sheets, and consultee agreement forms is required. Note that the term “assent” is not now used, nor does the consultee give “consent”. If a consultee is not prepared to sign a form with wording such as “I understand that [the participant] would have no objection to participating in this study” then that patient cannot be recruited. Similarly, if there is no consultee, then the person cannot be included in research.

Arrangements need to be made for the possibility that the participant regains capacity, and also arrangements should be made to allow them or a consultee to withdraw them from the study, in line with similar rights afforded to people with capacity. These arrangements will differ from study to study. Finally, all these processes clearly require that the staff involved in such studies 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 or more experienced staff, and for independent adjudication to be available in the event of uncertainty. This often requires a cadre of researchers who are specifically trained in the conduct of such studies.

Recruiting people with dementia

Despite significant potential barriers to recruitment, dementia trials have been successful in recruiting and supporting older research participants in clinical trials. In dementia trials it has become good practice to plan for the needs of older research participants when piloting, planning the physical environment/research facilities and coordinating research. Such good practice should become routine for all research involving older people. Successful recruitment starts at the planning stage. Piloting with a representative sample of older adults is essential to ensure instructions, forms, questionnaires, measurement instruments etc. are legible and appropriate for older adults who may have visual or other sensory impairments. Particular attention needs to be paid to the time needed by older research participants to complete different assessments, so that research time can be planned appropriately with, if necessary, breaks during assessment procedures. The physical environment in which research is conducted needs to be fit for purpose for older research 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 recruitment⁹. Provision of free taxi transport to and from study centres is often appreciated, and needs to be costed in to grant proposals.

There needs to be adequate provision of ramps, lifts and wheelchair access to study centres and any sites where assessments/investigations are to be conducted. Appropriate toilet facilities for people with mobility impairments need to be readily available.

Appointments for research participants should to be made at a time and date convenient to them. Where appropriate it can be helpful to confirm appointments made by telephone in writing, and to follow up with a reminder telephone call the day before a research appointment to confirm transport arrangements, venue and time, and to check that the appointment is still convenient.

It has become good practice in dementia research to include research participants' carers. 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 as the needs of the research participant when organising the logistics of appointments. Attention to detail at the planning stage particularly in relation to the practicalities of research, should help support the recruitment and reduce attrition rates.

Recruiting people with mental disability and those from black and ethnic minorities

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. The prevalence of mental incapacity increases with age, resulting in reduced ability to give informed consent. The representation of older people from an ethnic minority and those with mental disability in clinical trials is poor. Some views in the literature suggest that black patients may be less willing to engage in research¹⁰.

The choice of a 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 general practitioners 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 personalized reminders such as “missing u letters” is often helpful in maximizing retention¹¹.

It is also essential to include provision for reimbursement of travelling expenses in the research funds, and be aware of the participants’ expectations.

The researcher should develop links with key research centers 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 (IHW) to recruit from an ethnic minority¹².

Older patient and public involvement

Broadening patient and public involvement (PPI) in research is now an established goal of science policy in the UK¹³. 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.

Against this background, 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 recognized - consultation, collaboration and user control (see Box 1) and higher levels of PPI are encouraged.

There are several ways in which enhanced PPI can help with recruitment. INVOLVE, a national advisory group on public involvement in research, offers a wide range of reasons for involving patients and public in research. These suggest actions which may assist in recruitment, at all stages from design to peer encouragement¹⁴. The INVOLVE publication "Involving the public in NHS, public health and social care research: Briefing Notes for Researchers" provides a great deal of practical advice on PPI for researchers. In addition the Director of the NIHR provides examples of good PPI practice which may contribute to patient recruitment such as “Involvement of service users in designing questionnaires and

topic guides, conducting interviews and focus groups, reviewing transcripts and contributing to interpretation and preparing patient information”. Advice and training is accessible through regional Research Design Services and the Comprehensive Local Research Networks (CLRN) of the national Comprehensive Clinical Research Network (CCRN). Finally, the INVOLVE “People in Research” website provides additional resources for patients and members of the public to assist participation and improve the recruitment of the older people in research. Box 2 summarises how PPI can help with recruitment. Researchers may find it much more fruitful to make contacts with established organizations such as AgeUK, rather than set up new networks. Age UK has a research department which is highly experienced in providing guidance and support on the involvement of older people in research. It has lead 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.

www.peopleinresearch.org/

www.invo.org.uk/What extent to involve public.asp

www.ukcrn.org.uk/index/networks/comprehensive.html

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 user 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

Conclusions

Involving older participants in research has obvious benefits, not least the need to draw on the results of good quality research to inform best practice in the clinical management of our growing older population. Avoiding arbitrary upper age limits in protocols, for example, 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, best practice approaches to the planning and conduct of clinical studies which will enhance recruitment and improve retention, as well as providing an indication of likely recruitment and retention rates.

The European charter for the rights of older people in clinical trials (PREDICT) was launched in 2009. 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 greatest burden of ill health falls on the older population – it is time that research activity reflected this.

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Table 1. Age Ageing randomised controlled trials published between January 2008 and July 2010

Excluded from search – meta-analyses, systematic reviews, and observational studies. Also studies based on previous Randomised trials.

Reference	Topic	Setting and type of trial	No.s needed to recruit	No. screened	No. recruited	No. excluded	No. refusing	Period of follow up	Dropout	Power achieved?	Comment
Randomised trials											
Peri et al. Jan 2008;37:57-63	Activity levels	Residential care cluster	124	208	149	33 (15.8%)	26 (12.5%)	6 m	20 (13.4%) 13 died 11 transferred 1 withdrew	Probably not	Results likely contaminated by cross over between clusters
Azad et al. May 2008; 37: 282-287	Heart failure clinic	Outpatients Single blinded	200	Not stated	91	Not stated	Not stated	6m	7 (7.7%) not stated	no	Poor recruitment due to frailty and “limited resources”
Harrari et al. Sept 2008;37:565-571	Health risk appraisal	Primary Care Self report	2000	5982	2503	884 (14.7%)	1959 (33%)	1yr	648 (25.8%) did not return forms	yes	Large scale questionnaire intervention
Crotty et al. Nov 2008;37:628-633	Home vs day hospital post-hospital stay	Community Single blind	150	301	229	34 (11.3%) mainly travel reasons	38 (12.6%)	6m	11 (4.8%) 4 died 7 withdrew	Yes	
Harris et al. Nov 2008;37:659-665	Methods of increasing study recruitment	Postal and telephone unblinded	560	1529 available to recruit from	560 selected at random	273 multiple problems	N/A	Single time point study	N/A	Probably not	240 (43%) were recruited into the main study
Spice et al. Jan 2009;38:33-40	Falls	General Practices / secondary care cluster	450	728	516	212 (29%) multiple reasons	110 (15%)	1 yr	75 (14%) 38 died 26 withdrew 11 ineligible	yes	Trial of setting/ style of care
Moseley et al. Jan 2009; 38:74-80	Increased exercise after hip fracture	Rehab units and home Single blind	160	404	160	397 (49%) multiple reasons e.g. cognitive impairment	47 (11.6%)	16 weeks	10 (6.2%) 7 died 3 withdrew	probably	No differences shown with higher exercise levels
Gleason et al. Jan 2009;38:86-	Soy supplements	Community Double blind	Not stated	34 unclear	31	3 not free of illness or			1	yes	Presumably healthy volunteers perhaps from a panel?

93		placebo				cognitive problems					
Neyens et al. March 2009; 38:194-199	Falls	Nursing homes cluster	360	518	518	29 in intervention arm (12.6%) no reasons - all controls included	20 in intervention arm (8%)	1 yr	192 (37%) no reasons	yes	Intention to treat; may be select group of homes participated as 34 out of 119 homes agreed and 12 selected
Meyer et al. July 2009; 38: 417-423	Falls	Nursing homes cluster	1080	1972	1125	847 (43%) as no falls	20 nursing homes refused	1 yr	218 (19%) 190 died 28 moved	yes	Intervention was a risk assessment tool for falls - all residents included automatically so no individual refusals
Ciaschini et al. Nov 2009;38: 724-730	Falls	Community Not blind 1 centre	200	590	201	73 (12%) not at risk of falls	316 (54%)	1yr	25 (12%)	no	Adverts and direct clinician referral
Forster et al. Sept 2009; 38:576-583	Post-Stroke support	Community Single blind 2 centres		487	265	163 (33.5%) not disabled	59	6 m	23 (8.7%) 16 died 7 withdrew	yes	
Salonoja et al. May 2010; 39: 313-319	Medicine reduction	Community Not blind 1 centre	Not specific	612	591	21 (3.4%) multiple reasons	All agreed through adverts in a single town	1yr	61 (10.3%)	yes	Recruited by adverts so selective population: 1 time counselling to reduce sedatives
Boxer et al. July 2010; 39; 451-458	Drug treatment for sarcopenia	Community Double blind placebo	Not made clear	728 response s then 725 screened	99	329 not frail or normal DHEA levels	47 1 st wave 23 2 nd wave =70 total	6 months	12	yes	Recruited by mailing

{ Cox et al. March 2008 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 sept 2008 was a cost evaluation of a previously reported RCT and full details were not included in this paper;)

*More precise data lacking from article

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