Culture, consent, costs and care homes: enabling older people with dementia to participate in research

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(Received DD Month YYYY; final version received DD Month YYYY)
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Aging and Mental Health

Objectives

To describe factors that support and inhibit recruitment and participation of people with dementia living in care homes.

Method

This paper focuses on the methods used to recruit people with dementia to a longitudinal study that employed a mixed-method design to track events and care that older people with dementia experienced over two years in six care homes. A staged approach to recruitment was adopted involving separate meetings with staff, residents and relatives. Individual consent was secured with residents with dementia who could consent in the moment and for those without capacity, through mail and follow-up telephone contact with consultees. Data were collected on the frequency of meetings, issues raised by staff, consultees and people with dementia as well as the overall time taken to complete recruitment.

Results

Over five months, 133 older people with dementia were recruited (62% of sampling frame). The recruitment process was supported or hindered by the number of individuals and organisations that needed to be consulted, the care home culture, staff understanding of how people with dementia can be involved in research, and how they interpreted their role as mediators, protectors and gatekeepers.

Conclusions

Care homes are isolated communities of care. To achieve the research objectives researchers in the initial stages need to consider the philosophical underpinnings of individual care homes, and the politics of hierarchy both within the care home and between it, and other health professionals.
There is a need to develop credible infrastructures of support that enable people with dementia to participate in research.

**Key words:** dementia; care homes; recruitment
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Introduction

The role that care homes play in providing care and support to people with dementia at the end of their life is an area of increasing policy and research interest (Department of Health, 2008; National Council for Palliative Care, 2006). Older people with dementia however, are often excluded from research on end-of-life care and reliance is placed on the proxy accounts and views of others, or after-death-analysis through care notes and medical records (Goodman et al. 2009; Van der Steen, 2010). Although the challenges and complexities of recruiting people with dementia in care homes are acknowledged, (Zermansky, Allred, Petty & Raynor, 2007; Mental Capacity Act, Department of Constitutional Affairs, 2005) there is less discussion of the time and resources required to maximise participation, the layers of permissions and explanations required, or the support and information that older people with dementia, their relatives and care home staff may require in order to enable recruitment. Nor is there any consideration of the impact research can have on a care home as a small organisation.

This paper draws on the experience of recruiting 133 older people with dementia, resident in six care homes, to a longitudinal study on end-of-life care. It considers the time and resources involved in securing older people’s participation and what supported and hindered that process. It proposes that researchers and funders need to understand how the recruitment of people with dementia in care homes is shaped by care home culture, economic constraints, staff and relatives’ understanding of dementia and the contribution of research, and the need to tailor consent processes to the individual in ways that continue throughout a project. The paper concludes by arguing for the development of strategies that promote inclusionary research, the creation of networks of “research ready” care homes and the
development of guidance for all relevant stakeholders (including funders, researchers, care homes, NHS and Local Authority staff) on good research practice in care home settings.

**Background**

In the UK there are nearly 18,000 care homes that offer residential care for older people (Laing & Buisson, 2007). It is estimated that 36.5% of people with dementia live in care homes, this proportion increasing with age to 61% of people with dementia aged over 90 (Laing & Buisson, 2007). The majority of people do not enter a care home to die. Nevertheless, the assumption is that this will be the place where they spend the last years and months of their lives. The study’s aim was to understand the support and end-of-life care needs of older people with dementia living in (residential) care homes. This paper describes the barriers and facilitators to recruiting people with dementia to a study on end of life care.

**Methods**

The first phase of the study, the focus of this paper, had a prospective design, tracking the events and care older people with dementia experienced over two years. It had a mixed method design that employed both quantitative and qualitative methods of data collection. Once older people were recruited to the study, this included review of care notes at four-monthly intervals, interviews with people with dementia, care home staff and health care professionals, and documentary review of guidance and protocols on end-of-life care used by the care homes.

**Identification of care homes**

The Care Quality Commission’s (CQC, formerly Commission for Social Care Inspection) directory of care homes and care services was used to identify care homes. Those care homes
that met the inclusion criteria of being within an hour’s journey of the study centre, registered to provide residential care (i.e. no on-site nursing provision) for people with dementia, of having a minimum of 25 beds, and assessed as providing a good (2 star or above) standard of care, were identified. From this list, and following discussion with the local NHS primary care manager of community nursing services to establish that they had a reasonable working relationship with the care home and there were no issues of concern, ten care homes were purposively selected to reflect a range of ownership (private, charitable, faith based, large commercial chain and geographical location (urban, suburban, and rural) and invited to participate in the study. It was considered important at the point of introducing the study to the care home, because of the sensitivities of the research and the often critical press that care homes receive on their standards of care, to stress that they had been chosen because of their CQC good rating and recommendation from the CQC and had been identified by local health care providers as having a good working relationship with the health service. Following initial discussions, six care homes that agreed to take part and the research team followed up with separate meetings with staff, residents and relatives to discuss the scope and intention of the study, and gauge interest and willingness to participate.

Inclusion criteria for care home residents were that they were 65 years or older, with a documented diagnosis of dementia, or assessment by the senior care worker that the older person had cognitive impairment indicative of dementia and a validated measure of cognitive function impairment (completed with the researcher). Exclusion criteria were people with dementia who did not speak English, those whom the care home manager thought it inappropriate to approach (e.g. people in the terminal stage of the disease) and individuals who lacked capacity to consent and for whom a consultee could not be identified. A three-
stage process was proposed, designed to minimise pressure on individuals to participate and provide maximal opportunities for discussion.

- **Stage one** The care home manager will give the older person (and or their consultee) a letter of invitation to participate and an information booklet.

- **Stage two** A member of the care home staff will introduce the researcher to each older person (and/or their consultee) who has indicated an interest in the study, a time is agreed to meet and if appropriate an intermediary is present.

- **Stage three** Researcher meets with older person with dementia and where possible an intermediary to explain the study and begin the consenting. The intermediary’s role was to explain and if necessary interpret any areas of concern or lack of understanding. Consenting to participate was emphasised as an ongoing process that meant participation would be revisited and discussed throughout the study with the older person. A single information sheet on the study was given to participants to facilitate discussion. The sheet was designed to increase accessibility for an older person with cognitive impairment and used large black font, yellow paper, lay language, photo of the researcher and laminated.

No payment was offered to care home staff but staff were given gift vouchers in recognition of the time taken in helping in the completion of validated assessment tools. To capture information about the recruitment process the researchers recorded the number of telephone conversations, visits, meetings, who participated, and the number of follow-ups required to complete recruitment at each care home. Data were entered on to Microsoft Excel spreadsheets for each care home. In addition, field notes were kept as summaries of conversations and sources of contextual detail.
The study protocol was submitted to NHS Southampton and South West Hampshire Research Ethics Committee B (reference number 08/H0502/74) and approved 14th July 2008. Social and health care research governance approval was obtained from the relevant Local Authority and NHS Primary Care Trust.

Results

It took one full time researcher with support from three others who assisted recruitment on a short-term or part-time basis five months to recruit 133 people with dementia across the six care homes. The overall recruitment was 62.1% (133). This represented the 65 (73.9%) people with dementia who had sufficient capacity to understand the study purpose that agreed to participate, and the 68 (54%) residents whose personal consultees responded that in their opinion if their relatives could have responded, they would have agreed to take part in the study. Nine personal consultees thought the study would be of no interest to their relative and 49 did not respond despite letter and telephone follow up (table 1). There were core similarities between the care homes in terms of resident characteristics and care home staff profile and unsurprisingly those care homes with the highest number of eligible residents took the longest time to recruit (table 2). However, it was the complexities arising from their differences, specifically, their culture of working and how they understood the process of recruitment, mental capacity and their role in the research process that had the most impact on the recruitment process overall.

Culture of Care Homes

The care home managers and their deputies had varied perceptions, but little experience of research, and only one had a clinical qualification. It was evident from the range of questions and concerns expressed, that engagement with the study was informed by their willingness to
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talk about dying, their conceptualisation of dementia, and their interpretation of their role as
gatekeepers and understanding of the Mental Capacity Act (Department of Constitutional
Affairs, 2005).

Some care home managers were able to talk freely with the researchers about death
and dying in the care home, others acknowledged it happened but indicated it was something
they did not discuss with residents. One care home manager who subsequently declined to
participate was concerned that a study about dying could lead to adverse publicity for the
home.

The range of views held by care home managers about the care home as the
appropriate place for death and the relevance of research meant that as much time had to be
given to forming relationships with care staff as explaining the study to people with dementia
or their consultees.

All the care homes were registered to provide dementia care. Originally, it had been in the
study protocol to use a validated measure of cognitive function to identify potential
participants. It became apparent this could have unintended consequences, as some care home
managers wanted to use the results from a validated assessment of dementia as evidence to
justify raising a resident’s fees. Secondly, and following discussion with the steering
committee, it was decided that as the study aimed to reflect the experience of older people
with dementia in residential care it was appropriate to record as a finding how dementia had
been defined by the care home staff and recorded in the their care notes. Of the 133 residents
who were ultimately recruited to the study, over a quarter 26.3% (n=35) did not have a
dementia diagnoses recorded in the notes but were identified by the care home staff as having
memory problems and /or behaviours consistent with a diagnosis of dementia (e.g. memory
lapses, disorientation to time and place, lack of ability to problem solve, needing
help/prompts for personal care). Of those who had a recorded diagnosis of dementia in their
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care notes, 35.7% (n=35) had no reference to the type of dementia or its severity, and it was unclear how the diagnosis had been made. None of the care homes recorded severity of dementia (or assessments of deterioration) in their care notes. One care home manager (4) described how the care home actively avoided the word ‘dementia’, as they did not want to discriminate between their residents in this way. Paradoxically, this was the only care home that had a working relationship with the local memory clinic and would send residents for diagnosis. There was an assumption in this care home that for most people it was worth trying for consent unless it was clear that the person could not communicate or understand a conversation. Another care home (6) was similarly open and allowed the research team to approach all residents. Arguably, this reluctance to distinguish between people because of a diagnosis of dementia was indicative of a culture of inclusiveness and a commitment to involving the older people in the decision making process about participation in the research. The remaining four care homes assumed more of a gate-keeping role excluding certain residents at the outset whom they considered ineligible.

Care home staff’s beliefs about how much people with dementia should and could be included in research, and attitudes towards the possibilities of discussing dying in a care home environment prefigured and influenced decisions about researchers’ access to the older people, and how the conversations and explanations about the study were organised with residents, staff and family members. One care home manager commented on how regulation permeated all that they did; it informed the overall culture of care, how it was documented and ultimately their willingness to take on new activities and involvements such as research:

*Over the years, yes, over the years it’s [(regulation)] become worse, and we’re regulated so strictly; we have to be able to justify everything we do. (DCHM5 :24)*
Recruitment of older people with dementia was a staged process that was informed by how participation had been determined by the care home manager and by being undertaken in a residential community. In three of the six care homes meetings were held with residents as a group with their relatives present. These meetings were held on weekends. In two other care homes meetings were held at prearranged coffee mornings just with relatives present and in one, the care home manager felt that a meeting was not necessary. There were opportunities for questions and discussion from both residents and relatives and information leaflets were provided. This was followed by one or more conversations with individuals and over the next two weeks they were asked if their notes could be reviewed and/or whether they would be willing to take part in an interview. Researchers were often met with responses such as, “I don’t think I have any notes,” or, “I won’t be much use to you.” Relatives too had very low expectations, even though of the 65 (48.8%) older people recruited who had the capacity to consent to their notes being reviewed, many were also able to participate in an interview about living and dying in a care home and describe their views and preferences.

As many residents could not remember earlier encounters such as the meetings for the residents, information and questions were provided again and discussed. Residents could be sleeping, have visitors, or be involved in activities, and consequently the researchers would defer speaking to them. However, many of the older people had few diversions or opportunities for one to one conversations. In these situations, residents often prolonged conversations and there was a concern that participation was prompted by boredom and the need for diversion, and that, had there been alternatives, residents might not have been so willing to take part.

(Figure 1.)
**Consent and Consultees**

Participation in the study for an older person with dementia meant consenting to the reviews of their care home notes. The Mental Capacity Act (Department of Constitutional Affairs, 2005) emphasises that a person should be considered to have the capacity to consent unless proved otherwise (Fig. 1). To be assessed as having capacity the individual needs to retain the information given to consider if they want to take part. For this study, retention was defined as the period of the conversation. It was an on-going process, repeated at each encounter, to ensure continued consent and maximise the opportunities for participation.

The decision as to who could be approached to assess if they had capacity to consent for themselves (to an interview and/or having their notes reviewed) was partly influenced by staff’s acceptance that a person with dementia could consent in the moment and at each point that their participation was required. Not all care home staff accepted this definition of capacity or that this approach gave people with dementia the opportunity to contribute their opinions and feelings, even if they might not subsequently remember the conversation.

When the older person could not understand the study, a personal consultee had to be identified who, based on his/her knowledge of the person, could provide an opinion as to whether the older person would have consented to his/her care notes being reviewed. Under the Mental Capacity Act (Department of Constitutional Affairs, 2005), consultees cannot be people that are paid to look after the older person. The process for identifying and contacting consultees with each of the care homes was protracted. It had to be individually negotiated including adherence to data protection restrictions. Care home staff had to be involved in both identifying relatives and then contacting them or sending information about the study on behalf of the research team. The consultee (usually a relative) was contacted by letter accompanied by an information leaflet and a form inviting assent that in their opinion their
relative, when able to, would have consented to take part in the research. The researchers prepared these information packs but as the consultee contact details were protected by the Data Protection Act (Office of Public Sector Information, 1998), care home staff had to complete the consultees’ addresses and post the details out on the research team’s behalf. If no response was received in 2-4 weeks of sending the letter, then a member of the research team spoke with the consultee on the telephone from the care home, although some were also unable to be contacted in this way.

When consultees who were themselves frail and or had other health issues (n=4), care home managers suggested that, as it was not central to the care of their relative, they should not be approached. These residents were excluded from the sample as nobody else who knew the person sufficiently, could be contacted. Within the care home environment it was often the care home staff who knew the older person with dementia best, for example, knew if they valued their privacy and trusted only a limited number of people. Under the terms of the Mental Capacity Act (Department of Constitutional Affairs, 2005) they were excluded from providing an opinion, but senior care staff were however, involved in controlling whether or not they thought it was appropriate for the research team to approach an older person about participation in the study.

Overall the research team achieved a 61.1% response rate from consultees (table 1).

(Exercise 1.)

Costs to Researchers and Implications for funders

Table 2 shows the approximate number of visits and number of hours the researchers spent in the care home in order to complete recruitment. This includes initial meetings with
the staff, coffee mornings with residents and relatives, and one-on-one conversations with the older people who could discuss the study and answer questions. It does not include the time taken to secure ethics and governance approvals, waiting for responses from care homes, consultees, and arranging visits, the gaps between visits to accommodate care home schedules, waiting to see individuals or travel to the care home. It was also found to be efficient to have three researchers visit one care home on one day when recruiting residents who may be able to give consent. This was less disruptive to the care home and supportive for the researchers. Additional funding for research staff was received from the local Dementia and Neurodegenerative Diseases Research network specifically to support recruitment. The costs however of employing staff (including employer’s costs) to achieve this recruitment figure over the five month period are conservatively estimated as a proportion of researcher time at £27,300.

(Table 2.)

These findings have implications for conducting research in this setting, both in terms of time scale and resources needed and the impact multiple visits and researchers can have on a care home as an organisation.

*Costs to the Care home and staff*

Researchers made every effort to fit in with the care home regime and arranged visits at the care homes’ convenience. Despite this, the researchers were sensitive to unintended disruption caused to the care homes where visits might hinder resident care, interfere with routines and take up care home staff time. The amount of time and resources required from the care home staff to support the recruitment of residents with dementia was not quantified. However, for each of the six care homes, care home staff could be involved with up to three
meetings to discuss the study, supporting the identification of older people who had the capacity to participate, accompanying researchers to introduce them to the older people, and also be involved in contacting or mailing information to consultees on behalf of the research team. This was time that could have been used to provide care to the residents. Although the level of involvement required was discussed at the beginning of the study not all the care homes were able to release staff to support the recruitment process resulting in researchers having to make multiple visits and rely on the goodwill and availability of the staff.

**Discussion**

Zermansky et al. (2007), on the issue of consent in nursing homes, has argued that if the researchers follow all the governance and ethical processes it is very difficult to secure a level of consent/assent above 42%. This study achieved a slightly higher response rate in (residential) care homes of 62.1%. However, it was a resource intensive process that revealed how much preparatory work, and the many layers of permissions that were needed to support the recruitment process in care homes. Since the study was undertaken in residential care homes there were no clinician onsite with whom to liaise.

The care homes’ overall approach to care and their culture of working with older people shaped how staff worked with the research team to support or control those who were identified as possible participants. These influences also impacted on how care home staff engaged with the research, defined dementia and interpreted their role as mediators, protectors and gatekeepers. The delivery of research objectives in the initial stages of recruitment needs to consider not only the philosophical underpinnings of an individual care home, but also take into account the politics of hierarchy, both within the care home, and between it and other health professionals.
A research priority setting exercise for end of life care identified care homes as a priority area (Shipman, Gysels, White, et al., 2008). Care Homes are highly diverse, isolated communities of care (Froggatt, Davies & Meyer, 2009), and do not know what they should or should not expect from researchers, nor what are reasonable and unreasonable demands on their staff and residents. Increasingly however, they are becoming the treatment solutions for older people with dementia with ongoing and end-of-life care needs (Goodman and Davies, in press). It is a sector characterised by different types of ownership, provision and expertise with the result that recruitment can be an idiosyncratic process. Researchers can access care homes through multiple routes, none of which can involve consulting with the older person at the outset. This study’s experience of interpreting the Mental Capacity Act (Department of Constitutional Affairs, 2005) to recruit people with dementia suggests that this is a negotiated process that is poorly understood and sometimes confused with data protection legislation. Furthermore, in the absence of relatives to act as consultees and care homes that have no on-site clinical support or ongoing links with other professional services, identifying appropriate consultees who know the residents is problematic. Twenty three per cent (49) of care home residents did not have the opportunity to be recruited because of non-response from consultees.

Lawson (2000) in an ethnographic study in a hospice found it was necessary to work alongside staff to understand the culture and organisation of the hospice prior to beginning her study. There are parallels. Our experiences suggest time given to understanding how care home staff engage with research and the organisation of care within care homes facilitates the recruitment and research process as a shared endeavour. Particularly, in care homes where there are no on-site clinicians to interpret or liaise with the research team.

The majority of research on end-of-life care for people with dementia in care homes has been undertaken in the USA and the Netherlands (Goodman, Evans, Wilcock, Froggatt,
It is possible that the presence of minimum data sets, on-site physicians, and different governance procedures in these countries have an impact on access to residents and routinely collected data. There is a need for an international debate with the research community and providers of long term care to people with dementia, on how concerns about protecting this population, and current approaches to assessing capacity, do not exclude the group that has most to gain (Meehan, Meyer & Winter, 2002; Reed, Cook & Cook, 2004; Dewing, 2007).

It is also important to build into research funding, support for care homes that recognises the disruption and inconvenience participation in research causes even before data collection begins. This is in addition to long term strategies that ensure that care homes can benefit from participation through knowledge transfer, staff development and involvement in identifying research priorities and questions.

There was a deliberate selection bias in how the care homes were identified. They were recruited on the basis of a favourable assessment from the regulator and evidence of reasonable working relationships with health care providers. This was because when researching the study it was important that the findings did not reflect issues and problems of unsatisfactory care that were unrelated to the research questions. A further, less explicit, recruitment bias became evident because of the differing responses from the care homes to the study. This has implications for cluster samples and analysis of differing numbers of participants in each cluster/care home. There is remarkably little discussion of these issues in the methodological literature.

**Conclusions**

The findings from this paper support those of other studies that have tried to optimise the recruitment of people with dementia (Zermansky et al., 2007; Warner, McCarney, Griffin,
Hill & Fisher, 2008). Care homes, as communities of care, have the potential to be active partners in research. The experiences reported in this paper suggest that:

- Researchers and funders need to build in to projects, time to negotiate the multiple layers of permissions and explanations that can occur when seeking access to care homes and their residents that have dementia (care home owner organisations, care home managers, staff, relatives and friends.)

- That people with dementia, who may have memory lapses, can consent in the moment and express opinions and preferences about living in care homes and access to their notes for research purposes.

- There is a need to develop infrastructures of support that:
  - enable care homes to participate in research,
  - safeguard the time and resources for the care of older people,
  - as well as identify in advance, appropriate consultees for research purposes when people lack capacity.

- Initiatives such as the General Practice Research Framework (www.gprf.mrc.ac.uk) that have enabled General Practices to become research-ready and at the same time safeguard the interests of patients (e.g. patient caseloads who are aware they might be asked to take part in research, minimum standards in record keeping, training and support of staff in the research process and interest in evidence based care.)

- Researchers need to consider a model of reciprocal working that ensures a consistency of approach, minimum standards of care, sufficient finance and workforce, and opportunities for learning and support to facilitate the recruitment and execution of research.

- Arguably an equivalent network of research-ready care homes accredited to reflect minimum standards of care and understanding of the research process and safeguards is
needed. This would be of mutual benefit to researchers, care home staff, and ultimately the populations they serve.

Disclaimer: This study has received financial support from the National Institute for Health Research (NIHR) Programme Grants for Applied Research funding scheme. The views and opinions expressed therein do not necessarily reflect those of Central & North West London NHS Foundation Trust, the NHS, the NIHR or the Department of Health.
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Mental Capacity Act (2005) – Assessing Capacity

1. Does the person have an impairment of the mind or brain, or is there some sort of disturbance affecting the way their mind or brain works?

2. If so, does that impairment or disturbance mean that the person is unable to make the decision in question at the time it needs to be made?

Assessing ability to make decisions

1. Does the person have a general understanding of what decision they need to make and why they need to make it?

2. Does the person have a general understanding of the likely consequences of making, or not making this decision?

3. Is the person able to understand, retain, use and weigh up the information relevant to this decision?

4. Can the person communicate their decision? Would the services of a professional be helpful?

Figure 1. Mental Capacity Act sections 2 & 3 (Department of Constitutional Affairs, 2005) two-stage test of capacity
Table 1. Recruitment figures of older people with dementia at baseline

<table>
<thead>
<tr>
<th>Care Home</th>
<th>Individual Consent (number eligible for participation)</th>
<th>Individual Consent (% of total considered able to give consent)</th>
<th>Consultee positive response (% of total contacted to give opinion)</th>
<th>Consultee Negative response (% of total contacted to give opinion)</th>
<th>Non Responding Consultees (% of total contacted to give opinion)</th>
<th>Total Recruited (% of total matching inclusion criteria)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CH 1 (28)</td>
<td>5 (83.3)</td>
<td>15 (68.2)</td>
<td>1 (4.5)</td>
<td>5 (22.7)</td>
<td>20 (71.4)</td>
<td></td>
</tr>
<tr>
<td>CH 2 (40)</td>
<td>12 (50.0)</td>
<td>13 (81.3)</td>
<td>2 (12.5)</td>
<td>1 (6.3)</td>
<td>25 (62.5)</td>
<td></td>
</tr>
<tr>
<td>CH 3 (32)</td>
<td>6 (85.7)</td>
<td>10 (40.0)</td>
<td>3 (12.0)</td>
<td>12 (48.0)</td>
<td>16 (50.0)</td>
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</tr>
<tr>
<td>CH 4 (30)</td>
<td>11 (84.6)</td>
<td>12 (70.6)</td>
<td>2 (11.8)</td>
<td>3 (17.6)</td>
<td>23 (76.7)</td>
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<tr>
<td>CH 5 (63)</td>
<td>19 (73.1)</td>
<td>15 (40.5)</td>
<td>1 (2.7)</td>
<td>21 (56.8)</td>
<td>34 (54.0)</td>
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<tr>
<td>CH 6 (21)</td>
<td>12 (100.0)</td>
<td>3 (33.3)</td>
<td>0 (0.0)</td>
<td>6 (66.6)</td>
<td>15 (71.4)</td>
<td></td>
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<tr>
<td>Totals</td>
<td>65 (73.8)</td>
<td>68 (54.0)</td>
<td>9 (7.1)</td>
<td>49 (39.0%)</td>
<td>133 (62.1)</td>
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Table 2. Approximate number of researcher hours to complete recruitment

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<th>Care Home</th>
<th>Approx. no. of Visits</th>
<th>Approx. no. of hours</th>
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<td><strong>Total</strong></td>
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