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Recruiting hard to reach populations to studies: breaking the silence. An example from a study that recruited people with dementia.

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TITLE FOR COMMUNICATION ARTICLE:
Recruiting hard to reach populations to studies: breaking the silence. An example from a study that recruited people with dementia.

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TITLE: Recruiting hard to reach populations to studies: breaking the silence. An example from a study that recruited people with dementia.

ABSTRACT

Title: Recruiting hard to reach populations to studies: breaking the silence. An example from a study that recruited people with dementia.

Objective: To share the challenges of recruiting people with dementia to studies, using experiences from one recently completed trial as an exemplar.

Background: Research publications always cite participant numbers but the effort expended to achieve the sample size is rarely reported, even when the study involved recruiting a hard to reach population. A multi-site study of a psychosocial intervention for people with dementia is used here to illustrate the challenges. This study recruited 468 'dyads' (a person with dementia and a family carer together). The time taken to achieve this sample was longer than originally estimated, contributing to a study extension and the need for additional sites. Recruitment data revealed that certain sites were more successful than others, but why?

Methods: Secondary analysis of routinely collected recruitment data from three purposefully selected sites from a total of 15 sites, was examined to understand the strategies used and successful approaches.

Findings: At all sites the pool of potential recruits funnelled to a few. It took two sites 18 months longer than the third to achieve recruitment numbers despite additional efforts. Explanations given by potential participants for declining included ill health, reporting they were 'managing', time constraints, adjusting to a diagnosis of dementia and burden of study procedures.

Conclusion: Successful recruitment of people with dementia to studies, as one example of a hard to reach group, requires multiple strategies and necessitates close working between researchers and clinical services. It requires detailed understanding of the needs and

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perspectives of the specific population and knowledge about how individuals can be supported to participate in research. Experiences of recruitment should be disseminated so that knowledge generated can be used to inform planning and implementation of future research studies.

3

TITLE: Recruiting hard to reach populations to studies: breaking the silence. An example from a study that recruited people with dementia. (2,005 words excluding tables)

WHY THIS IS AN IMPORTANT TOPIC

Research publications report numbers of participants and usually numbers screened and excluded. Yet the effort expended to achieve required sample sizes are rarely reported even when studies recruited hard to reach populations. We contend that transparency about the challenges involved in recruiting hard-to-access populations and potential solutions to the challenges is required to enable future clinical studies to plan and recruit in a time efficient and cost effective manner.

People with dementia as an example of a hard to reach population

Dementia research is a global clinical and research priority [1,2]. In England it has been proposed that to meet future study requirements, the number of people with dementia participating in dementia research should increase from 4.5% of those diagnosed with dementia, to 10% [3]. Yet, it is well documented that people with dementia are a hard to reach population and recruiting the numbers needed for research is challenging [4–7]. This is particularly so for psychosocial research which requires the participant with dementia and often a family carer to consent to possible involvement in an intervention aimed at both people. These studies, like the example used in this article, can be perceived as being particularly demanding for potential recruits.

The example we use here is based on recruitment to a study which sought to evaluate the clinical and cost effectiveness of an occupational therapy intervention for community dwelling people with mild to moderate dementia and their family carers (dyads) [8]. Study inclusion criteria involved recruiting the dyad. The time taken to achieve the target sample (n=480) was longer than originally estimated and contributed towards a study extension and the resource intensive requirement to recruit further sites. Over the course of the study it became evident that certain of the 15 sites were more successful at achieving recruitment targets than others. As researchers involved in the management and delivery of this study we wanted to identify the reasons for this.

Evaluating recruitment

A secondary analysis of recruitment data routinely collected by three of 15 participating sites was conducted to compare differences and similarities between recruitment rates, the strategies used to promote recruitment and the outcomes of such strategies. The three sites (A, B and C) were purposefully selected because they each had large recruitment targets due to a substantial pool of potentially eligible participants being reportedly available at each.

Anonymised information was extracted from site based documentation. This included records of all contacts with potential recruits during screening and recruitment, and those made following recruitment for the duration of the participants' involvement in the study. Researcher notes, which recorded the reasons provided by potential participants for accepting, declining or ineligibility were also analysed.

Recruitment targets and results

As shown in Table 1, Site C recruited over the agreed target within the planned timeframe. In comparison, Sites A and B took 18 months longer to recruit 92% and 91% respectively of their target numbers.

Table 1 Recruitment targets, number of potential dyads, number of dyads consented, percentage of target achieved, and time taken, by site

	Site A	Site B	Site C
Target (dyads)	90	80	60
Potential dyads identified	332	233	144
Total number consented (% of potential pairs identified that 'converted' into participants)	83 (25%)	73 (31%)	73 (51%)
% of target achieved	92%	91%	122% *(13 dyads above target)*
Length of time taken to recruit (months)	29	29	11

NB: percentages rounded to whole numbers

Identified recruitment strategies

The differences and similarities in recruitment strategies at the three sites are summarised in Table 2. Similar strategies were employed at all three sites with memory services being the main source of participants at each. At Sites A and B, but not at Site C researchers maintained a regular presence in memory service clinics, so that they were readily available to talk to potential recruits. At Site B a research nurse also pre-screened clinical records to identify potentially eligible people to memory service clinicians in advance of routine appointments. Also, at this site only study information was displayed at GP practices at which this memory service offered post-diagnostic follow-up appointments. At Site C multidisciplinary clinical team meetings were used to identify potential recruits, this was not noted at the other two sites. At Sites A and C recruitment was extended into the non-

statutory sector. A further strategy, at Sites A and C was to contact eligible people who had taken part in previous dementia research studies. Site C identified 15 additional potential recruits this way and Site A identified five. This route was not available in Site B as no dementia research whereby people with dementia were asked for consent to be contacted about other research studies had taken place at this site.

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Table 2 Recruitment strategies used to identify potential participants, by site

	Site A	Site B	Site C
Recruitment strategy			
Within NHS site memory services			
Direct referral by memory services clinicians	✓	✓	✓
Regular presence in memory services clinics by researchers	✓	✓	-
Attendance at psychosocial intervention groups by researchers	✓	✓	✓
'Pre' screening of clinical records by research nurse	-	✓	-
Leaflets and posters displayed	✓	✓	✓
Ad-hoc mail outs targeting potentially eligible participants choosing to attend follow up appointments offered at local GP practices, instead of memory services at the hospital	-	✓	-
Within other services provided by the NHS site			
Potential participants identified by within multidisciplinary clinical meetings	-	-	✓
Occupational therapists delivering the intervention identifying potential participants	✓	✓	✓
Attendance at clinical team business meetings by researchers	✓	-	✓
Leaflets and posters displayed (other NHS Trust locations)	-	✓	✓
Research team made contact with people who had participated in other studies previously, and had agreed to be contacted about future studies	✓	-	✓
Involvement of other NHS providers			
Information displayed in GP practices associated with memory services	-	✓	-
Patient Identification Centre (PIC) in another NHS Trust	-	✓	-
Non NHS			
Attendance at community groups by research staff	✓	-	✓
Study promoted by researchers at local events	✓	✓	✓
One mail out via non-statutory sector organisation / sending non-statutory sector organisation staff study information	✓	-	✓
'Join Dementia Research' [1] (JDR) (https://www.joindementiaresearch.nihr.ac.uk): an online resource that enables people to register interest in participating in dementia research and thereby be 'matched' to relevant studies. Researchers then contact them directly. People who expressed interest living within the sites' locality, were sent information when JDR became active at each site.	✓	✓	✓

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Reasons for exclusion

The main reasons documented for exclusion are presented in Table 3. The two sites which took longest to recruit their target numbers (A and B) also had larger numbers of people excluded due to being ineligible or unwilling to participate.

Table 3 Main reasons recorded by research staff for exclusion by site

Reason for exclusion	Site A	Site B	Site C
Study inclusion criteria not met or exclusion criteria identified	53	18	8
No contact made	64	28	12
'Unable or unwilling to participate' recorded as reason	132	114	51
Total excluded	249	160	71

[1] inclusion criteria not met / exclusion criteria identified included person with dementia not living in the community, not having capacity to consent, not score 0.5-2 on clinical dementia rating scale [13] or no family carer available to participate, a dyad participated in an earlier phase of the study or was participating in another intervention study or was unable to communicate fluently in English

As Table 4 shows, reasons given by those unwilling or unable to participate (when provided), were recorded at all sites. It was not possible from the available records to determine if it was the person with dementia, the family carer or both members of the dyad who declined to participate. The numbers of potential participants excluded due to being unable or unwilling to participate at Sites A and B outnumbered those excluded for all other reasons including individuals that researchers had been unable to contact. Site C recorded the lowest number of people being unable or unwilling to participate. The 'other reasons' for declining category included; adjusting to the dementia diagnosis, participation being perceived to be a burden and personal circumstances (such as travel plans, moving house or bereavement).

Table 4 Recorded explanations for being unable or unwilling to participate, by site

Main explanation (if given) for being unable or unwilling to participate	Site A	Site B	Site C
Declined participation, no reason recorded	53	50	12
Physical ill health of either person	6	15	4
'Managing fine' reported	11	6	11
Time constraints reported	25	24	11
Other reasons recorded	37	19	13
Total potential participants recorded as unable or unwilling to participate	132	114	71

DISCUSSION

This secondary analysis of routinely collected recruitment data for one study involving people with dementia was highly informative. We found that successful recruitment of people with dementia, as one example of a hard to reach group, requires multiple strategies and necessitates close working between researchers and clinical services. All sites found recruitment to this psychosocial intervention study to be challenging, but one site did achieve the target numbers of participants within the allocated time.

Our findings showed the original pool of people available for recruitment quickly funnelled to a few at each site for a variety of reasons. Initial optimism regarding the potential pool of participants was fuelled by optimistic clinician estimates and our desire as researchers to be persuaded by these figures. It was also underscored by the need to work within the limitations set by the funder, as a better recruitment rate would be less costly and contribute towards a successful study. Alternatively, less optimistic recruitment estimates would raise doubts about study viability. This poses questions about how researchers can realistically estimate the recruitment efforts required for any study. We would like to encourage debate about this issue.

Novel contribution

We interrogated the challenges of recruiting to one dementia study and argue for routine sharing of such experiences between researchers. We identified several key issues that appeared to affect recruitment in this study, which are likely to have implications for research conducted with other hard to reach groups. Possible reasons for recruitment challenges are organisational and individual.

Organisational

Research site experience of recruitment to and running similar studies appears to be a critical issue. The exemplar in this paper involved recruiting a hard to reach population to a complex psychosocial intervention study, which potentially required significant time investment by participants. Whilst Sites A and B had links between clinicians and researchers, the most successful recruitment site (C) was also able to identify potentially eligible participants within multi-disciplinary clinical meetings, demonstrating active rather than passive clinical engagement in the study and consequently, the identification of those who were most appropriate to approach. Both Sites A and C approached people who had consented to be contacted for potential participation in other studies as one of their strategies. Due to previous experience of running such studies, Site C were able to approach greater numbers this way. It is well known that clinical staff can act as gatekeepers, they may be unclear about the benefits of research projects, worry about over-burdening patients or fear patients may feel pressurised to participate [6]. However, it appears Site C managed to overcome these issues and make research a positive aspect of clinical care. In comparison, other strategies appeared to have less traction.

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Individual factors

Alongside these organisational challenges, individual factors affected the responses of potential participants. It is well documented that people with dementia can be hard to reach [4,7,9]. Various reasons for this have been identified, including family carers wishing to protect people with dementia from potentially stressful situations or burden [10]. Although we could not determine whether this was the case from the available data it seems likely this could be a contributory factor to recruitment challenges, for example; some of the records examined noted family carers reporting the person with dementia did not accept their diagnosis, or became upset when dementia was mentioned. Linguistic difficulties, or people with dementia lacking capacity to consent have also been noted as reasons that can lead to recruitment difficulties for this hard to reach group [4] and in this exemplar, people with dementia were excluded for those reasons. Researcher notes indicated some potential participants reported they had 'too much on', suggesting participation was perceived by some as burdensome without offering enough potential benefit to compensate for this. Other researchers have found that studies can be perceived as time consuming particularly for adult children or that people with dementia may be concerned about burdening relatives with the role of study partner [11,12]. Reasons recorded for declining may also have been polite refusals obscuring other reasons for declining which remain unknown. The message here for wider research is that researchers need to understand and be able to respond appropriately to the needs and preferences of the specific hard to reach group. Generic research training is not sufficient.

Possible recruitment solutions

We suggest the following as potential strategies to improve recruitment efforts for future research studies involving hard to reach populations:

Firstly, making the potential benefits of research transparent to potential participants is important, as is the involvement of clinical services and family carers. Asking the person with the condition directly about their potential involvement, if they have the capacity to provide this, is essential. As our findings demonstrate, there are clear advantages in ensuring that relevant services are on board and perceive engagement in the research to be relevant to them and the people that they work with.

Secondly, national research registries whereby people with a specific condition or diagnosis and current or previous caregivers are asked for their consent to be approached for research participation can identify potential recruits for some studies. Further, local registries may be helpful; some NHS trusts in England are developing systems whereby patients can be asked for their permission to be contacted about relevant research at any point in their care pathway. If staff are persuaded by the potential benefits of research this strategy is likely to aid recruitment.

Thirdly, transparent reporting of recruitment strategies and how many people were initially identified as being potentially eligible including the contexts within which recruitment took place will support knowledge sharing. Analysis of recruitment methods should ideally be built into study designs to allow detailed reflection as an intrinsic part of large studies

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involving hard-to-access groups. The analysis used as an exemplar in this article was completed once the study had been designed and commenced, and had limitations. Despite this we contend that completing a similar analysis as studies progress, if building this into the initial plan is not feasible, is still worthwhile to enable learning to be shared, across study sites and with other research teams.

Fourthly, comprehensive researcher understanding of the perspectives and needs, including any special requirements of the specific hard to reach population being studied is necessary. This may well require additional researcher training and on-going support.

Conclusion

Successful recruitment of people from hard to reach groups requires multiple strategies and necessitates close working between researchers and relevant services. It requires detailed understanding of the needs and perspectives of the specific population and application of knowledge regarding how individuals can be supported to participate in research. Reporting the evaluation of recruitment strategies and experiences should be an expected output from large studies. This would enhance understanding about how to enable hard to reach populations to participate in studies.

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Declarations

Funding

This manuscript presents independent research funded by the National Institute for Health Research's Programme Grants for Applied Research Programme (RP-PG 0610-10108). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

Author statement

Becky Field (BF) and Gail Mountain (GM) developed the study concept and design for this paper. BF led data analysis and interpretation, assisted by GM, Jacqueline

Mundy, Jane Burgess, Jennifer Wenborn and Daniel Kelleher. BF drafted the

manuscript, all authors contributed to its revision and approved the final manuscript.

Declaration of conflicting interests

The authors confirm that there is no conflict of interest.

Availability of data and materials

The dataset(s) supporting the conclusions of this article is (are) included within the

article

Consent for publication – not applicable

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1 **TITLE: Recruiting hard to reach populations to studies: breaking the silence. An example**

2 **from a study that recruited people with dementia.**

3

4 **ABSTRACT**

5 **Title:** Recruiting hard to reach populations to studies: breaking the silence. An example from

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7

8 **Objective:** To share the challenges of recruiting people with dementia to studies, using

9 experiences from one recently completed trial as an exemplar.

10

11 **Background:** Research publications always cite participant numbers but the effort expended

12 to achieve the sample size is rarely reported, even when the study involved recruiting a hard

13 to reach population. A multi-site study of a psychosocial intervention for people with

14 dementia illustrates the challenges. This study recruited 468 'dyads' (a person with

15 dementia and a family carer together) from 15 sites but the time taken to achieve this was

16 longer than originally estimated. This led to a study extension and the need for additional

17 sites. Recruitment data revealed that certain sites were more successful than others, but

18 why? Can the knowledge gained be used to inform other studies?

19

20 **Methods:** Secondary analysis of routinely collected recruitment data from three

21 purposefully selected sites was examined to understand the strategies used and identify

22 successful approaches.

23

24 **Findings:** At all three sites the pool of potential recruits funnelled to a few participants. It

25 took two sites 18 months longer than the third to achieve recruitment numbers despite

26 additional efforts. Explanations given by potential participants for declining to take part

27 included ill health, reporting they were 'managing', time constraints, adjusting to a diagnosis

28 of dementia and burden of study procedures.

29

30 **Conclusion:** Successful recruitment of people with dementia to studies, as one example of a

31 hard to reach group, requires multiple strategies and close working between researchers

32 and clinical services. It requires detailed understanding of the needs and perspectives of the

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1   specific population and knowledge about how individuals can be supported to participate in

2   research. Experiences of recruitment should be disseminated so that knowledge generated

3   can be used to inform planning and implementation of future research studies.

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4

1 **TITLE:** Recruiting hard to reach populations to studies: breaking the silence. An example

2 from a study that recruited people with dementia. (2,716 words excluding tables)

3

4 **INTRODUCTION**

5 Research publications report numbers of participants and usually numbers screened and

6 excluded. Yet the effort expended to achieve required sample sizes are rarely reported even

7 when studies recruited hard to reach populations. We contend that transparency about the

8 challenges involved in recruiting hard-to-access populations and potential solutions to the

9 challenges is required to enable future clinical studies to plan and recruit in a time efficient

10 and cost effective manner.

11 Dementia research is a global clinical and research priority [1,2]. In England it has been

12 proposed that to meet future study requirements, the number of people with dementia

13 participating in dementia research should increase from 4.5% of those diagnosed with

14 dementia, to 10% [3]. Yet, it is well documented that people with dementia are a hard to

15 reach population and recruiting the numbers needed for research is challenging [4–7]. This

16 is particularly so for psychosocial research which requires the participant with dementia and

17 often a family carer to consent to possible involvement in an intervention aimed at both

18 people. These studies, like the example used in this article, can be perceived as being

19 particularly demanding for potential recruits.

20 The example we use here is based on recruitment to one study ('Valuing Active Life in

21 Dementia' (VALID)). VALID first adapted and developed an occupational therapy

22 intervention for community dwelling people with dementia and their family carers (dyads).

23 The intervention aimed to facilitate independence, meaningful activity, quality of life for the

24 person and carer competence. VALID then evaluated the clinical and cost effectiveness of

25 the intervention compared to usual care. All participants were asked to complete validated

26 instruments at baseline, three and six month follow-up. This involved each person

27 completing questionnaires at home, with a researcher. The intervention involved up to ten

28 home or community based sessions with dyads. These involved the dyad working together

29 with an occupational therapist to identify personal goals and practising suggested strategies

30 to achieve them. Further details of the VALID study are described elsewhere [8].

31 Study inclusion criteria involved recruiting the dyad. The time taken to achieve the target

32 sample (n=480) was longer than originally estimated and contributed towards a study

33 extension and the resource intensive requirement to recruit further sites. Over the course

34 of the study it became evident that certain of the 15 sites were more successful at achieving

35 recruitment targets than others. As researchers involved in the management and delivery of

36 this study we wanted to identify the reasons for this.

37 The objective of this paper is to share the challenges of recruiting people with dementia to

38 studies, using our experiences from the VALID study [8] as an exemplar.

39 **METHODS**

1. A secondary analysis of recruitment data routinely collected by three of 15 participating
2. sites was conducted to compare differences and similarities between recruitment at these
3. sites, the strategies used to promote recruitment and the outcomes of such strategies. The
4. three sites (A, B and C) were selected because they had participated in the VALID pilot
5. study which indicated a substantial pool of potentially eligible participants reportedly
6. available at each site and they had the resources available to support this secondary analysis.
7. Anonymised information was extracted from data routinely collected at each of these sites
8. via 'trial management logs'. Sites A and B used EXCEL for this purpose, Site C site used their
9. own, existing recruitment database. Each site collected core information to enable
10. screening for study inclusion criteria. This included records of all contacts with potential
11. recruits during screening and recruitment, and those made following recruitment for the
12. duration of the participants' involvement in the study. Researcher notes, which recorded
13. the reasons provided by potential participants for accepting, declining or ineligibility were
14. also analysed and categorised. The data were tabulated at each site to enable description of
15. the recruitment process, strategies and outcomes. Cross site analysis then compared these
16. findings.
17.
18. **FINDINGS**

19. **Site characteristics**

20. Site A served four diverse London boroughs. Site B was a Northern city with a predominately
21. urban population. Site C served an urban and rural population in the North of England. Sites
22. A and C had experience of recruiting to and delivery of psychosocial intervention dementia
23. research. This was the first large scale psychosocial intervention dementia study Site B had
24. participated in.

25. **Recruitment targets**
26. Recruitment targets for each site were based on the findings of a pilot study at each of
27. these three sites which examined feasibility of study procedures and recruitment. This, as
28. well as investigator experiences of successful recruitment to psychosocial dementia
29. research and numbers of occupational therapists trained and available to deliver the
30. intervention, indicated the numbers each site could be expected to recruit. The number,
31. type and experience of staff dedicated to recruitment varied at each site.
32.
33. Sites A, B, and C had targets of 90, 80 and 60 respectively. Initially recruitment was
34. scheduled for 18 months, but was extended when recruitment proved slower than
35. anticipated. As shown in Table 1, Site C recruited over the agreed target within the planned
36. timeframe. In comparison, sites A and B took 18 months longer to recruit 92% and 91%
37. respectively of their target numbers.
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1 **Table 1 Recruitment targets, number of potential dyads, number of dyads consented,**

2 **percentage of target achieved, and time taken, by site**

3

	Site A	Site B	Site C
Target (dyads)	90	80	60
Potential dyads identified during study recruitment	332	233	144
Total number consented (% of potential dyads identified that 'converted' into participants)	83 (25%)	73 (31%)	73 (51%)
% of target achieved	92%	91%	122% *(13 dyads above target)*
Length of time taken to recruit (months)	29	29	11

4 NB: percentages rounded to nearest whole number

5

6 *Identified recruitment strategies*

7 The differences and similarities in recruitment strategies at the three sites are summarised

8 in Table 2. Similar strategies were employed at all three sites with NHS memory services

9 being the main source of participants at each. Memory services provide specialist

10 diagnostic services and post-diagnostic support. At sites A and B, but not at Site C

11 researchers maintained a regular presence in memory service clinics, so that they were

12 readily available to talk to potential recruits. At Site B a research nurse also pre-screened

13 clinical records to identify potentially eligible people to memory service clinicians in advance

14 of routine appointments. Also, at this site only study information was displayed at GP

15 practices at which this memory service offered post-diagnostic follow-up appointments. At

16 Site C multidisciplinary clinical team meetings were used to identify potential recruits, this

17 was not noted at the other two sites. At sites A and C recruitment was extended into the

18 non-statutory sector (charities and organisations supporting people affected by dementia).

19 A further strategy, at sites A and C was to contact eligible people who had taken part in

20 previous dementia research studies. Site C identified 15 additional potential recruits this

21 way and Site A identified five. This route was not available in Site B as no dementia research

22 whereby people with dementia were asked for consent to be contacted about other

23 research studies had taken place at this site.

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7

Table 2 Recruitment strategies used to identify potential participants, by site

	Site A	Site B	Site C
Recruitment strategy			
Within NHS site memory services			
Direct referral by memory services clinicians	✓	✓	✓
Regular presence in memory services clinics by researchers	✓	✓	-
Attendance at psychosocial intervention groups by researchers	✓	✓	✓
'Pre' screening of clinical records by research nurse	-	✓	-
Leaflets and posters displayed	✓	✓	✓
Ad-hoc mail outs targeting potentially eligible participants choosing to attend follow up appointments offered at local GP practices, instead of memory services at the hospital	-	✓	-
Within other services provided by the NHS site			
Potential participants identified by within multidisciplinary clinical meetings	-	-	✓
Occupational therapists delivering the intervention identifying potential participants	✓	✓	✓
Attendance at clinical team business meetings by researchers	✓	-	✓
Leaflets and posters displayed (other NHS Trust locations)	-	✓	✓
Research team made contact with people who had participated in other studies previously, and had agreed to be contacted about future studies	✓	-	✓
Involvement of other NHS providers			
Information displayed in GP practices associated with memory services	-	✓	-
Patient Identification Centre (PIC) in another NHS Trust	-	✓	-
Non NHS			
Attendance at community groups by research staff	✓	-	✓
Study promoted by researchers at local events	✓	✓	✓
One mail out via non-statutory sector organisation / sending non-statutory sector organisation staff study information	✓	-	✓
'Join Dementia Research' [1] (JDR) (https://www.joindementiaresearch.nihr.ac.uk): an online resource that enables people to register interest in participating in dementia research and thereby be 'matched' to relevant studies. Researchers then contact them directly. People who expressed interest living within the sites' locality, were sent information when JDR became active at each site.	✓	✓	✓

1   *Reasons for exclusion*

2   The main reasons documented for exclusion are presented in Table 3. The two sites which

3   took longest to recruit their target numbers (A and B) also had larger numbers of people

4   excluded due to being ineligible or unwilling to participate.

5

6   **Table 3 Main reasons recorded by research staff for exclusion by site**

Reason for exclusion	Site A	Site B	Site C
Study inclusion criteria not met or exclusion criteria identified [1]	53 (21%)	18 (11%)	8 (11%)
No contact made	64 (26%)	28 (18%)	12 (17%)
'Unable or unwilling to participate' recorded as reason	132 (53%)	114 (71%)	51 (72%)
Total excluded	249	160	71

7   [1] inclusion criteria not met / exclusion criteria identified included person with dementia not living in the

8   community, not having capacity to consent, not score 0.5-2 on clinical dementia rating scale [9] or no family

9   carer available to participate, a dyad participated in an earlier phase of the study or was participating in

10   another intervention study or was unable to communicate fluently in English

11   As Table 4 shows, reasons given by those unwilling or unable to participate (when provided),

12   were recorded at all sites. It was not possible from the available records to determine if it

13   was the person with dementia, the family carer or both members of the dyad who declined

14   to participate. The numbers of potential participants excluded due to being unable or

15   unwilling to participate at sites A and B outnumbered those excluded for all other reasons

16   including individuals that researchers had been unable to contact. Site C recorded the

17   lowest number of people being unable or unwilling to participate. The 'other reasons' for

18   declining category included; adjusting to the dementia diagnosis, participation being

19   perceived to be a burden and personal circumstances (such as travel plans, moving house or

20   bereavement).

21   **Table 4 Recorded explanations for being unable or unwilling to participate, by site**

Main explanation (if given) for being unable or unwilling to participate	Site A	Site B	Site C
Declined participation, no reason recorded	53(40%)	50 (44%)	12(24%)
Physical ill health of either person	6 (5%)	15 (13%)	4 (8%)
'Managing fine' reported	11 (8%)	6 (5%)	11(22%)
Time constraints reported	25 (19%)	24 (21%)	11 (22%)
Other reasons recorded	37 (28%)	19 (17%)	13 (25%)
Total potential participants recorded as unable or unwilling to participate	132	114	51

22   *NB* percentages rounded to nearest whole number

9

1 **DISCUSSION**

2 This secondary analysis of routinely collected recruitment data for one study involving

3 people with dementia was highly informative. We found that successful recruitment of

4 people with dementia, as one example of a hard to reach group, requires multiple strategies

5 and necessitates close working between researchers and clinical services. All sites found

6 recruitment to this psychosocial intervention study to be challenging, but one site did

7 achieve the target numbers of participants within the allocated time.

8 Our findings showed the original pool of people available for recruitment quickly funnelled

9 to a few at each site for a variety of reasons. Initial optimism regarding the potential pool of

10 participants was fuelled by optimistic clinician estimates and our desire as researchers to be

11 persuaded by these figures. It was also underscored by the need to work within the

12 limitations set by the funder, as a better recruitment rate would be less costly and

13 contribute towards a successful study. Alternatively, less optimistic recruitment estimates

14 would raise doubts about study viability. This poses questions about how researchers can

15 realistically estimate the recruitment efforts required for any study. We would like to

16 encourage debate about this issue.

17 **Novel contribution**

18 We interrogated the challenges of recruiting to one dementia study and argue for routine

19 sharing of such experiences between researchers. We identified several key issues that

20 appeared to affect recruitment in this study, which are likely to have implications for

21 research conducted with other hard to reach groups. Possible reasons for recruitment

22 challenges are organisational and individual.

23 **Organisational factors**

24 Research site experience of recruitment to and running similar studies appears to be a

25 critical issue. The exemplar in this paper involved recruiting a hard to reach population to a

26 complex psychosocial intervention study, which potentially required significant time

27 investment by participants. Whilst sites A and C had established working relationships

28 between clinicians and site based researchers, the most successful recruitment site (C) was

29 also able to identify potentially eligible participants within multi-disciplinary clinical

30 meetings, demonstrating active rather than passive clinical engagement in the study and

31 consequently, the identification of those who were most appropriate to approach. Due to

32 previous experience of running such studies, both sites A and C approached people who had

33 previously consented to be contacted for potential participation in other studies as one of

34 their strategies. Site C was able to approach greater numbers this way. For Site B, this was

35 not possible. Staff at sites A and C were both experienced in delivering psychosocial

36 intervention dementia research, but recruited at different rates which was not expected.

37 This analysis confirms that no single factor is responsible for recruitment, rather effective

38 recruitment depends on the interplay between a combination of factors. Different

39 populations, demographics or research fatigue may have influenced the different

40 recruitment outcomes. The number of other research studies running at sites may also have

41 affected the engagement of NHS research and clinical services. An additional factor affecting

10

1 recruitment for psychosocial intervention studies such as this is the requirement for staff to
2 deliver the intervention. Recruitment of participants has to be matched with the availability
3 and sustainability of this workforce. In this study, sometimes recruitment at sites was
4 temporarily halted until an occupational therapist was available to deliver the intervention.
5 It is well known that clinical staff can act as gatekeepers, they may be unclear about the
6 benefits of research projects, worry about over-burdening patients or fear patients may feel
7 pressurised to participate [6]. However, it appears Site C managed to overcome these
8 issues and make research a positive aspect of clinical care.

Individual factors

10 Alongside these organisational challenges, individual factors affected the responses of
11 potential participants. It is well documented that people with dementia can be hard to
12 reach [4,7,10]. Various reasons for this have been identified, including family carers wishing
13 to protect people with dementia from potentially stressful situations or burden [11].
14 Although we could not determine whether this was the case from the available data it
15 seems likely this could be a contributory factor to recruitment challenges, for example;
16 some of the records examined noted family carers reporting the person with dementia did
17 not accept their diagnosis, or became upset when dementia was mentioned. Linguistic
18 difficulties, or people with dementia lacking capacity to consent have also been noted as
19 reasons that can lead to recruitment difficulties for this hard to reach group [4] and in this
20 exemplar, people with dementia were excluded for those reasons. Researcher notes
21 indicated some potential participants reported they had 'too much on', suggesting
22 participation was perceived by some as burdensome without offering enough potential
23 benefit to compensate for this. Other researchers have found that studies can be perceived
24 as time consuming particularly for adult children or that people with dementia may be
25 concerned about burdening relatives with the role of study partner [12,13]. Reasons
26 recorded for declining may also have been polite refusals obscuring other reasons for
27 declining which remain unknown. The message here is that researchers need to understand
28 and be able to respond appropriately to the needs and preferences of the specific hard to
29 reach group. Generic research training is not sufficient.

Possible recruitment solutions

31 We suggest the following as potential strategies to improve recruitment efforts for future
32 research studies involving hard to reach populations:

33 Firstly, making the potential benefits of research transparent to potential participants is
34 important, as is the involvement of clinical services and family carers. Law et al [14] found
35 people with dementia wanted to be asked directly and involvement in research can lead to
36 feeling valued and sense of being able to contribute. Asking the person with the condition
37 directly about their potential involvement, if they have the capacity to provide this, is
38 essential. As our findings demonstrate, there are also advantages in ensuring that relevant
39 services are on board and perceive engagement in the research to be relevant to them and
40 the people that they work with.   But, as Iliffe et al [15] noted in 2008, the need to support
41 research infrastructure for psychosocial dementia research remains.

11

1 Secondly, a national research registry whereby people with dementia and caregivers are
2 asked for consent to be approached for research participation can help identify potential
3 recruits [7,16]. Further, some NHS trusts in England are developing systems whereby
4 patients can be asked for their permission to be contacted about research at any point in
5 their care pathway. If staff are persuaded by the potential benefits of research this strategy
6 may aid recruitment.

7 Thirdly, transparent reporting of recruitment strategies and how many people were initially
8 identified as being potentially eligible including the contexts within which recruitment took
9 place will support knowledge sharing. Analysis of recruitment methods should ideally be
10 built into study designs to allow detailed reflection as an intrinsic part of large studies
11 involving hard-to-access groups. There is a need for research to examine the impact of type
12 of dementia diagnosis, age, co-morbidities, socio-economic status, ethnicity, education, or
13 type of caring relationship, as well as different recruitment methods, on participation or
14 non-participation, in studies to further illuminate influences on recruitment.

15 The analysis used as an exemplar in this article was completed once the study had been
16 designed and commenced, and had limitations. For example, resources meant we were able
17 to examine recruitment experiences at these three sites only, rather than all 15. Also we
18 cannot comment on the effectiveness of any single recruitment strategy used at each site or
19 the relationship of key characteristics of participants on recruitment outcomes. Despite this,
20 what we can say is that it seems an interplay of organisational and individual factors
21 influenced recruitment outcomes and this needs to be considered in future studies. We
22 contend that completing similar analyses as studies progress, if building this into the initial
23 plan is not feasible, is still worthwhile. Such work can enable learning to be shared, across
24 study sites and with other research teams.

25 Fourthly, comprehensive researcher understanding of the perspectives and needs, including
26 any special requirements of the specific hard to reach population being studied is necessary.
27 For example, identifying ways to engage people with cognitive impairments, perhaps
28 alongside comorbidities, sensory and physical impairments that limit the social participation
29 of people with dementia [17] may facilitate recruitment. Communication style is important
30 and may need adapting [18]. This may well require additional researcher training and on-
31 going support.

32 **CONCLUSIONS**

33 Successful recruitment of people from hard to reach groups, such as people with dementia,
34 requires multiple strategies and necessitates close working between researchers and
35 relevant services. It requires detailed understanding of the needs and perspectives of the
36 specific population and application of knowledge regarding how individuals can be
37 supported to participate in research. Reporting the evaluation of recruitment strategies and
38 experiences should be an expected output from large studies. This would enhance
39 understanding about how to enable hard to reach populations to participate in studies.

40

12

1   **Acknowledgements**

2   The VALID research team acknowledge the support of the National Institute for Health

3   Research Clinical Research Network.

4

5   The authors thank the people with dementia and family carer research participants, and

6   NHS staff, who supported the VALID research programme.

7

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21 **Declarations**

22 **Funding**

27 **Author statement**

28 Becky Field (BF) and Gail Mountain (GM) developed the study concept and design for this

29 paper. BF led data analysis and interpretation, assisted by GM, Laura Di Bona, Jacqueline

30 Mundy, Jane Burgess, Jennifer Wenborn, Daniel Kelleher. BF drafted the manuscript, all

31 authors contributed to its revision and approved the final manuscript.

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1   **Declaration of conflicting interests**

2   The authors confirm that there is no conflict of interest.

3   **Availability of data and materials**

4   The dataset(s) supporting the conclusions of this article is (are) included within the article

5   **Consent for publication** – not applicable

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