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Recruitment approaches and profiles of consenting family caregivers and people living with dementia: A recruitment study within a trial

Felicity A. Baker^{a,c,*}, Laura Blauth^b, Jodie Bloska^e, Anna A. Bukowska^d, Libby Flynn^a, Ming-Hung Hsu^e, Edyta Janus^d, Kjersti Johansson^c, Helen Odell-Miller^e, Hayley Miller^a, Carina Petrowitz^b, Jonathan Pool^e, Karett Stensæth^c, Jeanette Tamplin^a, Kate Teggelove^a, Thomas Wosch^b, Tanara Vieira Sousa^a

^a Faculty of Fine Arts and Music, The University of Melbourne, Melbourne, Victoria, Australia

^b Hochschule für Angewandte Wissenschaften Würzburg-Schweinfurt, Würzburg, Germany

^c Centre for Research in Music and Health, Norwegian Academy of Music, Oslo, Norway

^d Institute for Applied Science, University of Physical Education, Kraków, Poland

^e Cambridge Institute for Music Therapy Research, Anglia Ruskin University, Cambridge, UK

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ABSTRACT

Background: While studies have identified strategies that are useful for recruiting people living with dementia, none have focused on psychosocial interventions involving arts therapies, or have examined the profiles of older people living in the community who consent or decline participation, particularly during a global pandemic. We aimed to identify the most effective recruitment strategies according to participant characteristics and transnational differences and develop a profile of consenting and non-consenting participants.

Methods: Recruitment teams in Australia, Norway, Germany, Poland, and the United Kingdom, recorded participants' source of study awareness and characteristics of consenting and non-consenting participants. Distributions of participants 'consenting to participate' were compared and logistic regressions were used to estimate the odds ratios.

Results: Consenting female caregivers were disproportionately represented. Study awareness differed between countries but overall, most expressions of interest to participate were derived from referrals from professionals or organisations, or from databases of people wanting to participate in research. Troughs in recruitment rates occurred during Northern Hemisphere summer vacation periods, and during Christmas periods.

Conclusions: This study found that recruiting for a trial with community-dwelling family caregivers and people living with dementia is challenging, especially during a global pandemic. While spousal caregivers comprised the highest proportion of dyads recruited, overall spousal caregivers were more reluctant to consent to participate than adult child caregivers. More targeted recruitment strategies designed for minority groups are also needed to ensure broader representation in dementia treatment studies.

1. Background

Successfully recruiting to achieve the target sample size is a key aim of every clinical trial to ensure the trial is adequately powered. However, a recent Cochrane Review confirmed that almost half of clinical trials fail to reach their recruitment targets [1]. Researchers often face barriers during recruitment. These include inadequate or poorly designed trial promotional materials and difficulties recruiting a representative sample (for example, low uptake from some cultural groups). Other

participant characteristics such as health status and family context, including caregiver-care recipient relationship quality and poor language skills, have been reported to influence the perception of benefit and burden of participation and their understanding of the trial focus or participation expectations. Understanding this complex web of recruitment barriers is essential to a research team so that strategies to minimise these barriers can be actioned [2].

In the HOMESIDE randomised controlled trial (RCT) that were comparing the effects of music and reading activities on behavioural and

* Corresponding author. The University of Melbourne, The Conservatorium of Music, Gate 12, Royal Parade, Parkville, Melbourne, Victoria, 3010, Australia.

E-mail address: felicity.baker@unimelb.edu.au (F.A. Baker).

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psychological symptoms of dementia, depression, and quality of life over a 3 month period [3], we needed to recruit 495 dyads comprising people living with dementia (PLwD) and their family caregivers (CG) across five countries (Australia, UK, Germany, Poland and Norway) within a two-year recruitment period; a goal that we anticipated at the outset would be challenging to meet. To maximise our use of time, financial resources, and opportunities available, the team developed country-specific recruitment strategies and a universal recruitment monitoring tool to enable us to track the best recruitment approaches and to profile our sample of consenting and non-consenting dyads. This paper reports on these findings.

1.1. Reasons people accept or decline offers to participate in research

Research indicates that people volunteer to participate in research either for altruistic reasons or because they believe the intervention under investigation is likely to improve their health [4,5]. In countries without a universal healthcare system, such as the United States, people may agree to participate because they recognise that this provides an opportunity to receive fast and free treatment [5]. Conversely, health status can be a barrier, and people may decline participation because they do not want to risk destabilising their current health status [5]. Others are concerned that their unstable health places them at risk of forcibly discontinuing the trial [6].

The reasons that people choose not to participate in research include underlying scepticism, fear, and mistrust of the research process and/or research team [5]. People from minority groups who have had a history of mistreatment or exploitation in medical research have higher levels of mistrust [6–8]. As it stands, research conducted in Western developed countries typically has samples with an over-representation of white, middle class, highly educated men, and an under-representation of those from socially disadvantaged groups [5]. Recent immigrants are particularly challenging to recruit because they fear their health data may be reported to authorities, increasing their perceived risk of deportation [5]. While achieving a sample size sufficient to power the study is essential, an absence of data accurately representing diversity in the population may limit the generalisability of the findings and threaten external validity of the study [7]. Language barriers between the participant and recruiter may also impact the chance of recruitment success. When the research team and participant do not share the same language, arriving at informed consent may not be possible [6–9]. However, utilising interpreters can lead to successful enrolment [10,11].

Family members can be an influencing force in the decision for a person to enrol in a study. For example, a female may decline invitations to participate when her male partner expresses disapproval [8]. Alternatively, there may be pragmatic reasons for declining invitations, for example, potential participants having other competing obligations, such as caring for children or grandchildren [8]. Mulhall et al. [12], identified that lacking capacity posed inherent barriers, including difficulties with ethically obtaining informed consent and the reliance on ‘gatekeepers’, such as CGs or professional staff, for access to potential participants [12]. ‘Gatekeepers’ may not fully understand the principles and importance of randomisation and ‘treatment as usual’ and may refuse consent or create barriers to participation [12].

Increased participant burden is a factor influencing the decision whether to participate in research [4]. Burden may be experienced through feeling overwhelmed by the quantity of information received, or disappointment or anger at not having been allocated to the desired treatment arm. Further, high demands from trial requirements, such as the type and duration of study-related activities, may be a deterrent. Competing family and/or work commitments may limit opportunities to commit to research participation [13], especially when needing to co-ordinate with logistical challenges, such as having to travel for data collection. A systematic review by Brown et al. [8] found that lack of time was cited as the most common reason to decline participation irrespective of age group. Finally, as research methods changed from

face-to-face to virtual during the COVID-19 pandemic, many older participants declined due to lack of internet access, suitable equipment, and technological skills [14].

1.2. Recruitment strategies

Social marketing [15] has been applied for the past two decades to influence behaviour and improve the welfare of society [16], and has been identified as a suitable framework to organise and plan recruitment activities, including for studies of CGs of PLwD [17]. Within this framework, researchers focus on 1) identifying ways and places to access potential participants, 2) developing their research marketing products, 3) implementing a study promotional plan, 4) assessing the financial value of strategies, and 5) engaging partners to support recruitment [13]. In some countries, online research networks (eg. StepUp for Dementia Research [18]), enable widespread recruitment and this potential greatly increased recruitment during COVID-19 owing to the remote nature of the system [18].

Several systematic reviews have underlined the importance of developing, testing, and revising promotional materials (study flyers); making sure they are engaging enough to attract attention, are socially and culturally acceptable, and provide clear and adequate study information that is comprehensible, non-judgemental, and uses non-threatening language [19]. Promotional activities that have been identified as successful with different clinical populations include presenting to stakeholder groups, advertising on television and radio, disseminating flyers to stakeholder organisations, and sharing through social media [20]. The use of specific databases designed to link researchers with potential participants is also an increasingly used strategy [20].

The cost-benefit of promotional activities is not always reported in research studies. However, a recent systematic review found that contacting participants by letter or phone call invitation was the most economical strategy (US\$0.93c for letters, \$15.30 for telephone calls) [21]. For advertisements, web-based advertising generated the lowest cost per participant recruited (\$18.56 per participant) whereas non-web-based adverts were significantly more expensive (\$514.85 per patient). Research also indicates that engaging members of public and patient involvement groups can assist with improving the design of promotional materials and help research teams identify where and how to reach the target population [19].

Feedback from participants suggests that once identified, conversion to enrolments is often boosted when recruiters are warm, friendly, interested in potential participants’ wellbeing, and take time to thoroughly explain the research study aims and requirements [8,9,11]. Baker et al. [9] also found that the order of information communicated to potential participants influenced their willingness to participate in the study. They recommended that researchers trial and test their recruitment script for content order and language.

While the aforementioned studies of CGs and PLwD offer insights that might assist clinical trial teams to choose which recruitment strategies may be most effective, none have focused specifically on psychosocial interventions involving arts therapies, and none have examined the profiles of older people living in the community who consent or decline participation, particularly during a global pandemic. Our study within a trial (SWAT) aimed to address this gap thereby providing future research teams with deeper understanding of their target sample with respect to profiling by analysing the most successful recruitment strategies utilised in the HOMESIDE RCT [3]. To achieve this, we compared strategies according to participant characteristics and transnational differences and developed a profile of the consenting and non-consenting participants. While the SWAT study was not registered with the HTMR SWAT repository, the data were collected prospectively by those members of the research team responsible for recruitment.

2. Method

Our research questions were:

- 1) What are the profiles of consenting and non-consenting participants?
- 2) What are the most successful recruitment strategies by relationship (between the PLwD and person inquiring about the study)?
- 3) How do recruitment rates fluctuate according to time of year?

2.1. Study overview

The HOMESIDE randomised controlled trial tested the effectiveness of a home-based music intervention on the behavioural and psychological symptoms of dementia (BPSD) provided by family CGs who have been trained to use music in intentional ways during day-to-day activities and care [3]. The intervention was compared with reading activities (active control) and with standard care. All participants were offered the opportunity to participate in the music training (delivered by credentialed music therapists), and/or reading training programs (delivered by allied health professionals, such as occupational therapists), at the end of the study period irrespective of allocation. It is important to note that this study was conducted during the COVID-19 pandemic, which led to an early adjustment in study design to conduct the training intervention online. This subsequently also led to an adjustment in inclusion criteria – access to internet. Study elements including inclusion criteria are detailed in Table 1. Ethics approval was provided by the institutional Human Research Ethics Board in each country. Upon receipt of Expressions of Interest (EOIs), we obtained written consent from all participating caregivers and care recipients with the legal capacity to give informed consent to participate in the HOMESIDE trial before enrolment. If a care recipient did not have capacity to consent, we sought consent from the legal guardian for study participation.

During the recruitment phase we routinely captured demographic details and information on how participants became aware of the study. Sometimes the person expressing interest was the primary CG, at other times it was another person in close relationship with the CG and/or PLwD. Data capturing tools were developed by the study team to collect information about why they chose to consent or not-consent to participation, and any reasons for withdrawal. Recruitment teams in each country met weekly to discuss and record recruitment activities, recruitment opportunities, and review recruitment strategies to capitalise on potential options for reaching the target population. Each team explored different options for recruitment, including paid advertising, social media, commercial media (TV, radio, newspapers, magazines), YouTube recruitment videos, live presentations, direct contact with organisations, and accessing research databases.

Recruitment teams in each country differed according to available resources. The Australian team comprised of two recruiters who had direct contact with potential participants plus three other team members who supported the raising awareness of the study, and towards the end of the study engaged an external team to boost recruitment. The U.K. team consisted of two main recruiters, who also undertook screening two additional recruiters who engaged in giving presentations and contacting potential participants to gather EOIs, and intermittent support from three additional recruiters who contacted potential participants. The U.K. team also had recruitment support from the National Institute for Health Research (NIHR) Clinical Research Network, including nine National Health Service Trusts (NHS) research sites and two participant identification centres. The Norwegian team consisted of two main recruiters at any given time. One had the main responsibility for screening potential participants throughout the study. Other team members supported raising awareness of the study and had intermittent contact with potential participants. Seven other recruiters were engaged for shorter periods at different times in the study to give presentations

Table 1
HOMESIDE RCT study elements.

Study Element	Description
<i>Study Design</i>	Randomised controlled trial across 5 countries; Block permuted randomisation with stratification by participating site.
<i>Sample Size Setting</i>	Target N = 495 (dyads), 99 per country. People living with dementia (PLwD) and family caregivers (CG) living at home in the community
<i>Intervention 1 (Music Intervention)</i>	3 music training sessions provided to CG; CG delivers music interventions minimum of 2 x per week, 30 min, 12 weeks; training focuses on musical attunement, person-centred music experiences, music for reminiscence, movement, and relaxation
<i>Intervention 2 (Reading Intervention)</i>	3 reading training sessions provided to CG; CG delivers reading interventions minimum of 2 x per week, 30 min, 12 weeks; training focuses on using reading aloud to the PLwD (or reciting poems, prayers, prose, short stories, fairy tales, when unable to read), the PLwD reading aloud, listening to audio books, and discussing texts.
<i>Control Condition</i>	The CG will not be trained in either music or reading but will be instructed to care for the PLwD in their usual manner.
<i>Eligibility</i>	Inclusion Criteria - Dyads (cohabiting) who are close in relationship and where one member has a diagnosis of dementia according to International Statistical Classification of Diseases and Related Health Problems (ICD-10) - Dyads where the person with dementia (PwD) has a Neuropsychiatric Inventory-Questionnaire (NPI-Q) score of ≥ 6 Exclusion Criteria - Dyads where either or both the CG or PLwD have significant hearing impairments that are not resolved through the use of a hearing aid - Dyads with no access to internet
<i>Outcome Data Collection</i>	1. NPI-Q (primary outcome, neuropsychiatric symptoms). 2. Montgomery-Asberg Depression Rating Scale (depression) 3. Quality of Life – Alzheimer's Disease (Quality of Life of PLwD) 4. Mini Mental State Examination (cognition of PLwD) 5. Patient-Health Questionnaire-9 (depression, CG) 6. Resilience Scale (resilience, CG) 7. Short Sense of Competence Scale (CG competence) 8. Assessment of Quality of Life-6D (CG quality of life) 9. Quality of Caregiver-Patient Relationship (dyadic relationship quality) 10. EuroQoL-5D-5L (quality adjusted life years, PLwD) 11. Resource Utilisation in dementia (health care costs)

Note: PLwD = Person living with Dementia; CG – Caregiver.

and contact professional stakeholders, two of them also screened some potential participants. Two members of the German team were responsible for recruitment as a part of their total duties for the trial. The Polish team consisted of two main recruiters and two supporting recruiters and five other team members who participated in short periods of recruitment. Twice yearly, the recruitment teams from each country met to review and share recruitment strategies with the aim of identifying, testing, and reporting on the most effective recruitment strategies.

2.2. Statistical analysis

For this study, EOIs were categorised as “consenting to participate” or “not consenting to participate”. Participants who consented to participate in the study but were later assessed as ineligible were counted as “consenting to participate” as this study focused on successful strategies to recruit rather than on meeting eligibility criteria. Participants who expressed interest, but after knowing more about the study decided not to participate in the screening process were categorised as “not consenting to participate”. In an exploratory analysis, we compared the distributions of the two categories in the study using

the Pearson χ^2 test for categorical variables and the Kruskal Wallis test for continuous variables. Logistic regressions were used to estimate the odds ratio (OR) of a dyad 'consenting to participate' by considering participants' characteristics and the medium through which they became aware of the study. Analyses were performed using STATA version 17.

3. Results

A total of 432 (38.6%) of the 1118 EOIs resulted in a study enrolment. Of those who did not enroll in the study, 452 (40.4%) declined to participate in the study, and 222 (19.9%) did not meet inclusion criteria once screened, including 37 (3.4%) who did not have an NPI-Q severity score below 6 (Table 2).

Table 3 outlines the relationship between the person expressing interest in the study and the PLwD, the source of study awareness, and demographic information of the CG and PLwD (when known). Norway, UK, and Australia had similar trends in that the spouse/partner was the most likely person to make contact about the study and were most likely to be the CG. Poland, and to an extent Germany, had higher proportions of adult children (mostly daughters) enquiring about study participation and were also more likely to be the primary CG.

Female CGs were disproportionately represented ($p < 0.001$). Ages of CGs were similar across countries except for Poland where the higher proportion of adult children CGs lowered the mean age. The mean age of the PLwD was different between countries ($p = 0.027$) with Norway and UK having lowest age compared to other countries. With respect to the gender of the PLwD, Australia and Germany had relatively balanced samples between male and female. Poland's sample comprised mostly of female PLwD (79.2%), while Norway and UK had more males than females (58.7% and 57%, respectively $p < 0.001$). Alzheimer's disease was the most common dementia diagnosis across all countries and the second largest diagnostic group in the sample was unknown dementia type ($p < 0.001$). Those with a diagnosis of Vascular Dementia resulted in the greatest conversion to a study enrolment ($p = 0.035$).

There were significant between-country differences in the source of study awareness. Most notably, half of German EOIs were generated from an article published in a free pharmacy magazine. In United Kingdom (64.2%) and Poland (43.6%), EOIs came predominantly from referrals from professionals or organisations. Databases were the main source of EOIs in Australia (26.8%) and second in Germany (28.5%). Social media strategies were successful in Australia and Poland. When combining data from all countries, most EOIs came via referrals from professionals or organisations (34.3%) or from databases (19.1%) (Table 4).

When comparing the proportion of dyads that did not consent to participate according to CG relationship type, there was a significant difference between the number of spouse/partners who did not consent (59.9%, $p = 0.044$) compared with adult child and other relationship types. This was especially the case for Australia, and United Kingdom (Supplementary Table 1). In the case of Germany, a greater proportion of adult child CGs did not consent to participate (Supplementary Table 1).

To identify which strategies were more successful in attracting participants into the study we used a logistic model. Table 5 highlights the

odds ratio of participants consenting to participate in the study. Based on the Adjusted Model 1, we found that CG of people with Vascular Dementia were 1.98 more likely to consent to participate than CG of people with Alzheimer's Disease (95% CI 0.99–3.94). Child CG were 2.1 more likely to consent than a spouse/partner (95% CI 0.97–4.43), and CG of all other types of relationship were 4.96 more likely to consent than spouse/partner (95% CI 1.84–13.4).

Adjusted Model 2 combines the variables of the person who expresses interest in the study with those who are the primary CG. The results are consistent with the first model, with respect to dementia diagnosis. Research databases as a source of study awareness are 1.68 more likely to result in consent compared to presentations and flyers (95% CI 0.90–3.16). This model shows that when the contact person is also a caregiver, they are 2.29–3.56 times more likely to consent to participate, than when they are not the primary caregiver (Table 5).

Fig. 1 depicts the recruitment trends over time across the five countries. Note that Norway and Poland commenced recruitment later than the other countries due to delayed distribution of funds by their funding bodies and delays in receiving ethics approvals. Germany recruited 108 dyads between November 2019 and November 2021 (4.5 per month), United Kingdom recruited 112 dyads between November 2019 and February 2022 (4 per month), Australia recruited 108 dyads between November 2019 and June 2022 (3.5 dyads per month), Norway recruited 57 dyads between July 2020 and June 2022 (2.4 dyads per month) and Poland 47 dyads between May 2020 and July 2022 (2.2 dyads per month). Dips in recruitment occurred during the European summer (July) and during the Christmas period (November/December). Germany and the United Kingdom reached their target sample earlier than the other countries and ceased recruitment at that time. Australia, Poland, and Norway experienced a surge in randomisations during the last month of recruitment. Germany had a surge in randomisations from May 2021 until end of recruitment following publication of an article about the study in a pharmacy magazine with wide reach. From May 2020 recruitment and trial implementation were adjusted to accommodate COVID-19 conditions.

4. Discussion

Our data revealed several important trends in participant characteristics with respect to those expressing interest in and in consent to participate in the study. Overall, dyads including spousal CGs represented the highest proportion of EOIs and participation consents in our study (except for Poland, where adult children CG were highly represented). However, child CGs were twice as likely as spousal CGs to consent. There could be several reasons for this finding. First, adult child CGs may have felt more able to manage or incorporate the additional study requirements. As the CG-delivered intervention was to be provided at least two times per week, adult child CGs may have viewed this as more manageable within their day-to-day caregiving responsibilities, than spousal CGs. The anticipated burden may have been a factor that discouraged some spousal CGs to consent [4]. Second, adult child CGs may have felt more comfortable with the online delivery of the training program compared with older spousal CGs. It has already been noted that technology capability can be a deterrent in study participation of older people [14]. That said, the COVID-19 pandemic caused older

Table 2
Expressions of interest by country.

	Australia	Germany	Norway	Poland	United Kingdom	Total
Total EOIs	335 (100.0)	200 (100.0)	187 (100.0)	78 (100.0)	318 (100.0)	1118 (100.0)
Not consenting to Participate (not interested)	103 (30.8)	54 (27.0)	83 (44.4)	30 (38.5)	182 (57.2)	452 (40.4)
Consenting to participate	232 (69.2)	146 (73.0)	104 (55.6)	48 (61.5)	136 (42.8)	666 (59.6)
Not Eligible to the Study	123 (36.7)	32 (16.0)	44 (23.5)	0	23 (7.2)	222 (19.9)
PLwD died before enrolment	1 (0.3)	6 (3.0)	3 (1.6)	1 (1.3)	1 (0.3)	12 (1.1)
Accepted into the Study	108 (32.2)	108 (54.0)	57 (30.5)	47 (60.3)	112 (35.2)	432 (38.6)

Notes: n (%). Other reasons that cannot be characterised as not meeting eligibility criteria. EOI = Expression of Interest. PLwD = Person living with Dementia.

Table 3

EOIs by contact person, demographics of CG and PLwD, and recruitment strategy.

Participants Characteristics	Total (N = 1118)	Australia (N = 335)	Germany (N = 200)	Norway (N = 187)	Poland (N = 78)	United Kingdom (N = 318)	P-value
Relationship between the Contact Person and PLwD ¹							<0.001
Spouse/Partner	532/1095 (48.6)	156/313 (49.8)	66/199 (33.2)	94/187 (50.7)	10/78 (12.8)	206/318 (64.8)	
Daughter	348/1095 (31.8)	103/313 (32.9)	89/199 (44.7)	35/187 (18.7)	47/78 (60.3)	74/318 (23.3)	
Son	44/1095 (4.0)	7/313 (2.2)	14/199 (7.0)	2/187 (1.1)	5/78 (6.4)	16/318 (5.0)	
Relatives or Friends	22/1095 (2.0)	7/313 (2.2)	1/199 (0.5)	7/187 (3.7)	2/78 (2.6)	5/318 (1.6)	
Other	149/1095 (13.6)	40/313 (12.8)	29/199 (14.6)	49/187 (26.2)	14/78 (18.0)	17/318 (5.4)	
Relationship between the CG and PLwD ¹							<0.001
Spouse/Partner	491/880 (53.8)	164/305 (53.8)	72/188 (38.3)	133/181 (73.5)	7/54 (13.0)	115/152 (75.7)	
Child	305/880 (34.7)	106/305 (34.8)	88/188 (46.8)	42/181 (23.2)	38/54 (70.4)	31/152 (20.4)	
Other	84/880 (9.6)	35/305 (11.5)	28/188 (14.9)	6/181 (3.3)	9/54 (16.7)	6/152 (4.0)	
Dementia Diagnosis type ¹							<0.001
Alzheimer's Disease	378/796 (47.5)	129/302 (47.7)	71/169 (42.0)	71/129 (55.0)	33/54 (61.1)	74/142 (52.1)	
Vascular Dementia	75/796 (9.4)	29/302 (9.6)	18/169 (10.7)	9/129 (7.0)	7/54 (13.0)	12/142 (8.5)	
Other Dementias	151/796 (19.0)	58/302 (19.2)	25/169 (14.8)	13/129 (10.1)	6/54 (11.1)	49/142 (34.5)	
Don't know/No answer	192/796 (24.1)	86/302 (24.5)	55/169 (32.5)	36/129 (27.9)	8/54 (14.8)	7/142 (4.9)	
Age and Gender							
PLwD - Male ¹	376/751 (50.1)	131/273 (48.0)	69/144 (47.9)	101/172 (58.7)	10/48 (20.8)	65/114 (57.0)	<0.001
PLwD Age [years] ²	76.9 ± 8.9 (n = 445)	77.2 ± 8.5 (n = 113)	78.1 ± 9.3 (n = 108)	75.8 ± 7.5 (n = 62)	78.5 ± 10.7 (n = 48)	75.4 ± 8.5 (n = 114)	0.027
CG - Male ¹	148/746 (19.8)	49/264 (18.6)	27/141 (19.2)	39/140 (21.8)	2/48 (4.2)	31/114 (27.2)	0.017
CG Age [years] ²	64.1 ± 12.0 (n = 440)	65.1 ± 11.1 (n = 109)	61.8 ± 11.8 (n = 108)	70.6 ± 9.2 (n = 61)	51/6 ± 10.4 (n = 48)	67.0 ± 10.5 (n = 114)	<0.001
Source of Awareness about the Study ¹							<0.001
Presentations & Flyers	104/1108 (9.5)	17/325 (5.2)	14/200 (7.0)	42/187 (22.5)	2/78 (2.6)	30/318 (9.4)	
Referral from Professionals or Organisations	380/1108 (34.3)	67/325 (20.6)	13/200 (6.5)	62/187 (33.2)	34/78 (43.6)	204/318 (64.2)	
Databases	212/1108 (19.1)	87/325 (26.8)	57/200 (28.5)	0	0	68/318 (21.4)	
Online/Print Media	161/1108 (14.5)	38/325 (11.7)	100/200 (50.0)	18/187 (9.6)	4/78 (5.1)	1/318 (0.3)	
Live Media	35/1108 (3.2)	22/325 (6.8)	0	7/187 (3.7)	6/78 (7.7)	0	
Facebook	134/1108 (12.1)	82/325 (25.2)	2/200 (1.0)	18/187 (9.6)	22/78 (28.2)	10/318 (3.1)	
Word of Mouth/Don't know	81/1108 (7.3)	12/325 (3.7)	14/200 (7.0)	40/187 (21.4)	10/78 (12.8)	5/318 (1.6)	

Notes: ¹ n/N (%); Pearson X² test. ² mean ± SD. Kruskal Wallis test. PLwD = Person living with Dementia; CG = Caregiver. Missing data in several variables are related to the consent process: just necessary screen variables were questioned before to receive consent from CG and PLwD: variables as 'Age' were asked only after checked eligibility, what resulted in not enough information (* indicate the n for this variable).

people more broadly to become familiar with videoconferencing technology, so while technological capability may partly explain the higher conversion rate of adult child CGs compared with spousal CGs, the largest participant pool of CGs were spouses, suggesting that technological competence is not the only factor influencing consent to participate. A third and plausible reason for spousal CGs being less likely to consent to participate, may relate to their more intimate knowledge of the PLwD's needs or perceived unmet needs. Spouses know the PLwD's personal history intimately and may have better insights into whether they felt their partner would benefit from participation in the program. Finally, it is possible that adult children are highly motivated to: a) contribute to dementia research, b) to trial non-pharmacological interventions, c) to enhance their relationship with their parent, d) to find more effective care management strategies. Further investigation into the factors influencing research participation for adult child CG versus spousal CG of PLwD would be beneficial.

Our findings highlighted the difficulties encountered in recruiting PLwD and their family CGs. More than 2.5 EOIs had to be generated for every successful study enrolment, highlighting the importance of designing and piloting a recruitment strategy so that the study team can adequately plan and resource their recruitment approach. The substantial number of EOIs where potential participants did not meet our inclusion criteria (21%) or declined to participate when provided with more information about the study (38%), highlighted the importance of providing clear inclusion criteria and participation expectations in all advertising material. Noting transcultural trends, while Poland generated the least EOIs, their conversion rate was substantially higher than all other countries. Similarly, Germany received a high number of EOIs and consents as a direct result of an article in a pharmacy magazine. While between country comparisons of how information was conveyed to potential participants is beyond the scope of this paper, it is possible

that the information provided by the German and Polish recruitment sources, was more precise with respect to inclusion criteria and types of activities participants were expected to undertake. Australia had the highest level of ineligible EOIs, suggesting inclusion criteria needed to be more accurately conveyed, whereas the UK team had more declining to participate, suggesting information regarding study requirements needed to be more clearly articulated. Conversely, many of the dyads in Australia and the UK had more secondary CGs supporting the primary CG, so meeting eligibility criteria of being the "primary" CG was more challenging. Additionally, in the UK, recruitment was often facilitated by staff at National Health Service memory clinics rather than members of the research team, who may not have been as clear about what information to share with potential participants, or may have approached potential participants who were not yet ready to participate in research (for example, had just received their dementia diagnosis). Some EOIs resulted from "word of mouth" whereby potential participants were made aware of the study by other parties who may not have accurately conveyed our inclusion criteria or the need for active participation. When further details were then provided by the study team, many chose not to participate. Reasons for non-participation overall were notably: a) CG already highly burdened with care; b) long-term nature of the study; c) CG hoping for therapists to implement the intervention rather than being CG-directed; d) planned holidays, respite, or other activities during the study period that would deem them unable to meet adherence.

Our recruitment strategies highlighted that targeting referring professionals and organisations, as well as accessing databases of PLwD interested in research participation, such as Join Dementia Research [22] and StepUp for Dementia Research [18], were the most effective for generating expressions of interest and converting these into a consent to participate. However, there is likely an inherent bias in the database

Table 4

Demographics of participants who consented to participate.

Participants Characteristics	Total (N = 1118)	Consenting to Participate (N = 666)	Not Consenting to Participate (N = 452)	P-value
Relationship between the CG and PLwD ¹				0.044
Spouse/Partner	491/880 (55.8)	358/658 (54.1)	133/222 (59.9)	
Child	305/890 (34.7)	228/658 (35.7)	77/222 (34.7)	
Other	84/880 (9.6)	72/658 (10.8)	12/222 (5.5)	
Dementia Diagnosis type ¹				0.035
Alzheimer's Disease	378/796 (47.5)	282/591 (47.7)	96/205 (46.8)	
Vascular Dementia	75/796 (9.4)	64/591 (10.8)	11/205 (5.4)	
Other Dementias	151/796 (19.0)	114/591 (19.3)	37/205 (18/1)	
Don't know/No answer	192/796 (24.1)	131/591 (22.2)	61/205 (29.8)	
Age and Gender PLwD - Male ¹	376/751 (50.1)	293/589 (49.8)	83/162 (51.2)	0.737
PLwD Age [years] ² (n = 445) *	76.9 ± 8.9	76.9 ± 8.5	74.8 ± 10.2	0.580
CG - Male ¹	148/746 (19.8)	111/580 (19.1)	37/166 (22.3)	0.369
CG Age [years] ² (n = 440) *	64.1 ± 12.0	64.0 ± 12.0	68.2 ± 7.4	0.448
Source of Awareness about the Study ¹				<0.001
Presentations & Flyers	105/1108 (9.5)	63/664 (9.5)	42/444 (9.5)	
Referral from Professionals or Organisations	380/1108 (34.3)	182/664 (27.4)	198/444 (44.6)	
Databases	212/1108 (19.1)	155/664 (23.3)	57/444 (12.8)	
Online/Print Media	161/1108 (14.5)	109/664 (16.4)	52/444 (11.7)	
Live Media	35/1108 (3.2)	22/664 (3.3)	13/444 (2.9)	
Facebook	134/1108 (12.1)	77/664 (11.6)	57/444 (12.8)	
Word of Mouth/ Don't know	81/1108 (7.3)	56/664 (8.4)	25/444 (5.6)	

Notes: ¹ n/N (%); Pearson χ^2 test. ² mean ± SD. Kruskal Wallis test. PLwD = Person living with Dementia; CG = Caregiver. Missing data in several variables are related to the consent process: just necessary screen variables were questioned before to receive consent from CG and PLwD: variables as 'Age' were asked only after checked eligibility, what resulted in not enough information (* indicate the n for this variable).

samples as these include people who have already expressed an interest in participating in research. Paid and unpaid social media posts were effective in generating EOIs in some countries. As a largely low-cost approach to advertising study participation, we recommend this approach to complement access to databases and external referrals as optimal recruitment strategies.

Recruitment rates varied substantially between countries, suggesting the need for country-specific testing of recruitment strategies. Poland,

Table 5

Odds ratio of participants consenting to participate in the study.

	Crude Odds Ratio	Adjusted Odds Ratio (Model 1) (n = 782)	Adjusted Odds Ratio (Model 2) (n = 792)
Relationship between the Contact Person and PLwD			
Spouse/Partner	1	1	–
Daughter	0.89 (0.68–1.18)	0.41** (0.19–0.88)	–
Son	0.64 (0.35–1.19)	1.19 (0.23–6.19)	–
Relatives or Friends	0.49 (0.21–1.16)	0.13** (0.03–0.51)	–
Other	0.76 (0.53–1.1)	0.39** (0.18–0.84)	–
LR (4)	5.64 (p = 0.225)	–	–
Relationship between the CG and PLwD			
Spouse/Partner	1	1	–
Child	1.10 (0.79–1.52)	2.08*** (0.97–4.43)	–
Other	2.23** (1.17–4.23)	4.96** (1.84–13.40)	–
LR (2)	6.9 (p = 0.032)	–	–
Dementia Diagnosis type			
Alzheimer's Disease	1	1	1
Vascular Dementia	1.98** (1.0–3.91)	1.98*** (0.99–3.94)	2.11** (1.05–4.20)
Other Dementias	1.05 (0.67–1.62)	0.95 (0.61–1.50)	0.94 (0.60–1.47)
Don't know/No answer	0.73 (0.50–1.07)	0.89 (0.58–1.35)	0.81 (0.54–1.21)
LR (2)	9.05 (p = 0.029)	–	–
Source of Awareness about the Study			
Presentations & Flyers	1	1	1
Referral from Professionals or Organisations	0.61** (0.39–0.95)	1.44 (0.78–2.59)	1.42 (0.79–2.68)
Databases	1.81** (1.1–2.97)	1.65 (0.88–3.01)	1.68*** (0.90–3.16)
Online/Print Media	1.40 (0.84–2.33)	1.10 (0.58–2.05)	1.09 (0.58–2.05)
Live Media	1.12 (0.51–2.48)	1.52 (0.54–4.33)	1.31 (0.48–3.56)
Facebook	0.90 (0.54–1.51)	1.31 (0.65–2.63)	1.07 (0.55–2.09)
Word of Mouth/ Don't know	1.49 (0.81–2.75)	1.53 (0.71–3.30)	1.41 (0.56–2.98)
LR (6)	46.13 (p < 0.001)	–	–
Contact Person is ...			
Not a CG	1	–	1
a CG (Spouse/ Partner)	12.21* (8.65–17.25)	–	2.29** (1.35–3.89)
a CG (Child)	11.7* (8.02–17.09)	–	2.08** (1.21–3.56)
a CG (Other)	21.9* (10.94–43.80)	–	3.56** (1.55–8.15)
LR	317.8 (p < 0.001)	27.14 (p = 0.028)	26.95 (p = 0.008)
Log likelihood	–	–425.63	–440.02

Note: Results are Odds Ratio with 95% CI between parentheses. *p ≤ 0.001, ** 0.001 < p ≤ 0.05; ***0.05 < p ≤ 0.10.

with one of the larger and older populations, had the slowest rate of recruitment. Poland's population is 1.6 times larger than Australia's and yet Australia's rate was 1.6 times faster than Poland. The outbreak of the war in Ukraine in February 2022 may have influenced recruitment in Poland negatively at the end of their recruitment period, with citizens more focused on their safety and on supporting the large influx of Ukrainians crossing the border into Poland. Germany, with the largest population, was unsurprisingly first to reach and exceed its target sample. However, although 15 times larger in population than Norway,

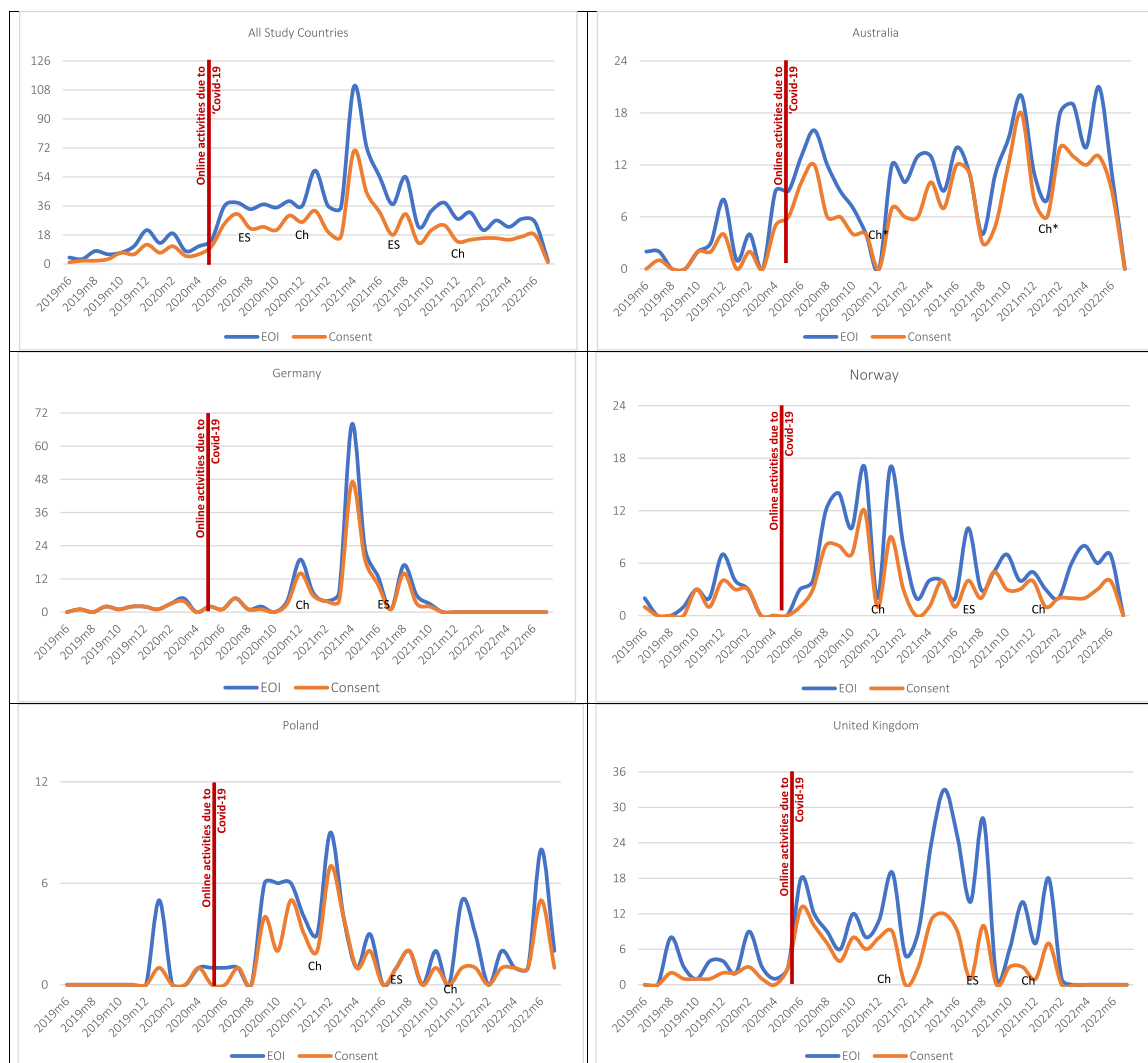


Fig. 1. Study enrolment rate by country

Notes: Change to 'Online activities due to Covid-19' outbreak occurred in May 2020. Ch = Christmas period. Ch* = Christmas period + Summer Holidays in Australia. ES = European Summer.

Germany's recruitment rate was only twice the rate of Norway, suggesting Norway had the most effective recruitment rate by population size.

Our data highlighted the periods of the year where there are peaks and troughs in recruitment rates. It was evident that summer vacations in July/August (Europe) and Christmas periods (all countries) corresponded with lower recruitment rates. While this is not surprising, it does highlight several considerations that trialists could consider when planning studies. In our study, we had initially planned a recruitment rate of 5 dyads per country over 24 months. However, in retrospect, we should have planned not to recruit in July/August and December, ultimately meaning that we would only recruit for 10 months per year (20 in total). That would automatically have increased our recruitment targets to 6 dyads per month. In our study, all countries needed to extend their recruitment period, and none managed to meet the targeted average of 5 dyads per month. While a month-by-month and country-by-country analysis of the EOIs correlating with COVID-19 lockdown periods is beyond the scope of this manuscript, it is highly likely that this affected our recruitment. During these periods, many people were focused on uncertainties posed by the pandemic, and thus felt overwhelmed and unable to commit to research participation.

In Norway, Poland, and Australia, the countries that extended their recruitment period to increase chances of reaching their target sample,

was the surge in EOIs at the end of the recruitment period. By informing organisations and communicating on social media that our recruitment period was coming to an end, we learned how effective the "enrol now or miss out" message was. In hindsight, it may have been better to commence this messaging 2–3 months earlier as EOIs continued to be submitted 2–3 weeks after recruitment had closed. Follow up of dyads previously ineligible due to low NPI-Q score may also have contributed to the surge in recruitment at the end of the study.

Study limitations and recommendations for future research.

The most significant limitation of this study was that it was conducted under unusual conditions – during the COVID-19 pandemic – and therefore, recruitment outcomes and the various recruitment strategies need to be interpreted with this unique period of history in mind. Similarly, the outbreak of the conflict between Russia and Ukraine is also a factor that needs to be considered, especially with respect to the Polish recruitment approach. Despite these factors, many useful learnings were derived from this study within a trial.

It was difficult to assess the impact of PLwD cognitive impairment on recruitment or on the perceived capability of the PLwD to participate in the study assessments, due to the amount of missing MMSE data. Future research could consider asking more direct questions about how comfortable CGs were with the PLwD participating in cognitive assessments. Furthermore, complete MMSE data could have indicated how

effectively we had supported the PLwD lacking capacity and their 'gatekeepers', such as caregivers, in understanding the principles and purposes of the interventions in order to consent to participation. As mentioned before, ethically obtaining consent from participants with varying capacity and the reliance on gatekeepers can pose challenges to recruitment. Therefore, communication strategies, such as using a two-stage assessment of capacity [23] plain-language information sheets and visual aids as in our study, might have played a key role in increasing enrolments of persons with incapacity based on their feelings and wishes rather than caregivers' attitudes towards and perceptions of dementia severity and other possible sources of bias. Moreover, the reasons for declining participation were not self-reported in our study. Therefore, qualitative research data could have explored this in more detail.

Our study did not collect ethnicity data and did not have large numbers of participants with a primary language other than the national language of their country, and therefore, there is an underrepresentation of people from minority groups, something not uncommon in research [6–8]. Future studies should consider developing specific strategies for engaging participants from minority groups. Lastly, this study was only implemented in five countries. A greater representation of the global south would provide important comparisons for understanding how to best recruit community-dwelling PLwD.

5. Conclusion

This study found that recruiting for a trial with community-dwelling family CGs and PLwD is challenging, especially during a global pandemic. We found that the most successful strategies were direct referrals from professionals and organisations and recruiting from dementia-specific research databases. While spousal CGs comprised the highest proportion of dyads recruited, overall spousal CGs were more reluctant to consent to participate than adult child CGs. More targeted recruitment strategies designed for minority groups are also needed to ensure broader representation in dementia treatment studies.

CRediT statements

Felicity A. Baker: Conceptualization, Investigation, Funding Acquisition, Methodology, Project administration, Supervision, Writing - Original Draft.

Laura Blauth: Investigation, Resources, Writing - Review & Editing.

Jodie Boska: Investigation, Resources, Writing - Review & Editing.

Anna A. Bukowska: Investigation, Funding Acquisition, Methodology, Writing - Review & Editing.

Libby Flynn: Investigation, Resources, Writing - Review & Editing.

Ming-Hung Hsu: Investigation, Resources, Writing - Review & Editing.

Edyta Janus: Investigation, Resources, Writing - Review & Editing.

Kjersti Johansson: Investigation, Resources, Writing - Review & Editing.

Helen Odell-Miller: Investigation, Funding Acquisition, Methodology, Writing - Review & Editing.

Hayley Miller: Investigation, Resources, Writing - Review & Editing.

Carina Petrowitz: Investigation, Resources, Writing - Review & Editing.

Jonathan Pool: Investigation, Resources, Writing - Review & Editing.

Karete Stensæth: Investigation, Funding Acquisition, Methodology, Writing - Review & Editing.

Jeanette Tamplin: Investigation, Funding Acquisition, Methodology, Writing - Review & Editing.

Kate TeggeLove: Investigation, Resources, Writing - Review & Editing.

Thomas Wosch: Investigation, Funding Acquisition, Methodology, Writing - Review & Editing.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.conctc.2023.101079>.

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