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Recruiting Persons with Dementia and Caregivers in a Clinical Trial: Dyads Perceptions

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Abstract

Recruitment for dementia research is challenging and costly. Using Ajzen's Theory of Planned Behavior we explored attitudes, perceived norms, and perceived behavioral control of persons living with dementia (PLWD) and their caregivers who participated in one clinical trial to better understand factors that influence dyads' decisions to enroll. We conducted semi-structured telephone interviews with 12 PLWD and 9 caregivers and utilized directed content analysis. Categories connected with positive attitudes about study enrollment were personal desires of wanting to learn and in-person meetings with knowledgeable staff. Additionally, participants said the money always helps in terms of the financial incentive. Participants reported enrolling to support another person (perceived norm). Study requirements were thought to be easy (perceived behavioral control). Participants highlighted the importance of flexible scheduling and study tasks being completed at their home. Findings can inform future recruitment efforts and should be investigated as effective recruitment methods in other clinical trials.

Keywords

dementia; recruitment; caregivers; population focus; dyad; qualitative; methods

Dementia represents a major public health epidemic. There were an estimated 5.8 million Americans living with dementia in 2020, and the population of persons living with dementia (PLWD) is projected to be approximately 14 million by 2060 (Alzheimer's Association, 2020). More than 16 million Americans provide informal (unpaid) care for PLWD

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(Alzheimer's Association, 2020). In 2019 alone, caregivers (CGs) of PLWD provided roughly 18.6 billion hours of unpaid care to loved ones (Alzheimer's Association, 2020). Furthermore, the National Institutes of Health was estimated to spend $2.8 billion dollars on Alzheimer's research in 2020 (Alzheimer's Impact Movement, 2020). Participation in research is critical to build the evidence around understanding the needs of PLWD and their CGs and to guide intervention development (Aoun et al., 2017).

There is a body of literature documenting challenges to recruiting for dementia research (Fargo et al., 2016; Grill et al., 2013; Watson et al., 2014) and proposed strategies to address these barriers (Carrié et al., 2012; Fargo et al., 2016; Grill, 2017; Grill & Galvin, 2014; Morrison et al., 2016; Nuño et al., 2017; Szabo et al., 2018). Despite these efforts, recruitment remains a challenge because it requires a significant investment of time and monetary resources to meet study enrollment goals (Bethell et al., 2018). Barriers to enrollment in research related to dementia include the invasive nature of research procedures, perceptions regarding the complexity of research, and potential for distress when addressing certain topics, as well as the historical unethical research practices previously involving Black and other minorities leading to distrust of research participation (Bethell et al., 2018; Lambe et al., 2011; Watson et al., 2014; Williams et al., 2010). Furthermore, travel outside of the home to participate in a research study further increases the rates of refusal to participate (Karlawish et al., 2008).

Some proposed strategies to address these barriers include requesting adequate funding to support recruitment activities, building trust with communities, conducting research at participants' homes, providing transportation, and collaborating with local aging and public health agencies (Bethell et al., 2018; Erves et al., 2017; Etkin et al., 2012; Karlawish et al., 2008; Watson et al., 2014). Yet, there remain challenges to recruiting participants. One study reported that on average almost three people were screened for everyone person enrolled in Alzheimer's drug trials (Grill & Karlawish, 2010).

Further recruitment complications exist when a CG is needed to support a PLWD throughout the duration of a research study and to provide relevant daily function information (Karlawish et al., 2008; Watson et al., 2014). Many research protocols require both a PLWD and a CG (i.e., a relative or a friend who provides informal care to the PLWD) to enroll in the study to ensure participant's safety and well-being as well as scientific integrity by serving as an informant and helping to provide clinical information such as medical history (Cary et al., 2015; Grill & Karlawish, 2017). Herein this pair is referred to as a dyad. Participating in a research study is another caregiving responsibility, which could further increase the CG demand.

There is limited research focused on dyads' decisions to enroll in clinical trials, despite the vastly growing clinical demand for mitigating poor outcomes for PLWD and their CGs. Qualitative research has elucidated strategies to improve recruitment efforts in other populations (Donovan et al., 2016; Horwood et al., 2016; Paramasivan et al., 2011; Wade et al., 2009), but has not been well utilized to gain insight into how to enhance recruitment of PLWD (Clement et al., 2019; Watson et al., 2014). One study, interviewing healthcare professionals, found that research participation options were not routinely discussed during

dementia clinical care, and other recruitment challenges included patient records not being up-to-date, complex study information sheets, and requirement of a study partner (Clement et al., 2019). One strategy for facilitating recruitment that emerged was asking all new patients for consent to be contacted about future research (Clement et al., 2019).

To learn more about PLWD and their CGs' perspectives on enrolling in clinical trials, we conducted dyad interviews and analyzed the data guided by the Theory of Planned Behavior (TPB) (Ajzen, 1991). A central factor of the TPB is the individual's intention to perform a behavior; thus, we selected this theory for its usefulness in understanding behavior. Intentions indicate how hard someone is willing to try to perform the behavior. Stronger intentions tend to signify a higher likelihood of performing the behavior; a person with an intent to perform a behavior should be successful in doing so if they are equipped with opportunities and resources.

The TPB postulates that there are three independent determinants of intention: attitude toward the behavior, subjective norm, and perceived behavioral control (Ajzen, 1991). Attitude toward the behavior refers to a person's evaluation of the behavior and the degree to which they have a favorable or unfavorable appraisal. Subjective norm is defined as perceived social pressure on whether the person should or should not perform the behavior. Perceived behavioral control refers to a person's perception of the ease or difficulty involved with performing a behavior. This is assumed to be influenced by a person's past experiences and obstacles they anticipate when performing the behavior. A person with confidence and self-efficacy beliefs coupled with their intent will likely be successful in completing a behavior attempt (Ajzen, 1991).

A general rule under the TPB is that when a person has a more favorable attitude and subjective norm, and greater perceived behavioral control toward the behavior, they should have a stronger individual intention to perform the behavior (Ajzen, 1991). However, the importance of these factors in the prediction of intention is expected to vary across each situation and the behavior under consideration. There may be situations where one or two of the factors are enough for intentions and in other cases where all three predictors make independent contributions to the intentions of performing the behavior.

Purpose

While prior research is informative for improving recruitment strategies from providers' perspectives, research is needed with PLWD and their CGs to illuminate their perspectives on what enhances or inhibits enrollment into dementia-related research studies. To the best of our knowledge, this is the first study to examine factors that contribute to dyads' decision to enroll in a clinical trial using the TPB. Thus, the aim of our study was to explore factors that influence dyads' decision to enroll in a clinical trial of a nonpharmacological behavioral intervention to identify strategies for improving enrollment of dyads into clinical trials.

Methods

Design

This study entailed telephone interviews with dyads composed of community-dwelling PLWD and their CGs who had considered enrolling in one nonpharmacological clinical trial (referred to as parent study). We used a qualitative descriptive approach (Kim et al., 2017) to help illuminate factors that influence dyads' decisions to enroll in a clinical trial and to build evidence in this underexplored phenomenon. We used a semi-structured interview guide based on the TPB to conduct our interviews.

Parent study details.—The Healthy Patterns Clinical Trial (NCT03682185) recruited community-dwelling PLWD and their CGs as dyads to test a phase III efficacy trial of a home-based activity intervention aimed at improving symptoms of circadian rhythm disorders and quality of life. Persons in the caregiving role were either a family member, a friend, or a paid CG who agreed to participate together with the PLWD to complete study activities. There were cases where a CG was providing support for two people (e.g., daughter caring for mother and father).

The inclusion criteria for the PLWD were as follows: English speaking, had a diagnosis of dementia or self-reported memory impairment [score of 0.5 or greater using the Clinical Dementia Rating Scale (Morris, 1993)], had self-reported sleep-wake disturbance (e.g., insomnia), and had a primary CG. Participants were recruited from Philadelphia, PA and the surrounding area.

Various recruitment methods were used including a direct mailing campaign using a list generated from the Academic Health System Electronic Health Record, study team members giving live presentations on health topics such as sleep then offering study information at older adult community centers, study team members attending senior events such as senior galas, hanging fliers around the city and at churches, advertising in newspapers and on public transportation, and asking participants to provide referrals. Study team members who gave presentations included the study recruitment specialist, an interventionist, and a health educator. These team members were racially diverse, and all had specialized dementia training.

Dyads were asked to join the Healthy Patterns study for a period of four months, which consisted of baseline measures, an active month of participation and a three-month follow-up call. Participants were randomized to either a timed activity intervention group or a health education group. The intervention contained targeted education related to the optimal timing of and types of activities to help improve sleep and memory while the health education group received general education such as how to talk to their doctor and advanced care planning.

Study tasks for both groups included participating in up to eight in-person home visits during the first month and answering questions related to health and everyday activities. Additionally, PLWD had to place a small cotton swab in their mouth for one minute to collect a saliva (spit) sample three times a day on Saturday and Sunday of the first and fourth

weekend of the study. CGs were asked to assist in cases where the PLWD was unable to obtain the saliva sample on their own. PLWD were asked to wear an actiwatch device that measured activity and inactivity during the study and CGs were asked to keep a daily sleep diary of the PLWD's sleep. After four months, dyads were asked to participate in a phone call which lasted about an hour and answer questions about their well-being. Dyads received $100 for the time spent on study-related activities; $50 was paid to the PLWD and $50 was paid to the CG at the completion of the fourth week of the study.

Data Collection

For our study, we sought to interview dyads who were eligible for and had considered enrolling in the Healthy Patterns clinical trial. This study protocol was reviewed by The University of Pennsylvania Institutional Review Board and deemed exempt. A trained research assistant and the last author (JS) were provided with the full list of participants who were contacted to join the parent study within the past year. We chose to draw from participants contacted within the last year to maximize their ability to recount the details. Study team members called the 61 dyads who had enrolled in the study and the 27 dyads who wanted more information about the study and then later decided not to enroll. Up to three calls to both participants of the dyad were placed to review our study aims. After three calls with no answer, the potential participant was listed as unable to reach.

For those that could be reached on the phone, the team member reviewed the study aims, read a consent form which included information that participation was voluntary, and answered questions related to participation. When a PLWD or a CG agreed to participate (provided verbal consent), an interview was scheduled. When possible, interviews were scheduled with both members of the dyad together. Individual interviews were conducted when scheduling difficulties prevented the dyad from participating in the interview together or if only one person from the dyad was interested in participating.

During the interview, questions were asked from a semi-structured interview guide that was developed by the team based on the TPB constructs and the aim of the study. We asked participants broad questions such as: "How did you hear about the study?" and "What were your initial thoughts about the study?" and probed a bit further with questions such as "How easy or difficult did you think it would be to participate in the study when you signed up?" The same interview guide was used during individual interviews and when the PLWD and CG were interviewed together. In the latter case, the interview questions and probes were presented in a manner to allow both participants to offer their perspective on each question.

Interviews were conducted between March and May of 2020. Most of the interviews were about 20 minutes long. Permission was received from all participants to audio-record the telephone interviews. All audio recordings were professionally transcribed, and transcriptions were confirmed to audio files. Each participant received a $10 gift card in the mail for their time and participation in this study.

Data Analysis

Transcripts were uploaded into NVivo version 12. The software was used to store and manage the data during analysis. One author (JS) with extensive qualitative research

experience independently coded the data. This researcher initially immersed herself in the transcripts to become familiar with the interview data. Then, she applied a directed content analysis that was guided by the TPB (Elo & Kyngäs, 2008). This deductive approach consisted of developing codes that were constructs from the TPB and assembling a codebook with corresponding definitions. Additionally, this approach allowed for additional inductive codes to be created during analysis when patterns were identified. All interviews were coded following the codebook, then the data were sorted based on the TPB and additional patterns were identified.

An RA completed an audit of all the coding and modifications were made after a discussion of findings. The first and last author held meetings to discuss the data and categories that emerged under the model constructs and reconciled different insights. The full team was in agreement with refinements that were made. Approaches to ensure trustworthiness were guided by Lincoln and Guba (1985) and included keeping a detailed codebook that accounted for initial categories, definitions, and decisions made during ongoing analysis (audit trail). Additionally, an audit of coding, in-depth review, and team consensus regarding findings and themes provided investigator triangulation.

Results

We had a list of PLWD and CGs from 88 dyads to contact by phone; 61 had enrolled in the parent study, 27 had declined to participate in the parent study. See Figure 1 for details. Our final sample consisted of 21 participants from 12 dyads (12 PLWD and 9 CGs). Five dyads were interviewed together. With three dyads, the PLWD and CG were interviewed separately. Additionally, two PLWD were interviewed individually and their CG did not participate. In one case, a primary CG was the support person for two PLWD (daughter was a CG for a wife and husband) and all three were interviewed separately. Thus, we conducted a total of 16 interviews. The 12 PLWD were primarily Black (92%), female (75%), with CDR scores of 0.5 (92%) and mean age of 73.4 (SD = 8.4). All CGs were female and their relationship with PLWD varied: daughter (41.2%; 5/12), friend (4/12; 33.3%), spouse (8.3%; 1/12), sibling (8.3%; 1/12), and paid CG (8.3%; 1/12).

We had one dyad who completed an interview that initially expressed interest in participating in the parent study and then chose not to enroll in the clinical trial. Due to only having one interview with a dyad that did not enroll in the clinical trial, we decided to not include this interview in the larger analysis. We do, however, recognize that important insights can be learned from this interview and therefore provide some details. The PLWD and paid CG learned about the clinical trial at a senior center when a parent study team member gave a presentation on sleep. This dyad explained they had previously been in a study together and were interested in improving the PLWD's sleep. The CG also said she was interested in the financial incentive and thought it would be an "easy study" to participate in. Due to the CG having a Monday through Friday work schedule and saliva samples needing to be collected during weekend days when the CG was not present to assist, she thought participation would not be feasible. In addition, the CG spoke with the PLWD's family about the study and explained that study team members would need to come

to PLWD's home. With this information "and because it wasn't somethin' bein' offered by her primary care physician, they [family] opt not to do it."

Below we focus on our findings from the persons who enrolled in the parent study and present the categories that emerged under each of the TPB constructs: attitudes toward joining, subjective norm, and perceived behavioral control.

Attitudes Toward Joining

We found that the participants in our study had generally positive attitudes towards joining the parent study. Below we describe the three categories that emerged under Attitudes Toward Joining. The first category described is personal desires of wanting to learn from being in the study. The second explains positive experiences of in-person meetings with knowledgeable staff during recruitment events. The final category, the money always helps, captures participants' reaction to the financial incentive with joining the study.

Wanting to learn.—We found that both CGs and PLWD joined the study because they wanted to learn information and gain knowledge. Some of the CGs expressed being hopeful that they would receive education on how to improve their own sleep. As one CG (#1) stated, "I thought I could learn some tricks on how I could stay asleep longer."

Additionally, a few of the CGs thought it was a good idea to join the study because their loved one living with dementia had sleep and memory problems. These CGs thought being in the study would be useful for gaining health education and some expressed their own learning goals for enrolling. For instance, one CG (#6) wanted to learn how the PLWD could get "better quality of sleep." Another CG thought being in the study would be a good way to learn more about dementia and help her deal with issues that her husband may have over time. An additional example was one CG (#3) telling us her reason for joining as:

> Well, I thought it would be something that would be helpful to my mother. I am a nurse. I was in one of the high schools in the area, and they were doin' a health fair. I always attend looking for information…We were talking, and then I thought this was a great thing for my mother—she was in her late 80s—to listen to, pay attention to, and some things that could help…That's why. That's what started it.
>
> (CG #3)

As for the PLWD, some voiced that they wanted to learn more about themselves. A small number of PLWD were interested in getting their results from the data collected. As one PLWD (#4) told us, "I just wanted to really do a comparison of the data that was collected independently that you did versus the data from the sleep study that I had weeks before that."

In-person meetings with knowledgeable staff.—Overall, the participants were pleased with learning about the study from an in-person meeting with a knowledgeable and personable study staff member. In all but one case, at least one person from the dyad learned about the main study from a study staff member during a scheduled in-person event. These in-person meetings involved study staff giving a presentation for recruitment purposes to a

group and/or being present at an information table at a senior event, health fair, or during gatherings at senior housing. Participants thought in-person, one-on-one contact with study staff was effective for getting them to enroll in the study because they were able to have their questions answered right away and learned who the staff were. Attributes of study staff were described as knowledgeable, professional, and friendly. One PLWD (#9) described her interaction with the study staff as important for deciding to enroll:

> They had literature. They were very professional. They were very professional, and like I said, they were charismatic, and they talked to us, you know what I mean? They talked to us and listened to us. They didn't talk at us. They were very supportive, very supportive.

For one PLWD (#2), having an information table at a health fair for study recruitment made her more comfortable with choosing to enroll in the study. She shared, "It helped me to realize that it was legitimate at a public gathering where permission had to be granted to be there. You know, so that's why I felt that it was okay to become involved with it."

We heard from only one dyad who pursued learning more about the study from an advertisement. This dyad (#6) learned about the main study from a flier available at their senior housing building. None of the dyads mentioned learning about the study through other recruitment advertising attempts or through referrals.

The money always helps.—Most of the participants were satisfied with the financial incentive offered for this study. Comments such as "The money always helps" (CG #7) and "It's always good to get a little extra" (PLWD #2) were made. One dyad (#10) interviewed together conveyed that any amount would have been enough because they learned something from being in the study. The CG also said "even if there really wasn't an amount of money, I think I probably still would have wanted to do it" in an effort to learn how to sleep better and have more energy for herself.

A couple of the participants expressed that they thought the financial incentive was too low for their required effort but participated anyway since it was their study partners who expressed interest in the study. A PLWD (#9) articulated that he thought his participation was worth double the financial incentive received. He also said, "I thought it was a little low, but I did it for my girlfriend". A CG who was a study partner to both her mother (PLWD #11) and stepfather (PLWD #12) said she would have preferred more money; however, the financial incentive she did receive helped her visit her mother and stepfather more often. When prompted, a few participants said that $10 or $25 would have been too low to participate due to the study requirements.

Subjective Norm

It varied as to whether the CG or the PLWD was the one interested in participating in the Healthy Patterns study first. Outside of consulting another person to be their study partner, participants did not talk to others about their interest in enrolling in the parent study. We did not learn from any of the participants that they had social pressure from others to enroll or not enroll. In fact, some participants discussed easily agreeing to participate in the study

when their study partner asked them to join as a way to provide support to someone they cared about.

Support another person.—We heard from some participants that they joined the study because they were happy to help their study partner who needed a second person to participate. One PLWD said she was willing to enroll after her friend approached her to join, and stated she was "just being cooperative for a friend" (PLWD #9). A few CGs told us they easily joined in support of their friends who needed a study partner. One CG (#2) said that the PLWD asked her to sit in, so she said yes, and added: "I'm here to support her in her endeavors and for what she needed, and the beneficial aspects of things to benefit her. I was just here to support her."

Perceived Behavioral Control

Several of the participants mentioned that they had participated in other research studies and wanted to help others by participating in the parent study. Conversely, others said the parent study was the first study they participated in. We learned from both those with research experience and those without, that at the time of study enrollment, they had thought it was going to be easy to participate and complete the requirements throughout the study duration.

Easy to participate.—CGs and PLWD recalled that they thought it would be easy to participate in the study at time of enrollment and did not perceive any barriers or anticipated difficulty with performing the related tasks for the study duration. A few of the participants mentioned that flexibility in scheduling research visits and the study taking place in their home added to the ease of participating. As an example, one CG (#9) shared,

> Easy, because they said they were coming to your home. You didn't have to go anywhere. By being in your home, it was like a comfort zone, too. You know you're in your own home. You feel more comfortable opposed to going somewhere else. You're feeling like, oh, okay, I'm not really familiar with this place. I was very comfortable because it was done in my home. Then I didn't have to travel. It was good for me.

Overall, participants did not share any feelings of the study being difficult for them to engage in when they enrolled. A few of the PLWD recalled at the time of study enrollment that they were a little worried about being able to correctly collect and store their saliva sample, although they didn't think that being in the study was going to be "complicated" (PLWD #8). Additionally, one CG (#3) explained that her mother needed her encouragement to join. The CG told us,

> I think because she is a little bit forgetful that she wasn't sure that she would be able to participate 'cause she might not remember. This was kind of what it was. She said, "If you think I can do it, then I'll do it".

Discussion

This study provides novel information regarding factors that influenced dyads' decision to enroll in a clinical trial. We used the TPB to facilitate understanding of enrolled

participants' behavioral intent to join the parent study. We identified three categories under the TPB construct of Attitudes Toward Joining: wanting to learn, in-person meetings with knowledgeable staff, and the money always helps, and one category for the constructs of Subjective Norm (supporting another person), and Perceived Behavioral Control (easy to participate). We found that our participants were positive in all three main TPB constructs. A positive attitude toward joining, the lack of negative social norm pressure, and the perception of ease in completing study tasks with perceived behavioral control together influenced dyads' positive intent and action to enroll in the parent study.

Wanting to learn was one of the reasons participants chose to enroll in the parent study. In all dyads, either the CG or the PLWD expressed an interest in educating themselves. Our findings are similar to another qualitative study that found that the personal benefit of education was one of the motivators for PLWD to enroll in a research registry (Lee et al., 2019). While the parent study described in this article had a core component of providing education to both the intervention and control group, we do recognize that not all clinical trials would incorporate education into their protocol. Based on our finding, we suggest investigators offer some type of education to promote study participation, even if it is after the study ends. One example is providing a health promotion education booklet related to the disease process being studied.

We also heard from a few participants that they wanted their individual results after being in the parent study to learn more about themselves. Other studies including PLWD and their CGs have shared that participants prefer updates on study progress, results, and outcomes from the study team (Bethell et al., 2018; Pierce et al., 2018). Thus, investigators developing procedures to provide individuals with results and communicating this plan for sharing data during the recruitment process can be an enabler for engaging persons with dementia and their care partners in research (Bethell et al., 2018).

We found that engaging with knowledgeable and personable study staff during community events was associated with positive attitudes of enrolling in the parent study. This method of contact was effective for attracting at least one member of a dyad to learn more about the study, recruit someone close to them to be a study partner, and to enroll in the parent study. Participants spoke highly of the study staff with whom they interacted. The staff members received specialized training in dementia, had engaging personalities, and allowed for ample time to interact with potential research participants. Research staff members developed relationships with potential participants, which may have facilitated enrollment. This highlights the importance of positive relationship building when recruiting participants which has been described as well in other studies (Bethell et al., 2018; Kost et al., 2011).

In addition to being knowledgeable about the study and dementia care, being able to communicate the information clearly and without jargon is also important in recruiting participants (Bethell et al., 2018; Burnell et al., 2015; Robinson et al., 2020). The research team was a diverse group and there was often congruence between the team members and participants. Almost all of our PLWD identified as Black. Black adults are less likely to enroll in Alzheimer's Disease clinical trials (Zhou et al., 2016), despite being almost 2 times more likely to have Alzheimer's Disease or other dementias (Gurland et al., 1999; Potter et

al., 2009; Rajan et al., 2019). Racial concordance, relationship building, and interpersonal skills may all be key factors in enhancing recruitment (Fête et al., 2019; Fryer et al., 2016; Huang et al., 2019).

Our results differ from one study; Morrison and colleagues found that direct mailing was the most effective and least expensive method in recruiting dyads of PLWD and their CGs in a clinical trial of a nonpharmacological intervention. Community outreach yielded the least number of dyads and was the costliest method (Morrison et al., 2016). However, hidden benefits such as enhancing study visibility, creating partnerships for future research, and establishing relationships with PLWD and their CGs were not captured (Gelman et al., 2013). Studies recruiting dyads should provide detailed analyses of recruitment strategies to inform future research.

The majority of our participants felt that at the time of enrollment the gift card offered after completing the parent study was a helpful incentive to join. Other researchers have found financial compensation to be a theme for motivation to participate in clinical research, although similar to our study, found that compensation is not often the primary motivator (Kost et al., 2011). We did however have two participants who thought the financial incentive offered was too low based on their study responsibilities. Investigators having difficulty with recruitment of dyads may want to explore the financial incentive amount being offered and potential participants' perceptions of the amount in relation to study responsibilities. Teams might want to consider increasing incentive amounts if potential participants feel it is too low and is a barrier to recruitment. In addition, research has illuminated that research participants appreciate other incentives such as refreshments, parking reimbursements, and covering transportation costs (Lee et al., 2019). Investigators may want to think creatively about the incentives they could offer in line with their study protocol to increase research participation. Future research should focus on appropriate amounts and allocation of funds between PLWD and CGs as necessary incentives to study partners to improve recruitment for dementia clinical trials and examine how incentives may affect results (Keating et al., 2008 as cited in Largent et al., 2018).

Under the Social Norm construct, we identified from the interviews that almost all participants made their own decisions to join the study and were not pressured by others to enroll or not enroll. We found participants enrolled in the trial because they wanted to support another person. Altruism has been found to be related to enrollment in clinical trials in other research works (Bardach et al., 2018; Cox, et al., 2019; Lee et al., 2019). For example, in a survey of 87 individuals enrolled in one dementia clinical trial, the majority of participants rated the potential to help themselves or a loved one and to help others in the future, as important factors that affected their decision to enroll in the trial; few respondents reported participating to make others happy (Bardach et al., 2018). Furthermore, in a national poll, 45% of CGs of persons with dementia indicated that providing help to someone with cognitive impairment was rewarding (National Poll on Healthy Aging, 2017). Taken together, participants in other studies were willing to enroll in hopes to help their loved one, which aligns with our results.

Our participants who had enrolled in the parent study did not describe any negative pressure from their study partner or family members regarding their enrollment decision. This may have been different with some of the dyads who were initially interested in the parent study but did not enroll and did not want to participate in the interviews for the current study. We were only able to interview one PLWD and paid CG who initially wanted to participate in the study and we learned it was the family who declined their participation. We do not have perspectives from other dyads who choose not to enroll in the parent study. Therefore, the Social Norm construct of the TPB model deserves more attention in future research and should include interviews with dyads who ultimately decline to participate in a clinical trial. Interviews may also need to extend beyond the dyad (e.g., interview family members) to learn their experiences, perceptions, and how their opinions and decisions affect clinical trial enrollment.

Additionally, our findings demonstrate the importance for researchers to consider perceived behavioral control when designing a study and potential participants' attitudes when recruiting. The parent study from which our participants were recruited from had various study requirements over four months. Participants who agreed to partake in our interviews expressed thoughts of ease (perceived behavioral control) related to completing the parent study requirements when considering study enrollment. Flexibility with scheduling and the study taking place in their home were expressed as beneficial features. Accommodating participant and study partner needs in terms of location and time have been previously documented as strategies for improving study enrollment (Watson et al., 2014). Altering study design to include home visits, a "comfort zone" as described by one of CGs in our study, and flexible scheduling may better serve participants and their CGs who might have other responsibilities during normal business hours (Watson et al., 2014). However, it is important to recognize that not all people want others entering their home, even for home health care due to embarrassment about living conditions and concerns over invasion of privacy and personal safety (Sefcik et al., 2017). Investigators may consider having options for potential participants, such as a home visit or a research office visit or virtual/telephone visit, in an effort to increase recruitment rates.

A few CRs did recall being a little worried about completing the saliva collection steps correctly but did not perceive it as complicated. We recognize that the ease to participate in a clinical trial varies greatly between diverse pharmacological and nonpharmacological clinical trials; our findings may have been different if we focused on a study that involved invasive or complex procedures or medications. Additionally, we were unable to reach the majority of participants we contacted for an interview (i.e., those who decided to enroll or not enroll in the parent study within the last year). Therefore, we might be missing alternative perceptions on the difficulty level of participating in the parent study.

Our study had additional limitations. We only spoke with dyads about their enrollment decisions for one clinical trial of a nonpharmacological intervention aimed at improving sleep in older adults living with dementia. Participant experiences and decisions to enroll in a clinical trial may vary from study to study. Furthermore, we called participants up to one year after choosing to be in the study and PLWD's memory impairments may have affected their responses to interview questions and contributed to a low rate of dyads returning our

phone calls. Additionally, we could not connect with some people because of disconnected telephone numbers. Thus, future research should include more detailed questions regarding enrollment at the first encounter when possible, or plan a routine follow-up call at the baseline assessment shortly after the decision is made to join or not join the study to ascertain the reason for their decision. Obtaining immediate information around dyads' decisions to not enroll in a clinical trial can help bolster our study findings, as we were able to only interview one dyad who ultimately did not enroll in the parent study. Information learned at baseline assessments could be helpful for study protocol alterations to improve recruitment.

Additionally, we have not learned about the experiences and perspectives of participants in the parent study who enrolled as a result of other recruitment techniques. These other recruitment techniques for the parent study included a direct mailing campaign, hanging fliers around the city, advertising in newspapers and on public transportation, and asking participants to provide referrals. Future qualitative research should purposefully sample participants who learned about clinical trials through these different recruitment strategies to see if there is variability in their behavioral intent based on advertising approaches.

Furthermore, participants who agreed to engage in our interviews were generally satisfied and positive about their experience with the parent study. We did not hear from participants who had a negative perception of enrolling in the parent study, and we acknowledge that our findings aligned with the TPB model are all positive. Nevertheless, this study provides important contributions to a phenomenon that is not well understood. A strength of this study is we have identified that a positive attitude toward joining, the lack of negative social norm pressure, and the perception of ease in completing study tasks all together influenced dyads' positive intent and action to enroll in a clinical trial. Our results also suggest that investigators should be mindful of participant satisfaction levels during recruitment and throughout the study. Satisfied participants may be more willing to participate in follow-up interviews and other clinical trials. Investigators could introduce a mechanism to elicit feedback on study experiences and work to improve any potential areas where negative feedback is received.

This research is timely as it aligns with United States national efforts that are underway to develop evidence-based methods for improving participant accrual in dementia-related research studies (National Institute on Aging, 2018). There are many challenges to recruiting dyads to participate in research studies. In this study, we explored the perspectives of PLWD-caregiver dyads on factors that influenced their decisions for participating in a nonpharmacological clinical trial. Elicited responses provide valuable implications for enhancing research enrollment into dyadic research. When designing future clinical trials, researchers need to consider what the dyads want from participating in the trials, and how to make their participation easier and more convenient. For example, researchers should consider dyads' needs for health education or knowledge that is meaningful for either or both members of the dyad, and for opportunity to interact with professional staff. In addition, researchers need to design the study to be conducted in a location that is comfortable and convenient for the dyads, make the procedures as easy as possible, include incentives commensurate with study tasks, and allow flexibility in scheduling.

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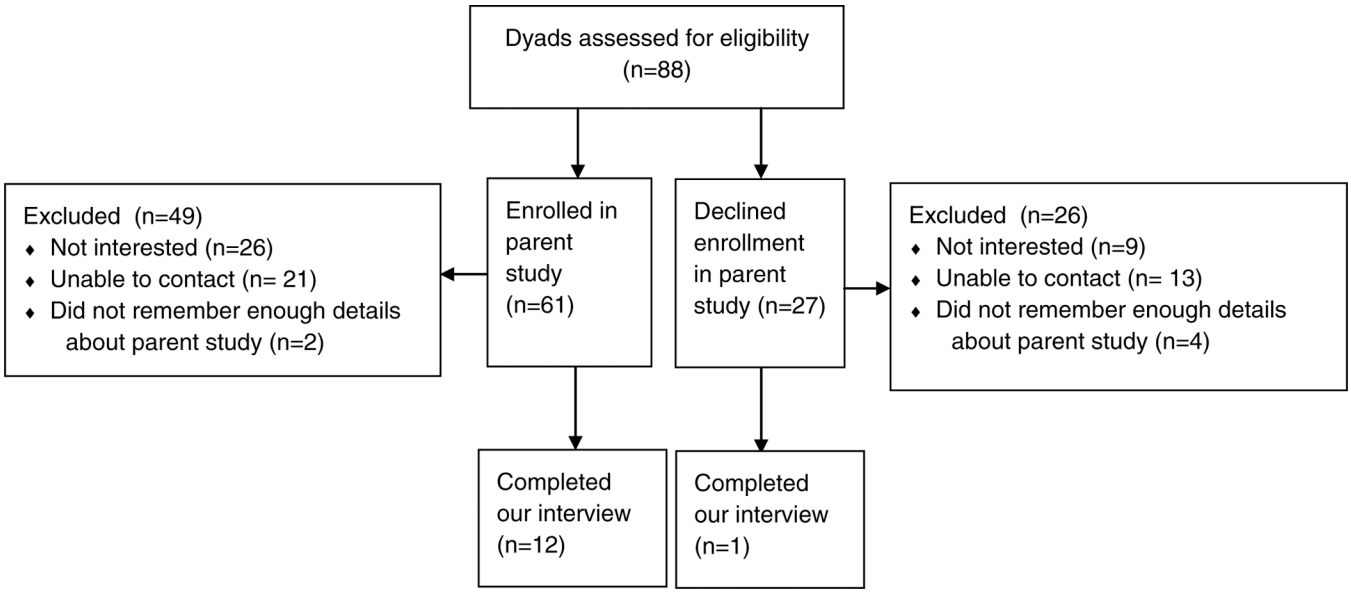

Figure 1.
Telephone call flow.