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Sandra Lee Spoelstra
Grand Valley State University, spoelsts@gvsu.edu

Alla Sikorskii
Michigan State University

Monica Schueller
Grand Valley State University, schuelmo@gvsu.edu

Viktoria Basso

Autumn Baldwin

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Engaging caregivers to use an evidence-based intervention for medicaid beneficiaries with Alzheimer's disease: a pilot study

Sandra L. Spoelstra[1] · Alla Sikorskii[2] · Monica Schueller[1] · Viktoria Basso[3] · Autumn Baldwin[1]

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Abstract

Background This pilot study aimed to adapt an intervention, engaging informal caregivers to help clinicians with providing care to improve (or maintain) physical function of individuals with Alzheimer's Disease or other dementias. To the best of our knowledge, for the first time, we report on use of the intervention in those with Alzheimer's Disease or other dementias.

Methods This was a 5-month mixed methods cohort study in a convenience sample of clinicians, caregivers, and beneficiaries at 3-Medicaid Home and Community-based Service sites in Michigan. Two content experts and 5 caregivers modified the intervention. We trained 116 clinicians to engage caregivers and 50 caregivers to help clinicians provide the modified intervention to 52 beneficiaries with Alzheimer's Disease or other dementias. Thematic analyses, descriptive statistics, counts, proportion comparisons, t-tests, and McNemar's tests were used to examine socio-demographics, clinician knowledge uptake and satisfaction with training and use of the intervention; caregiver self-efficacy, feasibility, acceptability, usability, and satisfaction with intervention and beneficiary outcomes (pre-/post).

Results Feasibility (enrolled/recruited = 78.5–86.7%), acceptability (7.55–8.35 [SD 1.50–2.06]), and usability (7.85–8.81 [SD 1.50–2.6]) of the modified intervention (1 = low;10 = high) were high. Pre-/post-intervention clinician knowledge (12.33–12.28, SD 1.80–2.84; -0.52, SD 1.95) was high. Caregiver self-efficacy increased (0.81 [SD 0.62] $p < 0.01$). Beneficiary outcomes did not improve nor decline (> 0.05).

Conclusions Engaging informal caregivers to assist clinicians with providing an intervention adapted to the needs of those with Alzheimer's Disease or other dementias was feasible, acceptable, and usable. Further testing in a broader sample of those with dementia in various settings is needed.

Keywords Informal Caregivers · Engagement · Medicaid Home and Community-based Services · Alzheimer's Disease · Dementia

Abbreviations

ADL	Activities of daily living
ABLE	Advancing Better Living for Elders
AD	Alzheimer's Disease

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✉ Sandra L. Spoelstra, spoelsts@gvsu.edu; Alla Sikorskii, sikorska@msu.edu; Monica Schueller, schuelmo@gvsu.edu; Viktoria Basso, bassov@mail.gvsu.edu; Autumn Baldwin, baldwiau@mail.gvsu.edu | [1]Kirkhof College of Nursing, Grand Valley State University, 301 Michigan St, Room C352, Grand Rapids, MI 49504, USA. [2]Department of Psychiatry, Michigan State University, 965 Wilson Road, East Lansing, MI 48824, USA. [3]Statistics, Grand Valley State University, 301 Michigan Street, Grand Rapids, Michigan 49504, USA.

ADEAR	Alzheimer's Disease Education and Referral
CAPABLE	Community Aging in Place, Advancing Better Living for Elders
ED	Emergency Department
GSE	General Self-Efficacy
HCBS	Home and Community-based Services
IADL	Instrumental activities of daily living
IRB	Internal Review Board
MDS-HC	Minimum Data Set-Home Care
OT	Occupational Therapist
RN	Registered Nurse
SW	Social Worker
SD	Standard Deviation

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1 Contributions to the literature

- This pilot study added care tailored to the needs of those with Alzheimer's Disease or other dementias to an evidence-based intervention (CAPABLE) to inform future studies, clinical care, and health policy.
- Clinicians in a Medicaid Home and Community-based Services (HCBS) program were trained to engage informal caregivers to help with providing an evidence-based intervention (CAPABLE) to those with Alzheimer's Disease or other dementias.
- Engaging informal caregivers to help clinicians with providing an evidence-based intervention to those with Alzheimer's Disease or other dementias were feasible and acceptable; and the adapted intervention (CAPABLE) was usable.

2 Background

Approximately 60 million people aged 65 and older live with Alzheimer's Disease (AD) or other dementias in the United States, and the number is projected to reach 139 million by 2050 [1–3]. Those with dementia often develop difficulty with physical function and cognitive capabilities over the course of the disease, necessitating the need for unpaid care by informal caregivers [1]. As a result, there are 16.3 million informal caregivers who care for someone with dementia [1, 4, 5]. Interventions that improve caregiver knowledge, and subsequently their self-efficacy, can improve the care provided to the individual with dementia [4]. However, most caregiver interventions focus on increasing caregiver confidence or reducing burden, stress, or depression. Consequently, a paucity of evidence exists on enhancing caregiver knowledge and skills when using evidence-based interventions, particularly while caring for someone with AD or other dementias.

We deployed an evidence-based intervention to improve (or maintain) physical function in a National Institutes on Aging study (parent trial) from 2018 to 2022 [6, 7]. We found 20.1% of the individuals eligible to receive the intervention did not take part due to poor cognition or inability to follow directions [7]. Cognitive decline and difficulty following directions are one of the earliest signs of dementia [1]. To the best of our knowledge, the intervention used in our parent trial had not been evaluated in individuals with dementia. Hence, we conducted a pilot study (2021–2022) to examine feasibility, acceptability, and usability of improving informal caregiver knowledge and skills so they could help clinicians with providing the intervention to individuals with dementia. This is important, as new ways of caring for the growing number of individuals with dementia are needed.

2.1 Parent trial

Our published papers [6, 7] described the intervention used in our parent trial to improve (or maintain) physical function of older adults in a Medicaid Home and Community-based Services (HCBS) program in Michigan. Briefly, we trained

clinicians to use the intervention and deployed a bundle of implementation strategies to provide the intervention to beneficiaries in addition to their usual care. The main outcomes were adoption and sustainability of the intervention in the HCBS program. We examined pre-/post-intervention clinician self-efficacy and attitude towards use of evidence and the beneficiary outcomes (instrumental activities of daily living [IADLs], activities of daily living [ADLs], depression, pain, falls, emergency department [ED] visits, and hospitalizations).

2.1.1 Medicaid home and community-based services program

Medicaid HCBS 1915(c) programs support low-income, disabled, or older adults who are living in the community [8]. The Michigan HCBS program cares for 12,000 beneficiaries who are eligible for nursing home admission, need assistance with IADLs or ADLs, have income less than 300% of the Federal poverty level, and have an informal caregiver [9]. Usual care includes registered nurse (RN) and social worker (SW) care management and 19-support services (e.g., transportation, counseling, meals, personal care, and medication management) [9]. More than 15% (> 1800) of the beneficiaries in the Michigan HCBS program have an AD or dementia diagnosis, which is likely to be under-reported [10].

2.1.2 Intervention

The intervention evolved from ABLE (Advancing Better Living for Elders), which included 5 occupational therapy (OT) home visits over 12-weeks to install assistive devices, modify the home, and teach energy conservation and one physical therapist visit to address functional concerns [6, 11, 12]. CAPABLE (Community Aging in Place, Advancing Better Living for Elders) expanded on ABLE, increasing to 6 OT visits, adding 4 RN visits to address health issues that impact function, and home alterations using a repair person (e.g., installs devices and environmental modifications) over to 16-weeks [13, 14]. CAPABLE was adapted to fit the Michigan HCBS program, adding SWs to address social and emotional needs and an aging-in-place toolkit (e.g., topics on bathing, constipation, and depression) to support self-management [15]. Flexibility in the number and type of home visits based on need were allowed [15]. Medicaid policy limited home alterations or modifications what was medically necessary [15].

2.2 Purpose

The purpose of this paper is to describe our pilot study, which engaged informal caregivers to help clinicians in providing the intervention to beneficiaries with dementia. There were 4 objectives. Objective 1: To add content tailored to the care of an individual with AD or other dementias to the intervention. Objective 2: To add engagement of informal caregivers to help provide the intervention to clinician training modules; to train the clinicians; and to examine the feasibility, acceptability, usability, and satisfaction of clinicians. Objective 3: To examine the feasibility, acceptability, usability, and satisfaction of informal caregivers with providing the intervention to those with dementia. Objective 4: To examine feasibility of use of the intervention by beneficiaries with dementia and their outcomes.

3 Methods

3.1 Study design

A 5-month mixed methods pilot study was conducted. Objective 1: Descriptive statistics and qualitative design were used to collect data from content experts and 5 consecutively enrolled informal caregivers of beneficiaries with AD in the HCBS program to modify the intervention. Consecutive enrollment is known to be effective in practice-based research [16–18]. Descriptive statistics and open-ended question design were used to Objective 2: Descriptive statistics and open-ended question design were used to examine clinician knowledge (pre-/post-test), feasibility, usability of the intervention, and satisfaction with training. Objective 3: Descriptive and pre-/post-intervention design were used to examine feasibility, acceptability, usability, and satisfaction of caregivers with the intervention. Objective 4: Pre-/post-intervention design were used to examine beneficiary outcomes.

3.2 Ethical considerations and consent to participate.

We obtained Internal Review Boards (IRBs) approval for the study from the university (#20-213-H) and State of Michigan (#201811-08-EA-R1). Informed consents were obtained from study participants (clinicians, informal caregivers, and beneficiaries) after full disclosure, as detailed in our procedures.

3.3 Study setting and participants

The setting for our study were 3 HCBS sites in Michigan from our parent trial. Participants included the following. In addition to the content experts, 5 informal caregivers of beneficiaries with AD assisted with modification of the intervention. A convenience sample of clinicians, beneficiaries who had an AD diagnosis and their informal caregivers were included.

3.4 Eligibility

Three groups of individuals were eligible to take part in the study: clinicians, informal caregivers, and beneficiaries. Included were RNs, SWs, and OTs (clinicians) employed at the sites, informal caregivers of a beneficiary with an AD or dementia diagnosis if they were 18 years of age or older and spoke English, and beneficiaries who were 65 years of age or older and had an AD or dementia diagnosis. Excluded were clinicians not employed at the sites, caregivers of individuals without dementia, less than 18 years of age, or non-English speaking, and beneficiaries who did not have a diagnosis of dementia or were less than 65 years of age.

3.5 Intervention modification

Caregiver engagement strategies that are known to be effective are use of short and succinct evidence-based interventions, use of high-quality clinicians, and use of supporting materials tailored to the needs of the persons cared for [19]. The parent trial intervention was evidence-based and used high-quality clinicians [6, 7, 11–15], two effective caregiver engagement. However, one strategy, supporting materials (toolkit) tailored to those with dementia was lacking.

Another problem is that the needs of older adults (44.3% of ADLs [e.g., bathing and grooming] and IADLs [e.g., shopping and banking]) are often not met by an informal caregiver [20]. This may be caused by an incongruence between caregiver training and the competencies needed to perform care. Caregiver competency domains include medical and nursing skills, assessment, collaborating, and communication [21]. However, most caregiver training programs focus on problem solving, use of community resources, and communication [22]. It may be possible that caregivers need training on assessment, nursing skills, home exercise, and planning.

Powell and colleagues [23] recommend use of a toolkit when implementing an intervention. Toolkit use is also known to increase adherence when using an evidence-based intervention [24]. To address gaps in the toolkit, content tailored to care of those with AD or other dementias and nursing skills (e.g., assessment) needed to be added prior to engaging caregivers to help clinicians provide the intervention to beneficiaries.

3.6 Procedures

To address the first objective study staff added content to the intervention toolkit from the Alzheimer's Disease Education and Referral (ADEAR) Center website [25] and the literature [26]. The toolkit was emailed to content experts and (after consent) mailed to informal caregivers for review. Study staff collected data (e.g., edits, additions, deletions, suggestions, and items needing clarity) from content experts and caregivers in Excel. Data were reviewed by the content experts and study staff using an iterative process to identify and agree upon toolkit changes. The revised toolkit was reviewed and approved by the IRBs prior to printing. The cost of printing a 4-color, wire bound toolkit, tabulated by section, was $25.32 per toolkit (see Additional file 1).

For the second objective study staff prepared the clinician training module (1-h, online). Five HCBS supervisors reviewed the module and provided input on improving the training, to assure training objectives were met. The training module was finalized (see Additional file 2). Clinician surveys were prepared in Qualtrics (baseline, pre-/post-test, satisfaction). An email was sent to each clinician, explaining the study and asking them to take part, which included links to the consent and initial surveys (baseline; pre-test); training module; toolkit; and final surveys (post-test; satisfaction).

If interested, the clinician completed the informed consent (prior to data collection), completed pre-surveys, reviewed the training module, and completed post-surveys.

To address the third and fourth objective, beneficiaries with AD and informal caregivers were identified by managers at the site. The manager called the caregiver and beneficiary to explain the study. If both were interested, the manager completed a screening form and provided the form to study staff. After receipt of the screening form, study staff mailed the consent and a toolkit to the caregiver, waited a week, then called the caregiver and beneficiary to conduct informed consent. If interested, the caregiver and beneficiary signed the forms and mailed them to the study staff. For beneficiaries who did not have the ability to understand informed consent, the caregiver functioned as surrogates, which is customary practice in AD trials [27–29]. After receipt of the signed consents, study staff completed the baseline survey (month 1) via phone and informed the site that the caregiver and beneficiary were enrolled in the study, and the clinician should begin to provide the intervention to the beneficiary. Study staff completed the monthly (2, 3, and 4) and exit (month 5) surveys via phone and obtained pre-intervention outcome data on the Minimum Data Set-Home Care (MDS-HC) from the electronic health record.

3.7 Measures and data collection

Field notes were used to collect qualitative data on intervention modifications from content experts and caregivers. Feasibility data were collected on the screening form (caregivers/beneficiaries) and in online surveys (clinicians). Clinician age, sex, race, ethnicity, discipline, knowledge (pre-/post-test), and satisfaction were collected via online surveys (quantitative) or in comments (qualitative). Caregiver age, sex, race, ethnicity, education level, and relationship to beneficiary (baseline); self-efficacy (baseline/exit); and acceptability, usability, and satisfaction with the toolkit (months 2–4/exit) measured on a scale of 1–10 (10-highest) and comments (qualitative) were collected via phone interviews. Beneficiary age, sex, race, ethnicity, and outcomes (same as parent trial) were collected from the MDS-HC assessment completed just prior to consent (pre-intervention) and via caregiver phone calls at exit (post-intervention). The General Self-efficacy (GSE) [30] and MDS-HC [31] are described in the parent trial protocol paper [6]. The GSE is a 10-item tool (Cronbach's alpha 0.79–0.90) [30]. Cronbach's alpha at baseline was 0.91 for the caregiver self-efficacy scale. The MDS-HC is a self-reported, person-centered assessment for the collection of beneficiary minimum essential nursing data, with reliability and validity, and used in the HCBS program since 1993 [31].

3.8 Statistical analyses

Thematic analyses (qualitative) were used to examine field notes and comments in surveys. Descriptive statistics were used to examine socio-demographic characteristics and satisfaction. Feasibility was reflected by the proportion of consenting caregivers and beneficiaries out of those who were eligible and approached. A proportion of caregivers who completed the exit assessment out of those who consented was also used. Counts of toolkit use reported by caregivers (months 2–4 and exit) were summarized to reflect acceptability. Self-efficacy of caregivers at baseline and exit were compared and was summarized using paired t-tests. Preliminary efficacy of the intervention delivered via engagement of informal caregivers to use the toolkit for AD or dementia beneficiaries were summarized from matched pairs t-tests for continuous variables and McNemar's tests for binary variables.

4 Results

4.1 Intervention modifications (Objective 1)

Two content experts and study staff critically examined the parent trial intervention and the ADEAR [25] website to tailor care of an individual with dementia. Nine new sections specific to AD or dementia were added to the toolkit used by the beneficiaries in the parent trial. The new sections were labeled advanced care planning; assessment; AD; agitation and aggression; delirium; hallucinations, delusions, and paranoia; physical activity and AD; rummaging and hiding things; wandering. In addition, 6 existing sections had content added tailored to the needs of those with AD or other dementias. The sections changed included bathing, fall prevention, home safety, medication management, pain, and sleep disruption. Finally, the language in the toolkit was changed to address use by either a beneficiary or an informal caregiver.

Five informal caregivers reviewed the 15 (9 new; 6 existing) modified toolkit sections. Mean age of the caregivers were 46.4 years (range 33–61; standard deviation [SD] 6.60). Four were female (80%) and one was male (20%). Four (80%) were White and one (20%) was African American. Three (60%) had an associate degree and two (40%) were high school educated. Caregivers suggested 131 additions, deletions, modifications, clarifications, or edits (compiled by toolkit section). All 5 caregivers stated: *"the toolkit will be very beneficial to new caregivers".*

Content experts and study staff reviewed the caregiver suggestions, using an iterative process to refine and collate the data, until agreement was reached on whether to accept or reject changes to the toolkit. Thirty modifications were made, and the toolkit was finalized for use in the pilot study (see Additional file 1).

4.2 Clinician outcomes (Objective 2)

The parent trial trained clinicians in the Michigan HCBS program to use of the intervention with beneficiaries [6, 7]. A continuing educating unit (CEU) on AD or other dementias causes, symptoms, and treatment was provided to clinicians in 2021. The pilot study training module built upon these prior modules, including an overview of the intervention and AD and dementia causes, symptoms, and treatment. Content on informal caregiver engagement with providing the intervention to beneficiaries was added to the training module. The toolkit and a pocket card to help identify beneficiaries who would benefit from use of the intervention and tips on caregiver engagement were provided to clinicians.

Figure 1 shows 78.5% (106 of 135) of the clinicians who were recruited chose to take part in the study (feasibility). Once enrolled, 95.3% (101 of 106) of the clinicians completed the entire study (acceptability).

Table 1 shows the clinician data. Mean age were 45.78 years (SD 10.48), and most were female (97.2%) and White (93.4%). Nearly equal numbers of RNs (55.2%) and SWs (42.9%) participated. Clinician knowledge did not change pre- to post-test (−0.52 [SD 1.95]), both were high. A high rate of satisfaction with the training content (8.09 [SD 1.60]) and format (7.55 [SD 2.06]) were found. Clinicians perceived that the content in the training module was new for both caregivers (8.35 [SD 1.50]) and clinicians (7.85 [SD 1.92]). Intent to use the intervention was high (8.23 [SD 1.71]) among this sample of clinicians (usability).

Clinicians made 12 comments in the satisfaction survey. Using an iterative process, 2 themes were identified. First, *"the toolkit will be helpful to caregivers"* (n = 9, 75%), and second, *"self-management strategies"* (n = 3, 25%). Clinicians commented multiple time about the usability of the intervention. *"The toolkit will help caregivers check for problems and manage issues prior to contacting me." "The information in the toolkit is packaged in a helpful manner."*

4.3 Caregiver outcomes (Objective 3)

Of those caregivers recruited, 86.2% (52 of 58) took part in the study (feasibility); and once enrolled, 69.2% (36 of 50) completed the entire study (acceptability) (Fig. 1). Upon consent (caregiver; beneficiary) study staff informed clinicians at the site that the caregiver and beneficiary were ready to utilize the intervention. The clinician, caregiver, and/or the beneficiary decided when to begin using the intervention.

Table 2 shows caregiver findings. Mean age were 63.28 years (SD 11.29), the majority were female (80%), White (88%), and high school (52%) or college (46%) educated. Over half (58%) of the caregivers were a child, a few were a spouse (16%), with the remainder varied (26%). Caregiver self-efficacy improved over the 5- months (2.67 [SD 0.62] to 3.42 [SD 0.38]; 0.81 [SD 0.62]; $t(34) = 7.70$, $p < 0.01$; and satisfaction with toolkit content (range: 8.60–9.07) and format (range: 8.95–9.07) were high. Most caregivers found the toolkit to be helpful (range: 7.98–8.81) (usability). No differences were found ($p > 0.05$) between caregivers who dropped out and those who completed the exit assessment (see Additional file 3). However, we did find that male caregivers had a higher rate of drop out (Chi-square(1) = 3.00, $p = 0.08$) than female caregivers.

Caregivers utilized every toolkit section more than once (Fig. 2). Overall, the toolkit was used 813 times. This included 433 (range 12–21) uses in month-2, 189 (range 4–11) uses in month-3, 74 (range 3–7) uses in month-4, and 117 (range 20–42) uses in month-5 (exit) (see Additional file 4). On average, caregivers used the toolkit 3.1 times the second month, 4.2 times the third month, 2.7 times the fourth month, and 3.1 times at exit.

There were 188 unique comments made by caregivers during phone interviews. Using an iterative process, 5 themes were identified from these comments, "*toolkit was helpful"* (n = 103, 54.8%), *"read the entire toolkit and believe most sections will be helpful at some point in time"* (n = 51, 27.1%), *"used the assessment instructions and grid"* (n = 20, 10.6%), "did not use the toolkit" (n = 8, 4.7%), and *"had COVID issues"* (n = 6, 3.2%). Over half (n = 27, 52%) of caregivers stated the toolkit would be most beneficial for new caregivers.

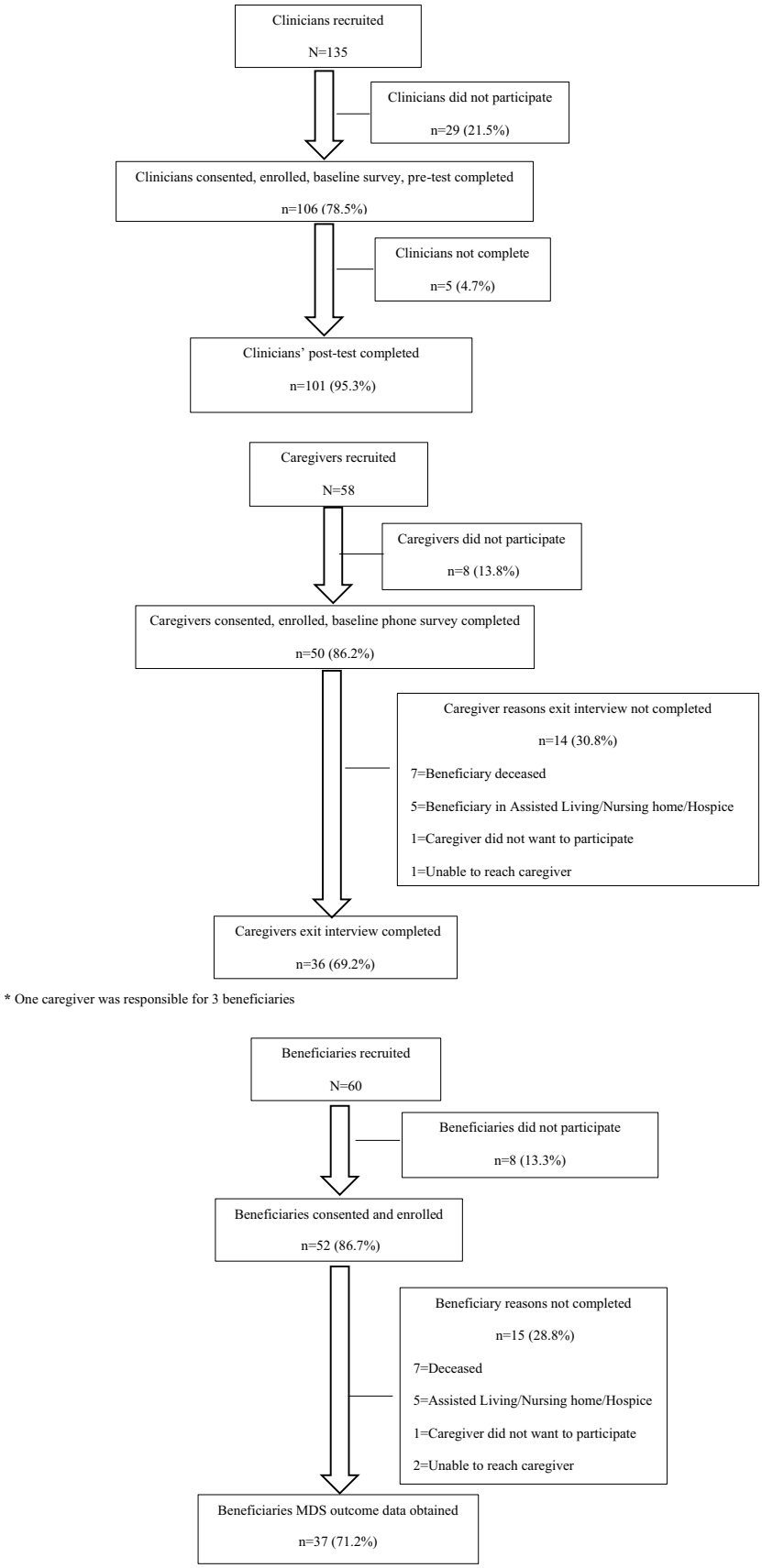

Fig. 1 CONSORT diagrams of clinician, caregiver, and beneficiary study participants

Table 1 Clinicians' characteristics, training satisfaction, role clarification, newness of content and intent to use, and knowledge

	N (%) or mean (SD)
Age	45.78 (10.48)
Sex	
Female	103 (97.2)
Male	3 (2.8)
Race	
White	99 (93.4)
Black or African American	2 (1.9)
Other	5 (4.7)
Ethnicity	
Hispanic	5 (4.8)
Discipline	
Social Worker	58 (55.2)
Registered Nurse	45 (42.9)
Other	2 (1.9)

	Mean (SD)
Satisfaction with training*	
Content	8.09 (1.60)
Format	7.55 (2.06)
Clarification of clinician's role*	8.35 (1.50)
Newness of training content*	7.85 (1.92)
Intent to use new information*	8.23 (1.71)

	Pre-test Mean (SD)	Post-test Mean (SD)	Change pre-/post-test Mean (SD)
Knowledge score	12.33 (1.80)	12.28 (2.84)	−0.52 (1.95)**

*Range of 1–10

**Knowledge score lower on post-test than pre-test; ($p < 0.05$)

There were 188 unique comments made by caregivers during phone interviews. Using an iterative process, 5 themes were identified from these comments, the most common theme was the "*toolkit was helpful"* (n = 103, 54.8%), *"read the entire toolkit and believe most sections will be helpful at some point in time"* (n = 51, 27.1%), *"used the assessment instructions and grid"* (n = 20, 10.6%), "did not use the toolkit" (n = 8, 4.7%), and *"had COVID issues"* (n = 6, 3.2%). Over half (n = 27, 52%) of caregivers stated the toolkit would have been most beneficial for a new caregiver.

Numerous caregivers commented about usability. *"I think this will really help me to take better care of my mother." "I think this will help caregivers to provide better care." "I am a good problem solver so this will help me be more independent as a caregiver." "I am now keeping a log of my mother's behaviors and observations to share with the physician and track them over time."* Notably, 4 caregivers stated they were *"unaware of the stages of AD"*, after reading the toolkit section regarding AD; and 5 caregivers stated that *"the information would also be helpful to caring for themself"* (e.g., depression, exercises, etc.).

4.4 Beneficiary outcomes (Objective 4)

Of those beneficiaries who were recruited, 86.7% (52 of 60) participated (feasibility); and once enrolled, 71.2% (37 of 52) completed the entire study (acceptability) (Fig. 1). As noted previously, clinicians at the site were informed that the caregiver and beneficiary were ready to use the intervention. The clinician, caregiver, and/or the beneficiary decided when to begin using the intervention.

The beneficiary findings are shown in Table 3. This group of beneficiaries were older (mean age 81.23 years [SD 9.27] than those in the parent trial [7], and mostly female (77%) and White (88%). Beneficiary outcomes did not improve nor decline significantly ($p > 0.05$) after use of the intervention (usability). Falls (29% to 38%), ED usage (23% to 32%), and hospitalizations (13% to 12%) were high at baseline and exit. Nor did summed depression (5.52–4.54 [SD 8.75–4.47]),

Table 2 Caregivers' characteristics, self-efficacy (baseline, exit; change baseline to exit); and satisfaction and helpfulness of toolkit

	N (%) or mean (SD)
Age	63.28 (11.29)
Sex	
Female	40 (80)
Male	10 (20)
Race	
White	44 (88)
Black or African American	4 (8)
Native American or Alaskan Native	1 (2)
More than 1 race	1 (2)
Ethnicity	
Hispanic	1 (2)
Education (highest level)	
High School	26 (52)
College	23 (46)
Middle School	1 (2)
Relationship to beneficiary	
Daughter/Son	29 (58)
Other*	13 (26)
Spouse	8 (16)

	Baseline Mean (SD)	Exit Mean (SD)	Change Baseline to Exit Mean (SD)
Self-efficacy	2.67 (0.62)**	3.42 (0.38)	0.81 (0.62)***

	Month 2 Mean (SD)	Month 3 Mean (SD)	Month 4 Mean (SD)	Exit Mean (SD)
Satisfaction with toolkit				
Content	8.78 (1.70)	9.03 (1.65)	9.07 (1.44)	8.60 (2.27)
Format	8.95 (1.77)	9.58 (0.84)	9.28 (1.25)	9.33 (1.71)
Helpfulness of toolkit	7.98 (2.16)	8.81 (1.79)	8.79 (1.88)	8.23 (2.34)

*One caregiver cared for 3 beneficiaries ("other" relationship with all three)

**Caregiver self-efficacy scale Cronbach's alpha 0.91 at baseline

***Change in self-efficacy is statistically significant $t(34) = 7.70$, $p < 0.01$

IADLs (42.69–42.22 [SD 9.67–11.40]), ADLs (22.44–23.49 [SD 17.09–19.56]), and pain (2.85–5.56 [SD 2.91–3.36]) scores improve nor decline. Comments from beneficiaries about use of the adapted intervention were not collected. Beneficiary comments on use of the intervention (usability) were reported in our main trial publication [7].

5 Discussion

From the first suspicion that something is wrong, through the progression of cognitive, behavioral, and social changes that occur in those with AD and other dementias, an persons quality of life can be affected in profound ways [1, 4]. Use of an evidence-based intervention like the one in our parent trial (CAPABLE) [13–15], could provide individuals with the AD or other dementias with comfort, dignity, and independence for a longer period; and benefit their informal caregivers by providing the knowledge and skills to provide better care [3, 5].

The intervention and clinician training used in the parent trial (CAPABLE) [13, 14] were modified to support informal caregiver engagement, so that the caregivers could help provide care to individuals with AD or other dementias. Content on known gaps in caregiver competencies [21] (e.g., assessment, nursing skills, home exercises, and planning) and care

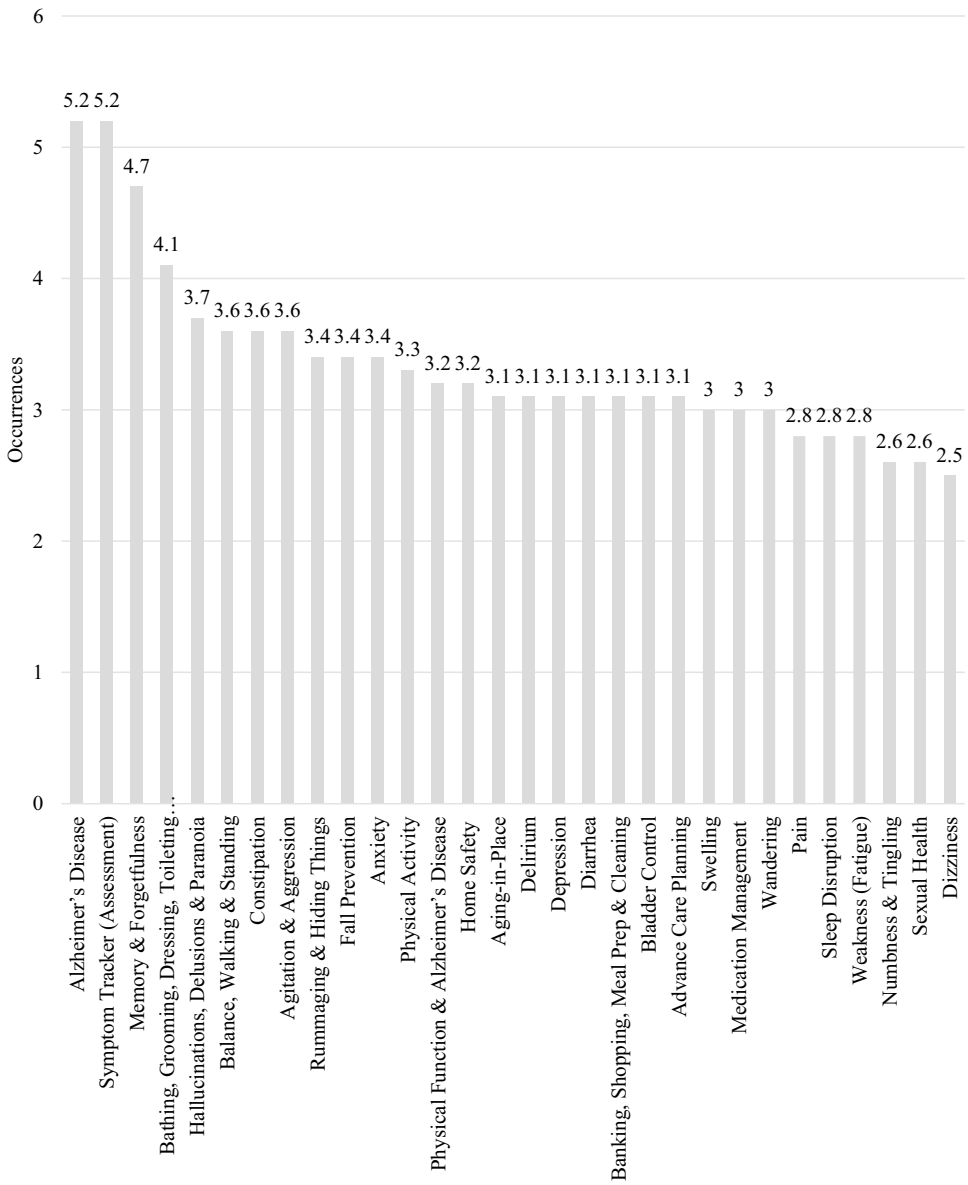

Fig. 2 Average number of times a toolkit section was used by a caregiver per month

tailored to the needs of a person with AD or other dementias (e.g., managing behavioral symptoms) were added to the clinician training module and toolkit used in the intervention [19, 21].

As this was the first known attempt to use the intervention (CAPABLE) [13–15] in individuals with dementia, we modified the intervention and examined feasibility, acceptability, and usability of the adapted intervention. Compared to similar types of trials [32, 33], the feasibility (78.5–86.7%), acceptability (7.55–8.35 [SD 1.50–2.06]) and usability (7.85–8.81 [SD 1.50–2.6]; 1-low) of the intervention were high in this convenience sample in the HCBS program.

A ceiling effect on clinician knowledge (pre-/post-test 82.2 to 81.9%) may have occurred due to prior training on the intervention, as multiple respondents scored near the upper limit [34]. As in prior work, clinicians were highly satisfied with the training and intended to use the knowledge gained when providing care to beneficiaries in this sample [7].

Similar to other studies [35], informal caregiver self-efficacy improved over the course of the study. Informal caregivers used the toolkit often (≥ 3 times a month) and for a prolonged period of time (5-months), comparable to other trials examining use of toolkits for caregivers of those with AD [36, 37]. Notably, caregivers used every section of the toolkit, not just those related to care of an individual with AD or other dementias.

No difference in beneficiary outcomes were found (pre-/post-intervention) over the course of the trial, nor did they decline. However, pain scores increased, although not significantly, given the size of the sample. Similar to other studies [38], this may have been due to caregiver report of pain (post) compared to an in-person assessment of the MDS-HC (pre) with a clinician.

Table 3 Beneficiaries' characteristics, ADLs, IADLs, pain, depression, falls, ED use, and hospitalizations at baseline and exit

			N (%) or Mean (SD)
Age			81.23 (9.27)
Sex			
Female			40 (77)
Male			12 (23)
Race			
White			46 (88)
Black or African American			4 (8)
Native America or Alaskan Native			1 (2)
Asian			1 (2)
Ethnicity			
Hispanic			1 (2)
	Baseline Mean (%)	Exit Mean (%)	Change Baseline to Exit Mean (%)
Falls			
None	37 (71)	23 (62)	(−9)
One or more	15 (29)	14 (38)	(−9)
ED usage	12 (23)	12 (32)	0 (+9)
Hospitalizations	7 (13)	8 (12)	(−1)
Depression summed score	5.52 (8.75)	4.54 (4.47)	−1.46 (9.92)
IADL summed score	42.69 (9.67)	42.22 (11.40)	−1.00 (7.86)
ADL summed score	24.44 (17.09)	23.49 (19.56)	−1.05 (11.55)
Pain summed score	2.85 (2.91)	5.56 (3.36)	2.69 (3.75)

Although the intervention (CAPABLE) we examined used different approaches and targeted a variety of outcomes, it did share common features with other interventions that improve (or maintain) the physical function and quality of life of individuals with dementia [39]. For example, the interventions provided training to clinicians, supported caregivers, used a standardized program that was individualized to meet the specific and unique needs of the person with dementia, and supplied a means to identify and solve problems [39].

Future research on adapted interventions, such as the one in this study, will benefit from lessons learned by these investigators. As researchers refine these approaches and develop new ones, it is important to continue to evaluate their efficacy and safety, identify more powerful and efficient approaches, train clinicians and caregivers to use them appropriately, increase the availability to those who will benefit from them the most, and continue to keep the quality of life of the person with AD or other dementias as a central focus of care.

5.1 Limitations

One limitation on use of a toolkit may be the cost of printing ($25.32), which may be prohibitive in settings that are financially constrained. Limitations of this study include a pilot pre- to post-design. As beneficiaries age, their outcomes worsen, but this study did not include a control group for a comparison. Also, use of different reporters, clinicians at baseline and caregivers at exit, could have influenced the results as a caregiver's perception of a beneficiary's function may differ from that of clinicians.

6 Conclusions

Despite our study limitations, in this sample in the Michigan Medicaid HCBS program, use of the modified intervention was feasible, acceptable, usable, and all users (clinicians, caregivers, and beneficiaries) were highly satisfied. These findings begin to suggest that use of an adapted evidence-based intervention (CAPABLE) that maintains or improves physical function may be feasible in those with AD and other dementias when informal caregivers are engaged to assist clinicians in providing care. Further testing in a broader sample and setting will need to occur prior to use.

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Availability of data and materials Datasets will be available upon request.

Code availability Not applicable.

Declarations

Ethics approval and consent to participate Protocol described here were approved by the University 20–213-H Institutional Review Board. Participants were informed about aims of study and methods for protection of data privacy. Informed consent was obtained from clinicians, caregivers, and beneficiaries. Reports contain aggregate data allowing no identification of individual participants.

Competing interests The authors declare they have no conflict of interests.

References

1. Alzheimer's Association. 2022 Alzheimer's disease facts and figures. https://www.alz.org/media/documents/alzheimers-facts-and-figures.pdf. Accessed 8 Feb 2022.
2. Zhu Y, Chen Y, Crimmins EM, Zissimopoulos JM. Sex, race, and age differences in prevalence of dementia in Medicare claims and survey data. J Gerontol B Psychol Sci Soc Sci. 2021;76:596–606.
3. Plassman BL, Langa KM, Fisher GG, Heeringa SG, Weir DR, Ofstedal MB, et al. Prevalence of dementia in the United States: the aging, demographics, and memory study. Neuroepidemiology. 2007;29:125–32.
4. National Alliance for Caregiving (NAC), AARP Public Policy Institute. Caregiving in the U.S. 2015. Washington DC: NAC and AARP Public Policy Institute; 2015.
5. Michas F. Alzheimer and other dementia caregivers' unpaid care in the U.S. 2011–2021. https://www.statista.com/statistics/216673/alzheimer-and-dementia-caregivers-unpaid-care-in-the-us/. Accessed 8 Feb 2022.
6. Spoelstra SL, Schueller M, Sikorskii A. Testing an implementation strategy bundle on adoption and sustainability of evidence to optimize physical function in community-dwelling disabled and older adults in a Medicaid waiver: a multi-site pragmatic hybrid type III protocol. Implement Sci. 2019;14:60.
7. Spoelstra SL, Schueller M, Basso V, Sikorskii A. A physical function intervention in community-dwelling disabled and older adults in a Medicaid waiver: results of a multi-site pragmatic hybrid type III cluster randomized trial comparing two implementation strategies. Implement Sci. 2022;17:57.

8. Centers for Medicare & Medicaid Services. Home & Community-Based Services 1915(c). https://www.medicaid.gov/medicaid/home-community-based-services/home-community-based-services-authorities/home-community-based-services-1915c/index.html. Accessed 8 Feb 2022.
9. State of Michigan. MI Choice Waiver Program. https://www.michigan.gov/mdhhs/assistance-programs/healthcare/seniors/michoicewaiver/mi-choice-waiver-program. Accessed 8 Feb 2022.
10. Stokes AC, Weiss J, Lundberg DJ, Xie W, Kim JK, Preston SH, et al. Estimates of the association of dementia with US mortality levels using linked survey and mortality records. JAMA Neurol. 2020;77:1543–50.
11. Gitlin LN, Winter L, Dennis MP, Hauck WW. Variation in response to a home intervention to support daily function by age, race, sex, and education. J Gerontol A Biol Sci Med Sci. 2008;63:745–50.
12. Gitlin LN, Winter L, Dennis MP, Corcoran M, Schinfeld S, Hauck WW. A randomized trial of a multicomponent home intervention to reduce functional difficulties in older adults. J Am Geriatr Soc. 2006;54:809–16.
13. Szanton SL, Leff B, Wolff JL, Roberts L, Gitlin LN. Home-based care program reduces disability and promotes aging in place. Health Aff (Millwood). 2016;35:1558–63.
14. Szanton SL, Wolff JW, Leff B, Thorpe RJ, Tanner EK, Boyd C, et al. CAPABLE trial: a randomized controlled trial of nurse, occupational therapist and handyman to reduce disability among older adults: rationale and design. Contemp Clin Trials. 2014;38:102–12.
15. Spoelstra S, Sikorskii A, Gitlin L, Schueller M, Kline M, Szanton SL. Dissemination of CAPABLE model of care in a Medicaid waiver program to improve physical function. J Am Geriatr Soc. 2009;67:363–70.
16. Francis NA. Single subject trials in primary care. Postgrad Med J. 2005;81:547–8.
17. Janosky JE. Use of the single subject design for practice based primary care research. Postgrad Med J. 2005;81:549–51.
18. Moloney ED, Smith D, Bennett K, O'Riordan D, Silke B. Do consultants differ? Inferences drawn from hospital in-patient enquiry (HIPE) discharge coding at an Irish teaching hospital. Postgrad Med J. 2005;81:327–32.
19. Morelli N, Barello S, Mayan M, Graffigna G. Supporting family caregiver engagement in the care of old persons living in hard to reach communities: a scoping review. Health Soc Care Community. 2019;27:1363–74.
20. Beach SR, Schulz R. Family caregiver factors associated with unmet needs for care of older adults. J Am Geriatr Soc. 2017;65:560–6.
21. Harvath TA, Archbold PG, Stewart B, Mongoven J, Bettega K. Assessing family caregiver preparedness: competencies for the caregiving role. Innov Aging. 2018;2:194.
22. Sousa L, Sequeira C, Ferré GC, Neves P, Lleixà -Fortuño M. Training programmes for family caregivers of people with dementia living at home: integrative review. J Clin Nurs. 2016;25:2757–67.
23. Powell BJ, Waltz TJ, Chinman MJ, Damschroder LJ, Smith JL, Matthieu MM, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. Implement Sci. 2015;10:21.
24. Hempel S, O'Hanlon C, Lim YW, Danz M, Larkin J, Rubenstein L. Spread tools: a systematic review of components, uptake, and effectiveness of quality improvement toolkits. Implement Sci. 2019;14:83.
25. National Institute on Aging. About the ADEAR Center. https://www.nia.nih.gov/health/about-adear-center. Accessed 11 May 2022
26. UK Oncology Nursing Society (UKONS). Oncology/haematology 24-hour triage rapid assessment and access toolkit. https://www.ukons.org/site/assets/files/1134/oncology_haematology_24_hour_triage.pdf. Accessed 16 May 2022.
27. Hartlieb KB, Jacques-Tiura AJ, Naar-King S, Ellis DA, Jen KC, Marshall S. Recruitment strategies and the retention of obese urban racial/ethnic minority adolescents in clinical trials: the FIT families project, Michigan, 2010–2014. Prev Chronic Dis. 2015;12: 140409.
28. Quinn C, Dunbar SB, Clark PC, Strickland OL. Challenges and strategies of dyad research: cardiovascular examples. Appl Nurs Res. 2010;23:e15–20.
29. Sygna K, Johansen S, Ruland CM. Recruitment challenges in clinical research including cancer patients and their caregivers. A randomized controlled trial study and lessons learned. Trials. 2015;16:428.
30. Schwarzer R, Jerusalem M. Generalized Self-Efficacy scale. In: Weinman J, Wright S, Johnston M, editors. Measures in health sychology: a user's portfolio. Causal and control beliefs. Windsor: NFER-NELSON; 1995. p. 35–7.
31. Fries BE, Shugarman LR, Morris JN, Simon SE, James M. A screening system for Michigan's home- and community-based long-term care programs. Gerontologist. 2002;42:462–74.
32. Oldenkamp M, Wittek RP, Hagedoorn M, Stolk RP, Smidt N. Survey nonresponse among informal caregivers: effects on the presence and magnitude of associations with caregiver burden and satisfaction. BMC Public Health. 2016;16:480.
33. Nuño MM, Gillen DL, Dosanjh KK, Brook J, Elashoff D, Ringman JM, et al. Attitudes toward clinical trials across the Alzheimer's disease spectrum. Alzheimers Res Ther. 2017;9:81.
34. Salkind NJ. Encyclopedia of research design. Thousand Oaks: SAGE Publications Inc; 2010.
35. Hendrix CC, Bailey DE Jr, Steinhauser KE, Olsen MK, Stechuchak KM, Lowman SG, et al. Effects of enhanced caregiver training program on cancer caregiver's self-efficacy, preparedness, and psychological well-being. Support Care Cancer. 2016;24:327–36.
36. Duggleby W, Swindle J, Peacock S. Self-administered intervention for caregivers of persons with Alzheimer's disease. Clin Nurs Res. 2014;23:20–35.
37. Horvath KJ, Trudeau SA, Rudolph JL, Trudeau PA, Duffy ME, Berlowitz D. Clinical trial of a home safety toolkit for Alzheimer's disease. Int J Alzheimers Dis. 2013;2013: 913606.
38. Bullock L, Bedson J, Jordan JL, Bartlam B, Chew-Graham CA, Campbell P. Pain assessment and pain treatment for community-dwelling people with dementia: a systematic review and narrative synthesis. Int J Geriatr Psychiatry. 2019;34:807–21.
39. Logsdon RG, McCurry SM, Teri L. Evidence-based interventions to improve quality of life for individuals with dementia. Alzheimer's Care Today. 2007;8:309–18.