



Regular Research Article

Does Telehealth Delivery of a Dyadic Dementia Care Program Provide a Noninferior Alternative to Face-To-Face Delivery of the Same Program? A Randomized, Controlled Trial

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ABSTRACT

Objective: This study aimed to determine whether delivery of a dyadic intervention using telehealth was noninferior to delivery of the same program using traditional face-to-face delivery through home visits. **Design:** We conducted a noninferiority randomized controlled trial. **Participants:** Participants had a diagnosis of dementia, were living in the community, and had an informal caregiver who reported difficulties in managing activities of daily living or behavioral symptoms. **Intervention:** Participants were randomized to receive either telehealth or home visit delivery of the same intervention program. **Measurements:** The primary outcome was the Caregiving Mastery Index, secondary outcomes included caregiver's perceptions of change, activities of daily living function, and type and frequency of behavioral symptoms of persons living with dementia. Therapists delivering the intervention recorded the time spent delivering the intervention as well as travel time. **Results:** Sixty-three dyads were recruited and randomized. Both groups reported improvements for the primary outcome, however, these were not statistically significant. There were no significant differences between groups for the primary outcome (mean difference 0.09 (95% confidence interval -1.26 to 1.45) or the secondary outcomes at 4 months. Both groups reported significant improvements in caregiver's perceptions of change. The amount of time spent delivering the content

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*of the program was similar between groups, however offering the intervention via telehealth significantly reduced travel time (mean 255.9 minutes versus mean 77.2 minutes, $p < 0.0001$). **Conclusion:** It is feasible to offer dyadic interventions via telehealth and doing so reduces travel time and results in similar benefits for families. (Am J Geriatr Psychiatry 2020; 28:673–682)*

BACKGROUND

The majority (70%) of people with dementia live in their own home and rely on family members and friends for assistance.¹ Families (described hereafter as care partners) of people with dementia are considered to be key therapeutic agents in care.² Gradual functional and cognitive decline lead to increased need for assistance from families, higher healthcare costs, and institutionalization.^{3,4} Over time it becomes increasingly difficult to support a person with dementia to remain at home as they require more assistance with activities of daily living⁵ and/or experience more distressing changes in their behavior.⁶ The World Health Organization (WHO) has recognized dementia as a public health priority and has urged governments to develop action plans to address the increasing need for care.⁷ Offering dementia care services which incorporate care partners and include strategies to cope with and delay functional decline have been identified as a priority.⁸ Furthermore, the WHO has spoken of both the need to research and translate effective care programs into practice and the need for special considerations to be made for particular populations at disadvantage, such as those in rural and remote areas.⁷

The evidence for nonpharmacologic interventions has been accumulating over the last 15 years. Interventions that promote functional independence and include skills training for care partners have been shown to reduce functional decline, decrease service utilization and improve quality of life for people with dementia.⁹ Interventions are not necessarily expected to increase scores on measures of function but to delay the rate of decline over time. Programs showing beneficial effects have been conducted over five to ten sessions and delivered in the home.¹⁰ One such intervention (“Care of Persons with dementia in their Environments” [COPE]) was found to be effective in a large randomized controlled trial ($n = 237$) conducted

in the United States and led by Gitlin and colleagues.¹¹ Results of the study showed that at four months the persons with dementia were significantly less dependent (Cohen $d = 0.43$). Care partners reported higher levels of wellbeing (Cohen $d = 0.3$). At 9 months, care partners reported “a great deal” of improvement in their lives overall and improved ability to support the person to remain living at home. Barriers to wide adoption may include barriers at the level of the individual (lack of training in evidence-based dementia interventions, lack of confidence working with people with dementia) and at the level of the organization (lack of time, inability to deliver home-based intervention).¹² While some of these barriers could be addressed through training allied health professionals, barriers relating to the capacity to perform multiple home visits are challenging to overcome without additional resources.

The use of telehealth technologies to deliver interventions for people with dementia and their care partners may reduce the costs of delivering the intervention, increase accessibility, and facilitate research translation.¹³ A systematic review found that approximately two thirds of studies examining telehealth interventions found that telehealth interventions were less costly and equally effective as non-telehealth alternatives.¹⁴ Furthermore, there is evidence demonstrating the economic benefits of offering telehealth for people with chronic health conditions.¹⁵ Studies have also demonstrated the feasibility of delivering telehealth intervention to frail older people living at home.¹⁶ Advances in technology mean that videoconferencing can now be achieved using readily available tablet computers and software. This may be used to complement other forms of communication such as e-mail and telephone use. Studies suggest that more interactive modalities (such as the internet) are preferable to those which involve use of the telephone alone.¹³ The use of telehealth programs designed to delay functional decline in people with dementia and improve caregiver sense of mastery and wellbeing has not yet been evaluated.

AIM

This study aimed to determine whether delivery of a dyadic dementia care program using telehealth methods was noninferior to delivery of the same program using the traditional face-to-face home visit delivery methods.

METHODS

This randomized controlled trial compared face-to-face and telehealth delivery of the same dyadic intervention for people with dementia. We chose to use a noninferiority model as we were interested in whether the new treatment (telehealth delivery) was “not worse” than the existing treatment (home visit delivery).¹⁷ The intervention was based on the COPE program but adapted for this trial. This trial was approved by the Southern Adelaide Human Research Ethics Committee and registered with the Australian New Zealand Clinical Trials Registry (ACTRN12617000117314).

The randomization sequence was generated by a statistician using SAS statistical software. The sequence was then transferred to sequentially numbered, opaque, sealed envelopes to conceal allocation from staff involved in recruitment, randomization, treatment, and outcome assessment.

Participants

Participants were recruited via different avenues including a memory clinic, aged care wards within a tertiary hospital, a community-based dementia education service, and local council newsletters. Participants were eligible for inclusion if they had a diagnosis of dementia or probable dementia or a score of less than 24/30 on the Mini Mental State Examination. Eligible participants required assistance with activities of daily living as reported by their carer and/or were experiencing changed behaviors associated with dementia such as apathy, restlessness, anxiety, and sleep disturbance overnight. They were required to have a family member or friend who was closely involved in their care and was able to participate in the intervention. This person (family/friend) needed to have identified that they were experiencing challenges

in providing care or coping with the symptoms of dementia. There were no other specific inclusion/exclusion criteria for the family/friend/supporter.

Sample size was determined by the formula described by Flight and Julious.¹⁸

$$n = \frac{(r + 1)(Z_{1-\beta} + Z_{1-\alpha})^2}{r\left(\frac{\mu_a - \mu_b - l}{\sigma}\right)^2}$$

Where r is the allocation ratio for the groups, α is type I error, β is type II error, l is noninferiority margin, σ is the population standard deviation of the primary outcome. For this study r was set to 1, β was set to 0.1, and α was set to 0.025. We set the effect size of Cohen's d as small, that is, $\frac{\mu_a - \mu_b}{\sigma} = 0.3$ and noninferiority margin at 4 points. Since we do not have data for the population's standard deviation of the Caregiver Mastery Index (primary outcome), we simulated the standard deviation to see the sample size requirements for the trial (Figure in Supplementary Material online). We determined that a total sample size 50–64 (with wide range of standard deviations of the primary outcome) would have 80%–90% power to reject the null hypothesis that telehealth group is inferior to home group visit.

Intervention

The intervention was an adapted version of the COPE dyadic intervention which was developed and tested by Gitlin et al.¹¹ The theory-based intervention involves assessment of the person with dementia, the care partner and their environment followed by identification of key care challenges. The intervention is delivered predominantly by an occupational therapist that works with the care partner to problem solve, educate, and build skills. The occupational therapist addresses stress management and works with the dyad to enhance activity engagement in the person with dementia. Strategies to address key care challenges are tailored to the capabilities and interests of the person with dementia, their care partner and the environment.

Within this trial a few modifications to the intervention were made. First, while the intervention usually involves two consultations with a nurse who provides education about medical management (e.g., pain, hydration, and medication management) and rules out underlying medical issues or untreated infection, this component was not provided. Most of

our participants were referred to the trial by someone employed within a health or long-term care service. Within these services, the person with dementia had very recently received a comprehensive assessment from a nurse with expertise in care of older people. We did not refer trial participants to another nurse for further assessment or treatment. In instances where the occupational therapist had concerns about medication, hydration, or infection, they recommended that the participant visit their general practitioner. Second, while the program is scheduled to be delivered in up to 10 home consultation visits, we altered the schedule so that it consisted of fewer, longer, consultations to increase the efficiency for both the clinician and the person with dementia and their carer. The program offered in this trial was scheduled to be delivered in up to eight consultations delivered over up to 16 weeks with each session lasting approximately 60 minutes each (either in home or through telehealth).

Participants allocated to the home visit group received up to eight visits in the home from the occupational therapist. Participants allocated to the telehealth group received the first two consultations in the home with the visiting therapist and the remaining six sessions were provided using telehealth technologies. The sessions in the home provided the opportunity for in-home environmental assessment, rapport building, and familiarity with the videoconferencing program. These participants were given the option of using their own device (laptop, tablet, or smartphone) and in these cases they were shown how to access the Cisco Webex software on their own device. Alternatively, they could loan a tablet which had the videoconferencing software already installed. The therapist spent time demonstrating and trialing videoconferencing with the participant during one of the first two consultations.

Occupational therapists who delivered the program received 2 days of training as well as an intervention manual and all the documentation required in order to deliver the program. Regular (fortnightly) meetings were held with interventionists to discuss cases and treatment plans and monitor fidelity to the intervention. Therapists also kept treatment notes, time logs, and recorded the dates in which key components of the program were offered. Occupational therapists were trained in how to use the tablet devices and videoconferencing software and had access to an information technology telehealth specialist for troubleshooting.

Outcomes Assessed

Assessments were conducted prior to randomization (baseline assessment) and following the 4-month intervention program (postintervention). We collected information about the characteristics of study participants (age, gender, and living arrangements) and the number and type of symptoms and time spent caregiving. Outcome assessments completed at the end of the intervention program were conducted by a research assistant not otherwise involved in the study and blinded to allocation.

Primary outcome

The primary outcome was the Caregiving Mastery Index.¹⁹ This was selected as the primary outcome measure as much of the focus of the intervention is on educating, training, and up-skilling the care partner to develop mastery despite expected decline in function in the person with dementia. The Index comprises six items which measure the carer's confidence and perception of providing care and managing care concerns. Each item is rated on a Likert scale and higher scores reflect greater mastery; total score ranges from 0 to 24. The Index has been used to measure other caregiver interventions.²⁰

Secondary outcomes

The Perceived Change Scale²¹ is a 13 item carer questionnaire. The scale assesses whether the care partner perceives things are getting better or worse in a number of areas including managing day to day care challenges, feeling overwhelmed, feeling upset, sleeping, and having time for oneself. The scale also uses a Likert scale and scores are totaled with higher scores reflecting better outcomes (range: 13–65). The Caregiver Assessment of Function and Upset is a psychometrically sound²² 15-item measure modeled on the Functional Independence Measure.²³ Instrumental activities of daily living (such as using the phone, shopping, and meal preparation) and basic activities of daily living (transfers, eating, and bathing) are assessed through discussion with the care partner and scores are given based on the person's function ranging from a score of 7 for independence to a score of 1 for complete help required. Scores can be reported as totals (range: 15–105) or subtotals (for

instrumental activities of daily living (range: 8–56) and basic activities of daily living (range: 7–49). The Caregiver Behavioral Occurrence and Upset Scale is modeled on the Agitated Behavior in Dementia Scale²⁴ which evaluates behaviors such as verbal aggression, refusing care, restlessness, anxiety, waking overnight, and repetitive questioning. The carer is asked to rate whether the behavior has occurred, how often, and how bothered or upset they were by the behavior. The scale used in the study was expanded and contained 22 items, therefore, capturing information about a wider range of behaviors. We used the measure to report the total number of behaviors experienced, the average frequency (by adding the frequency responses for behaviors identified as present and then dividing by the applicable number of behaviors) and the mean level of upset for applicable behaviors. At the assessment conducted postintervention, we asked care partners to complete a short questionnaire evaluating the usefulness of the program. The evaluation consisted of 12 questions and multiple-choice responses including whether they would recommend the program to others in similar situations. Therapists who delivered the intervention kept logs of their time, recording travel time as well as time spent directly with the research participant.

Data Analysis

Data were reported descriptively where applicable. We used linear mixed models with random intercept and compound symmetry covariance structure to calculate the mean difference for outcome variables at baseline and postintervention. The covariate variables for linear mixed models were randomization groups, visit (baseline and postintervention), visit \times group, and baseline score for the outcome variables. For linear mixed models, participants were treated as random effects (random intercept) in order to account for the repeated measurements at baseline and postintervention.

RESULTS

We recruited 63 dyads to the study between May 2017 and April 2019. Details regarding

recruitment and withdrawals are presented in [Figure 1](#)

As seen in [Table 1](#), there were slightly more males with dementia included in the study ($n = 38$, 60%) and more of the care partners were female ($n = 48$, 76%). Most care partners were spouses of the person with dementia. Cognitive assessment scores arising from the Mini Mental State Examination suggested that participants had mild-to-moderate severity impairment. On an average, the care partner reported that they had taken on carer duties for almost 3 years and reported their levels of knowledge about dementia (out of 10) as an average of 5.8 in the group receiving home visits and 6.6 in the people receiving telehealth intervention. Seven of the participants lived in towns classified as being rural and therefore had reduced access to specialist dementia services.

Effects of Intervention

Results from administration of the outcome measures by the blinded assessor are reported in [Table 2](#).

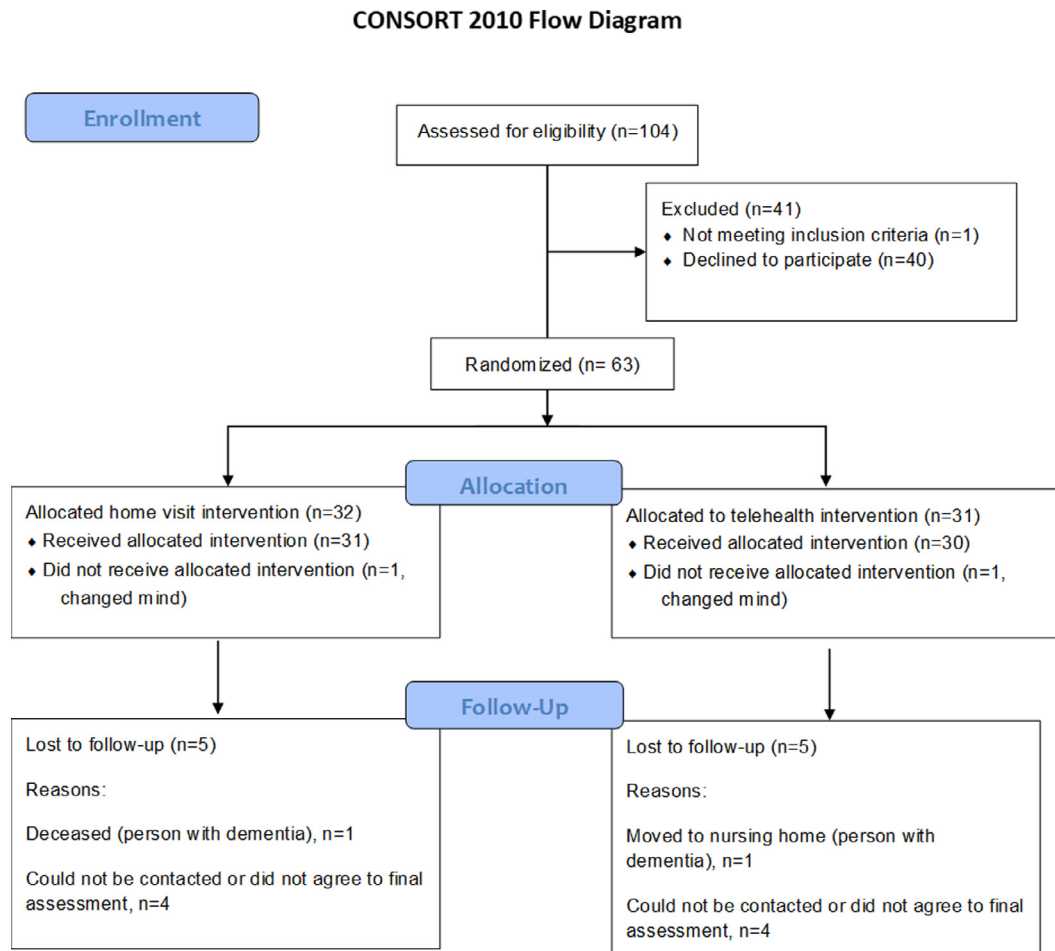
Within group differences

Both groups reported small but nonsignificant gains when administered the Caregiver Mastery Index. While the increased scores were nonsignificant, the intervention appeared to prevent the typical trajectory of decline associated with dementia in both arms. Both groups reported significant improvements in perceptions of caring measured using the Perceived Change Index. Participants allocated to the telehealth intervention arm experienced greater functional decline over time (according to the Caregiver Assessment of Function and Upset) but also a greater reduction in the number of behaviors reported.

Between group differences

The difference between groups for the Caregiver Mastery Index, the primary outcome measure, was 0.09 (95% confidence interval -1.26 to 1.45 , plotted in [Supplementary Figure 2](#)) suggesting that telehealth delivery of the intervention was noninferior to traditional face-to-face delivery of the intervention. There were no statistically significant differences between groups for any of the secondary outcomes assessed.

FIGURE 1. CONSORT flow diagram.



Therapist time spent delivering the intervention is presented in Table 3. The average amount of time spent delivering the intervention (content) was similar in both groups although slightly higher for those receiving home visits. However, the therapist spent considerably less time travelling for those who received telehealth intervention (after the initial two visits to the home). This suggests a significant cost saving when considering the wages of the occupational therapist. No adverse events were reported.

Overall, participants reported moderate-to-high levels of satisfaction with the program although participants allocated to receive home visits appear to provide somewhat more favorable responses.

DISCUSSION

We compared telehealth and home visit delivery of a dyadic intervention in a group of older people with mild-to-moderate severity dementia and their care partners. The results of this trial demonstrate that it was possible to adapt an evidence-based intervention which was designed to be offered in person and to offer the intervention using telehealth delivery. We found that telehealth delivery required less resource than home visits. Furthermore, our data suggests that clinical outcomes were not significantly different between groups and the telehealth model of delivery was noninferior.

TABLE 1. Characteristics of Participants

Characteristic	Home Visit Group (n = 32)	Telehealth Group (n = 31)
Age of person with dementia, mean (SD)	80.47 (7.198)	79.45 (6.52)
Gender of person with dementia, n (%)		
Male	23 (72)	15 (48)
Female	9 (28)	16 (52)
(S)MMSE (where available), mean (SD)	20.69 (4.51)	18.58 (5.46)
Relationship of care partner to person with dementia, n (%)		
Spouse	25	23
Child	6	7
Other	1	1
Gender of caregiver, n (%)		
Male	6 (19)	9 (29)
Female	26 (81)	22 (71)
Age of care partner, mean (SD)	70.66 (15.510)	69.47 (11.849)
Months of time care partner has spent caregiving, mean (SD)	31.66 (25.708)	36.83 (30.611)
Carer's self-rated knowledge about dementia (/10)	5.75 (2.664)	6.63 (2.236)

MMSE: Mini Mental State Examination; SD: standard deviation.

TABLE 2. Baseline and Post Intervention Data for Primary and Secondary Outcomes

Outcomes	Home Visit Group		Telehealth Group		Between Difference (95% CI)	p Value
	N	Mean (SE)	N	Mean (SE)		
Primary outcomes						
CMI (range 0-24)						
Baseline	32	16.6 (0.43)	31	16.5 (0.44)	-0.07 (-1.31 to 1.16)	0.905
Post intervention	27	17.3 (0.47)	25	17.4 (0.49)	0.09 (-1.26 to 1.45)	0.891
Within difference (95% CI)		-0.76 (-2.0 to 0.52)		-0.92 (-2.2 to 0.39)		
p value		0.2413		0.1647		
Secondary outcomes						
Baseline CAFU total (range 15-105)	32	65.9 (1.5)	31	66.0 (1.6)	0.09 (-4.3 to 4.5)	0.9693
Post intervention CAFU total	26	63.8 (1.7)	26	59.9 (1.7)	-3.9 (-8.7 to 1.0)	0.1165
Within difference (95% CI)		2.1 (-2.6 to 6.7)		6.0 (1.4 to 10.7)		
p value		0.3737		0.0123		
Baseline CAFU-IADL (range 8-56)	32	26.4 (0.99)	31	26.6 (1.0)	0.19 (-2.6 to 3.0)	0.8911
Post intervention CAFU-IADL	26	24.3 (1.1)	26	21.8 (1.1)	-2.5 (-5.6 to 0.63)	0.1156
Within difference (95% CI)		2.2 (-0.78 to 5.2)		4.9 (1.9 to 7.9)		
p value		0.1447		0.0019		
Baseline CAFU-BADL (range 7-49)	32	39.4 (0.92)	31	39.4 (0.94)	0.04 (-2.6 to 2.7)	0.9749
Postintervention CAFU-BADL	27	39.4 (1.0)	26	38.3 (1.0)	-1.1 (-3.9 to 1.8)	0.4658
Within difference (95% CI)		-0.04 (-2.8 to 2.7)		1.1 (-1.7 to 3.8)		
p value		0.9785		0.4482		
Baseline PCS (range 13-65)	31	32.5 (0.93)	31	32.1 (0.92)	-0.36 (-3.0 to 2.3)	0.7870
Post intervention PCS	27	40.1 (1.0)	26	37.7 (1.0)	-2.4 (-5.4 to 0.52)	0.1042
Within difference (95% CI)		-7.6 (-10.4 to -4.8)		-5.6 (-8.4 to -2.7)		
p value		<0.0001		0.0002		
Baseline behaviors	32	9.5 (0.34)	31	9.7 (0.34)	0.19 (-0.78 to 1.2)	0.6998
Postintervention behaviors	24	8.7 (0.39)	24	6.5 (0.39)	-2.1 (-3.3 to -1.04)	0.0003
Within difference (95% CI)		0.80 (-0.23 to 1.8)		3.1 (2.1-4.2)		
p value		0.1257		<0.0001		
Baseline upset	32	5.4 (0.18)	31	5.5 (0.18)	0.07 (-0.45 to 0.58)	0.7879
Postintervention upset	24	5.1 (0.21)	24	5.1 (0.21)	-0.006 (-0.59 to 0.58)	0.9834
Within difference (95% CI)		0.31 (-0.24 to 0.86)		0.39 (-0.17 to 0.94)		
p value		0.2617		0.1674		

BADL: basic activities of daily living; CAFU: Caregiver Assessment of Function and Upset; IADL: instrumental activities of daily living; PCS: Perceived Change Scale. Number of behaviors and Upset extracted from the Caregiver Behavioral Occurrence and Upset Scale.

Items in bold represent $p < 0.05$.

TABLE 3. Time (in minutes) Spent by Therapists Providing the Intervention

Time	Home Visit Group	Telehealth Group	p Value ^a
Therapist's travel time, mean (sd)	255.9 (189.4)	77.2 (79.6)	<0.0001
Face to face time, mean (sd)	337.4 (154.3)	307.9 (199.9)	0.5364

^a Note: p value calculated by Student t test.

When interpreting the findings, it is critical to reiterate that trial participants who were allocated to receive telehealth intervention commenced the intervention program with two visits from an occupational therapist in the home environment. These two visits may have been crucial for establishing rapport and develop a platform to continue the therapeutic relationship. Furthermore, these first two visits to the home offered the therapist the ability to properly assess and understand the home environment and observe the relationship and interactions between the person with dementia and their family members. Delivering the program in its entirety via telehealth may influence uptake and the therapeutic relationship.

This study builds on a growing body of evidence for technology-based interventions for people with dementia and their care partners. Multiple recent systematic reviews of randomized trials have shown that this field of research is growing.^{25–29} While the numbers of studies is still relatively small and the interventions tested vary, preliminary results suggest positive outcomes. Most of the evidence is for better outcomes for care partners rather than the person with dementia and it has been suggested that more research is needed that involves the dyad rather than the care partner alone.³⁰ Hopwood et al. examined internet-based interventions for care partners and suggested that benefits were greater when the content was personalized, when the intervention involved multiple components and when online contact with a health professional was involved.²⁸ Within the field, there is less research about the implementation of eHealth interventions within real world settings.³¹

Unlike other studies, both groups within this trial received the same intervention and the variable was the mode of delivery. Our results suggest that it is possible to assess, collaborate, problem solve, and personalize strategies with people with dementia and their care partners remotely using videoconferencing. The online environment offers the opportunity for additional resources such as videos, online information, and even peer support although these were not tested

in this study. The results of the study suggest that other interventions which have been found effective when delivered in person may also be adapted for telehealth delivery which increases access and equity. Therapists spent slightly less direct time with people receiving telehealth (although the difference was not statistically difference). Possible explanations include that there was less opportunity to model or role play via telehealth or there were fewer social conversations.

The World Health Organization has highlighted the potential benefits of digital health interventions (including telehealth) as a means of achieving universal health coverage.³² Yet it acknowledges that digital health interventions should complement rather than replace existing services. Living with dementia or caring for someone with dementia has been described as isolating³³ and many value personal interactions with healthcare professionals.

Limitations within this study include inability to complete outcome assessments on all participants recruited. Furthermore, the primary and secondary outcomes were all assessed following intervention and there was no follow up. Our participants were referred mostly following consultations at memory clinics and reported that they had considerable knowledge about dementia prior to commencing the program. Given the narrow margins of improvement, it is possible that this group (who were well connected with health services and people with expertise in dementia care) were already relatively highly functioning and therefore had less potential to achieve large gains in knowledge and skills. However, it is also important to note that dementia is a degenerative condition and for people who are in the moderate phase, further decline is anticipated over a period of 4 months and delaying decline is a good outcome. Furthermore, more than half of our participants with dementia were male and their care partners were female. Epidemiologic studies show that dementia is slightly more common in women and a proportion of people with dementia live alone and therefore there are some limitations to generalizability.³⁴

Due to the time span of the funding, we were unable to track participants' costs of care following completion of the intervention and we were unable to report data on cost effectiveness. We had initially planned to collect data using the DEMQOL as described on the trial registry. However, we discontinued this early in the trial as people with dementia and their care partners were reluctant to complete this due to the additional time involved in completion and the content of the questionnaire which some care partners objected to.

In an environment where resources are scarce, there is increasing interest in the use of telehealth interventions. This study suggests that evidence-based dyadic interventions can be adapted for telehealth delivery and could be made available to those who are currently unable to access such interventions through home visits.

AUTHOR CONTRIBUTIONS

KL was involved in conceptualizing the study, designing the work, acquiring the data, analyzing the data, interpreting the results and drafting the paper. EL was involved in analyzing the data and drafting the work. LC was involved in designing the work, interpreting the results and revising the paper for important intellectual content. OD was involved in designing the work, interpreting the data, revising

the paper for important intellectual content. LGr was involved in conceptualizing the study, designing the work, interpreting the results and revising the paper for important intellectual content. LGi was involved in designing the work, interpreting the results and revising the paper for important intellectual content. MC was involved in conceptualizing the study, designing the work, interpreting the results and revising the paper for important intellectual content.

DISCLOSURE

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SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.jagp.2020.02.009>.

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