

Effect of an eHealth intervention on older adults' quality of life and health-related outcomes: a randomized clinical trial



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BACKGROUND: By 2030, the number of US adults age ≥ 65 will exceed 70 million. Their quality of life has been declared a national priority by the US government.

OBJECTIVE: Assess effects of an eHealth intervention for older adults on quality of life, independence, and related outcomes.

DESIGN: Multi-site, 2-arm (1:1), non-blinded randomized clinical trial. Recruitment November 2013 to May 2015; data collection through November 2016.

SETTING: Three Wisconsin communities (urban, suburban, and rural).

PARTICIPANTS: Purposive community-based sample, 390 adults age ≥ 65 with health challenges. Exclusions: long-term care, inability to get out of bed/chair unassisted.

INTERVENTION: Access (vs. no access) to interactive website (ElderTree) designed to improve quality of life, social connection, and independence.

MEASURES: Primary outcome: quality of life (PROMIS Global Health). Secondary: independence (Instrumental Activities of Daily Living); social support (MOS Social Support); depression (Patient Health Questionnaire-8); falls prevention (Falls Behavioral Scale). Moderation: healthcare use (Medical Services Utilization). Both groups completed all measures at baseline, 6, and 12 months.

RESULTS: Three hundred ten participants (79%) completed the 12-month survey. There were no main effects of ElderTree over time. Moderation analyses indicated that among participants with high primary care use, ElderTree (vs. control) led to better trajectories for mental quality of life (OR=0.32, 95% CI 0.10–0.54, $P=0.005$), social support received (OR=0.17, 95% CI 0.05–0.29, $P=0.007$), social support provided (OR=0.29, 95% CI 0.13–0.45, $P<0.001$), and depression (OR= -0.20, 95% CI -0.39 to -0.01, $P=0.034$). Supplemental analyses suggested ElderTree may be more effective among people with multiple (vs. 0 or 1) chronic conditions.

LIMITATIONS: Once randomized, participants were not blind to the condition; self-reports may be subject to memory bias.

CONCLUSION: Interventions like ET may help improve quality of life and socio-emotional outcomes among older adults with more illness burden. Our next study focuses on this population.

TRIAL REGISTRATION: [ClinicalTrials.gov](#); registration ID number: NCT02128789

KEY WORDS: older adults; eHealth; telemedicine; quality of life; depression.

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INTRODUCTION

Quality of life (QOL) is a broad concept, encompassing many mental and physical variables. According to a survey of 7400 older adults from 22 countries, its most valued aspects later in life are feelings of energy and happiness, ability to complete activities of daily living, independence, general health, and mobility.¹ Other research with older adults indicates that QOL is strongly negatively predicted by depression,² loneliness,³ pain and functional limitations,⁴ and dependence on others.⁵ In one telling study, 80% of 194 older women said they would rather die than experience the reduced quality of life that would result from a hip fracture requiring admission to a nursing home.⁶

By 2030, the number of US adults age 65 and older will exceed 70 million.⁷ The Department of Health and Human Services' latest decennial report, *Healthy People 2020*, states that improving QOL for older adults is a chief goal in the next decade, for the sake of both individual patients and the US healthcare infrastructure, which is increasingly strained as the population ages.⁸ The current article reports on a randomized

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clinical trial of an online intervention designed to sustain or improve QOL among this growing cohort.

eHealth interventions to improve QOL have typically targeted a narrow range of outcomes (e.g., chronic pain, exercise, blood pressure, loneliness).^{9–14} Among studies focused on older adults, most have relied on small samples and quasi-experimental or non-equivalent control group designs.¹⁴ In a notable exception, Czaja randomized 300 older adults to receive the online Personal Reminder Information and Social Management (PRISM) system versus printed health-related information. PRISM included links to health-related information and local resources, email, games, and tutorials. At 6 months, the PRISM group (vs. control) reported less loneliness and more social support and well-being. These differences were no longer significant at 12 months.¹⁵

The current trial builds on this work, examining the effects of ElderTree (ET), an interactive website addressing key components of older adults' QOL. ET's design draws upon self-determination theory (SDT), which posits that feelings of competence, social connection, and intrinsic motivation or autonomy contribute to mental health, well-being, and QOL.^{16–18} ET aligns with the theory by providing information (promoting feelings of competence), connections to other seniors coping with similar issues (promoting social connection), and tools to aid self-management of health (promoting autonomy). SDT has been chosen as the theoretical basis because it is both broad and fundamental enough to underpin a complex, multifaceted eHealth intervention such as ET.

This was a randomized clinical trial (RCT) of older adults living in their homes. We hypothesized that those assigned to ET (vs. control) would show greater improvements over time in the primary outcome of QOL and secondary outcomes of independence, falls prevention, social support, and depression. We predicted that age, sex, and health indicators (risk factors, healthcare use) would moderate the impact of the study arm on these outcomes (Fig. 1). All outcomes were assessed at baseline, 6, and 12 months using validated measures.

METHODS

Trial Design and Participants

This was a non-blinded randomized clinical trial allocating 390 older adults equally (1:1) to the intervention (ET plus participants' usual access to information and communication) or control (participants' usual access to information and communication only). Participants were recruited from November 2013 to May 2015 from three Wisconsin communities (one urban, one suburban, one rural) for a 12-month intervention plus 6-month follow-up, during which time participants could continue to use ET if desired. The intervention period ended in November 2016.

Participants were adults ≥65 who met at least one of these risk factors in the preceding 12 months: (a) one or more falls, (b) receipt of home health services, (c) skilled nursing facility

stay, (d) emergency room visit, (e) hospital admission, and (f) sustained sadness or depression. In our original protocol, we specified three of the first five risk factors, but during pilot testing, this proved too restrictive; as a result, to achieve a sufficient sample, only one factor was required when recruitment for the RCT began. We excluded those living in (a) hospice centers, (b) nursing homes, or (c) assisted living without stove access, as well as those (d) needing bed or chair assistance.

We targeted a final sample of 300 (150 per group) after dropouts to provide minimum power (.80 at $P<.05$) to detect a modest effect size (Cohen's $d\geq.4$) with an 80% response rate, based on studies of other online interventions we have developed.^{19–22} The trial protocol and statistical plan were previously published.²³

Ethics

This study, including protocol changes, was approved by the University of Wisconsin–Madison's social/behavioral science institutional review board (IRB). We do not report 18-month data, owing to sharply reduced sample for follow-up. After 12-month data collection, some team researchers formed a company to market a smartphone application focused on drug addiction. Although the populations using ET versus the recovery app were different, IRB determined that participants should be re-consented, resulting in a decline in participation.

Intervention

Participants randomized to the intervention received ElderTree for 12 months. ElderTree evolved from related online interventions developed at the Center for Health Enhancement Systems Studies (CHESS) for various illnesses (e.g., cancer, HIV, asthma, addiction) and tested in randomized trials.^{19–22,24}

Rapid cycle testing during the design phase allowed us to determine which potential services were most promising and feasible for ET. The interface and services were developed in collaboration with over 300 older adults. As described elsewhere,^{23,25} we worked with state-funded Aging and Disability Resource Centers (ADRCs) in our three areas using the Asset-Based Community Development²⁶ process to understand the resources and challenges of each community. Community volunteers interviewed older adults individually and in groups, conducting tests of paper prototypes and on-screen iterations of the technology to gauge usability. This process resulted in an interactive website offering informational, social, self-management, and motivational services aimed at improving QOL. (See Fig. 2 for the home page and Table 1 for feature descriptions.)

Procedures and Randomization

Participants were recruited by grant-funded coordinators, one for each area, who reached out to older adults through

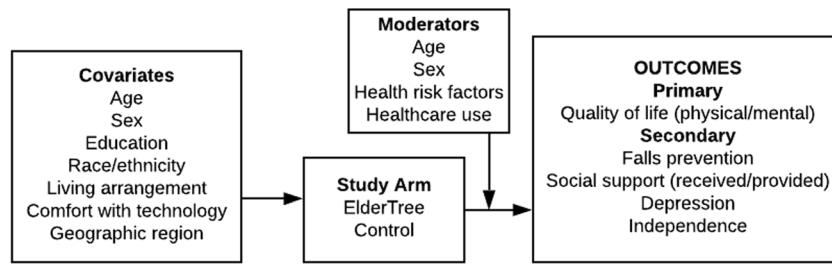


Figure 1. Study logic

presentations at health fairs, senior centers, churches, and other community venues, as well as each area's ADRC. After attending presentations, 871 older adults completed a form expressing interest and were assessed for eligibility. Coordinators mailed baseline surveys to those eligible and made home visits to go through the IRB-approved consent form, answer questions, and obtain written consent. During the visit, coordinators collected baseline surveys and described the condition to which the participant was randomized. Other researchers visited to give participants a computer and internet as needed (both conditions) and to train them in the use of ET (experimental condition).

A computer-generated random allocation sequence was used to randomize eligible participants in a 1:1 ratio to ET or control. Randomization was stratified by region (urban, suburban, rural), computer ownership (yes, no), and living status (alone, not alone); used random blocks of sizes 4 and 6; and was implemented by the project director using sequentially numbered sealed envelopes. The sequence was unknown to the onsite coordinators. Researchers who enrolled participants were blind to the envelope's contents until after consent was given.

Of 871 older adults assessed for eligibility, 390 agreed to participate, completed baseline surveys, and were randomized to study arm. After randomization, 1 was deemed ineligible, leaving 197 ET and 192 control participants. Of these, 351

(90.0%) completed 6-month surveys (174 ET, 177 control) and 310 (79.5%) completed 12-month surveys (159 ET, 151 control). To retain as many subjects as possible, the 12-month survey included 6 participants who completed baseline but not 6-month surveys (Fig. 3).

Table 2 shows age, sex, race/ethnicity, education, living arrangement, comfort with technology, geographic region, and baseline outcome metrics of the 390 participants.

Measures

Outcome and other measures were gauged at baseline, 6, and 12 months in paper surveys. After completing surveys, participants mailed them to the project director. Validated scales, described below, were used, with minor adaptations of questions to avoid redundancy, reduce burden, and increase readability. Cronbach's alpha, reported for each scale, is a measure of reliability; higher values indicate greater reliability.

Mental and physical QOL were measured using the Patient-Reported Outcomes Measurement Information System (PROMIS) Global Health scale.²⁷ Its 10 items subjectively assess physical and mental function, pain, fatigue, social satisfaction, role functioning, depression, and anxiety (Cronbach's α : baseline=0.88; 6 months=0.86; 12 months=0.87).

Independence was assessed with a 6-item modified Instrumental Activities of Daily Living (IADLs) checklist.²⁸



Figure 2. ElderTree home page

Table 1 Services Available on the ElderTree Intervention

Area of Site	Service	Service description	Theoretical basis
Personal	Thought of the day	Inspirational quote, refreshed daily	Motivation
	Search ElderTree	Tool for keyword searches on the site	Competence
	New content alerts	Notifications of new messages, comments, and content in each area	Competence, motivation
	My to-do list	Keep track of tasks and goals; schedule daily, weekly, and monthly reminders	Competence, motivation
Conversations	My health tracker	Keep track of up to 18 health markers (e.g., blood pressure, falls, sleep, mood); latest 3-month result trends are displayed in graph form to aid self-assessment, motivate healthy choices	Competence, motivation
	My bookmarks	Save and find favorite locations on ET	Competence
	My services	Keep track of service provider appointments; rate service providers; get alerts and reminders	Competence
	Private messages	Email-like function; send and receive private messages with ET members	Social
Information	Public discussions	Share thoughts, advice, and stories with ET members in discussion threads; social games and prompts from site monitors foster engagement	Social
	Family and friends	Invite family and friends to correspond privately through the ET system	Social
	Ask a coach	Send questions privately to specialized coaches (e.g., falls prevention)	Competence, motivation, social
	General resources	Informational websites vetted for quality; audio relaxation and meditation for stress reduction; games for pleasure and distraction	Competence
Other	Local resources	Information about community resources (e.g., ADRC, Silver Sneakers program)	Competence, motivation, social
	Bulletin board	Share information with ET members (e.g., upcoming events, news, recipes)	Competence, motivation, social
	Active living tips	Extensive, browsable list of health tips (e.g., nutrition, exercise, medication management) from experts, updated continuously	Competence, motivation
	Map your trip	Printable trip plans with custom variables (e.g., car vs. bus, avoiding left turns)	Competence, motivation
Other	My profile	Describe yourself for ET members; available in footer of every page	Social
	Members	Read profiles provided by ET members; available in footer of every page	Social
	Help	Introductory video and support contact info; available on every page	Competence, motivation

Theoretical bases are competence, intrinsic motivation/autonomy, and social connection constructs of self-determination theory

Participants reported how easily they could, for example, get to places outside the home, take medications, and deal with finances. Scores were averaged (Cronbach's α : baseline=0.76; 6 months=0.73; 12 months=0.71).

Social support, received and provided, was measured with 22 items (averaged) based on the Medical Outcomes Study (MOS) Social Support Survey.²⁹ Items assessed the frequency of positive social interaction, and giving and receiving of informational, emotional, affectionate, and tangible support (Cronbach's α : baseline=0.95; 6 months=0.96; 12 months=0.96).

Depression was measured with the 8-item Patient Health Questionnaire (items averaged).³⁰ Respondents indicated whether they, for example, had little interest in doing things; felt down, depressed, or hopeless; and had trouble sleeping (Cronbach's α : baseline=0.87; 6 months=0.85; 12 months=0.87).

Falls prevention was measured with a modified Falls Behavioral Scale for the Older Person^{31,32}; 15 items assessed the frequency of cognitive and protective adaptations, avoidance of risks, and attention when moving (Cronbach's α : baseline=0.62; 6 months=0.56; 12 months=0.54).

The use of health services was measured with a modified Medical Services Utilization Form.³³ For the last 6 months, participants estimated the number of visits made to their primary care clinic, emergency room, and urgent care, and reported overnight stays in hospital or long-term care (e.g., assisted living facility, nursing home).

ET use data were continuously collected in time-stamped log files, including logon, services used, duration, pages viewed, messages posted and received, weekly surveys completed, and responses to survey items. Future papers will examine system use and weekly survey responses within the current study.

Statistical Analyses

We hypothesized greater improvement over time for the ET group (vs. control) in QOL, social support, falls prevention, independence, and depression. Predictions were tested using cumulative link mixed models (CLMMs) for each outcome across the three time points (baseline, 6, 12 months). Like other mixed models, CLMMs allow some parameters in the model to be treated as random effects and can account for the use of repeated measures from the same respondents.³⁴ CLMMs offer several advantages over linear mixed models: They allow us to analyze ordinal responses without assuming response options are equally spaced or assigned cardinal values. They allow us to model individual responses accounting for their discrete bounded nature. Finally, this type of analysis resembles the intention to treat in that it retains participants who have incomplete data.

For each outcome separately, CLMM models were fit using the "clmm()" function from the ordinal package in R.³⁵ Random effects of intercept and slope for each participant over time were entered with the addition of random effects of the item. We used a CLMM with a logit link, also known as a

871 older adults assessed for eligibility

-481 excluded from the study

70 unable to reach

224 not interested

187 not eligible

8 vision issues

15 memory issues

3 in assisted living

34 too young

119 too healthy

7 wrong county

1 literacy issue

390 randomized

-1 determined ineligible

INTERVENTION 197

received ElderTree +
usual sources of
information and
communication

CONTROL 192
received usual sources
of information and
communication

-39 lost to follow-up

4 died

7 health reasons

2 entered assisted living/nursing home

4 did not like randomization

11 unknown

9 did not re-consent

+1 incomplete baseline, but completed 6-month survey

174 completed
6-month survey

177 completed
6-month survey

-47 lost to follow-up

8 died

2 health reasons

1 entered assisted living/nursing home

1 did not like randomization

8 unknown

27 did not re-consent

+6 completed 12-month survey but not 6-month survey

159 completed
12-month survey

151 completed
12-month survey

Figure 3. CONSORT diagram of participant flow

proportional odds mixed model. Predictor variables were time and study arm. Time was coded as a binary indicator for 6- and 12-month outcomes (time=1) compared to baseline (time=0). Models include an interaction between time and treatment variables as well as main effects. Under this setup, the magnitude of treatment effects is assumed to be constant over time, after baseline. Age, sex, education, race/ethnicity, living arrangement, geographic region, and comfort with technology were entered as covariates in each model.

Moderation analyses examined whether effects differed by age, sex, number of risk factors at baseline, ER and urgent care use, overnight stays in hospital or long-term care, and number of primary care (PC) visits in the 6 months

Table 2 Baseline Characteristics of Participants by Treatment Condition

Characteristic	ElderTree (n=197)	Control (n=193)	Total (N=390)
Age (years), mean (SD)	76.3 (7.4)	76.8 (7.5)	76.5 (7.4)
Female, n (%)	145 (73.6)	147 (76.2)	292 (74.9)
Race/ethnicity, n (%) ^a			
White	176 (89.3)	166 (86.0)	342 (87.7)
Black	19 (9.6)	24 (12.4)	43 (11.0)
Other	8 (4.1)	3 (1.6)	11 (2.8)
Education, n (%) ^b			
<High school (HS)	0 (0.0)	7 (3.6)	7 (1.8)
Some HS or diploma	74 (37.6)	70 (36.3)	144 (37.0)
Some college or post-HS	68 (34.5)	72 (37.5)	140 (36.0)
4-year degree or above	55 (27.9)	43 (22.4)	98 (25.2)
Living arrangement, n (%) ^a			
Living alone	121 (61.4)	127 (65.8)	248 (63.6)
Spouse/partner	61 (31.0)	55 (28.5)	116 (29.7)
Son or daughter	15 (7.6)	16 (8.3)	31 (8.0)
Other family or friends	3 (1.5)	3 (1.6)	6 (1.5)
Paid caregiver	1 (0.5)	0 (0.0)	1 (0.3)
No response	1 (0.5)	0 (0.0)	1 (0.3)
Comfort with technology, mean (SD)			
Smartphone or tablet (0–5) ^c	1.4 (1.8)	1.4 (1.8)	1.4 (1.8)
Desktop computer (0–5) ^c	3.2 (1.8)	2.8 (1.9)	3.0 (1.9)
Email (0–5) ^c	2.8 (2.1)	2.6 (2.1)	2.7 (2.1)
Facebook (0–5) ^c	1.7 (2.0)	1.4 (1.9)	1.5 (1.9)
Geographic area, n (%)			
Urban	49 (24.9)	46 (23.8)	95 (24.4)
Suburban	83 (42.1)	82 (42.5)	165 (42.3)
Rural	65 (33.0)	65 (33.7)	130 (33.3)
Outcome measures, mean (SD)			
Physical quality of life (1–5) ^c	3.44 (0.71)	3.41 (0.70)	3.42 (0.71)
Mental quality of life (1–5) ^c	3.40 (0.82)	3.31 (0.79)	3.36 (0.80)
Independence (1–4) ^d	1.38 (0.59)	1.32 (0.48)	1.35 (0.54)
Social support provided (1–5) ^c	3.80 (0.90)	3.68 (0.87)	3.74 (0.88)
Social support received (1–5) ^c	3.70 (0.92)	3.53 (0.94)	3.62 (0.93)
Depression (1–4) ^d	0.56 (0.58)	0.55 (0.55)	0.55 (0.57)
Falls prevention (1–4) ^c	2.92 (0.57)	2.87 (0.52)	2.89 (0.54)

No participant characteristics differed between treatment conditions (all $P > .05$ based on between-groups generalized linear model analysis).

^aNumbers may exceed group totals and 100% because participants could report more than one race/ethnicity and living arrangement.

^bNumbers do not total group total and 100% because one control participant did not report education level. ^cHigher scores=better outcomes. ^dLower scores=better outcomes

before baseline. Since the moderating effects of PC visits are unlikely to be the same when increasing from 0 to 1 visit versus, for example, 10 to 11 visits or even 2 to 3, we used the Freeman-Tukey transformation on the number of visits. This transformation can be used for count data as it is variance-stabilizing for a Poisson distribution.³⁶ These three-way interaction analyses (time \times study arm \times moderator) were run using the techniques described above for the main (time \times study arm) analyses.

To understand the interactions between time, study arm, and PC visits in the pre-baseline 6 months, number of visits was grouped into terciles using the “interactions” package for

Table 3 Inferential statistics for main and moderation analyses

Outcome measured	Log-odds estimate	95% CI (confidence interval)	P value	P value with FDR adjustment ^a
Main analyses: effects of condition (study arm × time)				
Mental quality of life	0.00	[−0.25, 0.25]	1.00	1.00
Physical quality of life	−0.07	[−0.32, 0.18]	0.57	0.80
Independence	−0.26	[−0.58, 0.05]	0.099	0.38
Social support provided	−0.12	[−0.30, 0.07]	0.21	0.49
Social support received	0.05	[−0.09, 0.19]	0.47	0.80
Falls prevention	−0.11	[−0.25, 0.03]	0.11	0.38
Depression	0.04	[−0.18, 0.26]	0.73	0.85
Moderation analyses: effects of condition × primary care use (study arm × time × primary care use)				
Mental quality of life	0.32	[0.10, 0.54]	0.005	0.016
Physical quality of life	0.09	[−0.12, 0.30]	0.42	0.49
Independence	0.21	[−0.04, 0.47]	0.097	0.14
Social support provided	0.29	[0.13, 0.45]	<0.001	0.002
Social support received	0.17	[0.05, 0.29]	0.007	0.016
Falls prevention	0.01	[−0.11, 0.14]	0.83	0.83
Depression	−0.20	[−0.39, −0.01]	0.034	0.060

The log-odds estimates represent the change in the probability of the most likely response option selected by participants. Larger estimate values=better quality of life, less independence, more social support, better falls prevention, and worse depression (dummy codes: control=0, ElderTree=1; baseline=0, after baseline=1). Results are covariate-adjusted for age, sex, education, race/ethnicity, living arrangement, geographic area, and comfort with technology. ^a Adjusted P values are based on the Benjamini-Hochberg procedure³⁸ for controlling FDR (false discovery rate) type I error

R³⁷: 0–1 visit (lower tercile: ET n=98, control n=93), 2 visits (middle tercile: ET n=43, control n=45), and 3+ (max=24) visits (upper tercile: ET n=53, control n=54). Three ET and 2 control participants did not report PC visits.

Role of the Funding Source

The Agency for Healthcare Research and Quality had no role in the design and conduct of the study; collection, management, analysis, interpretation of data; preparation, review, approval of the manuscript; or decision to submit for publication.

RESULTS

Contrary to prediction, we did not find a greater improvement over time in any outcome for participants who used ElderTree compared to those who did not. Table 3 presents the results of

the main analyses, including both unadjusted P values and type I error adjustments.³⁸ (The ElderTree and control groups' covariate-adjusted scores on outcome measures at baseline, 6, and 12 months are reported in Table 4; see Appendix 1 for detailed results for each outcome.) Given the lack of study arm effects, we did not test for mediation by self-determination theory constructs.

We then examined moderation. We did not find moderation by age, sex, or our health indicators—with the exception of primary care use. As shown in the bottom half of Table 3, among participants with high levels of primary care use (3+ visits) before the study, those in the ET arm (vs. control) showed greater improvements in mental QOL, social support provided and received, and depression (although the P value changed from 0.034 to 0.060 with the more conservative adjustment for multiple tests, as shown in Table 3). A trend toward greater independence is also suggested.

Table 4 Outcome Measure Scores at Each Time Point for All Participants

Outcome measured	Control (n=193)			ElderTree (n=197)		
	Baseline mean (SD)	6 months mean (SD)	12 months mean (SD)	Baseline mean (SD)	6 months mean (SD)	12 months mean (SD)
Mental quality of life	3.32 (0.79)	3.36 (0.74)	3.40 (0.84)	3.40 (0.78)	3.42 (0.73)	3.45 (0.83)
Physical quality of life	3.42 (0.68)	3.44 (0.67)	3.46 (0.79)	3.42 (0.67)	3.42 (0.66)	3.42 (0.78)
Independence	0.82 (0.21)	0.82 (0.20)	0.81 (0.23)	0.81 (0.21)	0.80 (0.20)	0.80 (0.23)
Social support provided	3.66 (0.93)	3.62 (0.80)	3.59 (1.01)	3.75 (0.92)	3.69 (0.78)	3.63 (1.00)
Social support received	3.50 (0.90)	3.52 (0.86)	3.53 (1.02)	3.69 (0.89)	3.69 (0.84)	3.70 (1.00)
Falls prevention	2.87 (0.53)	2.93 (0.50)	2.98 (0.56)	2.95 (0.52)	2.97 (0.50)	3.00 (0.55)
Depression	0.72 (0.20)	0.72 (0.19)	0.73 (0.22)	0.71 (0.20)	0.72 (0.19)	0.72 (0.21)

Values are covariate-adjusted estimates of scores on each outcome in each study arm at each time of measurement. Higher mean values=better quality of life (range 1–5), less independence (range 1–4), more support (range 1–5), better falls prevention (range 1–4), and worse depression (range 1–4)

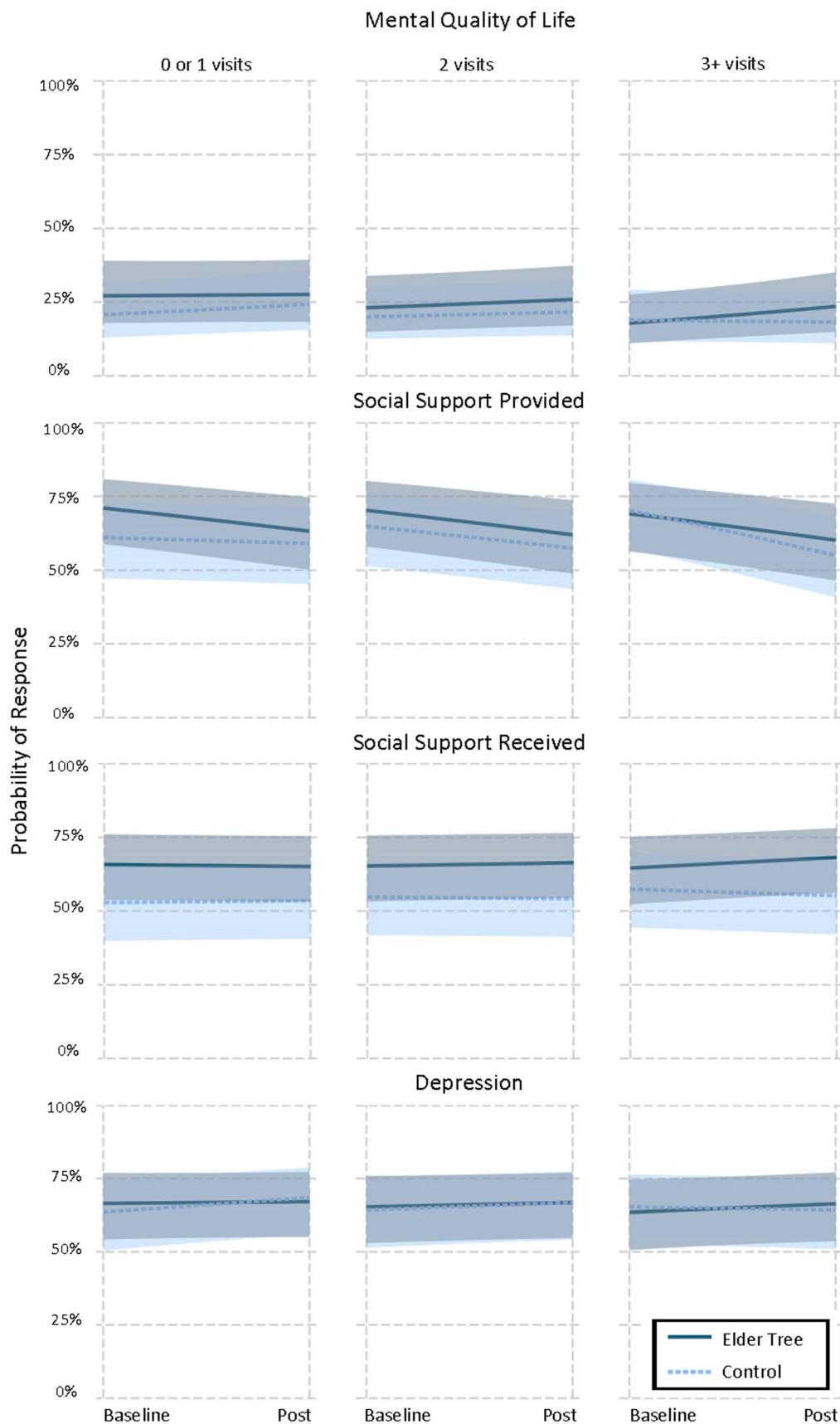


Figure 4. Probability of ElderTree vs. control participants, by number of primary care visits, responding "very good" or better, "often" or better, and "none at all" on measures of mental quality of life, social support, and depression, respectively (higher probabilities represent better outcomes over time; shaded areas are 95% confidence intervals)

Specifically, as shown in Figure 4, ET participants with the most (3+) primary care visits were 6.4% more likely than control participants with 3+ visits to report “very good” or better mental QOL, while ET participants with the fewest visits (0–1) were 3.1% less likely than control participants with 0–1 visit to do so. High-use ET participants were 6.2% more likely than their control counterparts to report “often” providing social support to others, while low-use ET participants were 5.8% less likely than low-use control participants to do so. High-use ET participants were 5.8% more likely than high-use controls to report “often” receiving social support from others; low-use ET participants were 1.3% less likely than low-use controls to do so. And finally, high-use ET participants were 3.9% more likely than controls to report no depression, while low-use ET participants were 4.4% less likely than controls to do so. Detailed results for all outcomes are provided in Appendix 2.

Post Hoc Supplemental Analysis

Results of moderation analyses regarding high levels of primary care use raised the possibility that patients struggling with chronic health conditions were benefiting most from ET. To explore this, we conducted Classification and Regression Tree (CART) analysis, using a checklist of conditions administered midway through data collection, on mental QOL, social support provided and received, and depression. CART has been increasingly used in public health research to identify target populations^{39,40}. This analysis indicated that for mental QOL, social support received, and depression, beneficial effects of ET centered on participants with multiple chronic conditions versus one or no condition. For methodological details and the full CART analysis, see Appendix 3.

DISCUSSION

In our study, the ElderTree eHealth system had no overall impact on quality of life or related outcomes for older adults with mild to moderate health challenges who were living in their homes. However, among participants with high levels of primary care use before the study, those assigned to ET showed more positive trajectories for mental quality of life, social support received and provided, and depression.

Our eligibility criteria, focused on health crises in the year prior to recruitment, were less stringent than originally planned. However, we did not find that participants who met more of those criteria benefited more from ET, suggesting that our initial assessment of relevant factors was wrong. The primary care moderation analyses and the post hoc CART analyses suggest that we might do better to focus on patients with chronic conditions rather than those who may have had a health crisis but recovered. We are currently conducting a second RCT to assess whether ET improves psychosocial and health outcomes among patients with multiple chronic conditions.⁴¹

According to the latest available data, 94% of Medicare spending is for patients with multiple chronic conditions.⁴² Treatment of chronic conditions generally occurs in primary care, with a focus on medication and lab results^{1,6,43,44} but limited time to discuss strategies for self-management or psychological well-being—although such strategies are vital.¹⁵ Interventions such as ET that monitor clinical signs, help with self-management of chronic conditions, offer education and motivation tools, and provide social and psychological support may play an increasing role going forward,^{45,46} especially as adoption rates increase among older adults.⁴⁷ This seems all the more likely in light of the COVID-19 pandemic, which advanced the role of telehealth in easing stress on the healthcare system.^{45,46}

Limitations

Although research staff who consented participants were blind to the condition, there was no meaningful way to blind participants once they were randomized (unlike in a drug trial). Despite this limitation, we reduced bias by giving all participants a laptop and internet access, and by having all participants complete the same measures using paper surveys. An additional limitation is that the survey responses are subject to memory biases. Our ET study currently in progress is using EHRs to verify self-reports.⁴¹

Conclusions

While no overall effect was found for our community-based population of older adults using ET, moderation analyses suggest the system might offer psychosocial benefits to patients using high levels of primary care, a healthcare use pattern linked to chronic conditions. Additional research based on these preliminary findings is underway.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s11606-021-06888-1>.

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Declarations:

Conflict of Interest: David H. Gustafson Sr. has a small shareholder interest in CHESS Health, a corporation that develops healthcare technology for patients and family members struggling with addiction; this relationship is managed by Dr. Gustafson and the UW-Madison's Conflict of Interest Committee. No other disclosures are reported.

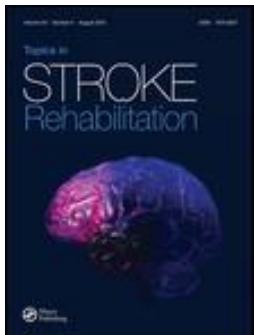
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Telephone Group Intervention for Older Stroke Caregivers

Robert J. Hartke and Rosemarie B. King

Purpose: This study evaluated the effectiveness of telephone groups for older, spousal caregivers of stroke survivors. **Method:** The 88 caregivers were mostly white females who were 70 years old on average and who had been providing care for an average of 3 years. Participants were randomized to treatment or control conditions, followed for 6 months, and assessed for depression, burden, loneliness, stress, and competence. Treatment participants engaged in an eight-session psychoeducational telephone group. **Results:** Treatment participants showed decreased stress over time but were not significantly different from control participants in the amount of change in stress. Control participants showed a significant increase in burden during the study; treatment participants showed a significant increase in competence. **Key words:** caregiver stress, depression, loneliness, stroke, telehealth, telephone

The stress of caregiving over time can result in emotional, physical, and social morbidities.^{1,2} Increased mortality,³ social isolation,⁴ as well as a range of disruptive emotional states^{5,6} have all been reported. Studies addressing the psychological consequences of caring for stroke survivors confirm significant levels of anxiety and depression in this population,⁷⁻¹¹ with rates of depression reported to be as high as 42%-52%, especially among spousal caregivers.^{10,12,13}

Group interventions to alleviate caregiver stress have been viewed as clinically effective by their ability to provide respite; affiliation and emotional support; perspective on the universality of caregiver stress; and education about resources, coping strategies, and problem solving.^{14,15} However, group interventions were most often praised anecdotally for their supportive effect and have shown disappointingly modest effect in moderating caregiver stress when submitted to empirical investigation.^{1,16-18} Research on caregiver groups has been criticized for its lack of specificity. Studies have been complicated by sampling prob-

lems, poorly delineated treatment paradigms, and broad outcome measures that lacked a direct relationship to the focus of intervention.¹⁵⁻¹⁸

Research findings have suggested that elder spouses may be particularly vulnerable to caregiver stress. Spouses are the first choice in a predictable hierarchy of probable caregivers.⁶ Pruchno and Potashnik¹⁹ indicated that spouses provided the most extensive and comprehensive care, maintained the role of caregiver longer, and tolerated greater levels of disability. Their own advanced age and health problems make

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elder, spousal caregivers a high-risk group for morbidities due to the stress of providing care.

The stress of caregiving has been related to the nature of functional disability in the care receiver.²⁰ Physical care tasks present different challenges and have been considered less stressful than more unpredictable, poorly resolved cognitive and behavioral problems.⁶ In the case of stroke, both physical and cognitive/behavioral disturbances may be intermingled, and this calls for a unique type of care. It also may take several months before deficits from a stroke are stabilized. MacNamara et al.⁸ reported that anxiety may actually increase with time even in the case of "successful" stroke caregivers.

The increasing availability of telecommunications and information technology has provided a new route for provision of health care services. Telehealth provides alternative ways of delivering interventions when distance, cost, and inconvenience prohibit conventional face-to-face contact.²¹ It has the potential to bring assistance to underserved groups, such as the homebound. Many caregivers are reluctant or unable to leave their disabled family member to travel distances and participate in face-to-face groups. Group treatment through telephone conference call is now feasible for delivery of support to caregivers. Liss et al.²¹ reviewed the application of telehealth to persons with chronic disabilities and found preliminary evidence supporting its effectiveness, but they noted a particular need for evaluation of telephone-based counseling. Galinsky et al.²² specifically reviewed literature on technology-based groups and surveyed practitioners on their knowledge, experience, and comfort level in this area. They cited

advantages to this format of accessibility, convenience and anonymity, and disadvantages of decreased interpersonal cues, technological problems, and limitations to group process, such as trust and cohesion. Galinsky et al.²² recommended preliminary guidelines for conducting phone-based groups, such as use of co-facilitators who are more active in guiding group process. Limited research using this intervention paradigm has been conducted by Evans and his associates.²³⁻²⁸ These studies have demonstrated the effectiveness of the intervention with older, blind, and otherwise severely disabled persons and have shown changes in loneliness, social involvement, and life satisfaction among other measures. Published studies of group interventions for caregivers provided by telephone conference call have just begun to appear in the literature. Brown et al.²⁹ compared the effectiveness of support groups delivered in person and by telephone for family caregivers of brain-injured adults, including stroke. Participants participated in 9 to 10 semi-structured group sessions either in person or on the phone, with group assignment depending upon the caregivers' distance from the sponsoring hospital. Rural caregivers were assigned to the telephone groups. Outcome measures were family functioning, burden, and mood disturbance. There were similar amounts of improvement found for both types of groups; participants showed significant reduction in mood disturbance regardless of mode of intervention. The study was complicated by group bias; rural caregivers (assigned to the telephone intervention) were less distressed across all assessment periods. Although both types of interventions were rated highly, the telephone

group participants were somewhat more satisfied with their experience. The investigators concluded that nothing essential was lost in conducting caregiver groups on the telephone when compared to traditional face-to-face participation.

The mechanism of change in caregiver stress intervention is often guided by a stress and coping model. Gatz et al.⁶ provided a summary model of caregiving stress with the following critical features: onset of a disabling event prompting care as the *stressor*; *appraisal* of the experience of caring; the *mediators* or coping skills brought to bear; and the *outcome* of successful caring or abandonment of the role. According to this model, an intervention on the caregiver's appraisal of self and situation, as well as on mediators such as care skills, knowledge of disability, and outside supports, can positively influence coping and subjective distress.

Failure to demonstrate effectiveness of interventions in caregiver stress research has been attributed to problems in outcome measurement. One means of focusing measurement has been to combine more established global measures with those that are more specific to the caregiving situation. Zarit³⁰ recommended a multidimensional, multivariate, multimethod approach wherever possible. Evans et al.^{23,26,27} and Jaureguy and Evans²⁸ have consistently shown that group telephone treatment decreases loneliness. Depression is widely recognized as a specific morbidity in caregivers in need of treatment.^{1,6,10} The high prevalence of depression among caregivers makes it a logical target of intervention. Depression among spousal stroke caregivers has been documented to be significantly higher than in the general older adult population.^{9,31} Sense of competence or self-efficacy^{32,33} has

been identified as a factor that mediates coping. Caregiver competence can buffer the experience of stress and has been shown to relate to depression.^{34,35} The assessment of the stressfulness of individually identified problems of providing care has value as a monitor of the unique accumulation of stress in the caregiving situation.³⁶ Finally, reduction in sense of burden has been associated with successful caregiver stress interventions.⁶ Higher subjective burden has affected caregiver decision making, such as nursing home placement.³⁷

The present study attempted to further explore the feasibility and effectiveness of a structured caregiver intervention delivered by teleconference. The study addressed past criticism of poor specificity in caregiving research by targeting older, spousal, stroke carers with a focused intervention and outcome measurements. The intervention was tailored to the stress of providing care to a stroke survivor and concentrated on caregiver appraisals and mediating factors of skills and resources according to a stress and coping model. Specific outcomes of depression, burden, loneliness, stress, and competence were assessed for change. The following specific hypotheses were tested:

1. Participants in the treatment group will show significant improvement in depression, loneliness, burden, competence, and stress between entrance into the study and completion of the intervention and will maintain gains at 6-month follow-up ($p < .05$).
2. Participants in the treatment group will show significant improvement in depression, loneliness, burden, competence, and stress in comparison to the control group at 6-month follow-up ($p < .05$).

Method

The current study utilized a randomized, treatment/control design to test the efficacy of a caregiver stress intervention. The intervention was designed according to a stress and coping model and was refined by input of a focus group of stroke caregivers. The newly designed intervention was compared to usual support provided to spousal, stroke caregivers.

Sample

Participants were spouses of stroke survivors who received acute rehabilitation at a free-standing rehabilitation center or at a rehabilitation unit of a major suburban medical center. Participants were recruited from review of their spouses' admission records; various print, radio, and television media advertisements and news features; and targeted community outreach. Criteria for inclusion in the study were (a) 60 years of age or older, (b) married or spousal equivalent and living with the stroke survivor, (c) primary caregiver for a minimum of 1 month, (d) not currently in a caregiver support group, and (e) a telephone in the home and sufficient hearing to participate in telephone conference calls and individual assessment interviews. A primary caregiver was defined as someone who was providing emotional support in addition to participating in care in at least one of the following three areas: personal care, instrumental activities of daily living, decision making or informal case management. It was felt that participants had to be in their role as primary caregiver for a minimum of 1 month in order to benefit from the intervention.

Over 500 people were solicited for participation. Of the 124 participants who were successfully recruited, 36 dropped out during the course of the study, resulting in a 29% dropout rate. Significantly more treatment participants ($n = 25$) dropped out of the study than controls ($n = 11$) ($\chi^2 = 4.37, p < .05$). The most frequent reason for dropping out of the control group was difficulty scheduling follow-up evaluations, whereas the most frequent reasons for dropping out of the treatment group were death of spouse or perception of a lack of need for the intervention. A total of 88 persons participated in the study to conclusion and were assessed at all time periods, with 43 cases in the treatment condition and 45 in the control condition. **Table 1** provides a description of the sample on relevant demographic factors. Treatment group participants had spouses who were more significantly impaired on the FIM™* motor scale, and the caregivers in this condition also significantly more often reported receiving help with their spouses' care.

Measures

Table 2 lists the means, medians, and standard deviations by group and time for the study outcome measures.

Depression

The Center for Epidemiologic Studies—Depression Scale (CES-D) was a 20-item self-report scale³⁸ that measured the presence and severity of depressive symptomatology during the preceding week on a 3-point scale ranging from 0 for *rarely* to 3 for *all the time*.

*FIM™ is a trademark of the Uniform Data System for Medical Rehabilitation, a division of UB Foundation Activities, Inc.

Table 1. Sample characteristics

	Treatment (n = 43)	Control (n = 45)	Total sample (N = 88)
	Mean (SD)	Mean (SD)	Mean (SD)
Age	69.74 (5.39)	69.69 (6.59)	69.72 (6.00)
Years caregiving	3.18 (4.91)	2.73 (2.77)	2.95 (3.95)
Years of education	13.77 (2.39)	14.11 (2.97)	13.94 (2.69)
Years married to current spouse	43.37 (9.88)	42.13 (12.38)	42.74 (11.18)
FIM™ scores of spouse			
Motor ^a	58.98 (21.56)	69.42 (17.60)	64.32 (20.22)
Cognition	27.23 (5.72)	28.20 (5.66)	27.73 (5.68)
	n (%)	n (%)	n (%)
Gender			
Male	11 (26%)	10 (22%)	21 (24%)
Female	32 (74%)	35 (78%)	67 (76%)
Race			
White	34 (79%)	37 (82%)	71 (81%)
African American	7 (16%)	6 (13%)	13 (15%)
Other	2 (5%)	2 (5%)	4 (4%)
Receiving help with care ^b	34 (79%)	26 (58%)	60 (68%)
Source of help			
Family	15 (44%)	10 (38%)	25 (42%)
Other	19 (56%)	16 (62%)	35 (58%)

^at = -2.48, p < .05. ^bχ² = 4.60, p < .05.

Scores ranged from 0–60, with higher scores representing greater symptom severity and a score of 16 being the usual cutoff to denote depression. The scale has been shown to be internally consistent with coefficients as high as .85 to .90³⁸ and .86 to .88 in a longitudinal study of stroke caregivers.³⁹ The scale has been shown to be a valid screening measure for depression in community samples,⁴⁰ medical patients (e.g., stroke patients⁴¹), and caregivers.^{9,19,42,43} Internal consistency coefficients for the current study were .85 (Time 1) and .87 (Time 2).

Loneliness

The UCLA Loneliness Scale was originally developed by Russell et al.⁴⁴ as a 20-item self-report scale and was revised by Russell et al.⁴⁵ to a 10-item version focused on the

psychological experience of loneliness. Respondents rated frequency of occurrence of symptoms of loneliness on a 4-point scale ranging from 1 for *never* to 4 for *often*, with higher scores reflecting greater loneliness. Russell et al.⁴⁵ reported the internal consistency of the revised measure to be high ($\alpha = .94$) for the longer version and also demonstrated a significant relationship between the scale and a self-labeling loneliness index and other social behaviors. Knight et al.⁴⁶ renormed the scale on a general adult population and reported internal consistency to be .83 to .86 for the short version with mean scores ranging from 17.4 to 17.9. The scale has been successfully utilized in the assessment of spousal caregivers.⁴⁷ Internal consistency coefficients for the current study were .80 (Time 1) and .79 (Time 2).

Table 2. Means, medians, and standard deviations for outcome measures by time and group

Measure	Time 1		Time 2		Time 3	
	Mean	(SD)	Mean	(SD)	Mean	(SD)
Burden Interview ^{a,*}						
Treatment	31.58	13.78	30.77	13.29	31.04	15.39
Control	25.11	10.84			29.78	12.09
CES-Depression ^{a,*}						
Treatment	13.93	9.71	13.19	9.63	14.16	10.28
Control	9.49	6.72			10.09	7.55
UCLA-Loneliness ^{a,*}						
Treatment	19.15	6.54	18.21	5.74	18.44	5.74
Control	16.36	4.22			16.67	4.71
Pressing Problem Index ^{a,*}						
Treatment	6.18	1.55	5.48	1.64	5.39	1.52
Control	5.52	1.32			5.12	1.50
	Mean	(SD)	Median	Mean	(SD)	Median
Caregiver Competence ^{b,**}						
Treatment	13.74	2.02	14.00	14.35	2.23	15.00
Control	14.87	1.42	15.00			
				14.07	2.16	15.00
				14.69	1.62	15.00

^at test. ^bMann-Whitney U.

*p < .05 at Time 1; for depression also at Time 3. **p < .01 at Time 1.

Competence

The Caregiver Competence Scale was developed by Pearlin et al.³² to measure the construct of competence in a stress and coping model of caregiving. It was a 4-item, 4-point self-rating scale ranging from 1 for *not at all* to 4 for *very much* in which the participants were asked to rate their sense of competence and confidence in their role as a caregiver. Total scores ranged from 4 to 16 with higher scores denoting greater competence. Pearlin et al.³² indicated adequate internal consistency ($\alpha = .74$). Internal consistency coefficients for the current study were .78 (Time 1) and .81 (Time 2).

Burden

The Burden Interview (BI)⁴⁸ was a 22-item scale in which caregivers were asked

about feelings of stress, guilt, and resentment in their caring role. Responses were ratings of frequency on a 4-point scale ranging from 0 for *never* to 4 for *nearly always*. Item ratings were summed to achieve a total score that ranged from 0 to 88, with higher scores indicating a greater sense of burden. Evidence for concurrent validity⁴⁸ and internal consistency alphas ranging from .88 to .91⁴⁹ have been reported. Confirmatory factor analysis indicated the BI was comprised of two scales, personal strain and role strain.⁵⁰ Internal consistency coefficients for the current study were .85 (Time 1) and .88 (Time 2).

Stress

The Pressing Problem Index (PPI)³⁶ was obtained from a semi-structured interview in which participants were

asked to appraise their caregiving situation by identifying current problems in providing care and assessing their severity. For each problem enumerated, the participant rated how stressful the problem is and how effectively the problem is managed. The scales were numbered from 1 to 5 (1 = *not stressful and effective*; 5 = *very stressful and effective*). A total index was derived by computing a composite score for each problem (the sum of the stress rating and the reverse scored effectiveness rating) and dividing by the total number of problems. A higher score indicated greater stress and less effective management. Toseland et al.³⁶ reported a significant decrease in the PPI among caregivers in peer and professionally led support groups compared with a respite-only group.

Functional level

The FIM™ was used to assess the functional status of the care receiver. Function was rated for 18 items on a 7-point response set from *maximum dependence* (1) to *independent without assistance* (7). Thirteen items and five items comprised motor and cognitive scales, respectively. The cognitive scale included language, social interaction, problem solving, and memory ratings. Higher scores indicated greater functional independence. Scores ranged from 18 to 125 for the total FIM. Intraclass correlations for scales have ranged from .89 (cognitive) to .94 (motor).⁵¹ The scale has been shown to demonstrate adequate intra-rater reliability.⁵² Internal consistency coefficients for the current study were .95 (motor) and .68 (cognitive).

Demographic and caregiving information

All participants were administered a questionnaire about basic demographic information and details of their caregiving situation, including amount of additional help received, therapies provided to spouse, and prior experience with support groups.

Treatment evaluation

All participants in the experimental condition responded to questions to evaluate the treatment subjectively, including assessment of specific features of the group, what they liked most and least, and what they would change. At the final 6-month follow-up, participants in the experimental condition were asked about subsequent use of written materials and frequency and nature of ongoing contact with other support group members. Control participants were asked about their use and evaluation of the reading materials that were provided to them.

Procedure

Recruitment was carried out over a 4-year period. Participants reviewed and signed an Institutional Review Board-approved consent form when agreeing to join the study. They were assessed with measures of depression, loneliness, competence, burden, and stress (PPI). Questionnaires were administered to gather demographic and caregiving facts. Participants were then randomly assigned to a usual care or the telephone support group intervention condition and were followed for 6 months to test the enduring effects of the intervention. Participants in the experimental condition were assessed when entering the study

(Time 1), immediately after support group participation (Time 2), and 6 months after entering the study (Time 3). Participants in the usual care condition were assessed when entering the study (Time 1) and after 6 months (Time 3) only. At Time 2, participants in the experimental condition also gave subjective feedback about their experience in the group; at Time 3, they were asked about further contact with group members and use of reading materials provided to them. At Time 3, participants in the usual care condition were asked about any counseling sought during the interim period and their use of reading materials provided to them. All assessments were conducted by members of the research staff via individual telephone interviews.

The telephone support group met for eight 1-hour sessions and followed a structured, psychoeducational format. A group manual that outlined the eight topics of discussion was mailed to each participant. These included:

- a session to introduce participants to one another and the group philosophy,
- facts about stroke and caregiving,
- communicating with your spouse,
- dealing with your spouse's problematic feelings and behavior,
- your stress as a caregiver,
- taking care of yourself as a caregiver,
- resources for you in the community as a caregiver, and
- a concluding session for review, future goal-setting, and termination.

The manual included an audiotape of a relaxation procedure and a publication on stress management. Each participant was given a list of the stressful problems in caregiving that they had identified during the initial assessment. Sixteen groups were

conducted through the course of the study, with the size of each group varying from three to six members. Most groups had two group facilitators who were clinicians in the areas of psychology, social work, or nursing. The original protocol called for in-person luncheons for the first and last meetings of each group. However, these in-person meetings became too difficult to schedule. Consequently, almost all groups were conducted exclusively by telephone conference call initiated by the group facilitators over a period of approximately 8 weeks.

Guidelines were developed and communicated to the participants during the introduction of each group in order to address the special features of telephone conference calls and to emphasize the peer support component of the intervention. Confidentiality was stressed by asking participants to keep private the personal reactions of others in the group. When possible, participants were asked to disable the call waiting feature on their phone to reduce intrusions. They were also encouraged to find a private space in their home during the sessions (away from the care receiver) so that they could speak freely. The need for consistent attendance was emphasized because the presence of each participant was valued for his or her contributions in the sessions. Participants were asked to identify themselves when they spoke during the initial sessions until voice recognition could be established. Pictures of the group facilitators were included in the treatment manual. Finally, to augment the supportive nature of the intervention, participants were encouraged to have contacts with one another outside of the group meetings; with the group's permission, a list of their names, addresses, and phone numbers

was mailed to each of them.

Participants in the control condition received the same stress management publication included in the treatment manual as well as a brief written description of caregiver stress and stroke. All participants in both conditions were given small mementos (e.g., specially designed mugs and cards) of their participation in the study to help them positively identify with their role as caregiver and express gratitude for their time and effort.

Analysis

Objective evaluations

Descriptive statistics and frequencies were calculated for important sample characteristics, and groups were tested for equivalence using independent *t* and chi-square tests as appropriate. The treatment and control groups were tested at Time 1 for equivalence on the dependent variables using independent *t* tests for depression, burden, loneliness, and stress. A Mann-Whitney U statistic was used to test for equivalence for competence as this measure did not meet the assumption of normal distribution.

Hypothesis 1. Within-group comparisons for the treatment condition were tested with repeated-measures analyses of variance (ANOVAs) over the three time intervals separately for depression, burden, loneliness, and stress (as measured by the PPI). The competence scores were not normally distributed, thus a Friedman's ANOVA was performed to test differences in this variable within the treatment group over time.

Hypothesis 2. Despite randomization, the treatment and control groups were not equivalent on the outcome measures at

Time 1 (see **Table 2**). Therefore, difference scores were calculated on the five dependent variables between Time 1 and Time 3. Between-group comparisons were performed using the difference scores with independent *t* tests for depression, burden, loneliness, and stress. Because the competence change scores were not normally distributed, a Mann-Whitney U statistic was used to test group difference on this dependent variable. A repeated-measures ANOVA was also performed on the stress measure for all participants having both Time 1 and Time 3 completed assessments with group as the independent variable.

Subjective evaluations

Frequencies were tabulated for specific questions, and content analysis was completed for open-ended questions.

Results

Objective evaluation

As shown in **Table 1**, the majority of the sample was white and female with an average age of nearly 70 years and more than a high-school education. The participants were mostly in longstanding marriages with the stroke survivor and, on average, had been providing care for nearly 3 years. However, 25% of the sample had been in the caregiver role for less than 6 months. The majority were receiving some help from outside of the family. The participants were caring for spouses who needed minimal assistance to supervision overall. The treatment and control groups were equivalent on most of these characteristics, except that the caregivers in the treatment group

Table 3. Treatment group means on outcome variables by time ($N = 43$)

Variable	Time			Statistic
	T1	T2	T3	
Depression	13.93	13.19	14.16	.30
Burden	31.58	30.77	31.04	.15
Loneliness	19.12	18.21	18.44	.92
Stress	6.08	5.44	5.40	5.34*** ^a
Competence	13.74	14.35	14.07	4.92 ^b

^a $n = 38$. ^bFriedman's ANOVA with chi-square statistic.

** $p < .01$.

had spouses who were more motorically impaired, and they were more frequently receiving assistance in providing care.

Despite random assignment, the treatment group was more distressed overall at the Time 1 assessment with significantly higher levels of depression, burden, loneliness, and stress and lower sense of competence (see **Table 2**). **Table 3** shows the within-group change over time for the treatment group (Hypothesis 1). There were no significant changes in depression, burden, loneliness, or competence from entry into the study (Time 1) to the 6-month follow-up (Time 3). However, there was a significant reduction in stress, as measured by the PPI, over time [$F(2, 74) = 5.34, p < .01$]. Post hoc analysis showed the change to be significant from Time 1 to Time 2 [$t(37) = 2.71, p < .01$] and from Time 1 to Time 3 [$t(37) = 2.68, p < .05$]. Between-group comparisons were made on the basis of change scores, given the lack of group equivalence at Time 1. As shown in **Table 4**, there were no significant differences in the degree of change between treatment and control groups for depression, loneliness, or stress. The group differences in change scores were significant for burden and competence [$t(86) = -2.40, p < .05$, for burden; $U = -2.15$,

$p < .05$, for competence]. Compared to the treatment group, the control participants showed significantly greater change in burden between Time 1 and Time 3. The treatment participants showed a significant gain in their sense of competence from Time 1 to Time 3. For the repeated-measures ANOVA comparing the two groups on stress over time, there was a significant effect overall for time [$F(1, 80) = 12.47, p < .01$] but no significant interaction between group and time.

Subjective support group evaluation and 6-month follow-up

Results of specific questions are summarized in **Table 5**. In general, participants expressed a high level of satisfaction with various aspects of the group and, similarly, felt that most of the characteristics of the group identified in **Table 5** were important. Only 20% of the participants indicated a willingness to meet in person. When questioned about contact with one another outside of the group, 27% indicated that they had spoken with at least one other group member one or more times while the support group was in process; at 6-month follow-up, 35% had spoken with another

Table 4. Change score (T1-T3) comparison between treatment and control groups

Variable	Mean change		<i>t</i> statistic
	Treatment	Control	
Depression	.23	.60	-.22
Burden	-.54	4.17	-2.40*
Loneliness	-.67	.31	-1.04
Stress	-.74	-.40	-1.10
Competence	.33	-.18	-2.15*.a

^aMann-Whitney U; *z* score shown.**p* < .05.**Table 5.** Summary of subjective evaluation of telephone support group (*N* = 41)

Item	%
1. Satisfaction with...	
number of sessions	good-excellent 83%
length of each session (1 hr.)	76%
relevance of topics discussed	93%
telephone vs. in-person meetings	85%
facilitator helpfulness	98%
overall experience	93%
2. Importance of...	important-very important
group discussion	90%
convenience of phone meetings	85%
group manual	90%
relaxation tape ^a	40%
contact with other caregivers	88%
group leader knowledge	98%
3. Would have participated in person?	20%
4. One or more contacts with group participants outside of the group sessions	
during group meetings	27%
at 6-month follow up ^b	35%
5. Had used written materials one or more times at 6-month follow-up ^c	68%

^a*n* = 35. ^b*n* = 43. ^c*n* = 28.

group member. The majority of these con-

tacts (81%–82%) were by telephone. Finally, when questioned at the 6-month follow-up, 68% of the participants had referred to the treatment manual and associated materials at least once.

Treatment condition participants were questioned about their barriers to in-person attendance. The vast majority of their comments focused on their inability to obtain coverage for their spouses' care needs in their absence and their inability or unwillingness to travel a distance for in-person meetings. When questioned about what they liked most about the group experience, the participants most frequently identified various interpersonal benefits, especially peer contact. They appreciated the honest, empathic communication that allowed for emotional ventilation, comparison with one another, and the experience of the commonality of caregiver problems. Relating to other participants often brought a downward comparison in which they experienced someone else as having a more difficult situation. Secondarily, participants liked the content of the intervention, especially the written materials provided, resources mentioned during sessions, solutions to specific care problems, and the expertise of the group facilitators.

The most frequent criticisms of the group

focused on technical problems associated with phone use, such as not being able to hear all of the participants, as well as the loss of intimacy due to the absence of in-person contact. Other most frequent criticisms centered on the intervention as a whole or individual session time being too short and specific complaints about a disruptive group member. When asked what they would like to see changed about the intervention, participants indicated a desire to meet in-person while simultaneously acknowledging the difficulties for them in doing so. Of equal frequency, participants commented that they would have liked the intervention to have been extended, either by having more meetings or longer sessions.

At 6-month follow-up, 98% of the participants in the control condition ($n = 43$) had reviewed the reading material sent to them and 85% ($n = 39$) rated it as good to excellent. However, when asked about how useful the information was to them, only 36% ($n = 36$) could mention at least one coping strategy drawn from the reading, while 64% had minimal or nonspecific comments. Only 19% ($n = 32$) had any comments about how the information could have been made more useful to them.

Discussion

The current study provides limited evidence of the effectiveness of the telephone conference group format as a means of intervention for caregivers. The study hypotheses were partially supported. The treatment group showed a decrease in stress related to their caregiving problems. However, when compared to the control group over time, the magnitude of the change was not significantly different. While the treatment group

remained largely unchanged in the experience of burden, burden significantly increased in the control group over time. Treatment participants also showed significant gain in caregiver competence in comparison to control participants who remained relatively unchanged throughout the study on this outcome variable. The groups were positively rated by the participants in most ways, and the study demonstrated the feasibility of conducting this type of structured group treatment entirely over the phone.

The PPI was the most targeted outcome measure in the study. The items assessed came directly from the spouses' caregiving experiences, and the participants in the treatment condition were given their personal list of problems to which they could refer during the group sessions. This level of specificity could have made the stress measure more sensitive to change. Because of the open-ended discussion involved in the measurement, however, the process of identifying and rating the problems may have been therapeutic in itself. Thus, the control participants may have experienced a beneficial effect from the initial administration of the measure and subsequent rating of the same problems. The pattern of change in burden between the treatment and control groups suggests that the intervention may have prevented rather than reduced the accumulation of strain over time. Only the control participants increased in burden scores over the study, while the treatment participants remained relatively stable. The emotional outlet and comparison with others provided by the group may have helped achieve this effect. In their open-ended comments, participants noted that they felt free to express themselves and spoke "from the heart" and that

others often had worse problems. The increase in the sense of competence in the caregiving role among treatment participants may have also been a result of the content and process of the intervention. Participants in the groups were able to share their knowledge and strategies with one another and obtain affirmation of their contribution to their spouses' recovery. Participants noted that they learned from each other, were allowed to contribute to the group, and felt they were among equals.

The lack of significant change in depression and loneliness among the treatment participants and between the two study conditions may be due to the lack of consistent, specific focus on these issues in the intervention. It was surprising, however, that the treatment participants did not show a significant decline in loneliness given the results of prior studies with telephone group support for the homebound.^{23,27} Further, lack of social involvement was one of the most frequently mentioned types of problems on the PPI.⁴ It is possible that the time-limited phone contact may have been insufficient to substantially reverse the participants' sense of isolation. Even though the group members were encouraged to have informal contact with one another outside of group meetings, only a minority did so. Also, the disruption of the marital relationship due to the stroke with the resulting loss of personal and social companionship may have been too large a void to be adequately filled through this type of peer contact.

Evaluation by group participants

Similar to the findings of Brown et al.,²⁹ the subjective comments of the treatment

group participants generally reflect a high rate of satisfaction with the telephone format and endorsement of the importance of the program. Within the context of this broad approval rating, the participants frequently stated a desire for an extended intervention and were ambivalent about meeting over the telephone. They complained of difficulty hearing others and wished they could have met in person, although 80% stated they could not do so. The fact that the study was conducted in a large metropolitan area could have contributed to this ambivalence. Participants were generally not as widely dispersed as might be the case in a rural setting. In-person contact was generally possible but was not very convenient. In the participants' open-ended comments, the interpersonal aspects of the group were most frequently cited as beneficial and the content of the intervention was less frequently mentioned. However, while only a minority of group participants had additional contact with one another, a majority continued to refer to the treatment manual. These contradictory reactions may reflect the limits of the structure and length of the group. A psychoeducational, time-limited, group format over the telephone may not move beyond initial positive group cohesion to a more emotionally intimate experience.²² Similarly, the time limit may preclude sufficient integration of the information to achieve an enduring impact on coping. Notably, none of the participants commented on the advantage of anonymity provided by only telephone contact.²² It may be that caregivers (generally not a stigmatized group) do not wish for anonymity but appreciate being known, especially by others in a similar situation.

Limited comments from the control group suggest that they reviewed and appreciated the written information sent to them, but without ongoing contact, they may not have integrated the content into their role as caregiver in a useful way.

Clinical implications

The study results indicate both the feasibility and limitations of applying this format to caregivers in the clinical setting. The appeal of teleconference intervention lies in the convenience it can offer caregivers who may feel too constrained by time and distance to engage in face-to-face contact. However, the current study suggests limits to the impact one can achieve when using this form of intervention exclusively. Combinations of in-person and telephone sessions to foster relationship building and to reinforce effects over time may be a reasonable, more powerful alternative. Continuing technological advances that include visual input (such as video conferencing) will add other options to combine with traditional in-person gatherings. In the telephone group format, it appears that structured sessions and associated written material and use of group leaders comfortable with the format all contribute to a successful subjective experience for the participants.

Further, some of the caregivers in this study had been in their role for many years and had also provided care to their parents in the past. As caregivers, their coping patterns had stabilized and they were difficult to modify. This observation suggests that early intervention when caregivers are establishing their role behavior may have a greater impact.

Study limitations and future research needs

There are several limitations that should be considered in interpreting the results of this study. The sample of caregivers had spouses who, on average, were not experiencing severe impairments from their stroke and the majority were receiving additional, outside assistance. In addition, caregivers were not selected on the basis of their level of distress. These characteristics may have diminished the impact of certain aspects of the intervention. Sampling was also restricted to older spouses who have been found to benefit less from interventions than adult children.¹⁷ The intervention design and choice of assessments may have been too general despite efforts at increasing specificity. The treatment program was ambitious in its scope considering the limited number of sessions. As confirmation of the latter limitation, the group participants expressed a desire for more contact in their evaluative comments. A more exclusive focus (such as coaching of a particular skill or management of mood) may have been a more realistic approach for a successful impact in a short time frame. Finally, the attention and materials provided to the control group may have been sufficient to lessen the difference between the two conditions and the resulting outcomes.

Future research will be important in further developing this form of intervention to address the needs of stroke caregivers. Evaluation of combinations of formats and greater specification in both interventions and assessment are necessary. Innovative approaches to respite care are needed to free caregivers to obtain help for themselves. The identification of characteristics that differentiate those caregivers who might be more

receptive to teleconference versus in-person contact would also be useful to encourage caregivers to access help. For example, the stressed caregiver who is reluctant to accept help might be persuaded to join a telephone group because of its convenience and anonymity. After having a positive experience in this format, they might be encouraged to access in-person support. Finally, the problems of the study illustrate the ongoing need to refine design and measurement in caregiver stress research in order to determine how to best assist and sustain the growing number of family caregivers who are an

essential, but fragile and often neglected, component of long-term care after stroke.

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Article

An Evaluation of a Low-Intensity Cognitive Behavioral Therapy mHealth-Supported Intervention to Reduce Loneliness in Older People

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Abstract: There is a high prevalence of loneliness among older people, especially in residential care settings. Loneliness is often accompanied by maladaptive cognitions which can affect the maintenance and establishment of meaningful social connections. This study implemented and evaluated a low-intensity Cognitive Behavior Therapy (LI-CBT) mHealth-supported intervention which targeted maladaptive cognitions in older people (≥ 60 years) experiencing loneliness. The three-month intervention using WhatsApp was implemented with older people in four inner-city residential care facilities. The intervention included three components: technology acceptance, psycho-education, and individualized positively worded messages addressing maladaptive cognitions. The intervention was evaluated using a randomized control design. Key outcomes were measured pre-, post-, and one month after the intervention. There were significant changes in social cognition (YSQ-SF $T_0-T_1-T_2$, $X^2 = 9.69$, $p = 0.008$) and loneliness levels (total loneliness $T_0-T_1-T_2$, $X^2 = 14.62$, $p = 0.001$), and an increase in WhatsApp usage ($T_0 = 26\%$ vs. $T_1 = 60\%$, $X^2 = 15.22$, $p = 0.019$). At 1-month follow-up, even with a significant reduction in WhatsApp usage, a significant reduction in loneliness was maintained. LI-CBT delivered via instant messaging may be effective in reducing loneliness experienced by older people.

Keywords: older people; loneliness; mHealth; low-intensity CBT; smartphone; WhatsApp

1. Introduction and Background

Relocation to residential care may bring about changes in social network structures and social network density for older people [1–3]. This can result in social isolation, loneliness and reduced mental well-being [4,5], with loneliness prevalence reported as high as 56% among older people living in residential care in Norway [6]. Loneliness, seen as the cognitive discrepancy between desired and actual quality and quantity of relationships [7], may result in negative or maladaptive cognitions commonly expressed by people experiencing loneliness [8,9] that can interfere with the development or maintenance of social connections [8,10]. Loneliness has pathophysiological effects on older people which increase mortality [11].

There are a plethora of primary studies, and systematic reviews addressing loneliness in older people [5,12,13]. Various social and psychological interventions have been recommended to address loneliness in older people, including interventions using technology [5,9,14,15], with varying degrees of effectiveness [16] and differing levels of quality in evaluation design [8,9]. Interventions addressing

maladaptive or negative social cognitions have been reported to be most effective in reducing loneliness by changing social behavior and thereby improving social connections [8,9]. Improvement in social connections can contribute to healthy ageing and improved cognitive functioning [17,18]. Previously held beliefs that face-to-face interaction is the gold standard of social participation [19] has been challenged, with evidence that feelings of connection can also be established via communication technology [3]. Social media and instant messaging have been cited as instances of communication technology that may improve social networks by maintaining visibility, re-awakening previous social networks, or development of new networks [20–23]. Instant messaging using mobile cellular phones can be used to address maladaptive cognitions, but older people are reported to be less inclined to use technological communication to initiate social connections [24]. MHealth projects for older people are often viewed with skepticism in regard to cost, perceived poor technology acceptance and ageism [25,26], but when appropriate consideration is given to facilitating conditions [25,27,28] and cost [29,30] older people are capable of learning new technology [25]. Despite studies examining older people' existing engagement with social media and its effects on loneliness [21,31] a gap exists for intervention studies that specifically target loneliness using social media. Chipps et al. [14] in their umbrella review of systematic reviews examining eInterventions targeting loneliness in older people failed to identify any mHealth interventions in the included primary studies. Chen and Schulz [12] in their systematic review of communication technology interventions, suggested further studies in the fields of loneliness and social media to identify the opportunities to reduce loneliness in older people. This study accordingly sought to implement and evaluate a low-intensity cognitive behavioral therapy (LI-CBT) mHealth-supported intervention delivered via mobile instant messaging (WhatsApp) to address maladaptive cognitions and reduce loneliness in older people living in a residential setting.

2. mLINCC—A LI-CBT Intervention Supported by WhatsApp

A LI-CBT intervention, *Living In Network Connected Communities* (mLINCC) to be delivered on WhatsApp, was developed by a stakeholder group consisting of a CBT specialist psychologist, a mental health nurse, and an mHealth expert. The intervention was informed by a theoretical framework of loneliness [32,33] and evidence from two umbrella reviews on the effectiveness of interventions to address loneliness [14,34]. A gap in mHealth interventions was identified [14,23] along with strong evidence that social cognition interventions [8,9] and psycho-education [35] were most effective in addressing loneliness and the need for participants to be actively involved in the intervention [35].

The three-month intervention had three distinct phases involving threads of trust, social network development, and gerontechnology self-efficacy, reinforced with homework assignments requiring a WhatsApp response [36] and a weekly face-to-face Help Desk for technological support [37]. All participants in the intervention group (IG) were added to the mLINCC WhatsApp group, which was a closed group and at cross-over a separate WhatsApp group (mLINCC 2) for the control group (CG). Apart from the closed groups, participants were able to use the smartphone and communication on mLINCC as they chose and there was no incentive for increased use. The data package selected to offer the greatest financial sustainability post-intervention, allowed for any form of WhatsApp interaction apart from WhatsApp calls. No participants had previously used WhatsApp; in the IG apart from one participant all owned feature (basic) mobile phones which did not support such applications as WhatsApp, predominantly making calls and the participant who owned a smartphone used it as a feature (basic) mobile phone. In the first phase (2 weeks), technology acceptance was developed through activities which included the selection of a smartphone and four 90-min face-to-face (F2F) group-training sessions on the use of the smartphone and WhatsApp. The participants could keep the phones post-intervention but would be responsible for the purchase of data (600 Mb for ZAR15.00/month/US \$1.10). In the second phase (2 weeks), psycho-education was delivered through four 90-min F2F sessions on factors underlying loneliness. Key messages from these sessions were confirmed through messages on WhatsApp. In phase three (1 month) individualized messages with positively framed content aimed at countering maladaptive cognitions were sent to participants via

WhatsApp. Individual maladaptive cognitions were identified through the administration of the Young Schema Questionnaire short-form (YSQ-SF)—Disconnection and Rejection domain. The messages were constructed by the CBT specialist and each message had two components: acknowledgment of the maladaptive cognition linked to loneliness, and a positively framed counter message to allow the participants an opportunity to reflect on the cognitive distortion and its influence on their feelings and behaviors (Table 1). The final phase was a maintenance stage (1 month) during which just the weekly Help Desk was continued, with the moderator still presiding over the WhatsApp group though not participating.

Table 1. Example of Mistrust schema and a positively framed message.

Item on YSQ-SF	Acknowledgment of Schema (Day 1)	Positively Framed Message Delivered on mLINCC (Voice Note and Text) (Day 2)
I am quite suspicious of other people's motives		Counter message; Not all people have negative intentions. There are genuine and trustworthy people in the world.
It is only a matter of time before someone betrays me		Unfortunately, negative expectations can act as a barrier to your being able to reach out to others. You can change this. Try to evaluate the accuracy of your beliefs. Look back on your life and identify someone who really cared about you. Think about what made this person different.
I feel that people will take advantage of me		
I feel that I cannot let my guard down in the presence of other people, or else they will intentionally hurt me	It is understandable that you may feel suspicious of other people and worry that they may hurt you, take advantage of you, or have ulterior motives, especially if these types of experiences have happened in the past.	
I am usually on the lookout for other people's ulterior or hidden motives		

3. Methodology

Setting: The study was conducted in a Non-Government Organization (NGO) which offers accommodation for resource-restricted residents, ranging from independent living to frail care and services throughout the city to 1900 older people (≥ 60 years).

Study design: A randomized control study with two groups—IG and CG—was conducted to evaluate the intervention. Due to the nature of the intervention there was no blinding. Participants were randomly assigned to the IG or the CG. The CG received usual care, which was a generic wellness program for all residents. For ethical reasons, on completion of the intervention the CG also received the intervention, receiving their smartphones and all resources at this cross-over point. The study was approved by the Humanities and Social Sciences Ethics Committee (HSSREC) of the University of KwaZulu-Natal. (HSS/1169/016D) on 16 September 2016, followed by gatekeeper permission from the research site. Approval was received to feature the WhatsApp brand in the printed material (Asset Request # 34292).

Population and sampling: The population was 828 residents living in four inner-city residential NGO care facilities ($n = 828$) in a large South African city. Eligible participants were identified through a cross-sectional survey of a random sample of 277 residents and met the criteria for inclusion: namely, ≥ 60 years, residing in the residence, willing to participate, cognitively intact on the Subjective Memory Complaint Clinical (SMCC) [38] and socially isolated (≤ 15 on the Friendship Scale) [39], or lonely (2–6 on de Jong Gierveld Loneliness Scale (DJGLS) [40] [6-item]) or with decreased mental well-being (World Health Organization-Five Well-Being Index, (WHO-5) [41] score < 13) (Figure 1) A minimum sample size of 52 participants was estimated to provide a medium to large effect size.

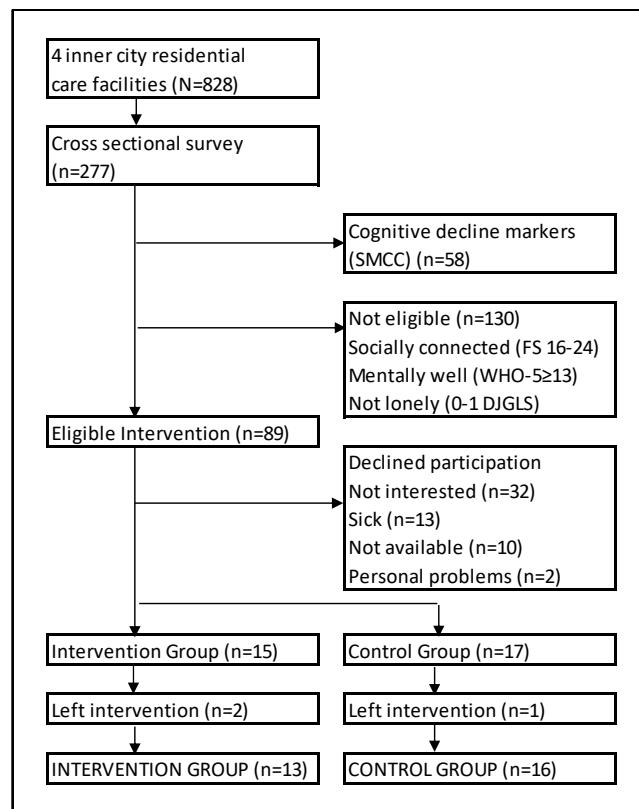


Figure 1. Participant allocation and attrition. DJGLS: de Jong Gierveld Loneliness Scale; FS = Friendship Scale; SMCC: Subjective Memory Complaint Clinical; WHO-5: WHO (five) Well-being Index.

Research instrument: A standard researcher-administered questionnaire was used to capture the key outcome measurements of WhatsApp usage, social cognitions, loneliness, and mental well-being. The questionnaire captured data on demographics and WhatsApp usage, social cognition (Disconnection and Rejection domain of the Young Schema Questionnaire (YSQ-SF 3)) [42], loneliness (6-item) (DJGLS) [40], and mental well-being (WHO-5) [41] (Table 2).

Table 2. Outcome measures.

Measure	Description
Usage	Frequency of mobile phone use to contact family or friends (less than monthly, monthly, weekly, or daily). Predominant function used on mobile phone.
Social Cognition	Disconnection and Rejection domain and related schemas of the YSQ-SF (Abandonment, Defectiveness, Emotional Deprivation, Mistrust and Social Isolation) [43]. Using a 6-point Likert scale rating the most accurate description over the past year from “Completely untrue of me” (1) to “Describes me perfectly” (6) [43–45]. YSQ-SF has established reliability and validity in Eastern (Cronbach α 0.72–0.90) and Western settings (Cronbach α 0.81–0.94) [44] and with the elderly [45].
Loneliness	The DJGLS is a 6-item scale (0–6) with two sub-scales of emotional (0–3) and social loneliness (0–3) [40]. A score of six represents extreme loneliness and three of extreme emotional or social loneliness, measured on its sub-scales [40]. It is recommended for use in the elderly [46], reliable and well validated [40].
Mental well-being	The WHO-5 is a 5-item scale using a 6-point Likert rating and is a first screener for depression (raw score <13) [41,47]. The scale items are positive statements based on mood, vitality and general interest over a two-week period [41].

Data collection: The questionnaire was administered three times: pre-intervention (T_0), post-intervention (T_1) and one month post-intervention (T_2). The participants provided written informed consent and the LI-CBT mHealth-supported intervention was conducted from March to June 2018. In preparation, research assistants (1:4 participants) were trained and resource materials prepared (manuals, stylus pens, and phone pouches) [48–50].

Data analysis: Data from the questionnaires were entered into SPSS v.25. Ages were categorized into younger old (60–79 years) and older old (80+ years) and time in residence (1–18 months and ≥ 19 months). Summary scores for all outcome measures were calculated. Items in DJGLS were reverse scored for emotional loneliness subscale. Non-parametric Friedman test ($X[2]$) was used to detect within-group differences in the intervention across three time periods tests, followed by Wilcoxon signed rank test (W) to compare the time points for significance ($p \leq 0.05$). Differences between groups were compared using Mann-Whitney-U (U) and due to the small sample and different sample sizes, Hedges' g calculated effect sizes ($[M_1 - M_2] / SD_{\text{pooled}}$ and weighted) (<https://www.socscistatistics.com/effectsize/default3.aspx>). Missing data was handled by excluding cases pairwise. Cronbach's alpha was used to test the internal consistency of the subscale and scale scores (≥ 0.70 good).

4. Results

Demographics

Eighty-nine respondents ($n = 89$) were eligible to participate in the intervention, and 32 (35.95%) agreed to participate (Figure 1). Of the eligible participants 32 (35.95%) were not interested, 13 (14.61%) ill, 10 (11.24%) were not available and two participants declined for personal problems (Figure 1). Eligible participants who declined participation showed similar levels of mental well-being (WHO-5 $m = 16.5/25 \pm 4.9$) and total loneliness ($m = 3.14/6 \pm 1.59$) to the participants. Fifteen participants were allocated to the IG and 17 to the CG, resulting in 13 (IG) and 16 (CG) participants after attrition (Figure 1). The participants were between 61 and 87 years ($m = 74.93 \pm 6.41$ years), mainly female, Asian/Indian, widowed, and primary school and lesser-educated. Nearly two thirds of the participants had lived in the residences for 19 months or longer ($n = 20$, 62.5%) (Table 2). Cronbach-alpha was measured at T_0 and shown to be good for YSQ-SF and all five schemas and the WHO-5, but low internal constancy for social loneliness ($\alpha = 0.55$).

At T_0 there were no significant demographic or outcome differences between the IG and CG (Table 3). At the start of the intervention, only slightly more than half of participants (54.84%) used their mobile phones weekly to contact family or friends (Table 4), with the majority ($n = 26$, 83.87%) using the call function. The total group ($n = 32$) were mostly mentally well, but showed moderate levels of maladaptive social cognitions on the selected domain (YSQ-SF $m = 78.38/150 \pm 25.06$), with *Social Isolation* rated the highest, and moderate levels of loneliness (total loneliness $m = 3.56/6 \pm 1.24$; emotional loneliness $m = 1.63/3 \pm 0.83$; social loneliness $m = 1.94/3 \pm 0.72$) (Table 4).

Table 3. Baseline demographics ($n = 32$).

Variable of Interest	Total Participants ($n = 32$)	IG $n = 15$ (46.88%)	CG $n = 17$ (53.13%)	Statistic	<i>p</i> -Value
Age group				$X^2 = 0.41$	$p = 0.522$
Younger old (60–79)	27 (84.4%)	12 (80.0%)	15 (88.2%)		
Older old (80+)	5 (15.6%)	3 (20.0%)	2 (11.8%)		
Gender				$X^2 = 0.54$	$p = 0.659$
Males	6 (18.8%)	2 (13.3%)	4 (23.5%)		
Females	26 (81.3%)	13 (86.7%)	13 (76.5%)		

Table 3. Cont.

Variable of Interest	Total Participants (n = 32)	IG n = 15 (46.88%)	CG n = 17 (53.13%)	Statistic	p-Value
Marital status				$\chi^2 = 1.31$	$p = 0.726$
Never married	7 (21.9%)	3 (20.0%)	4 (23.5%)		
Married	5 (15.6%)	3 (20.0%)	2 (11.8%)		
Separated/divorced	9 (28.1%)	3 (20.0%)	6 (35.3%)		
Widowed	11 (34.4%)	6 (40.0%)	5 (29.4%)		
Highest Education				$\chi^2 = 1.00$	$p = 0.755$
Pre-primary and lower	18 (56.3%)	8 (53.3%)	10 (58.8%)		
2° and 3° education	14 (43.8%)	7 (46.7%)	7 (41.2%)		
Time living in res				$\chi^2 = 0.21$	$p = 0.647$
1–18 months	12 (37.5%)	5 (33.3%)	7 (41.2%)		
≥19 months	20 (62.5%)	10 (66.7%)	10 (58.8%)		
Children				$\chi^2 = 0.03$	$p = 0.589$
No children	9 (28.1%)	4 (26.7%)	5 (29.4%)		
Yes children	23 (71.9%)	11 (73.3%)	12 (70.6%)		
Grandchildren				$\chi^2 = 0.74$	$p = 0.388$
No grandchildren	11 (34.4%)	4 (26.7%)	7 (41.2%)		
Yes grandchildren	21 (65.6%)	11 (73.3%)	10 (58.8%)		

Table 4. Baseline outcome measures (n = 32).

Variable of Interest	Total Participants (n = 32)	IG n = 15 (46.88%)	CG n = 17 (53.13%)	Statistic	p-Value
Usage mobile phone					
Mobile function used most Calls (n = 31)	26 (83.87%)	13 (92.86%)	13 (76.5%)	$\chi^2 = 2.89$	$p = 0.409$
Frequency network contact with mobile phone Weekly (n = 31)	17 (54.84%)	7 (50.0%)	10 (58.8%)	$\chi^2 = 1.41$	$p = 0.703$
Cognition (YSQ-SF domain Disconnection and Rejection)					
Total YSQ-SF/150, α 0.75	78.38 ± 25.06	83.53 ± 19.30	73.82 ± 29.05	$U = 0.46$	$p = 0.478$
Emotional dep./30, α 0.80	16.91 ± 6.16	18.93 ± 5.65	15.12 ± 6.18	$U = -1.52$	$p = 0.128$
Social Isolation/30, α 0.78	16.72 ± 5.99	17.87 ± 5.68	15.71 ± 6.23	$U = -0.57$	$p = 0.570$
Abandonment/30, α 0.81	15.28 ± 7.28	16.80 ± 5.98	13.94 ± 8.21	$U = -1.03$	$p = 0.305$
Defectiveness/30, α 0.80	14.78 ± 5.66	14.80 ± 5.19	14.76 ± 6.21	$U = -0.11$	$p = 0.910$
Mistrust/25, α 0.78	14.69 ± 5.50	15.13 ± 5.28	14.29 ± 5.82	$U = -0.30$	$p = 0.762$
Loneliness (DJGLS)					
Loneliness total/6, α 0.61	3.56 ± 1.24	3.53 ± 1.30	3.59 ± 1.23	$U = -0.35$	$p = 0.727$
Emotional loneliness/3, α 0.65	1.63 ± 0.83	1.73 ± 0.80	1.53 ± 0.87	$U = 0.48$	$p = 0.477$
Social loneliness/3, α 0.55	1.94 ± 0.72	1.80 ± 0.68	2.06 ± 0.75	$U = -1.01$	$p = 0.314$
Mental well-being (WHO-5)					
WHO-5/25, α 0.81	16.22 ± 5.32	15.07 ± 6.87	17.24 ± 3.35	$U = -1.01$	$p = 0.314$

CG: Control group; dep: Deprivation; DJGLS: de Jong Gierveld loneliness scale; IG: Intervention group; WHO-5: WHO-five Well-being Index; YSQ-SF: Young Schema Questionnaire (Short form); Note: Differences between intervention and control groups for usage of mobile phone were tested using Chi-square tests (χ^2) and cognition, loneliness, and mental well-being were tested using non-parametric test (Mann-Whitney U); Significance was set as $p < 0.05$.

The effectiveness of the intervention was evaluated at three time points ($T_0-T_1-T_2$). In the IG at $T_0-T_1-T_2$, a significant increase in the frequency of mobile phone usage ($\chi^2 = 8.90, p = 0.012$) and WhatsApp ($\chi^2 = 12.17, p = 0.002$) was recorded, as opposed to the CG where no significant changes in the frequency of usage of the mobile phone were recorded. In the IG from T_1 to T_2 , the significant increase in the frequency of daily smartphone usage ($T_0 = 26\% \text{ vs. } T_1 = 60\%, \chi^2 = 15.22, p = 0.019$) was

not maintained with a significant reduction by the end of the intervention ($T_1 = 60\%$ vs. $T_2 = 53.3\%$, $X^2 = 13.48, p = 0.036$). Monitoring of participants' smartphone activity was only possible through the WhatsApp group (mLINCC) and not through their encrypted messages. On mLINCC there was evidence of participants' active use of all functions offered by the select WhatsApp data package (excluded WhatsApp calls), except for the function of creating a voice message. While recording a voice message and the simultaneous requirement of holding the voice message icon appeared to present co-ordination challenges.

Over the intervention ($T_0-T_1-T_2$), the IG showed significant decreases in the total YSQ-SF ($X^2 = 9.69, p = 0.008$) and the schemas (*Social Isolation* $X^2 = 16.45, p \leq 0.001$, *Emotional Deprivation* $X^2 = 11.04, p = 0.003$, *Defectiveness* $X^2 = 9.50, p = 0.009$) except in the schemas *Abandonment* and *Mistrust* (Table 5). This was accompanied by a significant reduction ($T_0-T_1-T_2$) in total loneliness ($X^2 = 14.62, p = 0.001$) and emotional loneliness ($X^2 = 15.80, p = < 0.001$). In comparison. ($T_0-T_1-T_2$), the CG participants became more lonely (total loneliness, $W = 5.51, p = 0.064$) and significantly more emotionally lonely ($X^2 = 12.29, p = 0.002$) (Table 5). For the IG, T_0 to T_1 showed the most significant reductions for all measurements (YSQ-SF (YSQ-SF $W = -2.34, p = 0.019$, Social Isolation $W = -3.06, p = 0.002$, Defectiveness $W = -2.72, p = 0.007$, Emotional Deprivation $W = -2.45, p = 0.014$, Abandonment $W = -2.08, p = 0.037$, total loneliness $W = -2.16, p = 0.031$, emotional loneliness $W = -2.27, p = 0.023$)) (Table 5). During the post-intervention period (T_1-T_2), the CG had significantly higher loneliness (total) ($p = 0.011$) and emotional loneliness ($p = 0.003$) (Table 5).

Comparing the overall effect between the IG and CG pre- and post-intervention (T_0-T_1) the IG had significantly improved WhatsApp usage (IG 73.3% vs. CG 11.8%, $X^2 = 16.22, p \leq 0.001$), with accompanying significantly greater improvements in their social cognitions for *Social Isolation* (IG 7.08 ± 5.62 vs. CG $1.29 \pm 6.08, U = -2.39, p = 0.015$), *Emotional Deprivation* (IG 6.69 ± 7.58 vs. CG $1.12 \pm 7.75, U = -2.24, p = 0.025$), *Abandonment* (IG 6.69 ± 7.58 vs. CG $1.12 \pm 7.75, U = -2.24, p = 0.025$). The improvements in loneliness and mental well-being were not significant between the groups at T_1 (Table 6). However, in the post-intervention period (T_1-T_2), the significant increase in WhatsApp users (IG 66.7% vs. CG 5.9%, $X^2 = 17.08, p \leq 0.001$), was accompanied by significant improvements in the IG compared to the CG in all levels of loneliness (Total loneliness IG 0.92 ± 1.26 vs. CG $-1.53 \pm 2.00, U = -3.28, p = 0.001$; emotional loneliness IG 0.31 ± 0.75 vs. CG $1.12 \pm 1.11, U = -3.36, p = 0.001$; social loneliness (IG 0.62 ± 1.04 vs CG $-0.41 \pm 1.18, U = 2.36, p = 0.028$) (Table 5). The largest effect size was for total loneliness and emotional loneliness (total loneliness $ES = 1.50$, emotional loneliness $ES = 2.26$) ($p \leq 0.001$) (Table 6), with small effect sizes for social loneliness ($ES = 0.47$) and mental well-being at T_2 ($ES = 0.41$) (Table 6).

Table 5. Pre- and Post-intervention comparisons of social cognitions, loneliness, and mental well-being.

	Scale Item	m, sd (T ₀)	m, sd (T ₁)	m, sd (T ₂)	p-Value (T ₀ –T ₂) (F)	p-Value T ₀ –T ₁ (W)	p-Value T ₁ –T ₂ (W)	p-Value T ₀ –T ₂ (W)
Social Cognition (YSQ-SF)								
IG (T ₀ n = 15, T ₁ and T ₂ , n = 13)	Total YSQ-SF/150	83.53 ± 19.30	53.85 ± 25.30	52.62 ± 15.99	0.008 *	0.019 *	0.969	0.003 *
	Emotional Dep./30	18.93 ± 5.65	12.31 ± 8.29	10.23 ± 2.46	0.003 *	0.014 *	0.582	0.003 *
	Social Isolation/30	17.87 ± 5.68	10.38 ± 4.33	10.23 ± 3.59	<0.001 *	0.002 *	0.755	0.002 *
	Abandonment/30	16.80 ± 5.98	10.23 ± 5.72	10.69 ± 5.17	0.193	0.037 *	0.655	0.041 *
	Mistrust/30	15.13 ± 5.28	12.92 ± 6.65	12.08 ± 3.93	0.787	0.576	0.688	0.263
	Defectiveness/30	14.80 ± 5.19	8.00 ± 4.08	9.38 ± 3.36	0.009 *	0.007 *	0.089	0.025 *
Loneliness (DJGLS)								
	Total loneliness/6	3.53 ± 1.30	2.31 ± 1.49	1.38 ± 1.33	0.001 *	0.031 *	0.028 *	0.003 *
	Social loneliness/3	1.80 ± 0.68	1.69 ± 0.75	1.08 ± 0.86	0.086	0.655	0.054	0.058
	Emotional loneliness/3	1.73 ± 0.80	0.62 ± 0.96	0.31 ± 0.63	<0.001 *	0.023 *	0.157	0.003 *
Mental well-being (WHO-5)								
CG (T ₀ –T ₂ n = 17)	WHO-5/25	15.07 ± 6.87	17.15 ± 6.31	16.54 ± 4.54	0.341	0.161	0.504	0.643
	Social Cognition (YSQ-SF)							
	Total YSQ-SF/150	73.82 ± 29.05	70.59 ± 22.15	78.00 ± 14.77	0.275	0.642	0.170	0.413
	Emotional Dep./30	15.12 ± 6.18	14.00 ± 5.40	16.06 ± 4.18	0.476	0.534	0.195	0.704
	Abandonment/30	13.94 ± 8.21	13.82 ± 5.58	14.41 ± 5.08	0.570	0.887	0.670	0.932
	Social Isolation/30	15.71 ± 6.23	14.41 ± 5.01	16.47 ± 3.69	0.279	0.377	0.129	0.660
	Mistrust/30	14.29 ± 5.82	15.94 ± 5.32	17.65 ± 4.86	0.566	0.225	0.147	0.117
	Defectiveness/30	14.76 ± 6.21	12.41 ± 5.43	13.41 ± 5.35	0.729	0.116	0.529	0.378
	Loneliness (DJGLS)							
	Total loneliness/6	3.59 ± 1.23	2.47 ± 2.10	4.00 ± 1.32	0.064	0.086	0.011 *	0.282
	Social loneliness/3	2.06 ± 0.75	1.47 ± 1.18	1.88 ± 0.57	0.414	0.080	0.176	0.386
	Emotional loneliness/3	1.53 ± 0.87	1.00 ± 1.12	2.12 ± 0.70	0.002 *	0.075	0.003 *	0.704
Mental well-being (WHO-5)								
	WHO-5/25	17.24 ± 3.35	16.76 ± 4.70	16.47 ± 4.00	0.591	0.584	0.699	0.413

CG: Control group; DJGLS: de Jong Gierveld loneliness scale; Dep.: Deprivation; F: Friedman test; IG: Intervention group; T: Time; WHO-5: WHO (five) Well-being Index; W: Wilcoxon Signed Rank test; YSQ-SF: Young Schema Questionnaire (Short form); Note: Differences between baseline/pre-intervention (T₀), post-intervention (T₁), post-maintenance (T₂) were tested using non-parametric Friedman test; Differences between T₀–T₁, T₁–T₂, T₀–T₂ were tested using Wilcoxon mean signed test (W); Significance was set as p < 0.05 *.

Table 6. Between group comparisons of changes through the stages for social cognitions, loneliness, and mental well-being.

Scale Item	T ₀ –T ₁			T ₁ –T ₂			T ₀ –T ₂			Effect Size (Hedge's g)
	IG (n = 13) (M, Sd of Differences)	CG (n = 17) (M, Sd of Differences)	p-Value	IG (n = 13) (M, Sd of Differences)	CG (n = 17) (M, Sd of Differences)	p-Value	IG (n = 13) (M, Sd of Differences)	CG (n = 17) (M, Sd of Differences)	p-Value	
Social Cognition (YSQ-SF)										
Total YSQ-SF	28.31 ± 34.13	3.24 ± 25.94	0.065	1.23 ± 15.79	-7.41 ± 21.56	0.133	-29.54 ± 25.18	4.18 ± 29.13	0.006 *	1.23 ***
Emotional Dep.	6.69 ± 7.58	1.12 ± 7.75	0.025 *	2.08 ± 8.10	-2.06 ± 6.80	0.229	-8.77 ± 6.58	0.94 ± 8.64	0.002 *	1.24 ***
Abandonment	6.69 ± 7.58	1.12 ± 7.75	0.025 *	-0.46 ± 4.60	-0.59 ± 7.29	0.805	-5.77 ± 7.54	0.47 ± 8.78	0.053	0.75 **
Social Isolation	7.08 ± 5.62	1.29 ± 6.08	0.015 *	0.15 ± 3.18	-2.06 ± 5.86	0.183	-7.23 ± 5.73	0.76 ± 6.58	0.002 *	1.28 ***
Mistrust	1.92 ± 10.16	-1.65 ± 6.73	0.300	0.85 ± 4.78	-1.71 ± 4.95	0.245	-2.77 ± 7.93	3.35 ± 7.75	0.048 *	0.78 **
Defectiveness	6.38 ± 5.85	2.35 ± 5.93	0.059	-1.38 ± 2.63	-1.00 ± 6.02	0.680	-5.00 ± 6.58	-1.35 ± 6.22	0.123	0.57 **
Loneliness (DJGLS)										
Total loneliness	1.15 ± 1.57	1.12 ± 2.34	0.902	0.92 ± 1.26	-1.53 ± 2.00	0.001 *	-2.08 ± 1.75	0.41 ± 1.58	<0.001 *	1.50 ***
Social loneliness	0.08 ± 0.64	0.59 ± 1.50	0.408	0.62 ± 1.04	-0.41 ± 1.18	0.028 *	-0.69 ± 1.18	-0.18 ± 1.01	0.229	0.47 *
Emotional loneliness	1.08 ± 1.26	0.53 ± 1.18	0.157	0.31 ± 0.75	-1.12 ± 1.11	0.001 *	-1.38 ± 0.87	0.59 ± 0.87	<0.001 *	2.26 ***
Mental well-being (WHO-5)										
WHO-5	-1.92 ± 4.21	0.47 ± 4.26	0.113	0.62 ± 4.94	0.29 ± 4.43	0.621	1.31 ± 5.91	-0.76 ± 4.40	0.363	0.41 *

CG: Control group; Dep.: Deprivation; DJGLS: de Jong Gierveld loneliness scale; IG: Intervention group; WHO-5: WHO (five) Well-being Index; YSQ-SF: Young Schema Questionnaire (Short form); Note: Mean and standard deviations of differences between pre- and post-intervention (T₀–T₁) and post-intervention and post-maintenance (T₁–T₂) between IG and CG were tested using non-parametric test (Mann-Whitney-U test); Significance was set as $p < 0.05$ *. Effect sizes calculated for T₀–T₂ using Hedges' g.* 0.2: small effect size, ** 0.5 medium effect size, *** 0.8 large effect size.

5. Discussion

Although the study sample size was small, the LI-CBT WhatsApp intervention was effective in significantly adjusting maladaptive social cognitions and reducing loneliness in older people in this setting and can be used in other resource-restricted settings and non-resource-restricted settings. Customization of the intervention is suggested in tailoring the positively worded MIM to be culturally and contextually specific. In future at the invitation to the intervention a period of experimentation with a smartphone in a low risk setting has the possibility of increasing enrolment. The study though delivered using WhatsApp concurred with the study by Chiang et al. [15] involving reminiscence in older men ($n = 92$) which showed the effectiveness of targeting maladaptive social cognitions in the reduction of loneliness.

Improved cognition and a reduction in loneliness was significantly evident post-intervention (except social loneliness) and was maintained one month after the active intervention. The continued effect, despite some decrease in WhatsApp usage possibly due to the lessening of the novelty effect [51], may be related to the changes in the format and frequency of communication with the social networks from participants' initial preference for mobile phone calls to their use instead of WhatsApp, which allowed them to maintain or develop contact with both kin and non-kin networks.

The social cognition schema which demonstrated the largest effect size (ES = 1.28) was *Social Isolation*, with changes in the feelings of alienation, not belonging, being an outsider, and socially different. *Social Isolation* has predictive validity for depression [52], and links to emotional loneliness [53]. Similarly, deprivation is a core component of loneliness [7] and the large effect on *Emotional Deprivation* (ES = 1.24), which involved improved feelings of nurturance, empathy and protection may further reduce emotional loneliness [53]. Improvement in the schemas of *Emotional Deprivation*, *Social Isolation*, and emotional loneliness were paralleled with an increase in smartphone contact with social networks. The findings suggest that through the network link in the intervention, the participants found nurturance and a sense of belonging and inclusion, and were able to experience relationship salience [19].

The effect for social loneliness (ES = 0.47) was small and appeared more resistant to change. The IG participants showed slower changes in their perceptions of adequacy in the number of people in the social networks and it was only after the maintenance period that social loneliness showed a near significant change. This may relate to the progressive nature of loneliness, with dissipation of emotional loneliness preceding dissipation of social loneliness [54]. It was anticipated that social loneliness improvement would have occurred earlier due to the early face-to-face interaction among participants and the group-based interventions, reported to be of value in the reduction of loneliness [9,32]. The resistance to change in social loneliness may also relate to the resistance to change in the schema of *Mistrust*, needing a change to occur in the cognitive appraisal of relationships before there is a change in the social deficit [54]. The cognitive appraisal of *Mistrust* can be a problem for social engagement: trust, which is often likened to the "glue" that binds society [55], is closely intertwined with social loneliness. Edwards [56], following Putnam's various propositions in relation to social capital, states that trust is foundational to civic culture and is the outcome of a person's correct prediction of others' co-operative behavior, facilitated by external conditions. In addition, Pope et al. [57] note that the higher the level of trust, the greater the possibility of social participation. Because *Mistrust* is linked to social loneliness it may also be interwoven with the schema of *Defectiveness* leading to feelings of shame, inadequacy, and hypersensitivity to criticism that hamper trust and relationship development. A further possible factor relates to socio-emotional selectivity theory, according to which older people select to maintain contact with their closest, familiar relationships [57] rather than building new relationships [58,59]. Lastly, delayed changes in social loneliness, may be related to South Africa being a country with low levels of trust [54] and with older people showing lower trust levels than younger people [55]. Mistrust is often higher in settings such as South Africa that have high levels of crime, social inequalities, low income and political corruption [55].

6. Conclusions

The unique LI-CBT mHealth supported by the social networking platform of WhatsApp (mLINCC) incorporated face-to-face development of technological readiness in smartphone usage, psycho-education, and the delivery of positively worded mobile instant messages. Overall the intervention showed significant improvements in maladaptive cognitions, and loneliness, highlighting the role of cognitive appraisals in the subjective experience of loneliness. In addition, the unique use of WhatsApp and the crafting of a LI-CBT mHealth-supported intervention that addressed technological readiness in smartphone usage mitigated against loneliness experienced by cognitively intact older people living in residential care settings. The study demonstrated the possibility of the delivery of LI-CBT by a non-psychologist in a low resourced setting in Africa and demonstrated the ability of older people to learn smartphone technology thereby facilitating e-inclusion.

7. Recommendations

It is recommended that residential care facilities implement measures to facilitate residents' positive cognitive appraisals of relationships and contexts such as regular psycho-education sessions. It is further recommended that the study is repeated with a larger sample, over for a longer period, possibly six months, and involves community dwelling older people. In particular, this should be conducted in Africa, where there is a paucity of comparable loneliness studies. In addition, further studies on the development of trust among older people could result in a measure to increase enrolment in intervention programs targeting loneliness.

8. Limitations

Overall, the study found that a low-intensity CBT intervention, tailored to individuals, can be delivered to older people using smart phones and instant messaging with potential to reduce loneliness, although some limitations in the study should be noted. Firstly, the sample size was low, with eligible participants showing low intent to participate (64.04%), which may be a side-effect of being lonely and may require different study recruitment in future studies. This is confirmed by high attrition rates in loneliness studies [51,60–62] due to higher levels of physical ill-health in older people experiencing loneliness [63], coupled with reticence to use smartphone technology possibly due to anxiety levels or a reduced sense of self-efficacy [27]. The low number of participants in the study and the high number of demographics variables and outcome measures could have had an impact on significance. Secondly, a limitation in the use of the DJGLS in this setting should be noted, with possible misinterpretation by the participants of the terms "plenty", "many" and "enough" in the DJGLS [64] that may have influenced ratings of social isolation, and also the notably low reliability in the social loneliness subscale for this study in comparison with other studies [40]. Thirdly, the nature of the study design did not enable differentiation between the various components or the vehicle of delivery of the intervention, and it is recommended that factorial and smart designs be used for future evaluations.

Author Contributions: All three authors were involved in the conceptualization, visualization and methodology of the study. J.C. and A.P. supervised the study, M.A.J. carried out the investigations, the analysis and the preparation of the original draft. J.C. validated the analyses, and J.C. and A.P. reviewed and edited the article.

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Effect of Layperson-Delivered, Empathy-Focused Program of Telephone Calls on Loneliness, Depression, and Anxiety Among Adults During the COVID-19 Pandemic A Randomized Clinical Trial

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 Supplemental content

IMPORTANCE Loneliness is a risk factor for many clinical conditions, but there are few effective interventions deployable at scale.

OBJECTIVE To determine whether a layperson-delivered, empathy-focused program of telephone calls could rapidly improve loneliness, depression, and anxiety in at-risk adults.

DESIGN, SETTING, AND PARTICIPANTS From July 6 to September 24, 2020, we recruited and followed up 240 adults who were assigned to receive calls (intervention group) or no calls (control group) via block randomization. Loneliness, depression, and anxiety were measured using validated scales at enrollment and after 4 weeks. Intention-to-treat analyses were conducted. Meals on Wheels Central Texas (MOWCTX) clients received calls in their homes or wherever they might have been when the call was received. The study included MOWCTX clients who fit their service criteria, including being homebound and expressing a need for food. A total of 296 participants were screened, of whom 240 were randomized to intervention or control.

INTERVENTIONS Sixteen callers, aged 17 to 23 years, were briefly trained in empathetic conversational techniques. Each called 6 to 9 participants over 4 weeks daily for the first 5 days, after which clients could choose to drop down to fewer calls but no less than 2 calls a week.

MAIN OUTCOMES AND MEASURES Primary outcome was loneliness (3-item UCLA Loneliness Scale, range 3-9; and 6-item De Jong Gierveld Loneliness [De Jong] Scale, range 0-6). Secondary outcomes were depression (Personal Health Questionnaire for Depression), anxiety (Generalized Anxiety Disorder scale), and self-rated health (Short Form Health Survey Questionnaire).

RESULTS The 240 participants were aged 27 to 101 years, with 63% aged at least 65 years ($n = 149$ of 232), 56% living alone ($n = 135$ of 240), 79% women ($n = 190$ of 240), 39% Black or African American ($n = 94$ of 240), and 22% Hispanic or Latino ($n = 52$ of 240), and all reported at least 1 chronic condition. Of 240 participants enrolled, 13 were lost to follow-up in the intervention arm and 1 in the control arm. Postassessment differences between intervention and control after 4 weeks showed an improvement of 1.1 on the UCLA Loneliness Scale (95% CI, 0.5-1.7; $P < .001$; Cohen d of 0.48), and improvement of 0.32 on De Jong (95% CI, -0.20 to 0.81; $P = .06$; Cohen d , 0.17) for loneliness; an improvement of 1.5 on the Personal Health Questionnaire for Depression (95% CI, 0.22-2.7; $P < .001$; Cohen d , 0.31) for depression; and an improvement of 1.8 on the Generalized Anxiety Disorder scale (95% CI, 0.44 to 3.2; $P < .001$; Cohen d , 0.35) for anxiety. General physical health on the Short Form Health Questionnaire Survey showed no change, but mental health improved by 2.6 (95% CI, 0.81 to 4.4; $P = .003$; Cohen d of 0.46).

CONCLUSIONS AND RELEVANCE A layperson-delivered, empathy-oriented telephone call program reduced loneliness, depression, and anxiety compared with the control group and improved the general mental health of participants within 4 weeks. Future research can determine whether effects on depression and anxiety can be extended to maximize clinical relevance.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT04595708

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Loneliness has been indicated as a risk factor for overall mortality and conditions from stroke to heart disease.¹ It is associated with depression and anxiety, even if the direction and degree of causality is unclear.² With the onset of coronavirus disease 2019 (COVID-19), there has been concern about the effect of increased isolation on loneliness and other mental health conditions.³⁻⁷ For older adults, those most socioeconomically vulnerable are likely to be at greatest risk.^{8,9}

Few interventions have been shown to be effective,¹ and the mental health workforce is already constrained. A systematic review of randomized interventions through 2010 found that structured, cognitive behavioral therapy (CBT)-based approaches were most effective but require trained counselors.¹⁰ In 2020,¹¹ a video-conferenced behavioral activation intervention (a component of CBT) delivered by lay counselors over 5 weeks showed promising results.¹¹

Comparison between studies is difficult because several tools are used to measure loneliness. Two prominent scales include the De Jong Gierveld Loneliness Scale (De Jong) and the UCLA Loneliness Scale.¹² The De Jong Scale is used in Europe, has been compared internationally,¹³ and may be useful for an elderly population.¹⁰ The 20-item UCLA Scale is frequently used in the United States and has a 3-item version for telephone administration.¹⁴ There are no established values to assess difference for clinically meaningful change.

In March 2020, we became aware of the challenges facing Meals on Wheels Central Texas (MOWCTX) clients because of reduced contact. In response, we designed a program that could be rapidly spun up and deployed. The telephone calls program involves laypeople engaging regularly, with empathetic intention, through telephone calls with participants. Empathy was functionally defined as prioritizing listening and eliciting conversation from the participant on topics of their choice. The protocol included an initial exposure to daily calls. Once exposed to the experience, participants chose the frequency of calls they prefer. Our goal was to test the program's effectiveness in combating loneliness and other mental health conditions we expected may be worsening during COVID-19.

Methods

This study was approved by University of Texas at Austin's institutional review board on June 26, 2020. Participants provided verbal consent on the telephone. CONSORT reporting guidelines were followed.¹⁵ The formal trial protocols can be found in [Supplement 1](#).

Population

Participants were clients of MOWCTX. Staff introduced the study using a script and received permission to share contact information. Study personnel followed up via telephone to confirm interest and eligibility, obtain verbal consent to the research protocol, enroll, and collect baseline measurements. All MOWCTX clients were eligible except those with cognitive impairments, previously assessed through family report or via a case manager, or those in a hospice program.

Key Points

Question Can a program of empathetic conversations delivered by laypeople via telephone reduce loneliness, depression, and anxiety in at-risk older adults?

Findings In this randomized clinical trial of 240 older adults receiving services through a Meals on Wheels organization, a 4-week empathy-oriented telephone program delivered by rapidly trained lay callers during the coronavirus disease 2019 pandemic improved loneliness, depression, anxiety, and general mental health.

Meaning In this study, loneliness, depression, and anxiety were rapidly reduced through layperson-delivered calls that focused on empathetic listening, suggesting a scalable approach to persistent mental health challenges of older adults.

Intervention Program

Study personnel recruited callers through mailing lists and personal networks. Sixteen people from ages 17 to 23 years, including 14 college undergraduates, 1 person entering community college, and 1 graduate student, were recruited to deliver calls to participants (*callers*). Callers volunteered but were paid a stipend of \$200 at the end of the program.

Callers were trained through a 1-hour videoconferenced session. The goal presented to callers was to learn from those they called by asking specific questions about topics raised by participants. No conversational prompts were provided nor training on CBT or its components. A short video was used to demonstrate techniques through role playing. Separately, callers received handouts and videotaped instructions on the logistics of the program (<1 hour).

Each caller supported a panel of 6 to 9 participants over 4 weeks. Calls were targeted to be less than 10 minutes; however, callers reported that calls could run longer. We did not limit time with the participant. Study personnel facilitated a 1-hour weekly, voluntary feedback session with callers.

The program was designed to maximize the participants' perceived benefit. Calls were placed at the time of day participants requested. All participants were called 5 days during the first week. After this, participants chose the frequency of calls, with a minimum of 2 and maximum of 5 a week. Most (58%; n = 70 of 120) chose to continue to be called 5 times a week for the remaining 3 weeks; few (2%; n = 3 of 120) chose 4 a week, 17% (n = 20 of 120) chose 3 a week, and 22% (n = 27 of 120) chose 2 a week.

Callers used a Redcap system to track daily interactions, including whether a participant did not pick up, follow-up items for the next conversation, and any escalation-related issues. Calls were made through Amazon Connect and were not recorded.

The MOWCTX organization provided a list of escalation categories, including participant safety, food, or financial concerns. If a participant reported these concerns, the caller contacted MOWCTX staff to ensure the participant received a follow-up call. Thirty-four escalations were made during the study.

Randomization and Blinding

Prior to randomization, participants were told they would either receive a program of calls for 4 weeks (intervention) or receive no calls until 4 weeks later for the follow-up and a \$10 gift card (control). After consent and baseline measurements were completed, participants were randomized in blocks of 4 and 6 to intervention or control arms. A biostatistician did the randomization allocation, which was then uploaded to Redcap. In the intervention arm, participants were assigned to a caller's panel once a sufficient number had consented so that each caller began with a full panel. Participants were called within 1 to 3 days after baseline collection. In the control arm, participants received no further contact until 4 weeks later, when they were called for follow-up assessment and subsequently sent the gift card.

A research associate, who was not involved in randomization, collected baseline and follow-up measures and was blinded to allocation arm, except for the final questions in the follow-up assessing satisfaction, which only displayed for intervention participants. Final assessments occurred 29 to 35 days after baseline.

Measures

The primary outcome was loneliness, measured with the 6-item De Jong Scale (score range, 0-6)¹⁶ and the 3-item UCLA Loneliness Scale (score range, 3-9),¹² higher numbers implying greater loneliness. Secondary outcomes included depression symptoms measured by the Personal Health Questionnaire for Depression (PHQ-8), anxiety symptoms measured by the Generalized Anxiety Disorder scale (GAD-7), social connection through the 6-item Lubben Social Network Scale (LSNS), and the 12-item general health questionnaire (Short Form Health Survey Questionnaire [SF-12], version 1.0, Mental and Physical Health components).¹⁷ We expected the physical scale of SF-12 and the LSNS not to be affected by this intervention; hence, they were included to help assess the specificity of the intervention effects. We measured demographic data through self-report based on investigator-defined categories, including age, sex, race/ethnicity, chronic conditions, medication use, marital status, and their degree of social interaction before and after COVID-19. Race/ethnicity was recorded to better prepare for replicability. Satisfaction was assessed at the end of the follow-up survey only for the intervention group (unblinded) through the question, "How satisfied were you with receiving the regular calls," with a score of 1 to 5 ("very unsatisfied" to "very satisfied").

Statistical Analysis

The study was powered on the primary outcome measures with the assumption that the rank-order stability of the UCLA and De Jong instruments would be 0.6 from baseline to following intervention. Under those assumptions we targeted 125 participants in each arm to achieve 80% to 90% power to detect a small effect ($f = 0.09$ to $f = 0.10$) for differential change in the 2 arms, with $\alpha = .05$. Not encountering predicted dropouts, we stopped recruitment at 120 in each arm that still had sufficient power for to detect an effect. To our knowledge, there

are currently no prespecified clinically meaningful differences established for these measures.

We conducted linear and logistic mixed-effect regressions for all outcomes. Logistic mixed-effect regressions were run in addition to linear mixed-effect regressions when instruments had well-established clinical cutoffs for mild (5-9), moderate (10-19), or severe (>20) depression (PHQ-8)¹⁸ or anxiety (GAD-7)¹⁹ to gauge clinical significance. To accommodate the variability in the day of final assessment, the models were fit using the participant specific time that elapsed between baseline (set to day = 0) and the final assessment. The fixed-effects portion of the model only included the intercept, intervention group, days, and their interaction. The main effect of interest is the cross-level interaction of intervention group with days (ie, group by pre/post). We modeled person by time effects as nested in callers and assigned all participants in the control group to a single cluster to estimate and adjust the effect of clustering from shared callers. The models were fit with random effects of callers as well as participant intercept. We additionally tested for the random effect of days, but this term was not statistically significant for any of the outcomes. Although the random variance of callers was also not statistically significant for all outcomes except the mental health scale of SF-12, we retained it in the models to adjust for the small clustering effect of shared callers. To control for inflations of type I errors, Bonferroni corrections were applied separately to the primary outcomes (De Jong and UCLA loneliness; $\alpha = .025$) and secondary outcomes (PHQ-8, GAD-7, and SF-12 mental health; $\alpha = .017$). All analyses were conducted using Stata, version 16.1 (StataCorp), with full information maximum likelihood using an intention-to-treat framework.

Results

Participants

From July to August 2020, we received 510 referrals from MOWCTX, of whom 296 were successfully contacted. A total of 240 participants were enrolled and randomized into the study as described in the CONSORT diagram in Figure 1, with 120 in each arm. Of those in the intervention arm, 9 chose to drop out of the program, 7 on the 1st or 2nd, 1 on the 4th, and 1 on the 17th day of a connected call. One participant was removed from the program because of safety concerns that were escalated via MOWCTX to state services for support. After the program ended, 3 additional participants in the intervention arm and 1 in the control arm could not be contacted over 10 unsuccessful call days for follow-up data collection.

We compared the 13 individuals who were lost to follow-up in the intervention group with those who completed all of the assessments on baseline characteristics to assess patterns in dropout. Those who dropped out did not differ from those who completed all of the assessments on average age, chronic disease status, self-rated health, none of the primary or secondary outcome measures, or the distribution of categorical demographic characteristics such as sex and race/ethnicity distribution (White non-Hispanic vs other).

Figure 1. CONSORT Diagram: Flow of Participants Through the Trial

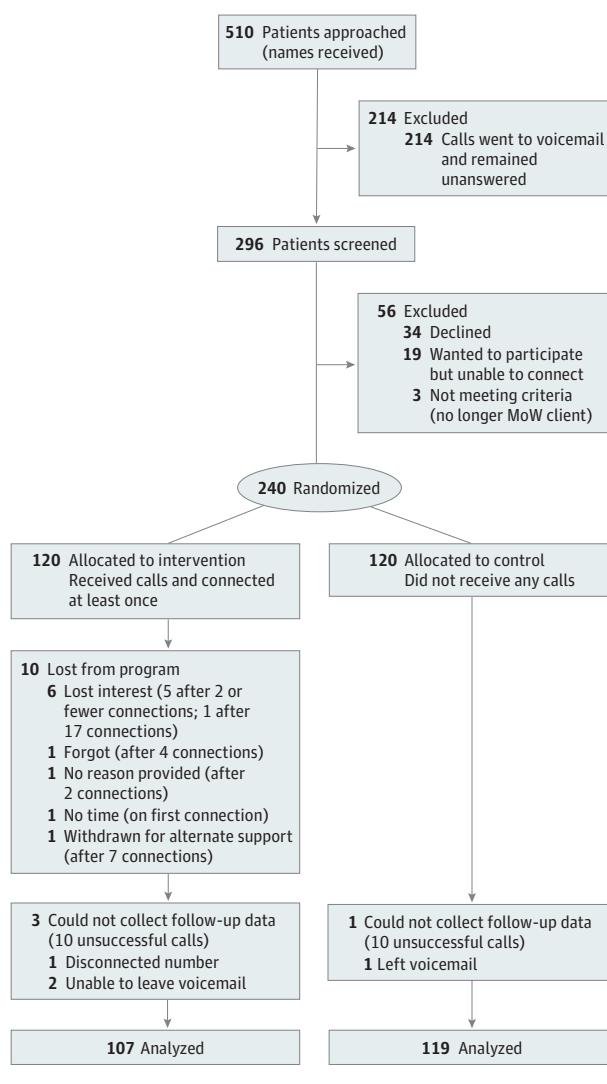


Table 1. Baseline Characteristics of the Sample in the Control and Intervention Arms

Characteristic	No. (%)	
	Control (n = 120)	Intervention (n = 120)
Age, mean (SD), y	68.7 (12.8)	69.4 (11.5)
Female	95 (79)	95 (79)
Ethnicity: Hispanic or Latino	26 (22)	26 (22)
Race		
American Indian	1 (1)	1 (1)
Asian	1 (1)	0
African American	49 (41)	45 (38)
White	42 (35)	51 (43)
Unreported	27 (23)	23 (19)
Chronic disease		
Diabetes	51 (42.5)	49 (41)
Heart disease	28 (23)	36 (30)
Kidney disease	6 (5)	10 (8)
High blood pressure	40 (33)	42 (35)
High cholesterol	8 (7)	6 (5)
Other	78 (65)	85 (71)
At least 1 medication	106 (90)	109 (92)
Living alone	68 (57)	67 (56)
Marital status		
Married	20 (17)	26 (22)
Single, divorced, widowed	100 (83)	94 (78)
Impact of COVID-19 on social contacts		
Visitors during COVID-19	72 (60)	68 (57)
Visitors pre-COVID-19	93 (78)	95 (79)
COVID-19 changed contact	80 (67.5)	79 (66)
Pre-COVID-19 outside activities	80 (67.5)	76 (63)
Self-rated health, mean (SD)	2.5 (.97)	2.5 (1.1)

Abbreviation: COVID-19, coronavirus disease 2019.

Population

Table 1 shows the demographic characteristics of participants. More than one-third identified as African American, most were female, more than half were living alone, all participants in both arms had at least 1 chronic disease diagnosis, and self-rated health (range 0-4) was “good” on average in both groups. Only a minority reported being married; the rest were divorced, widowed, or single. These characteristics are typical of the MOWCTX client base. Most participants believed COVID-19 had changed their degree of social contact, although most still expressed that they received some visitors.

Main Analysis

Participants in the intervention group improved from pre to post assessments of loneliness to a greater extent on the UCLA Scale than on the De Jong Scale; the latter did not achieve statistical significance (Table 2). Participants in the intervention group improved from a mean of 6.5 to 5.2 on the UCLA Scale and in the control group from 6.5 to 6.3 (group difference

of 1.1; 95%CI, 0.5-1.1; $P < .001$; Cohen d of 0.48). Participants in the intervention group improved from a mean of 2.4 to 2.2 on the De Jong Scale, and in the control group did not change from a mean of 2.5 (group difference of 0.32; 95% CI, -0.20 to 0.81; $P = .06$).

Depression and anxiety both improved in the intervention compared with the control group using continuous measures of these scales. Depression improved from a mean of 6.3 to 4.8 on the PHQ-8, and in the control arm, deteriorated from a mean of 6.2 to 6.3 (group difference of 1.5; 95% CI, 0.22-2.7; $P < .001$; Cohen d of 0.31). For participants in the intervention group, anxiety improved from a mean of 5.9 to 4.1 on the GAD-7, and in the control arm, deteriorated from a mean of 5.8 to 6.0 (group difference of 1.8; 95% CI, 0.44-3.2; $P < .001$; Cohen d of 0.35).

To evaluate the clinical relevance of the improvements in depression and anxiety, we examined whether the proportion of participants who were at least mildly symptomatic (anxious or depressed) at baseline (scores of ≥ 5 on both scales) decreased to asymptomatic status at the postassessment stage differentially for the intervention and control groups. Results were consistent with significant reductions in anxiety, with

Table 2. Loneliness, Mental and General Health, and Social Connections in Intervention and Control Arms at Baseline and After 4 Weeks of Intervention

Measurement	Time	Control	Intervention	Group difference at the postassessment stage		P value for group × days ^b	ICC (95% CI) ^c
		Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	Cohen d ^a		
UCLA	Pre	6.5 (6.1 to 6.9)	6.5 (6.1 to 6.9)	1.1 (.50 to 1.7)	0.48	<.001	0.72 (0.62 to 0.80)
	Post	6.3 (5.9 to 6.8)	5.2 (4.8 to 5.6)				
De Jong	Pre	2.5 (2.1 to 2.8)	2.4 (2.1 to 2.8)	0.32 (-0.20 to 0.81)	0.17	.06	0.80 (0.75 to 0.84)
	Post	2.5 (2.1 to 2.8)	2.2 (1.8 to 2.5)				
LSNS	Pre	13.1 (11.9 to 14.3)	12.6 (11.3 to 13.8)	1.1 (-.67 to 3.0)	0.17	.37	0.80 (0.72 to 0.86)
	Post	13.0 (11.8 to 14.3)	11.9 (10.6 to 13.2)				
PHQ-8	Pre	6.2 (5.3 to 7.1)	6.3 (5.5 to 7.1)	1.5 (0.22 to 2.7)	0.31	<.001	0.78 (0.72 to 0.83)
	Post	6.3 (5.3 to 7.2)	4.8 (4.0 to 5.6)				
PHQ-8 ≥ 5, proportion (95% CI) ^d	Pre	0.58 (0.48 to 0.66)	0.59 (0.50 to 0.68)	0.09 (-0.03 to 0.23)	NA	.05	NA
	Post	0.54 (0.44 to 0.63)	0.44 (0.34 to 0.54)				
GAD-7	Pre	5.8 (4.8 to 6.9)	5.9 (4.9 to 6.9)	1.8 (0.44 to 3.2)	0.35	<.001	0.73 (0.66 to 0.78)
	Post	6.0 (4.9 to 7.0)	4.1 (3.2 to 5.0)				
GAD-7 ≥ 5, proportion (95% CI) ^d	Pre	0.49 (0.40 to 0.58)	0.50 (0.41 to 0.59)	0.14 (0.01 to 0.27)	NA	.02	NA
	Post	0.50 (0.40 to 0.59)	0.36 (0.27 to 0.45)				
SF-12 physical health	Pre	32.0 (29.9 to 34.1)	32.0 (29.8 to 33.2)	0.51 (-2.4 to 3.4)	0.05	.98	0.75 (0.69 to 0.80)
	Post	33.9 (31.8 to 36.0)	33.4 (31.4 to 35.3)				
SF-12 mental health ^{e,f}	Pre	44.3 (42.9 to 45.7)	42.5 (41.2 to 43.8)	2.6 (0.81 to 4.4)	0.46	.003	0.53 (0.44 to 0.63)
	Post	44.5 (43.3 to 45.7)	45.1 (43.8 to 46.3)				

Abbreviations: De Jong, De Jong Gierveld Loneliness Scale; GAD-7, Generalized Anxiety Disorder scale; ICC, intraclass correlation coefficient; LSNS, Lubben Social Network Scale; PHQ-8, Personal Health Questionnaire for Depression; SF-12, Short Form Health Survey Questionnaire; UCLA, UCLA Loneliness Scale.

^a Cohen d for the group difference at the postassessment stage.

^b P value for the interaction of group × days, the substantive effect of interest from mixed-effect regressions.

^c ICC and random variance approached 0 in all instances except for the mental health scale of the SF-12 for the caller's cluster. In these instances, we did not include point estimates in the table.

^d The cells report the observed proportion meeting the clinical cutoff in each of the 4 cells, associated 95% CIs, and proportion differences. The P values and the ICCs are obtained from the mixed logistic regressions.

^e The direction of the interaction effect for SF-12 mental health scale concerned differences in within-group change rather than group differences at the postassessment stage. It is those differences that are presented in the group difference at the postassessment column of this table.

^f The ICC values given in the top concern participant clusters and the values of ICC below it concern caller clusters.

50% of those with mild or greater anxiety ($n = 60$ of 120) in the intervention arm reducing to 36% ($n = 38$ of 107), while 49% of those with mild or greater anxiety ($n = 59$ of 120) in the control arm increased to 50% ($n = 59$ of 119) (group difference of 14%; 95% CI, 1%-27%; $P = .02$). Although there was a reduction in those with mild or greater depression in the intervention arm relative to the control arm, it was not statistically significant (group difference of 9%; 95% CI, -3% to 23%; $P = .05$). Finally, on the SF-12 mental health scale, intervention group participants' scores improved from a mean of 42.5 to 45.1 and control participants' scores improved from 44.3 to 44.5 (difference of 2.6; 95% CI, 0.81-4.4; $P = .003$; Cohen d, 0.46). Consistent with expectations, we did not see statistically significant changes in scores on the SF-12 Physical Health scale or in LSNS, which assesses more objective measures of social isolation. Finally, for participants in the intervention group, mean satisfaction was 4.52 (of a maximum of 5), with 65% of those assessed reporting as "very satisfied" and 88% reporting as "somewhat satisfied" or "very satisfied."

The effect sizes were generally small to moderate for those outcomes that showed a statistically significant difference in improvements between intervention and control groups as shown in box plots in Figure 2. Positive differences are consistent with improvement in a given outcome. Figure 2 de-

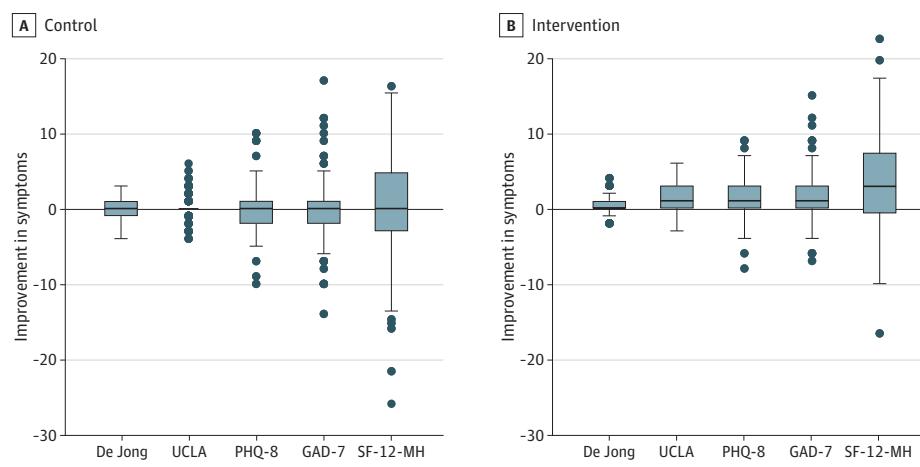
picts the improvements in the context of the wide range of baseline scores for all participants.

Discussion

A 4-week, telephone-based, empathy-focused program delivered during the summer of 2020 reduced loneliness, depression, and anxiety in homebound, largely single, adults who require meals from a community-based provider.

Few prior programs have been shown to reduce loneliness through high-quality randomized trials. The studies that have shown moderate to larger reductions in loneliness implement some form of cognitive behavioral therapy.¹⁰ Choi et al¹¹ showed improvements in loneliness of similar effect size to those we obtained when videoconferenced lay counselors implemented behavioral activation-focused sessions over 5 weeks with a similar population from Meals on Wheels organizations.¹¹ Chiang et al²⁰ showed a large improvement effect size (UCLA-20) for nursing home residents in Taiwan who were exposed to an 8-week reminiscence intervention. The reminiscence intervention focused on participants sharing experiences rather than a structured approach to maladaptive cognition. Both programs also significantly improved depression.

Figure 2. Box Plots of Changes in Loneliness, Depression, Anxiety, and General Mental Health Over 4 Weeks in the Intervention and Control Arms



Box plot indicates median, interquartile range, and lower and upper adjacent values. De Jong indicates De Jong Gierveld Loneliness Scale; GAD-7, Generalized Anxiety Disorder scale; PHQ-8, Personal Health Questionnaire for Depression; SF-12-MH, Short Form Health Survey Questionnaire Mental Health; UCLA, UCLA Loneliness Scale.

Our results are consistent with these prior studies and extend to effects on anxiety and general mental health. We did not screen for anxiety or depression, yet the program significantly reduced the proportion of participants who reported being at least mildly anxious at baseline.

The effect on loneliness varied in magnitude for the 2 instruments used to assess loneliness. The scales have slightly different item content and emphasize affective (UCLA) vs more cognitive (De Jong) approaches to understanding and measuring loneliness.¹⁰ The intervention presented here was designed to affect how people feel rather than how they think. This may explain the differential sensitivity of the 2 scales.

Compared with other intervention programs designed to reduce loneliness, our program required 2 hours of training for callers, no degree requirements, and no training on new tools for participants. The intervention was modeled as a continual support program, with higher frequency of contact in the first week dropping based on personal preference to lower frequency of contact. Although participants reported a high degree of satisfaction with the calls, we are unable to comment on whether the degree of empathy of callers or duration of conversations affected outcomes. However, caller characteristics likely had a minimal effect on reported outcomes because caller random variability was not significant in any of the models except for SF-12 mental health scale. However, all recruited callers were likely to want to serve this population, suggesting a potential factor in replicating these effects.

Limitations

A major limitation of this study is that it is unclear whether benefits are sustained after 4 weeks. Two prior, successful,

loneliness programs showed sustained effects 4 to 6 weeks after program delivery had ended.^{11,20} Future work should address whether improvements can be sustained, or enhanced, with a longer implementation period. Additionally, future research might explore the effect of this program when participants are screened for mental health conditions or stratified based on age. It may be particularly interesting to assess whether the program can play a protective role for those at risk of clinical anxiety or depression. Another limitation is that we cannot distinguish between the effect of being called vs the empathetic nature of the engagement. However, prior work has shown no impact of a weekly check-in call.¹¹ We also observed higher dropouts in the intervention arm ($n = 13$) relative to control ($n = 1$), 7 occurring after only 2 connections, citing time and interest. Future program design might focus on minimizing early dropouts before participants have had a chance to experience program benefits. Finally, our study was not designed to uncover whether reductions in loneliness mediated improvements in mental health scores. Additionally, a strength and potential limitation of this study is that it was implemented during the COVID-19 pandemic.

Conclusions

In this randomized clinical trial, a program of empathetic telephone calls tailored to participant preferences resulted in improvements in loneliness, depression, and anxiety over a 4-week period. The use of lay callers, deliberate but brief approach on training, and the use of ubiquitous telephones made the approach easily deployable and scalable.

ARTICLE INFORMATION

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Critical revision of the manuscript for important intellectual content: Kahlon, Aksan, Aubrey, Clark, Jacobs, Mundhenk, Sebastian.

Statistical analysis: Aksan.

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Changes in Self-Reported Health and Psychosocial Outcomes in Older Adults Enrolled in Sedentary Behavior Intervention Study

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Abstract

Purpose: To estimate changes in self-reported health and psychosocial factors associated with a 12-week sedentary behavior intervention for older adults.

Design: Exploratory secondary analysis of pilot randomized controlled trial.

Setting: Kaiser Permanente Washington

Subjects: Sixty adults aged 60 to 89 with body mass index $\geq 30 \text{ kg/m}^2$.

Intervention: Participants were randomized to the I-STAND intervention or control group. I-STAND involved 6 coaching sessions, a study workbook, Jawbone UP activity tracker to prompt breaks from sitting, and activPAL feedback on objective sitting time.

Measures: At baseline and 12-week follow-up, participants completed a survey with validated measures of self-reported health outcomes (depression, stress, memory/concentration, sleep, pain, ability to do daily activities, energy, and quality of life) and modified scales measuring psychosocial factors (perceived benefits/barriers, social support, self-efficacy, and sedentary habit strength) regarding sedentary behavior.

Analysis: Generalized linear models assessed associations between group assignment and change in each self-reported health and psychosocial score, adjusting for baseline scores.

Results: I-STAND participants demonstrated improvements in self-efficacy ($\beta = 0.35$, 95% confidence interval [CI]: 0.10 to 0.60) and reduced habit strength ($\beta = -0.23$, 95% CI: -0.42 to -0.04) compared to control participants. There were no significant differences in self-reported health outcomes, although power was limited in this exploratory analysis.

Conclusion: A sedentary behavior reduction intervention for older adults resulted in improvements for some psychosocial factors. Health outcomes may require longer than 12 weeks to observe improvements.

Keywords

sedentary behavior, sitting, older adults, seniors, elderly, psychosocial, self-efficacy, habit, habit formation, wearables, inclinometer

Purpose

Older adults represent the most sedentary age-group, sitting 8 to 11 h/d.¹ Sedentary behavior (SB) is defined as activities spent exerting minimal energy (<1.5 Metabolic equivalent tasks (METs)) while seated or lying down.² Sedentary behavior has emerged as a risk factor for health distinct from physical activity (PA) and associated with mortality and chronic conditions in older adults.³ To address this risk, several pilot studies have demonstrated feasibility of reducing SB among older adults.⁴⁻¹⁰

However, it is unknown whether an SB intervention impacts indicators of self-reported health such as functional and mental health that are important to healthy aging.¹¹ Emerging

evidence on sedentary older adults suggests that functional and mental health outcomes may vary.^{12,13} Two systematic reviews found SB generally associated with poorer mental health; however, cognitively engaging sedentary activities such as reading and computer use were associated with better cognitive

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functioning.^{12,13} The majority of these findings were observational, highlighting the need for SB interventions to evaluate changes in functional and mental health outcomes that are important to healthy aging.¹¹

Further, unlike PA interventions,¹⁴ there is little information about potential mechanisms specifically for SB intervention effectiveness. No studies have examined whether potential psychosocial mediators such as self-efficacy, decisional balance, sedentary habit strength (automatic nature of ingrained sitting habits), and social support are impacted by an SB intervention and could be driving observed changes in SB patterns. Therefore, this study examined whether a pilot 12-week SB intervention changed self-reported health and psychosocial outcomes for sedentary older adults.

Methods

Design

This exploratory secondary analysis uses data from a pilot randomized controlled trial conducted at Kaiser Permanente Washington (KPWA) Health Research Institute, between February 2016 and February 2017. Research activities were approved by the institutional review board of KPWA. Detailed study methods can be found in the published protocol.¹⁵

Sample

Older adults were recruited from KPWA membership panels to participate in a 12-week SB intervention. Using electronic health records, we identified potentially eligible participants (aged 60-89, baseline body mass index [BMI] 30-50 kg/m², not residing in long-term care or skilled nursing, and no diagnosis of dementia or serious mental or potentially terminal illness). Participants were excluded if they reported during telephone screening that they were unable to stand, walk 1 block, were participating in another intervention study, sat <6 h/d, could not communicate by phone, or could not speak and read English. Written informed consent was collected at baseline, and participants were compensated \$50 per visit at in-person baseline and follow-up assessments.

Interventions

I-STAND. The I-STAND intervention was informed by social-cognitive theory,¹⁶ the ecological model,¹⁷ and habit formation theory.¹⁸ Participants randomized to I-STAND worked with health coaches to reduce SB by discussing the health benefits of reducing SB, setting personalized goals, problem-solving barriers, modifying home and work environments, and using reminder strategies to prompt sitting breaks. Participants received 2 in-person health coach visits and 4 biweekly calls over 12 weeks. Participants received study workbooks, Jawbone UP wristbands programmed to gently vibrate after 15 minutes of inactivity, and feedback charts summarizing activPAL data (objectively measures SB) collected at baseline and weeks 1, 2, and 6.¹⁵

Healthy Living. Participants randomized to the control condition received a self-study program that included a workbook on age-appropriate topics (e.g., fall safety, urinary incontinence, managing medications), 1 in-person health coach session, and 5 biweekly mailings with self-directed goal sheets.

Measures

Sociodemographic characteristics, self-reported health outcomes, and psychosocial factors were measured using baseline and follow-up surveys. Validated scales assessed self-reported health outcomes. For the following measures, high scores indicate worse health: *depressive symptoms* (Patient Health Questionnaire-8),¹⁹ *perceived stress* (Perceived Stress Scale),²⁰ *lapses in memory and concentration* (Cognitive Failures Questionnaire),²¹ *sleep disturbance* (Patient-Reported Outcomes Measurement Information System [PROMIS]-short form),²² and *pain intensity* (PROMIS).²³ For the following measures, high scores indicate better health: *ability to do daily activities* using lower extremity function (Late Life Function and Disability Instrument: Function Component),²⁴ *energy* (Short Form-36),²⁵ and *global quality of life* (PROMIS).²⁶ Scoring protocol was followed for all validated measures.

At the time of this study, no validated measures existed for assessing older adult psychosocial factors specifically for SB. Therefore, measures were adapted from validated PA measures of the same psychosocial constructs. For all measures, high scores indicate high levels of the measured construct: *perceived benefits and barriers* (Exercise Benefits/Barriers Scale²⁷ with sedentary-specific additions), *social support* (Social Support and Exercise Survey²⁸), *self-efficacy* (Patient-centered Assessment & Counseling for Exercise survey [PACE]²⁹), and *sedentary habits* (PACE²⁹ and Self-Report Habit Index³⁰). Response options for all psychosocial measures ranged from 1 to 5, and scores were averaged across items for interpretability. Item descriptions and internal consistencies (Cronbach α)³¹ are provided in Supplemental Appendix A.

Analyses

Descriptive statistics summarize baseline characteristics overall and by randomization group. Complete case analysis resulted in different analytic sample sizes for each outcome. Generalized linear models assessed difference in mean change from baseline to 12 weeks between intervention and control groups for each outcome, adjusted for baseline scores of the dependent variable. To facilitate comparison of the magnitude of estimated intervention effects across the various outcomes that are measured on different scales, and for comparison with other studies, standardized effect sizes (Cohen d) were also calculated for each outcome.³² Effect sizes were interpreted as small (≤ 0.20), moderate (0.21-0.79), and large (≥ 0.80).³² Analyses were conducted using STATA 15.³³

Table 1. Standardized Effects and Mean Change in Self-Reported Health and Psychosocial Outcomes Measured at Baseline and 12 Weeks for Control (n = 31) and Intervention (n = 29) Participants Enrolled in a Sedentary Behavior Intervention Study.

	Baseline		12-Week Follow-Up		Difference in Mean Change ^a			Standardized Effect	
	Control, Mean (SD)	Intervention, Mean (SD)	Control, Mean (SD)	Intervention, Mean (SD)	β	95% CI	P	d^b	95% CI
Self-reported health outcomes									
Depressive symptoms	12.2 (3.9)	11.4 (3.2)	11.2 (3.1)	10.2 (2.2)	-0.62	(-1.60 to 0.36)	0.22	-0.16	(-0.73 to 0.40)
Perceived stress	12.2 (5.3)	11.2 (5.8)	9.4 (5.1)	10.5 (6.7)	2.11	(-0.40 to 4.62)	0.10	0.52	(-0.06 to 1.09)
Lapses in memory and concentration	17.3 (3.0)	18.1 (3.8)	17.0 (3.0)	17.3 (3.2)	-0.14	(-1.17 to 0.90)	0.80	-0.14	(-0.69 to 0.40)
Sleep disturbance	47.7 (8.9)	45.4 (8.1)	46.5 (9.3)	43.8 (8.3)	-1.31	(-4.79 to 2.18)	0.46	-0.11	(-0.65 to 0.43)
Pain intensity	52.9 (7.7)	53.9 (8.3)	51.8 (9.3)	52.1 (8.5)	-1.98	(-5.13 to 1.17)	0.22	-0.41	(-0.95 to 0.14)
Ability to do daily activities	25.5 (4.8)	25.1 (4.9)	26.5 (5.0)	25.1 (4.8)	-0.34	(-1.44 to 0.75)	0.54	-0.15	(-0.69 to 0.40)
Energy	53.0 (18.9)	52.2 (18.1)	56.2 (18.9)	55.3 (19.9)	2.53	(-4.08 to 9.14)	0.45	0.25	(-0.29 to 0.79)
Quality of life, physical	45.2 (6.5)	44.7 (6.5)	47.8 (6.0)	45.8 (6.0)	-0.39	(-2.83 to 2.05)	0.75	0.07	(-0.49 to 0.63)
Quality of life, mental	50.1 (6.4)	50.5 (8.3)	52.6 (5.2)	51.0 (8.1)	-1.06	(-3.52 to 1.40)	0.40	-0.16	(-0.71 to 0.39)
Psychosocial outcomes									
Perceived benefits	4.1 (0.5)	3.9 (1.0)	4.1 (0.6)	4.2 (0.5)	0.11	(-0.20 to 0.42)	0.49	0.30	(-0.26 to 0.85)
Perceived barriers	2.7 (0.8)	2.8 (0.8)	2.8 (0.5)	2.7 (0.8)	-0.18	(-0.55 to 0.19)	0.34	-0.42	(-0.98 to 0.13)
Social support	4.0 (0.9)	3.9 (1.0)	3.9 (1.0)	3.8 (0.8)	0.01	(-0.49 to 0.51)	0.98	0.05	(-0.50 to 0.60)
Self-efficacy	3.9 (0.5)	3.8 (0.5)	3.7 (0.6)	4.0 (0.7)	0.35	(0.10 to 0.60)	0.01	0.78	(0.21 to 1.33)
Sedentary habit strength	3.5 (0.4)	3.6 (0.4)	3.5 (0.5)	3.4 (0.5)	-0.23	(-0.42 to -0.04)	0.02	-0.69	(-1.25 to -0.13)

Abbreviations: CI, confidence interval; SD, standard deviation. Note: Bold indicates a p-value < 0.05.

^aAdjusted for baseline scores.

^bCohen d, defined as the difference in mean change score divided by the pooled standard deviation of change scores.

Results

Sixty participants were randomized to I-STAND (n = 29) or Healthy Living (n = 31). Participants were 68% female, 87% white, with an average age of 68, and average BMI of 36 (Supplemental Appendix B). One participant failed to complete the baseline survey. Six participants dropped out of Healthy Living (2 wanted the intervention, 2 cited health problems, 1 was too busy, and 1 did not specify a reason). No participants dropped out of the I-STAND intervention group. The resulting analytic sample included 53 participants.

For self-reported health outcomes, there were no significant differences in mean change scores between the intervention and control groups (Table 1). For psychosocial outcomes, I-STAND increased self-efficacy scores an average 0.35 points on a 5-point scale ($\beta = 0.35$, 95% confidence interval [CI]: 0.10 to 0.60; $d = .78$) and decreased SB habit strength by an average 0.23 points on a 5-point scale ($\beta = -0.23$, 95% CI: -0.42 to -0.36]; $d = -0.69$) compared to Healthy Living. There were no significant differences in mean change scores for social support, perceived benefits, or perceived barriers to reducing SB.

Discussion

A 12-week intervention to disrupt SB and reduce sitting time among older adults significantly improved self-efficacy to reduce sitting and reduced habit strength and automaticity of SB compared to a control group. However, there were no

statistically significant changes for other psychosocial measures of social support, perceived benefits, or perceived barriers. Although the direction of change for most self-reported health outcomes suggests improvement in the I-STAND group, analyses found no significant change.

Among older adults with high BMI—for whom PA is very low¹⁰—confidence to reduce SB improved. In fact, I-STAND's effect on change in self-efficacy ($d = 0.78$) was stronger than the average effect of PA interventions ($d = 0.37$) included in a systematic review of 24 intervention studies on PA self-efficacy.¹⁴ Sedentary behavior reduction may be more feasible than PA for this population.

Findings suggest the importance of including intervention components that address strong sedentary habits. Because SB reduction needs to occur frequently, throughout the day, the automaticity of sitting must come under conscious decision-making processes to disrupt automatic habits.¹⁸ This differs from approaches in PA interventions, whereby researchers typically promote single bouts of PA. I-STAND's moderate effect on changes in habit strength ($d = -0.69$) suggests that having a variety of reminder strategies to prompt breaks from sitting can help older adults reduce sedentary habits.

More research is needed to understand the impact of an SB intervention on changes in subsequent functional and mental health outcomes. The finding of no significant changes in self-reported health is in contrast to cross-sectional studies that have found SB associated with poorer mental health and consistent with one longitudinal study that found no association with mental health.¹³ Timing/temporality and a possible

bidirectional relationship must be considered when studying the relationship between SB and mental health. Our findings suggest that sitting less does not have a potent or quick impact on self-perceived health status. It may be that standing more does not meaningfully impact self-reported health or that 12 weeks is insufficient for health improvements to occur. Changes in self-reported health may also depend on the magnitude of change or whether SB was replaced with light PA versus standing only.

This study has several limitations. First, as a pilot trial, the sample size was not selected to detect significant differences in secondary outcomes. However, estimated effects provide important information regarding potential intervention impact. Second, many outcomes were considered in this exploratory analysis, raising the possibility of type 1 errors and spurious findings. Third, validated instruments assessing psychosocial outcomes for SB do not currently exist, so psychosocial items were adapted from PA questionnaires. Fourth, there was differential dropout by group, which may have biased findings toward the null if those who dropped out of the control group were less healthy than those who did not drop out. Finally, participants were predominantly white, female, and well-educated older adults; thus, results may not generalize to other populations.

Study strengths include a highly sedentary population that has multiple chronic conditions. This is the first study to assess self-reported health and psychosocial outcomes related to an SB intervention in older adults from a randomized controlled trial.

SO WHAT

What is already known on this topic?

Older adults are the most sedentary age-group. Sedentary behavior (SB) interventions are feasible and effective at reducing SB for older adults, but little is known about mechanisms for intervention effectiveness and whether SB interventions impact functional and mental health important to healthy aging.

What does this article add?

An SB intervention improved confidence to reduce sitting time and reduced the strength and automaticity of sedentary habits. Improvements for health outcomes may require a longer follow-up period to observe changes.

What are the implications for health promotion practice or research?

Understanding effective mechanisms for reducing SB will be important for designing future trials. Larger studies that follow older adults over a longer period are needed to better understand impact of SB on health.

Findings from this study make important contributions to the emerging field of SB research and have implications for sedentary older adults with high BMI. Future studies with larger samples are needed to confirm findings. Future studies should explore whether psychosocial factors mediate the relationship between an SB intervention and objectively measured SB.

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Declaration of Conflicting Interests

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Supplemental Material

Supplemental material for this article is available online.

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A Pilot Randomized Trial of an Intervention to Enhance the Health-Promoting Effects of Older Adults' Activity Portfolios: The Engaged4Life Program

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A Pilot Randomized Trial of an Intervention to Enhance the Health-Promoting Effects of Older Adults' Activity Portfolios: The Engaged4Life Program

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ABSTRACT

The purpose of this study was to evaluate the feasibility and outcomes of the Engaged4Life program, an intervention to encourage inactive community-dwelling older adults to embed physical activity, cognitive activity, and social interaction into their everyday lives in contexts that are personally meaningful and natural for them. Fifteen participants were randomized to the intervention group (technology-assisted self-monitoring of daily activity via pedometers and daily tablet-based surveys; psychoeducation + goal-setting via a 3-hour workshop; and peer mentoring via phone 2x/week for 2.5 weeks) and 15 to the control (technology-assisted self-monitoring only). Recruitment was shown to be feasible and efficient, but not able to reach the target for men. Retention rate was 83% and participants manifested high adherence and engagement with the intervention. Though this pilot trial was not powered to demonstrate significant differences between groups, daily steps increased by 431 (11% increase) from baseline to Week 4 for the intervention ($p < .05$), but decreased by 458 for the control, for a net difference of 889 steps ($p < .05$). Findings were sustained at Week 8 ($p < .01$). In a future trial, difficulties in recruiting men, barriers due to the technology-intensive design, and the optimization of secondary outcome measures should be addressed.

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Maintaining health and well-being throughout longer lives represents a significant public health challenge in this era of population aging. Research points to the importance of an active lifestyle, comprised of physical activity (PA), cognitive activity (CA), and social interaction (SI), in preventing or restoring poor health and functional decline (Bassuk, Glass, & Berkman, 1999; Berkman, 1995; Fried et al., 1998; Glass, De Leon,

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Marottoli, & Berkman, 1999; Seeman, 1996; Wagner, LaCroix, Buchner, & Larson, 1992; Wilson et al., 1999) as well as cognitive decline (Fratiglioni, Paillard-Borg, & Winblad, 2004; Wang, Karp, Winblad, & Fratiglioni, 2002). However, promoting and sustaining active lifestyles in adults of any age, and particularly in older adults, has proven to be difficult (Katula et al., 2007; Resnicow et al., 2002). In general, the majority of public health interventions aimed at promoting an active lifestyle have focused on increasing a single lifestyle behavior, i.e., PA (Chase, 2013; Zubala et al., 2017), CA (Ball et al., 2002; Klimova, 2016; Rebok & Balcerak, 1989), or SI (Heaven et al., 2013). Few have focused on increasing multiple lifestyle factors simultaneously and in contexts that are meaningful and natural for participants.

The Social Model of Health Promotion (SMHP), proposed by Linda Fried and colleagues in 2004, offers a framework for such an intervention. The SMHP's primary assertion is that roles or activities have health benefits to the extent that they require PA, CA, and SI, and that activities that carry personal meaning (PM) or confer a sense of purpose may have stronger health-promoting effects than activities that do not. This model has been extensively and rigorously tested through experimental studies of the Experience Corps program (Fried et al., 2004; Hong & Morrow-Howell, 2010; Varma et al., 2016), an elementary school-based community volunteering program designed to be intensive enough (15 hours per week) to get older adult participants out of the house and physically active in the community, cognitively stimulated by reading to children, and socially integrated by building relationship with children and teachers within the school, all toward a meaningful goal of improving the reading skills of children in their own communities. However, this program is not yet widely accessible in the US and is particularly inaccessible in rural areas. Further, formal volunteering is not necessarily an activity that is attractive or accessible to all older adults (Heaven et al., 2013; Jenkinson et al., 2013).

To overcome these barriers, our interest was in evaluating the feasibility and outcomes of what we call an "engagement model" of health promotion that applies the principles of the SMHP to older adults' daily lives and activities more generally. The engagement model empowers older adults to enhance or supplement their existing "activity portfolios"—i.e., the various activities that they engage with on a day-to-day basis—in ways that naturally incorporate PA, CA, and SI. Such an approach allows for personalization or tailoring that meets individual's specific needs, interests, and constraints, which has been strongly recommended in community based settings (Task Force on Community Preventive Services, 2002). Further, the approach emphasizes the prioritization of activities that are personally meaningful, allowing the goals of engagement to be varied (e.g., motivated by generativity, curiosity, or pleasure) so that health promotion motives can be ancillary.

In order to facilitate the desired behavior change that we hoped to see from this engagement approach (i.e., participants take on new or modify existing activities of their own choosing that can increase PA, CA, SI, and PM), it was important to embed evidence-based behavior change strategies into the intervention. In a meta-analysis by Chase (2013), a multi-component approach was found to be more successful than single-component approaches in changing health behavior. Chase (2013) also identified commonly employed behavior-change strategies from the health promotion intervention literature, which include: (1) behavioral strategies that introduce observable and participatory physical actions, e.g., technology-based approaches that involve prompting and self-monitoring, (2) cognitive strategies that aim to alter or enhance thought processes, attitudes, or beliefs related to a specific behavior, e.g., education and goal-setting activities, and barrier identification and management, and (3) social strategies that provide peer support and encouragement, e.g., peer mentoring. Thus, all three of these strategies were employed in a multi-pronged approach to facilitate the desired behavior change: (1) technology-assisted self-monitoring of daily activity via pedometers and daily tablet-based surveys (behavioral strategy); (2) psychoeducation + goal-setting via a 3-hour workshop (cognitive strategies); and (3) peer mentoring via phone 2×/week for 2.5 weeks (social strategy).

Such an approach has never been tested in a randomized controlled trial and little work has been done to provide a basis for designing such a trial. Thus, the aim of this pilot randomized controlled trial was to assess the feasibility and outcomes of the Engaged4Life program, a novel, multi-component intervention designed to encourage inactive community-dwelling older adults to increase multiple lifestyle factors simultaneously and in contexts that are meaningful and natural for them. The specific objectives were to: (a) explore the feasibility of the recruitment procedure, (b) evaluate participants' adherence to and engagement with the various study components, including overall retention rates, and (c) assess the primary and secondary outcomes of the intervention, compared to a technology-assisted self-monitoring only control group, for the purpose of informing future efficacy trials. Daily step-count (via FITBIT® pedometers at baseline, Week 4 and Week 8) was the primary outcome and daily CA, quantity and quality of SIs, and perceptions of meaning (via a daily tablet-based self-report survey at baseline and Week 4) were the secondary outcomes. We hypothesized that participants in the intervention group would experience increased daily steps (PA), as well as increased daily CA, quantity and quality of SIs, and perceptions of meaning from baseline to Week 4, compared to the control group. We also hypothesized that positive changes in daily steps would be maintained in the intervention group when assessed 1 month after the end of the intervention period.

Methods

Study design, setting, and participants

The study was an 8-week, parallel, 2-arm pilot randomized controlled trial. Recruitment started on August 1st and ended on August 31st, 2015. Outcome data were collected from September to November 2015. The trial was registered retrospectively with clinicaltrials.gov (NCT03337204, date: November 8, 2017) and approved by the Boston College IRB (protocol # 15.063.04) and the Massachusetts Executive Office of Elder Affairs' Elder Rights Review Committee. The study adheres to the CONSORT extension to pilot trials guidelines (Eldridge et al., 2016).

Participants were recruited from a diverse, middle-income city just outside of Boston, Massachusetts. This was city ranked in the upper quartile for population density and diversity when compared to the other cities and towns in Massachusetts and in the middle quartile for median household income and per capita income in 2016 (Massachusetts Hometown Locator, 2016). We partnered with the local senior center and advertised through the senior center's newsletter, which is published in the local newspaper and distributed to businesses and non-profits all over the city. We also distributed study flyers to community-based organizations in the area (i.e., the local Area Agency on Aging, churches, community centers), local businesses (e.g., hair dressers, grocery stores, barber shops, etc.), neighborhood bulletin boards, housing complexes, and word of mouth. Incentives for participation included a \$50 VISA Gift Card, a FITBIT® Zip (Fitbit, Inc., San Francisco, USA), and free iPad® Mini (Apple, Inc., Cupertino, USA) training. Interested individuals who called the study phone line were screened via telephone by two research assistants (2nd year masters-level social work students who had completed coursework in aging, trained by the first author).

Those who were eligible to participate were: (1) age 65 or older, (2) relatively inactive, as determined by a score of <10 on a modified version of the Health Enhancement Lifestyle Profile (Hwang & Peralta-Catipon, 2015) where only the domains of exercise, social and productive activity, and leisure were included, (3) a city resident, (4) willing to be randomly assigned, and (5) available for relevant study dates. In addition, those who were living in an assisted living/nursing home facility, had significant cognitive impairment (those with >2 errors on a six-item cognitive screener by Callahan, Unverzagt, Hui, Perkins, & Hendrie (2002)), or who reported that a doctor has told them that it is unsafe to participate in PA were ineligible to participate.

After interested individuals were screened for eligibility, as described above, the Tripod Random Allocation Software (<http://mahmoodsaghaei.tripod.com/Softwares/randalloc.html>) was used to generate the random allocation sequence using a 1:1 ratio. A blocking approach was used to ensure

close balance of the numbers in each group as we proceeded through recruitment. Intervention assignments were placed in sealed, non-translucent envelopes by the first author and screeners (trained research assistants) chose the envelopes, in sequence, to assign eligible individuals to an intervention group. This was done to conceal the random allocation sequence to the screeners until interventions were assigned. Participants were blinded to treatment group. Enrollees were mailed the informed consent and baseline self-administered survey and were asked to bring these completed forms to the study information and training session. See Figure 1

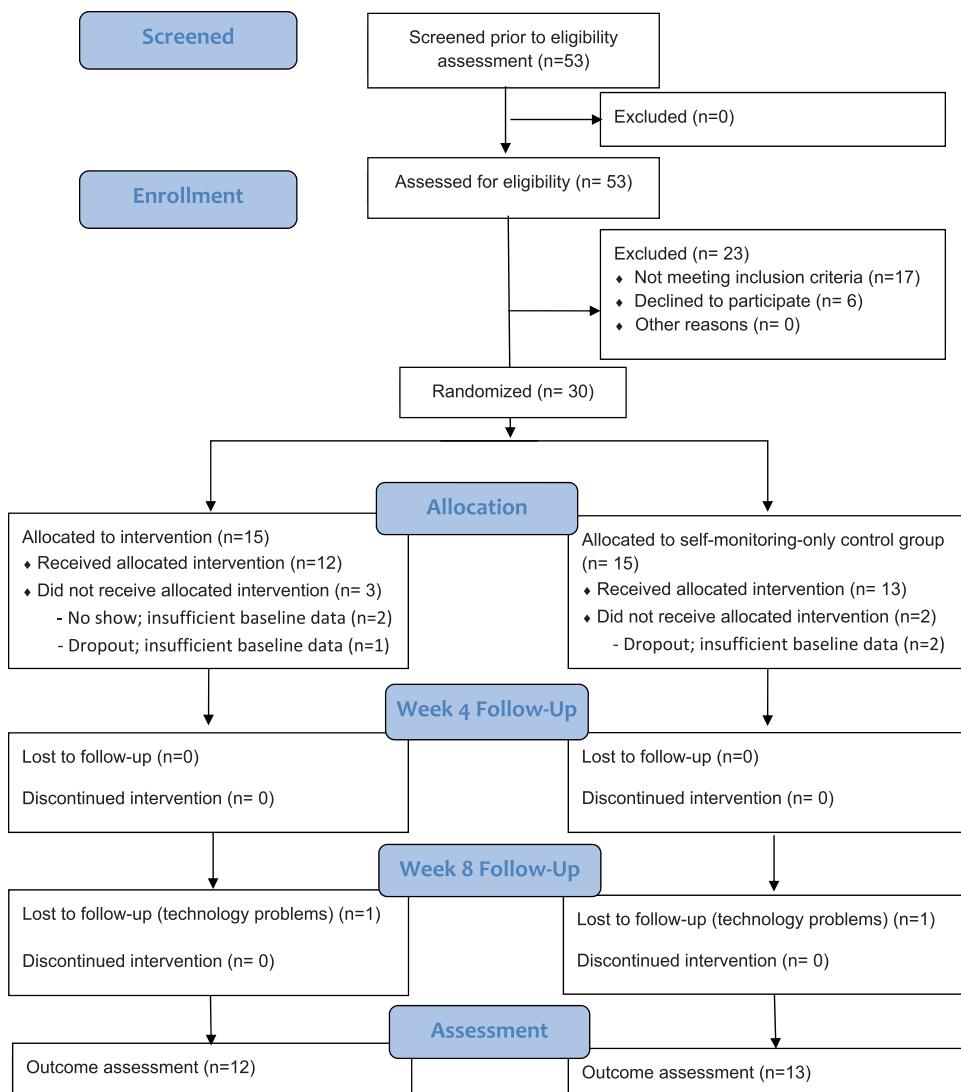


Figure 1. CONSORT* diagram summarizing flow of participants through the Engaged4Life Study. * Specifically the CONSORT extension to pilot trials (Eldridge et al., 2016)

for a CONSORT diagram (extension to pilot trials, Eldridge et al., 2016) of the flow of participants through the study. The goal was to have 15 individuals participate in each arm of the study with an equal balance of men and women, however as discussed in the results section, we had difficulty recruiting men and there was some loss of participants over the course of the study, thus the final sample for the outcome assessment was 12 for the intervention group and 13 for the control group.

Intervention

There were two study arms: the intervention arm and the self-monitoring-only control arm. The intervention arm received: (a) technology-assisted self-monitoring of daily activity via pedometers (to measure PA) and daily tablet-based surveys (to measure CA, SI, and PM), (b) psychoeducation + goal-setting (via a 3-hour workshop), and (c) one-on-one peer mentoring (via phone 2×/week for 2.5 weeks) to support goal implementation. The self-monitoring-only control arm received only component A, technology-assisted self-monitoring of activity engagement. The Engaged4Life program was designed by the core research team in partnership with two key groups: (1) an interdisciplinary advisory committee of academics/experts, and (2) ESC Discovery, a program of Empower Success Corps, based in Boston, MA, that has extensive expertise in delivering workshops intended to support and facilitate the exploration of new opportunities for meaningful engagement in later life, as well as training peers who can support such exploration.

Technology-assisted self-monitoring

Randomized participants were invited to a 1.5-hour study orientation/technology training session during which they received a FITBIT® Zip pedometer to wear daily (for the entire 8-weeks of the study) and received training on how to use an iPad® Mini tablet to complete a survey just before bed each night for an initial 7-day study period (T0, baseline) and then again for a second 7-day study period 4-weeks later (T1). The tablet survey asked questions about CA, SI, and PM activity engagement during that day. The first author of this paper developed the training materials (including a take-home manual) and led the training sessions. Research staff were available if participants had questions or needed troubleshooting help. A 2-day “warm-up” period was provided where participants could practice using the new technology before the 7-day baseline data tracking began. The training also emphasized good practices for remembering to wear the pedometer and completing the daily surveys.

Psychoeducation + goal-setting

There were two primary components to the 3-hour Engaged4Life Workshop, which was facilitated by a professional facilitator provided by our partners from the ESC Discovery program of Empower Success Corps: (1) psychoeducation and (2) goal-setting. In the psychoeducation module, participants receive information on how PA, CA, SI, and PM activity engagement affects health and well-being in later life. The imagery of a compass navigating the “The Road to an Engaged Life” is used as a metaphor and participants are guided through exercises and discussions focused on “continued engagement” as a key component of healthy aging using the four compass points for engaged living: Move (PA), Think (CA), Connect (SI), Enrich (PM). For each compass point, participants: (1) are provided with research-based information about *why* increasing their engagement in that domain is important, (2) participate in a brief demonstration, (3) receive guidelines around increasing engagement in the domain, and (4) are given a variety of examples and a resource guide with additional examples/local resources.

Participants are then asked to reflect, through a structured activity, on their current “activity portfolio” (i.e., list the activities they engage in on a day-to-day or weekly basis), and assess the extent to which these activities require them to be physically, cognitively, and socially active, and are personally meaningful. Peer mentors assigned to each group provide support and help with this activity as needed. In the goal-setting module, participants work in small groups with a peer mentor to set personalized, long- and short-term goals for themselves focused on either *enhancing* or *supplementing* their activity portfolios in ways that increase PA, CA, SI, and PM. Participants have broad latitude to choose any type of goal for themselves as long as they feel that goal(s)/activities are personally meaningful and they could find ways to embed PA, CA, and SI within or across the various new or enhanced activities. One participant, for example, decided this would be a good opportunity to rekindle her strained relationship with her daughter. Her short-term goals focused on reaching out to her daughter to make amends and then arranging to meet her daughter and granddaughter for an active outing a couple of days per week. These goals were not only extremely personally meaningful to her, but they also explicitly required increased PA (i.e., playing at a playground or going for a walk) and SI. Her long-term goal was to maintain a strong, positive relationship with her daughter and granddaughter moving forward and to make these outings an ongoing, regular occurrence.

One-on-one peer mentoring

Peer mentors were similar-age peers who have an interest in helping others achieve their personal goals. Most, but not all, of the peer mentors for this study lived in the same city as the participants. Peer mentors were recruited through referrals, screen-outs from main study (for scoring ≥ 10 on the HELP

screener), and alumni of the EngAGE Study, which was a study focused on active older adults led by the first author. Peer mentors attended a 2-hour training session consisting of the following components: (1) study overview, (2) roles and responsibilities of peer mentor, (3) communication and interpersonal skills, (4) active listening, critical thinking, and strategies for engaging participants, and (5) ethics and resources.

The five peer mentors were each assigned to mentor two–three study participants. They provided support and guidance in small group settings during the Engaged4Life Workshop and then the peer mentors followed-up with each of their mentees individually via phone. The original protocol indicated that the peer mentoring sessions would occur twice a week for three weeks. However, due to a religious holiday that fell on the Monday of Week 1, the Engage4Life workshop was pushed to that Wednesday, resulting in limited time to complete two peer mentoring sessions in Week 1. Thus, participants and mentors were instructed to complete one session during Week 1, and two during Weeks 2 and 3, for a total of five sessions over 2.5 weeks. During these phone calls, peer mentors checked-in with participants to see how they were doing implementing their short-term goals, provided moral support, and helped to brainstorm solutions for overcoming any barriers their mentees were facing in implementing their goals.

Measurements

Feasibility measures

To evaluate the feasibility of the recruitment procedure, we assessed *response to the recruitment materials* (expressed as the number of individuals screened over the 4-week recruitment period and the gender breakdown therein), *the speed of recruitment* (expressed as the number of participants recruited per week of the recruitment period), and *efficiency of the recruitment* (expressed as the ratio of randomized to screened individuals). To evaluate retention, we assessed *adherence to wearing the pedometer* (measured as the percentage of valid days, with a valid day being defined as one in which the pedometer registered a step count above zero) and *adherence to completing the daily activity engagement surveys*. *The percentage of participants who completed the study* was also evaluated and reasons for discontinuation were identified.

To evaluate participant engagement, we assessed *the percentage of participants who attended the workshop* and participants' *self-reported experience of the workshop* with regard to four dimensions: the overall quality of workshop, the style of the facilitator, the helpfulness of the content for them, and whether they learned new information. The response scale ranged from 1 (*poor*) to 5 (*excellent*). Engagement in the peer mentoring component of the intervention was assessed by asking peer mentors to complete session recording logs after each session with their mentees.

Specifically, we evaluated *the proportion of the prescribed peer mentor sessions completed, average length of individuals' sessions, and peer mentors' ratings of the session in four domains*: Do you feel the session was productive?, Do you feel the session was efficient?, Do you feel you provided support to your mentee?, and Do you think your mentee felt more confident at the end of the session?. The response scale ranged from 1 (*not at all*) to 4 (*very much so*). Those in the intervention group were also asked to rate their *satisfaction with their peer mentors along each of 12 dimensions* (e.g., “my peer mentor provided me with useful information,” “my peer mentor regularly contacted me during the given times,” and “my peer mentor is knowledgeable about how to overcome barriers”). The response scale ranged from 1 (*strongly disagree*) to 5 (*strongly agree*). We report on each of these items separately.

Outcome measures

Though this was a pilot study that was not adequately powered to assess differences between groups, we evaluated several outcomes of the intervention for the purpose of informing a future trial. The primary outcome was *physical activity (PA)*, measured as the number of steps per day, which has been validated as a measure of free-living PA (Tully, McBride, Heron, & Hunter, 2014). The same FITBIT® Zip pedometers that were used for the technology-assisted self-monitoring portion of the intervention in both groups were employed to objectively measure steps/day. Mean daily step count from the first 7 days of wearing the pedometer was used as a baseline value (T0, Week 1), which began after the introduction/technology training session but before the Engaged4Life workshop. The T1 mean daily step count was calculated from the 7-day period starting 22 days after baseline data collection began (Week 4), which started during the last week of peer mentoring for the intervention group. And finally, the T2 mean daily step count was calculated from the 7-day period starting 50 days after baseline data collection began (Week 8), which was approximately 1-month post-intervention. FITABASE (<https://www.fitabase.com/>) was used to aggregate data across multiple FITBIT® devices for research purposes. The square root of the mean daily step count was used in analyses to normalize the distribution of this variable, as this transformation is commonly used for reducing right skewness and has been applied to step count data in multiple prior studies (Arredondo, Elder, Marshall, & Baquero, 2007; Ostendorf et al., 2018).

Secondary outcomes included daily CA, SI, and PM. As above, the same iPad® Mini tablets that were used for the self-monitoring portion of the intervention in both groups were employed to subjectively measure CA, SI, and PM through daily surveys that were completed each night before bed by participants. Participants were only asked to complete the daily CA, SI, and

PM surveys for the first 7 days of the study (T0, Week 1), and the 7 days starting 22 days later (T1, Week 4). The mean score across each 7-day period was used for analyses.

Cognitive activity (CA) was measured as the number of cognitively stimulating activities participants had engaged in that day from a list of 14 activities, plus 1 optional write-in activity, including reading books, magazines, or newspapers (including online); playing word games such as crossword, puzzles, or Sudoku; and taking a class or attending an educational lecture. In the absence of existing daily measures, this measure was developed for the purposes of the current study based on the approach of Lachman, Agrigoroaei, Murphy, and Tun (2010), and with feedback from Engaged4Life advisory committee.

Social interaction (SI) questions focused on the quantity and quality of SIs engaged in that day. Quantity of SI was measured as participants' response to the question "In total, about how many hours did you spend engaging with others today (include in-person, by telephone, or by video; do NOT include email, text, or social media)?" The response options included: 1 (*not at all*), 2, (*less than 1 hour*), 3 (*1–2 hours*), 4 (*2–4 hours*), 5 (*4–6 hours*), and 6 (*6 or more hours*). Quality of SI's was assessed using two variables. Participants were asked to rate how stressful and how positive/uplifting their SIs were that day on a scale from 0 (*not at all*) to 6 (*extremely*). These measures were adapted from Dunton, Atienza, Castro, and King (2009).

Personal meaning (PM) was assessed using four questions that asked whether participants did anything that day that: (1) benefited others, (2) left them feeling personally satisfied or accomplished, (3) felt significant in the broader scheme of things, or (4) were personally meaningful. Response options ranged from 0 (*not at all*) to 2 (*to a great extent*). In the absence of existing daily measures, these items were developed for the purpose of the current study and averaged for a total score (Cronbach's $\alpha = .88$).

Statistical analysis

Outcome analysis focused on testing differences across the two intervention arms (between-group differences) and across the T0 (Week 1), T1 (Week 4), and T2 (Week 8) assessment points for the primary outcome and across the T0 and T1 assessments points for the secondary outcomes (within-group differences), as well as the treatment-by-time interaction. First, demographic characteristics and outcome variables were evaluated at baseline for the total sample as well as for each arm of the intervention. *t*-Tests were used for continuous variables and Chi-Square tests were used for binary or categorical variables to evaluate the success of the randomization and identify factors that should be controlled for in outcome analyses.

Next, given the repeated measures design of the study where daily observations (Level 1) were nested within participants (Level 2, 25 participants), the multilevel mixed-effects linear regression procedure (*xtmixed*) available in Stata IC 13.1 was used to specify two-level linear mixed effects (LME) models. LME models examined whether outcome trajectories differed between each of the treatment groups across the study period, using restricted maximum likelihood estimation. LME accommodates missing data for participants with missing data points, thus models could use data from the subset of the sample who were lost to follow-up (see [Figure 1](#)). Intercepts and slopes were modeled as random effects; treatment, time, and treatment-by-time were modeled as fixed effects. Effect sizes were calculated from the unstandardized coefficients associated with treatment-by-time interactions using methods described by Feingold ([2009](#)) and reported in the variables' natural metric. Given the exploratory nature of this investigation and the small sample size, all analyses used $\alpha = 0.05$ for statistical significance without correction for number of tests.

Results

Feasibility results

Overall, recruitment was feasible and speed and efficiency was high. A total of 53 individuals responded to the recruitment materials by calling the study telephone line over the course of the 4-week recruitment period and all were screened for eligibility (see [Figure 1](#)), for an average of 13.25 (± 7.5) screened per week. Of those 53, 23 were excluded from the study (74%, $n = 17$, were determined to be ineligible according to the study's inclusion/exclusion criteria, and 26%, $n = 6$, were eligible but declined to participate). Therefore, on average, 7.5 (± 3.8) participants were recruited per week and for every 1.77 individuals screened, 1 was randomized. When we met our goal of 30 eligible participants, recruitment was closed.

However, when it came to our a-priori goal to recruit equal numbers of men and women into the study, recruitment efforts were less successful. Of those 53 who were screened, 41 (77%) were women and 12 (23%) were men. We reached our quota of eligible women ($n = 15$) by the third week of recruitment and started placing additional women that screened eligible on a wait list. Despite increased efforts to recruit men, such as reaching out to community-based organizations that tend to serve men like Veterans of Foreign Wars and American Legions, we did not reach our target for men by the end of our 4-week recruitment window, and chose to accept the women on the waitlist into the study rather than delay the start date. In total, 30 individuals—22 (73%) women and 8 (27%) men—were randomized.

Five of the 30 participants, or 17% of those who were randomized, dropped out of the study (see [Figure 1](#)). These included: (1) one male and one female participant in the intervention group who were no-shows for the study orientation/training; and (2) a female participant in the intervention group and two male participants in the control group who discontinued immediately after the initial training session due to dissatisfaction with the required technology component of the study. All of the study drop-outs occurred before baseline outcome data were collected (i.e., at the technology training stage). This initial drop-out might have been avoided if baseline data had been collected prior to randomization and if the self-monitoring component/outcome assessment was less technology intensive, which was overwhelming to some participants. The overall retention rate was 83% and the final sample size for outcome assessment was 25, with 12 in the intervention group (9 women and 3 men) and 13 in the control group (11 women and 2 men).

The 25 participants manifested high adherence to the study protocol and the intervention group also exhibited a high level of engagement with the various components of the intervention. Participants wore the pedometer on 93% (± 8) of the days during the 8-week intervention period and completed the daily self-report activity data (via tablet) on 94% (± 15) of the 14 days (two 7-day periods) that they were asked to complete surveys.

Finally, among those who were in the intervention group ($n = 12$), we evaluated participant engagement (see [Table 1](#)). The Engaged4Life Workshop was attended by 12/12 (100%) participants were highly satisfied, on average, with satisfaction item means ranging from 4.38 to 4.77 on a scale of 1 (*poor*) and 5 (*excellent*). On average, 4 out of the 5 prescribed peer mentoring telephone sessions (80%) were completed ($M = 4.0 \pm 1.04$). All peer mentors completed structured session recording logs to quantify participant engagement in the peer mentoring sessions (completed immediately after each session). Peer mentoring sessions ranged in length from 10 to 60 minutes ($M = 27.83 \pm 9.23$). Peer mentors reported, on a scale of 1 (*not at all*) to 4 (*very much so*), that the sessions were highly productive ($M = 3.53 \pm 0.58$), efficient ($M = 3.42 \pm 0.63$), that they provided support to their mentee ($M = 3.53 \pm 0.58$) and that their mentee felt more confident at the end of the session ($M = 3.34 \pm 0.59$). Finally, the intervention group was highly satisfied, overall, with their peer mentors, with satisfaction item means ranging from 4.00 to 4.57 on a scale of 1 (*strongly disagree*) to 5 (*strongly agree*). However, it appears that there is room for improvement with regard to peer mentor knowledge about community resources ($M = 4.00 \pm 0.88$), whether peer mentoring, per se, has helped them feel empowered to change their activity levels for the better ($M = 4.08 \pm 1.12$), or to improve their activity roadmap ($M = 4.00 \pm 0.91$), and enjoyment of working on a one-on-one basis with the peer mentor ($M = 4.00 \pm 0.91$).

Table 1. Measures evaluating feasibility: Participant engagement in the intervention.

	Mean	SD	Range
Participants' evaluation of the Engaged4Life Workshop			
Overall quality of workshop ^a	4.54	0.78	3–5
Style of Facilitator ^a	4.77	0.60	3–5
Helpfulness of the content for you ^a	4.38	0.77	3–5
Did you learn new information today? ^a	4.38	0.77	3–5
Peer Mentor Ratings of Participant Engagement in the Peer Mentoring Sessions			
Number of sessions completed	4.00	1.04	2–5
Length of session (minutes)	27.83	9.23	10–60
Do you feel the session was productive? ^b	3.53	0.58	2–4
Do you feel the session was efficient? ^b	3.42	0.63	2–4
Do you feel you provided support to your mentee? ^b	3.53	0.58	2–4
Do you think your mentee felt more confident at the end of the session? ^b	3.35	0.59	2–4
Participants' Satisfaction with Peer Mentor			
My peer mentor provided me with useful information. ^c	4.29	0.83	2–5
My peer mentor regularly contacted me during the given times. ^c	4.57	0.51	4–5
My peer mentor made an effort to get to know me. ^c	4.43	0.65	3–5
I made an effort to get to know my peer mentor. ^c	4.21	0.70	3–5
My peer mentor is knowledgeable about community resources. ^c	4.00	0.88	3–5
My peer mentor is skilled at facilitating discussions. ^c	4.43	0.65	3–5
My peer mentor is knowledgeable about how to overcome barriers. ^c	4.14	0.86	3–5
Overall, my peer mentor has been helpful. ^c	4.43	0.65	3–5
Peer mentoring has helped me feel empowered to change my activity levels for the better. ^c	4.08	1.12	1–5
I feel like my activity roadmap has improved as a result of peer mentoring. ^c	4.00	0.91	2–5
I enjoy working on a one-on-one basis with my peer mentor. ^c	4.00	0.91	2–5
Peer mentoring has made me better prepared to implement positive changes in my activity. ^c	4.15	0.99	2–5

^aThose in the intervention group were asked to rate their experience with the Engaged4Life Workshop (at the end of the workshop) with regard to these four dimensions on the following response scale: 1 = Poor to 5 = Excellent.

^bPeer mentors were asked to rate their experience after each peer mentoring session with regard to the these four dimensions on the following response scale: 1 = Not at all to 4 = Very much so.

^cThose in the intervention group were asked to rate their satisfaction with their peer mentors along each of these 12 dimensions (at T1) on the following response scale: 1 = Strongly Disagree to 5 = Strongly Agree.

Evaluation of primary and secondary outcomes

Baseline characteristics are reported in Table 2 on the 25 individuals for whom we have outcome data. The majority of participants were women (80%), non-Hispanic White (92%), retired (68%), and married (52%). The sample mean for education was 4.72, falling between an associate's degrees and a bachelor's degree, and the mean total household income for the sample was 4.32, falling between \$60k–79k and \$80k–99k per year. At baseline, the mean number of steps/day was approximately 4,547 (± 398). Less than 5,000 steps per day are considered sedentary (Tudor-Locke et al., 2011).

Though this pilot randomized controlled trial was not powered to demonstrate significant differences between study groups, findings provide some important information for future efficacy trials. At baseline, the control group ($5,363 \pm 322$) had a higher average number of steps/day than the

Table 2. Baseline characteristics of total sample and by treatment arm.

	Total sample (N = 25)				Intervention (N = 12)		Self-monitoring-only control (N = 13)		Sig. ^f
	Mean/%	SD	Min	Max	Mean/%	SD	Mean/%	SD	
Outcome measures									
Steps per day (square root) ^a	67.43	19.96	23.13	100.49	61.15	20.87	73.23	17.94	
Daily no. of cognitive activities ^b	4.60	1.48	1.86	7.86	4.52	1.84	4.68	1.14	
Daily social interactions (SI)									
No. of hours spent in SI ^b	4.14	0.78	2.57	5.57	4.07	0.81	4.21	0.77	
Stressful SI ^b	0.38	0.55	0	1.57	0.40	0.61	0.37	0.51	
Positive/uplifting SI ^b	3.65	1.37	0	5.14	3.73	1.58	3.58	1.19	
Daily personal meaning ^b	1.21	0.41	0.54	1.89	1.32	0.41	1.11	0.40	
Demographic characteristics									
Age	72.92	6.65	65	91	75.75	8.04	70.31	3.73	*
Female	80.00%				75.00%		84.6%		
Retired ^c	68.00%				76.92%		61.54%		
Married	52.00%				53.85%		46.15%		
Non-Hispanic White	92.00%				100.00%		84.62%		
Education ^d	4.72	1.59	2	7	3.83	1.53	5.54	1.20	**
Total household income ^e	4.32	2.34	1	8	3.91	2.51	4.73	2.20	

^aAssessed objectively via FITBIT® Zip pedometer, daily steps were averaged across the 7 days within person and then averaged across people.

^bAssessed through daily surveys; daily scores were averaged across the 7 days within person and then averaged across people.

^cParticipant reported officially retiring from a paid job and no longer working for pay.

^d1 = some high school; 2 = high school diploma or GED; 3 = some college, no degree; 4 = 2-year college degree; 5 = 4-year college degree; 6 = master's degree, 7 = doctoral degree; 8 = professional degree (MD, JD).

^e1 = under \$20,000; 2 = \$20,000–\$39,999; 3 = \$40,000–\$59,999; 4 = \$60,000–\$79,999; 5 = \$80,000–\$99,999; 6 = \$100,000–\$119,999; 7 = \$120,000–\$139,999; 8 = \$140,000 and above.

^fSignificance levels represent *t*-tests between the intervention group and the control group for continuous variables and Chi-square tests for binary variables.

p*<.05; *p*<.01

intervention group ($3,739 \pm 436$); however, these differences did not reach a level of statistical significance. The intervention group was, on average, older (77.75 years and 70.31 years, respectively, $t[23] = -2.20$, $p < .05$) and had lower education (3.83 and 5.54, respectively, $t[23] = 3.12$, $p < .01$) than the control group. Thus, all outcome analyses were adjusted for age and education.

Findings of LME models (see Table 3) reveal that daily steps increased by an average of 431 (11% increase) from baseline to T1 for the intervention group ($p < .05$), but decreased by 458 for the control (see Figure 2). Further, the significant treatment-by-time interaction for the T1 model indicates the intervention group improved compared to the control group by 889 steps ($p < .05$). This result is comparable to effect sizes observed in walking interventions of similar intensity for older adults (Tudor-Locke et al., 2011). Findings were sustained at T2, such that daily steps remained significantly higher relative to baseline for the intervention group (an increase

**Table 3.** Impact of the Engaged4Life intervention versus self-monitoring-only control on outcome measures.

	T0, Baseline	T1, 4-week follow-up	T2, 8-week follow-up	Effect Size, %
PRIMARY OUTCOME				
Steps per day (raw), M/SE^a	3,887.53(16.24)	4,318.26(18.45)	4,164.30(21.67)	11,7
Intervention group	5,364.49(14.86)	4,906.35(17.00)	4,758.82 (19.81)	-9, -11
Self-monitored-only control group				
Steps per day (square root), $B(95\% CI)^b$				
Treatment (ref = intervention group)	-	-9.26(-23.52, 5.00)	-11.55(-26.72, 3.61)	
Time (ref = post-test T1 or post-test T2)	-	-4.57(-9.02, -0.11)*	-4.60(-9.21, 0.014)*	
Treatment \times Time	-	7.76(1.62, 13.90)*	9.45(3.11, 15.80)**	
SECONDARY OUTCOMES				
Daily No. of cognitive activities, M/SE^a	4.53(0.41)	4.69(0.44)	4	
Intervention group	4.69(0.39)	4.71(0.42)	0	
Self-monitored-only control group				
Daily social interactions (SI), M/SE^a				
No. of hours in SI, M/SE^a				
Intervention group	4.07(0.21)	3.99(0.21)	-2	
Self-monitored-only control group	4.21(0.20)	4.43(0.20)	5	
Stressful SI, M/SE^a				
Intervention group	0.39(0.16)	0.52(0.14)	33	
Self-monitored-only control group	0.38(0.16)	0.22(0.13)	-42	
Positive/uplifting SI, M/SE^a				
Intervention group	3.73(0.39)	3.51(0.40)	-6	
Self-monitored-only control group	3.59(0.37)	3.20(0.38)	-11	
Daily personal meaning, M/SE^a				
Intervention group	1.32(0.11)	1.28(0.11)	-3	
Self-monitored-only control group	1.11(0.11)	1.00(0.10)	-10	
Daily No. of cognitive activities, $B(95\% CI)^b$				
Treatment (ref = intervention group)	-	-0.37(-1.82, 1.06)		
Time (ref = post-test T1)	-	-0.16(-0.62, 0.31)		
Treatment \times time	-	-0.12(-0.52, 0.75)		
Daily social interactions (SI), $B(95\% CI)^b$				
No. of hours in SI, $B(95\% CI)^b$				

(Continued)

**Table 3.** (Continued).

	T0, Baseline	T1, 4-week follow-up	T2, 8-week follow-up	Effect Size, %
Treatment (ref = intervention group)	-	0.11(-0.56, 0.78)		
Time (ref = post-test T1)	-	0.07(-0.33, 0.47)		
Treatment × time	-	-0.29(-0.84, 0.27)		
Stressful SI, B(95% CI) ^b				
Treatment (ref = intervention group)	-	-0.62(-1.06, -0.19)		
Time (ref = post-test T1)	-	-0.14(-0.56, 0.27)		
Treatment × time	-	0.30(-0.28, 0.87)		
Positive uplifting SI, B(95% CI) ^b				
Treatment (ref = intervention group)	-	-0.28(-1.58, 1.02)		
Time (ref = post-test T1)	-	0.22(-0.40, 0.85)		
Treatment × time	-	0.17(-0.69, 1.02)		
Daily personal meaning, B(95% CI) ^b				
Treatment (ref = intervention group)	-	-0.36(-0.71, 0.00)		
Time (ref = post-test T1)	-	0.04(-0.17, 0.24)		
Treatment × time	-	0.07(-0.21, 0.35)		

Note: * $p < .05$; ** $p < .01$.^aAdjusted means based on results of Linear Mixed Effects Models adjusted for age and education.^bResults of Linear Mixed Effects Models adjusted for age and education.

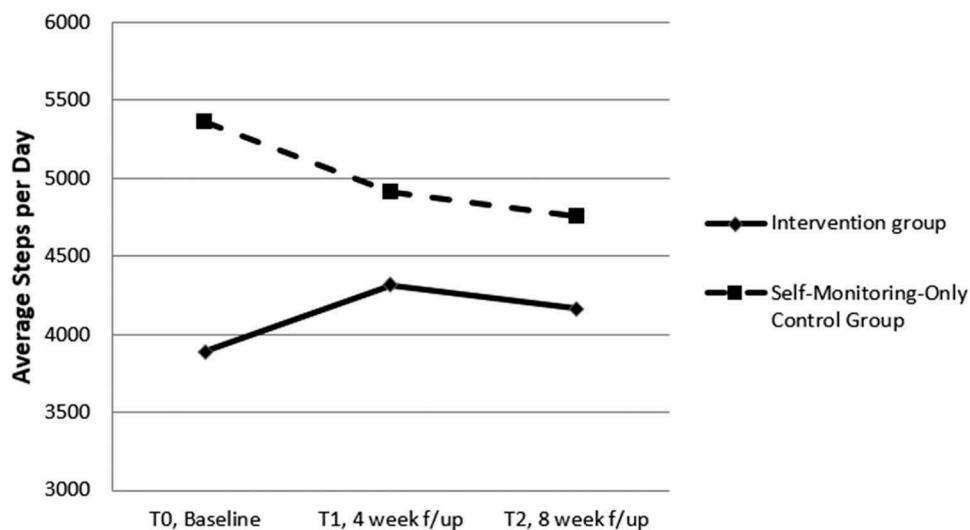


Figure 2. Average steps/day at baseline, 4-week, and 8-week follow-up by treatment arm. Note: Adjusted means based on results of Linear Mixed Effects Models adjusted for age and education

of 277 steps), but not the control (decrease of 606) and the intervention group improved compared to the control group by 883 steps ($p < .01$). It should be noted that the intervention group's average steps per day decreased by 154 steps between T1 and T2; however, this decrease was offset by the control groups' comparable decrease during the same time period (decrease of 148 steps).

With regard to the secondary outcome variables, daily number of cognitive activities increased slightly from baseline to T1 for the intervention group (an increase of .16 of an activity, or 4%), but not for the control group (a .02 increase, 0%). Daily number of hours in SIs actually decreased by 2% for the intervention group and increased by 5% for the control group. Stressful SIs increased by 33% for the intervention group and decreased by 42% for the control group. Positive/uplifting SIs decreased for both groups, and daily PM decreased for both groups, but slightly more so for the control group. However, none of these differences from baseline to T1 for either treatment arm were statistically significant, nor was there evidence that the intervention group was significantly different with regard to these outcome variables relative to the control group.

Discussion

Our "engagement model" of health promotion, guided by the SMHP, may be an effective approach for increasing active lifestyles among inactive, community-dwelling older adults. Findings from this pilot study indicate that recruitment was feasible, in that it was relatively fast and efficient; the



participants manifested excellent adherence to the study protocol and the intervention group exhibited a high level of engagement with the various components of the intervention; and outcome assessment results suggest that the intervention shows promise in increasing steps per day compared to the control group over both 4-week and an 8-week periods. This pilot study has also identified several issues that need to be addressed when designing future trials, namely the difficulties in recruiting men, barriers due to the technology-intensive design, and the optimization of secondary outcome measures.

Results in the context of other literature

Our approach in this study was similar in many respects to Varma et al. (2016), who reported on the effects of the Experience Corps program (a high-intensity community volunteering program for older adults also guided by the SMHP) on walking behavior specifically using a sex-stratified RCT. These authors found no effect after 12 months, and after 24 months, women, but not men, in the intervention group showed an increased amount of walking activity, averaging 1,500 greater steps/day compared with the control group, compared to women in the control group who showed a decline of 1,192 steps/day at 24 months compared to baseline. Unlike the lagged effect seen in the Experience Corps trial, in our study, the increase in the daily step count compared to the control group was detectable in the short term (4 and 8 weeks). This could be explained by the explicit use of behavioral, cognitive, and social behavior change strategies to encourage individuals to make changes in their activity portfolios with regard to PA, CA, SI, and PM immediately, whereas the changes to participants' activity portfolio more broadly took years in the Experience Corps study (and only in women). Also, while our small sample of men ($n = 5$) was too small to conduct gender subsample analyses, it would be important in future studies of the Engaged4Life intervention to assess whether there was a differential effect for women and men.

However, the Engaged4Life Program did not result in changes in cognitive or social well-being outcomes over the 4-week study period, but the Experience Corps program has shown effects on more distal cognitive and social outcomes (Barron et al., 2009; Carlson et al., 2008; Fried et al., 2004, 2013; Hong & Morrow-Howell, 2010). Our lack of findings with regard to more proximal measures of CA, SI, and PM may be due to the wide discretion that participants were given in how they chose to supplement or enhance their activity portfolios, all of which may have got participants out of the house and into the community more often (thus increasing walking behavior), but not all of which offered the same "dosage" of SI or cognitive stimulation. It could also be that the reason volunteering or taking on new

activities has an effect on outcomes such as health and well-being is because these activities serve as pathways to other productive social and civic activities, and it may be that the rewards and benefits of such an intervention may only occur after a period of acclimation to the new activities.

In general, the improvements in the daily number of steps observed in our study were comparable to those reported in pedometer-based interventions in older adults. In a review of pedometer-based interventions with community-dwelling older adults populations, Tudor-Locke et al. (2011) found a weighted increase of approximately 775 steps/day; however, the studies reviewed ranged in length from short term (2 weeks) to long term (11 months). For our study, the intervention group improved compared to the control group by 883 steps at 4 weeks and by 889 steps by 8 weeks. In a pedometer-based intervention of similar length (8 weeks), Culos-Reed, Stephenson, Doyle-Baker, and Dickinson (2008) found an increase from baseline of 914 steps. In a large trial with 571 primary care patients at risk of type 2 diabetes, a pedometer-based intervention (supported with an initial 3-h group-based structured education program) increased the mean daily step count by 411 after 12 months compared to control group (Yates et al., 2017), however, participants in this study had relatively high baseline PA levels (6,585 steps per day). In another primary care trial with baseline PA levels similar to what we saw in our study (4,771 steps per day) and a shorter follow-up period (8 weeks), improvements of 1,029 steps per day were observed, despite no additional education component (Glynn et al., 2014).

Interestingly, the control group had a higher number of steps per day than the intervention group at baseline ($5,363 \pm 322$ vs. $3,739 \pm 436$). The control group was also younger, on average, and more educated than the intervention group. Thus, one potential explanation for the findings could be that there was simply more room for improvement in the intervention group than in the control group. However, it is possible that this observed difference could reflect an initial “start-up effect” for the control group of using the FITBIT® in the absence of any other upcoming programming. This explanation is supported by prior research on pedometer-only PA interventions, which tend to find that without any additional support or programming, activity levels increase initially and then drop off quickly (Sullivan & Lachman, 2016). This issue could have been prevented had baseline data collection occurred prior to randomization.

One of the strengths of our study is that we objectively assessed participant adherence to wearing the pedometer on a daily basis (93%) and completing the daily self-report activity survey (via tablet) (94%). This is a very important factor because low adherence can hinder what would be an otherwise well-designed intervention. Vetrovsky et al. (2018) found 83% pedometer wear adherence and Cadmus-Bertram, Marcus, Patterson, Parker, and Morey (2015) found 80%, however, neither of these studies was focused on an older

adult population per se. The comparatively high adherence levels observed in our study indicate that the 1.5-hour study orientation/technology training session, which emphasized good practices for remembering to wear the pedometer and completing the daily surveys, was an effective tool for increasing adherence.

One of the objectives of our pilot study was to explore the feasibility of the recruitment procedure because the success of research in community-based settings often depends on the recruitment of the target number of participants; indeed, many RCTs fail to recruit the actual target number. Our strategy of: (1) partnering with the local senior centers, (2) advertising widely throughout the community via both local newspapers and flyers posted across the community at local businesses, churches, non-profits, and housing complexes, and (3) offering a range of incentives that were well-described in recruitment materials, including a \$50 VISA Gift Card, a FITBIT® Zip, and free iPad® Mini training, resulted in fast and efficient recruitment of the target number participants ($n = 30$) over a 4-week period. However, the approach did not reach the targeted number of men. This finding is consistent with a large body of literature reporting that men are often under-represented in health promotion programs (see Anderson, Seff, Batra, Bhatt, & Palmer, 2016). Anderson et al. found that barriers to the participation of men in exercise programs include: women outnumbering men in the implementation sites and programs, perception of exercise programs as feminine, and preference for other activities. It seems that our Engaged4Life program could be attractive to men, in that it does not focus on an exercise program and does, in fact, allow individuals to choose activities that are of personal interest, but this was not necessarily emphasized in recruitment materials. Further, partnering with a senior center to implement the intervention, which may have a reputation in the community for being female-dominated, may have impeded the recruitment of men into the study.

Finally, retention in our trial (83%) was similar to Buman et al. (2011), who observed an 85% retention rate at the end of the trial and follow-up at 18 months was 61%. Vetrovsky et al. (2018), on the other hand, reported 100% retention. However, this may be explained by their pre-randomization procedure that demanded patients to upload their pedometer data to a website prior to randomization, which 27% failed to do. If this had been done post-randomization, the retention rate might have been much more in line with our study. In the Engaged4Life study, all of the study drop-outs occurred post-randomization, but prior to baseline outcome data collection (i.e., at the technology training stage). This initial drop-out might have been avoided if baseline data had been collected prior to randomization and if the self-monitoring component/outcome assessment was less technology intensive, which was overwhelming to some participants.

Limitations

Strengths of the study include the wide range of feasibility measures that were assessed, the randomized design to test the intervention effect compared to a self-monitoring-only control group, the use of both objective and subjective measures of activity engagement, and the 4-week and 8-week follow-ups. Nevertheless, this pilot study has some limitations to acknowledge and address in future studies. First, the sample size was small, and we were not able to follow participants beyond the 2-month period. Additionally, we focused on steps per day, which represents only one component of total PA and our measures of CA, SI, and PM were limited due to lack of standardized measures of daily activities in these domains. It is possible that these measures were not sensitive enough for our purposes. Finally, though the study sample included an at-risk segment of the older adult population (those at-risk for poor health due to sedentary lifestyles), the time and technological requirements of the trial and the use of volunteers may have resulted in selection of more health-conscious community members.

Implications for practice

The study was intended as a pilot study and yielded important findings supporting the feasibility of future trials, specifically:

- (1) Recruitment of the target number of participants was fast and efficient over a 4-week period.
- (2) Participants manifested excellent adherence to the study protocol.
- (3) The Engaged4Life program was well accepted by participants in the intervention group who manifested high engagement in all components of the intervention.
- (4) Though not sufficiently powered to demonstrate differences between groups, the study indicated that the intervention might have the potential to increase steps per day compared to the control group over both a 4-week and an 8-week period.

On the other hand, the study has also revealed possible areas for improvement:

- (1) The difficulties in recruiting men may be addressed in future trials by tailoring recruitment strategies (e.g., using images of men in recruitment materials) and considering partnering with community-based organizations that are less female dominated.

- (2) The drop-out of individuals due to feeling overwhelmed by the technology requirements could be addressed by using a less technology-intensive design, for example, by replacing the daily tablet-based surveys with paper and pencil surveys.
- (3) Baseline data collection should occur prior to randomization.
- (4) Explore alternative measures of secondary outcomes that might be more sensitive to change or that measure CA, SI, and PM in a more fine-grained manner.
- (5) A longer follow-up of at least 12 months is generally required in health promotion interventions to assess the maintenance of the intervention effect; a future trial might consider continuing the peer mentoring phone calls accordingly.
- (6) Explicate which components or combination of components is critical to the observed behavior change.

Conclusion

In sum, by testing the feasibility and outcomes of an “engagement model” of health promotion that applies the principles of the SMHP to older adults’ daily lives and activities, we merge insights from both the productive aging (Morrow-Howell, Hinterlong, & Sherraden, 2001) and the health promotion literatures. More research is necessary to test the Engaged4Life program’s efficacy and effectiveness over a longer period of time and to document the process mechanisms responsible for its effects on a larger scale.

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Targeting Socially Isolated Older Adults: A Process Evaluation of the Senior Centre Without Walls Social and Educational Program

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Abstract

The Seniors Centre Without Walls (SCWOW) program provides free social and educational programming for older adults via telephone. The target population for SCWOW is socially isolated older adults, a hard to reach population. The aim of this process evaluation was to examine whether SCWOW was reaching its target population and to gather participant feedback about program implementation and the perceived satisfaction and impact of the program. Telephone interviews were conducted with 26 participants (92% females; aged 57–85 years). Forty-two percent of the sample was socially isolated and more than half reported being lonely. Participants reported having no difficulty using the telephone system. On average, participants were very satisfied with the program and reported that SCWOW had several positive effects (e.g., connecting to the larger community, affecting mental well-being). Importantly, no barriers to participation were identified. The study suggests that telephone-based programs can successfully reach socially isolated older adults.

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A large body of research has documented the negative effects that being socially isolated or lonely can have on older people's health and general well-being (e.g., Cacioppo et al., 2002; House, Landis, & Umberson, 1988). There is also evidence that being lonely is associated with a greater likelihood of entering a nursing home (Russell, Cutrona, de la Mora, & Wallace, 1997). Research out of Manitoba, Canada, has shown that approximately 30% of Manitobans (aged 72+ years) identify themselves as being moderately to extremely lonely (Newall et al., 2009) and that being lonely or socially isolated has implications for older Manitoban's health, physical activity, and even longevity (Havens & Hall, 1999; Newall, Chipperfield, Bailis, & Stewart, 2012).

Given the negative impact that social isolation and loneliness can have on older adults, it is not surprising that social participation and inclusion were identified as important indicators of age-friendly cities by the World Health Organization (WHO, 2007). According to WHO (2007), an age-friendly city is one where "policies, services and structures related to the physical and social environment are designed to support and enable older people to age actively" (p. 5). From this perspective, addressing the social problems of social isolation and loneliness can and should be done at the community level.

Offering programs and services targeting the socially isolated is important for improving the health outcomes of older adults and for potentially making communities more age-friendly. However, some of the characteristics that may predispose older people to become socially isolated or lonely (e.g., widowhood, low income, poor health, living alone, caregiving; e.g., Cloutier-Fisher & Kobayashi, 2009; Havens & Hall, 1999; Pinquart & Sorensen, 2001) may also make it difficult for individuals to partake in traditional social activities held in their community. A major question arises: How can services and programs reach the socially isolated? The present study evaluated a social and educational program offered in Manitoba, Canada, called Senior Centre Without Walls (SCWOW), specifically designed for socially isolated older adults.

Definition and Prevalence of Social Isolation and Loneliness

For the purpose of the present study, social isolation was defined as a lack or absence of meaningful social contact and opportunities (e.g., Scharf & de Jong Gierveld, 2008; Wenger & Burholt, 2004). However, of note, there is little

consensus or consistency on how social isolation is measured or defined, making it problematic for researchers and practitioners to compare studies or identify/target the socially isolated (Sabir et al., 2009). Moreover, it is difficult to differentiate between the socially isolated who may benefit from outreach and those who prefer to be alone. Accordingly, assessing loneliness, a subjective feeling that the quantity/quality of one's social relationships is insufficient (de Jong Gierveld, 1987), can provide important complementary information on people's social relationships.

Notwithstanding the measurement issues, research suggests that a significant proportion of older adults are lonely and/or isolated. Approximately 20% to 40% of older adults report moderate to severe *loneliness* (e.g., Newall et al., 2009; Pinquart & Sorensen, 2001; Weeks, 1994; Wenger & Burholt, 2004), and it appears that prevalence rates for social isolation could be as high as 20% of older community-dwelling adults. Cloutier-Fisher and Kobayashi (2009) found that 17.5% of older Canadians (65+ years) were socially isolated. A recent study out of British Columbia, Canada, classified 17% of older adults (65+ years) as socially isolated based on a scale measuring relationships with relatives and friends (Kobayashi, Cloutier-Fisher, & Roth, 2009). Using this same scale on European samples, Lubben et al. (2006) found that 11% to 20% of older adults (65+ years) were socially isolated. This means that one out of five older people may be isolated from crucial social resources and support, making it particularly important to identify and provide appropriate programs or interventions for these individuals.

Addressing Social Isolation and Loneliness

A variety of approaches have been taken to address social isolation or loneliness in later life, including group or one-on-one interventions (for reviews, see Cattan, White, Bond, & Learmouth, 2005; Findlay, 2003; Hogan, Linden, & Najarian, 2002; Masi, Chen, Hawkley, & Cacioppo, 2011) and even interventions using the Internet (e.g., White et al., 1999). However, few studies have examined the use of the telephone as a way of reaching the socially isolated (Cattan, Kime, & Bagnall, 2011). It is possible that using the telephone to reach the socially isolated may be particularly effective, as the reasons older adults are isolated may create barriers to participating in face-to-face groups or social activities. Cattan et al. (2011) found that a telephone befriending service presented a low-cost way for older adults to increase their confidence and to be more socially active in general. For the present study, we had a unique opportunity to examine an ongoing social and educational telephone program that older people could access free of charge from their own homes.

Senior Centre Without Walls Program in Winnipeg, Manitoba

The SCWOW program was introduced in Winnipeg, Manitoba, in 2009 by the nonprofit organization, Age & Opportunity: Support Services for Older Adults. The social program was inspired by the SCWOW program developed out of San Francisco, California. Indeed, several such programs now exist worldwide, with Winnipeg's being the first in Canada. SCWOW capitalizes on the idea that programming could be *brought to people* through something most people possess in their very own living rooms: a telephone. This low-technological concept is an alternative to having older people participate in programming at Senior Centres or other organizations. In this way, SCWOW is particularly suited for individuals who are socially isolated due to, for example, physical, financial, or geographical reasons.

The SCWOW program is open to anyone aged 55+ years living in Manitoba, a large prairie province in the center of Canada in which approximately 30% of seniors (65+ years) live in rural locations (Statistics Canada, 2006) and 70% live in urban centers, the largest being the province's capital city Winnipeg (population approximately 650,000). Typically four times a year, Age & Opportunity releases a SCWOW program calendar offering 30+ social and educational sessions. The program offers a variety of daytime and evening sessions including one-time sessions (e.g., "Australian Tour," "Nutrition and Healthy Aging," "National Aboriginal Day") and longer-term sessions (e.g., "Meditation Series," "Brain Teasers," "Education and Support Groups" for people with chronic lung disease and their caregivers, "Book Clubs," "Coffee Talks"). Sessions are offered at specific times and are facilitated by invited guests, health professionals, or Age & Opportunity staff and volunteers. That is, individuals are linked on the telephone, calling in for particular sessions at a set time, with a session leader. Participants can register at any time of year for SCWOW via a toll-free telephone number, mail, or fax. At the time of registration, participants can choose to be *called* for their sessions, or they can call in using a toll-free number. This same number is used for all sessions. Packages are mailed to participants for many sessions to provide more tactile materials, such as scent samples for "Aromatherapy."

The Present Study

The aim of the present project was to perform a process evaluation of SCWOW that would address questions surrounding the implementation of the program. This study was completed as part of a larger program of research on age friendliness in Manitoba, Canada (e.g., see Menec, Hutton, Newall, Nowicki, Spina, & Veselyuk, 2013. Menec, Means, Keating, Parkhurst, & Eales, 2011; Novek & Menec, 2013).

The specific objectives of the present study were as follows:

1. To examine who is participating and whether the SCWOW program is reaching its target population of isolated older adults.
2. To gather information from participants about the implementation of, satisfaction with, and perceived impact of the program.

Method

Procedure

This project was completed in collaboration with Age & Opportunity, Winnipeg. Ethical approval for the project was received from the University of Manitoba Bannatyne Campus Research Ethics Board (H2011:201). At the time of registration for SCWOW, people indicated whether they would be willing to have their name and telephone number given to a researcher from the University of Manitoba who would then contact them for their feedback. An interview schedule containing both closed- and open-ended questions was used to collect information from participants via telephone.

Participants

All individuals taking part in SCWOW for the May to September 2011 and October to December 2011 sessions were eligible ($N = 62$). Telephone interviews were conducted with participants near the end of each 4-month term. Twenty-nine people were willing to be contacted by a researcher, and 26 interviews were completed (two later refused; one was unavailable).

Measures

Sociodemographic variables. Sociodemographic information was gathered on age (in years), gender, marital status, housing, living arrangements (living alone or with others), location of residence (urban, rural), education level, and perceived income adequacy.

Health and limitations. Participants' perceived general health was assessed (excellent to poor), and they were asked whether they had a serious health problem (yes/no). Participants were asked whether they were limited in what they would like to do by their health, income, or residence location (yes/no).

Table I. Listing of Open-Ended Questions.**Access/barriers**

1. How did you hear about the program?
2. What was your main reason for trying the program?
3. What did you think about the call-in system?
4. Are there things that make participating in Senior Centre Without Walls programming hard? If yes, what can Age & Opportunity do to help?
5. Have you ever registered for a program, and then not participated? And if so, how come?

Satisfaction

1. Can you comment on how satisfied you are with the program?
2. What do you think about the content of Senior Centre Without Walls programs?

Impact

1. Does the Senior Centre Without Walls program provide you with something that you are not getting elsewhere?
2. In your experience, has participating in this program changed anything in your life or attitude?

Loneliness. Participants were asked, “if we divide people into four categories where ‘1’ is the *not lonely*, ‘2’ is the *moderately lonely*, ‘3’ is the *severely lonely*, and ‘4’ is the *extremely lonely*, what do you consider yourself to be?”

Social isolation and meaningful social contact. Participants were asked an open-ended question: “Sometimes people can feel isolated because they do not have as many opportunities to socialize or to do fun activities as they would like. Do you feel isolated at all? If yes, how come?” Participants were also asked about their meaningful social contact (source, frequency, satisfaction).

Program feedback: Quantitative questions. Participants were asked about their overall satisfaction with the program (1 = *not at all satisfied* to 5 = *extremely satisfied*) and whether they *agreed* or *disagreed* with statements about SCWOW (e.g., *I found pleasure and enjoyment in participating in the groups*; *I would recommend this program to others*). Note that these questions were modified from the San Francisco (California) SCWOW evaluation form.

Program feedback: Qualitative questions. Table 1 shows the questions asked of participants that were designed to tap into (a) access/barriers, (b) satisfaction with the program, and (c) impact of the program.

Analysis of Qualitative Data

The interviews were completed by the first author, who wrote down participant responses verbatim. Responses were analyzed for common themes by the first author. For the questions requiring more straightforward answers such as “how did you hear about the program” or “how come participant missed a session,” responses were simply grouped based on similarity (e.g., missed a session due to a conflicting appointment) and then tallied to determine the most common responses. For the more open-ended questions, for example, the two questions tapping into the impact of the program, the first author reviewed the responses for each question and identified keywords (e.g., “making friends,” “connecting with others”). Next, the different keywords were grouped based on common underlying themes and a label was created (e.g., “feeling more connected”).

Results

Participant Characteristics

On average, participants had been taking part in SCWOW for two terms. The average age of the participants was 71 years (range 57-85 years). Twenty-four (92.3%) participants were women. Marital status varied with 31% widowed, 27% divorced, 23% married, and 19% single. About 73% of the participants lived in Winnipeg, and 27% lived in rural Manitoba. Most participants (73.1%) lived alone. About 38% of the participants had some high school education or had completed high school, whereas the remaining 61.5% had some university or a university degree. On average, participants reported that their income met their needs “with difficulty.” Last, although people generally reported having “good” health, most people (69%) had at least one health problem that they considered serious (e.g., hip problems, eyesight loss).

Identifying the Socially Isolated

To identify the socially isolated, participants were asked directly whether they felt isolated and, if applicable, the reason that they were isolated. If people gave either a firm “yes” or “no” response, they were categorized accordingly as isolated ($n = 8$) or not ($n = 9$), respectively. For the nine participants who gave less clear responses (“not really,” “depends,” etc.), those who indicated having daily meaningful social contact ($n = 6$), were categorized as *not* isolated. The remaining three people who did not have daily social contact were categorized as isolated. Based on these criteria, 42.3% (11/26) were socially isolated.

Table 2. Characteristics of Isolated Versus Not Isolated Participants.

Characteristics	Not isolated (n = 15)		Isolated (n = 11)	
	N	%	N	%
Health limitations				
Yes	10	66.7	11	100.0
No	5	33.3	0	
Income limitations				
Yes	7	50.0	9	81.8
No	7	50.0	2	18.2
Location limitations				
Yes	5	33.3	7	63.6
No	10	66.7	4	36.4
Frequency of meaningful contact				
Less than daily	4	28.6	9	90.0
Daily	10	71.4	1	10.0
Satisfaction with meaningful contact				
No	3	21.4	7	70.0
Yes	11	78.6	3	30.0
Lonely				
Yes	6	40.0	8	80.0
No	9	60.0	2	20.0
SCWOW makes feel like a community				
Disagree	5	38.5	2	18.2
Agree	8	61.5	9	81.8
Satisfaction with SCWOW				
Somewhat satisfied	2	13.3	0	0.0
Satisfied	5	33.3	2	18.2
Very satisfied	7	46.7	4	36.4
Extremely satisfied	1	6.7	5	45.5

Note. Due to missing responses, some columns will not add up to total N. SCWOW = The Senior Centre Without Walls.

Limitations due to Health, Income, or Residence Location

People may be socially isolated for a variety of reasons. We examined limitations in health, income, and residence location. The majority of the participants reported being limited (and some even housebound) because of their health (81% of participants). They were also limited by their income (64% of the participants), followed by where they lived (46%). In examining these limitations further, we found that compared with the not isolated, the isolated participants were much more limited in what they could do (Table 2). For example, all the isolated individuals were limited by their health and 81% by their income.

Table 3. Responses to Feedback Question Statements.

Feedback questions	% Agreement
a. I found pleasure and enjoyment in participating in the groups.	96.2
b. I would recommend this program to others.	100.0
c. I plan to continue participating in this program.	96.0
d. I feel as if I belong to a community as a result of this program.	70.8
e. I found the activities mentally stimulating.	92.0
f. I feel as if I have something to look forward to as a result of the program.	96.0
g. Satisfaction with SCWOW	
Somewhat satisfied	7.7
Satisfied	26.9
Very satisfied	42.3
Extremely satisfied	23.1

Note. SCWOW = The Senior Centre Without Walls.

Compared with 33% of not isolated, 63% of the socially isolated participants were limited by where they lived. In sum, the socially isolated participants were more limited by their health, income, and residence location.

Social Contact and Loneliness

When participants were asked where they get the most *meaningful social contact* with people in their daily life, about half mentioned their spouses, families, and friends (12/26; 46%), and others mentioned sources such as church, coffee shop, and Seniors Centre. SCWOW was also mentioned as a main source of meaningful social contact by some. Comparing the isolated and not isolated (Table 2), 29% of the not isolated had *less* than daily meaningful social contact, whereas 90% of the isolated did. Similarly, 79% of the not isolated were satisfied with their amount of social contact, whereas, 30% of the isolated were satisfied.

In terms of loneliness, we found that for the full sample, 56% of the participants were lonely. Moreover, we found that 80% of the isolated participants were lonely, compared with 40% of the not isolated who were lonely (Table 2). In sum, not surprisingly, the socially isolated participants reported having less meaningful social contacts and being more lonely.

Program Feedback: Quantitative Data

All participants agreed that they would recommend this program to others, and most enjoyed the groups and activities and planned to continue with the program in the future (Table 3). Thus, people were overall “very satisfied”

with the program ($M = 3.8$). Participants were less in unison on whether they thought that SCWOW helped them to feel as if they were part of a community, with about 70% agreeing with this statement.

We examined these last two questions on satisfaction and community more thoroughly by comparing the responses of the isolated with the not isolated (Table 2). As shown in the table, 82% of the socially isolated agreed that SCWOW helped them feel as if they were part of a community, compared with 62% of the not isolated. The isolated were more satisfied with the SCWOW program, as 82% were either very or extremely satisfied with the program, compared with 53% of the not isolated.

Program Feedback: Qualitative Data

The following section provides details about participant responses to open-ended questions that were designed to tap into (a) access/barriers, (b) satisfaction/dissatisfaction, and (c) perceived impact of SCWOW.

Access and barriers. Part of accessing programs is hearing about them in the first place. Participants most commonly heard about the SCWOW program via Age & Opportunity (brochure, poster, representative visiting a community group), followed by newspapers, newsletters, and Seniors Centres. Four people heard about the program through a health professional (e.g., social worker, mental health), which would seem to be a promising entry point into social programs for the socially isolated.

Participants reported little to no barriers in terms of accessing SCWOW. For example, people reported that the telephone system was easy to use and that they appreciated how the call-in number was the same for all the programs. Indeed, the majority of participants indicated that there was nothing at all that made participating in SCWOW difficult. If people registered and missed a session, it was due primarily to scheduling conflicts. In this vein, some people wished that there were more evening sessions when they had no appointments.

Of note, the most common reason for participating in SCWOW was because participants could access the programming from their home. Therefore, being able to access programming from home, using an easy-to-use technology, might break down many of the more common barriers to participation such transportation, cost of programs, or health problems.

Although accessing SCWOW appeared to pose no difficulty, several people did report barriers in being an active participant on the telephone. Participants noted problems with people monopolizing the conversation, not knowing whether you have been heard on the telephone, and difficulties

keeping people focused on the topic. These problems are illustrated by the following comments:

Sometimes we get out of focus. People just talk about themselves. There needs to be some housekeeping rules. (Female, aged 58 years)

The lapses in phone conversations was hard. There were delays. Sometimes you did not know if [the facilitator] heard you. I didn't want to interrupt. [The facilitator] did a good job considering the number of people on the phone though, overall. (Female, aged 63 years)

Satisfaction with program. As highlighted by the following comments, overall, people were satisfied with the program content, with some noting that they especially appreciated the staff and facilitators:

Facilitators are fantastic. They are always in a good mood (which is not easy). (Female, aged 60 years)

I enjoy the content. I especially like the travel ones, though I have missed a few. I was able to get a code for listening later in the evening though. (Female, aged 77 years)

Not everyone was satisfied with the program, however. Participants who were less satisfied with the content seemed to find that the program did not suit their needs or interests, as illustrated by the following comments:

I think the program was great. Not all of it was my cup of tea though. (Female, aged 63 years)

I am needing to be active and so being on the telephone just doesn't do it for me. (Female, age 69)

Perceived impact. There were several subthemes that emerged surrounding the perceived impact of the program as follows: feeling more connected, impact on mental well-being, something to look forward to, and increases knowledge.

Feeling more connected. Several participants noted not being able to take part in many activities outside of their homes because of health problems or living in a remote location. Therefore, an important aspect of the program was that it made them feel more connected to other people and the outside world. The formation of friendships was a common theme, as people

appreciated making friends over the phone, and discovering that they had things in common with others. On the flip side, participants appreciated getting to know others *in different* circumstances, as some reported that they had learned more about what it is like to have different problems or to be homebound, and felt relief knowing that SCWOW existed if/when they were to become less mobile themselves. The following comments highlight some of these feelings of connection:

It makes me more connected with the outside world. We have a wonderful lunch in the apartment but I can't go downstairs anymore. I can't sit for any length of time. The [SCWOW] program is an added boon to be able to converse with more than one person. I can't get dressed sometimes, but I can sit and be comfortable for the programming. (Female, aged 76 years)

Main thing is you feel more connected. And I find I have things in common with people. There are some people who are not mobile who really get a lot out of it. It is good to know that if I ended up in the same position [not mobile] that there is something there. (Female, aged 66 years)

I am happy I joined. When I became widowed I realized I was sheltered. Makes you feel good to have a friendly voice all the time on the line! It makes you realize that we're all in the same boat. It is nice to be able to talk. And you become friends. (Female, aged 70 years)

Impact on mental well-being. Participants specifically brought up the impact of SCWOW on their mental well-being, mentioning that SCWOW helped them feel less lonely, feel happier, and deal better with their depression. It appears that having the option to participate in a session when they want to and need to, and having something to look forward to, helped with people's mental well-being. These ideas are illustrated by the following comments:

I like the conversations, the interactions, with thoughts. I don't quite feel so lonely because I can pick up the phone and have friends in my living room! (Female, aged 76 years)

I suffer from depression, and the program made it easier to deal with. If I have a bad day, I will have an interesting day to look forward to. It has helped a lot! (Female, aged 60 years)

Something to look forward to. Participants valued SCWOW for giving them something to look forward to and to help provide structure or purpose to their

day. One person noted that they received few visits and, therefore, especially appreciated looking forward to a call from SCWOW:

When you [have my health condition], a lot of people don't want to come the way they used to. When you know you're getting a call, that's something to look forward to. (Female, aged 85 years)

It gives you something to look forward to. It is better for a person to have a schedule, you know, a shape and a form to your day. (Female, aged 76 years)

Increases knowledge. Participants simply appreciated the knowledge gained through SCWOW, for example, on a new language, or on different cultures and events. Learning about health issues such as arthritis was also appreciated. Several participants felt that SCWOW helped open their minds or develop new interests, as illustrated here:

It's given me more broader things to think about. I really liked the [Folk Festival] pavilions. You read over the materials and then I had questions in my mind already. I had lots of questions and they [facilitators] were good at answering the questions. It opens up your mind. (Female, aged 63 years)

Discussion

In the present study, we gathered sociodemographic and health information on participants of the SCWOW program and obtained feedback on the programming in terms of satisfaction, barriers to participating, and personal impact of the program. The study is important as it provided an opportunity for older participants themselves to voice their feedback on a rather unique program offering social and educational opportunities over telephone. The study also allowed an examination of whether the program was reaching its target population of socially isolated adults, and whether the program was being delivered in a way appropriate to the needs of this group, with little barriers.

Reaching the Socially Isolated

A main research question was whether SCWOW was reaching the socially isolated. Studies indicate that approximately 17% to 20% of older adults aged 65+ years are socially isolated (Cloutier-Fisher & Kobayashi, 2009; Kobayashi et al., 2009; Lubben et al., 2006). In comparison, we found that 42% of the SCWOW sample was isolated. Thus, it appears that Age & Opportunity's

SCWOW program is successfully reaching socially isolated older adults. Moreover, we found that the socially isolated were particularly limited by their health, income, and residence location and that most were lonely and had unsatisfactory social contact. Taken together, these are important findings as they suggest that it is not simply the more “socially engaged” older person who is also engaging in SCWOW but rather people who may not be able to access other programs due to health, income, or geographic limitations.

Removing Barriers and Providing Opportunities for Choice

Another aim of this study was to examine barriers to participating in SCWOW. First, people reported having no major difficulty using the telephone system. Second, it was revealing that no major barriers were mentioned by the participants. Perhaps this is because there were no cost barriers and transportation was not an issue because it is offered out of people’s own homes. Indeed, the participants reported that an important aspect of why they joined SCWOW was because it was accessible from their homes. Having the programming offered from home, with a variety of content, and times of day also provides participants with an incredible amount of choice and personal control over their own participation in SCWOW. This aspect of enhancing opportunities for control or self-efficacy over their participation and social contact could do much to improve the well-being of socially isolated participants (e.g., Baltes & Baltes, 1990; Schulz & Heckhausen, 1996) and may transfer to other parts of people’s lives (e.g., Cattan et al., 2011). Interestingly, simply knowing that SCWOW was available appeared to provide some of the “not isolated” respondents a sense of relief because SCWOW would be there if they were to become isolated or less mobile. This suggests that SCWOW could serve as a tool to prevent social isolation or loneliness, a form of primary prevention (Uchino, 2009). In sum, the fact that it is flexible, free, offered from home, and via telephone are all important and unique aspects of the SCWOW program. SCWOW appears to be filling a gap by providing people with a way to be connected and take advantage of social and educational programs when and if they want to, and regardless of where they live, how poor their health is, and whether they have a high or low level of income.

Next Steps

The quantitative and qualitative results from this study point to some areas that could be focused on in the future. For example, “younger” older adults were not well represented in our study, as only 12% of the sample was below 60 years. Therefore, it is unclear whether these “younger” older adults would

have different feedback. In addition, men were not well represented in our sample; however, this seems to reflect the fact that there are, by far, more women participating in the program than men (Age & Opportunity Program Manager, personal communication, July 27, 2012). Therefore, it seems that more specific targeting will need to be done to identify *men* who may be isolated and living in the community. This is a particularly important issue as males may be particularly at risk for loneliness, especially those living alone (e.g., Greenfield & Russell, 2011). It is possible that men would respond better to particular activities/programs or that the over-the-telephone nature of the program is not as suitable for men. This all remains speculation, however, as the results of this study do not provide sufficient insights, and, in general, the research literature on older men and participation in social programs is scarce (Reynolds, 2011).

Developing programming designed to facilitate friendship formations might also be of value, as more than half the sample was lonely. Some participants requested more (or longer) coffee talk social sessions offered at different days and times. Offering more social programming (such as coffee talk) might help foster a sense of community. On this note, it should be stated that telephone communication is not necessarily a substitute for face-to-face interaction. Cattan et al. (2011), for example, found that participants of a telephone befriending service wanted to meet their "befriender" to put a face to their name. In other words, SCWOW should not be seen as a replacement for important programming that includes transportation to and from Senior Centres, for example. Rather, there ideally should be a variety of social programming options that suit different needs.

Finally, it was sometimes difficult for people to be an active participant over phone because of, for example, individuals monopolizing the conversation. This can be a challenge to any group setting; however, given the lack of visual cues over the telephone, it may be even more challenging. Moreover, as the program becomes more popular, with greater numbers, this will no doubt be an issue that will need to be continually addressed.

Satisfaction With Program and Potential Impact

An important consideration of this study was whether people were satisfied with the program and what impact it had on the participants. In general, participants of SCWOW were satisfied with the program, and this was even more apparent when we examined only the socially isolated. In addition, compared with the "not isolated," the socially isolated tended to report that SCWOW made them feel as if they were part of a community. As it is a difficult feat to create a sense of community, this seems a promising finding.

An important finding was that participants reported that SCWOW had a positive impact on their mental well-being in terms of helping with their loneliness and depression. In addition, SCWOW made people feel more connected to the outside world and to other people. By providing opportunities for older people to interact with others (whether they choose to take advantage of these opportunities or not), the SCWOW program is helping to create a more age-friendly community. Moreover, given that the nonprofit organization Age & Opportunity provides other services, SCWOW is linking people not only with other participants but also with the larger support system as well.

Limitations

Our study design precludes us from making *causal* conclusions about the impact of SCWOW. To move toward making these sorts of conclusions would have required that we restrict *who* participated in the program to create a control and intervention group and ideally assess participants' social isolation pre- and post-participation. Given that SCWOW was designed to be as open and accessible to all, restricting participation was not a viable route to take for this study. To try to get a sense of the potential impact of the program, we simply asked participants their thoughts. Of course, a limitation of our study is that we do not have information on the non-responders in terms of their satisfaction with the program. It is not known whether those who are satisfied with the program were particularly apt to participate in this study. In addition, another limitation was the small sample size for the current study. Having a larger sample would have helped to increase confidence in the generalizability of research findings. Another limitation was the use of a self-reported measure of social isolation. It would have been more ideal to have responses from an objective social isolation scale so that results could be directly compared with other larger studies. Directly asking about social isolation and allowing participants to reveal reasons for social isolation did allow us, however, to perhaps capture some of the nuances of isolation. For example, in one case, follow-up questions revealed that although the respondent lived with others, she or he was basically alone and housebound during most of the day. As another example, someone who reported being isolated but also had daily contact was referring to daily visits by a home care worker.

To conclude, MacCourt (2007) discussed key features that should to be taken into account when designing programs for older adults, including the need to deliver services in ways that are appropriate to the needs of the target group. In this respect, a program such as SCWOW may be on the right track.

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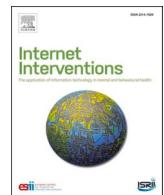
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A pilot randomized controlled trial of a group intervention via Zoom to relieve loneliness and depressive symptoms among older persons during the COVID-19 outbreak



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ABSTRACT

While effective in reducing infections, social distancing during the COVID-19 outbreak may carry ill effects on the mental health of older adults. The present study explored the efficacy of a short-term digital group intervention aimed at providing seniors with the tools and skills necessary for improving their coping ability during these stressful times. A total of 82 community-dwelling adults aged between 65 and 90 ($M_{age} = 72$ years, $SD = 5.63$) were randomized to either an intervention group ($n = 64$) or a wait-list control group ($n = 18$). The intervention comprised online guided sessions in small groups in which behavioral and cognitive techniques were learned and practiced via the ZOOM videoconferencing platform. Loneliness and depression levels were measured pre- and post-participation. The results demonstrated a significant improvement in the intervention group in terms of both loneliness and depressive symptoms, compared with the control group. Results of mixed effect models indicated a medium ameliorative effect on loneliness ($d = 0.58$), while that for depressive symptoms was only marginally significant and smaller in size ($d = 0.43$). Our intervention presents a relatively simple and effective technique that can be efficiently utilized to support older adults both during emergencies such as the COVID-19 outbreak, as well as in more routine times for older adults who live alone or reside in remote areas.

1. Background

The SARS-CoV-2 virus which has been spreading around the world, has widely affected the lives of many – especially at-risk populations including older adults. Alongside studies examining the sequelae of the disease itself, it is also important to address the possible negative consequences of measures taken, first and foremost - social distancing and home isolation (Galea et al., 2020). Although these actions may be effective in “flattening the curve” for a population, they can also lead to increased loneliness and alienation for the individual (McGinty et al., 2020), with potential ill effects on both mental and physical health (Clarfield and Jotkowitz, 2020). Loneliness and social isolation among

older people are strongly and independently associated with increased depression, high blood pressure, sleep disorders, and even deterioration in cognitive function (Courtin and Knapp, 2017). Similar findings are also supported by recent evidence reporting elevated levels of depression and anxiety due to the COVID-19 pandemic, and indicating older adults as especially vulnerable in this regard (Rajkumar, 2020). Clearly, this pandemic is going to be with us for the foreseeable future. Thus, it is of utmost importance to battle the potential consequences of social distancing and to equip older adults with appropriate tools for optimal coping.

Previous studies that focused on strategies to reduce loneliness reported two main coping styles which can generally be classified into

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social- and non-social behaviors (Pettigrew and Roberts, 2008). Social behavioral strategies to alleviate loneliness include interacting with family, friends, and others; while non-social behavior involves solitary activities such as reading, gardening, or meditating (Kharicha et al., 2018). Each of these strategies (social vs. non-social) entails benefits and costs, and neither is considered to fit all (Schoenmakers et al., 2012). The COVID-19 pandemic has posed a significant challenge in this regard since the ability to implement social strategies to combat rising loneliness was greatly reduced, especially among at-risk populations such as older persons.

New information and communication technology (ICT) (e.g., WhatsApp, Zoom, etc.) offers a convenient solution in this regard (Wind et al., 2020). During the COVID-19 outbreak, ICT can enable the remote maintenance of social connections (Anderson and Perrin, 2017; Baym, 2015). Furthermore, it also allows the conveyance of digital interventions (whether in a group or individual setting) over which therapeutic techniques and skills can be learned and practiced by older adults to promote effective coping, as well as alleviate loneliness, distress, and other mental health conditions (Andersson, 2018; Andersson et al., 2019; Mahlo and Windsor, 2020). Thus, internet-based interventions can allow individuals to adopt social, non-social, or even integrated coping strategies - according to their preference. Therapeutic approaches that were found effective in decreasing loneliness as well as depression among older adults include, among others, Cognitive Behavioral Therapy (CBT) (Smith et al., 2020; Vanderweele et al., 2011). This type of intervention targets cognitive biases as well as behaviors that comprise some of the underlying mechanisms that maintain loneliness and associated depression (Hawley and Cacioppo, 2010). Empirical evidence also suggests that CBT techniques are also effective for reducing loneliness (Käll et al., 2020a; Vanderweele et al., 2011) and depressive symptoms (Dear et al., 2015; Smith et al., 2017). Applying CBT for loneliness and for depression is not new (Cacioppo et al., 2015; Kooistra et al., 2016; Watts et al., 2013), and is based on the notion that people that experience loneliness may have negative beliefs and appraisals, and that these may even perpetuate loneliness.

CBT techniques and skills in this specific context focus on identifying non-adaptive cognitive schemes and using cognitive restructuring to promote better coping (Beck, 1979). Interventions that combine CBT techniques for maladaptive cognitions were reported to be more effective in treating loneliness than interventions that focused solely on increasing social interactions and activities (Masi et al., 2011). Recent evidence suggests that internet-based CBT interventions are useful in alleviating loneliness (Käll et al., 2020a; Käll et al., 2020b). Unfortunately, very few digital interventions have been developed and validated to address these issues among older adults, and even fewer are directly related to coping with the current challenges posed by the global pandemic (Zubatsky et al., 2020).

This study reports a pilot randomized control trial (RCT) aimed at assessing the provision of CBT tools and skills necessary for improving older persons' coping abilities, alleviating loneliness and decreasing depressive symptoms during the COVID-19 outbreak. The trial was implemented through a short-term digital group intervention via Zoom. We hypothesized that older persons who participated in a special COVID-19 focused program, which provided relevant CBT training aimed at promoting better coping with the stressful situation created as a result of the pandemic and is also known to successfully reduce the effects of negative beliefs and appraisals, would demonstrate a decrease in levels of depressive symptoms and loneliness compared to a wait-list control group.

2. Methods

A pilot-RCT study with a wait-list control group among community-dwelling older (65+) adults in Israel.

2.1. Participants

Participants were recruited via an advertisement to WhatsApp groups of older persons established by a local NGO responsible for promoting digital literacy among older adults. Eligible participants were community-dwelling adults aged 65 and older who are proficient in Hebrew and could provide informed consent. Additional inclusion criteria were having an active internet connection, possessing at least one device that enables online communication, and having a minimal ability to operate this device (i.e., turning it on and off).

2.2. Procedure

The study took place over three months between April–June 2020. Following approval by the Institutional Review Board, an invitation to participate was circulated among prospective participants. All applicants ($n = 124$) were screened for eligibility within the recruitment process (Fig. 1). In the first step, 37 applicants were excluded due to: age (<65) (21) or non-response (16). In addition, one participant withdrew from the study for personal reasons, leaving 86 eligible (rate of eligibility: $86/124 = 69\%$). All provided informed consent and were randomized via a 4:1 ratio into either intervention or control group (comprising a waitlist for the intervention). The randomization process was conducted independently by a research coordinator who was not involved in any further aspects of the intervention and data collection, using a table of random numbers with no further constraints. The rationale for the 4:1 randomization ratio (vs. an even ratio which is the classic ratio in RCTs) was mainly ethical – that is, to provide treatment as quickly as possible to as many people that were, at the time, isolated at their home for an unknown period due to the viral outbreak, with reports indicating high rates of adverse mental health effects among older persons in particular (Armitage and Nellums, 2020; Tyrrell and Williams, 2020).

After randomization, participants filled in pre-participation questionnaires (T0), and we ensured that the Zoom platform was installed on their computer or smartphone, and that their skill level of operating it was satisfactory. If necessary, remote assistance (via telephone) was provided in downloading, installing and independently using the app. At this point, intervention participants were assigned to small groups of up to seven participants. Thirteen participants withdrew from the intervention group ($n = 68$) during the program for health reasons (5), due to technical difficulties operating Zoom (3) or out of lack of interest (5). In the control group ($n = 18$) only nine participants commenced the intervention following the end of the waiting period. The others withdrew due to lack of interest (6) or non-response (3) (adherence rate $13/[68 + 9] = 83\%$). The final sample consisted of 82 participants ($n = 64$ intervention; and $n = 18$ controls). A total of eleven groups were conducted, with 5–7 participants in each.

2.3. Intervention

The intervention included seven twice-weekly online guided group sessions via Zoom. The moderators were clinical social workers who underwent designated training by a senior clinical social worker from the research team. The purpose of the intervention was twofold: a) to provide a "place" for social interaction that was dramatically reduced at the time and to enable participants to share their hardships within a supportive atmosphere - emerging care needs as a result of the pandemic eruption (Steinman et al., 2020); and b) to create a safe virtual learning space to acquire cognitive and behavioral skills related to coping with the pandemic with attendant social isolation and to mitigate the potential mental health effects - i.e., loneliness and associated depression. Each session lasted between 60 and 90 min, and consisted of a) a guided group discussion (lasted 20–30 min), and b) learning and practicing cognitive-behavioral techniques and skills (CB intervention) such as relaxation, guided imagery of a 'safe place', identifying non-adaptive

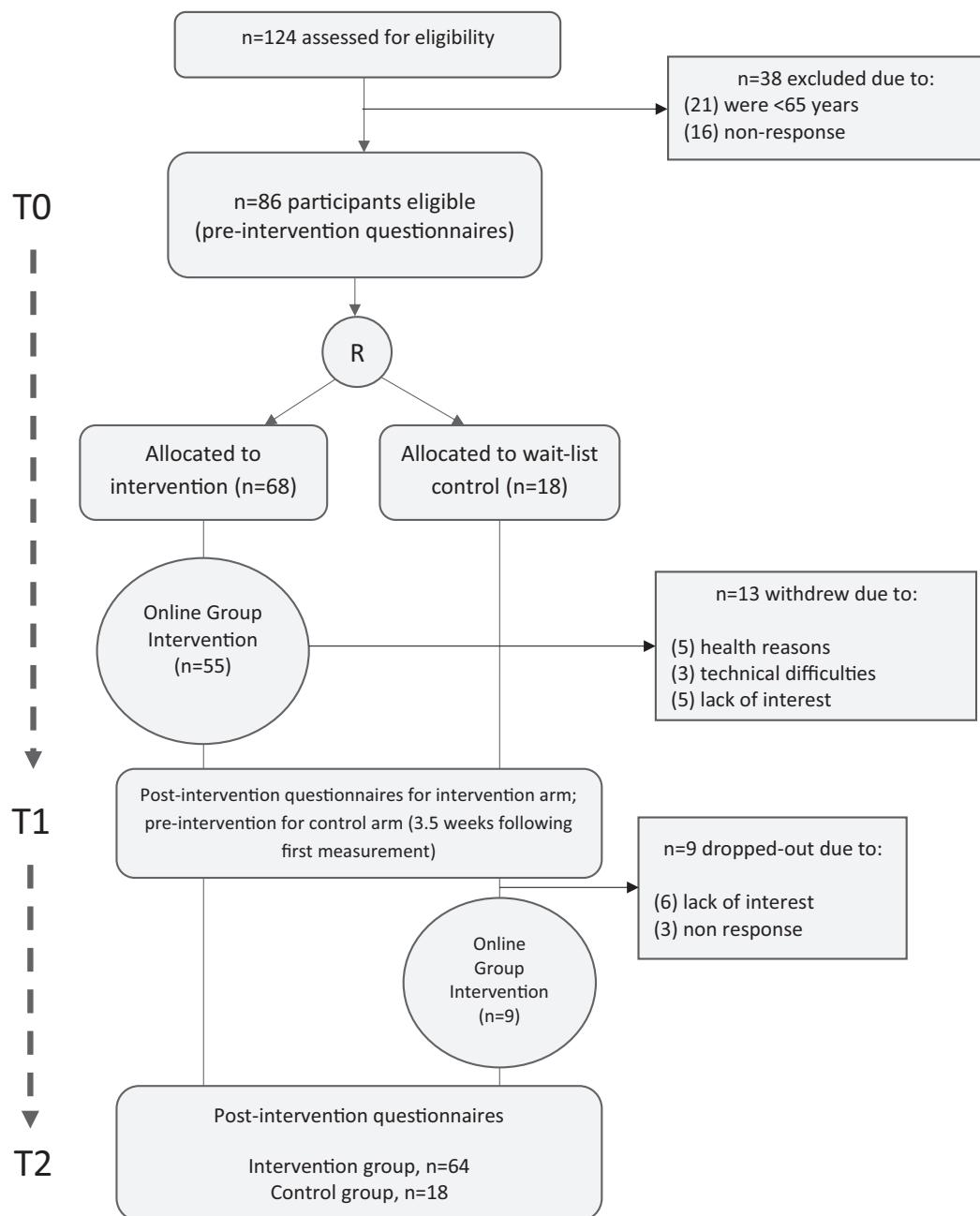


Fig. 1. Study flow chart and timeline.

cognitive schemas, cognitive restructuring, and constructing positive self-talk (lasted 40–60 min) (Satre et al., 2006; Tatrow and Montgomery, 2006). Mindfulness techniques were taught as well, as part of distancing strategies. Table 1 depicts a description of the intervention structure and the content delivered in each session.

All participants filled out online questionnaires twice: at pre- (T0) and immediately post-participation (T1). The waitlist control group participants were assessed twice before entering the intervention group (the two measurements took place about three weeks apart), completing a total of three measurements (compared with two measurements in the intervention group) (see Fig. 1). The link to the online questionnaire (web-based survey, <https://www.qualtrics.com>) was distributed by the groups' moderators to the participants' mobile phone or email, according to their preference, near the beginning and end of the intervention: that is, no more than 48 h pre- or post-participation.

2.4. Measures

2.4.1. Loneliness

A validated three-item version of the UCLA Loneliness Scale (Hughes et al., 2004) was used to examine perceptions related to lack of companionship, social exclusion, and social isolation. The response categories were coded as 1 (*hardly ever*), 2 (*some of the time*), and 3 (*often*). The responses were summed, with a range of 3–9. Higher scores indicated greater loneliness.

2.4.2. Depressive symptoms

Depression and severity of relevant symptoms were assessed using a 9-item depression severity measure. This measure is part of the Patient Health Questionnaire (PHQ-9), and it is used as a diagnostic instrument for common mental disorders (Kroenke et al., 2001). The PHQ-9 scores each of the DSM-V criteria as 0 (*not at all*) to 3 (*nearly every day*). The

Table 1

Digital group intervention: general structure and sessional content, techniques and skills.

Session	Part A – group discussion	Part B – learning and practicing skills and techniques
1	Introduction: Moderator introduces him/herself and details the program outline and the group's aims. Group members introduce themselves by turn. Each member is invited to share their current hardships and points of strength. A discussion is held and rules are established regarding proper group conduct and ways of communication.	
2	Group members are invited to share both a pleasant and an unpleasant experience they had in the past week.	Positive mantras & relaxation
3	Group members are invited to share a memory of a place (domestic or abroad) they enjoyed visiting.	Guided imagery of a "safe place"
4	Group members are invited to share a memory of a past experience with which they felt they coped well, a brave act they performed or of how they managed to get out of trouble.	Guided imagery of a "safe place", followed by introduction to non-adaptive cognitive patterns of thinking ^a and negative self-talk
5	Group members are invited to share an experience in which their own thoughts had failed them.	Practice the use of positive mantras and guided imagery to change negative self-talk and thinking patterns.
6	Group members are invited to share their current stress relief and coping techniques (e.g. self-acceptance; relying on significant other(s); finding comfort in food; self-distraction etc.).	Cognitive reconstruction and constructing positive self talk. Mindfulness techniques for distancing thoughts and sensations
7	Conclusion: Review of what was learned and practiced during the past sessions. Participants are invited to provide their feedback. Discussion on ways to keep in touch and of how to continue practicing.	

^a Based on the work of Albert Ellis [Ellis, A. Overcoming destructive beliefs, feelings, and behaviors: New directions for rational emotive behavior therapy. Prometheus Books; 2010].

responses were summed, with a range of 0–27.

2.4.3. Socio-demographic data

Age, gender, educational level, and household composition (dichotomized: live alone vs. live with other[s]).

2.5. Statistical analysis

Statistical pre-post analyses were conducted with repeated-measures mixed ANOVA. Additionally, we calculated effect sizes (=Hedges' g - used for groups with different sample size) for the between-group differences in the primary outcome, reported and interpreted according to Cohen's d (Cohen, 1988). Participants who did not complete any questionnaire or never received the allocated intervention were excluded from the analysis. All statistical analyses were conducted using SPSS (version 26, SPSS Inc., Chicago, IL, USA).

3. Results

3.1. Participants' characteristics

Table 2 presents the demographic characteristics of the participants and baseline scores of study measures, by intervention and control group. The study and control groups were largely similar.

Out of the 77 participants who provided pre-intervention data, thirteen dropped out during the intervention period (17% withdrawal rate). No significant differences were found between those participants who completed the intervention ($n = 64$) and those who dropped out

Table 2

Baseline comparisons between the intervention group and wait-list control group.

	Intervention group ($n = 64$)	Control group ($n = 18$)	p-Value
Sociodemographic characteristics			
Gender	52 (81%)	14 (78%)	0.743
Age ^a	72.1 (5.3)	71.7 (6.8)	0.799
Household composition -	24 (37.5%)	6 (35%)	0.867
Living alone			
Tertiary education	48 (76%)	10 (59%)	0.155
Study measures			
Depression (PHQ-9)	6.6 (5.2)	6.3 (4.9)	0.852
Loneliness	5.43 (2)	6.11 (1.9)	0.209

^a Participants were aged between 65 and 90 years.

early - either in demographics or in baseline scores of study measures; see Table S1 in Appendix 1.

3.2. Efficacy analysis

We observed a positive change between pre- and post-intervention loneliness and depressive symptoms (Fig. 2). Loneliness (score range is 3–9) decreased within the intervention group from a mean (SD) of 5.4 (2.0) to 4.8 (1.7), which corresponded to a pre-post effect size of $d = 0.32$. Conversely, the wait-list control group loneliness score increased from 6.1 (1.9) to 6.4 (1.7), (pre-post effect size $d = -0.166$). Repeated-measures mixed ANOVA revealed a significant main effect of time*group interaction ($F(1,78) = 5.59, p = 0.02, \eta^2 = 0.07, 95\% \text{ CI } [0.00, 0.16]$). The significant interaction indicated that the groups differed in loneliness scores post-intervention. The main effect of time did not reach statistical significance ($F(1,78) = 0.57, p = 0.45, \eta^2 = 0.001, 95\% \text{ CI } [0, 0.06]$). The calculated effect size for the between-group difference in loneliness scores was based on the mixed-model estimates and corresponded to $d = 0.58$, indicating a medium effect size of the intervention.

The depressive symptoms score (ranging between 0 and 27) decreased within the intervention group from a mean (SD) of 6.3 (5.3) to 5.2 (4.7), which corresponded to a pre-post effect size of $d = 0.21$. Conversely, the wait-list control group depressive symptoms score increased from 6.3 (5) to 7.1 (6.1), (pre-post effect size $d = -0.13$). Repeated-measures mixed ANOVA revealed a marginally significant main effect of time*group interaction ($F(1,79) = 3.82, p = 0.05, \eta^2 = 0.05, 95\% \text{ CI } [0, 0.14]$), indicating a marginally significant difference between the groups post-intervention. The main effect of time ($F(1,79) = 0.35, p = 0.55, \eta^2 = 0.00, 95\% \text{ CI } [0, 0.05]$) did not reach statistical significance. The calculated effect size for the between-group difference in depressive symptoms was based on the mixed-model estimates and corresponded to $d = 0.45$, indicating a small effect size.

4. Discussion

In this study we presented a pilot RCT of an intervention aimed at helping community-dwelling older adults cope with the consequences of social distancing resulting from the COVID-19 outbreak. The surge of interest in and acceptance of digital tools among both health and social care providers as well as users that has been prompted by the global crisis (Torous et al., 2020) offers a unique and important opportunity to explore the effectiveness and potential of various digital initiatives that offer support and mental health care (Zhou et al., 2020). The current intervention model combines various coping-related cognitive-behavioral strategies in an online group setting, thus addressing some of the negative effects of COVID-19 while complying with social distancing guidelines. The results indicate that the study intervention resulted in positive outcomes in terms of both loneliness and depressive symptoms among the intervention group and indicated that such techniques can be successfully applied in online group settings. Furthermore, the social

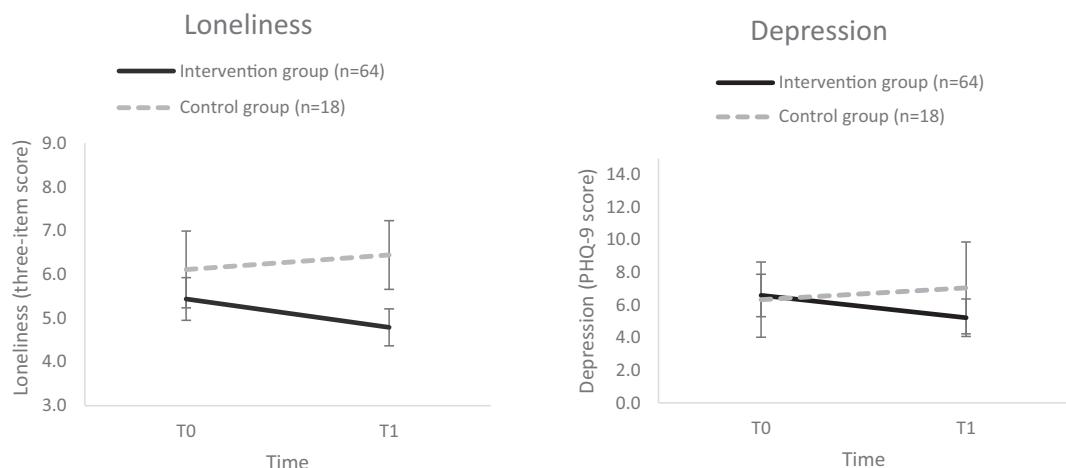


Fig. 2. Analysis of the three-item loneliness score and depression symptoms severity score (PHQ) from baseline measurement (T0) to end of program (T1) in intervention group and wait-list control group. The graphic presents mean values and 95% confidence interval.

aspect and group discussions, which were designed to provide a safe space for sharing hardships, may have helped the participants to feel that they were not alone; and thus, may have contributed to the decrease in loneliness and depressive symptoms. However, this could not be firmly determined in the current study and remains the goal for future research.

Our intervention presents a relatively simple measure that can be implemented for older community dwelling adults who feel isolated and distressed, while at the same time maintaining relevant social distance guidelines. The structured format of the intervention makes it simple for practitioners to implement, as indicated by the fact that in this study it was guided by social workers who underwent brief training. The availability of various components allows group instructors to emphasize different aspects based on the group's needs. Thus, community organizations working with older people can adopt similar interventions to help them in the times of a pandemic. This intervention will be especially relevant to those older adults who live alone, live in remote areas or are homebound (Chen and Schulz, 2016) and not just during a pandemic – as loneliness and social isolation have constituted public health concerns for older adults also during routine daily life (Cudjoe and Kotwal, 2020).

In this regard, there are several challenges for future implementation of such interventions. First, the time, logistic and financial resources required to provide this guided group intervention were substantial and exceed those of common self-help unguided interventions: these necessary resources included recruiting qualified moderators, providing protocol-specific training, and of course paying for their time. Although we believe that the benefits of the program detailed above outweigh the costs of the intervention, we see much importance in investing more research to reduce costs and make the program more sustainable when implemented on a large-scale (Lin et al., 2015). A potential path to reduce costs can be related to guidance intensity, which is considered a prominent cost factor of internet-based interventions (Weisel et al., 2019); recent evidence suggests that high level of therapist-support is not essential when treating loneliness (Käll et al., 2020b). Thus, taking an integrated approach that includes partial guidance or guidance upon request can be helpful in cases of scarce resources. This can be performed through, for example, using a combination of guided synchronous sessions and online self-help treatment modules (Etzelmueller et al., 2018). Another challenge relates to the recruitment procedure. Using online platforms as a primary source for recruitment may lead to the exclusion of ICT non-users, people of low socioeconomic status, and other marginalized groups who may well be those most in need of such interventions. It is thus necessary to establish a more generalizable approach to participant enrollment through national or local health and

social care institutions to allow for a comprehensive mapping of older individuals in order to locate people who live alone, and/or have background illnesses (i.e., those who constitute the most at-risk subgroup in the current pandemic context). In the event of future outbreaks, this kind of mapping will enable a rapid implementation of the protocol.

Study limitations include the small sample and the use of an unequal allocation (4,1) to the study's arms. While our findings are encouraging, efficacy should be further validated in a larger RCT (Chen and Schulz, 2016), a more socially and linguistically heterogeneous study sample and by using a 1:1 randomization ratio to avoid the possible loss of statistical power (Dumville et al., 2006). Moreover, although randomized within, we utilized a convenience sample with participants who were more likely to have already enjoyed relatively high digital literacy (Fang et al., 2019). Future studies should examine the intervention with adults that have different levels of digital capabilities. The dropout rate, which in the current study reached 17%, should also be considered as a potential source of bias. However, since no significant differences were observed between these participants and those who completed the full program, we believe this did not adversely affect the outcomes in a significant manner.

To conclude, this pilot RCT demonstrated the potential utility of a short-term intervention to improve the mental health of older adults during the COVID-19 pandemic. The intervention met the relevant social distance guidelines and promoted individual coping and social connections online. We utilized a short, simple tool that can be widely implemented in various communities; its relevance extends beyond the current pandemic - as the techniques and skills acquired can be applied in other forms of social crisis as well as during routine life after this epidemic dies down in order to promote the mental health of older adults who live alone and/or reside in remote areas.

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.invent.2021.100368>.

Declaration of competing interest

The authors have no conflict of interest to declare.

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dedicated moderators. We would also like to thank Ganit Goren, Adi Vilenski, Shachar Michael and Milca Hanukoglo - our dedicated moderators, and to Ayelet Yogeve, our research coordinator, for her valuable work and devotion to this project.

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Harnessing Peer Support in an Online Intervention for Older Adults with Depression

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Objective: This pilot study evaluated the feasibility and efficacy of two methods of delivering a cognitive behaviorally informed Internet intervention for depression for adults 65 years and older. **Methods:** Forty-seven participants were enrolled and assigned to receive one of two versions of the Internet intervention, either delivered individually (III) or with peer support (II+PS), or to a wait list control group (WLC). Primary outcomes included change in depressive symptoms from baseline to post-intervention (week 8), site use, self-reported usability, and coach time. Secondary outcomes included measures of social support and isolation and anxiety. **Results:** Follow-up data were provided by 85.1% (40 of 47) of enrolled participants. There were significant differences in depression change across groups ($F_{(2,37)} = 3.81, p = 0.03$). Greater reductions in depressive symptoms were found for the III ($p = 0.02$) and II+PS ($p = 0.03$) compared with WLC, and significantly less coach time was required in the II+PS ($p = 0.003$). **Conclusions:** These results highlight the potential of cognitive-behaviorally informed Internet interventions for older adults with depression, and indicate that peer-supported programs are both acceptable and equivalent to individually delivered Internet interventions. Including peer support may be a viable and potentially more cost-effective option for disseminating online treatments for depression for older adults. (Am J Geriatr Psychiatry 2017; 25:1109–1119)

Key Words: Depression, internet interventions, peer support, online, technology

Depression in later life is common and undertreated,¹ and is associated with decreased quality of life and increased rates of disability,² morbidity, and mortality.³ Untreated depression is burdensome for society, substantially increasing healthcare utilization and costs.^{4,5} Despite numerous evidence-based interventions shown to effectively

reduce late-life depression,⁶ many older adults experience barriers that limit access to care.^{7,8}

The Internet offers opportunities for depression treatment that could dramatically impact older adults' access to care.⁹ Programs delivered online have several advantages, as they remove restrictions imposed by clinics, such as hours, clinician availability, and geographical

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restrictions, thus resolving transportation and mobility related barriers. Internet interventions also offer access to care from anywhere with a working Internet connection, at any time, and as often as needed. This enhanced accessibility offers a more private, and potentially more comfortable, treatment option.

Many Internet interventions that target behavior change and symptom reduction are based on cognitive behavioral therapy (CBT), and such interventions have been developed for a wide range of mental health problems. The efficacy of CBT-based Internet interventions for treating depression in younger and middle-aged adults is well established.^{10,11} Although older adults have historically been underrepresented in this research,¹² emerging evidence supports the efficacy and acceptability of CBT-based Internet interventions for reducing symptoms of depression and anxiety in adults aged over 60 years.¹³⁻¹⁷

Despite these positive results, self-guided Internet interventions tend to see high rates of dropout and poor adherence.¹⁸ Human support can reduce problems with attrition and engagement, and most studies demonstrate that Internet interventions provided with support produce better outcomes.¹⁹ The inclusion of human supporters, however, reduces intervention scalability because of the cost of providing care and the limited availability of supporters.²⁰ Thus, the need for innovative solutions to improve engagement and manage attrition has been voiced.²¹

Peer support could potentially promote engagement while decreasing costs and increasing reach by reducing the need for professional support. To date, few researchers have attempted to harness peer support in online interventions for depression. There has been some evidence that peer support can improve adherence to Internet interventions and reduce depression,²² although a large trial found that peer support reduced adherence to Internet training relative to Internet training alone.²³

The aim of this study was to explore the feasibility of using peer support to reduce the coach time required for an Internet intervention for depressed older adults. The intervention was delivered either individually (individual Internet intervention; III) or with peer support (Internet intervention with peer support; II+PS), relative to a waitlist control (WLC). Primary outcomes included change in depression, use, self-reported usability, and coach time; secondary outcomes included self-reported social support and isolation, and

anxiety. We hypothesized that greater symptom reduction would be observed for III and II+PS relative to WLC, that II+PS would require less coach time, and that both III and II+PS would demonstrate feasibility and acceptability as evaluated by site use and usability ratings.

METHODS

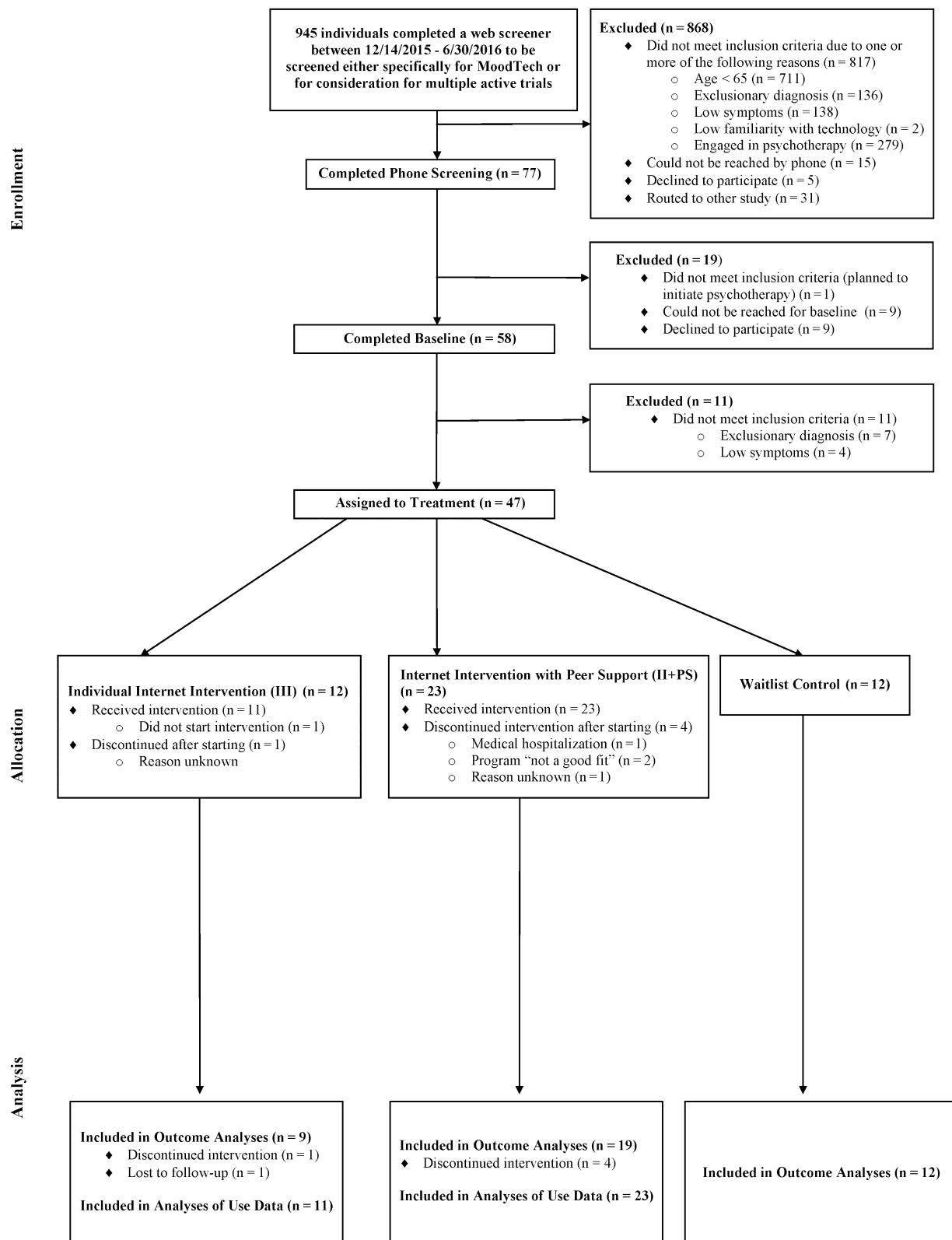
Participants

Participants were recruited from clinical research registries, online and community advertisements, and clinic referral. Participants needed to read and speak English, be at least 65 years old, have elevated depressive symptoms at screening (score of ≥ 8 on the Patient Health Questionnaire-8 or score of >7 on the Geriatric Depression Scale-15), have a telephone, e-mail address, basic Internet skills, and Internet access. Participants were excluded if they were receiving or planning to receive psychotherapy during the trial or if they met criteria for a diagnosis for which participation could be inappropriate (e.g., psychotic disorder, cognitive impairment).

Procedures

This study was approved by the Northwestern University institutional review board, registered on the Clinical Trials Registry as NCT02841787. Figure 1 shows participant flow and allocation. Potential participants were directed to a Web site to complete a general screener used for multiple trials. Individuals who indicated interest in this study specifically or agreed to be screened for all studies and who met preliminary screening criteria were contacted to complete phone screening. Participants meeting eligibility after screening were invited to complete informed consent and a baseline eligibility assessment including online questionnaires and telephone administration of the Mini International Neuropsychiatric Interview²⁴ and the Telephone Interview of Cognitive Symptoms.²⁵ Participants who remained eligible were invited to participate.

Because participants assigned to the II+PS progressed through the program as a group, proper randomization would require recruiting a participant pool large enough to be randomized to all three

FIGURE 1. Participant flow through the study.

arms, all eligible on the same day. As this was a small pilot, this was not feasible. Therefore, group assignment was performed in blocks of 10 to 12, and assignment order was pre-specified as follows: II+PS, WLC, II+PS, III. Two groups were allocated to II+PS to provide additional experience with this novel intervention component. WLC participants received access to III following the 8-week waiting period. Assessments were administered online at baseline (\leq 2 weeks prior to intervention start) and week 8 via REDCap.²⁶ Participants could earn up to \$155 for completing research assessments. Compensation was not dependent on participation in the intervention or coaching.

Intervention

MoodTech is an 8-week online intervention for depression based on CBT principles developed for adults aged 65 years and older. It was built on the ThinkFeelDo platform²⁷ and was accessible via computers, tablets, and mobile phones. There were 16 lessons (two per week) that included didactic content and followed two character storylines (see Table, Supplemental Digital Content 1). Each lesson ended with directions to practice skills using program tools. Tools focused on core skills: 1) cognitive restructuring (Think); 2) mood and emotion monitoring (Feel); 3) behavioral activation (Do); 4) relaxation/mindfulness (Relax); and 5) goal setting (Achieve).

Peer support features were designed to promote social engagement and adherence via accountability.²⁸ Features included profiles and an “activity feed” that displayed lesson completion, “status” posts, and participant-selected tool content. Participants interacted by “liking” or “commenting” on the activity feed, and through a “nudge” feature that sent an automated e-mail to another participant. These features aimed to support the development of bond (e.g., profiles, “status”, “likes”) and accountability (e.g., “likes”, “comments,” and “nudges”).

Coaching and Group Moderation

Individual coaching and group moderation were provided by two clinical psychologists (KNT, JH) and were based on the Efficiency Model of Support.²⁹ Individual coaching was provided via phone calls and

messages. Coaches used a dashboard to view participant activity and responses to a weekly symptom questionnaire, and to send and receive messages.

For both III and II+PS, participants had an orientation call with their coach on the first day of the program to establish goals and set expectations for contact. Coaches were instructed to keep this call to 45 minutes or less. For III, coaches provided weekly coaching to all participants via brief (10–15 minute) calls and messages, depending on participant’s preference. In these interactions, coaches were instructed to reinforce progress and address problems that could interfere with benefit (i.e., failure points) by helping participants overcome technical problems (usability), encouraging use (engagement), answering conceptual questions (knowledge) and supporting skill application to specific problems (fit, implementation).²⁹ Coaches also responded to all participant messages, and outreached when participants were unresponsive for more than 1 week. Coaches tracked all time spent on phone and message communications.

For II+PS, coaches primarily interacted with participants through group moderation. Moderation involved daily (weekday) review of the feed to monitor safety, identify unanswered questions, and reinforce use. Templatized discussion questions and group use statistics (e.g., percent lessons completed) were posted weekly. Individual coaching was provided in two cases: upon request, or when the moderator determined that outreach was indicated (e.g., if a participant failed to login for more than 1 week; a question to the group went unanswered for more than 48 hours; use of site features in a manner that could negatively impact others). Moderators tracked all time spent on individual coaching. Group moderation time was not formally tracked as it was a high frequency/low time activity, and was estimated at 2 minutes per weekday.

Measures

Clinical and social outcomes were assessed using self-report questionnaires. The Patient Health Questionnaire 9-item (PHQ-9)³⁰ and the Generalized Anxiety Disorder 7-item (GAD-7)³¹ measured depression and anxiety, respectively. The Patient Reported Outcome Measurement Information System (PROMIS) Social Isolation 6-items evaluated social isolation, including feelings of being avoided, excluded, detached, or

disconnected from others.³² The Social Provisions Scale (SPS)³³ measured social support, providing a total score and six subscales (attachment, social integration, reassurance of worth, reliable alliance, guidance, and opportunity for nurturance). MoodTech usability, acceptability, and satisfaction were assessed using the System Usability Scale (SUS),³⁴ which provides a measure of overall usability, and the USE questionnaire,³⁵ which measures usability dimensions (usefulness, satisfaction, ease of use, ease of learning).

Use was examined using sessions, lesson completion, and use of peer support features. A session was defined as a sequence of user-initiated actions separated by less than 10 minutes between events. Sessions were examined rather than logins to provide a more accurate understanding of use (e.g., connectivity problems can cause logins without user actions, artificially inflating use).

Statistical Analysis

Descriptive statistics were computed for demographic, clinical characteristics, and social outcome measures. Differences in baseline characteristics between groups were compared using a one-way analysis of variance (ANOVA) for age, the nonparametric Kruskal-Wallis tests for all other continuous characteristics, and χ^2 or Fisher's exact test for categorical variables. Associations between clinical characteristics and change in outcome measures were assessed using Spearman correlation coefficients for continuous variables and either two-sample t tests for two-group categorical variables or one-way ANOVAs for categorical variables with three groups. Differences in coaching time, program use (e.g., sessions), and usability ratings were calculated using two-sample t tests; differences in weekly lesson completion were compared using Fisher's exact tests. One-way ANOVAs evaluated group differences in change in clinical outcomes from baseline to week 8. Pairwise comparisons for significant omnibus tests were conducted using two-sample t tests. Within-group differences between baseline and week 8 outcomes were evaluated using paired t tests. Unless otherwise specified, $\alpha = 0.05$ for two-sided tests were used to determine statistical significance. All analyses were performed using SAS, version 9.4 (Cary, NC).

RESULTS

Participants

Forty-seven participants were enrolled and assigned to one of three groups: II +PS ($N = 23$), WLC ($N = 12$), or III ($N = 12$). Baseline characteristics are presented in Table 1. Tests of baseline characteristics between groups did not indicate any significant differences (all p values >0.10). Flow through the study is depicted in Figure 1. Participants were included in outcome analyses if they completed assessments at both baseline and week 8; 85.1% (40 of 47) met this criterion. Because this was a small pilot study with very low rates of missing data, intent-to-treat analyses were not conducted.

Primary Outcomes

Depression

Reductions in depression were significant for III and II+PS groups, but not for WLC (see Table 2). Significant differences were found in depression change between groups ($F_{(2,37)} = 3.81$, $p = 0.03$). Pairwise comparisons revealed differences in depression change between III and WLC ($t_{(19)} = 2.5$, $p = 0.02$) and between II+PS and WLC ($t_{(29)} = 2.22$, $p = 0.03$). No significant differences in depression change were found between III and II+PS ($t_{(28)} = 0.41$, $p = 0.68$).

Attrition and Site Use

Two of 11 participants who initiated III (18%) and 4 of 23 participants who initiated II+PS (17%) withdrew (see Figure 1). Mean number of sessions across the 8-week intervention was 45.6 (SD: 24.9) for III ($N = 11$) and 49.1 (SD: 35.8) for II+PS ($N = 23$); differences were not significant ($p > 0.50$). Average number of lessons completed (III, M: 11.7, SD: 3.8; II+PS, M: 11.3, SD: 4.5; $p > 0.50$) was not significantly different between groups ($p > 0.50$). Table 3 displays weekly sessions and lesson completion; no significant differences were found between groups for any week (all p values >0.10). Use of peer support features was generally high, though variability was observed across participants (M: 48.8, SD: 85.8, range: 0–392). Nearly all II+PS participants (22 of 23) used at least one peer support feature (see Table 4). "Comment" and "like" features were used

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TABLE 1. Sample Demographic Characteristics

Variable	N (%) or Median (IQR)			
	Total N = 47	III N = 12	II + PS N = 23	WLC N = 12
Age (years), mean ± SD	69.6 ± 4.1	69.2 ± 3.4	69.5 ± 4.3	70 ± 4.7
Sex				
Female	32 (68.1)	8 (66.7)	16 (69.6)	8 (66.7)
Male	15 (31.9)	4 (33.3)	7 (30.4)	4 (33.3)
Ethnicity				
Not Hispanic or Latino	46 (97.9)	12 (100)	22 (95.7)	12 (100)
Hispanic or Latino	1 (2.1)	0 (0)	1 (4.4)	0 (0)
Race				
Black/African American	2 (4.3)	0 (0)	1 (4.4)	1 (8.3)
White	41 (87.2)	11 (91.7)	19 (82.6)	11 (91.7)
More than one race	3 (6.4)	1 (8.3)	2 (8.7)	0 (0)
Declined to report	1 (2.1)	0 (0)	1 (4.4)	0 (0)
Annual gross household income (x1000)	41 (29–50)	37.5 (33–45)	37 (22.2–50)	50 (34–115)
Marital status				
No partner	29 (61.7)	8 (66.7)	16 (69.6)	5 (41.7)
Partner	18 (38.3)	4 (33.3)	7 (30.4)	7 (58.3)
Education				
Some high school	1 (2.1)	0 (0)	0 (0)	1 (8.3)
Some college	7 (14.9)	1 (8.3)	5 (21.7)	1 (8.3)
2-yr college (Associate's)	7 (14.9)	0 (0)	5 (21.7)	2 (16.7)
4-yr college (Bachelor's)	13 (27.7)	3 (25)	6 (26.1)	4 (33.3)
Master's degree	12 (25.5)	5 (41.7)	5 (21.7)	2 (16.7)
Doctoral degree (PhD, MD, JD)	7 (14.9)	3 (25)	2 (8.7)	2 (16.7)
Employment status				
Employed	10 (21.3)	3 (25)	4 (17.4)	3 (25)
Retired	34 (72.3)	9 (75)	18 (78.3)	7 (58.3)
Unemployed/disability	3 (6.4)	0 (0)	1 (4.4)	2 (16.7)
Insured				
Medicare	40 (87)	10 (83.3)	19 (86.4)	11 (91.7)
Medicaid	4 (8.7)	1 (8.3)	3 (13.6)	0 (0)
Taking antidepressant medication				
No	31 (67.4)	7 (58.3)	17 (77.3)	7 (58.3)
Yes	15 (32.6)	5 (41.7)	5 (22.7)	5 (41.7)

Notes: Tests of baseline characteristics between groups were conducted using a one-way ANOVA for age, the nonparametric Kruskal-Wallis tests for all other continuous characteristics, and χ^2 or Fisher's exact test for categorical variables. No significant differences were found between groups for any baseline characteristic (all p values >0.10).

III: individual Internet intervention; II+PS: Internet intervention with peer support; WLC: wait list control.

TABLE 2. Within-group Differences for PHQ-9 and GAD-7

Group	Measure	Baseline	Week 8	Difference	t	df	Cohen's d	p
III (N = 9)	PHQ-9	10.6 ± 3.2	5.1 ± 2.8	-5.4 ± 2.4	6.8	8	2.27	<.0001
	GAD-7	6.1 ± 2.1	2.3 ± 1.9	-3.8 ± 2.8	4.09	8	1.36	<.01
II+PS (N = 19)	PHQ-9	11.2 ± 5.4	6.4 ± 4.2	-4.8 ± 4.4	4.77	18	1.09	<.0001
	GAD-7	6.7 ± 4.8	4.7 ± 3.5	-2 ± 4.4	1.95	17	0.46	0.07
WLC (N = 12)	PHQ-9	9.3 ± 3.7	8.2 ± 5.7	-1.1 ± 4.7	.79	11	0.23	0.44
	GAD-7	5.8 ± 4	7.2 ± 4.7	1.3 ± 2.3	-1.97	11	-0.57	0.08

Notes: Possible range of scores for the PHQ-9 was 0–27 and for the GAD-7 was 0–21. Scores are reported as means and standard deviations. Mean differences were evaluated using paired t tests for each group separately. **Bold** values indicate within-group change. PHQ-9: Patient Health Questionnaire, 9-items; GAD-7: Generalized Anxiety Disorder Scale, 7 items; III: individual Internet intervention; II+PS: Internet intervention with peer support; WLC: wait list control; df: degrees of freedom.

TABLE 3. Use of the MoodTech intervention: Weekly Site Sessions and Lesson Completion

Week	Site Sessions		Lesson Completion		
			Lesson	N, %	N, %
	M ± SD			III N = 11	II+PS N = 23
1	9.2 ± 4.4	11 ± 6.8	1	10, 91	22, 96
			2	11, 100	20, 87
2	7 ± 4.1	7.5 ± 6.2	3	11, 100	21, 91
			4	9, 82	17, 74
3	6.2 ± 4.5	7.2 ± 6.1	5	10, 91	19, 83
			6	9, 82	13, 56
4	5.8 ± 4.8	5.7 ± 6.5	7	9, 83	17, 74
			8	8, 73	16, 70
5	5.1 ± 4.6	5.4 ± 5.1	9	9, 82	16, 70
			10	7, 63	18, 78
6	4.4 ± 3.4	4.6 ± 5.1	11	8, 73	17, 74
			12	4, 36	11, 48
7	4.2 ± 2.9	3.4 ± 3.2	13	5, 45	14, 61
			14	5, 45	11, 48
8	4.4 ± 3.6	4.2 ± 3.6	15	8, 73	14, 61
			16	6, 55	14, 61

Notes: Two-sample t tests comparing site sessions were not significant for any week (all p values <0.10). Fisher's exact tests comparing groups on lesson completion were not significant for any week (all p values >0.20).

M: Mean; SD: standard deviation; III: individual Internet intervention; II+PS: Internet intervention with peer support.

TABLE 4. Use of Peer Support Features

Feature	Participants	Min	Max	M	SD
	N, %	# of times used			
Like	19, 82.6%	1	227	25.7	52
Comment	19, 82.6%	1	96	20.3	23.6
Nudge	9, 39.1%	1	24	5.7	8.2
Status	10, 43.5%	2	48	19.7	16.6

Notes: N represents the participants who use the specified tool once or more. Descriptives include only participants who used the specified tool at least once. Min: minimum; Max: maximum; M: mean; SD: standard deviation. Number of times used represents total 8-week trial.

by most participants (83%) at least once; less than half used "status" or "nudge" features (44% and 39%, respectively).

Usability and Acceptability

Per industry standards, a SUS score of 68 is average and scores greater than 70 are considered "acceptable," with higher scores indicating more positive attitudes.³⁶ At week 8, III participants' (N = 9) overall

usability ratings were average (M: 68.75, SD: 16.09), whereas II+PS ratings (N = 21) were below average (M: 60.5, SD: 16.69), but not significantly different from III. Scores on USE subscales ranged from 0 (strongly disagree) to 7 (strongly agree), and fell in the average to below average range for both groups. III participants' (N = 9) mean scores were 4.39 (SD: 1.45) for usefulness, 3.82 (SD: 1.34) for ease of use, 4.48 (SD: 1.8) for ease of learning, and 4.48 (SD: 1.8) for satisfaction. II+PS participants' (N = 21) mean scores were 4.05 (SD: 1.3) for usefulness, 3.55 (SD: 1.28) for ease of use, 3.46 (SD: 1.53) for ease of learning, and 3.52 (SD: 1.31) for satisfaction. No significant differences were found between groups on any subscale (all p values >0.10).

Coaching

Average number of and time spent on messages and calls and group moderation were examined. Significant differences were found between III and II+PS (see Table 5). Total coaching minutes was significantly greater for III compared with II+PS ($t_{(26)} = 3.32$, $p = 0.003$). Compared with II+PS participants, III participants received nearly twice the messages ($t_{(26)} = 4.70$, $p < 0.001$) and coaches spent more than twice the time on average messaging III participants ($t_{(26)} = 3.56$, $p = 0.001$). Differences in number of calls and call time were not significant (all p values >0.05).

Secondary Outcomes

Anxiety

Change in anxiety was significantly different between groups ($F_{(2,36)} = 5.96$, $p = 0.006$; see Table 2). Pairwise comparisons indicated significant differences comparing III and WLC ($t_{(19)} = 4.58$, $p < 0.001$) and II+PS and WLC ($t_{(29)} = 2.39$, $p = 0.03$), but differences between III and II+PS were not significant ($t_{(26)} = 1.12$, $p = 0.28$). Table 2 presents means and SDs and t tests of within-group differences for each group.

Social Support and Isolation

Social isolation scores were converted to T-scores. Baseline scores fell in the average range (33) for all groups (III, M: 55.9, SD: 4.8; II+PS, M: 57.4, SD: 6.3; WLC, M: 54, SD: 6.7). Change in social isolation was not significantly different between groups ($p > 0.10$),

TABLE 5. Average Coaching Time per Participant by Group

	N	Messages		Calls		Moderation	Total Time
		M ± SD	M ± SD	M ± SD	M ± SD	M	M ± SD
		Minutes	Number	Minutes	Number	Minutes	Minutes
III	9	65.22 ± 29.92	14.78 ± 2.11	69.11 ± 22.35	2.33 ± 1.00	na	134.33 ± 28.43
II + PS	19	31.74 ± 19.60	7.58 ± 4.32	53.74 ± 18.44	1.84 ± .83	6.96	92.43 ± 32.36

Notes: Two-sample t tests were used to compare group differences. df = 26. **Bold** values indicate significant differences. Minutes on group moderation are estimated; see Methods section for more information.

M: mean; SD: standard deviation; III: individual Internet intervention; II+PS: Internet intervention with peer support.

and change was not significant within each group (all p values >0.10).

No significant differences were found between groups on change in total SPS ($p > 0.10$), or any subscale (all p values >0.10). Significant change was observed within the II+PS group on SPS total score ($t_{(18)} = -2.26$, $p = 0.04$), and guidance ($t_{(18)} = -2.36$, $p = 0.04$) and reliable alliance ($t_{(18)} = -2.15$, $p = 0.03$) subscales. Examination of within-group change was not significant for III and WLC for SPS total score or subscales (all p values >0.05).

DISCUSSION

This pilot study demonstrates the feasibility and preliminary efficacy of MoodTech, and indicates that adults aged 65 years and older will use and can benefit from coached Internet interventions for depression delivered individually and with peer support. Compared with a WLC, reductions in depression were observed for all participants who received MoodTech, with an average drop of 5 points on the PHQ-9. The present findings are consistent with reductions in depression observed in the only prior randomized controlled trial (RCT)¹⁷ to evaluate the efficacy of a guided Internet intervention for depressed adults aged 60 years and older, and extends these findings to a slightly older sample (M: 69.6 years, SD: 4.1, range: 65–83). Program usage was high, with an average of 45 sessions for III and 49 for II+PS, and retention was good for both groups (approximately 80%). Retention and usage are similar to other trials of Internet interventions with older adults^{15–17} and higher relative to trials with younger adults (<65 years).³⁷

Significantly less time was spent coaching participants when peer support was included, suggesting that

embedding peer support in Internet interventions could reduce coach time, thus increasing cost-effectiveness. Notably, compared with coach time reported in the previously mentioned RCT (M: 45.07 minutes, SD: 32.51 minutes),¹⁷ coach time in the present study was about 89 minutes more for III and 47 minutes more for II+PS. Our procedures included an initial 45-minute orientation call, which significantly increased coach time per person for both methods of delivery. Reducing or eliminating this call, or conducting this call with groups of participants, could result in coach times comparable to the RCT for II+PS. Coach time in III could be further reduced by altering coach guidelines regarding the maximum coach minutes per week to align with guidelines from the prior RCT (≤ 10 minutes/week).

Usability scores indicate that MoodTech is acceptable and generally satisfactory in its current form, without significant usability issues. Nevertheless, overall average and neutral ratings suggest that there is room for improvement. Uptake of peer support features was high, suggesting that participants were motivated to interact with and support each other, yet usability ratings were lower for II+PS, possibly due to frustration with the design of peer support features. Although all but one participant used either the “like” or “comment” features at least once, several participants expressed confusion about how and where to view “likes” and “comments” and less than half used the “status” or “nudge” features. Further, although instructions regarding use of peer support features were provided during the orientation call and within the program, coach feedback indicated that there was confusion regarding the location and function of the “status” feature, as well as the function of the “nudge” feature, which participants ultimately used to deepen established connections with other group members (i.e., reinforce bond) rather than to engage disengaged

participants (i.e., accountability). Coaches also received negative feedback about the location and functionality of the activity feed, with some participants expressing disappointment regarding the feed functionality and how this limited their ability to connect with others.

Low-average usability ratings, combined with feedback from coaches, point to various design improvements that should be considered for future iterations. First, while font size could be manually increased for lessons, this was not possible for other aspects of the program (e.g., tools), which was problematic. To increase accessibility and satisfaction, the size of all aspects of the program should be adjustable. Second, coaches noted that some participants struggled to complete the practice assignments because the instructions were embedded in lessons. Incorporating interactive tools into the lessons, or featuring practice assignments on the homepage, could resolve this issue. Third, for II+PS, the activity feed should be displayed somewhere prominent. Last, because certain activities were automatically posted to the feed, participant posts were quickly buried, and interacting with peers required motivation, patience, and solid understanding of feed functionality. Thus, the design of the activity feed should be altered to support (versus thwart) peer interactions (e.g., specific types of posts “pop to the top”).

Finally, although no significant differences were seen between groups on change in social support, significant increases on overall support and subscales of guidance and reliable alliance were observed for II+PS, suggesting that peer support adds unique benefits that could confer larger protective benefits.^{38,39} Because of limited follow-up, we cannot know the nature of these increases in social support. They may be temporary, reflecting the tangible increase in peer support from the intervention. Alternatively, perhaps they reflect a perspective shift—for example, due to social learning/comparison that changed participants’ willingness to utilize existing support.⁴⁰

This study had several strengths, including the fact that participants were older (M: 69 years) than prior trials of Internet interventions. Additionally, to our knowledge, this was the first Internet intervention for depressed older adults to embed peer support. Peer support has previously been provided separately from online interventions,²³ requiring extra effort from participants to complete both. This study demonstrates the

potential benefits of embedding peer support, including improved adherence compared with a prior trial²³ and reduced burden on participants.

Several limitations should be considered. First, this field trial used blocked, non-random enrollment. It is possible that unmeasured differences across the treatment arms (e.g., participants who enrolled early in the recruitment period may have been more motivated than those who enrolled later) account for these findings. Findings should therefore be interpreted as supporting further investigation rather than encouraging implementation. The sample size was relatively small, and was primarily non-Hispanic white and highly educated. Although this sample was somewhat representative of individuals who historically participate in online interventions, the feasibility and acceptability of this program remains unknown for more diverse samples, and for those who do not have pre-existing familiarity with the Internet and would not volunteer to participate. Finally, it was not possible to blind coaches to intervention condition, which could have biased time spent coaching.

Conclusions

This study demonstrated feasibility, acceptability, and preliminary efficacy of MoodTech and highlights the potential benefits of including peer support in online interventions for older adults with depression. User feedback and usability data suggest that further design work is required to develop a technology platform that more fully meets the needs of older adults. Further examination of the role of individual coaching and group moderation is also warranted, such as testing differences in outcome in response to systematic variation in the amount and type of human support. These basic design questions notwithstanding, this study supports the conduct of larger-scale RCTs to validate the use of peer support in Internet interventions for older adults, and extending this work to evaluate long-term effects.

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older people in the Chicagoland area who have expressed a willingness to participate in research studies on the provision of care to aging patients and that was created and is supported by Northwestern University's Buehler Center on Aging, Health, and Society. REDCap electronic data tools hosted at Northwestern University were used in this trial. REDCap is supported at the Feinberg School of Medicine by the Northwestern University Clinical and Translational Science (NUCATS) Institute. Research reported in this publication was supported, in part, by the National Institutes of Health National Center for Advancing

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APPENDIX: SUPPLEMENTARY MATERIAL

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Layperson-Supported Internet-Delivered Cognitive Behavioral Therapy for Depression Among Older Adults

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Abstract

Purpose: This study explores the feasibility, acceptability, and treatment outcomes of Empower@Home, a digital cognitive behavioral therapy intervention for geriatric depression.

Method: Participants with depressive symptoms ($\text{PHQ-9} \geq 5$) underwent a nine-session remote intervention supported by a lay coach ($N = 103$).

Results: Most participants (91%) completed all nine sessions (mean = 8.5). According to the Treatment Evaluation Inventory, participant attitudes toward the program were largely positive. A medium effect in depression reduction was observed following the intervention (Cohen's $d = 0.75$) and at a 10-week follow-up (Cohen's $d = 0.60$). This reduction was large (Cohen's $d = 1.31$ at posttest and Cohen's $d = 1.18$ at 10-week follow-up) among those who presented with moderate depression at baseline ($\text{PHQ-9} \geq 10$). Significant improvements were also reported in anxiety, social isolation, loneliness, and behavioral activation.

Discussion: Empower@Home is a promising, acceptable digital mental health intervention for treating depression in older adults.

Keywords

iCBT, digital mental health intervention, human support, geriatric depression

Depression, a leading cause of disability globally, negatively affects older adults' health and quality of life. The global burden of depression has been exacerbated by the COVID-19 pandemic, which has exposed the gaps in mental health systems in most countries (Santomauro et al., 2021). Digital mental health interventions (DMHIs), behavioral and psychological intervention strategies using technology such as websites and mobile apps, are a potentially cost-effective and scalable option for addressing the growing unmet mental health needs among older adults. Many DMHIs can be used repeatedly with different patients without losing their therapeutic power at reduced marginal cost, making them especially helpful in under-resourced settings (Muñoz, 2010). One of the most studied DMHIs is internet-based cognitive-behavioral therapy (iCBT), which imparts core CBT techniques through automated lessons delivered via dedicated websites or apps. A meta-analysis showed that iCBT has benefits comparable to face-to-face CBT in mixed-age samples (Andrews et al., 2018). Emerging evidence supports its acceptability and benefits among older adults, including high-risk subgroups (Cremers et al., 2022; Read et al., 2020; Tomasino et al., 2017).

Despite the increasing popularity of iCBT, very few programs have been intentionally designed for older adults

(Dear et al., 2013; Tomasino et al., 2017). Systematic reviews showed that older adults were underrepresented in iCBT trials, many of which excluded participants of advanced age (Crabb et al., 2012; Xiang et al., 2020). Tailoring treatment to specific populations, contexts, and settings increases uptake, acceptability, and sustainability (Barrera et al., 2013; Krebs et al., 2010). The lack of tailored solutions may explain why some studies testing generic iCBT programs reported limited effects, unsatisfied participants, and usability problems (Xiang et al., 2020). These challenges are more likely to affect older adult subgroups who experience mental health disparities—individuals who tend to be older, less technologically adept, and have more functional impairments (Cremers et al., 2022).

Our team developed Empower@Home to address the shortage of DMHIs tailored for older adults. Like many

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iCBT programs, Empower@Home can be entirely self-guided and completed without external human support, defined as contact with a human to increase users' ability to use the DMHI to obtain the intended treatment outcome (Schueller et al., 2017). However, supported-iCBT is generally more efficacious and associated with better adherence than un-supported interventions (Andersson et al., 2009; Baumeister et al., 2014). External support may be particularly beneficial for populations with lower educational attainment and technology literacy. In this pilot study, we tested the intervention supported by laypersons without specialized mental health training or licensure. We focused on using laypersons as supporters to address the shortage of mental health professionals and to improve the prospects that the intervention will be implemented and sustained in real-world settings. The findings from this innovative intervention are presented for the first time in this manuscript.

This study aimed to examine the feasibility, acceptability, and preliminary effects of Empower@Home supported by lay persons. The following hypotheses were tested:

Hypothesis 1: The layperson-supported Empower@Home is feasible among older adults with depressive symptoms, as indicated by its retention and completion rates comparable to or exceeding those reported in published studies of similar interventions.

Hypothesis 2: The layperson-supported Empower@Home is acceptable to older adults with depressive symptoms, as indicated by scores exceeding the benchmark on validated measures of treatment acceptability.

Hypothesis 3: Empower@Home participants have reduced depressive symptoms after the intervention and at the 10-week follow-up, compared to their baseline symptoms scores.

Hypothesis 4: Empower@Home participants have reduced anxiety symptoms, social isolation, and loneliness after the intervention, compared to their baseline symptoms scores.

In addition to these hypotheses, we also have exploratory aims to examine potential mechanisms and moderators.

Method

Participants

Participants were recruited into the study on a rolling basis from multiple community social service agencies in Michigan and research volunteer registries (UMHealthResearch and Participant Resource Pool at the Healthier Black Elders Center). All participants entered the study between May and September 2022. Participants needed to (a) read and speak English, (b) be at least 50 years old, (c) have at least mild depressive symptoms at screening (≥ 5 on the Patient Health Questionnaire-9 [PHQ-9]) (Santomauro et al., 2021), and (d) reside in the state of Michigan. Individuals were ineligible if they had (a) probable

dementia based on the Blessed Orientation, Memory, and Concentration test (score >9) (Katzman et al., 1983), (b) elevated suicide risk, defined as having a moderate or high risk based on the 6-item Columbia-Suicide Severity Rating Scale (C-SSRS) (Posner et al., 2011), (c) a terminal illness with less than 6 months to live or unstable physical health conditions based on self-report, (d) severe vision impairment based on self-report (i.e., legally blind), or (e) possible recent or current substance use disorders based on the CAGE screener (Brown et al., 1998). Device ownership, prior computer use, or internet access were not required.

Procedures

This study was approved by the University of Michigan institutional review board and registered prospectively on ClinicalTrials.gov as NCT05384704. A single-group uncontrolled open trial design was employed, comparing pre- and posttreatment outcomes. Figure 1 shows participant flow and allocation. Potential participants on research volunteer registries were directed to a website to complete a prescreening survey. Those meeting preliminary screening criteria were contacted for a phone screening. Referrals from community agencies received the phone screening without completing the online prescreening survey due to concerns about limited technology access. Participants meeting eligibility criteria after phone screening were invited to complete informed consent and a baseline assessment over the phone.

At the end of the baseline, each participant was assigned an "empower coach" and scheduled for their first telephone coaching meeting within 2 weeks. All participants received program access for up to 10 weeks. Participants who lacked device access or preferred a study device received a Samsung Galaxy Tab S4 10.5-inch tablet with 4G cellular data and a stylus pen. All study devices had restricted functionality (e.g., Users cannot view web content unrelated to the study). Each participant also received a printed workbook. Program materials were sent via UPS at no cost to the participants, including free return shipping of study devices. At the end of 10 weeks, participants were invited to complete a posttest and a final follow-up 10 weeks after the posttest, both conducted over the phone. All study data were entered and managed using REDCap electronic data capture tools hosted at the University of Michigan (Harris et al., 2009; Harris et al., 2019). Participants could earn up to \$100 USD for completing research assessments. Compensation was based on the completion of assessments and not dependent on participation in the intervention or coach meetings.

Intervention

Empower@Home is a web-based intervention for depression based on CBT principles developed for older adults. It was built on a custom learning management system and is accessible via computers, tablets, and mobile phones. It consists of

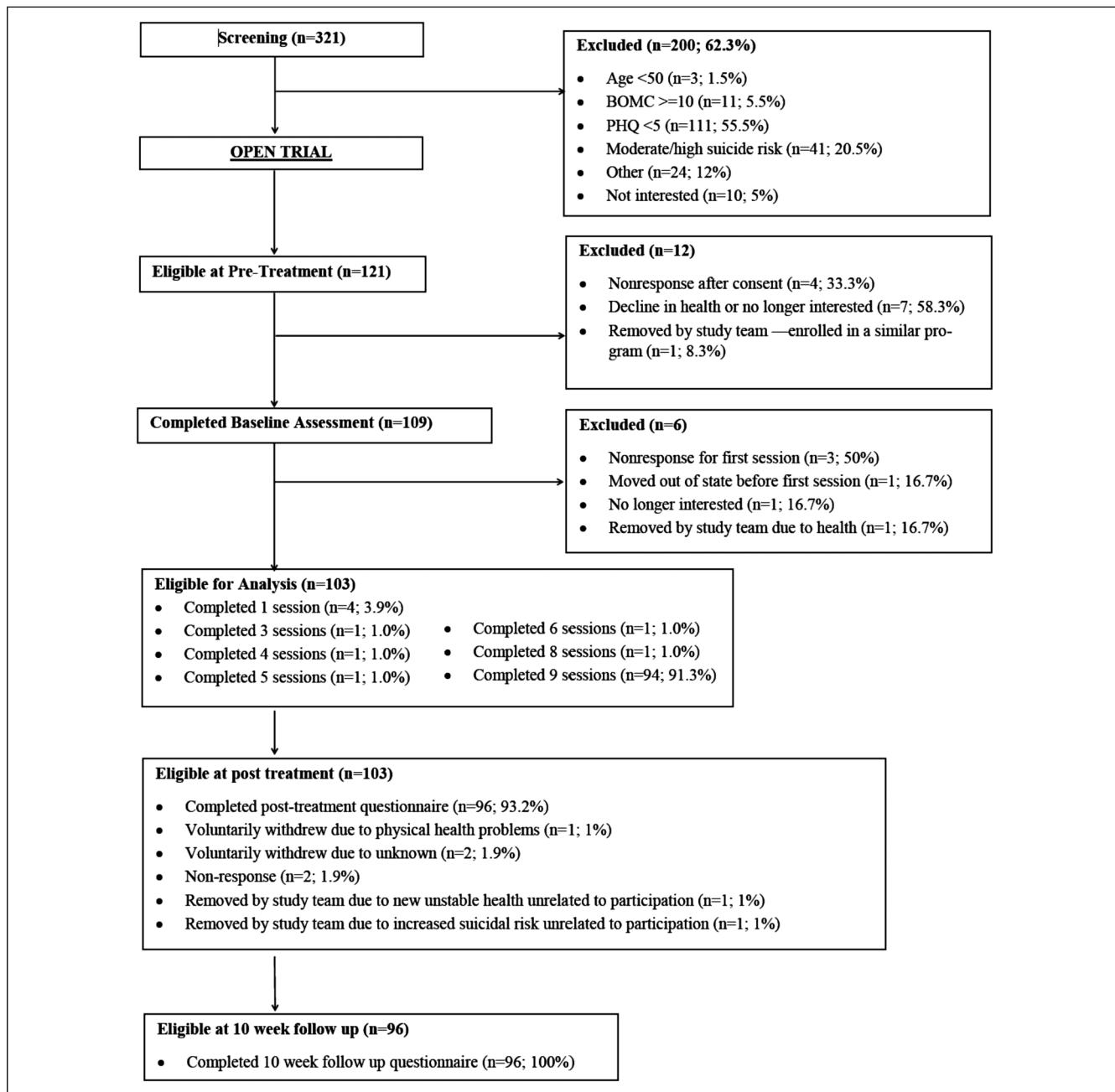


Figure 1. Participant flow chart. Note. BOMC = blessed orientation, memory, and concentration test; PHQ-9 = patient health questionnaire-9.

9 online lessons, including didactic content, interactive exercises, inspirational quotes, and an animated character-driven story to enhance engagement. The lessons are sequenced, and the completion of the first lesson unlocks the next, and so on. Each lesson ends with directions to do home practices, where users practice skills using program tools. Tools focus on core CBT skills, including behavioral activation and problem-solving (Doing Tools), cognitive restructuring (Thinking Tools), relaxation, mindfulness, mood monitoring (Feeling Tools), and effective

communication (Communication Tools). Participants received a large print workbook containing session summaries, interactive exercises, wellness resources, and materials related to home practice exercises.

Coaching. Each participant received support from a coach for up to 10 weeks. Coaches were instructed to call each participant weekly for up to 1 hour per call. Coaches' roles are based on the efficiency model of support, a model for understanding the provision of human support in DMHIs ([Schueller et al.,](#)

2017). It discusses how failure points under five categories, usability (ease of use), engagement (motivation), fit (meeting user's needs), knowledge (how to use a tool), and implementation (how to apply the tool to the user's life) can prevent users from benefiting from DMHIs. Human support can address these failure points, and the amount of support should be efficient to optimize the ratio of benefit to resources devoted to it. Applying these principles, Empower coaches are trained to tailor their approach to meet client needs. For example, coaches can offer to go through online sessions with the participant if they have low motivation or frequently experience technical challenges. For highly motivated clients who experience little technical issues, coaches will encourage them to complete online sessions on their own and invite them to discuss the session during the weekly coaching calls and provide guidance on homework assignments. This tailored approach is rooted in self-determination and optimizes staff time.

Coach Qualification and Training. In the pilot study, seven research assistants acted as coaches, including two undergraduate students majoring in Biopsychology, Cognition, and Neuroscience, three master's students in social work, one person with a Bachelor of Social Work degree, and one person with a Master of Social Work degree. The master-prepared coach had 1 year of case management experience; the rest had little training or experience in psychotherapy with actual patients. Hence, they were all considered lay coaches without specialized mental health training or independent clinical licensure. The PI (Xiang) and a licensed clinical social worker (Kayser) supervised the coaches and conducted weekly group supervision meetings.

Coach training involves a hybrid curriculum, including self-paced online learning (~5 h) and a live Zoom training session (90 min) with the PI (Xiang). A training handout accompanies the online training, which includes psychoeducation on geriatric depression, light CBT training, and an introduction to the program and the study. The live Zoom training covers technical support, frequently asked questions, study procedures, and logistics. The minimum training requirement for coaches was intended to mimic real-world implementation settings. Coaches tracked time spent meeting with clients and self-reported the type of assistance provided during each meeting from a pre-determined checklist (e.g., simple feedback, homework review, technical assistance). Coaches also documented whether participants completed the online lessons on their own.

A structured coaching guide is provided to each coach. This guide includes a program introduction, conceptualization of the coach roles, technical tutorial, and a session-by-session coaching guide. The technical tutorial covers the tablet (if applicable) and online program login (which was identified as a top challenge for technology novices with dexterity issues based on our prior work). The session-by-session guide is further broken down into web pages or program components, marked with the %

corresponding to the progress within a session displayed at the bottom of each web page. For example, at 33%, the participants watch a 2-min psychoeducational video on the symptoms of depression. The coaching guide includes a "coaching point" after this video, prompting the coach to invite the participant to share what they have learned from this video. Some coaching points are marked as "required"—coaches must cover the required discussion points—and some are optional and provided as suggestions. For example, a required coaching point occurs after the biweekly PHQ-9 "mood self-check" as this pertains to symptom self-monitoring, an important CBT technique. The coach is directed to help the participant understand the purpose of symptom self-monitoring and interpretation of their scores. In summary, the coaching guide is structured to make it easy for novice coaches, which is important given that they are laypersons without specialized mental health training. It also provides ample space to allow tailoring to clients' particular needs and preferences.

Measures

Empower@Home feasibility was measured via the number of online lessons completed over the 10 weeks. Acceptability was assessed posttest using the modified version of the Treatment Evaluation Inventory (TEI) developed explicitly for evaluating geriatric depression treatment (Schueller et al., 2017). The TEI has 11 items, including 8 positively worded items and 3 negatively worded items. The TEI score ranges from 11 to 77, and a score of ≥ 44 indicates favorable attitudes toward the treatment (Landreville & Guérette, 1998). We modified the TEI by rephrasing the original TEI items from questions to statements and reducing the responses from a 7-point Likert scale to a 5-point Likert scale to ease respondents' burden. As used in the present study, the modified TEI had a total score ranging from 11 to 55, and a score of ≥ 32 indicates favorable attitudes toward the treatment. The TEI had acceptable reliability among Empower@Home participants (Cronbach's alpha = .77).

The primary clinical outcome is depressive symptoms, measured using the PHQ-9. While the PHQ-9 was not specifically designed for older adults, it is one of the most commonly used screening tools in primary care. According to a systematic review, most iCBT studies with older adults use the PHQ-9 as their primary outcome measure (Xiang et al., 2020). We opted for PHQ-9 given its strong psychometric properties (Santomauro et al., 2021) and to allow for comparison with similar interventions. Scores 5, 10, 15, and 20 on the PHQ-9 represent thresholds of mild, moderate, moderately severe, and severe depressive symptoms, respectively. A 5-point change is clinically significant. A score of less than 10 suggests a partial response, and a score of less than 5 represents remission (Santomauro et al., 2021). PHQ-9 was administered over the phone by research staff at screening, posttreatment, and 10-week follow-up. In addition,

Table 1. Descriptive Statistics of the Study Sample ($n=103$).

Sociodemographic Variables	<i>n</i>	<i>M</i> (<i>SD</i>) or %
Age in years	103	63.73 (8.59)
Sex		
Female	81	78.6%
Male	22	21.4%
Race/ethnicity		
White or Caucasian, Non-Hispanic	81	78.6%
African American or Black	17	16.5%
Other racial/ethnic minorities	5	4.9%
Education		
High school or less	11	10.7%
Some college but no degree	12	11.7%
2-year college degree (Associate's)	22	21.4%
4-year college degree (Bachelor's)	32	31.0%
Graduate degree	26	25.2%
Household income		
\$0–19,999	21	23.6%
\$20,000–49,999	32	36.0%
≥\$50,000	36	40.5%
Marital status		
Married or partnered	46	44.7%
Divorced, separated, widowed	35	34.0%
Never married	22	21.4%
Living alone	45	43.7%
Chronic disease count ^a		
0	18	17.5%
1	30	29.1%
2	26	25.2%
≥3	29	28.2%
ADL/IADL limitations count ^b		
0	60	58.3%
1	19	18.5%
≥2	24	23.0%
Own a computer, laptop, or tablet	81	78.6%
Used study device for participation	38	36.9%
Self-rated confidence with technology		
Completely confident	42	40.8%
Fairly confident	43	41.8%
Somewhat confident	13	12.6%
Slightly confident or not confident	5	4.8%
Taking antidepressant medication	38	36.9%
Pretreatment PHQ-9 Score		
5–9	64	62.1%
10–14	31	30.1%
15–19	5	4.9%
20+	3	2.9%

Note. PHQ-9 = patient health questionnaire-9.

^aChronic disease count was the sum of self-reported conditions including hypertension, diabetes, chronic lung disease, chronic kidney disease, heart disease, stroke, arthritis, and cancer. ^bADL/IADL included self-reported difficulties with dressing, eating, toileting, bathing, getting in our out of bed, shopping for groceries, preparing hot meals, making phone calls, taking medications, and managing finances.

participants completed up to five self-administered PHQ-9 surveys built into the online program, occurring in sessions 1, 3, 5, 7, and 9.

Secondary outcomes include anxiety symptoms, social isolation, and loneliness, all measured at the baseline and the posttreatment. Generalized Anxiety Disorder 7-item (GAD-7) is a validated population-based survey instrument measuring anxiety symptoms (Spitzer et al., 2006). The Duke Social Support Index (DSSI) 10-item measures social support in older adults, including social interaction and satisfaction with social support (Koenig et al., 1993). The Patient Reported Outcome Measurement Information System-Social Isolation (PROMIS-Social Isolation) contains eight items and evaluates feelings of being avoided, excluded, detached, or disconnected (Carlozzi et al., 2019; Cella et al., 2010). In addition, behavioral activation was measured using the 9-item Behavioral Activation for Depression Scale-Short Form (BADS-SF), which includes subscales for activation and avoidance to explore treatment mechanisms (Manos et al., 2011).

Statistical Analysis

Descriptive statistics were computed for pretreatment socio-demographic and psychosocial outcomes. Within-group differences in psychosocial outcomes were evaluated using paired *t*-tests. Linear mixed modeling was used to test within-group changes in PHQ-9 scores over time, involving up to 5 in-session assessments occurring every other week. In addition, we examined clinical significance metrics, including (a) the proportion of participants who scored <5 at post-treatment, (b) the proportion of participants who scored ≥10 on the PHQ-9 at pretreatment and subsequently <10 at posttreatment, and (c) the proportion of participants with ≥5 points reduction on the PHQ-9 at posttreatment (Santomauro et al., 2021). Two-tailed tests at $\alpha=.05$ were used to determine statistical significance. Analyses of the primary clinical outcome were intention-to-treat using the last observation carried forward. Analyses of secondary clinical outcomes involved pairwise deletion. All analyses were conducted using Stata 15 SE (StataCorp, College Station, TX).

Results

Descriptive Statistics of the Study Participants

Figure 1 illustrates that our study sample consisted of 103 participants who commenced the intervention program. All of these individuals were incorporated into the intention-to-treat analysis. Participants averaged 63.7 years of age (*SD*=8.59), ranging from 50 to 95. Most were female (78.6%), non-Hispanic White (78.6%), and college-educated (56.2%).

Just below a quarter had less than \$20,000 in annual household income (23.6%), and less than half lived alone (43.7%). Over half of the participants had at least two chronic health conditions (53.4%) and reported no difficulties with activities of daily living or instrumental activities of daily living (58.3%). Most had mild depressive symptoms at pretreatment (62.1%), followed by moderate (30.1%), moderately severe (4.9%), and severe symptoms (2.9%) ([Table 1](#)).

Coaching

The mean number of coaching meetings was 8.4 per participant, averaging 34.5 min ($SD=20$) per meeting. According to coach self-reports, the top assistance provided by coaches was simple feedback (79% of the coaching calls), followed by facilitating understanding of lesson content (77.7%), reviewing or assisting with home practice (74.4%), technical assistance (19.2%), and assisting with the implementation of tools (15.5%). Coaches reported going through at least a portion of the online lessons with the participants during slightly over half of the coach meetings (51.7%).

Hypothesis 1

Hypothesis 1: The layperson-supported Empower@Home is feasible among older adults with depressive symptoms, as indicated by its retention and completion rates comparable to or exceeding those reported in published studies of similar interventions.

The results supported hypothesis 1. Out of the 103 participants, 96 completed posttests and 10-week follow-ups. This resulted in a 93% retention rate at the posttest stage and a 100% retention rate at the 10-week follow-up among those who completed the posttest. These rates surpass the typical benchmark of an 80% retention rate. On average, participants completed 8.5 out of 9 online sessions. Notably, 91.3% of

the participants finished all nine sessions ($n=103$). Among the 96 who completed the posttest, 94 finished all nine sessions. These completion rates surpass those found in most studies of similar interventions included in a systematic review ([Xiang et al., 2020](#)), a point elaborated further in the discussion section.

Hypothesis 2

Hypothesis 2: The layperson-supported Empower@Home is acceptable to older adults with depressive symptoms, as indicated by scores exceeding the benchmark on validated measures of treatment acceptability.

The results supported hypothesis 2. The range for the modified TEI scores was from 37 to 55 among study participants, with an average score of 46. This average equals 64 on the original TEI scale and exceeds the benchmark score 32. In addition, [Table 2](#) shows that the overwhelming majority of posttest completers ($n=96$) agreed or strongly agreed that this program was an acceptable way of dealing with depressed moods (94.8%), that they would recommend this program to others who experience depressed moods (95.8%), and that they believed this program was likely to be effective (92.7%). Most participants (92.7%) reported being satisfied or very satisfied with the program. Conversely, slightly over a third agreed or strongly agreed that the program required much effort (36.5%), and below a fifth reported discomfort during the treatment (17.7%). Four participants (4.2%) reported undesirable side effects from the program. Overall, these results suggest favorable attitudes toward the treatment among the participants.

Hypothesis 3

Hypothesis 3: Empower@Home participants have reduced depressive symptoms after the intervention and at the

Table 2. Treatment Acceptability Measured by the Treatment Evaluation Inventory ($N=96$).

Acceptability and Satisfaction Items	<i>n</i>	% Agree or Strongly Agree
I find the program requires a lot of effort	35	36.5
I find this program an acceptable way of dealing with depressed moods	91	94.8
I like the procedures used in this program	93	96.9
I believe this program is likely to be effective	89	92.7
I feel confident in performing the tasks required to participate in the program	90	93.8
I feel that I understand the program and how it works	93	96.9
I experienced discomfort during this program	17	17.7
I believe this program is likely to result in permanent improvement	77	80.2
Overall, I have a positive reaction to this program	90	93.8
I would recommend this program to others who experience depressed moods	92	95.8
There are undesirable side effects from this program	4	4.2
Rate your overall satisfaction with the program	89	92.7 ^a

Note. ^aStatistics presented here represented the number and percentage of people who reported "Satisfied" or "Very Satisfied" when asked, "How would you rate your overall satisfaction with the program?"

10-week follow-up, compared to their baseline symptoms scores.

The results supported hypothesis 3. As shown in Table 3, paired *t*-tests revealed a significant reduction in depressive symptoms from pretreatment to posttest ($t=7.64, p<.001$) and from pretreatment to follow-up ($t=6.09, p<.001$) in the entire sample ($n=103$). Within-group effect size Cohen's $d=0.75$ at posttest and .60 at 10-week follow-up, indicating medium effects. The effect sizes were large among those with moderate depression ($\text{PHQ-9} \geq 10$) at pretreatment (Cohen's $d=1.31$ at posttest and Cohen's $d=1.18$ at follow-up).

Moreover, linear mixed modeling with random intercept and slope involving up to 5 in-session assessments showed a significant linear time effect over 10 weeks of active intervention ($b=-1.13$ [95% CI, -1.3 to -0.96], $p<.001$). The predicted PHQ-9 score decreased by over one point every 2 weeks while the participants were engaged with the online program.

In addition to statistically significant results, metrics of clinical significance were also in the expected direction. Table 4 shows that at the posttest, half of the participants achieved remission ($\text{PHQ-9} < 5$), and 43.7% had a clinically significant improvement (≥ 5 -point reduction on the PHQ-9). Among those with moderate depression ($\text{PHQ-9} \geq 10$)

10) at pretreatment, 82.1% had a partial response ($\text{PHQ-9} < 10$), 41% achieved remission, and 66.7% had a clinically significant improvement at the posttest.

Hypothesis 4

Hypothesis 4: Empower@Home participants have reduced anxiety symptoms, social isolation, and loneliness after the intervention, compared to their baseline symptoms scores.

The results supported hypothesis 4. As shown in Table 5, paired *t*-tests revealed significant improvement in secondary outcomes from pretreatment and posttest among posttest completers ($n=96$). The within-group effect size was large for anxiety symptoms as measured with the GAD-9 (Cohen's $d=0.80$) and small for DSSI-10 for social support (Cohen's $d=0.36$) and the PROMIS 8a for loneliness (Cohen's $d=0.30$).

Exploratory Analysis

We explored correlates of treatment effects, defined as the change in PHQ-9 scores from pre- to posttreatment (i.e., a positive change score suggests symptom reduction). The more severe the pretreatment symptoms were, the larger the PHQ-9 change score at posttreatment ($b=.79, p<.001$). In

Table 3. Means, Standard Deviations, and Effect Size for Primary Clinical Outcome PHQ-9.

	<i>n</i>	Means (SD)			Within-group Cohen's d (95% CI)	
		Pre	Post	Follow-Up	Pre vs. Post	Pre vs. Follow-Up
PHQ-9 ≥ 5 at Pre	103	9.23 (3.82)	5.49 (4.30)	6.47 (4.42)	0.75 (0.53, 0.97)	0.60 (0.39, 0.81)
PHQ-9 ≥ 10 at Pre	39	13.08 (3.44)	6.38 (4.84)	7.7 (4.8)	1.31 (0.88, 1.74)	1.18 (0.76, 1.59)

Note. PHQ-9 = patient health questionnaire-9; CI = confidence interval. All analyses were intention-to-treat using the last available observation carried forward. Effect sizes were calculated using pretreatment scores to subtract posttest scores so that a positive effect size indicates a reduction or improvement in depressive symptoms as measured by PHQ-9. Paired *t*-test statistics for PHQ-9 score changes from pre to post and from pre to follow-up were all significant at $p<.001$.

Table 4. Clinically Significant Improvements in Depressive Symptoms Metrics.

Changes in PHQ-9 Scores at Posttreatment Assessment Points Relative to Pretreatment	<i>n</i>	% of Sample
In the entire sample ($N=103$)		
≥ 5 -point reduction of pretreatment scores at posttreatment	45	43.7
≥ 5 -point reduction of pretreatment scores at 10-week follow-up	33	32.0
PHQ-9 < 5 at posttreatment	52	50.5
PHQ-9 < 5 at 10-week follow-up	40	38.8
Among those with moderate depression at pretreatment ($\text{PHQ} \geq 10$) ($N=39$)		
≥ 5 -point reduction of pretreatment scores at posttreatment	26	66.7
≥ 5 -point reduction of pretreatment scores at 10-week follow-up	24	61.5
PHQ-9 < 10 at posttreatment	32	82.1
PHQ-9 < 10 at 10-week follow-up	27	69.2
PHQ-9 < 5 at posttreatment	16	41.0
PHQ-9 < 5 at 10-week follow-up	12	30.8

Note. PHQ-9 = patient health questionnaire-9.

Table 5. Means, Standard Deviations, and Effect Sizes for Secondary Clinical Outcomes.

	n	Means (SD)		Test Statistics	Within-group Cohen's d Pre vs. Post
		Pre	Post		
GAD-7	95	7.59 (4.65)	4.03 (3.50)	$t(94) = 7.77, p < .001$	0.80 (.56, 1.03)
DSSI-10	94	23.11 (3.54)	24.19 (3.26)	$t(93) = 3.52, p < .001$	0.36 (.15, .57)
PROMIS-8a	93	20.14 (5.91)	18.54 (6.47)	$t(92) = 2.90, p < .005$	0.30 (.09, .51)
BADS-SF	90	33.9 (1.18)	39.0 (1.07)	$t(89) = 4.98, p < .005$	0.52 (.30, .74)

Note. GAD-7 = Generalized Anxiety Disorder-7 items; DSSI-10 = Duke Social Support Index; PROMIS-8a = Patient Reported Outcomes Measurement Information System-Social Isolation 8a; BADS-SF = Behavioral Activation for Depression Scale-Short Form. All analyses were conducted with participants who completed the posttest, excluding those with occasional missing data on some items. To facilitate the interpretation of results, t-test statistics and effect sizes were calculated such that a positive statistic indicated improved outcomes (i.e., decreased scores on the GAD-7 and PROMIS-8a and increased scores on the DSSI-10 and BADS-SF).

addition, BADS-SF scores for behavioral activation increased significantly at the posttest with a moderate effect size (Cohen's $d = 0.52$). BADS-SF change scores were positively associated with PHQ-9 change scores in multiple regression adjusting for pretreatment PHQ-9 scores ($b = .12, p = .006$).

Discussion

This pilot study evaluated the acceptability and treatment outcomes of a DMHI called Empower@Home, a web-delivered CBT program for treating the core symptoms of depression among older adults. Although Empower@Home can be entirely self-guided, the study tested a layperson-supported format, where participants received support from a lay coach. Study findings demonstrate the feasibility and preliminary effects of the treatment modality and suggest that older adults will utilize and benefit from DMHIs for depression facilitated by lay coaches.

Retention and treatment adherence of Empower@Home were excellent, comparable or higher than most iCBT trials. According to a systematic review of iCBT trials with older adults (Xiang et al., 2020), treatment completion rates ranged from 55% to 92%, with all except one study reporting an 80% or lower adherence rate. In our previous study of Beating the Blues™, a commercially available iCBT program not specifically designed for older adults, only a quarter of participants completed the program, even with intense in-home support (Xiang et al., 2020). In contrast, over 90% of Empower@Home participants completed the program, including 98% of posttest completers. Low user engagement with DMHIs is a known issue and a barrier to realizing the benefits of these interventions in real-world settings (Gan et al., 2021).

There are several possible explanations for the superior adherence rate of Empower@Home. Supported DMHIs have better adherence rates than self-guided programs (Cuijpers et al., 2019; Karyotaki et al., 2021). Support from coaches may have boosted accountability, made the program more interactive, and facilitated the routinization of session engagement. Another possible reason is the

increased global demand for mental health treatments since the COVID-19 pandemic (World Health Organization, 2022). Reports from our community partners serving older adults in Michigan echoed these global trends. Participants may be motivated to finish the program due to a desire to feel better and barriers to accessing alternative treatment options.

Overall acceptability and satisfaction ratings of Empower@Home are similar to reports from a behavioral activation program delivered via video conference by bachelor's level lay counselors (Choi et al., 2021) and higher than those of Beating the Blues™ in our previous study (Xiang et al., 2020). For example, 94.8% of Empower@Home participants found the program acceptable for dealing with depressed moods compared to 71.4% of Beating the Blues™ users in our previous study. On the other hand, one-third of Empower@Home users reported that the program required much effort (36.5%), compared to over half of Beating the Blues™ users (52.4%) in our previous study. Moreover, fewer Empower@Home users (17.7%) experienced discomfort than Beating the Blues™ users (28.6%) in our previous study.

The preliminary effects of Empower@home are in line with those from previous studies. A meta-analysis of iCBT trials involving older adults showed a pooled within-group Cohen's $d = 1.27$ with an average pretreatment PHQ-9 score of 12.6 (Xiang et al., 2020). The effect size of .75 in our sample may appear smaller than the pooled average, but that is mainly due to a lower pretreatment PHQ-9 score ($M = 9.2$). Most studies used the $\text{PHQ-9} \geq 10$ threshold, while we used a lower threshold of ≥ 5 , which is more prone to floor effects. Our exploratory analysis showed that pretreatment symptom severity was significantly associated with treatment effects. We found a Cohen's $d = 1.31$ among those with $\text{PHQ-9} \geq 10$ at pretreatment, slightly larger than the pooled average from previous trials. The clinically meaningful improvement metrics of Empower@Home were slightly better than those from iCBT programs supported by clinical psychologists (Dear et al., 2013; Titov et al., 2015). However, therapist involvement in these programs was less

intense and required less time commitment than “empower coaches”.

These treatment benefits were sustained at the 10-week follow-up, although a significant albeit slight drop from the posttest occurred. Decaying of treatment effects over time is not uncommon (Palacios et al., 2022). Due to our uncontrolled design, it was unclear whether the leveling off in treatment effects at the follow-up indicated a lack of sustained impact of the program itself or due to other external reasons. Of note, baselines in this study occurred between May and September, posttests occurred between August and December 2022, and the 10-week follow-up occurred between October 2022 and February 2023. Michigan is known for its long and cold winters with grey skies, so the occasional “winter blues” and the more serious seasonal depression may explain the slight drop in treatment effects at follow-up.

Limitations

The study’s primary limitation is the uncontrolled design, which limits its ability to determine treatment effectiveness. A small randomized controlled trial of Empower@Home is underway and will provide more rigorous findings regarding treatment effects (Kayser et al., 2023). Another limitation is its generalizability. Although participants came from all parts of Michigan, including its metropolitan and rural areas, their education levels and technology device ownership exceeded the national and state averages among older adults (U.S. Census Bureau, 2022). The overrepresentation of highly educated and tech-savvy participants was not unexpected, given the majority came from a research volunteer registry that required internet access to sign up. Additional exploratory analysis showed that study device usage did not predict PHQ-9 change scores in multiple regression adjusting for pretreatment PHQ-9 scores, age, education, and income. However, how well iCBT will work among socioeconomically disadvantaged older adults remains unclear. In addition, it is unclear how coaches enhance treatment outcomes and whether the program will be similarly beneficial with less intense or no support. Analyses of qualitative data collected from the pilot study are underway, which will shed light on these unanswered questions. Finally, the follow-up period is relatively short, and secondary clinical outcomes were not re-assessed at the 10-week follow-up to reduce participant burden. Studies with extended follow-up periods are needed to determine if the intervention has sustained effects.

Implications for Social Work Practice

The adaptable nature of the coach-client relationship in Empower@Home, ranging from guided completion to more autonomous use based on clients’ needs and preferences, aligns well with social work’s emphasis on self-determination. The program’s self-guided structure respects

and encourages the autonomy of older adults, while the coach’s role in providing feedback, technical assistance, and guidance mirrors the supportive function of social workers.

DMHIs like Empower@Home serve as a valuable resource for social work practitioners working with older adults, such as case managers and care coordinators, especially those facing persistent treatment barriers such as transportation issues and financial constraints. While potential challenges like access to technology and hesitance to use digital platforms exist, we have found that most older adults are open to learning and utilizing DMHIs, especially with demonstrations and sustained support. Social work practitioners are uniquely positioned to introduce evidence-supported DMHIs to older adults who are not yet familiar with the technology. Macro social work practitioners should also be aware of DMHIs such as Empower@Home and consider this a method to democratize access to mental health care, particularly for marginalized or underserved communities.

It is important to emphasize that while DMHIs like Empower@Home can effectively treat depression, they are not intended to replace the crucial role of mental health professionals, such as Licensed Clinical Social Workers (LCSWs). Instead, they should be considered supplementary tools that mental health professionals can use in their practice. These digital interventions can be used alongside traditional one-on-one therapy provided by LCSWs by providing additional, easily accessible resources that clients can utilize outside therapy sessions. They can also serve as intermediate support between therapy sessions or as a resource for clients waiting for traditional treatments.

Conclusion

This uncontrolled study found that iCBT supported by lay coaches is a feasible and acceptable treatment modality for reducing depression and improving psychosocial outcomes among older adults. If confirmed effective in future controlled trials, this treatment modality can be scaled up and implemented in community settings to substantially improve treatment access and outcomes among underserved older adults with mental health needs.

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Long-Term Effects on Loneliness of a Computer-Tailored Intervention for Older Adults With Chronic Diseases: A Randomized Controlled Trial

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Abstract

Objectives: This study explores the effects of the Active Plus intervention aiming to decrease loneliness among older adults (>65 years) with chronic diseases. **Methods:** A randomized controlled trial (RCT) was performed ($N = 585$; age: $M = 74.5$ years, $SD = 6.4$), assessing loneliness at baseline, 6 months and 12 months. Outcome measures in the multilevel linear regression analyses were total, social and emotional loneliness. **Results:** At 12 months, significant decreases in total ($B = -.37$, $p = .01$) and social loneliness ($B = -.24$, $p = .02$) were found. Age was a significant moderator for total and social loneliness; however, the intervention was effective only for participants aged 80 years and older. **Discussion:** The Active Plus intervention showed a significant decrease in total and social loneliness and was especially beneficial for the vulnerable age group of 80 years and older. A more comprehensive tool for measuring social activity and mobility impairments, and using a longer time frame to detect loneliness changes, may form interesting future research.

Keywords

loneliness, older adults, chronic diseases, mobility impairments

Introduction

Most countries in the world are faced with demographic distributions that shift towards older ages. In 2019, 1 in 10 people was aged 65 years or over, which is projected to increase to 1 in 6 people by 2050 (United Nations, 2019). In high-income countries, the portion of older adults (>65 years) in this distribution is even higher (He et al., 2016). Older age is not only accompanied with a decline in health but also with life transitions, such as retirement from working life and the loss of a spouse (Holt-Lunstad, 2018; National Academies of Sciences, Engineering, and Medicine, 2020; World Health Organisation, 2018b). These changes clear the path for the onset and continuance of loneliness, especially for older adults with chronic diseases (van Hees et al., 2020; Wrzus et al., 2013). As loneliness has been found to be a risk factor for mortality almost equally detrimental as smoking, obesity or physical inactivity (Holt-Lunstad et al., 2015), interventions to reduce loneliness among the most vulnerable groups of older adults are called for.

An often used definition for loneliness is ‘the unpleasant experience or feelings associated with a lack of close

relationships’ (de Jong-Gierveld, 1998). This definition demonstrates that loneliness is a qualitative appraisal rather than an objective state: the size of one’s social network is subordinated to how the relationships within that network are valued (Cohen-Mansfield & Perach, 2015; de Jong-Gierveld, 1998; McHugh Power et al., 2018). Loneliness is often considered a bi-dimensional construct consisting of social and emotional loneliness (Dahlberg & McKee, 2014; Dutch Central Bureau of Statistics, 2018; McHugh Power et al., 2018). Social loneliness refers to the perceived absence of

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a social network, such as a circle of friends or acquaintances that fulfil a need of belonging, while emotional loneliness refers to the perceived absence of an intimate partner or close friend who provides a feeling of close attachment (Dahlberg & McKee, 2014; de Jong-Gierveld, 1998).

Both the prevalence and severity of loneliness increase with age. In the age group of 65–74 years, 44% reports being lonely, rising to 53% in the age group of 75–84 years and 63% for those of 85 years and older (Dutch Central Bureau of Statistics, 2016); these figures are in line with other high-income countries (European Union, 2015; National Academies of Sciences, Engineering and Medicine, 2020). Loneliness is more prevalent, and more severe, in older adults with a chronic disease, than in those without (Meek et al., 2018; Richard et al., 2017).

Loneliness has been found to be closely related to many aspects of health (Holt-Lunstad et al., 2015; Rico-Uribe et al., 2016; Tilvis et al., 2011; Valtorta et al., 2016). Physical health is affected as older adults not only experience an overall decline of physical abilities with age, but the majority of older adults develop one or more chronic diseases, such as type 2 diabetes, arthritis, cardiovascular diseases or chronic obstructive pulmonary disease (COPD) (Courtin & Knapp, 2017; Leigh-Hunt et al., 2017; Luo et al., 2012; Ong et al., 2016; The Lancet, 2020). Moreover, the prevalence of chronic diseases increases with age: in the age category of 65–74 years, 82% of the Dutch population has a chronic disease, which increases to 90% from the age of 75 years and over (Dutch Department of Health Wellbeing and Sports, 2016a); other high-income countries show similar numbers (European Union, 2015; World Health Organisation, 2018a).

Although literature shows no uniform definition of what a chronic disease is, most definitions include the presence of some form of mobility impairment (Goodman et al., 2013; McKenna et al., 2010). These mobility impairments potentially threaten social and mental health as research has consistently shown that mobility impairments are associated with diminished social participation (Everard et al., 2000; Mendes de Leon et al., 2003; Puts et al., 2007), with higher feelings of loneliness (Griffith et al., 2017; Nicolaisen & Thorsen, 2012; Smith & Victor, 2018; van Hees et al., 2020) and with depression or anxiety (Adams et al., 2004; Cacioppo & Cacioppo, 2014; Global Council on Brain Health, 2017; Heinrich & Gullone, 2006). A negative spiral may occur as lonely individuals tend to withdraw increasingly from social life (Asante & Castillo, 2018; Cohen-Mansfield et al., 2016; Courtin & Knapp, 2017).

In addition to these health issues, several societal changes increase the risk of loneliness for older adults. Due to the budget limitations in social care, older adults are stimulated to live independently at home for as long as possible instead of moving into a retirement home, resulting in more and more older adults living alone (Dutch Department of Health Wellbeing and Sports, 2018; Valtorta & Hanratty, 2012).

Conversely, due to the decline in physical and cognitive functioning that is accompanied with older age, a decrease in daily activities and societal participation may be seen which for those living alone is especially challenging (de Hond et al., 2019; Tak et al., 2013).

The increasing prevalence of loneliness and severity of related health risks have been the basis for the increased societal and academic interest in preventing and alleviating loneliness among older adults, making it a major target in governmental public health policies worldwide (World Health Organisation, 2018b). Although this is substantiated by the number and variety of interventions targeting loneliness in older adults (e.g. improving social skills, enhancing social support, increasing opportunities for social contact and addressing maladaptive social cognition) (Courtin & Knapp, 2017; Fakoya et al., 2020; Jarvis et al., 2020), there still seems to be a dearth in research focussing on alleviating loneliness among older adults with mobility impairments caused by chronic diseases, a target population that is especially vulnerable for loneliness (Petitte et al., 2015; Poscia et al., 2018).

In this study, we examine the effects of the Active Plus intervention on loneliness among that specific target population. This computer-tailored intervention was originally developed for the general public of 50 years and over (Peels et al., 2012) and has later been adapted for the specific target population of older adults with chronic diseases (Boekhout et al., 2017; Volders et al., 2019). The intervention aims primarily to increase physical activity (PA) and cognitive functioning and secondarily to decrease loneliness by offering a computer-tailored advice. The development of the intervention (Boekhout et al., 2017; Volders et al., 2019) and the limited effects on PA (Volders et al., 2020) have been described previously. The computer-tailored advice emphasizes the importance of social connectedness and suggests ways to increase social activity while being physically active, in order to decrease loneliness. The negative association between social activity and loneliness has often been described in the literature (Bruggencate et al., 2018; Cohen-Mansfield & Perach, 2015; Gardiner et al., 2018), and as such, stimulating social activity in order to decrease loneliness is an often used approach in interventions (Dickens et al., 2011; Robins et al., 2016a, 2016b).

A previously performed quasi experimental study by Boekhout et al. (2019) into the effects of Active Plus on loneliness showed a decreased total loneliness among the participants of the intervention (i.e. single older adults with mobility impairments). Considering the often cited meta-analysis of Masi et al. (2011), showing that social activity is less suited to alleviate emotional loneliness, we mainly expect to find effects on total and social loneliness. In addition, exploratory analyses for a potential moderating role of gender, marital status, age, degree of impairment and educational attainment will be performed as a recent study by van

[Hees et al. \(2020\)](#) demonstrated that these demographics were associated with loneliness.

Methods

Study Design

This study is part of clustered randomized controlled intervention trial (RCT) into the efficacy of the Active Plus intervention. Active Plus primarily aims to stimulate cognitive functioning and PA and secondarily to decrease loneliness. The intervention is developed for the target population of older adults, independently living in the community, with chronic diseases. The rationale and description of the study protocol has previously been described extensively ([Volders et al., 2019](#)).

For this study, a clustered two-group RCT was performed, in which participants were allocated to either the Active Plus intervention group or to a waiting list control group, with assessments at baseline, 6 months and 12 months. The study was conducted following the Declaration of Helsinki ([World Medical Association, 2013](#)). All participants provided written informed consent.

Procedure and Participants

Participants were recruited through seven municipalities in the Netherlands that agreed to participate in this RCT. As these municipalities in themselves are not comparable regarding socio-economic status, randomization was done on a neighbourhood level within each municipality. The municipalities each selected two neighbourhoods with comparable socio-economic statuses ([Association of Dutch Municipalities, 2020](#)) that were randomly assigned to either an intervention group neighbourhood or a control group neighbourhood (ratio 1:1). Randomization was performed by the researchers by means of online randomizer software ([Haahr, 2020](#)). Per neighbourhood, the municipalities sent direct postal mailings to 250–2000 addresses of independently living older adults (aged 65 years or older). The mailing consisted of a personalized information letter and a prepaid response card including informed consent that could be returned to the researchers. Enrolment lasted from February to July 2018. Inclusion criteria were 65 years or older, fluent in Dutch, having at least one mobility affecting chronic disease (e.g., COPD), arthritis, osteoporosis, chronic heart disease) or other mobility affecting physical condition (e.g., visual or hearing impairments). Exclusion criteria were severe self-reported cognitive impairments, using a wheelchair or not being able to walk at least 100 m (with or without the help of a walker or walking stick). Both the intervention group and waiting list control group received a paper questionnaire with a prepaid return envelope as well as access codes for the Active Plus website where the questionnaire

could be completed online, giving the participant a choice between these two delivery modes (i.e. paper or online). The 4-month lasting intervention then commenced for the intervention group. The second and third questionnaire followed after 6 and 12 months in the same procedure as the baseline measurement. The participants in the waiting list control group were given access to the Active Plus intervention directly after the 12 months assessment. Next to filling in the questionnaires, participants also wore accelerometers to assess PA and took cognitive functioning tests on computer/tablets in the presence of researchers. As these assessments are not part of the present study, these assessments are not described here in further detail: more information can be found in [Volders et al. \(2019\)](#). Figure 1 presents the flow chart of the study.

Intervention

Active Plus is a systematically developed computer-tailored intervention, which was adapted for independently living older adults (65+ years) with chronic diseases. The intervention provides participants with three individualized PA advices (delivered by paper and online) over a time frame of 4 months. These advices are based on 2 questionnaires (also delivered by paper and online) that were filled in on baseline and after 3 months. The first advice, based on the baseline questionnaire, addresses mainly pre-motivational psychosocial constructs such as awareness raising of the benefits of being physically active with other people and informing people about exercise clubs for their age group or chronic disease that are available in the local municipality. The second advice, also based on the baseline questionnaire, focuses on motivational psychosocial constructs such as increasing the perceived self-efficacy and attitude towards making new social contacts for enacting in PA: this is done, for example, by explaining that for everyone attending an exercise club for the first time with unfamiliar people, it may feel awkward at first but that generally everyone is accepted in a social and friendly way. In the third advice, based on the second questionnaire, post-motivational psychosocial constructs are targeted, such as action planning: this is, for example, done by showing a prefilled week calendar that suggests activities such as ‘walking the dog(s) together with my neighbour’. Depending on the stage of change the participant is in, the focus of the individual advice may shift.

The advice is tailored to the individual’s needs by computer tailoring. In this tailoring, the participants’ demographics, stages of change, psychosocial characteristics, and their degree of mobility impairment are considered. For example, a female participant in the contemplation stage of becoming more active may be shown a role model video of a woman in the same age category who tells about the benefits that being more active has brought her; a male participant who is in the preparation stage may be shown a comparable role model story of a man in his age category but then with an emphasis

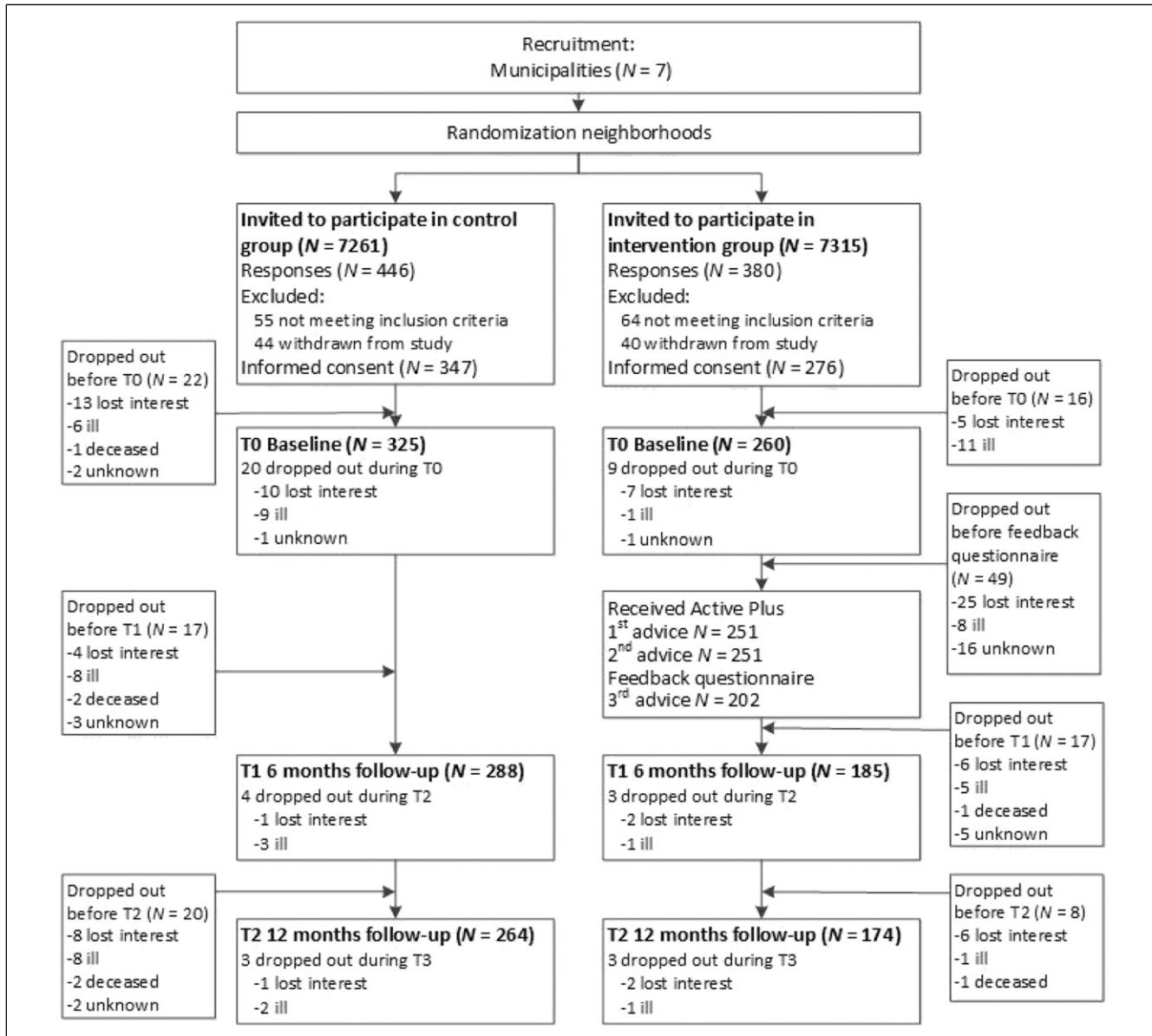


Figure 1. Flow chart of the study.

on finding social support for becoming more active. Another example is that a participant with a mild degree of arthritis in the lower limbs may receive the advice to join a swimming club, whereas a participant with a high degree of arthritis in the upper limbs may receive an advice to join a walking club. The advice is presented in a mainly text-based format (for both the paper and online delivery method) which is complemented with graphic materials like charts, pictures (written delivery mode) and videos (online delivery mode). As the intervention is implemented by municipalities or even in specific neighbourhoods, extensive information on physical or social activities that are available locally has been added to the advice.

Measures

Loneliness

Loneliness is assessed by the 6-item De Jong Gierveld Loneliness Scale. This self-report questionnaire is widely used in Europe, and its psychometric qualities are considered acceptable with a scale reliability ranging between .80 and .90 Cronbach's alpha and a scale homogeneity ranging between .30 and .50 (Gierveld & Tilburg, 2006). The scale has three items evaluating social loneliness (e.g. 'There are plenty of people I can rely on when I have problems') and three items evaluating emotional loneliness (e.g. 'I experience a general feeling of emptiness'). These subscales can be combined to

a total loneliness score. The original 5-point scale of this questionnaire (i.e. yes!, yes, more or less, no, no!) was adapted to a 10-point scale (1 = absolutely not and 10 = absolutely sure) to better align the scale with the target population's preference for distinct words instead of exclamation marks and for comparable point scales (Krosnick and Presser, 2010; Remillard et al., 2014). Similar to the data handling as described in the manual (de Jong Gierveld & Van Tilburg, 1999), after recoding the items in the correct direction, answers from 1 to 5 represent no loneliness, and answers from 6 to 10 represent loneliness. When one item or more is not answered, no score for social or emotional loneliness can be calculated: for the total score of loneliness, a maximum of one item may be missing. The mean is then taken for answers that indicate loneliness, resulting in a potential score of loneliness between 0 and 3 for the social and emotional subscales and between 0 and 6 for the total loneliness score, with higher scores indicating more loneliness.

Demographics

Several demographics were corrected for in the analyses as these are known to affect loneliness (Gouveia et al., 2017; Ku et al., 2016; Shvedko et al., 2017; van Hees et al., 2020), including age (in years), gender (0 = male/1 = female), marital status (1 = living alone/2 = living with spouse), educational attainment, body mass index (BMI) (length in metres divided by squared weight in kilograms) and degree of mobility impairments. Educational attainment was categorized into low (i.e. primary, basic vocational or lower general level = 1), moderate (i.e. medium vocational, higher general secondary or preparatory academic level = 2) or high (higher vocational or university level = 3). The degree of the mobility impairment was assessed with 15 items, 14 for most prevalent chronic diseases (i.e. COPD and arthritis) or physical conditions (i.e. visual or hearing impairments) and 1 for any other chronic diseases not mentioned. For each item, participants could indicate the degree of mobility impairment on a 5-point scale (ranging from 0 = not impaired to 4 = severely impaired). The degree of impairment was categorized into three categories being 1 = little impaired (with a maximum score of 1 on at least one item), 2 = medium impaired (with a maximum score of 2 on at least one item) and 3 = severely impaired (with at least a score of 3 or 4 on at least one item).

Analyses

Baseline differences between the intervention and control groups were analysed by chi-square tests (categorical variables), Mann–Whitney U-tests (skewed continuous variables) and ANOVA tests (non-skewed continuous variables). Binary logistic regression was conducted to assess selective dropout at 6 and 12 months.

As measurement points are nested within the participants, and with participants originating from different municipalities, a potential interdependence was present. Therefore, multilevel linear regression analyses were performed with measurement points as level 1, participants as level 2 and municipality as level 3. The analyses demonstrated that the intraclass coefficients (ICC) for the dependent variables of social loneliness, emotional loneliness and total loneliness were all smaller than .01. As a result, two-level analyses were performed. Participants were included as random effect in the model; measurement points, group and the interaction between measurement points and group were included in the models as fixed effects to assess the intervention effects over time. Intervention effects between the intervention group and control group were compared between baseline and 6 months follow-up and between baseline and 12 months follow-up. For all analyses, age, gender, educational level, marital status, BMI and degree of impairment were added as covariates. Continuous variables were standardized. Confidence intervals (CIs) were calculated for all outcomes. Analyses were conducted on an intention-to-treat basis without any ad hoc imputation (Twisk et al., 2013).

Exploratory differences regarding intervention efficacy were assessed for degree of impairment, age, gender, educational level, marital status and BMI. Three-way interaction terms (time x group x covariate) of significant covariates were added to the model. When a three-way interaction term was significant, subgroup effects were examined by repeating the analyses. In these multilevel analyses, the two-level data structure was applied again. Subgroups were defined by the categories of the covariates for categorical variables. For the continuous variables of age and BMI, the groups were split at, respectively, 80 years or older or 79 years and younger and at obese or non-obese (limit at 30 kg/m²).

All analyses were performed with R (R Core Team, 2019). In all analyses, a reproducibility level of 95% was applied ($\alpha = .05$). Since interaction terms have less power, the significance levels were set to $p < .10$ for the interaction terms. Sample size was found to be sufficient, based on sample size calculations that were performed a priori on the primary outcome measures of the intervention, and are described elaborately elsewhere (Volders et al., 2019).

Results

Study Population

A total of 623 participants provided informed consent and were included in the study (see Figure 1). Before baseline, 38 withdrew, resulting in 585 participants at baseline (age: $M = 74.5$ years, $SD = 6.4$), with an almost equal gender distribution (48.4% men). Living with a spouse was the most prevalent marital status (80.7%). Regarding educational attainment, 51.2% was low educated. Most participants (51.2%) were medium impaired. No significant baseline

differences were found between the intervention and control groups (see Table 1). A subgroup analysis for loneliness, where the groups were split in younger than 80 years and 80 years and over, however, showed that the intervention group was significantly more lonely than the control group (see Table 1).

Dropout at 6 months and 12 months was, respectively, 19.1% (112/585) and 25.1% (147/585). Participating in the intervention group (6 months: $OR = 5.85$, 95% CI = 3.38; 10.56, $p \leq .001$; 12 months: $OR = 2.72$, 95% CI = 1.76; 4.25, $p \leq .001$) and older age (6 months: $OR = 1.09$, 95% CI = 1.05; 1.14, $p \leq .001$; 12 months: $OR = 1.08$, 95% CI = 1.04; 1.12, $p \leq .001$) were predictors of dropout at both 6 and 12 months after baseline. In addition, a low education was a predictor of

dropout at 12 months ($OR = 2.03$, 95% CI = 1.16; 3.66, $p = .015$). In the control group, the most frequent reason for dropout (30 out of 64 dropouts) was being too ill to continue, while intervention group participants mostly (48 out of 89 dropouts) dropped out due to a loss of interest. For the outcome measure of loneliness, 29 participants of the total of 585 had a missing baseline measurement of loneliness: in the analyses at 6 and 12 months, an additional 21 participants were missing and could not be included in the analyses.

Intervention Effects

Table 2 shows the intervention effects on loneliness. 12 months after baseline, participants in the Active Plus

Table 1. Baseline Participant Characteristics of The Control Group and The Intervention Group.

	Control group (N = 325)	Intervention group (N = 260)	p value
Demographic characteristics			
Age in years, mean (SD)	74.46 (6.22)	74.20 (6.60)	.62
Gender, N (%)			
Male	164 (50.5%)	138 (53.1%)	.59
Female	161 (49.5%)	122 (46.9%)	
Marital status, N (%)			
Living single	50 (16.6%)	56 (22.6%)	.09
Living together	252 (83.4%)	192 (77.4%)	
Education, N (%)			
Low	151 (50.3%)	127 (52.3%)	.54
Middle	60 (20.0%)	54 (22.2%)	
High	89 (29.7%)	62 (25.5%)	
Health-related characteristics			
BMI, median (IQR)*	26.9 (24.1–29.4)	26.9 (24.4–29.8)	.35
Degree of impairment, N (%)			
Little impaired	34 (11.1%)	29 (11.6%)	.39
Medium impaired	134 (43.8%)	123 (49.0%)	
Severely impaired	138 (45.1%)	99 (39.4%)	
Loneliness, N	305	251	
Total loneliness, mean (SD); %	1.84 (1.80); 51.5**	2.02 (1.94); 51.3	.27***
Social loneliness, mean (SD); %	.83 (1.12); 42.2	.95 (1.23); 43.8	.23
Emotional loneliness, mean (SD); %	1.00 (1.19); 48.5	1.06 (1.20); 51.8	.55

Notes. SD = standard deviation; IQR = interquartile range; BMI = body mass index. *non-normally distributed variable tested with Mann-Whitney U test. **percentage of total intervention or control group that reports being lonely; ***p value for differences in mean.

Table 2. Intervention Effects (Group x Time Interaction) on Loneliness Outcomes for 6 and 12 Months Follow-Up*.

	N	Effect after 6 months				Effect after 12 months			
		B	SE	95%CI	P	B	SE	95%CI	P
Loneliness									
Total loneliness	535	-.17	.15	-.47; .12	.24	-.37	.15	-.67; -.08	.01
Social loneliness	535	-.13	.10	-.32; .06	.19	-.24	.10	-.43; -.04	.02
Emotional loneliness	535	-.05	.11	-.26; .16	.67	-.14	.11	-.35; .08	.21

Notes. SE = standard error; CI = confidence interval. *Effects are reported as intervention group versus control group as control group served as reference group adjusted for covariates.

group scored significantly lower on total loneliness ($B = -.37$, $SE = .15$, $p = .01$) and social loneliness ($B = -.24$, $SE = .10$, $p = .02$) after adjusting for potential confounders, indicating less loneliness in the intervention group. No significant differences between the intervention and control groups were found in emotional loneliness.

Moderation Effects

Although the intervention is individually tailored, it is possible that not all subsets of participants react similar to the intervention. To explore this, analyses for subgroups were performed. These exploratory analyses (see Table 3) showed that only for age a significant moderation effect (intervention group vs. control group) was present. Intervention group participants of 80 years or older had significantly lower total loneliness scores at both 6 months after baseline ($B = -.82$, $p = .03$) and at 12 months after baseline ($B = -.76$, $p = .05$) compared to control group participants of 80 years or older. However, the intervention effect was not present in participants younger than 80 years (6m: $B = -.01$, $p = .95$; 12m: $B = -.26$, $p = .11$). This moderation effect of age was also present in social loneliness, where the intervention was only effective for participants of 80 years or older (6m: $B = -.60$, $p = .01$; 12m: $B = -.57$, $p = .02$), as opposed to participants younger than 80 years ($B = -.01$, $p = .94$; 12m: $B = -.15$, $p = .19$). For emotional loneliness, no moderation effect was found.

Discussion

This study investigated the effects of the Active Plus intervention on loneliness among the target population of independently living older adults with chronic diseases. At 12 months, a significant intervention effect was found for total loneliness and for social loneliness but not for emotional loneliness. Age was a significant moderator for total and social loneliness at 6 and 12 months: only in the age group of 80 years and over, the Active Plus intervention was effective.

The significant effect that we found on total loneliness is in line with several reviews demonstrating that stimulating social activity while being physically active, which the Active

Plus intervention does, can contribute to alleviating loneliness (Dickens et al., 2011; Robins et al., 2016a, 2016b). Several characteristics of the Active Plus intervention, such as being developed within the context of a theoretical basis (Dickens et al., 2011), integration in the community setting and stimulation of participation in local activities (Gardiner et al., 2018), are known to increase the effects of these types of interventions and can therefore contribute to our findings. However, not all previous research distinguishes between social and emotional loneliness, which is important to take into consideration. For our intervention, as expected, only social loneliness showed a significant effect. Although many loneliness interventions employ social activity as a means to decrease overall loneliness (Asante & Castillo, 2018; Courtin & Knapp, 2017), some studies have suggested that stimulating social activity has the potential to decrease social loneliness but is not an appropriate method to decrease emotional loneliness (Machielse, 2015; Masi et al., 2011; O'Rourke et al., 2018). By increasing social activity, individuals may acquire more social contacts and thus decrease their social loneliness, but an increase in the quantity of social contacts does not necessarily mean that these contacts provide a deep emotional bond, which is a prerequisite for decreasing emotional loneliness. That we did find an effect on social but not on emotional loneliness is thus as expected, considering the design of the intervention.

When interpreting our results, it is important to take into consideration the characteristics of our intervention group of whom 43% was medium impaired and 45% was severely impaired. Severe mobility impairments are known to impede the potential to be socially active, for example, when they restrict access to private or public transport and thus limit the possibilities to join social activities or to visit others (Dahlberg et al., 2015; Robins et al., 2016a, 2016b). This is also corroborated by a 5-year longitudinal study (Newall et al., 2014) who showed that decreases in loneliness were only seen in those who perceived a change of control over their life situation: as severe mobility impairments are known to negatively affect feelings of control (Barlow et al., 2015; Hawley & Cacioppo, 2010), this could implicate that loneliness is very difficult to decrease for those with higher degrees of mobility impairments. This may indicate that the

Table 3. Moderation of Intervention Effects (Group x Time Interaction) on Loneliness Outcomes for 6 and 12 Months Follow-Up in Subgroups*.

Subgroup	Effect after 12 months					Effect after 12 months				
	N	B	SE	CI	p	B	SE	CI	p	
Total loneliness	≥80 years	114	-.82	.37	-.15;-.09	.03	-.76	.39	-.15; .00	.05
	<80 years	421	-.01	.16	-.32; .31	.95	-.26	.16	-.58; .06	.11
Social loneliness	≥80 years	114	-.60	.22	-.104;-.17	.01	-.57	.24	-.103;-.11	.02
	<80 years	421	-.01	.11	-.22; .21	.94	-.15	.11	-.36; .07	.19

Notes. SE = standard error; CI = confidence interval. *Effects are reported as intervention group versus control group as control group served as reference group in the different subgroups adjusted for covariates.

fact that our intervention did show effects among this group of participants is particularly auspicious. A potential implication for practice may be that future interventions need to stronger address possibilities of being socially active when mobility impairments are present. For future interventions, it may also be useful to carefully consider which measurement instrument is used to determine the degree in which social activity is impeded by mobility impairments. Although validated instruments exist, they may not be suitable for the group of independently living older adults with mobility impairments: these instruments are often designed for the more fragile who require substantial help from others in daily life (Ustün et al., 2010; Ware et al., 1995). A more precise measurement instrument for measuring the degree in which social activity is impeded by the degree of mobility impairments or by the type and features of a specific chronic disease may enhance the computer tailoring of the advice and therefore also the effects of the intervention.

Our findings may also be explained by age differences in normative expectations regarding loneliness. Due to normative expectations, individuals in their twenties, for example, may feel lonely when having only two close friends as in that age group the perceived norm is to have a large group of friends, whereas individuals in their seventies or eighties may feel blessed for still having one or two close friends (Luhmann & Hawley, 2016). These normative expectations may thus result in a lower incentive among older adults to actively intensify or expand present close contacts. Also, for older people, the quality instead of the quantity of social contacts is more negatively related to loneliness (Green et al., 2001; Victor & Yang, 2012): as it takes time to acquire contacts of a certain quality, emotional loneliness is harder to change than social loneliness. This may also explain why for the entire intervention group, no intervention effects for either social, emotional or total loneliness were found at 6 months. A recent meta-analysis has shown that loneliness has trait-like features making it a relatively stable sensation for older adults that may stay present fairly long and irrespective of changes in their current circumstances (Mund et al., 2020). It may therefore be that changes in loneliness are better assessed after a longer time frame than done in our study.

Only age and marital status were significantly related to loneliness: age was positively associated with total and emotional loneliness (i.e. the older, the more lonely), and living alone was associated with more emotional loneliness. A recent study by van Hees et al. (2020) demonstrated that being older, living alone, the male gender, being more disabled and being lower educated were associated with higher levels of loneliness. As in our sample, most participants have medium to severe mobility impairment and the large majority is lower educated, our findings are not very divergent from that study, with only gender showing no significant relation to loneliness. Age proved to be the sole significant moderator: only in the age group of 80 years and over, the Active Plus

intervention was effective in decreasing total and social loneliness, both at 6 and at 12 months. An explanation may be found in the prevalence of loneliness which of all age groups is the highest in the oldest age groups. In our sample, loneliness was significantly higher in the age group of 80 years and older than in the age group younger than 80 years (total loneliness 62.7% vs. 48.4%; social loneliness 45.0% vs. 42.3%; emotional loneliness 63.3% vs. 47.3%). These figures are in line with national prevalence data showing that 44% of older adults between 65 and 74 years report being lonely, increasing to 63% in those over 85 years (Dutch Department of Health Wellbeing and Sports, 2016b). Qualter et al. (2015) suggest that interventions that focus on alleviating loneliness by stimulating social activity may be especially beneficial to the most vulnerable groups where loneliness is already higher, such as the oldest old. This age group is generally less able to connect with others as they have fewer opportunities to engage socially. As the Active Plus intervention offers these opportunities by suggesting social activities that are easy to integrate in daily life, it may therefore be especially suited to decrease social loneliness for the vulnerable group of the oldest old. For the future, this suitability may even be enhanced by incorporating into the computer-tailored advice what social activities the participants find the most meaningful: it has been argued that interventions to decrease loneliness are more effective when people are linked with others and with activities they find meaningful (Pels & Kleinert, 2016; Steffens et al., 2016). A study on the use, appreciation and working mechanisms of the intervention may also shine a light on what variables need extra attention in the computer tailoring of advice and would thus form an interesting line of future research.

Methodological Issues

Although our study provides relevant insights derived from a study with a methodological vigorous design, some methodological issues should be noted. First of all, the initial response rate of 6% is relatively low, although meaningful comparisons are difficult to make as most studies report only on dropout and not on response rates (Zubala et al., 2017). As information on non-participants is not available, it is impossible to analyse the characteristics of those who are not drawn to these kind of interventions. However, our dropout rate was 25.1% which is relatively low compared to similar studies (Eysenbach, 2005). Moreover, as selective dropout was only present during the intervention period and for older participants, this dropout does not detract from the good generalizability of our research: the distribution of gender, educational attainment, number of comorbidities, BMI and loneliness is well in line with the average Dutch population (Dutch Department of Health Wellbeing and Sports, 2020). By performing multilevel regression analyses to the incomplete dataset, we handled missing data in the most accurate way as this method has proven to result in better

estimations than using multiple imputation (Twisk et al., 2013).

Secondly, adherence to the intervention was not tested: to what extent participants actually read or used the intervention advice is thus unknown. However, studies into previous versions of the Active Plus intervention demonstrated that the printed materials were read by more than 93% of the participants (Peels et al., 2013). As participants received the intervention materials both printed and online, exposure in the present study is expected to be comparable.

Thirdly, we enhanced the scale of the loneliness questionnaire to better align with the needs of our specific target population. As these enhancements were performed in line with recommendations for designing questionnaires for older adults (Krosnick and Presser, 2010; Remillard et al., 2014), we expect that the validity of the questionnaire remains intact.

Fourthly, we categorized the degree of mobility impairment into low, medium or severe by taking the highest degree of impairment as perceived by the participant caused by any of their chronic diseases. Some studies have demonstrated that certain combinations of chronic diseases increase the total degree of mobility impairment beyond what could be expected based on the degree of impairment of the individual chronic diseases (Raina et al., 2020). Incorporating this in our questionnaire could have given a more complete insight and is thus recommendable for future studies.

Conclusions

To our knowledge, this is the first RCT that analyses the effects of an intervention on loneliness by stimulating social activity while being physically active for the target population of older adults with chronic diseases. As societies are ageing and age is often accompanied with the onset and deterioration of both chronic diseases and loneliness, this is a target population that is growing in importance. Notwithstanding the above-mentioned limitations, our findings indicated that the Active Plus intervention was able to decrease total and social loneliness on the long term among the target population. Subgroup analyses demonstrated that especially the vulnerable age group of 80 years and older seemed to benefit more from Active Plus. For future research, it may be advisable to use a more comprehensive tool for measuring social activity and mobility impairments and to use a longer time frame in order to better detect changes in loneliness.

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Declaration of Conflicting of Interest

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Ethical Approval

The study is ethically approved by the Research Ethics Committee (CETO) of the Open University. The trial is registered in the Dutch Trial Register, protocol number NL6005.

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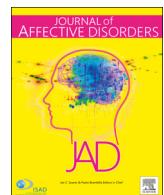
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Research paper

Evaluation of a guided internet-based self-help intervention for older adults after spousal bereavement or separation/divorce: A randomised controlled trial



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ABSTRACT

Background: While several internet interventions target severe prolonged grief symptoms after bereavement, no randomised controlled trial investigated interventions for prolonged grief after separation/divorce.

Methods: This randomised controlled trial aimed to evaluate the efficacy of a guided internet-based self-help intervention for prolonged grief symptoms after spousal bereavement or separation/divorce compared to a wait-list control group. Furthermore, we analysed whether the intervention was also efficacious for participants with milder grief symptoms.

Results: A total of 110 participants were mainly recruited by newspaper articles. Average age was 51 years, 77% were separated/divorced, 79% were female. Dropout rate was 11%. Compared to the control group, the intervention resulted in significant reductions in grief ($d = 0.81$), depression ($d = 0.59$), psychopathological distress ($d = 0.39$) (primary outcomes), embitterment ($d = 0.37$), loneliness ($d = 0.37$) and an increase in life satisfaction ($d = -0.41$) (secondary outcomes). These gains were maintained over three months. Improvements were similar among widowed and separated/divorced participants as well as among participants with low, medium or high levels of grief at baseline.

Limitations: Limitations include the self-selective sample and a rather small number of widowed participants.

Conclusions: Findings indicate that an internet intervention based on models for coping with grief after bereavement was not only beneficial for widowed but also separated or divorced participants. Furthermore, also participants with lower levels of grief at baseline benefitted from the intervention. This corroborates that indicated prevention efforts for grief are efficacious.

1. Introduction

Grief and psychological distress are normative reactions after the loss of a partner and most individuals adapt after a certain time. However, some individuals experience prolonged grief symptoms or develop even a Persistent Complex Bereavement Disorder (Aoun et al., 2015; Kersting et al., 2011; Shear et al., 2013), which is characterised by persistent separation distress, frequent or disabling cognitive, emotional and behavioural symptoms such as avoidance of reminders of the loved one, difficulties moving on with life and functional impairment (e.g. Prigerson et al., 2009).

Several models identify characteristics of a positive adaptation after

bereavement. The task model of mourning for example posits that accepting the reality of the loss, experiencing the pain of grief, adjusting to an environment without the deceased person, and withdrawing emotional energy and reinvesting it in another relationship are crucial for a positive adaptation after a loss (Worden, 2009). The dual-process model of coping with bereavement underlines the importance of oscillating between loss-oriented tasks such as grief work and expressing emotions towards the deceased and restoration-oriented tasks such as engaging in new activities, distracting from grief, and finding new roles and identities (Stroebe and Schut, 1999).

Most research has focused on severe prolonged grief after bereavement, but not on grief after a separation or divorce. As the number

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of divorces among adults over 50 year has considerably increased during the last decades (Brown and Lin, 2012), grief after a separation or divorce is an understudied, but very relevant issue. Both, spousal bereavement and separation/divorce share common characteristics. Both events require a dissolution of social and emotional ties, the reorganisation of daily routine and the formation of a new identity and a new perspective for the future (Znoj, 2016).

While, to the best of our knowledge, no previous randomised controlled trial has focused on treating prolonged grief symptoms after a divorce, there is broad evidence that interventions for prolonged severe grief after bereavement were efficacious (Currier et al., 2008; Wittouck et al., 2011). Interventions after the loss of a spouse, a child or another significant person generally include the exposure to the experience of the loss, cognitive reappraisal of the loss, and integration and restoration of the experience of the loss into daily life (Shear et al., 2005; Boelen et al., 2007). Recently, efficacious internet-based interventions have complemented face-to-face grief counselling or therapy (Eisma et al., 2015; Litz et al., 2014; van der Houwen et al., 2010; Wagner et al., 2006). Effect sizes in guided internet-based interventions were in the moderate to large range. Advantages of internet interventions are the flexible usage independent of time and place, usage at a self-determined pace, a high level of autonomy and privacy, and lower costs (Schröder et al., 2016).

Conflicting results exist regarding trials for preventing complicated grief after bereavement. Meta-analyses found no effects for preventive interventions (Currier et al., 2008; Neimeyer, 2000; Wittouck et al., 2011). Currier et al. (2008) differentiated between universal, selective and indicated intervention and found that indicated preventive interventions for individuals who manifest difficulties with coping with bereavement benefitted for preventive interventions. A controlled trial on an indicated preventive internet intervention for prolonged grief disorders (Litz et al., 2014) corroborated these results. The intervention focused on self-care, social reengagement and goal-focused activities without components of exposure or cognitive reappraisal and found moderate to large effect sizes.

1.1. Objectives

In a randomised controlled trial, we aimed to evaluate the acceptability and efficacy of a guided internet-based self-help intervention for prolonged grief symptoms after spousal bereavement and separation/divorce in comparison to a wait-list control group. We expected that the intervention called LIVIA would have beneficial effects on grief, depression symptoms and psychological distress (primary outcomes), as well as on embitterment, loneliness, and satisfaction with life (secondary outcomes). We expected the effects to be stable in the three-month follow-up.

Secondly, we assumed that the intervention, which was based on models for treating prolonged severe grief after bereavement, would be efficacious for widowed as well as for separated/divorced participants. Considering similar adaptation tasks after spousal bereavement and separation/divorce, such as the dissolution of emotional ties, the formation of a new identity and a new perspective for the future, we expected that similar therapeutic techniques would be efficacious. In addition, LIVIA had a strong focus on resource activating interventions and strategies for finding comfort and self-care. We assumed that these techniques would also be suitable for treating grief after a separation/divorce.

Thirdly, we hypothesised that LIVIA would not only be efficacious for participants with severe grief, but also for participants with mild grief symptoms at baseline who seek help for coping with grief, with psychological distress or the psychosocial adaptation to the loss. This would corroborate previous studies which showed the efficacy of indicated prevention, i.e. interventions for individuals who manifest problems adapting to the loss of a spouse, but do not meet predefined criteria for psychological disorders (Currier et al., 2008).

2. Methods

2.1. Participants

The 110 participants were recruited between June 2016 and July 2017, mostly by newspaper articles and internet-self-help forums. All interested individuals registered on the study website, received the study information and were required to complete the baseline screening questionnaires and a telephone interview for assessing the severity of grief symptoms and the eligibility prior to randomisation. Participants gave informed consent first electronically and then orally in the telephone interview.

Eligibility criteria

Inclusion criteria were the following:

- 1 Experience of spousal bereavement or a separation/divorce more than six months prior to enrolling in the study.
- 2 Seeking help for coping with prolonged grief symptoms, psychological distress or the psychosocial adaptation to a life without the partner.
- 3 Having internet access.
- 4 Mastery of the German language.
- 5 An informed consent by the participant.

Exclusion criteria were the following:

- 1 Severe psychological or somatic disorders which needed immediate treatment and acute suicidality (BDI suicide item >1 or suicidal ideation in the telephone interview).
- 2 No emergency plan: In the telephone interview, an emergency plan was developed which specified a health care professional, to whom participants could have turned to in an acute crisis. If no such person or health care service was found, individuals were excluded from the intervention.
- 3 Concomitant psychotherapy, and /or prescribed drugs against depression or anxiety if prescription or dosage has changed in the month prior or during the self-help intervention.
- 4 Inability to follow the procedures of the study, e.g. due to comprehension problems.

The email-supporters (see below) allocated eligible individuals 1:1 to the wait-list control and the intervention group. Participants in the wait-list control condition received access to the intervention 12 weeks after the baseline interview. Randomisation was performed using the True Random Number Generator on Random.org run by the Randomness and Integrity Services Ltd in Dublin (Haahr, 1998). The allocation list was concealed from the investigators and participants. Fig. 1 displays the study flowchart.

2.2. Measures

Primary outcome measures included the 16-item Texas Revised Inventory of Grief – German Version (TRIG-D, Znoj, 2008) to assess the severity of grief symptoms. Answer categories were 1 = completely true to 5 = completely false. Cronbach alpha was between 0.82 at pre and 0.89 at post measurement. The TRIG showed good reliability in different samples (Montano et al., 2016) and consists of items which are applicable for different sources of grief including separation or divorce. The factorial validity was established and found to be temporally invariant over 2–12 months post-loss (Futterman et al., 2010).

Depression symptoms were assessed with the German version of the Beck Depression Inventory II (BDI-II, Kühner et al., 2007), a 21-item measure on a scale from 0 to 3 (Cronbach alpha 0.87–0.90). General psychopathological distress was assessed with the German version of the Brief Symptom Inventory (BSI). The 53 items measured a broad range of somatic and psychopathological symptoms within seven days

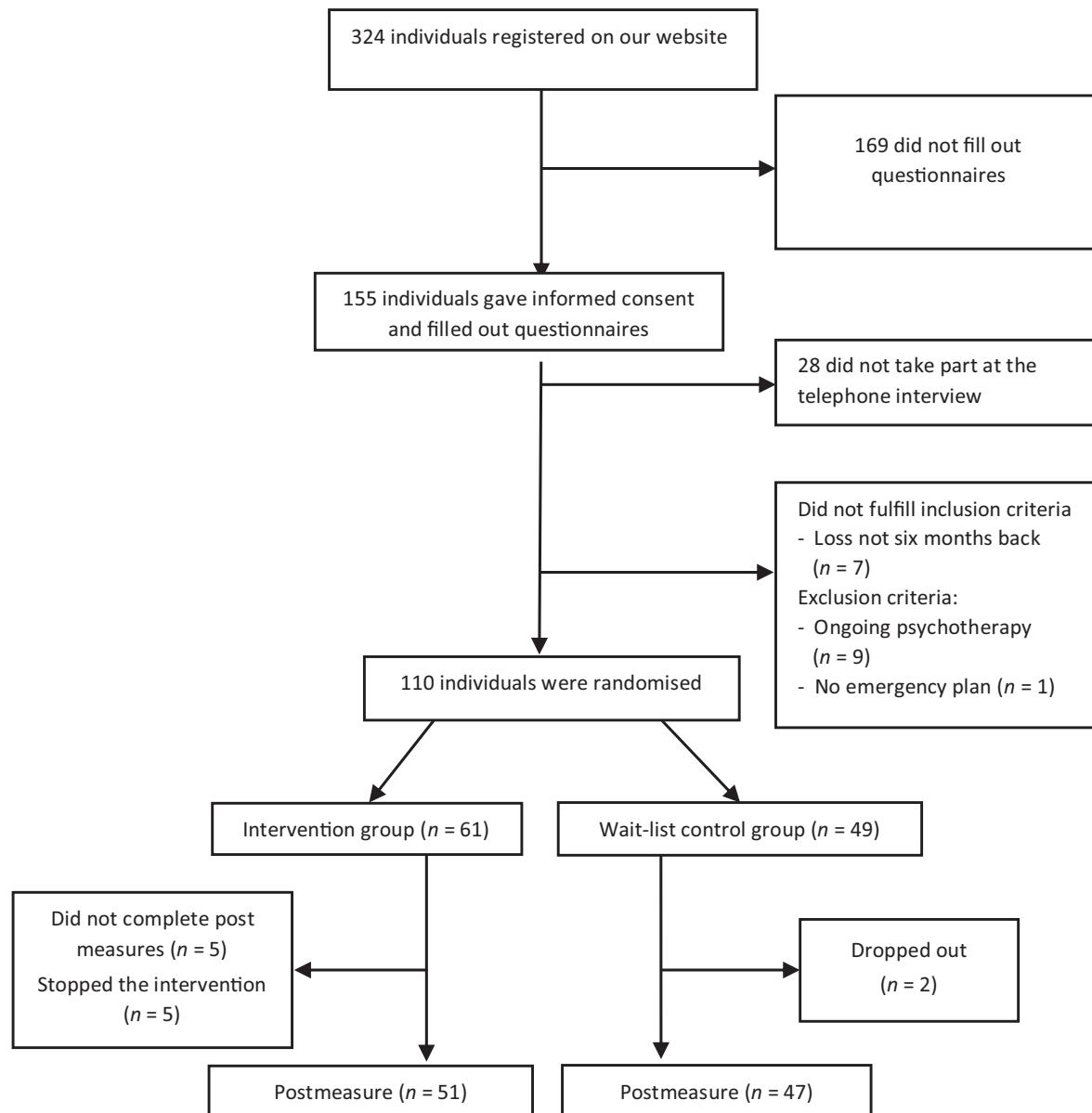


Fig. 1. LIVIA flow chart study design.

prior to completing the questionnaire (Franke, 2000). Answer categories range from 0 = not at all to 4 = very much (Cronbach alpha 0.96).

Secondary outcome measures included the short version of the Embitterment Scale (Znoj and Schnyder, 2014). The six items measured embitterment from 0 = I don't agree to 4 = I agree (Cronbach alpha 0.78–0.84). Furthermore, loneliness was assessed with the De Jong Gierveld Short Scale for Emotional and Social Loneliness (De Jong Gierveld and Van Tilburg, 2010), a six-item scale with answer categories from 0 = no to 5 = yes (Cronbach alpha 0.76–0.79). Life satisfaction was assessed with the German version of the Satisfaction with Life Scale (Diener et al., 1985; Schumacher, 2003). It consists of five items with answer categories from 1 = completely disagree to 7 = completely agree (Cronbach alpha 0.76–0.86).

Eleven items assessed the satisfaction with the intervention, e.g. "How satisfied were you with the support you received with the programme?" Response categories range from 1 = not at all to 4 = very much.

All self-report questionnaires were completed online using Qualtrics (Qualtrics, n.d.).

Baseline measurement was at t0, post measurement t1 was at week 12 after the start of the intervention/the waiting condition, post measurement/follow-up t2 was at week 24 after the start of the intervention (see Fig. 1).

Trained email-supporters assessed the criteria of the DSM-5 diagnosis of a Persistent Complex Bereavement Disorder (American Psychiatric Association, 2013) in the telephone interview. In order to apply these criteria to our study, we assessed the persistence of the symptoms already six months after the loss instead of 12 months and employed the interview to individuals who lost their spouse through separation/divorce.

2.3. Intervention

The guided internet-based self-help "LIVIA" addressed older adults who experienced spousal bereavement or a separation/divorce and sought help for coping with prolonged grief symptoms, psychological distress or adaptation problems in daily life. Participants were encouraged to work through one session a week. The intervention was based on the task model of mourning (Worden, 2009) and the dual-

Table 1
Content of the ten self-help sessions.

1. Psychoeducation	Information about the self-help intervention, grief reactions, emotional reactions after separation or divorce and the treatment of grief.
2. Assessment of current situation	Assessment of emotional reactions after the interpersonal loss, changes in life since and obstacles for a positive adaptation.
3. Fostering positive thoughts and emotions	Information about emotion regulation and cognitive-behavioural strategies for promoting positive thoughts and emotions. Protocols for practising these strategies in daily life.
4. Finding comfort	Suggestions for self-soothing strategies and assignments to promote positive feelings (e.g. diary for positive experiences).
5. Self-care	Assessment of the current physical, emotional and practical self-care, of self-care goals and suggestions for fostering self-care in daily life.
6. Accepting memories and pain	Writing up the story of the loss to integrate painful memories into the autobiographical memory
7. Unfinished business	Writing tasks to identify unfinished business and to find ways how to put issues at rest.
8. Creating a new life without the partner	Identification of changes in daily routine since the loss and sources of support and strengths before and after the loss.
9. Social relationships	Identifying and activating resources in daily life. Information about posttraumatic growth.
10. Redefinition of the relationship to the lost partner	Assessment of current relationships using a sociogram, defining aims regarding relationships, e.g., building up new social contacts, and suggestions how to promote social well-being.
	Writing a farewell letter to the lost partner mentioning the future importance of the loss and how participants will continue their life without their partners.

process model of coping with bereavement (Stroebe and Schut, 1999). The cognitive-behavioural internet intervention consisted of ten text-based sessions, and included (a) information about interpersonal loss and an assessment of the current personal situation; (b) exposure and loss-oriented interventions for accepting memories and pain and addressing unfinished business; (c) resources and restoration-oriented interventions for fostering positive emotions, self-care, positive social relationships and creating a new life without the partner. The intervention was similar for widowed and separated/divorced participants apart from adaptations regarding psychoeducation, accepting memories and telling the story of the loss. Table 1 presents detail of the intervention (see also Brodbeck et al., 2017).

Participants received weekly e-mail support from one of five female Master of Science students who were in their last term of a graduate programme in clinical psychology at the Department of Clinical Psychology and Psychotherapy of the University of Berne, Switzerland. A fully trained psychotherapist supervised the e-mail-supporters. In short half-standardised emails, the supporters (a) acknowledged the participants for their work with the intervention; (b) motivated them to continue their work, and (c) answered questions regarding the intervention or provided help in the case of technical problems. Additionally, participants could contact the supporters via a contact button in the programme.

2.4. Statistical analyses

Analyses were conducted according to the intention-to-treat paradigm. We conducted multilevel mixed-effects models with repeated measures data in SPSS to evaluate the efficacy of the intervention and the stability of the effects. We used restricted maximum likelihood (REML) estimation, which is recommended for small group samples and yields asymptotically efficient estimators for balanced and unbalanced designs (Heck et al., 2010). Mixed-effects model have several advantages. They take into account the dependency of the data and account for the correlation of the repeated measures within individuals. Furthermore, mixed-effects models use all available data of each participant and estimates parameter of missing values (Bell and Fairclough, 2014; Gueorguieva and Krystal, 2004). We computed single models for each outcome variable. Only models with a first order autoregressive covariance structure converged and provided the best model fit based on the Bayesian Information Criteria (BIC).

The pre – post comparisons of all outcome measures included time as a within-group variable, the condition as a between-group variable and an interaction term time by group for cross-level interactions. To analyse the effects of the baseline levels of grief, we computed tertiles for creating groups with low, moderate and high levels of grief. To test whether the intervention was also efficacious for separated/divorced participants and those with a low level of grief, we used within-group

pre-post effect sizes. Group sizes were too small for including cross-level three-way interaction terms in the mixed-effects models to test moderation effects. We calculated a Reliable Change Index (RCI, Jacobson and Truax, 1991) as measure of clinical change. To test the stability of the effects from post-treatment to follow-up, we included only time as within-group factor in the mixed-effects models. Only participants who completed the post-measure were included in the stability analyses. We used t-tests for independent samples for analysing differences between widowed and separated/divorced participants and between dropout and completers. We used χ^2 -tests for comparing the number of participants who showed reliable change in the intervention and the wait-list control group.

As within- and between-group effect sizes, we calculated Cohens d based on the estimated means and the observed pooled standard deviations. We computed effect sizes sensu Morris (2008) for the pre-post comparison for the intervention group and the wait-list group controlling for the baseline measures.

A power analyses specified the sample size needed based on a probability level of 0.05 and a power of 0.80 using a single level repeated measures ANOVA with G*Power (Faul et al., 2009). We assumed a large effect found in previous studies (Eisma et al., 2015; Litz et al., 2014; Wagner et al., 2006) for the comparison of the intervention group and the wait-list control group. The minimum sample size for between factors pre-post comparisons was 40 individuals. Expecting a dropout rate of 40%, we aimed at recruiting at least 56 participants.

3. Results

3.1. Baseline characteristics

Table 2 presents the baseline characteristics of the participants. The sample consisted of 110 German-speaking adults among whom 23% were widowed and 77% were separated or divorced. Mean age was 51 years, 72% of the participants were female. The majority were of Swiss origin (73%) and went to a vocational school (37%) or university (34%). The average time since the event was two years ($M = 2.20$, $SD = 2.90$). About a quarter of the participants (24.5%) reached the B, C, and D criteria of a Persistent Complex Bereavement Disorder in the DSM-5. The participants reported higher levels of grief symptoms than the validation sample of the TRIG-D, which included parents who lost a child (Znoj, 2008). The average total psychopathology score in the BSI was 47.74 ($SD = 30.20$). The average total depression score indicated by the BDI-II was 20.50 ($SD = 10.32$); 30.90% of the participants reported a mild depression, 27.3% a moderate and 15.5% a severe depression.

Table 3 compares widowed and separated/divorced participants at baseline. Compared to widowed participants, participants in the separated/divorced group were significantly younger (48 vs. 63 years) and

Table 2

Demographics and sample characteristics at baseline for the intervention and the waiting control group.

	Total N = 110 n (%)	Intervention group n = 61 n (%)	Wait-list control group n = 49 n (%)
Age (M, SD)	51.33 (14.17)	50.25 (13.32)	52.70 (15.22)
Gender			
Female	79 (72%)	46 (75%)	33 (67%)
Male	31 (28%)	15 (25%)	16 (33%)
Event			
Spousal bereavement	25 (23%)	12 (20%)	13 (26%)
Separation/divorce	85 (77%)	49 (80%)	36 (74%)
Current marital status			
Separated	33 (30%)	17 (28%)	16 (33%)
Divorced	27 (25%)	14 (23%)	13 (27%)
Single	22 (20%)	14 (23%)	08 (16%)
Married/cohabiting	04 (3%)	04 (6%)	—
Widowed	24 (22%)	12 (20%)	12 (24%)
Education			
Compulsory school	02 (2%)	01 (1%)	01 (2%)
Apprenticeship	20 (18%)	15 (25%)	05 (10%)
Secondary II	10 (9%)	03 (5%)	07 (15%)
Technical college	40 (37%)	20 (33%)	20 (42%)
University	37 (34%)	22 (36%)	15 (31%)
Nationality			
Swiss	80 (73%)	47 (77%)	33 (67%)
German speaking countries	24 (22%)	11 (18%)	13 (27%)
Other countries	06 (5%)	03 (5%)	03 (6%)
Years since event (M, SD)	02.20 (2.90)	02.10 (3.40)	02.32 (2.16)
Duration relationship (M, SD)	17.15 (13.83)	15.93 (12.51)	18.72 (15.36)
Persistent Complex Bereavement Disorder ^a	27 (24.5%)	16 (26.2%)	11 (22.4%)

^a Modified criteria: symptoms persistent for 6 instead of 12 months; criteria also applied to separated/divorced participants.

reported a shorter duration of the relationship (14 vs. 29 years). Significantly more separated/divorced participants reached the B, C, and D criteria of a Persistent Complex Bereavement Disorder in the DSM-5. Regarding the primary outcome variables, widowed and separated/divorced participants reported a similar level of grief, as well as depressive and psychopathological distress at baseline. For the secondary outcome variables, separated/divorced participants reported significantly more embitterment and lower life satisfaction as well as a trend towards more loneliness.

3.2. Adherence to treatment and dropout analysis

Participants of the intervention group completed on average eight of the ten modules ($M = 8.05$, $SD = 2.86$), 57.4% completed all modules. Two individuals did not start the self-help intervention (3.3%). Widowed and separated/divorced participants did not differ in terms of adherence ($M_B = 8.50$, $SD_B = 3.00$, vs. $M_D = 7.94$, $SD_D = 2.85$, $t(59) = -0.61$, $p = .548$, $d = 0.19$).

Of the 110 randomised individuals, 98 (89.1%) completed the post measurement, whereas 12 individuals (11%) did not fill out the post measurement (see Fig. 1). Completers and individuals who did not fill out the post questionnaires did not significantly differ in terms of baseline characteristics such demographics or level of distress ($p > .101$). However, participants who did not fill out the post-questionnaires were more often in the intervention group (16.4% vs. 4.1%, $\chi^2(1) = 4.24$, $p = .040$, $phi = 0.20$) and completed significantly fewer sessions than completers ($M_{Do} = 3.60$, $SD_{Do} = 4.03$ vs. $M_C = 8.61$, $SD_C = 2.09$, $t(59) = 5.82$, $p < .0001$, $d = 2.12$). Among those who started at least one session (59 of 61 individuals in the intervention

group), dropout was 13.6%.

At follow-up, 49 of 61 participants in the intervention group completed the questionnaires (80.3%). Dropout at follow-up was associated with younger age ($M_{Do} = 42.50$, $SD_{Do} = 13.47$ vs. $M_C = 52.50$, $SD_C = 12.71$, $t(59) = 2.33$, $p = .023$, $d = 0.78$), lower life satisfaction at baseline ($M_{Do} = 4.53$, $SD_{Do} = 1.12$ vs. $M_C = 3.78$, $SD_C = 1.04$, $t(57) = 2.09$, $p = .041$, $d = -0.71$), more severe grief symptoms at post measurement ($M_{Do} = 3.50$, $SD_{Do} = 0.71$ vs. $M_C = 2.71$, $SD_C = 0.84$, $t(49) = -2.02$, $p = .049$, $d = -0.97$) and fewer completed sessions ($M_{Do} = 4.08$, $SD_{Do} = 3.87$ vs. $M_C = 8.69$, $SD_C = 2.06$, $t(59) = 5.72$, $p < .0001$, $d = 1.87$). These relationships suggest a missing at random (MAR) mechanism, which is a requirement for using mixed-effects models to deal with missing data (Bell and Fairclough, 2014).

3.3. Overall effects at post-treatment

Table 4 presents the results of the mixed-effects model analyses, the observed and estimated means and standard deviations for all outcome variables. The models revealed significant group by time interactions for the primary and secondary outcome measures (b between -0.22 for general psychopathological distress and -0.59 for grief symptoms, $p < .025$). Thus, LIVIA resulted in significant reductions in grief, depression symptoms, psychopathological distress, embitterment loneliness and an increase in life satisfaction compared to the wait-list group. Between group effect sizes controlling for pre-measurement sensu Morris (2008) were large for grief ($d = 0.81$), moderate for depression symptoms ($d = 0.59$) and small for the other outcomes (d between 0.37 and 0.41).

The reliable change index indicated that at post measurement, 27.9% of the intervention group achieved reliable change on grief symptoms, 32.8% on depression symptoms, 45.9% on general psychopathological distress (primary outcomes) and 9.8% improved embitterment, 21.3% loneliness, and 1.6% life satisfaction (secondary outcomes). In the wait-list control group, 12.2% improved grief symptoms, 10.2% depression symptoms, 16.3% general psychopathological distress, 4.1% embitterment, 8.2% loneliness, and 0.0% life satisfaction. Significantly more participants in the intervention group compared to the wait-list control group achieved reliable improvements for all outcome variables ($\chi^2 > 4.92$, $p < .027$) except embitterment and life satisfaction.

Regarding negative effects, RCI showed that in the intervention group, 9.8% deteriorated on general psychopathological distress, 1.6% increased embitterment and 1.6% decreased life satisfaction. In the control group, 4.1% deteriorated on grief, 2.0% on depression or general psychopathological distress, 4.1% on embitterment, 2.0% on loneliness, and 16.3% on life satisfaction. As the number of participants with negative effects was small, we compared participants with any negative effect in any outcome in the intervention group ($n = 8$, 14.8%) and in the wait-list control group ($n = 13$, 27.7%). There was no significant difference between the two groups ($Z = 2.52$, $p = .113$, $phi = 0.16$).

3.4. Treatment satisfaction

Overall, participants reported a high level of satisfaction with the intervention ($M = 3.35$, $SD = 0.52$), lying between “satisfied” and “very satisfied”. There was no significant difference between widowed and separated/divorced participants ($M_B = 3.36$, $SD_B = 0.32$ vs. $M_D = 3.35$, $SD_D = 0.56$, $t(48) = -0.07$, $p = .948$).

3.5. Stability of the effects

Table 4 presents the post-follow-up effect sizes and the observed means and standard deviations of all outcome measures for the treatment group three months after the post measurement. There were no

Table 3

Demographics and sample characteristics at baseline of widowed and separated/divorced participants.

	Widowed n = 25 n (%)	Separated/divorced n = 85 n (%)	Test statistic n (%)	p	ES ^c
Age (M, SD)	63.40 (7.77)	47.74 (13.68)	t(71) = -7.27	.001	1.24
Gender					
Female	20 (80%)	59 (69%)	$\chi^2(1) = 1.07$.301	0.10
Male	05 (20%)	26 (31%)			
Condition					
Intervention group	12 (48%)	49 (58%)	$\chi^2(1) = 0.73$.394	0.08
Waiting control group	13 (52%)	36 (42%)			
Current marital status					
Separated	—	33 (39%)	$\chi^2(4) = 84.75$.000	0.88
Divorced	02 (8%)	25 (29%)			
Single	—	22 (26%)			
Married/Cohabiting	01 (4%)	03 (4%)			
Widowed	22 (88%)	02 (2%)			
Education					
Compulsory school	—	02 (2%)	$\chi^2(4) = 2.63$.622	0.155
Apprenticeship	06 (24%)	14 (17%)			
Secondary II	02 (8%)	08 (10%)			
Technical college	11 (44%)	29 (34%)			
University	06 (24%)	31 (37%)			
Nationality					
Swiss	15 (60%)	65 (76%)	$\chi^2(2) = 3.83$.147	0.19
German speaking countries	09 (36%)	15 (18%)			
Other countries	01 (4%)	05 (6%)			
Years since event (M, SD)	02.09 (1.73)	02.23 (3.17)	U = 950.00	.420	0.15
Duration relationship (M, SD)	29.03 (14.33)	13.57 (11.54)	U = 418.50	.000	0.96
Persistent Complex Bereavement Disorder ^{a,b}	2 (8.0%)	25 (29.4%)	$\chi^2(1) = 4.78$.029	-0.21
Grief ^b (M, SD)	3.51 (0.60)	3.38 (0.73)	t(105) = -0.83	.377	-0.19
Depression ^b (M, SD)	0.95 (0.39)	0.96 (0.50)	t(105) = 0.12	.876	0.02
Psychopathology ^b (M, SD)	0.82 (0.36)	0.88 (0.56)	t(63.4) = 0.60	.548	0.13
Embitterment ^b (M, SD)	1.24 (0.72)	1.69 (0.91)	t(105) = 2.28	.011	0.55
Loneliness ^b (M, SD)	2.61 (0.78)	2.92 (0.86)	t(105) = 1.62	.090	0.40
Life satisfaction ^b (M, SD)	4.80 (0.92)	4.28 (1.13)	t(105) = -2.30	.014	-0.51

^a Modified criteria: symptoms persistent for 6 instead of 12 months; criteria also applied to separated/divorced participants.^b Bootstrap 1000 samples.^c ES = Cohen's *d* for continuous data or Cramer's *V* for ordinal data.

significant post-treatment to follow-up changes for any measure (grief: $b = -0.10$, $t(45.08) = -1.39$, $p = .170$ CI [-0.25, 0.05]; depression symptoms: $b = -0.07$, $t(45.96) = -1.82$, $p = .076$ CI [-0.16, 0.01]; general psychopathological distress: $b = 0.02$, $t(45.35) = 0.44$, $p = .665$ CI [-0.09, 0.14]; embitterment: $b = -0.01$, $t(45.48) = -0.10$, $p = .919$ CI [-0.21, 0.19]; loneliness: $b = -0.01$, $t(46.13) = 0.12$, $p = .906$ CI [-0.23, 0.20]; life satisfaction: $b = 13$, $t(45.71) = 0.96$, $p = .343$ CI [-0.14, 0.40]).

3.6. Efficacy for widowed and separated/divorce participants

Table 5 presents the means and standard deviations at pre, post and follow-up measurement, and the pre-post effect sizes for widowed and separated/divorced participants. Separated/divorced participants showed large effect sizes for an improvement in grief ($d = 0.94$) and depression symptoms ($d = 0.83$), moderate effect sizes for general psychopathology ($d = 0.66$) and loneliness ($d = 0.63$) and a small effect for embitterment ($d = 0.45$). Widowed participants showed a large effect for depression symptoms ($d = 0.80$), moderate effect sizes for grief ($d = 0.62$), loneliness ($d = 0.67$), and embitterment ($d = 0.56$), as well as a small effect for general psychopathological distress ($d = 0.43$). Life satisfaction did not improve among widowed participants. Average effect sizes were 0.61 for separated/divorced and 0.49 for widowed participants.

3.7. Efficacy for participants with low, medium and high levels of grief at baseline

LIVIA had similar effects at low, medium and high levels of grief at

baseline. Almost all within-group pre-post effect sizes apart from life satisfaction were in moderate to large range. Grief and depression showed the strongest effects. Average effect sizes were 0.73 for the low grief group, 0.76 for the medium grief group and 0.67 for the high grief group.

4. Discussion

This is the first randomised controlled trial for prolonged grief symptoms that not only included participants after spousal bereavement, but also after separation or divorce. It established the efficacy of a guided internet-based self-help intervention called LIVIA for prolonged grief symptoms for widowed as well as separated/divorced participants compared to a wait-list control group. Thus, it extends existing knowledge by showing that LIVIA, which was developed based on models for coping with grief after bereavement, was efficacious for participants after separation/divorce. Furthermore, while most previous internet interventions included only participants with severe grief prolonged symptoms, LIVIA was also efficacious for help-seeking individuals with milder prolonged symptoms.

Inclusion criteria encompassed that the loss had to be more than six months before enrolling in the study and that participants were not in a concurrent psychotherapy. In contrast to other studies, we did not include a severity criterion for grief. Nevertheless, at baseline participants were considerably distressed and reported higher levels of grief symptoms than the validation sample of the TRIG-D, which included parents who lost a child (Znoj, 2008). A quarter of the participants reached the B, C, and D criteria of a Persistent Complex Bereavement Disorder of the DSM-5. An at least mild depression reported 73% of the participants

Table 4
Efficacy of LIVIA: intervention versus wait-list control group and stability of the effects.

Domain	Pre-treatment		Post-treatment (observed)		Follow-up (observed)		Follow-up (estimated)		Time \times treatment		Pre-post Within group ^a d_{cohens} , [95% CI]	Between group ^a d_{ppc2} sensu Morris	Post-follow-up ^b
	M (SD)	n	M (SD)	n	M (SD)	n	M (SE)	n	β , $t(df), p$ [95% CI]				
Grief	Treatment	3.49 (0.73)	60	2.79 (0.86)	51	2.79 (0.12)	61	2.67 (0.94)	49	2.68 (0.13)	51	$B = -0.57, t(95.11) = -4.08, p < .001,$ [-0.85, -0.29]	-0.88, [-0.35, 1.40]
		3.33 (0.66)	48	3.22 (0.86)	47	3.20 (0.13)	49					-0.17, [-0.40, 0.74]	-0.12 [-0.43, 0.67]
Depression	Treatment	1.04 (0.53)	61	0.62 (0.50)	51	0.61 (0.07)	61	0.54 (0.48)	49	0.54 (0.07)	51	$B = -0.29, t(95.90) = -4.03, p < .001,$ [-0.44, -0.15]	-0.84, [-0.31, 1.36]
		0.92 (0.43)	49	0.77 (0.50)	47	0.78 (0.07)	49					-0.30, [-0.26, 0.86]	-0.16 [-0.39, 0.71]
Psychopathology	Treatment	0.95 (0.64)	61	0.60 (0.52)	51	0.60 (0.07)	61	0.78 (0.73)	49	0.80 (0.10)	51	$\beta = -0.22, t(98.17) = -2.61, p = .011,$ [-0.38, -0.05]	-0.60, [-0.09, 1.11]
		0.86 (0.51)	49	0.72 (0.44)	47	0.73 (0.07)	49					-0.25, [-0.31, 0.81]	-0.31 [-0.87, 0.24]
Embitterment	Treatment	1.58 (0.85)	61	1.19 (0.90)	51	1.18 (0.13)	61	1.18 (0.91)	49	1.17 (0.13)	51	$\beta = -0.34, t(96.69) = -2.83, p = .006,$ [-0.57, -0.10]	-0.45, [-0.06, 0.95]
		1.66 (0.95)	49	1.57 (1.01)	47	1.60 (0.14)	49					-0.06, [-0.50, 0.62]	-0.02 [-0.53, 0.57]
Loneliness	Treatment	2.89 (0.77)	61	2.43 (0.82)	51	2.39 (0.12)	61	2.42 (0.89)	49	2.41 (0.13)	51	$\beta = -0.33, t(98.52) = -2.27, p = .025,$ [-0.61, -0.42]	-0.63, [-0.11, 1.14]
		2.84 (0.95)	49	2.63 (0.88)	47	2.66 (0.12)	49					-0.20, [-0.37, 0.76]	-0.02 [-0.53, 0.57]
Life satisfaction	Treatment	4.38 (1.14)	59	4.59 (1.16)	51	4.56 (0.16)	61	4.73 (1.17)	49	4.72 (0.17)	51	$\beta = 0.49, t(95.16) = 2.74, p = .007, t(0.14,$ 0.85]	-0.16, [-0.66, 0.35]
		4.43 (1.10)	49	4.20 (1.25)	47	4.15 (0.18)	49					-0.24, [-0.32, 0.80]	-0.12 [-0.66, 0.44]

^a Estimated values.^b Only for participants of the intervention group with a post measure ($n = 51$).

Table 5

Moderator analyses for participants in the intervention group: Efficacy for divorced and bereaved participants and for different levels of grief at baseline.

Measure		Pre-treatment	n	Post-treatment (observed)	n	Post-treatment (estimated)	n	Pre-post within group ^a
		M (SD)		M (SD)		M (SE)		<i>d</i> _{Cohen} [95% CI]
Grief	Divorced	3.48 (0.74)	48	2.73 (0.86)	41	2.73 (0.13)	49	0.94 [0.34, 1.53]
	Widowed	3.52 (0.73)	12	3.02 (0.84)	10	3.03 (0.27)	12	0.62 [-0.54, 1.78]
Depression	Divorced	1.06 (0.55)	49	0.63 (0.51)	41	0.62 (0.08)	49	0.83 [0.25, 1.41]
	Widowed	0.94 (0.46)	12	0.56 (0.46)	10	0.57 (0.15)	12	0.80 [-0.37, 1.98]
Psychopathology	Divorced	0.99 (0.69)	49	0.61 (0.50)	41	0.61 (0.08)	49	0.66 [0.09, 1.24]
	Widowed	0.78 (0.28)	12	0.58 (0.60)	10	0.58 (0.16)	12	0.43 [-0.72, 1.57]
Embitterment	Divorced	1.70 (0.87)	49	1.31 (0.90)	41	1.30 (0.14)	49	0.45 [-0.12, 1.02]
	Widowed	1.06 (0.53)	12	0.68 (0.71)	10	0.71 (0.27)	12	0.56 [-0.56, 1.71]
Loneliness	Divorced	2.95 (0.78)	49	2.48 (0.85)	41	2.44 (0.13)	49	0.63 [0.05, 1.20]
	Widowed	2.63 (0.66)	12	2.23 (0.71)	10	2.18 (0.26)	12	0.67 [-0.49, 1.83]
Life satisfaction	Divorced	4.29 (1.15)	47	4.54 (1.22)	41	4.54 (0.19)	49	-0.21 [-0.78, 0.36]
	Widowed	4.73 (1.06)	12	4.80 (0.94)	10	4.61 (0.38)	12	0.13 [-1.00, 1.26]
Level of grief								
Grief	Low	2.60 (0.42)	17	2.15 (0.69)	15	1.94 (0.15)	17	1.16 [0.13, 2.18]
	Medium	3.41 (0.19)	20	2.67 (0.57)	16	2.69 (0.10)	20	1.70 [0.67, 2.72]
	High	4.21 (0.35)	23	3.31 (0.80)	19	3.45 (0.14)	23	1.23 [0.34, 2.12]
Depression	Low	0.73 (0.40)	17	0.39 (0.28)	15	0.38 (0.11)	17	1.01 [0.00, 2.02]
	Medium	0.98 (0.41)	20	0.57 (0.42)	16	0.57 (0.07)	20	0.99 [0.06, 1.92]
	High	1.31 (0.59)	23	0.78 (0.59)	19	0.76 (0.10)	23	0.93 [0.07, 1.79]
Psychopathology	Low	0.62 (0.37)	17	0.42 (0.24)	15	0.40 (0.11)	17	0.71 [-0.27, 1.69]
	Medium	0.92 (0.49)	20	0.51 (0.30)	16	0.56 (0.07)	20	0.89 [-0.03, 1.81]
	High	1.14 (0.74)	23	0.76 (0.69)	19	0.73 (0.10)	23	0.57 [-0.26, 1.41]
Embitterment	Low	1.24 (0.78)	17	0.83 (0.85)	15	0.87 (0.20)	17	0.43 [-0.53, 1.39]
	Medium	1.53 (0.72)	20	1.10 (0.61)	16	1.12 (0.12)	20	0.61 [-0.28, 1.51]
	High	1.82 (0.92)	23	1.41 (0.95)	19	1.36 (0.18)	23	0.49 [-0.34, 1.32]
Loneliness	Low	2.64 (0.84)	17	2.31 (0.73)	15	2.29 (0.19)	17	0.45 [-0.52, 1.41]
	Medium	2.68 (0.58)	20	2.24 (0.78)	16	2.34 (0.12)	20	0.50 [-0.40, 1.39]
	High	3.19 (0.72)	23	2.56 (0.78)	19	2.39 (0.17)	23	1.07 [0.19, 1.94]
Life satisfaction	Low	4.75 (1.02)	17	5.13 (0.94)	15	5.01 (0.27)	17	-0.27 [-1.22, 0.69]
	Medium	4.40 (1.14)	20	4.60 (0.96)	16	4.61 (0.16)	20	-0.20 [-1.08, 0.68]
	High	4.07 (1.19)	22	4.20 (1.37)	19	4.20 (0.24)	23	-0.10 [-0.94, 0.74]

^a Estimated values.

(Beck et al., 1996). However, psychopathological distress was lower than in treatment seeking Swiss outpatients (Brodbeck et al., 2014).

4.1. Efficacy compared to the wait-list control group

Participants reported high levels of satisfaction with the self-help intervention. Furthermore, dropout among those who started the first session was relatively low with 14%. This is higher than in Wagner et al. (2006) with 8% and similar to Kersting et al. (2013) with 14%. Other internet interventions on prolonged grief symptoms found higher dropout rates (17% in Litz et al., 2014; 24% in Kersting et al., 2011; 46% in Eisma et al., 2015; and 59% in Van der Houwen et al., 2010). The high level of satisfaction with the intervention, the low dropout rate and a completer rate of 57.4% for all sessions indicated that the self-help intervention is feasible and well accepted for widowed and separated/divorced participants.

LIVIA significantly decreased a broad range of outcomes, i.e. grief, depression symptoms and psychological distress (primary outcomes), as well as embitterment, loneliness, and improved satisfaction with life compared to the wait-list control group. Participants maintained these gains over three months after completing the intervention. The largest effects were found for grief and depression symptoms. In contrast, life satisfaction and embitterment were more difficult to improve. This may reflect the fact that LIVIA consisted mainly of components, which were supposed to improve grief and depression, i.e. exposure and loss-oriented interventions for accepting memories and pain and addressing unfinished business, as well as resources and restoration-oriented interventions for fostering positive emotions, self-care, positive social relationships and creating a new life without the partner. Additional components may be needed to improve embitterment. Embittered individuals often perceive their state as caused by others or by a higher hostile force. Cognitive-behavioural interventions could target this persistent focus on injustice by reframing techniques, changing the

perspective or using “wisdom strategies” (Linden et al., 2011).

In this study, the between group effect sizes for grief ($d = 0.81$) and depression ($d = 0.56$) were lower than those in Wagner et al. (2006) ($d = 1.07$ for grief, 0.82 for depression, $N = 51$) and Litz et al. (2014) ($d = 1.10$ for grief, 0.71 for depression, $N = 84$) but higher than those in van der Houwen et al. (2010) ($d = 0.25$ for grief and 0.15 for depression, $N = 757$). Small inconsistent differences were found compared to Kersting et al. (2011) ($d = 0.69$ for grief, $d = 0.53$ for depression, $N = 78$) and Kersting et al. (2013) ($d = 0.56$ for grief, 0.63 for depression, $N = 228$). When computing separate analyses for the low, moderate and high grief groups, the within-group effect sizes were considerably larger due to smaller standard deviations in the three groups than those for the whole sample. Within-group effect sizes were then in the same range as in Wagner et al. (2006) and Litz et al. (2014) who had more restrictive inclusion criteria in terms of severity of grief symptoms.

4.2. Comparison of widowed and separated/divorced participants

At baseline, widowed and separated/divorced participants reported similar levels of grief, depression and psychopathological distress. In spite of the lack of theoretical models and interventions, grief among separated/divorced participants is thus a similarly prevalent emotion as among widowed participants. Furthermore, divorced participants reported significantly higher embitterment, lower life satisfaction and a trend towards more loneliness than widowed participants did. This broader range of negative emotions among separated/divorced participants compared to widowed participants may reflect the more diverse circumstances of a divorce, a more difficult relationship before the separation and ongoing conflicts with the ex-partner. Even though many individuals may cope well with their separation or divorce, the high levels of distress among help-seeking separated/divorced participants and the high response rates illustrate the need to offer interventions for

this group.

Even though the sample size was not large enough for a formal moderation test with a three-way interaction term for treatment*time*event, effect sizes indicate that LIVIA was efficacious for separated/divorced participants (average within-group $d = 0.61$). This is interesting as the theoretical background of LIVIA included models for coping with grief after bereavement and techniques which were used in traditional bereavement interventions. Effect sizes in the group of widowed participants were moderate to large for depression, grief, em- bitterment and loneliness (average within-group $d = 0.49$). However confidence intervals for these effect sizes included 0, indicating that it cannot be ruled out that the effect size in the population is not different from 0. The wide confidence intervals in this group and thus the lower precision of the estimate may reflect the low sample size of widowed participants in the intervention group. Therefore, these results have to be confirmed in other studies with larger samples.

4.3. Efficacy for milder grief symptoms

In line with Currier et al. (2008) and Litz et al. (2014), LIVIA was efficacious for participants with lower grief levels at baseline, suggesting that LIVIA may work as indicated prevention for reducing prolonged grief and depression. This stands in contrast to meta-analyses that concluded that preventive interventions after bereavement are generally not efficacious (Neimeyer, 2000; Wittouck et al., 2011). These divergent results highlight the need to differentiate between universal, selective and indicated prevention in the context of bereavement and divorce. Importantly, we recruited individuals who sought help for coping with the loss of a partner independent of their level of grief. Help-seeking as criterion may be more relevant for the efficacy of a grief intervention than the severity of symptoms which is normally used to distinguish prevention from treatment. One inclusion criteria was, that the loss was six months prior to enrolling to the study. Further research on the prevention of grief should explore the efficacy of preventive intervention offered earlier in the mourning process. Furthermore, dismantling studies should investigate whether confrontation and exposure to the experience of the loss are also necessary (a) for indicated prevention or only for the treatment of severe prolonged grief symptoms and (b) for separated/divorced or only for widowed older adults. The analysis of moderator variables may aid future selective indication and adaptations for different needs.

4.4. Limitations

Several limitations of this study have to be considered. The sample consisted of self-selected individuals who were interested in taking part in an internet-based intervention. The number of widowed participants in the intervention group was rather small. Older widow(er)s who take part in an internet intervention might be a selective group of older adults who are more flexible and interested in new developments. Other widowed older adults might prefer or benefit more from a face-to-face intervention. Furthermore, the randomisation was not performed blockwise and was not stratified by the event spousal bereavement vs. separation/divorce. As the sample size was lower than the recommended size of 200 individuals, the simple randomisation procedure resulted in different sample sizes for the intervention and the wait-list control group. However, we found no significant differences between the two groups at baseline. Another limitation is that we measured outcomes only with self-report questionnaires and did not assess a clinical diagnosis of a Persistent Complex Bereavement Disorder at post measurement. Furthermore, we were only able to examine the stability of the improvements in the intervention group as the wait-list control group received access to the intervention after the 12-week waiting period.

Despite these limitations, the present study shows that the internet-based self-help intervention was beneficial for widowed as well as

separated/divorced individuals. Furthermore, the efficacy for individuals with a lower grief level at baseline suggests that more preventive efforts can be undertaken for help-seeking older adults who do not present severe grief symptoms.

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Declarations of interest

None.

All authors have approved the final article.

Declarations

Ethical Approval and Consent to participate

Ethical approval has been obtained by the Cantonal Ethics committee Berne (BASEC2016-00180). We have obtained informed consent from all participants in the study.

CRediT authorship contribution statement

Jeanette Brodbeck: Visualization, Data curation, Supervision, Formal analysis, Writing - original draft, Validation. **Thomas Berger:** Visualization, Data curation, Supervision, Validation. **Nicola Biesold:** Data curation, Formal analysis, Validation. **Franziska Rockstroh:** Formal analysis, Validation. **Hans Joerg Znoj:** Visualization, Data curation, Supervision, Validation.

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Regular Research Article

One Year Impact on Social Connectedness for Homebound Older Adults: Randomized Controlled Trial of Tele-delivered Behavioral Activation Versus Tele-delivered Friendly Visits

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ABSTRACT

Objectives: Lonely and socially isolated homebound older participants of a randomized trial comparing behavioral activation (BA) versus friendly visiting, both delivered by lay counselors using tele-videoconferencing, were reassessed at 1-year to determine whether benefits at 12 weeks were maintained over time. **Methods:** The study reinterviewed 64/89 (71.9%) participants. **Results:** The positive 12-week impact of tailored BA on 3 indicators of social connectedness (loneliness, social interaction and satisfactions with social support) was maintained, albeit to a lesser degree, over 1 year. The positive impact on depressive symptoms and disability was also maintained. **Conclusions:** The intervention's potential reach and scalability are suggested by several factors: participants were recruited by home delivered meals programs during routine assessments; the intervention was brief and delivered by lay counselors; care delivery by tele-videoconferencing is increasingly common. The 1 year outcomes indicate that brief BA delivered by tele-video conferencing can have an enduring impact on social connectedness. (Am J Geriatr Psychiatry 2021; 29:771–776)

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Highlights

- **What is the primary question addressed by this study?** Does brief behavioral activation tailored for social connectedness and delivered using televideo-conferencing (Tele-BA) by lay counselors for homebound older adults have an enduring impact at one-year follow-up?
- **What is the main finding of this study?** Tele-BA's positive impact on three indicators of social connectedness (loneliness, social interaction and satisfactions with social support), depression, and disability was maintained, albeit to a lesser degree, at 12-month follow-up.
- **What is the meaning of the finding?** Lay-counselor and tele-delivered BA can be an effective intervention to increase social connectedness in isolated and lonely homebound older adults.

OBJECTIVES

The COVID-19 pandemic has thrown the risk and sequelae of social isolation and loneliness in homebound older adults into stark relief. The pandemic, with its "stay-at-home" orders, further isolated older adults who were already homebound for functional/medical reasons.

We previously reported that brief (5-session), tailored behavioral activation (BA) delivered by lay counselors using tele-videoconferencing was a feasible and effective strategy to reduce loneliness and social isolation in homebound older adults at 6 and 12 week follow-up.¹ While the sample purposely excluded individuals with moderate to severe depression, the intervention also reduced mild depressive symptoms. The intervention was compared to friendly visiting, similarly delivered.

As BA is designed to help participants develop enduring skills, we questioned whether the positive impact of the intervention (*tele-BA*) on social connectedness would persist beyond 12 weeks. This report explores the duration of the intervention's effect using 12-month follow-up interviews of study participants.

METHODS

Participants and setting

Participants were home-delivered meal (HDM) clients aged ≥ 50 years in urban Texas or rural New Hampshire who reported loneliness (UCLA Loneliness Scale² ≥ 6) to case managers during their annual HDM assessment, gave oral consent for study

referral, met formal study criteria when assessed by research staff and provided written IRB-approved informed consent. Exclusion criteria included moderate-severe depressive symptoms (Patient Health Questionnaire [PHQ]-9³ score ≥ 10), probable dementia (Blessed Orientation, Memory, and Concentration⁴ [BOMC] > 9), self-reported substance abuse, and active suicidal ideation.

Of 278 referrals, 89 individuals met criteria and were randomized into two RCT arms each receiving 5, 1-hour weekly tele-video sessions of: (1) *Tele-BA* (n = 43); and (2) *Tele-FV*: (n = 46). Study staff provided and/or helped participants set up the videoconferencing equipment. Participants completed baseline, 6-week and 12-week follow-up assessment; for this report, we attempted to recontact all baseline participants for 1-year follow-up.

Intervention: Tele-BA as Treatment Condition and Tele-FV as Active Control

BA is a brief, structured behavioral approach that aims to increase and reinforce healthy behavior (e.g., engaging in meaningful activities aligned with personal values and beliefs) and to decrease depressive behavior (e.g., staying in bed all day). As described elsewhere,⁵ we adapted BA to increase and reinforce social connectedness through coaching and collaborating with participants on strategies to engage in rewarding activities and mitigate barriers to those activities.

Friendly visiting (FV) is a common strategy to provide social contact to isolated older adults. Our *Tele-FV* sessions mirrored traditional FV sessions by engaging participants in conversation and

giving support without direct coaching of coping skill development.

Measures

Social connectedness was assessed by three indicators: loneliness (PROMIS Social Isolation Scale⁶; SIC); social interaction (Duke Social Support Index⁷ [DSSI] subscale) and perceived social support (DSSI subscale). Secondary outcomes included depressive symptoms (PHQ-9) and disability (12-item WHO Disability Assessment Schedule;⁸ WHODAS). At baseline, *Tele-BA* and *Tele-FV* participants did not differ on sociodemographic characteristics or study outcomes.

Analysis

Treatment effects for the SIC, DSSI subscales, PHQ-9, and WHODAS were analyzed in an identical manner. All models were fit using mixed-effects regression models implemented using the lmer function from the lme4 and lmerTest packages using R version 4.0.3 in RStudio 1.4.1103. Mixed models make use of all complete observations. In this study, each observation represents an individual time point. Participants are included if they have data from one or more time points, thus representing the intent-to-treat (ITT) principle in longitudinal data.⁹ The models were estimated using maximum likelihood under the missing at random assumption. Participants were a random variable on which random intercept were estimated (i.e., time points were nested within participant). Models included the pretreatment assessment of the outcome as a covariate and follow-up assessments at 6-, 12-, and 52-weeks were included as outcomes. We assessed four models: (1) an unconditional time (i.e., no time variables), containing only the mean-centered baseline assessment of the outcome, (2) a linear time model, (3) a quadratic time model, and (4) a natural log time model. The four unconditional growth models were compared using the Akaike information criterion (AIC) to determine which model was the best fit to the data. A model whose AIC was lower by 2 or greater than a comparison model was a substantially better model.¹⁰

After the unconditional growth model was established, a dummy variable representing the treatment effect (i.e., 1 if *Tele-BA*; 0 if *Tele-FV*) was

added to the model. Estimated marginal means for both conditions were computed from the final models and pairwise differences between these values were estimated (i.e., *Tele-BA* v. *Tele-FV*) to obtain model-predicted mean differences. The group differences between the estimated marginal means were divided by the pooled standard deviation of the baseline assessment of the outcome to obtain a standardized effect size ($d_{GMA\text{-}raw}$) that is equivalent to traditional standardized mean difference effect sizes (e.g., Cohen's d).

In the first step of establishing the unconditional growth models prior to modeling treatment effects, models with the baseline measure of the outcome as a covariate differed significantly from unconditional means models for each outcome; thus, the baseline measure of the outcome was included in all subsequent models. Next, comparisons of the unconditional growth model with the baseline covariate were compared with three additional unconditional growth models: linear, quadratic, and the natural log. Deviance tests indicated that there were no differences between the unconditional model and the unconditional linear, quadratic, or log models for any of the outcomes, indicating that there was no evidence that models of change across time were a better fit than the unconditional means models which indicates that the outcomes were stable across all three follow-up assessments.

RESULTS

Participant Characteristics

The study successfully reinterviewed 71.9% (64/89) of the original participants at one year; reinterviewed participants did not vary significantly from noninterviewed by study group (*Tele-BA* versus *Tele-FV*), study site (New Hampshire versus Texas), sociodemographic variables, or baseline social connectedness scores. Sample characteristics were: 61.8% female, mean age = 73.9 years, varied race/ethnicity (61.8% white, 18.0% black, 14.6% Hispanic), 68.2% lived alone, 61.3% incomes <\$20,000/year, residents averaged >60 miles from study site and reported, on average, low social connectedness on all indicators. These factors did not vary at baseline by treatment group.

One Year Impact on Social Connectedness for Homebound Older Adults

FIGURE 1. Mean scores over time: Loneliness assessed by PROMIS-L: (range 8–40, higher scores indicate greater perceived loneliness); Social Interaction assessed by Duke Social Support Index Social Interaction Subscale (range 4–12, higher scores indicate more social interaction and less isolation); Mixed effect models over 12 months demonstrated that, Tele-BA participants, compared to Tele-FV, reported lower levels of loneliness ($t[81] = -3.05, p = 0.003$) and higher social interaction ($t[82] = 2.26, p = 0.026$).



Treatment Effects of Tele-BA versus Tele-FV

At one year, *Tele-BA* participants, compared to *Tele-FV*, reported higher social interaction ($t[82] = 2.26, p = 0.026; d_{GMA-\text{raw}} = 0.32$) and satisfaction with social support ($t[83] = 2.31, p = 0.023; d_{GMA-\text{raw}} = 0.29$) and lower levels of loneliness ($t[81] = -3.05, p = 0.003; d_{GMA-\text{raw}} = -0.35$), depression ($t[82] = -3.47, p = 0.001; d_{GMA-\text{raw}} = -0.59$), and disability ($t[83] = -2.90, p = 0.005; d_{GMA-\text{raw}} = -0.40$). As seen in Figure 1 for loneliness and social isolation, the relative greater improvement in all indicators of social

connectedness for *Tele-BA* participants diminished over the course of the year but scores remained better compared to baseline and to *Tele-FV*. The same patterns were found for depressive symptoms. Disability scores continued to decline for *Tele-BA* participants, but not *Tele-FV* over the year.

CONCLUSIONS

The principal finding of this brief report is that the previously described positive 12-week impact

of behavioral activation, tailored to address social connectedness, on homebound older adults was maintained, albeit to a lesser degree, over one year. This positive impact was observed for three indicators of social connectedness (loneliness, social interaction and satisfactions with social support) as well as depressive symptoms and disability. Both BA and the comparison arm (friendly visiting; FV) were delivered by lay counselors using tele-video technology, suggesting their potential scalability.

Strengths of the study include the collaboration with aging services agencies that serve homebound older adults; their capacity to identify and recruit clients who might benefit from the intervention extended the reach and potential scalability of the intervention. Our use of lay counselors also suggests that aging services agencies may be well positioned to provide *tele-BA* themselves. The success in conducting follow-up interviews of 72% of the original sample suggests that participants were satisfied with the experience. The interventions' brevity (5 sessions) also helps their scalability.

An implication of the findings is that while the impact of *tele-BA* was positive, it also declined somewhat beyond the 6 and 12-week follow-up assessments suggesting that booster sessions may further strengthen or maintain its effect. Limitations are the lack of information about clients who may have met study criteria but did not agree to study referral (possibly refusing the intervention and/or research participation), lack of geographic generalizability, and exclusion of people with moderate depressive symptoms who might also benefit from the intervention.

When we started the study, use of tele-video to deliver interventions with homebound older adults had some research evidence but was less common in real-world practice. The COVID-19 pandemic exacerbated the problem of loneliness and isolation, but also hastened the use of tele-video to deliver mental health interventions remotely. These trends coupled with the study findings indicate that using technology to deliver interventions is not only feasible and acceptable but can be used effectively to increase social

connectedness in isolated and lonely homebound older adults. Based on these one-year outcomes, *Tele-BA*'s focus on skill development suggests that such interventions may have an enduring impact.

APPROVALS

The study was approved by the Institutional Review Boards of Dartmouth College/Dartmouth-Hitchcock, and University of Texas at Austin; ClinicalTrials.gov Identifier: NCT04131790

AUTHOR CONTRIBUTIONS

Each of the authors made a substantial contribution to the study conception (Bruce, Choi, Pepin), design (Bruce, Choi, Pepin, Marti), data acquisition (Bruce, Choi, Pepin, Stevens), and/or data analysis (Marti); all authors made a significant contribution to the interpretation of data and to drafting and revising the work critically for important intellectual content. All authors gave final approval of the version to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

DISCLOSURE

Authors express their gratitude toward two community partners, the New Hampshire Coalition of Aging and Meals on Wheels Central Texas, their case managers, and all participants in the study. We appreciate the support of the AARP Foundation, which has identified social connectedness as a research priority.

No disclosures to report for any author.

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Original Investigation | Geriatrics

Effect of Telehealth Treatment by Lay Counselors vs by Clinicians on Depressive Symptoms Among Older Adults Who Are Homebound A Randomized Clinical Trial

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Abstract

IMPORTANCE Older adults who are homebound and have low income have limited access to psychosocial treatments because of their homebound state and geriatric mental health workforce shortages.

OBJECTIVE To evaluate clinical effectiveness of a brief, aging service-integrated, videoconferenced behavioral activation (tele-BA) treatment delivered by lay counselors compared with videoconferenced problem-solving therapy (tele-PST) delivered by licensed clinicians and attention control (AC; telephone support calls).

DESIGN, SETTING, AND PARTICIPANTS This 3-group randomized clinical trial using a randomization prior to consent approach included individuals aged 50 years or older who were homebound and had 24-item Hamilton Depression Rating Scale (HAMD) scores of 15 or greater between February 15, 2016, and April 15, 2019. Tele-BA and tele-PST participants received 5 weekly treatment sessions. Assessments were performed at baseline and 12, 24, and 36 weeks after baseline. Intention-to-treat statistical analyses were performed from January 1, 2020, to February 15, 2020.

INTERVENTIONS Tele-BA participants were taught 5 steps for reinforcing healthy behaviors to improve mood, physical functioning, and social engagement. Tele-PST participants were taught a 7-step approach for problem solving coping skills.

MAIN OUTCOMES AND MEASURES The primary outcome was the 24-item HAMD scores. Response (ie, $\geq 50\%$ reduction in HAMD) and remission (ie, HAMD < 10) rates and effect sizes for clinically meaningful differences were examined. Secondary outcomes were disability, social engagement and activity frequency, and satisfaction with participation in social roles.

RESULTS A total of 277 participants were enrolled, including 193 (69.7%) women, 83 (30.0%) who were Black, 81 (29.2%) who were Hispanic, and 255 (92.1%) with income of \$35 000 or less. The mean (SD) age was 67.5 (8.9) years. Among these, 90 participants were randomized to tele-BA, 93 participants were randomized to tele-PST, and 94 participants were randomized to the AC. Compared with participants in the AC group, participants in the tele-BA and tele-PST groups had significantly higher response and remission rates and medium to large effect sizes (tele-BA: raw growth modeling analysis $d = 0.62$ [95% CI, 0.35 to 0.89]; $P < .001$; tele-PST: raw growth modeling analysis $d = 1.00$ [95% CI, 0.73 to 1.26]; $P < .001$) for HAMD scores. While tele-PST was significantly more effective than tele-BA for reducing HAMD scores ($t_{258} = -2.79$; $P = .006$), there was no difference between tele-BA and tele-PST on secondary outcomes.

Key Points

Question Is tele-delivered behavioral activation (tele-BA) treatment by bachelor's-level lay counselors for older adults who are depressed and homebound with low income clinically effective?

Findings In this randomized clinical trial with 277 participants, tele-BA by lay counselors and tele-delivered problem-solving therapy by licensed clinicians were significantly more effective than telephone support calls in improving depressive symptoms, disability, social engagement and activities, and satisfaction with participation in social roles. Tele-BA was significantly less effective than tele-delivered problem-solving therapy in reducing depressive symptoms, but there were no differences in other outcomes.

Meaning These findings suggest that tele-BA by lay counselors for older adults with low income who are homebound was an effective depression treatment.

Visual Abstract

Invited Commentary

Supplemental content

Author affiliations and article information are listed at the end of this article.

(continued)

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Abstract (continued)

CONCLUSIONS AND RELEVANCE In this randomized clinical trial, participants who received tele-BA by lay counselors achieved statistically and clinically meaningful changes in depressive symptoms. Given shortages of licensed mental health clinicians, tele- and lay counselor-delivered services may help improve access to evidence-based depression treatment for large numbers of underserved older adults.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: [NCT02600754](#).

JAMA Network Open. 2020;3(8):e2015648. doi:[10.1001/jamanetworkopen.2020.15648](#)

Introduction

The number of older adults who are disabled and homebound is increasing. Of Medicare beneficiaries aged 65 years or older, 8.3% were chronically homebound between 2011 and 2017, and 26.2% were at rapid risk of becoming homebound over the 7-year period.¹ Older adults who are homebound (three-quarters of whom are women and one-third of whom are not White) tend to be socioeconomically disadvantaged.² In addition, their rates of depression are 2- to 3-fold higher than their nonhomebound peers.³⁻⁵ While pharmacotherapy is the primary treatment for geriatric depression, its effectiveness is especially low for these older adults, as it does not address their multiple life stressors that are depression risk factors.⁶ Pharmacotherapy has also been found inadequate for treating older adults with persistent depressive disorder with cerebrovascular or neurodegenerative comorbidities.⁷

Our previous randomized clinical trial (RCT)⁸ found that brief, videoconferenced problem-solving therapy (tele-PST) delivered by licensed clinicians was highly effective for older adults with low income who were depressed and homebound. However, given geriatric mental health workforce shortages, a more scalable approach to improving access to depression treatment for these older adults could be to deploy lay counselors.^{9,10} Lay counselor interventions have been found effective for depression prevention and treatment in other countries.^{11,12} Lay counselors, also known as *psychological well-being practitioners*, are critical to the stepped care model of the UK's National Health Service's Improving Access to Psychological Therapies program.^{13,14} In the US, bachelor's-level lay counselor-provided cognitive behavioral therapy (CBT) was as effective as PhD-level expert-provided CBT for older adults with generalized anxiety disorder.^{15,16}

Behavioral activation (BA) is the most widely used lay counselor-provided depression treatment, as its simpler approach compared with more complex treatment modalities (eg, CBT) is well suited for lay counselors without professional mental health training.¹⁷ A large RCT in the UK¹⁷ compared BA delivered by mental health workers without professional training in psychotherapy with CBT delivered by psychotherapists and found that BA was not inferior to CBT in depression, anxiety, and physical health outcomes, while costs were lower and quality-adjusted life-year outcomes were better.

In this RCT, we tested the clinical effectiveness of a brief, videoconferenced BA (tele-BA) delivered by bachelor's-level counselors for older adults with low income who were depressed and homebound. Tele-BA was compared with tele-PST delivered by master's-level clinicians and an attention control (AC) consisting of telephone support calls by research assistants. All interventionists were embedded in a large aging service agency that provides home-delivered meals and case management for older adults who are disabled. The rationales for integrating depression treatment in an aging service agency were that aging service case managers are well situated to identify depression because of their close and supportive contacts with older adults who are homebound and that coordinating depression treatment and case management is necessary for older adults with low income who tend to have multiple comorbid health, financial, and other life stressors.

Study hypotheses were that both tele-BA and tele-PST would be more effective than AC at 12, 24, and 36 weeks after baseline, resulting in lower depressive symptoms (primary outcome), and lower disability, higher social engagement and social activities, and higher satisfaction with social roles (secondary outcomes) and that tele-BA would be less effective than tele-PST, but both would result in clinically meaningful outcomes in terms of response and remission rates and effect sizes.¹⁸ To our knowledge, this is the first RCT to test the effectiveness of aging service-embedded tele-BA by lay counselors for older adults with low income who are homebound. This analysis could have significant implications for training the geriatric mental health workforce in a rapidly aging society and improving access to depression treatment for growing numbers of older adults who are homebound.

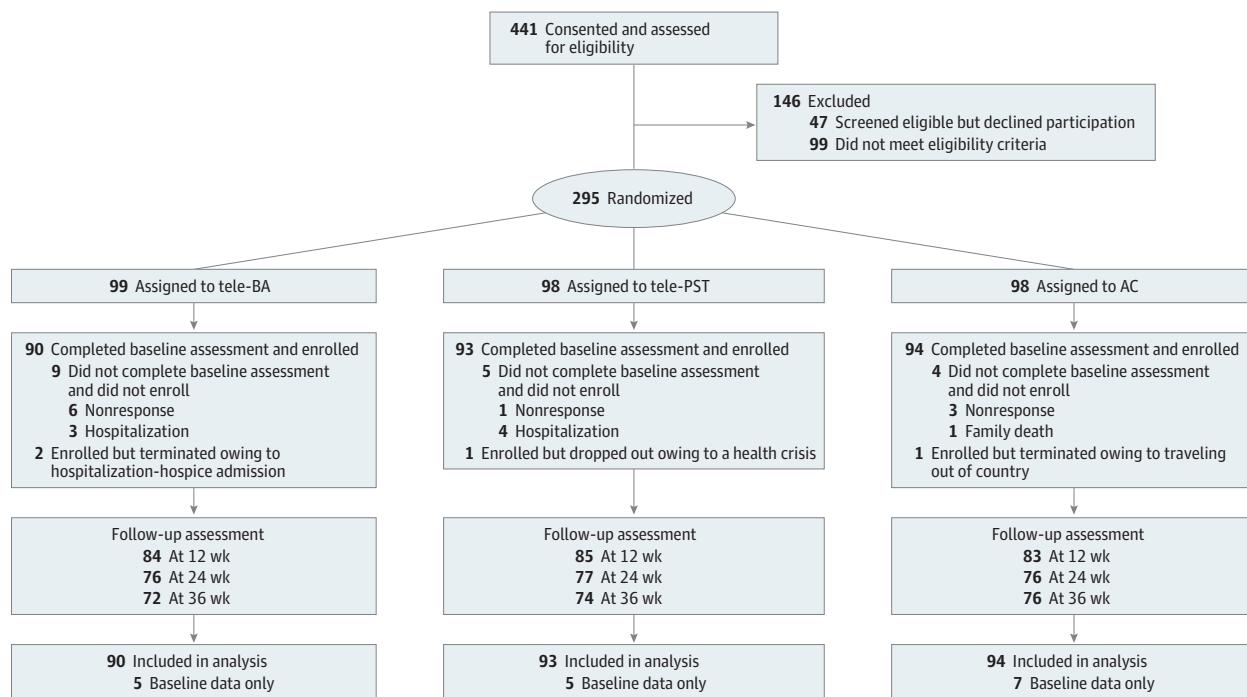
Methods

The University of Texas at Austin institutional review board approved this study. All participants provided written informed consent prior to baseline assessments (Trial Protocol in [Supplement 1](#)). This study is reported following the Consolidated Standards of Reporting Trials ([CONSORT](#)) reporting guideline.

Participants

From February 15, 2015, to April 15, 2019, home-delivered meals and aging services case managers referred 505 individuals aged 50 years or older who were homebound (ie, not able to leave home without others' assistance owing to physical or functional health problems) and who were residing in Central Texas to the study team. Of these individuals, 441 consented to screening, 295 were eligible, and 277 completed the baseline assessment and were enrolled ([Figure 1](#)). Inclusion criteria were moderately severe to severe depressive symptoms (defined as 24-item Hamilton Depression Rating Scale [HAMD]^{19,20} score ≥ 15); self-identifying as non-Hispanic White, Black, or Hispanic (other

Figure 1. Participant Flow Through the Study



racial/ethnic groups were not included because they were <2% of home-delivered meal recipients in the target area); and English or Spanish proficiency. Exclusion criteria were high suicide risk, probable dementia, bipolar disorder, psychotic disorder, substance misuse, antidepressant medication intake or modification within the past 8 weeks, and current participation in any psychotherapy.

Study Design and Procedures

In an RCT design with randomization prior to consent (a preferred public health approach²¹), a random assignment sequence generated by the project's biostatistician (C.N.M.) was used to assign referred, potentially eligible individuals into 3 RCT groups prior to screening: (1) five 1-hour weekly sessions of tele-BA, (2) five 1-hour weekly sessions of tele-PST, or (3) five 30- to 45-minute weekly AC telephone support calls (to control for any social interaction effect). Five sessions meet the PST's 4-session minimum dose.²² Most of the participants in our previous tele-PST study were able to master training content in 4 to 5 sessions.²³

All participants received home-delivered meals and case management services as usual and 2 monthly booster calls. To reflect real-world practice, the tele-BA, tele-PST, or AC interventionist assigned to work with the participant conducted an in-home baseline assessment 1 week prior to treatment or AC calls. Following the baseline assessment, tele-BA and tele-PST participants received tele-delivery equipment (a secure laptop with a Health Insurance Portability and Accountability Act-compliant videoconferencing platform and a 4G wireless card) plus instructions and all written session materials (for psychoeducation, handouts, and worksheets). Only a few participants had their own computers or internet service.

Trained assessors conducted follow-up assessments at 12, 24, and 36 weeks after baseline, mostly at participants' homes, with a few exceptions (eg, telephone assessments for participants no longer residing in the area at time of follow-up). Blinding of treatment conditions was not possible, as we also assessed treatment acceptability for tele-BA and tele-PST participants. However, assessors were not informed of study hypotheses. No tele-BA or tele-PST participants dropped out during treatment owing to dislike of or disagreement with treatment modalities or sessions, but a few participants were terminated during the intervention phase owing to a long-term hospitalization or hospice admission. In total, 25 participants (9.1%) were not assessed at 12 weeks, 48 participants (17.3%) were not assessed at 24 weeks, and 55 participants (19.9%) were not assessed at 36 weeks (Figure 1). Attrition rates did not significantly differ by treatment condition. There were no trial-related adverse events.

Treatments, Interventionist Training, and Fidelity Monitoring

Two lay counselors used a 5-step tele-BA manual that we adapted from the BA manual by Lejuez et al.²⁴ Sessions were designed to decrease behaviors that maintain or contribute to depression and increase or reinforce meaningful, healthy, and enjoyable behaviors for improving mood, physical functioning, and social engagement and activities through goal setting and activity planning. Before working with participants, lay counselors, one with a bachelor's degree in social work, the other with a bachelor's degree in communication, received a 50-hour didactic training in depression, BA, and care coordination and practiced tele-BA sessions with 3 older adults who were homebound and depressed under the supervision of a licensed clinical social worker (L.S.). The licensed clinical social worker also provided clinical supervision and fidelity monitoring of 20% of all sessions during the intervention phase.

Two tele-PST therapists used the 7-step PST-primary care (PC) manual developed for PC patients²⁵ that was successfully used in our previous tele-PST study.⁸ In addition to training in problem-solving skills, PST also addresses anhedonia and psychomotor retardation through behavioral activation.²⁵ The developer of PST-PC (M.H.) provided certification, clinical supervision, and fidelity monitoring of tele-PST therapists following the same procedures as in tele-BA. In AC, research assistants engaged participants, with techniques including genuine regard and adding perspective, and provided nonspecific support.

Measures

Depressive Symptoms

The 24-item HAMD consists of the GRID-HAMD-21 structured interview guide¹⁸ augmented with 3 additional items that assess feelings of hopelessness, helplessness, and worthlessness, as these cognitive processes are thought to be more sensitive to depression in older adults.¹⁹ Consistent with other geriatric depression studies,^{26,27} we defined response as 50% or greater reduction in HAMD score since baseline²⁸ and remission as HAMD score less than 10.

Disability

Disability was measured using the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0)²⁹ to measure degree of in 6 domains of functioning: cognition, mobility, self-care, getting along, life activities, and participation. Scores were measured on a scale of 0 to 4, with 0 indicating no difficulty and 4, extreme difficulty or cannot do.

Social Engagement and Activities

We used the 10-item Social Engagement and Activity Questionnaire (SEAQ) to measure frequency of social engagement and activities that were likely to result from tele-BA or tele-PST. Scores were measured on a scale of 0 to 5, with 0 indicating not at all and 5 indicating every day. We developed the SEAQ based on our previous tele-PST data and validated it with data from this study.³⁰

Satisfaction With Participation in Social Roles

We used the 6-item, Patient-Reported Outcomes Measurement Information System Item Bank version 1.0 Satisfaction with Participation in Social Roles (SPSR)—Short Form 6a³¹ to measure contentment with one's ability to carry out social roles, including regular personal, household, and family responsibilities over the past 7 days. Scores ranged from 0 to 4, with 0 indicating not at all and 4, very much.

Participant characteristics at baseline are reported for descriptive purposes and include sociodemographic characteristics; number of chronic illnesses (range, 0-9; including arthritis; diabetes; hypertension; heart disease; stroke; emphysema, chronic bronchitis, or other lung problems; kidney disease; liver disease; and cancer); impairments in activities (range, 0-6) or instrumental activities of daily living (range, 0-6); pain ratings (range 0-10); antidepressant, anxiolytic, and analgesic medication intake; and Structured Clinical Interview for *Diagnostic and Statistical Manual of Mental Disorders* (Fifth Edition)³² depression diagnosis.

Statistical Analysis

Participant Characteristics at Baseline

Between-group 1-way analysis of variance (with Bonferroni-corrected post hoc tests), χ^2 tests, and t tests were used to assess group differences in participant characteristics. All tests of significance were 2 tailed with a set at .05.

Treatment Effect

With 277 participants (intraclass correlation coefficient, 0.80 and time variable coded as the weeks), power was 0.80 for $d = 0.45$ and 0.95 for $d = 0.60$ for 2-tailed $\alpha < .05$ in examining hypothesized differences between tele-BA and tele-PST compared with AC and between tele-BA and tele-PST. In addition to response and remission rates, treatment effects for each outcome were analyzed in an identical manner. All models were fit using mixed-effects regression models³³ implemented using the *lmer* function from the *lme4*³⁴ and *lmerTest*³⁵ packages using RStudio statistical software version 1.2.5033 (R Project for Statistical Computing). Mixed models are a powerful option for representing the intent-to-treat population in longitudinal data in which participants are missing data at some time points,³⁶ as it includes all time points containing complete data for variables included in a putative model. Linear mixed models were estimated using maximum likelihood under the missing at random

assumption. Models included the pretreatment assessment of the outcome as a covariate and random intercept for participants (ie, time points were nested within participant). All follow-up assessments were included as outcomes. Prior to entering treatment effects in the models, we fit the following models to establish an unconditional growth model: (1) an unconditional time (ie, no time variables) model that contained only the mean-centered baseline assessment of the outcome, (2) a linear time model, (3) a quadratic time model, and (4) a natural log time model. The unconditional growth models were compared using Akaike information criterion values to determine which unconditional growth model was the best fit to the data. Models whose Akaike information criterion was lower than a comparison model by 2 or more were substantially better models.³⁷

After establishing the unconditional growth model, treatment effects, coded using dummy variables for tele-BA and tele-PST (eg, 1 if tele-PST and 0 otherwise), were entered. In addition to the primary models, we examined age at baseline as a covariate and the treatment group by age interaction but found no significant effect. As an additional sensitivity analysis, we fit the final models using log-transformed values of the outcomes and found an identical pattern of significant effects. In the final models, mean estimates across all follow-ups were computed and pairwise differences between the conditions were estimated (ie, AC vs tele-BA, AC vs tele-PST, and tele-PST vs tele-BA) using estimated marginal means implemented with the R *emmeans* package³⁸ to obtain model-predicted mean differences. These mean differences were divided by the pooled baseline SD of the outcome variable to obtain a standardized effect size (raw growth modeling analysis *d*) equivalent to traditional standardized effect sizes for mean differences between groups (eg, Cohen *d*).³⁹

Results

Participant Characteristics at Baseline

Among 277 participants, 193 (69.7%) were women, 83 (30.0%) were Black, and 81 (29.2%) were Hispanic (**Table 1**). The mean (SD) age was 67.5 (8.9) years, and 255 participants (92.1%) had an annual income of \$35 000 or less. Our study cohort closely represented the overall population of individuals in the study area who receive home-delivered meals. Almost two-thirds of participants (172 participants [62.1%]) had persistent depressive disorder and 142 participants (51.3%) were using 1 or more antidepressant medications.

A total of 90 participants were enrolled in tele-BA, 93 participants were enrolled in tele-PST, and 94 participants were enrolled in the AC group. Participants did not differ among groups on HAMD, WHODAS, and SPSR scores at baseline. Groups differed only on age ($F_{2,274} = 4.12$) and SEAQ scores ($F_{2,273} = 9.74$) with tele-PST participants being approximately 3 years younger and reporting higher SEAQ frequency than tele-BA or AC participants.

Treatment Effects

At the 12-week follow-up, tele-PST participants had the highest response rate (51.8% [95% CI, 40.7% to 62.7%]), followed by tele-BA participants (32.1% [95% CI, 22.4% to 43.2%]) and then AC participants (12.0% [95% CI, 6.6% to 21.0%]) ($P < .001$). Remission rates were significantly higher in the tele-BA (29.8% [95% CI, 20.3% to 40.7%]) and tele-PST (35.3% [95% CI, 25.2% to 46.4%]) groups ($P = .52$) compared with AC participants (9.6% [95% CI, 4.9% to 18.2%]) ($P < .001$).

Assessment of longitudinal models based on the intent-to-treat approach indicated that the unconditional time model did not differ from models containing time parameters with the exception of the HAMD model, which exhibited a significant negative linear effect for time ($t_{463} = -2.43$; $P = .02$), indicating a linear decrease in HAMD scores between the 12- and 36-week assessments. Despite the linear time effect, we present the HAMD model without a time parameter for consistency of presentation. Sensitivity analyses indicated that treatment main effects were consistent in models with and without time. The unconditional time model pools the 3 follow-up assessments so that treatment group differences represent the mean group difference across all follow-up assessments.

Compared with participants in the AC group, participants in the tele-BA and tele-PST groups had significantly reduced HAMD scores across all follow-up assessments (tele-BA: estimate, -3.56 [95% CI, -5.09 to -2.03]; $P < .001$; tele-PST: estimate, -5.72 [95% CI, -7.23 to -4.20]; $P < .001$). Scores for WHODAS scores across all follow-up assessments were similarly reduced among the

Table 1. Participant Characteristics at Baseline and Response and Remission at 12-Week Follow-up

Characteristic	No. (%)			
	Tele-BA (n = 90)	Tele-PST (n = 93)	Attention control (n = 94)	P value
Age, mean (SD), y ^a	68.7 (9.5)	65.5 (8.1)	68.4 (8.7)	.02
Sex				
Women	66 (73.3)	63 (67.7)	64 (68.1)	
Men	24 (26.7)	30 (32.3)	30 (31.9)	.66
Race/ethnicity				
Non-Hispanic White	36 (40.0)	46 (44.1)	36 (38.3)	
Non-Hispanic Black	29 (32.2)	28 (30.1)	26 (27.7)	.75
Hispanic	25 (27.8)	24 (25.8)	32 (34.0)	
Living alone	46 (51.1)	42 (45.2)	50 (53.2)	.52
Education				
<High school	21 (23.3)	18 (19.4)	31 (36.2)	
High school diploma	19 (21.1)	11 (11.8)	15 (16.0)	
Some college or associate's degree	31 (34.4)	35 (37.6)	26 (27.7)	.06
Bachelor's degree or higher	19 (21.1)	29 (31.2)	19 (20.2)	
Household income, \$				
≤15 000	49 (54.4)	42 (45.2)	59 (62.8)	
15 001-25 000	22 (24.4)	25 (26.9)	26 (27.7)	.08
25 001-35 000	12 (13.3)	15 (16.1)	5 (5.3)	
≥35 001	7 (7.8)	11 (11.8)	4 (4.3)	
Self-rated financial status				
Just manage to get by	74 (82.2)	77 (82.8)	79 (84.0)	
Have enough to get along, even a little extra	13 (14.4)	15 (16.1)	14 (14.9)	.77
Money is not a problem	3 (3.3)	1 (1.1)	1 (1.1)	
No. of chronic illnesses, mean (SD) ^b	3.6 (1.6)	3.9 (1.6)	3.8 (1.7)	.38
No. of ADL impairment, mean (SD) ^c	1.8 (1.5)	1.9 (1.6)	1.9 (1.6)	.91
No. of IADL impairment, mean (SD) ^c	2.7 (1.3)	3.2 (1.4)	3.0 (1.6)	.36
Pain rating, mean (SD) ^d	5.4 (2.9)	4.8 (2.7)	4.7 (3.2)	.20
Prescription medication intake				
Antidepressant	48 (53.3)	50 (53.8)	44 (46.8)	.57
Antianxiety or sleep	35 (38.9)	39 (41.9)	29 (30.9)	.27
Analgesic	59 (65.6)	62 (66.7)	54 (57.4)	.36
SCID-5 diagnosis				
Major depressive disorder, single episode	16 (17.8)	12 (13.0)	14 (15.2)	
Major depressive disorder, recurrent episode	16 (17.8)	19 (20.7)	22 (23.9)	.70
Persistent depressive disorder, dysthymia	58 (64.4)	60 (65.2)	54 (58.7)	
Unspecified or missing	0	1 (1.1)	2 (2.2)	
Depressive symptoms score, mean (SD) ^e	23.2 (5.7)	22.7 (5.7)	22.9 (5.7)	.75
Disability score, mean (SD) ^f	22.8 (8.0)	23.9 (9.4)	23.0 (9.8)	.71
Social engagement and activities, mean (SD) ^g	11.2 (5.2)	14.3 (6.6)	10.9 (5.7)	<.001
Satisfaction with participation in social roles, mean (SD) ^h	15.0 (6.5)	14.0 (5.9)	14.2 (5.7)	.51
Depressive symptoms at 12 wk, % (95% CI) ⁱ				
Response ^j	32.1 (22.4-43.2)	51.8 (40.7-62.7)	12.0 (6.6-21.0)	<.001
Remission ^k	29.8 (20.3-40.7)	35.3 (25.2-46.4)	9.6 (4.9-18.2)	<.001

Abbreviations: ADL, activities of daily living; IADL, instrumental activities of daily living; SCID-5, Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders (Fifth Edition); tele-BA, tele-delivered behavioral activation treatment by a lay counselor; tele-PST, tele-delivered problem-solving therapy by a clinician.

^a Analysis of variance results Bonferroni-corrected: $F_2 = 4.115$; $P = .02$ (Tele-BA = AC < Tele-PST).

^b Range, 0 to 9.

^c Range, 0 to 6.

^d Range, 0 to 10.

^e Measured using 24-item Hamilton Depression Rating Scale.

^f Measured using 12-item World Health Organization Disability Assessment Schedule.

^g Measured using 10-item Social Engagement and Activity Questionnaire. Analysis of variance results Bonferroni corrected: $F_2 = 9.741$; $P < .001$ (Tele-BA = AC < Tele-PST).

^h Measured using Satisfaction with Participation in Social Roles—Short Form 6a.

ⁱ Measured using the 24-item Hamilton Depression Rating Scale. Includes 84 participants in the tele-BA group, 85 participants in the tele-PST group, and 83 participants in the active control.

^j Response was defined as 50% or greater reduction of HAMD score from baseline. Fisher exact tests of differences were $P = .01$ between Tele-BA and Tele-PST, $P = .003$ between Tele-BA and AC, and $P = .001$ between Tele-PST and AC.

^k Remission was defined as HAMD score less than 10. Fisher exact tests of differences were $P = .52$ between Tele-BA and Tele-PST, $P = .002$ between Tele-BA and AC, and $P < .001$ between Tele-PST and AC.

tele-BA and tele-PST groups compared with the AC group, and scores for SEAQ and SPSR were significantly increased (**Table 2**).

Follow-up means estimated from the mixed models show that HAMD scores decreased in the tele-BA (12.4 [95% CI, 11.3 to 13.5]) and tele-PST (14.6 [95% CI, 13.5 to 15.6]) groups (**Table 3**). While this difference was statistically significant ($P = .006$), tele-BA and tele-PST did not significantly differ on any secondary outcome across all follow-up assessments (**Figure 2**). Compared with the AC group, the effect sizes of the tele-BA group were 0.62 (95% CI, 0.35 to 0.89) for depression, 0.43 (95% CI, 0.21 to 0.65) for disability, -0.51 (95% CI, -0.74 to -0.27) for SEAQ, and -0.47 (95% CI, -0.69 to -0.24) for SPSR, and effect sizes for the tele-PST group were 1.00 (95% CI, 0.73 to 1.26) for depression, 0.42 (95% CI, 0.20 to 0.64) for disability, -0.58 (95% CI, -0.82 to -0.34) for SEAQ, and -0.55 (95% CI, -0.77 to -0.33) for SPSR outcomes.

Table 2. Mixed Model Treatment Effect Parameters for Primary and Secondary Outcome Models

Outcome	Estimate (95% CI)	P value
Depressive symptoms ^a		
Intercept	18.12 (17.05 to 19.19)	<.001
Baseline score	0.60 (0.49 to 0.71)	<.001
Tele-BA vs AC	-3.56 (-5.09 to -2.03)	<.001
Tele-PST vs AC	-5.72 (-7.23 to -4.20)	<.001
Disability ^b		
Intercept	22.21 (20.79 to 23.63)	<.001
Baseline score	0.52 (0.43 to 0.61)	<.001
Tele-BA vs AC	-3.91 (-5.93 to -1.89)	<.001
Tele-PST vs AC	-3.80 (-5.81 to -1.80)	<.001
Social engagement and activities ^c		
Intercept	10.29 (9.31 to 11.26)	<.001
Baseline score	0.45 (0.35 to 0.54)	<.001
Tele-BA v. AC	2.97 (1.59 to 4.35)	<.001
Tele-PST v. AC	3.38 (1.97 to 4.78)	<.001
Satisfaction with participation in social roles ^d		
Intercept	14.54 (13.59 to 15.49)	<.001
Baseline score	0.52 (0.43 to 0.61)	<.001
Tele-BA v. AC	2.81 (1.46 to 4.17)	<.001
Tele-PST v. AC	3.32 (1.98 to 4.67)	<.001

Abbreviations: AC, active control; tele-BA, tele-delivered behavioral activation treatment by a lay counselor; tele-PST, tele-delivered problem-solving therapy by a clinician.

^a Measured using 24-item Hamilton Depression Rating Scale.

^b Measured using 12-item World Health Organization Disability Assessment Schedule.

^c Measured using 10-item Social Engagement and Activity Questionnaire.

^d Measured using Satisfaction with Participation in Social Roles—Short Form 6a.

Table 3. Model-Based Mean Estimates From Mixed Models Across All Follow-Ups, Pairwise Treatment Contrasts, and Standardized Effect Size Estimates

Measure	Estimates across all follow-ups, mean (95% CI)			Treatment condition contrast, t (P value)			Standard effect size (95% CI)		
	Tele-BA	Tele-PST	AC	Tele-BA vs AC	Tele-PST vs AC	Tele-PST vs tele-BA	Tele-BA vs AC	Tele-PST vs AC	Tele-PST vs tele-BA
HAMD	14.6 (13.5 to 15.6)	12.4 (11.3 to 13.5)	18.1 (17.0 to 19.2)	4.58 (<.001) ^a	7.42 (<.001) ^b	-2.79 (.006) ^a	0.62 (0.35 to 0.89)	1.00 (0.73 to 1.26)	-0.38 (-0.64 to -0.11)
WHODAS 2.0	18.3 (16.9 to 19.7)	18.4 (17.0 to 19.8)	22.2 (20.8 to 23.6)	3.81 (<.001) ^c	3.73 (<.001) ^a	0.10 (.92) ^d	0.43 (0.21 to 0.65)	0.42 (0.20 to 0.64)	0.01 (-0.21 to 0.23)
SEAQ	13.3 (12.3 to 14.2)	13.7 (12.7 to 14.7)	10.3 (9.3 to 11.3)	-4.23 (<.001) ^e	-4.72 (<.001) ^e	0.57 (.57) ^f	-0.51 (-0.74 to -0.27)	-0.58 (-0.82 to -0.34)	0.07 (-0.17 to 0.31)
SPSR	17.4 (16.4 to 18.3)	17.9 (16.9 to 18.8)	14.5 (13.6 to 15.5)	-4.08 (<.001) ^e	-4.86 (<.001) ^g	0.74 (.46) ^g	-0.47 (-0.69 to -0.24)	-0.55 (-0.77 to -0.33)	0.08 (-0.14 to 0.31)

Abbreviations: AC, active control; HAMD, 24-item Hamilton Depression Rating Scale; SEAQ, 10-item Social Engagement and Activity Questionnaire; SPSR, Satisfaction with Participation in Social Roles—Short Form 6a; tele-BA, tele-delivered behavioral activation treatment by a lay counselor; tele-PST, tele-delivered problem-solving therapy by a clinician; WHODAS, 12-item World Health Organization Disability Assessment Schedule.

^a df = 256.

^b df = 257.

^c df = 254.

^d df = 253.

^e df = 255.

^a df = 258.

^b df = 259.

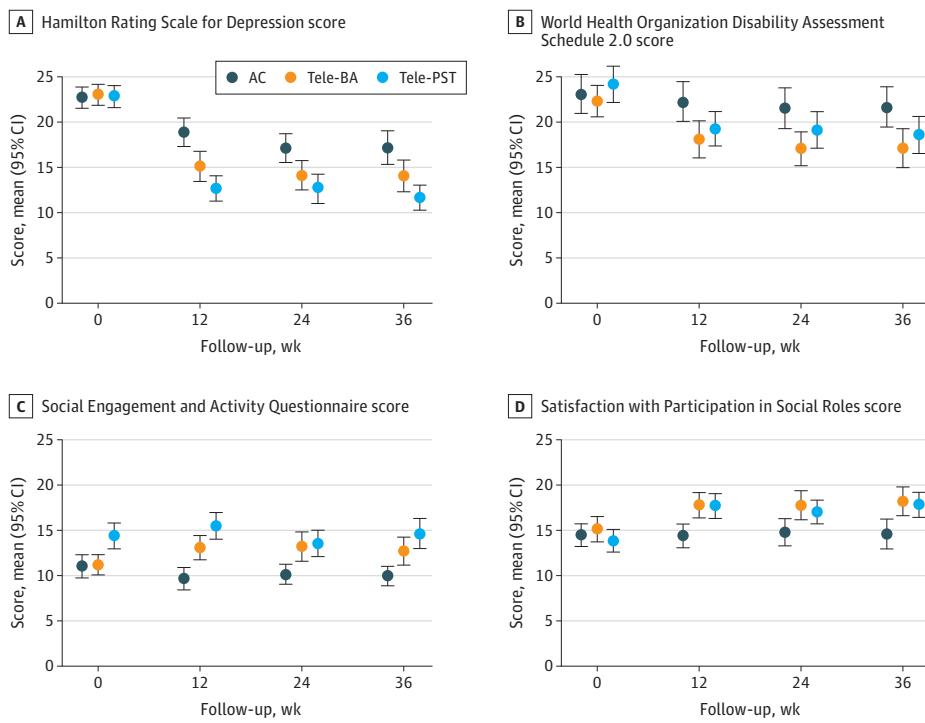
Discussion

The findings of this RCT suggest that lay counselors can deliver evidence-based treatment with fidelity to achieve clinically meaningful changes in depression, disability, and activity levels, with the effects persisting at 36 weeks, among older adults with low income who are homebound. Although tele-BA participants' HAMD score reduction at follow-up was 2 points less than that among tele-PST participants, the 0.62 effect size for tele-BA compared with AC is an impressive outcome, especially since AC participants also experienced some symptom reduction, likely owing to caring social interactions for these socially isolated older adults. This effect size compares favorably to that found in a meta-analysis of 27 psychotherapy trials for late-life depression (0.73 [95% CI, 0.51 to 0.95]).⁴⁰ The 30% remission rate among tele-BA participants also compares favorably with the rate of remission found in a meta-analysis of 51 double-blind RCTs of antidepressants vs placebo for older adults (33.7% vs 27.2%).⁴¹ Furthermore, there was no evidence that the effects of tele-BA significantly differed from those of tele-PST on secondary outcomes. As noted, almost two-thirds of participants had persistent depressive disorder, which tends to be resistant to pharmacotherapy. These positive outcomes show that tele-BA or tele-PST could be offered in combination with or in lieu of pharmacotherapy.

These findings are important given high rates of depression among increasing numbers of older adults who are homebound, which in turn contribute to further physical and mental deterioration and higher health care costs. Especially with the tragic sequelae of coronavirus disease 2019 in nursing homes,⁴² the number of older adults who are homebound is likely to increase more rapidly in the future.

One strength of this study is that participants were racially/ethnically diverse, reflecting the increasing diversity among older adults in the US population. Along with shortages of licensed mental health professionals, older adults who are depressed, homebound, and members of racial/ethnic minority groups and have low income face even more barriers to accessing psychotherapy than their peers who are more socioeconomically advantaged, as they often lack transportation. In-home

Figure 2. Outcome Scores by Treatment Groups Across Assessments



AC indicates attention control; tele-BA, tele-delivered behavioral activation treatment by a lay counselor; and tele-PST, tele-delivered problem-solving therapy by a clinician.

psychotherapy is rarely available. Given these challenges in providing depression treatment to older adults who are at increased risk, aging service-integrated tele-BA by lay counselors is a viable option. During routine screenings, aging service case managers are best situated to identify depression and refer older adults to treatment. Older adults with low income also need case management and other supportive services along with depression treatment, given the many stressors they face owing to limited financial resources and multiple health problems. The Older Americans Act⁴³ stipulates funding for aging-service agencies to provide mental health services directly or to purchase these services. This funding may be used to employ bachelor's-level mental health workers who can expand the reach of mental health services for older adults at increased risk who are not being adequately served by the existing mental health service systems.

Tele-delivery is also necessary because travel costs associated with in-person sessions are significant barriers to treatment scalability and sustainability. The combined costs of the Health Insurance Portability and Accountability Act-compliant videoconferencing platform, which was minimal for each participant, and hot spot internet connection for those without an existing internet connection are significantly less than travel time and mileage reimbursement for interventionists. Therefore, tele-delivery is less resource intensive than in-person delivery regarding travel times and economies of scale (ie, higher interventionist-to-client ratio).

Limitations

This study has some limitations, one of which is that all participants resided in a single, large metropolitan area, which may limit generalizability of the findings to non-metropolitan areas. Another limitation is the lack of a longer (ie, beyond 9 months) follow-up period.

Conclusions

This RCT found that the effects of tele-BA by lay counselors for older adults who were housebound with low income compared favorably with the effects of tele-PST delivered by licensed clinicians. Faced with licensed mental health clinician shortages, tele- and lay counselor-delivered services have potential for easy replication and sustainability and can improve access to evidence-based depression treatment for large numbers of underserved older adults.

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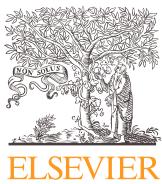
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SUPPLEMENT 1.**Trial Protocol****SUPPLEMENT 2.****Data Sharing Statement**



Regular Research Article

Improving Social Connectedness for Homebound Older Adults: Randomized Controlled Trial of Tele-Delivered Behavioral Activation Versus Tele-Delivered Friendly Visits

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ABSTRACT

Objective: To test the acceptability and effectiveness of a lay-coach-facilitated, videoconferenced, short-term behavioral activation (Tele-BA) intervention for improving social connectedness among homebound older adults. **Methods:** We employed a two-site, participant-randomized controlled trial with 89 older adults (averaging 74 years old) who were recipients of, and initially screened by, home-delivered meals programs. All participants reported loneliness; many reported being socially isolated and/or dissatisfaction with social support. Participants received five weekly videoconference sessions of either Tele-BA or Tele-FV (friendly visits; active control). Three primary outcomes were social interaction (Duke Social Support Index [DSSI] Social Interaction Subscale), subjective loneliness (PROMIS Social Isolation Scale), and DSSI Satisfaction with Social Support Subscale. Depression severity (PHQ-9) and disability (WHODAS 2.0) were secondary outcomes. Mixed-effects regression models were fit to evaluate outcomes at 6- and 12-weeks follow-up. **Results:** Compared to Tele-FV participants, Tele-BA participants had greater increase in social interaction ($t[81] = 2.42, p = 0.018$) and satisfaction with social support ($t[82] = 2.00, p = 0.049$) and decrease in loneliness ($t[81] = -3.08, p = 0.003$), depression ($t[82] = -3.46, p = 0.001$), and disability ($t[81] = -2.29, p = 0.025$). **Conclusion:** A short-term, lay-coach-facilitated Tele-BA is a promising intervention for the growing numbers of homebound older adults lacking social connectedness. The intervention holds promise for scalability in programs that already serve homebound older adults. More

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research is needed to solidify the clinical evidence base, cost-effectiveness and sustainability of Tele-BA delivered by lay coaches for homebound and other older adults. (Am J Geriatr Psychiatry 2020; 28:698–708)

INTRODUCTION

A large body of research, reaching back well over a century to the writings of Durkheim, has documented the positive impact of social connectedness in promoting physical, functional, mental, and cognitive health and reducing healthcare expenditures and mortality.^{1–10} Whether measured by objective indicators of social isolation or subjective indicators such as loneliness or perceived social support, many U.S. older adults report low social connectedness, making it a significant public health concern.^{11,12} These data underscore the importance of identifying feasible and effective strategies to improve social connectedness as a way of enhancing the well-being of older adults in a rapidly aging society.

Given their medical burden and mobility limitations, homebound older adults are at higher risk for social isolation and loneliness than their mobile peers.^{13,14} Especially for low-income homebound older adults, lack of financial resources and transportation along with multiple stressors associated with managing chronic illnesses and disability pose significant barriers to maintaining social contacts and activities.¹⁵ This risk is concerning given the growing number of homebound seniors. Between 2011 and 2017, 8.3% of Medicare beneficiaries aged 65+ were chronically homebound (i.e., left the home ≤1/week in the past month) and 26.2% were at high risk of becoming homebound over the next seven years.¹⁶ Using broader criteria (e.g., needing assistive devices to move around at home or personal assistance outside of one's home), nearly 20% of new enrollees in AARP Medicare Supplement plans in five states were homebound.¹⁷

A wide range of interventions using different mechanisms (e.g., social facilitation, psychotherapy, befriending/visitation, animal intervention, and skill development) have been tested for their impact on social connectedness among older adults. Systematic reviews show a majority of interventions reported some success, although the quality of evidence was generally weak (e.g., few randomized control trials).^{18,19} Most studies have tested in-person group

interventions which pose participation barriers for homebound older adults. However, a recent systematic review¹⁹ found individual-based interventions involving technology, such as videoconference and computer/web-based, show promise for improving social connectedness.

In the present study, we report outcomes of a two-site, participant-randomized controlled trial that tested the effectiveness of videoconferenced, lay-coach facilitated, short-term behavioral activation (Tele-BA) versus videoconferenced friendly visit (Tele-FV) as an active control for largely low-income, socially isolated, but not clinically depressed, homebound older adults in both urban and rural areas. We employed tele-delivery as it is less resource intensive than in-person delivery regarding travel times (for both rural and urban areas) and economies of scale (i.e., higher coach-to-client ratio). Older adults in our previous programs have been receptive to in-home tele-delivery given its convenience and privacy.²⁰ We tested a lay-coach model given current and projected shortage of professional geriatric mental health providers.²¹ Evidence confirms lay-people can deliver psychosocial interventions with efficacy and fidelity, especially interventions like BA that are straightforward and highly structured.^{22,23}

Our primary hypothesis was that Tele-BA would be more effective than Tele-FV in enhancing social connectedness, specifically testing reductions in social isolation (through increased social interaction) and loneliness, and increased satisfaction with social support. We also explored whether Tele-BA, compared to Tele-FV, reduced mild depressive symptoms and disability. Evidence of effectiveness would be important given the potential scalability of such an intervention in aging services and other agencies that care for one of the most vulnerable groups of older adults.

METHODS

Participants and Setting

Study participants were referred to the investigators by case managers of a home-delivered meals

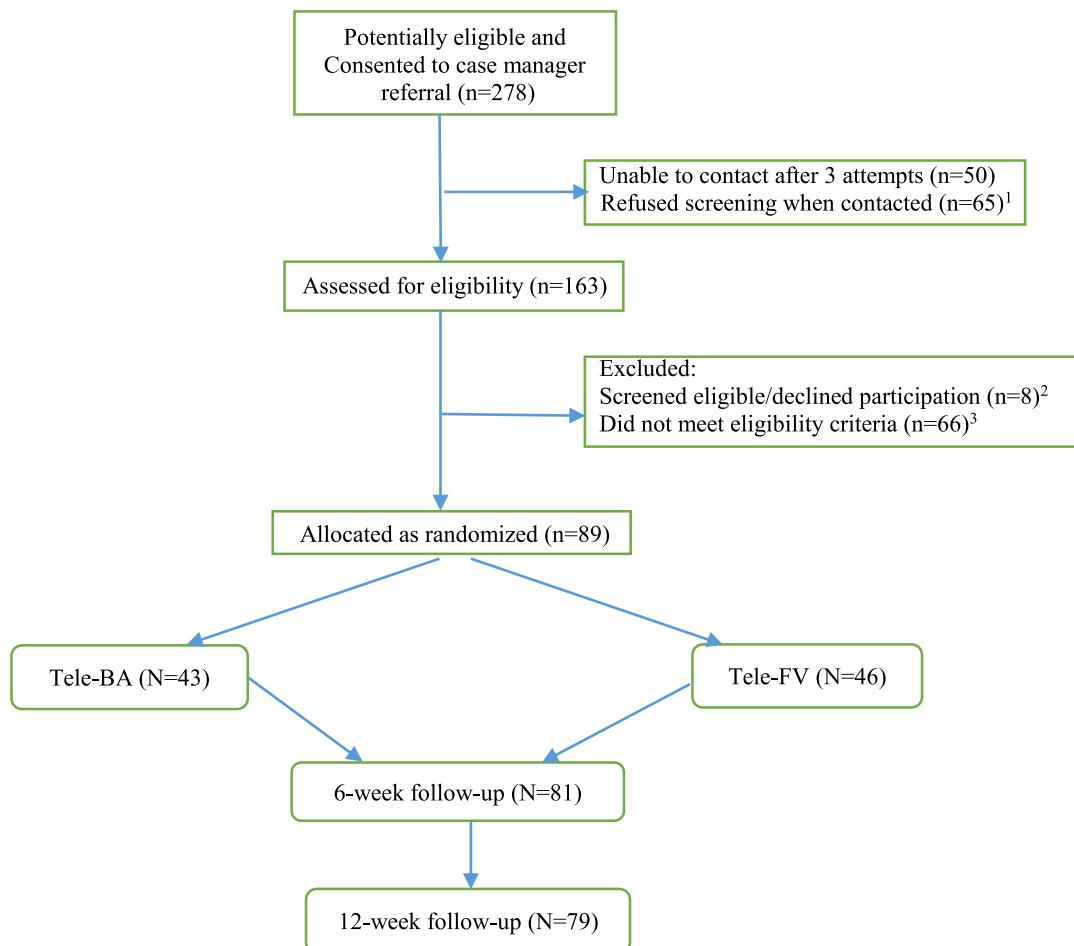
(HDM) program in a large city in Central Texas and a HDM program of the New Hampshire consortium of five aging service agencies that largely serve rural areas. The Older Americans Act requires HDM programs to conduct initial eligibility and annual recertification assessments of each client. Case managers introduced the study to potentially eligible (i.e., cognitively intact, no substance abuse) clients who reported feeling lonely (≥ 6 of the possible score range of 3-9 on the 3-item UCLA Loneliness Scale¹¹). Case managers obtained oral consent from older adults to be contacted by study personnel to receive a detailed description of the study and complete an eligibility screen.

The inclusion criteria were study confirmation of loneliness (UCLA Loneliness Scale¹¹ ≥ 6), no-to-mild

depressive symptoms (Patient Health Questionnaire [PHQ]-9²⁴ <10), and willingness to participate. The age inclusion was 50+ in Texas and 60+ in New Hampshire (consistent with each HDM program's eligibility criteria). The exclusion criteria were probable cognitive impairment (the Blessed Orientation, Memory, and Concentration²⁵ >9), any substance abuse, and active suicidal ideation.

Shown in *Figure 1*, 89 individuals of 278 referrals were both eligible and consented to participate; of the remainder, 50 could not be contacted, 73 declined participation (either before or after screening), and 66 did not meet eligibility criteria. Written informed consent, approved by the authors' institutional review boards, was obtained after study procedures had been fully explained during an in-home visit. Consented

FIGURE 1. CONSORT flow chart.



participants were randomized into two arms, each consisting of 5 weekly, 1-hour videoconferenced sessions: 1) *Tele-BA* ($n = 43$), and 2) *Tele-FV* ($n = 46$).

Participants' Tele-BA or Tele-FV interventionist (i.e., bachelor's-level, lay coach or friendly visitor) conducted an in-home baseline assessment and then demonstrated use of videoconferencing. Videoconferencing equipment (laptop with preloaded HIPAA-compliant videoconferencing platform) was loaned to a majority of participants. Those owning a computer received assistance downloading the videoconferencing platform. Participants without internet access were provided a wireless card (mobile hotspot). For Tele-BA participants, this visit also served as a preparatory session in which they were oriented to Tele-BA session materials (handouts, activity sheets). Tele-FV participants were instructed to think about topics/issues that they would like to discuss during Tele-FV sessions. Follow-up assessments at 6 and 12 weeks were done over telephone by trained assessors. Formal assessments were not conducted during intervention sessions. Given the study's aims, biomarker data were not collected.

Intervention: Tele-BA as Treatment Condition and Tele-FV as Active Control

Tele-BA: BA is a brief, structured behavioral approach that aims to increase and reinforce wellness-promoting behaviors (e.g., engaging in meaningful life activities aligned with personal values) and to decrease depressive behaviors.^{26,27} BA may be especially suitable for improving social connectedness among homebound older adults, as they typically have limited opportunities for social engagement. For this study, we tailored the BA manual²⁷ by modifying the psychoeducation content to focus on social connectedness. Lay coaches worked with participants to identify and schedule values-based, rewarding social engagement and activities and to use strategies to reduce and problem-solve barriers to social connectedness. Participants first reviewed their daily activity patterns, and then chose activity goals, worked on specific implementation plans, and reviewed their successes and areas for improvement. Tele-BA had five sessions, consistent with our previous, highly effective tele-delivered psychotherapy for depressed homebound older adults.²⁰

Tele-FV was chosen as an active comparison as friendly visiting has long been used by agencies to

address loneliness and isolation in their homebound clientele.²⁸ Friendly visitors engaged participants using supportive techniques such as adding perspective and facilitating self-expression,²⁹ without direct coaching of specific coping skill development. For consistency with Tele-BA, we delivered five sessions of friendly visiting through teleconferencing, thereby focusing the trial on the intervention and not its mode of delivery.

Tele-BA and Tele-FV interventionists were initially trained by the second author and received ongoing supervision by the second author (in New Hampshire) and the first author (in Texas). Intervention fidelity was monitored by supervisors' listening to recorded sessions and using a rating scale previously developed and tested by the research team. All Tele-BA and Tele-FV interventionists achieved and maintained satisfactory ratings.

Primary Outcome Measures

For primary outcomes, we assessed three indicators 1) *Objective Social Isolation* using the 4-item Social Interaction Subscale of the Duke Social Support Index (DSSI-I); 2) *Loneliness* using the 8-item PROMIS (Patient-Reported Outcomes Measurement Information System) Social Isolation Scale (PROMIS-L), and 3) *Subjective Satisfaction with Social Support* using the 6-item Social Satisfaction Subscale of the Duke Social Support Index (DSSI-S). Each DSSI item is measured on a 1–3 point scale, with lower scores indicating less social interaction (DSSI-I) and less satisfaction with social support (DSSI-S).³⁰ The PROMIS-L measures perceived isolation and detachment from other people and has been validated for individuals living with chronic conditions.³¹ In this study, we used raw PROMIS-L scores (range: 8–40), with higher scores indicating greater loneliness. All three scales have evidence of reliability and validity with older adults.^{32,33}

Secondary Outcome Measures

Secondary outcomes included depressive symptom severity using the PHQ-9²⁴ and disability using the 12-item World Health Organization Disability Assessment Schedule (WHODAS 2.0).³⁴ The PHQ-9 has demonstrated high internal consistency (>0.90) in previous projects with homebound older adults.³⁵ WHODAS 2.0 covers six domains of disability 1)

cognition; 2) mobility; 3) self-care; 4) getting along; 5) life activities; and 6) participation. Scores range from 0 to 48, with higher scores indicating greater disability.

Analysis

Of 89 participants, 81 and 80 completed intervention sessions and 6-week and 12-week follow-up assessments, respectively. Scales had minimal missing data; only nine items were missing across the five outcomes and no respondent was missing more than one item for any given scale. For summed scales scores, missing items were replaced with the mean of the respondents' nonmissing items on the scale.

Prior to fitting analytic models, Fisher's exact tests and two-sample t tests or Welch two sample t tests, in the event of unequal variances, were used to assess whether there were differences in Tele-BA and Tele-FV participant characteristics, including the baseline assessments of the outcomes. These characteristics were compared across the Texas and New Hampshire sites. All tests of significance were two-tailed with α set at 0.05. We did not adjust reported p values due to fact that we do not consider the outcomes to be redundant thus comprise a family of tests³⁶; nevertheless, we acknowledge that under α levels used herein, 5% of tests represent a Type I error.

Postintervention treatment group difference on the DSSI-I, PROMIS-L, DSSI-S, PHQ-9, and WHODAS were analyzed from an intent-to-treat approach by fitting mixed-effects regression models³⁷ using the lmer function from the lme4³⁸ and lmerTest³⁹ packages implemented using RStudio⁴⁰ 1.0.143. All models included a random intercept for participants and the 6- and 12-week assessments were treated as the dependent variable. Prior to evaluating treatment effects, we fit the following sequence of models for each outcome to establish an unconditional growth model: (a) an unconditional means (i.e., no independent variables) model, (b) the mean-centered baseline measure of the outcome was added as a covariate, and (c) time was added to assess change between 6- and 12-weeks post-intervention. Each model was compared to the prior model in the sequence using a deviance test; if the models differed, the more complex model was selected; if not, the simpler model was retained. After establishing an unconditional growth model, the treatment effect, using a dummy variable

for Tele-BA (i.e., 1 if Tele-BA and 0 if Tele-FV), was added to the model. Following recommendations from Feingold,⁴¹ effect sizes for the treatment effect were estimated by dividing the difference between the estimated means of treatment groups by the pooled baseline standard deviation. The formula generates an effect size ($d_{GMA-raw}$) in a growth model context that is equivalent to traditional effect sizes (e.g., Cohen's d).

RESULTS

Participant Characteristics

Participants averaged 74 ($SD = 9.0$) years; 62% were female; 18% were non-Hispanic Black and 15% were Hispanic; 68% lived alone; 83% had household income less than \$29,000, without any difference between Tele-BA and Tele-FV groups (Table 1). The only site differences were racial/ethnic distribution, activities of daily living (ADL)/instrumental activities of daily living (IADL) limitations, and travel distance/time. Consistent with the demographics of the two states, Texas had a higher proportion of racial/ethnic minorities (55% versus 14% in New Hampshire, $p < 0.001$). Texas participants had more ADL/IADL limitations than New Hampshire participants (4.0 [$SD = 2.1$] versus 2.4 [$SD = 2.4$] in New Hampshire, $t [87] = 3.19$, $p = 0.002$). Because the Texas site was urban while the New Hampshire site was primarily rural, the difference in travel distance (17 [$SD = 9.2$] miles in Texas versus 132 [$SD = 41.5$] miles in New Hampshire, Welch's $t [37] = 16.24$, $p < 0.001$) was also expected.

Outcome Measures at Baseline and Follow-Up: Descriptive Findings

At baseline, Tele-BA and Tele-FV groups did not differ on any outcome measure (Table 2). Their scores reflect medium levels of objective social interaction/isolation (DSSI-I), loneliness (PROMIS-L), and satisfaction with support (DSSI-S). Although participants with clinically significant depression were excluded, many reported mild depression (PHQ-9) and disability (WHODAS). At 6-week follow-up, Tele-BA participants reported more social interaction and less loneliness and depression than Tele-FV participants; and at 12-weeks follow-up, depression scores were lower for

TABLE 1. Participants' Demographic Characteristics and Baseline Scores

	Total Sample N = 89		Tele-BA N = 43		Tele-FV N = 46		p ^a
	%	n	%	n	%	n	
New Hampshire	40.4	36	44.2	19	37.0	17	0.523
Female	61.8	55	67.4	29	56.5	26	0.383
Race/ethnicity							0.196
White	61.8	55	52.5	22	71.7	33	
Black	18.0	16	25.6	11	10.9	5	
Hispanic	14.6	13	16.3	7	13.0	6	
Other	5.6	5	7.0	3	4.3	2	
Marital status							0.170
Married	11.2	10	11.6	5	10.9	5	
Widowed	38.2	34	34.9	15	41.3	19	
Divorced/separated	36.0	32	46.5	20	26.1	12	
Never married	14.6	13	7.0	3	21.7	10	
Living arrangement							0.241
Alone	68.2	60	72.1	31	64.4	29	
Spouse	11.4	10	11.6	5	11.1	5	
Adult child	9.1	8	11.6	5	6.7	3	
Other	11.4	10	4.7	2	17.8	8	
Income							0.555
<\$10,000	19.3	17	16.7	7	21.7	10	
\$10,000-\$14,999	25.0	22	26.2	11	23.9	11	
\$15,000-\$19,000	17.0	15	16.7	7	17.4	8	
\$20,000-\$29,000	21.6	19	16.7	7	26.1	12	
>\$29,000	17.0	15	23.8	10	10.8	5	
	Mean	SD	Mean	SD	Mean	SD	
Age	73.9	9.0	74.4	8.2	73.5	9.8	0.664
ADL/IADL	3.3	2.4	3.7	2.6	3.0	2.1	0.184
Miles from site	63.6	62.6	68.9	68.4	58.5	56.9	0.435
Travel time from site	88.5	67.6	93.6	72.6	83.7	63.1	0.490

ADL/IADL: activities of daily living/instrumental activities of daily living (range 0-12); SD: standard deviation; Tele-BA: tele-delivered behavioral activation; Tele-FV: tele-delivered friendly visit.

^a Probability values for differences between Tele-BA and Tele-FV groups were calculated using Fisher exact tests for categorical variables and two-sample *t* tests (df = 87) for the age, ADL/IADL, miles from site, and travel time from site variables.

Tele-BA participants than Tele-FV participants. Almost all Tele-BA and Tele-FV participants provided extremely positive, unsolicited feedback on how much they enjoyed and drew benefits from the program.

Treatment Effects of Tele-BA Versus Tele-FV

In establishing the unconditional growth models, models containing the baseline measure of the outcome as a covariate were significantly different from the unconditional means model for all outcomes and, thus, the covariate was retained in each model. Models containing a time effect did not differ from the prior model in the sequence except for the PHQ-9 model, which had a significant negative effect for

time ($t [80] = -2.07$, $p = 0.042$) indicating a decrease in PHQ-9 between the 6-week and 12-week assessments. We present all models as unconditional mean models (i.e., not time effects) for a consistent presentation.¹ Because there are no time parameters in the unconditional means model, the intercept, which is the only fixed effect, estimates a grand mean across all outcome measures; when additional parameters, such as treatment groups, are entered, they test for group differences in the grand mean. Results presented in Table 3 show that Tele-BA participants reported higher levels of social interaction ($t [81] = 2.42$, $p = 0.018$) and satisfaction with social support ($t [82] = 2.00$, $p = 0.049$) and lower levels of loneliness ($t [81] = -3.08$, $p = 0.003$), depression ($t [82] = -3.46$,

¹ We did conduct sensitivity analyses to confirm that the reported treatment effects for PHQ-9 were consistent in models that did include time.

Tele-BA for Homebound Older Adults

TABLE 2. Means (SD) of Primary and Secondary Outcomes at Baseline and 6- and 12-Week Follow-Ups

Variable	Baseline	6-Week Follow-Up	12-Week Follow-Up
Social Interaction (DSSI-I)			
Tele-BA	8.2 (SD = 1.6)	8.8 (SD = 1.6)	8.4 (SD = 1.6)
Tele-FV	8.0 (SD = 1.5)	7.8 (SD = 1.6)	7.8 (SD = 1.8)
Loneliness (PROMIS-L)			
Tele-BA	21.0 (SD = 6.2)	17.9 (SD = 6.1)	16.8 (SD = 6.2)
Tele-FV	20.3 (SD = 8.0)	19.6 (SD = 7.9)	20.3 (SD = 8.1)
Satisfaction with Social Support (DSSI-S)			
Tele-BA	13.9 (SD = 3.2)	14.4 (SD = 3.0)	14.9 (SD = 2.9)
Tele-FV	14.1 (SD = 3.1)	14.0 (SD = 3.4)	13.7 (SD = 3.2)
Depression Severity (PHQ-9)			
Tele-BA	7.2 (SD = 4.0)	5.9 (SD = 3.8)	4.7 (SD = 3.0)
Tele-FV	7.7 (SD = 4.5)	8.3 (SD = 4.9)	8.0 (SD = 5.5)
Disability (WHODAS)			
Tele-BA	18.6 (SD = 6.9)	15.6 (SD = 6.5)	15.5 (SD = 7.6)
Tele-FV	16.4 (SD = 8.6)	16.0 (SD = 9.1)	17.1 (SD = 9.1)

DSSI-I: Duke Social Support Index Social Interaction Subscale (range 4-12, higher scores indicate more social interaction and less isolation); PROMIS-L: PROMIS Social Isolation Scale (range 8-40, higher scores indicate greater perceived loneliness); DSSI-S: Duke Social Support Index Satisfaction with Social Support Subscale (range 6-18, high scores indicate greater satisfaction/less dissatisfaction); PHQ-9; Patient Health Questionnaire-9 (range 0-9, based on inclusion criteria; higher scores indicate greater depressive symptom severity); WHODAS: World Health Organization Disability Assessment Schedule 2.0 (range 0-48, higher scores indicate greater disability).

$p = 0.001$), and disability ($t [81] = -2.29$, $p = 0.025$). Effect sizes show that Tele-BA had a medium effect on reducing loneliness and small-to-medium effects on the rest of the outcome measures, all in the expected directions.

DISCUSSION

The principal finding of this randomized controlled trial is that among socially isolated, homebound older adults who were HDM recipients in New Hampshire

and Texas, a short-term behavioral activation delivered by nonclinicians using videoconferencing (Tele-BA) was associated with significantly greater improvements in all three facets of social connectedness at 12-week follow-up compared to customary friendly visiting similarly delivered via videoconferencing (Tele-FV). Tele-BA participants, compared to those receiving Tele-FV, reported greater increases in social interactions (signifying decreases in social isolation) and satisfaction with social support and greater decrease in loneliness. Compared to Tele-FV, Tele-BA was also associated with greater declines in depressive symptoms and disability.

TABLE 3. Mixed Model Parameter for Post-Intervention Differences in Primary and Secondary Outcomes

Outcome	Parameter	Estimate	SE	t	df	p	$d_{GMA\text{-}raw}$
Social Interaction (DSSI-I)	Intercept	7.91	0.16	50.98	81	<0.001	
	Baseline DSSI-I	0.68	0.07	9.29	81	<0.001	
	Tele-BA	0.56	0.23	2.42	81	0.018	0.36
Loneliness (PROMIS-L)	Intercept	19.96	0.61	32.79	81	<0.001	
	Baseline PROMIS-L	0.71	0.06	11.49	81	<0.001	
	Tele-BA	-2.78	0.90	-3.08	81	0.003	-0.60
Satisfaction with Social Support (DSSI-S)	Intercept	13.80	0.31	44.19	81	<0.001	
	Baseline DSSI-S	0.64	0.07	8.83	81	<0.001	
	Tele-BA	0.93	0.46	2.00	82	0.049	0.29
Depression Severity (PHQ-9)	Intercept	8.00	0.50	16.11	82	<0.0001	
	Baseline PHQ-9	0.57	0.09	6.61	81	<0.001	
	Tele-BA	-2.55	0.74	-3.46	82	0.001	-0.39
Disability (WHODAS)	Intercept	17.54	0.77	22.85	81	<0.001	
	Baseline WHODAS	0.74	0.07	9.94	80	<0.001	
	Tele-BA	-2.61	1.14	-2.29	81	0.025	-0.34

SE: standard error.

The medium effect sizes for Tele-BA compared to Tele-FV is worth noting given that FV also provided social support for these isolated older adults.

These findings are important given homebound older adults' greater risk for social isolation and loneliness compared to their mobile peers,^{13,14} which, in turn, increases their risk for further deterioration of physical and mental health. Homebound older adults, many of whom are low income, have limited opportunities for social engagement due to their mobility impairment and report profound loneliness. As explicated below, the study was designed with these factors in mind.

BA is a client/patient-directed and personalized intervention modality in which the client and coach work collaboratively to accomplish goals that the client identifies. For this study, the coaches focused on educating and coaching their clients on social connectedness. While clients could choose any goals they wanted, all chose goals related to increasing meaningful social contact and reducing loneliness. We compared BA to FV as the latter is a commonly used strategy to increase social contact among homebound older adults. We expected that both BA and FV clients would benefit from the extra social contact, but that only BA clients would learn how to overcome barriers to social connectedness and to use skills for maintaining social connectedness over time. Indeed, although participants in Tele-FV reported enjoying the weekly social interactions, any effect of Tele-FV on outcomes were apparently not sustained beyond the sessions.

As shown by decreased depression (PHQ-9) and disability (WHODAS) scores, using BA to enhance social connectedness with homebound older adults appears to have the added benefit of improving mental health and functioning. The impact on depression is noteworthy as most participants entered the study with mild depressive symptoms. While even mild depressive symptoms contribute to poor functional outcomes,⁴² many trials targeting mild depression have had little impact. Often both study arms improve or, as in our own studies of homebound older adults, mild depression persists over time regardless of interventions that have benefited patients with greater depression severity.^{43,44} In this trial where the intervention focused on social connectedness, participants with mild depression saw declines in depression severity.

Given the challenges of providing psychosocial interventions to homebound older adults, the study used strategies for delivering BA that would enhance

potential scalability and sustainability. To address the ever-growing geriatric workforce shortages,²¹ lay coaches were trained and supervised by mental health professionals to provide BA sessions with fidelity. To reduce costs and burden associated with transportation, we utilized videoconferencing, hence Tele-BA. As lack of broadband access in some rural areas and high internet subscription fees in both urban and rural areas are barriers to implementing tele-delivery, we loaned many participants a laptop and wireless card. Almost all participants, regardless of age, showed high acceptance of tele-sessions for its convenience and functionality. The study had minimal dropouts (9%); most occurred in the beginning of the trial in the few cases when, for logistical reasons, the interventionist was not the same person who conducted the in-home assessment and set up the technology. While anecdotal, this finding suggests the importance of in-person contact prior to initiating tele-sessions.

A fundamental barrier to addressing social connectedness among homebound, socially isolated older adults is having a mechanism for identifying individuals who might need such an intervention and an infrastructure for delivering it. As in our studies of depression, we collaborated with existing service (e.g., HDM, home health) providers for homebound seniors. In both states, investigators had developed meaningful research partnerships with their regional aging service providers. Indeed, this study was prompted by our agency collaborators who recognized the importance of depression, but identified low social connectedness as potentially more prevalent, equally devastating, and a problem more readily acknowledged by their clients.

The study has several important limitations. Of note, while strength of the study is that it built on routine screening conducted by the HDM agencies, we had little oversight of the recruitment process. Thus, we cannot estimate the extent to which our sample represents HDM clients who might be eligible for the study. A related limitation was the sample size; while sufficiently large to demonstrate significance for moderate-to-large effect sizes, it was not large enough to assess mediating effects. Sample size reflects several important challenges as discussed below, to recruitment and enrollment of older adults for social connectedness interventions.

First, the relationships among the different facets of social connectedness can be complex, and social isolation does not necessarily indicate loneliness which is

the perceived discrepancy between a person's preferred and actual social relations.⁴⁵ In some cases, especially in rural NH, clients reported that isolation was a chosen way of life and saw no need for an intervention. In other cases, despite evidence of loneliness and even social isolation, some clients who lived in geographic proximity to children and grandchildren were not willing to participate – worrying that their involvement might indicate a failure of relatives to meet their social needs or reinforce their concern of being a burden to family members.

Second, a significant number of referred older adults were not eligible for the study because of moderate-to-severe depressive symptoms. This finding was not surprising given the association between depression and both objective and subjective indicators of social connectedness.⁵ A side benefit of screening was providing an opportunity to refer clients for depression treatment. While depression referral is often not successful, either because services are not available and/or older adults deny needing or wanting treatment,⁴⁶ our study successfully engaged depressed clients by discussing their symptoms in the context of isolation and loneliness and by directly connecting them with a service provider (i.e., "warm handoff"). This success suggests that approaching depression through the lens of social connectedness may be a useful strategy for improving access to care.

In conclusion, we draw the following research, policy, and clinical implications from the study findings. First, short-term Tele-BA is a promising intervention for the growing number of homebound older adults in the population who experience social isolation, loneliness, or dissatisfaction with social support. More research is needed to solidify the clinical evidence base and to evaluate delivery cost and cost-effectiveness. Second, the potential for scalability is enhanced by successful lay-coach-facilitated Tele-BA for homebound and other older adults. Given the challenges of broadband access and cost, however, policy measures to improve feasibility of tele-delivery for underserved population groups will significantly

increase the likelihood of widespread dissemination. Third, given its deleterious health effects, aging-service and healthcare providers should consider routine assessment and interventions to enhance social connectedness especially among homebound older adults. Future research conducted in partnership with community-based aging-service agencies can examine scalability and sustainability.

AUTHOR CONTRIBUTIONS

Each of the authors made a substantial contribution to the study conception (Choi, Pepin, Bruce), design (Choi, Pepin, Marti, Bruce), data acquisition (Choi, Pepin, Stevens, Bruce), and/or data analysis (Marti); all authors made a significant contribution to the interpretation of data and to drafting and revising the work critically for important intellectual content. All authors gave final approval of the version to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

DISCLOSURE

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RESEARCH ARTICLE

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TALKING TIME: A pilot randomized controlled trial investigating social support for informal caregivers via the telephone

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Abstract

Background: Caring for people with dementia at home requires considerable time, organization and commitment. Therefore, informal caregivers of people with dementia are often overburdened. This study examined the effects of the telephone-based Talking Time intervention, which is an approach used to strengthen the psychological health-related quality of life (HRQoL) and social support of informal caregivers of people with dementia living at home.

Methods: This study was a Medical Research Council framework phase two randomized controlled trial. The intervention consisted of a preliminary talk, information booklet, six structured telephone-based support group meetings and a structured written self-evaluation of each support group meeting. The control participants performed their usual individual self-organized care. After completing the data collection, the control group received the Talking Time intervention for fidelity reasons. The primary outcome was the self-rated psychological HRQoL of the informal caregivers, which was measured with the mental component summary of the General Health Survey Questionnaire Short Form 12 (SF-12).

Results: Thirty-eight informal caregivers and their relatives were included and allocated to the intervention or control groups ($n = 19$ each). After 3 months, the Talking Time intervention group demonstrated an increase in the self-rated psychological HRQoL scores, whereas the scores decreased in the control group. However, the standardized effect size of 1.65 (95% Confidence Interval, $-0.44 - 3.75$) was not significant. Additionally, the secondary outcomes demonstrated no significant results. The differences between the groups in most outcomes were in the expected direction. No adverse effects were identified due to the intervention.

Conclusions: The Talking Time intervention is feasible and shows nonsignificant promising results with regard to the self-rated psychological HRQoL. After further adjustment, the intervention needs to be evaluated in a full trial.

Trial registration: Clinical Trials: [NCT02806583](https://clinicaltrials.gov/ct2/show/NCT02806583), June 9, 2016 (retrospectively registered).

Keywords: Dementia, Informal caregivers, Psychosocial interventions, Telephone-based intervention, Social support, Health-related quality of life

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Background

Informal care, which means supervision, support and assistance with daily living activities, is nonprofessional care provided by people in a patient's social environment. Usually, a spouse or a child is the informal caregiver of a person with dementia living at home [1]. Worldwide, informal caregivers remain the cornerstone for care recipients living at home [2], and half of those care recipients are people with dementia [3]. Supporting and caring for people with dementia requires time, personal engagement and day-to-day management. Due to their care responsibilities, informal caregivers of people with dementia often show higher stress levels than caregivers of physically frail elderly people [4] and have an increased risk of becoming physically and mentally ill. The care responsibility increases over the course of dementia, especially as challenging behaviors occur and cognitive abilities decline [5].

Internationally [5], the promotion of social support is a promising intervention approach that is needed due to policy requirements and the limited service offered by statutory long-term care insurance systems, which vary depending on the country-specific health care systems and the principle of subsidiarity. This principle suggests that larger social or state units should have a subsidiary function and perform only those tasks that cannot be performed by a smaller unit. In the case of the German long-term care insurance system, care is a social task that should be primarily performed by the family members of the person who is in need [6].

Available evidence suggests that social support interventions can decrease psychological and nonpsychological burdens [7], decrease social isolation and loneliness [8, 9] and protect against the occurrence of dementia [5, 10]. However, a recent review demonstrated the potential benefit of such intervention while also highlighting the generally inconsistent results. Therefore, this review recommends the performance of further high quality trials [5]. The Talking Time intervention builds on the following definition of social support by Cohen et al. [11]: "*the social resources that persons perceive to be available or that are actually provided to them by nonprofessionals in the context of both formal support groups and informal helping relationships*".

Informal caregivers, who are permanently and continuously responsible for people with dementia, are often unable to participate in social support groups because accessibility in rural regions is poor [15–17], especially when the support is to take place outside the home [12–14]. However, new so-called remote interventions offer the possibility of contacting social support services by means of telephone calls, video calls, online networks and chat forums so that informal caregivers can keep in touch with groups offering the support needed and can

thus overcome the problems of the location where they live [5].

So far, however, there are hardly any such remote interventions for social support services in Germany. In an evaluation study, Jonas and colleagues [12], identified various barriers such as a weak internet connection in rural areas, anxiety about using a computer or concerns about the internet-based intervention in general.

Telephone connections are available in almost every household in Germany and older people are usually experienced in the use of telephone technology. However, there is a lack of offers of telephone-based social support for informal caregivers of people with dementia in Germany. Likewise, no studies have been made on the effectiveness of such telephone-based services available in Germany so far.

Therefore, the purpose of the Talking Time study was to conduct the first evaluation of the feasibility and effectiveness (including possible detrimental effects) of a new intervention based on telephone-based support groups [13]. Contrary to traditional psycho-educative approaches the Talking Time intervention basically follows the principles of theme-centered interaction (TCI) according to Ruth Cohn [14]. That means that the focus of the intervention is the reciprocal exchange of experience between informal caregivers as well as joint learning. In doing so, especially the therapeutic group effect factors "universality of suffering" and "interpersonal learning" by Yalom [15] may influence their HRQoL. This is the main advantage of the TALKING TIME intervention compared to classical approaches in lecture format. Since TALKING TIME is also based on the principles of behavioral therapy [16] (problem solving), and the perspective of systemic therapy [16] (role change), the HRQoL of informal caregivers may also be influenced by these factors.

In this paper, we present the results of the recruitment, retention and effectiveness evaluation.

Methods

Trial design

The Talking Time study was an MRC framework phase two [17] randomized controlled trial [13, 18]. Measurements were assessed at the following two measurement points: T₀ at the baseline and T₁ after 3 months. The effect evaluation was based on an outcome model of the stress process of informal caregivers [19, 20]. The trial also included a continued process evaluation (will be published later) throughout the study [13]. Moreover, the trial followed the CONSORT statement [21].

Recruitment and participants

We used the methodology previously described by Berwig and colleagues [13]. The sample consisted of

informal caregivers and, if possible, the particular relative with dementia. The recruitment was based on several public relations strategies (e.g., information folder, articles in journals of health insurance companies, and announcements disseminated via relevant journals, memory clinics, Alzheimer's disease associations and relevant websites). Those interested in participating in the study were contacted by the recruiting center by telephone or e-mail and verbally informed about the study in a telephone call. In the case of continuing interest in participating, the study information and informed consent declarations were sent to the caregivers and persons with dementia via postal mail. After the signed informed consent forms were returned to the recruiting center, the inclusion and exclusion criteria were assessed via telephone interviews.

The inclusion criteria for the informal caregivers were as follows: (1) The caregiver was living or sharing cooking facilities with the relative with dementia or providing care for a relative with dementia for at least 4 h on at least 4 days a week during the past 6 months. (2) Moreover, the informal caregivers needed access to a telephone connection to be able to participate in the intervention and the data collection procedure. (3) The relative with dementia had to have a medical dementia diagnosed based on the criteria of the International Classification of Diseases 10th Revision (ICD-10) [22]: F00.-* = Alzheimer's disease or related disorders, F01.-* = vascular dementia, or F03.-* = unspecified dementia.

The exclusion criteria for informal caregivers were a lack of German language skills, an actual psychiatric diagnosis (ICD-10: F10.-*, F20.-*, F00 – F09, F05.-*, F06.-*, F08, F09, or F25.-*), and a risk of suicide. Also excluded were people with dementia with the ICD diagnosis (F02.-*), except dementia due to primary Parkinson's disease (F02.3*) and Lewy body disease (F02.8/G31.82).

The abovementioned criteria were determined via telephone and assessed by a psychologist experienced in gerontopsychiatry and psychodiagnostics. If necessary, an uncertain diagnosis was clarified with the physician who made the diagnosis by means of a release from confidentiality.

Sample size

We used the methodology previously described by Berwig et al. [13]. The sample size calculation was based on the effect size for psychological health-related quality of life (HRQoL, primary outcome). Based on the results of one German study [23], we assumed a conservative effect size of 0.70. With consideration of the individual level randomization, a significance level of $\alpha = 0.05$, a two-sided two-sample t-test, a power of 80%, an estimated dropout rate of 20% [24] and the aforementioned effect size, we computed a target sample size of 88

participants (44 in each group). The software used for the sample size calculation was G*Power [25].

Randomization

We used the methodology previously described by Berwig and colleagues [13]. The informal caregivers were block randomized. The blocks had a length of eight, and within a block, four caregivers were allocated to the intervention group, the other four to the control group via a random permutation. These groups of four informal caregivers formed the telephone groups.

The randomization was performed by an external data manager who was not involved in the study intervention or data analysis. Only the team performing the intervention was informed about the group assignments. The statistician and researchers responsible for data collection were blinded regarding the group assignments. The inclusion criteria and baseline data of the study were assessed before the randomization of participants.

Intervention

We used the interventions previously described by Berwig and colleagues [13].

Intervention group

The intervention consists of four fixed components. All components are free of charge and were delivered as follows:

Component 1: telephone-based preliminary talk

Prior to the start of the support groups, the moderator conducted a preliminary telephone conversation, lasting approximately 30 min, with each informal caregiver. Information about the current care situation, information about the group process, and the rules for the group conversation were shared.

Component 2: information booklet

To support the thematic introduction of each support group meeting (component 3), each participant received an information booklet developed for the TALKING TIME study that summarized the information on the themes of self-care, access to assistance and support, communication with healthcare providers, communication with family and friends, and improving interactions with the relative with dementia (see component 3). The information booklet could be used as a workbook (e.g., for notes) during the support group meeting. The booklet also included a checklist regarding technical issues (e.g., "What is the battery status of my telephone?") that needed to be considered prior to each group session.

Component 3: structured telephone-based support groups

Each participant had to participate in six telephone-based support group sessions. The support group sessions had a length of approximately 1 h and were scheduled to occur every 2 weeks over a three-month period. One psychologist who is experienced at working with informal caregivers of people with dementia moderated the support group session (each with four participants). At the beginning of a support group session, one of the mentioned five themes (component 2) was introduced by the moderator. After the thematic introduction, the remaining 45 to 50 min were available for a moderated exchange and discussion among the informal caregivers. At the end of a telephone call, the content of each meeting was summarized by the moderator.

Component 4: structured evaluation of each support group session

After each support group session, a structured questionnaire form was distributed to each support group participant. With this questionnaire, the informal caregivers were directed to reflect on each support group session individually. The completed questionnaire was returned to the moderator of the support group sessions. The moderator used the information to prepare for the following support group session. Moreover, after pseudonymization, the completed questionnaires were used as data sources for the process evaluation.

Control group

The informal caregivers in the control group performed their usual individual self-organized care between T₀ and T₁ without any additional support related to the Talking Time trial. To enhance the study fidelity, the informal caregivers received the Talking Time intervention after the T₁ data collection was complete.

Outcomes

We used the outcomes previously described by Berwig et al. [13]. The primary outcome of self-rated psychological HRQoL was measured with the mental component summary (MCS) of the General Health Survey Questionnaire Short Form 12 (SF-12) [26, 27]. The SF-12 is widely used and has been shown to be feasible for telephone interviews [27].

The secondary outcomes for the informal caregivers were the self-rated physical HRQoL, social support, social conflicts, and caregiver reactions, as well as the proxy-rated challenging behavior of the care recipients with dementia.

The physical HRQoL was assessed with the second domain of the SF-12, the physical component summary (PCS). The PCS and the MCS consist of six items each with scores ranging from 0 to 100; higher scores indicate

higher HRQoL. Both SF-12 component scores have shown adequate reliability and validity [28].

The perceived social support received by the informal caregivers was measured with the Perceived Social Support Caregiving instrument (PSSC, 9 items) [29, 30]. The item scores are summed to obtain a total score, which reflects the level of social support and social conflict; the scores can range from 9 to 45. Higher scores indicate a higher level of social support. The original PSSC has been demonstrated to be sufficiently reliable and valid [29]. This version was guideline-driven [31] and translated into German as a part of the Talking Time project.

The caregiver reactions were rated with the caregiver reaction scale (CRS) [32–34]. The instrument consisted of 24 items reflecting caregiver self-esteem (7 items, range: 7 to 35), lack of family support (5 items, range: 5 to 25), financial impact (3 items, range: 3 to 15), daily schedule impact (5 items, range 5 to 25), and health impact (4 items, range: 4 to 20). Based on the recommendation by Given et al. [32], we computed the subscale scores, where higher scores indicated a stronger impact. The German version of the CRS has been demonstrated to have sufficient internal consistency and structural validity [33]. In general, the secondary outcomes were assessed for the in-depth analysis of the intervention effect and possible adverse effects on the informal caregiver.

The challenging behavior of relatives with dementia was assessed to investigate possible adverse effects on the level of care received. The assessment was based on proxy ratings by informal caregivers using the Neuropsychiatric Inventory-Q (NPI-Q) [35]. This measurement makes it possible to assess the prevalence and severity of the following 12 different behaviors and psychological symptoms related to dementia: 1. delusion, 2. hallucination, 3. depression, 4. anxiety, 5. euphoria, 6. aggression, 7. apathy, 8. disinhibition, 9. irritability, 10. aberrant motor behavior, 11. sleep problems, and 12. eating disorders. The measurement results in a total score ranging from 0 to 36, with higher scores indicating more challenging behaviors. The NPI-Q has been shown to have adequate reliability and validity [35].

As control variables, the cognitive abilities, activities of daily living of the care recipient with dementia and possible social conflicts of the informal caregiver were assessed with the General Practitioner Assessment of Cognition (GPCOG, total score: 0 to 6) [36, 37], the Functional Activities Questionnaire (FAQ, total score: 0 to 30) [38, 39] and the Social Conflict Scale (SCS) [29, 30], respectively. Higher total scores indicate more impaired functions or greater social conflicts.

The sociodemographic data, e.g., age and gender of the informal caregiver and the care recipient with dementia and the care dependency level as defined by the

German long-term care insurance of the person with dementia, were rated with single items. The educational level of the informal caregiver was assessed based on the procedure of the Consortium to Establish a Registry for Alzheimer's Disease (CERAD) [40].

The data collection was performed during telephone interviews. Each participating informal caregiver received a printed TALKING TIME questionnaire with all measures and items prior to the telephone interview. Telephone interviews were initiated by members of the research team, who are registered nurses and academically qualified nursing researchers experienced in data collection procedures in dementia research. A comprehensive instruction manual regarding data collection and data handling was provided to support each interviewer.

Statistical analysis

We used the statistical methods described by Berwig et al. [13]. The baseline characteristics of the participants were described by relative frequencies or means (\pm standard deviations). For the analysis of the primary and secondary outcomes, linear models were used to estimate the expected values of the dependent variables. The dependent variables were defined as the differences in the outcome measurements between the two time points ($T_1 - T_0$).

Within the models, the independent variable was the study group. Based on our outcome model [41], the final model was adjusted to the baseline data of self-rated physical health, perceived social support, caregiver self-esteem, caregiver lack of family support, caregiver impact on finances score, caregiver impact on daily schedule score, caregiver impact on health score and the irritability of the people with dementia. Because of significant baseline differences between the intervention and control groups, the model was further adjusted to the T_0 data of the FAQ score and self-rated psychological HRQoL. The usage of difference scores as the dependent variable and baseline scores as the adjusting variable is frequently applied in cases of baseline differences between groups [42, 43]. Based on missing data, the single challenging behavior irritability was used as a representative variable for challenging behaviors (as a covariate and secondary outcome). Irritability was chosen because a recent review identified irritability as the most burdensome behavior of people with dementia for informal caregivers [44].

For each group (intervention, control), the least square means (model-based estimated) and their 95% confidence intervals (CI-95%)s are presented. This analysis was repeated for all secondary outcomes using the model of the primary outcome analysis. The statistical analysis was performed using R statistical software version 3.2.4 [45]. The statistical analysis was based on the principles of intention-to-treat.

Results

Participant recruitment and retention

Of the 101 informal caregivers screened, 38 informal caregivers were eligible at the baseline and were incorporated into the analysis. Of these participants, 36 completed the study (Fig. 1). Among the excluded caregivers, $N = 33$ did not meet the inclusion criteria, and $N = 30$ declined to participate. Reasons for the refusal were an assumed high burden due to study participation ($N = 4$), lack of time resources for study participation ($N = 6$), different intervention content assumed ($N = 10$), declined participation by care recipient with dementia ($N = 4$) and no contact after the first call ($N = 4$). The reasons for the exclusion of potential study participants were: lack of information regarding the medical dementia diagnosis of the care recipient ($N = 8$), care recipient with a frontotemporal dementia ($N = 6$), care recipient was admitted to a nursing home ($N = 7$), the weekly time spent on care by an informal caregiver was too short ($N = 7$), potential study participants were not the relative of the person with dementia ($N = 2$), the care recipient died during the recruitment phase ($N = 2$) and an psychiatric diagnosis ($N = 1$).

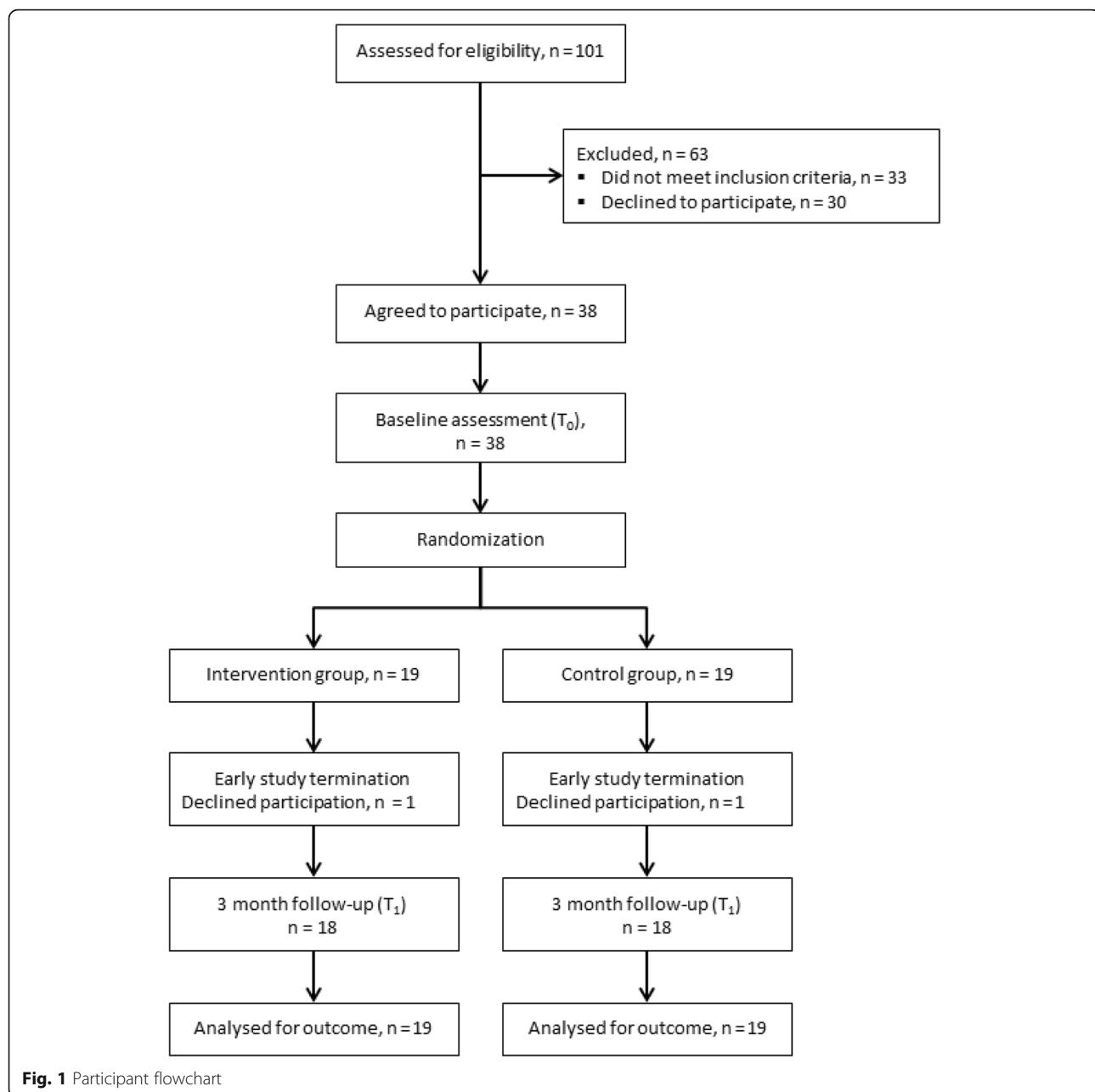
Table 1 presents the baseline characteristics of the informal caregivers and their relatives with dementia. These characteristics were generally comparable between the two groups, with the exception of the self-rated psychological HRQoL for informal caregivers ($p = 0.001$) and the activities of daily living of the care recipients ($p = 0.04$). In addition, the care dependency of the people with dementia in the intervention was overall higher than that in the control group. However, the difference was not significant ($p = 0.07$).

Intervention effects

The overall effect of the primary outcome, i.e., the difference in the self-rated psychological HRQoL scores between T_0 and T_1 as measured with the MCS of the SF-12, demonstrated a standardized effect size of 1.65, CI-95%: -0.44 – 3.75 (covariate adjusted model in Table 2). The model without the covariate adjustment yielded similar results (Table 2: standardized effect size 0.57, CI-95%: -1.47 – 2.60). Figure 2 illustrates the differences between the intervention and control groups.

The MCS score demonstrates a positive difference between T_0 and T_1 of 3.3 in the intervention group (estimated least square mean; CI-95%: -0.9 – 7.6) compared to the control group (-2.4, CI-95%: -7.3 – 2.4).

For the secondary outcomes (Table 3), the adjusted differences between the intervention and control groups, were 0.12 (standardized effect size), CI-95%: CI: -1.98 – 2.21 for self-rated physical HRQoL, 0.43, CI-95% -1.67 – 2.52 for perceived social support, -0.31, CI-95%: -2.41 – 1.79 for caregiver self-esteem, -2.56, CI-95%: -4.65 –



–0.46 for caregiver lack of family support, –0.46, CI-95%: –2.55 – 1.63 for caregiver impact on finances, –0.42, CI-95%: –2.51 – 1.68 for caregiver impact on daily schedule, 0.52, CI-95%: –1.58 – 2.61 for caregiver impact on health and 1.22, CI-95%: –0.87 – 3.31 for irritability of the relative with dementia.

Discussion

The results of the Talking Time trial regarding the change in self-rated psychological HRQoL showed a promising nonsignificant difference between the intervention and control group in the expected direction

(standardized effect size: 1.65 [–0.44–3.75]). The observed nonsignificant group differences for the secondary outcomes occurred in the expected direction, with the exception of the caregiver's self-esteem, the impact on the caregiver's health and the irritability score for people with dementia. Overall, the differences in the secondary outcomes are small and showed no indication of possible adverse effects of the intervention.

To the best of our knowledge, there have been five previous trials regarding the effectiveness of telephone-based social support intervention for informal caregivers and their relatives with dementia. A comparison of these

Table 1 Characteristics of the informal caregivers and the people with dementia at the baseline

T ₀	Intervention group <i>N</i> = 19	Control group <i>N</i> = 19	Test results (<i>p</i> -values)
Informal caregivers of people with dementia			
Sociodemographics			
Age, years	67.4 (± 8.1)	64.1 (± 10.6)	0.29 ^a
Women	16 (84) ^d	16 (84) ^c	0.68 ^a
Number of children			0.11 ^b
1	3 (18)	8 (44)	
2	8 (47)	9 (50)	
3	5 (29)	1 (6)	
5	1 (6)	0	
Level of education			0.26 ^b
No educational degree (max. 7 years of education)	0 (0)	0 (0)	
School-leaving certificate	3 (16)	2 (11)	
General Certificate of Secondary Education	8 (42)	13 (68)	
Higher education entrance qualification (A-levels)	8 (42)	4 (21)	
Level of occupational education			0.73 ^b
None	0 (0)	0 (0)	
Occupational training	12 (63)	13 (68)	
Academic qualification between 3 and 5 years	7 (37)	6 (32)	
Currently employed	6 (32)	8 (42)	0.5 ^a
Living with person with dementia (Yes)	16 (84)	14 (78) ^c	0.6 ^a
Relationship to person with dementia, spouse	12 (63)	11 (61) ^c	0.9 ^a
Outcomes			
Self-rated psychological HRQoL score (0–100)	45.2 (± 8.5)	37.0 (± 10.7) ^c	0.01^a
Self-rated physical HRQoL score (0–100)	45.5 (± 10.3)	44.9 (± 11.9) ^c	0.87 ^a
Social support score (9–45)	28.5 (± 9.3)	23.6 (± 9.3)	0.12 ^a
Social conflict score (3–15)	6.3 (± 3.7)	6.7 (± 3.6)	0.76 ^a
Caregiver Reaction			
Caregiver self-esteem (7–35)	27.2 (± 4.8)	25.1 (± 5.5) ^d	0.22 ^a
Lack of family support (5–25)	13.4 (± 5.6)	13.2 (± 4.0)	0.92 ^a
Impact on finances (3–15)	7.6 (± 3.3)	8.3 (± 2.8)	0.49 ^a
Impact on daily schedule (5–25)	18.6 (± 3.6)	18.2 (± 2.4)	0.71 ^a
Impact on health (4–20)	10.5 (± 2.6)	11.2 (± 3.2) ^c	0.51 ^a
People with dementia			
Sociodemographics			
Age, years	76.3 (± 8.3) ^c	76.0 (± 8.0) ^c	0.9 ^a
Women	4 (22) ^c	8 (44) ^c	0.16 ^a
Years living with dementia diagnosis	6.8 (± 5.2) ^c	6.2 (± 12.4) ^c	0.85 ^a
Care dependency level ^e			0.07 ^b
None	3 (17)	5 (28)	
1	2 (11)	7 (39)	
2	10 (56)	3 (17)	
3	3 (17)	3 (17)	

Table 1 Characteristics of the informal caregivers and the people with dementia at the baseline (Continued)

T ₀	Intervention group N = 19	Control group N = 19	Test results (p-values)
Informal caregivers of people with dementia			
Cognition (6–0)			0.28 ^b
= 0	14 (78)	11 (61)	
≥ 1	4 (22)	7 (39)	
Activities of daily living score (0–30)	26.2 (± 6.2) ^c	21.6 (± 7.0) ^c	0.04 ^a

Data are the mean (SD) or number (%)

^a ANOVA^b Chi-squared test^c One missing^d Two missing^e As determined by expert raters of the medical service of the statutory long-term care

trials with the Talking Time study is limited because previous trials were heterogeneous in terms of design, intervention and outcome measurements [46–50]. Our study can be best compared with the design and intervention of two studies [47, 49]. Similar to the Talking Time intervention, the CONNECT intervention [49] was based on the Reach II study [50]. In the two-armed, randomized controlled trial by Martindale-Adams et al. [49], no effects were observed on patient behaviors, care burden, depression, and general well-being after twelve months. Informal caregivers participated in 15

structured telephone-based support group sessions, while others were provided with written information. The caregivers participated in sessions biweekly for the first 2 months and monthly thereafter for 1 year. Compared to the Talking Time intervention, the number of CONNECT support groups was higher, but the time period between the group sessions was longer after the first 2 months. The recruitment took place in one Veterans Affairs medical center via information leaflets placed in the center and others that were mailed to possibly relevant patients [49]. The authors mentioned no

Table 2 Intervention effects on the informal caregiver with regard to the primary outcome based on an intention-to-treat analysis (adjusted and not adjusted for covariates at the baseline)

Overall n = 38 informal caregivers	Difference between T ₁ and T ₀
Adjusted for covariates ^a	Estimated score [95% CI]
Self-rated psychological HRQoL score (0–100, MCS, primary outcome)	
Intervention group (n = 17)	3.3 [-0.9–7.6]
Control group 1 (n = 14)	-2.4 [-7.3–2.4]
Effect size ^b	5.77 [-1.53–13.07]
Standardized effect size ^c	1.65[-0.44–3.75]
Covariates for adjustment: regression parameter [95% CI]	
PCS score	0.1 [-0.3–0.5]
PSSC-Score	0.1 [-0.3–0.5]
CRS self-esteem score	-0.3 [-1.2–0.7]
CRS lack of family support score	-0.2 [-0.8–0.5]
CRS impact on finances score	0.3 [-0.9–1.5]
CRS impact on daily schedule score	-0.7 [-2.1–0.7]
CRS impact on health score	-1.2 [-3.1–0.7]
MCS score (baseline)	-0.5 [-1.0–0.0]
NPI-Q irritability score	0.9 [-2.8–4.7]
FAQ score	-0.1 [-0.8–0.6]
Not adjusted	
Self-rated psychological HRQoL score (0–100, MCS, primary outcome)	
Intervention group 2 (n = 18)	1.21 [-3.03–5.44]
Control group 1 (n = 17)	-0.48 [-4.84–3.87]
Effect size ^b	1.69. [-4.39–7.77]
Standardized effect size ^c	0.57[-1.47–2.60]

^a Covariates: physical component score, caregiver self-esteem, caregiver lack of family support, caregiver impact on finances, caregiver impact on daily schedule, caregiver impact on health, perceived social support, irritability, functional activities, mental component score

^b Effect size: computed as difference in estimated scores

^c Standardized effect sizes: computed as difference in estimated scores divided by standard deviation

CI-95% confidence interval 95%, Estimated score model-based estimated least square means, MCS Mental Component Summary, PCS Physical Component Summary, PSSC Perceived Social Support Caregiving, CRS Caregiver Reaction Scale, NPI-Q Neuropsychiatric Inventory – Q, FAQ Functional Activities Questionnaire, QoL-AD Quality of Life Alzheimer's Disease scale, NPI-NH Neuropsychiatric Inventory

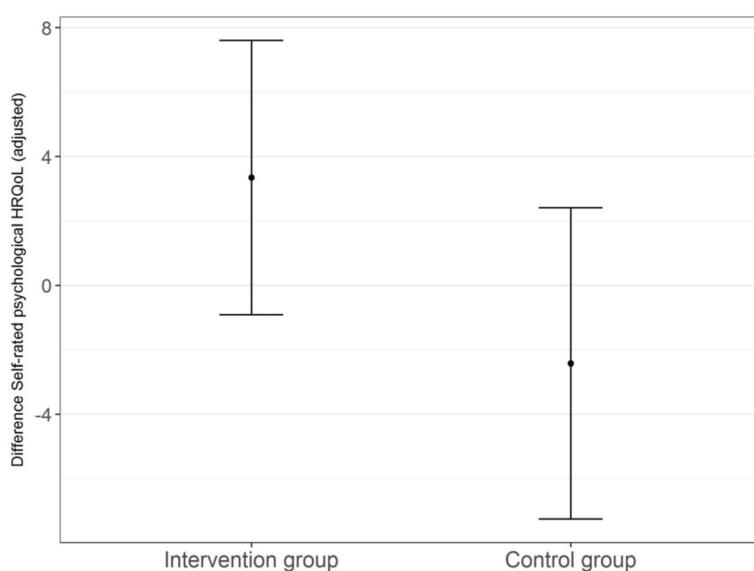


Fig. 2 Differences in self-rated psychological HRQoL scores (estimated least square means; CI = 95%) in the intervention and control groups between T_1 and T_0 , adjusted for covariates

recruitment or retention difficulties and had an inclusion rate of 48% (based on the number of screened persons) and a rate of participants who were lost to follow-up of 10% [49]. In that study, inclusion criteria concerning the living situation of the informal caregivers and the care provided each week were applied [49]. In contrast to the Talking time study, this protocol did not result in recruitment challenges.

The study conducted by Winter et al. [47] was also a two-armed, randomized controlled trial evaluating the effect of telephone-based support groups for female informal caregivers after 6 months in terms of alleviating depression and the burden of care and enhancing a sense of personal gains. Similar to the Talking Time study, this trial demonstrated a nonsignificant tendency for the outcomes to change (control = usual care) in the expected direction [47]. The telephone-based groups consisted of five caregivers and a trained social worker and occurred every week. The recruitment was based on targeted mailing to adult day center users, clinical programs and newspaper ads. No inclusion criteria were applied to the living situation of the informal caregivers and the care provided per week. No detailed information regarding recruitment and retention rates was reported [47].

The aforementioned Reach II study evaluated a multi-component intervention consisting of twelve individualized counseling sessions (nine on site and three via telephone), which were conducted over half a year. In addition, once a month for 5 months, structured telephone support group sessions took place. The trial demonstrated a significant improvement in the quality of life of caregivers and a lower prevalence of clinical

depression in the intervention group compared to the control group (control = educational materials and three brief check-in calls) [50]. Unfortunately, the study provided no information about the effectiveness of their individual components, which makes a comparison with the Talking Time study difficult. This also applies to the other available studies [46, 48]. The recruitment took place at five study centers and occurred in memory disorder clinics, primary care clinics, social service agencies, physician offices, churches and community centers. In that study, information brochures were used. Moreover, public service announcements on radio stations, newspaper articles, television, targeted newsletters and community presentations were used [50]. Based on this extensive recruitment procedure, the recruitment rate was 65%, and no challenges concerning recruitment were reported. The inclusion criteria regarding the living situation of informal caregivers and the care provided per week were the same for the REACH II study [50] and the Talking Time trial. The rate of participants who were lost to follow-up after 6 months was 9% [50].

This comparison between recruitment and retention procedures and rates reveals the need for a more advanced recruitment procedure for an MRC framework phase III trial investigating the Talking Time intervention. First, we recommend the inclusion of more recruitment centers and financial funding for public relations strategies targeting informal caregivers and their relatives with dementia who are living at home. Second, if possible, informal caregivers who participated in this study should be integrated as testimonials for the recruitment of study participants in a future trial.

Table 3 Intervention effects on secondary outcomes based on an intention-to-treat analysis (adjusted for covariates at the baseline)

Overall n = 38 caregivers Adjusted for covariates ^a	Differences between T ₁ and T ₀ Effect Size/Estimated score [95% CI]	
	Informal caregivers	
Self-rated physical HRQoL (0–100, PCS)		0.12 [-1.98–2.21]
Intervention group (n = 17)		-1.7 [-6.4–3.0]
Control group (n = 14)		-2.1 [-7.4–3.2]
Perceived Social Support Caregiving (9–45, PSSC)		0.43 [-1.67–2.52]
Intervention group (n = 17)		3.9 [0.2–7.7]
Control group (n = 14)		2.6 [-1.6–6.9]
CRS self-esteem (7–35)		-0.31 [-2.41–1.79]
Intervention group (n = 16)		-0.3 [-2.1–1.5]
Control group (n = 14)		0.1 [-1.8–2.1]
CRS lack of family support (5–25)		-2.56 [-4.65 - -0.46]
Intervention group (n = 17)		-1.1 [-2.2–0.1]
Control group (n = 14)		1.3 [0.0–2.6]
CRS impact on finances (3–15)		-0.46 [-2.55–1.63]
Intervention group (n = 17)		-0.7 [-1.7–0.2]
Control group (n = 14)		-0.4 [-1.5–0.7]
CRS impact on daily schedule (5–25)		-0.42 [-2.51–1.68]
Intervention group (n = 17)		-0.1 [-1.8–1.5]
Control group (n = 14)		0.4 [-1.4–2.3]
CRS impact on health score (4–20)		0.52 [-1.58–2.61]
Intervention group (n = 17)		0.9 [-0.2–1.9]
Control group (n = 14)		0.4 [-0.8–1.6]
People with dementia		
NPI-Q irritability (0–3)		1.22 [-0.87–3.31]
Intervention group (n = 17)		0.2 [-0.3–0.6]
Control group (n = 14)		-0.3 [-0.7–0.2]

^a Covariates depending on the respective secondary outcome: physical component score, caregiver self-esteem, caregiver lack of family support, caregiver impact on finances, caregiver impact on daily schedule, caregiver impact on health, perceived social support, irritability, functional activities, mental component score
CI 95% confidence interval 95%, Effect Size / Estimated score = top row shows the standardized effect size CI and p-value, lower rows show the model-based estimated least square means of the intervention effect, PCS Physical Component Summary, PSSC Perceived Social Support Caregiving, CRS Caregiver Reaction Scale, NPI-Q Neuropsychiatric Inventory – Q, FAQ Functional Activities Questionnaire

Third, the participation of informal caregivers as part of the planning team for a future trial and especially for the planning of the recruitment approach is recommended.

Fourth, recruitment materials or media for a future trial, such as a trial website or a folder, should include a detailed description of the intervention and the inclusion and exclusion criteria in plain language. The fact that the intervention was group-based seems to have had no effect on recruitment.

Strengths and limitations

The main strengths of our trial are that it is the first evaluation of the Talking Time intervention based on a rigorous experimental design. The applied study design and intervention resulted in a small dropout rate of 5% of the study participants. The outcome model of the

Talking Time study is based on the models of informal caregivers' stress processes [13]. Our results give no indication that one of the secondary outcomes is preferable as a primary outcome in future studies. The application of outcomes such as depression [47, 49] seems to not adequately reflect the components of the Talking Time intervention.

Our methodological approach was accompanied by various limitations. First, the preplanned sample size was not achieved (target sample size: n = 88; realized sample size: n = 38). Thus, this study has low statistical power and type II error is possible. A new sample size calculation based on the planned values (effect size = 0.7, α = 0.05) and the sample size of N = 38 demonstrated a power of = 55.56%. The possible reasons for this unsatisfactory sample size included a restricted recruitment

time and rigorous inclusion criteria (e.g., providing care for a relative with dementia for at least 4 hours on least 4 days each week during the past 6 months), the use of only one recruitment center and the lack of financial funding for public relation strategies to inform informal caregivers and their relatives about the opportunity to participate in the study.

Second, our primary outcomes of the self-rated psychological HRQoL and the FAQ score showed significant baseline differences between groups. The baseline difference in the self-rated psychological HRQoL scores, with higher scores in the intervention group and lower scores in the control group, may have led to an underestimation of the effect size. All participants in the intervention and control groups knew that they were part of a trial (Hawthorne effect). This knowledge may have influenced the participants in both groups. However, this does not result in a confounded comparability of the group results.

Third, our study design did not allow analysis of the long-term effects of the Talking Time intervention. Another trial should be conducted to investigate the long-term effects after 6 months of the intervention.

Fourth, apart from the Talking Time intervention, we have not assessed additional types (e.g. respite care) of informal caregiver support during the intervention phase. For a future trial we recommend that this data are collected during the intervention period.

Fifth, information regarding individual actions of each informal caregiver to participate in the telephone-based social support groups and the consequences of the Talking Time intervention for the respective care arrangement can only be answered after the analysis of the process evaluation data.

Conclusion

The results of our trial identified a promising but not statistically significant change in self-rated psychological HRQoL scores after intervention. The recruitment process was more difficult than expected. The comparison with previous trials leads to the assumption that there is a need for an advanced recruitment procedure including several recruitment centers and financial funding for public relations strategies targeting informal caregivers and their relatives with dementia living at home. Moreover, less stringent inclusion criteria regarding caregivers may be more useful. For example, it may be sufficient for inclusion if a person who cares for a person with dementia is the primary caregiver and responsible for the stability of care. In addition, recruitment materials, that include a detailed description of the intervention and the inclusion and exclusion criteria in plain language, will be helpful to make participant recruitment successful. In addition, informal caregivers

themselves should be part of the planning team of a future trial and especially with regard to the recruitment strategy.

Finally, the results of the study and the results of our process evaluation (in preparation) will provide insight into the further development of the intervention. The process evaluation will give additional information regarding fidelity, dosage and context. The fidelity results will provide information on the satisfaction of the study participants with the intervention components and on the extent to which the intervention meets the needs of informal caregivers of people with dementia. In general, our study protocol appears to be feasible, with the exception of the recruitment procedure.

For comparison reasons, a harmonization of study designs and outcomes should be sought for future trials investigating telephone-based social support interventions (e.g., follow-up assessment 6 months after the intervention).

Abbreviations

CERAD: Consortium to Establish a Registry for Alzheimer's Disease; CRS: Caregiver reaction scale; FAQ: Functional Activities Questionnaire; GPCOG: General Practitioner Assessment of Cognition; ICD-10: International Classification of Diseases 10th Revision; HRQoL: Health-related quality of life; MCS: Mental component summary; NPI-Q: Neuropsychiatric Inventory-Q; PCS: Physical component summary; PSSC: Perceived Social Support Caregiving instrument; PwD: People with dementia; SCS: Social Conflict Scale; SF-12: General Health Survey Questionnaire Short Form 12; TCI: Theme-centered interaction

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Authors' contributions

MND, BA, KW, DT, MH and MB designed the study. MND wrote the first draft of the manuscript and was responsible for the revisions. BA, KW, DT, SSP, AS, MH, and MB helped draft the manuscript. All authors have read and approved the final manuscript.

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Availability of data and materials

All of the data necessary for a meta-analysis are contained within the manuscript and its supplementary files. The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The Ethics Committee of the University of Leipzig approved the study (registration number 052/16-ek). For further information about the research design, see Berwig et al. [13]. Written information about the study was given to informal caregivers and people with dementia or the legal representative of a person with dementia. Written informed consent was obtained from informal caregivers and people with dementia or the legal representative of a person with dementia.

Consent for publication

Not applicable.

Competing interests

All authors declare that they have no competing interests. MND is a member.

of the BMC Health Services Research editorial board, but was not involved in the review process.

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RESEARCH ARTICLE

Behavioural activation to prevent depression and loneliness among socially isolated older people with long-term conditions: The BASIL COVID-19 pilot randomised controlled trial

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Abstract

Background

Older adults, including those with long-term conditions (LTCs), are vulnerable to social isolation. They are likely to have become more socially isolated during the Coronavirus Disease 2019 (COVID-19) pandemic, often due to advice to “shield” to protect them from infection. This places them at particular risk of depression and loneliness. There is a need for brief scalable psychosocial interventions to mitigate the psychological impacts of social isolation. Behavioural activation (BA) is a credible candidate intervention, but a trial is needed.

Methods and findings

We undertook an external pilot parallel randomised trial (ISRCTN94091479) designed to test recruitment, retention and engagement with, and the acceptability and preliminary effects of the intervention. Participants aged ≥ 65 years with 2 or more LTCs were recruited in primary care and randomised by computer and with concealed allocation between June and October 2020. BA was offered to intervention participants ($n = 47$), and control participants received usual primary care ($n = 49$). Assessment of outcome was made blind to treatment allocation. The primary outcome was depression severity (measured using the Patient Health Questionnaire 9 (PHQ-9)). We also measured health-related quality of life (measured by the Short Form (SF)-12v2 mental component scale (MCS) and physical component scale (PCS)), anxiety (measured by the Generalised Anxiety Disorder 7 (GAD-7)), perceived social and emotional loneliness (measured by the De Jong Gierveld Scale: 11-item

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Abbreviations: AMD, adjusted mean difference; BA, behavioural activation; BASIL, Behavioural Activation in Social Isolation; BSW, BASIL support worker; CASPER, Collaborative care and active surveillance for Screen-Positive Elders with subthreshold depression; CI, confidence interval; CONSORT, Consolidated Standards of Reporting Trials; COPD, chronic obstructive pulmonary disease; COVID-19, Coronavirus Disease 2019; DASS, Depression Anxiety Stress Scales; GAD-7, Generalised Anxiety Disorder 7; GP, general practitioner; ICC, intercluster correlation; LTC, long-term condition; MCS, mental component scale; NHS, National Health Service; NIHR, National Institute for Health Research; PCS, physical component scale; PGfAR, Programme Grants for Applied Research; PHE, Public Health England; PHQ-9, Patient Health Questionnaire 9; PPI, patient and public involvement; PPI AG, patient and public involvement advisory group; QOF, Quality and Outcomes Framework; RCT, randomised controlled trial; SAP, Statistical Analysis Plan; SARS-CoV-2, Severe Acute Respiratory Syndrome Coronavirus 2; SD, standard deviation; SF, Short Form; TFA, Theoretical Framework of Acceptability; TIA, transient ischemic attack.

loneliness scale). Outcome was measured at 1 and 3 months. The mean age of participants was aged 74 years (standard deviation (SD) 5.5) and they were mostly White ($n = 92$, 95.8%), and approximately two-thirds of the sample were female ($n = 59$, 61.5%). Remote recruitment was possible, and 45/47 (95.7%) randomised to the intervention completed 1 or more sessions (median 6 sessions) out of 8. A total of 90 (93.8%) completed the 1-month follow-up, and 86 (89.6%) completed the 3-month follow-up, with similar rates for control (1 month: 45/49 and 3 months 44/49) and intervention (1 month: 45/47 and 3 months: 42/47) follow-up. Between-group comparisons were made using a confidence interval (CI) approach, and by adjusting for the covariate of interest at baseline. At 1 month (the primary clinical outcome point), the median number of completed sessions for people receiving the BA intervention was 3, and almost all participants were still receiving the BA intervention. The between-group comparison for the primary clinical outcome at 1 month was an adjusted between-group mean difference of -0.50 PHQ-9 points (95% CI -2.01 to 1.01), but only a small number of participants had completed the intervention at this point. At 3 months, the PHQ-9 adjusted mean difference (AMD) was 0.19 (95% CI -1.36 to 1.75). When we examined loneliness, the adjusted between-group difference in the De Jong Gierveld Loneliness Scale at 1 month was 0.28 (95% CI -0.51 to 1.06) and at 3 months -0.87 (95% CI -1.56 to -0.18), suggesting evidence of benefit of the intervention at this time point. For anxiety, the GAD adjusted between-group difference at 1 month was 0.20 (-1.33 , 1.73) and at 3 months 0.31 (-1.08 , 1.70). For the SF-12 (physical component score), the adjusted between-group difference at 1 month was 0.34 (-4.17 , 4.85) and at 3 months 0.11 (-4.46 , 4.67). For the SF-12 (mental component score), the adjusted between-group difference at 1 month was 1.91 (-2.64 , 5.15) and at 3 months 1.26 (-2.64 , 5.15). Participants who withdrew had minimal depressive symptoms at entry. There were no adverse events. The Behavioural Activation in Social Isolation (BASIL) study had 2 main limitations. First, we found that the intervention was still being delivered at the prespecified primary outcome point, and this fed into the design of the main trial where a primary outcome of 3 months is now collected. Second, this was a pilot trial and was not designed to test between-group differences with high levels of statistical power. Type 2 errors are likely to have occurred, and a larger trial is now underway to test for robust effects and replicate signals of effectiveness in important secondary outcomes such as loneliness.

Conclusions

In this study, we observed that BA is a credible intervention to mitigate the psychological impacts of COVID-19 isolation for older adults. We demonstrated that it is feasible to undertake a trial of BA. The intervention can be delivered remotely and at scale, but should be reserved for older adults with evidence of depressive symptoms. The significant reduction in loneliness is unlikely to be a chance finding, and replication will be explored in a fully powered randomised controlled trial (RCT).

Trial registration

[ISRCTN94091479](#).

Author summary

Why was this study done?

- Older people with long-term conditions (LTCs) have been impacted by the Coronavirus Disease 2019 (COVID-19) pandemic and its restrictions. They are at risk of social isolation and, in turn, this could cause depression and loneliness, which are bad for health. Psychological approaches, such as behavioural activation (BA), could be helpful.
- A fair test is needed to demonstrate if BA can prevent the onset of depression and loneliness, but before we can do this, it is important to test this out in a smaller scale study.

What did the researchers do and find?

- We designed a brief telephone-delivered intervention based on sound psychological principles known as BA. Here, we present the result of a pilot trial.
- We demonstrate that the intervention is acceptable to older people who are socially isolated as a consequence of the pandemic. We tested whether it is possible to collect important outcomes in the short term.
- There was some preliminary evidence that levels of loneliness were reduced at 3 months when BA is offered.

What do these findings mean?

- This was a smaller scale pilot study, and our procedures worked well.
- If BA is shown to work, then this will be useful for policymakers in offering support to people who are socially isolated.
- This will also be useful once the COVID-19 pandemic has passed, since loneliness is common in older populations, and effective scalable solutions will be needed even after COVID-19.
- The Behavioural Activation in Social Isolation (BASIL) pilot trial was not designed to test differences in outcomes between the 2 groups. We will now test this in a much larger study.

Introduction

In March 2020, a pandemic due to a new virus, the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), was declared. The first wave reached the United Kingdom within a short period of time, and, in March 2020, the UK governments (including devolved nations) administered a national stay-at-home order (“lockdown”), which included instructions for people to follow physical social distancing and self-isolation guidelines and recommendations

for strict isolation (“shielding”) for the most vulnerable (such as those with long-term conditions (LTCs) and older people) in order to protect their own and others’ health and to avoid a sudden increase in demand on the National Health Service (NHS). Shielding orders were eased in the second half of 2020 but were reintroduced in January 2021 as part of a further lockdown in response to subsequent Coronavirus Disease 2019 (COVID-19) waves. Many people with LTCs have remained avoidant of social contact in order to protect themselves from COVID-19 throughout the pandemic, irrespective of official guidance [1]. Similar recommendations and restrictions were also set in place in many healthcare systems around the world.

The mental health of the population has deteriorated during COVID-19 [2]. Many report social isolation, and the incidence of depression and anxiety has increased for older people and those with medical vulnerabilities [3]. A plausible mechanism for this is that COVID-19 restrictions have led to disruption of daily routine, loss of social contact and heightened isolation, and increased loneliness, which are each powerful precipitants of mental ill health [4]. Anticipating these behavioural and psychological consequences, a rapid review published in *The Lancet* [5] highlighted the detrimental impacts on mental health of quarantine, but offered limited advice on how this could be mitigated.

Social isolation, social disconnectedness, perceived isolation, and loneliness are known to be linked to common mental health problems, such as depression in older people [4,6]. The impairments in quality of life associated with depression are comparable to those of major physical illness [7]. Loneliness is a risk factor for depression and is also known to be detrimental to physical health and life expectancy [8,9].

Loneliness is not an inevitable consequence of social isolation, and strategies to prevent or mitigate loneliness were recognised as a population priority even before COVID-19 [10,11]. There are a number of promising interventions that focus on using social networks [12] or adapting the strategies central to cognitive behavioural therapy [13]. It is recognised that strategies that, for instance, maintain social connectedness could be important in ensuring the population mental health of older people [14], particularly during the pandemic [4] and in the planning for post-pandemic recovery [15]. If a brief effective intervention for depression and loneliness could be delivered at distance (such as via telephone) and at scale, then this would lead to significant benefits to the NHS and society. This could potentially mitigate the immediate and longer lasting psychological impacts of COVID-19 on vulnerable populations, including older people and those with LTCs [16].

Our research collaborative has previously developed, with input from older adults and carers, a credible intervention that can potentially meet these needs in populations of older people [17], and we have evaluated this in older populations with high rates of multiple LTCs [18,19]. Behavioural activation (BA) is a practical treatment that explores how physical inactivity and low mood are linked and result in a reduction of valued activity [20]. Within BA, the therapist and patient work together to develop a collaborative treatment plan that seeks to reinstate (or replace, if former activities are no longer possible) behaviours that connect people to sources of positive reinforcement (meaningful activity), including social connectedness. However, this has not yet been tested in a large-scale clinical trial or in the context of the COVID-19 pandemic where social isolation is more prevalent. Small-scale trials of BA delivered to socially isolated older people have produced encouraging preliminary results [21], but there is not yet sufficient research evidence to support whole-scale adoption or to inform the population response to COVID-19.

Along with many researchers working in the field of mental health, we were keen to use our existing research expertise and research capacity to help mitigate the impact of the COVID-19 pandemic. We therefore adapted our previous and ongoing work programme in early 2020 to

answer the following question: “Can we prevent or ameliorate depression and loneliness in older people with long-term conditions during isolation?”.

In this paper, we present the rationale and results of a pilot randomised controlled trial (RCT) of manualised BA, adapted specifically to be delivered at scale and remotely (via the telephone or video call) for older adults who may have become socially isolated as a consequence of COVID-19. To the best of our knowledge, this is the first study to use behavioural approaches to prevent loneliness and depression in the COVID-19 pandemic. In this pilot RCT, we sought to assess the feasibility of recruiting and randomising participants to a trial of BA, of delivering the intervention, and of retaining participants in the trial. The primary clinical outcome was depression severity, as measured by the Patient Health Questionnaire 9 (PHQ-9), at 1 month post-randomisation; secondary clinical outcomes were health-related quality of life, anxiety, and perceived social and emotional loneliness.

Methods

Study design and participants

The Behavioural Activation in Social Isolation (BASIL) study is an external pilot RCT [22] and includes a concurrent qualitative study. The BASIL pilot is designed to provide key information on methods of recruitment, intervention uptake, retention, experience of the BA intervention for our target population, and acceptability of the intervention and training for intervention practitioners (hereafter BASIL support workers (BSWs)).

The COVID-19 responsive BASIL trials programme is supported by the National Institute for Health Research (NIHR) under grant RP-PG-0217-20006 and was adopted by the NIHR Urgent Public Health programme on May 28, 2020 [23]. The protocol for the BASIL pilot study was preregistered (ISRCTN94091479) on June 9, 2020, and recruitment took place between June 23 and October 15, 2020 (18 weeks in total). Older adults at risk of loneliness and depression as a consequence of social isolation under COVID-19 restrictions were recruited from primary care registers in the North East of England. They were randomised to receive either usual primary care from their general practice or BA intervention in addition to usual care (see below for full description of usual care and BA intervention).

- **Inclusion criteria:** Older adults (65 years or over) with 2 or more physical LTCs. The pragmatic definition and type of LTCs mirror that applied in primary care in the UK [24], and we focused on common LTCs experienced by older people (asthma/chronic obstructive pulmonary disease (COPD), diabetes, hypertension/coronary heart disease, and stroke) according to the primary care Quality and Outcomes Framework (QOF) [25], but also included conditions such as musculoskeletal problems and chronic pain. Participants included those subject to Government guidelines regarding COVID-19 self-isolation, social distancing, and shielding as relevant to their health conditions and age (although this was not a requirement and these requirements changed during the study period).
- **Exclusion criteria:** Older adults who have cognitive impairment, bipolar disorder/psychosis/psychotic symptoms, alcohol or drug dependence, in the palliative phase of illness, have active suicidal ideation, are currently receiving psychological therapy, or are unable to speak or understand English.

Potentially eligible patients were contacted by telephone by staff working with the general practices. Those patients who expressed an interest in the study during this initial telephone contact provided their verbal “permission to contact” for a member of the study team to

contact them by telephone to discuss the study and determine eligibility. Interested patients could also complete an online consent form or contact the study team directly.

Randomisation, concealment of allocation, and masking

After consent, eligible participants completed a baseline questionnaire over the telephone with a study researcher. Consent was obtained, either in written form or via verbal consent [recorded] over the telephone. Participants were then randomised and informed of their group allocation (intervention or usual care with signposting). Participants were allocated in a 1:1 ratio using simple randomisation without stratification. Treatment allocation was concealed from study researchers at the point of recruitment using an automated computer data entry system, administered remotely by the York Trials Unit and using a computer-generated code. Owing to the nature of the intervention, none of the participants, general practices, study clinicians, or BSWs could be blinded to treatment allocation. General practitioners (GPs) were informed by letter of participant treatment allocation. Outcome assessment was by self-report, and study researchers facilitating the telephone-based outcome assessment were blind to treatment allocation.

Intervention (BA)

The intervention (BA within a collaborative care framework) has been described elsewhere [18] and was adapted for the purposes of the BASIL trial. Within the BASIL BA intervention, the therapist (BSW) and participant worked together to develop a collaborative treatment plan that sought to reinstate (or replace, if former activities were no longer possible because of social isolation and/or LTCs) behaviours that connect them to sources of positive reinforcement (valued activity). BA has the potential to address depression and loneliness in the presence of social isolation in this way [17,26] and the simplicity of BA made it suitable for delivery in the context of COVID-19.

Intervention participants were offered up to 8 sessions over a 4- to 6-week period delivered by trained BSWs, accompanied by participant materials. Participants in the intervention group were provided with a BASIL BA workbook. This booklet was modified to take account of government guidance regarding the need for social isolation/physical distancing and enforced isolation for those people most at risk (“extremely vulnerable” people). For example, the BASIL booklet discussed ways to replace activities that are no longer possible with ones that preserve social distancing while helping participants stay connected with the activities and people important to them; illustrative patient stories included in the booklet were modified to take account of COVID-19 restrictions. Examples of replacement activities from the BASIL self-help manual are presented in [Box 1](#). BA acknowledged the disruption to people’s lives and usual routines and encouraged the establishment of a balanced daily routine. The intervention also recognised that participants may be worried about the current situation due to COVID-19 and suggested strategies to help cope.

All intervention sessions were delivered remotely via telephone or video call, according to participant preference. The first session was scheduled to last approximately 1 hour, with subsequent sessions lasting approximately 30 minutes.

Depression symptom monitoring at each intervention session was undertaken using a validated depression scale (the Depression Anxiety Stress Scales (DASS) [27]) with scores guiding decision-making by BSWs and guided by supervision provided by clinical members of the study team. Where risk or significant clinical deterioration was noted, the participant was supported to access more formal healthcare interventions (including mental health care) via their GP. Where feasible and where considered appropriate and acceptable by the participant and

Box 1. BASIL examples of replacement activities using functional equivalence. See [17] for a description of the principles of BA and its application in older people with LTCs

BA pays particular attention to the function the behaviour holds for an individual and that reinforcement is determined functionally. An important consequence of this view is the idea of functional equivalence. A specific form of a behaviour may have served a particular function for a person; however, that behaviour may no longer be possible due to physical health problems or COVID-19 lockdown. In this situation, an aim of treatment was to identify a functionally equivalent behaviour that is different and therefore still possible despite physical changes or shielding, but which may serve the same function for a person. Below are 2 illustrative examples of functionally equivalent goals from the BASIL self-help manual.

Functionally equivalent goal, example 1

Sandra decided that she would like to increase her activity levels and said she would have liked to go to the Age UK exercise group. However, Sandra realised that this will not be happening due to the need for physical distancing. The BASIL Support Worker advised that there are exercises online, and she could help Sandra access these. In addition, many TV channels are showing exercises that can be done at home.

Functionally equivalent goal, example 2

Sandra would like to have a cup of tea with her friend Shirley but realises that this is not possible. She and Shirley used to meet up on a regular basis, before the ministroke (TIA), and she really missed their chats. She thought that she might suggest a regular ‘virtual meeting’, rather than just a quick telephone call, if the Support Worker can help her gain confidence with using her smart phone.

BSW, the intervention was extended to include involvement of a participant’s informal care-giver/significant other. Intervention participants continued to receive their usual care/treatment (where this was feasible given COVID-19) alongside the BASIL intervention, and no treatment was withheld.

Comparator (usual GP care)

Participants in the control group received usual care as provided by their current NHS and/or third sector providers. In addition, control participants were “signposted” to reputable sources of self-help and information, including advice on how to keep mentally and physically well. Examples of such sources was the Public Health England’s (PHE) “Guidance for the public on the mental health and wellbeing aspects of coronavirus (COVID-19)” [28] and Age UK [29].

Outcome measures

Demographic information was obtained at baseline and included age, sex, LTC type, socioeconomic status, ethnicity, education, marital status, and number of children.

The primary objective for this pilot trial was to obtain estimates of key feasibility measures including rates of recruitment, randomisation, retention, intervention delivery, and engagement.

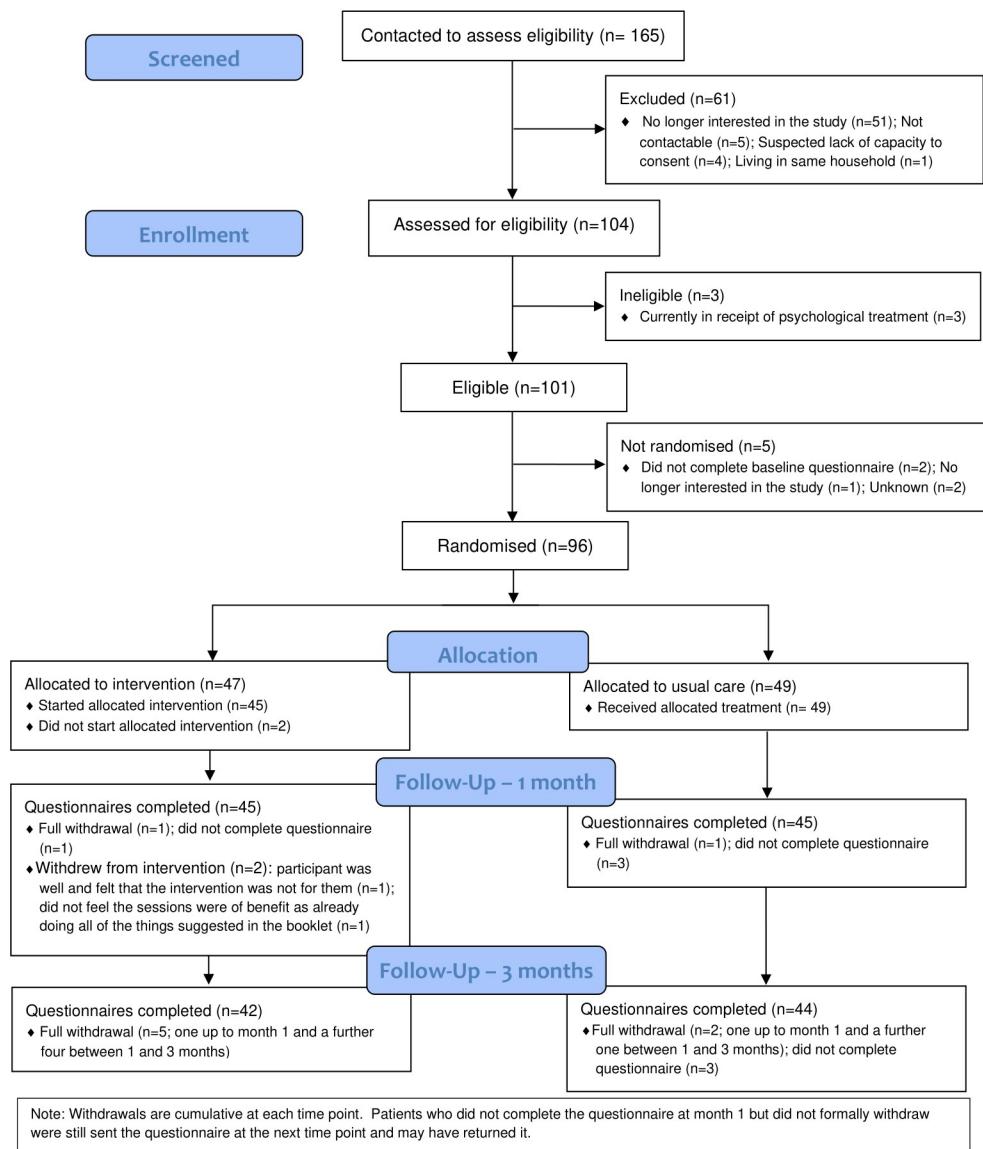
The primary clinical outcome was self-reported symptoms of depression, assessed by the PHQ-9 [30]. The PHQ-9 was also administered at screening to ascertain risk of self-harm or suicide and again at baseline, 1 and 3 months post-randomisation. The primary time point was 1 month. Other secondary clinical outcomes measured at baseline, 1 and 3 months, were health-related quality of life (measured by the Short Form (SF)-12v2 mental component scale (MCS) and physical component scale (PCS)) [31], anxiety (measured by the GAD-7) [32], perceived social and emotional loneliness (measured by the De Jong Gierveld Scale: 11-item loneliness scale), and questions relating to COVID-19 circumstances and adherence to government guidelines [33]. The PHQ-9 is scored from 0 to 27, the GAD-7 from 0 to 21, and the De Jong Gierveld Loneliness Scale from 0 to 11 (emotional subscale from 0 to 6 and social from 0 to 5), for each a higher score indicates a worse outcome. The physical and mental health component scores of the SF-12v2 range from 0 to 100, where a higher score indicates better health. We also tested our ability to collect resource use data, but these data are not summarised or described, since there was no planned economic evaluation in this pilot trial.

Sample size and statistical analysis

Sample size. The primary aim of the BASIL pilot trial was to test the feasibility of the intervention and the methods of recruitment, randomisation, and follow-up [22]. Sample size calculations were based on estimating attrition and standard deviation (SD) of the primary outcome. We aimed to recruit 100 participants. The intervention was delivered by BSWs and allowed for potential clustering by BSWs assuming an intercluster correlation (ICC) of 0.01 and mean cluster size of 15 based upon previous studies [18]. The effective sample size was therefore 88. Anticipating 15% to 20% of participants would be lost to follow-up (based on 17% in the CollAborative care and active surveillance for Screen-Positive EldeRs with sub-threshold depression (CASPER) trial of older adults [18]), this would result in an effective sample size of at least 70 participants, which is sufficient to allow reasonably robust estimates of the SD of the primary outcome measure to inform the sample size calculation for a definitive trial [34,35]. See Statistical Analysis Plan (SAP) in [S1 Data](#).

Statistical analysis. This study is reported as per the Consolidated Standards of Reporting Trials (CONSORT) guideline (see [S2 Data](#)). The flow of participants through the pilot trial (number of people identified, approached, screened, eligible, randomised, receiving the intervention, and providing outcome data) is detailed in a CONSORT flow diagram as per pilot trial recommendations [[Fig 1](#)] [22,36]. The number of individuals withdrawing from the intervention and/or the trial, and any reasons for withdrawal, was summarised by trial arm. All baseline and outcome data were summarised descriptively, by trial arm, using mean and SD for continuous outcomes, and count and percentage for categorical data. To quantify the acceptability of the intervention, the number and duration of sessions were summarised.

For each of the clinical outcomes, missing item level data were handled according to the user guides. No other methods for imputing missing data were employed, which was deemed appropriate as there were minimal missing data, and this was a pilot trial where all analyses were purely exploratory. Linear regression was used to explore differences in the clinical outcomes, adjusting for the baseline measure of the score as a covariate (ANCOVA approach), between groups at 1 and 3 months. Model assumptions were assessed, and no concerning deviations or observations were observed. The adjusted mean difference (AMD) and 95% confidence interval (CI) was reported as preliminary estimates of effect, but this pilot trial was not powered to show efficacy. We attach an SAP as a Supporting information ([S1 Data](#)).



Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ*. 2016;355.

Fig 1. CONSORT flow diagram.

<https://doi.org/10.1371/journal.pmed.1003779.g001>

Process evaluation

A nested qualitative study was conducted to provide important learning about the study processes and acceptability of the BASIL intervention. We planned semi-structured interviews of up to 15 participants who completed the BASIL intervention (“completers”), up to 10 participants who did not complete the intervention (“non-completers”), and all BSWs who delivered the intervention ($n = 9$). Interviews explored views and experiences of the study and acceptability of the intervention. Initial thematic analysis [37] and subsequent analysis sensitised by the Theoretical Framework of Acceptability (TFA) [38] were undertaken.

Patient and public involvement (PPI)

The BASIL trial was informed by a patient and public involvement advisory group (PPI AG) who were working with the research collective on the existing NIHR-funded research programme. This PPI AG included older adults with lived experience of mental health and/or physical health conditions and caregivers. The PPI AG were consulted on many aspects of the trial design including modification of the BA intervention for BASIL, remote recruitment of BASIL participants, and the relevance and readability of study recruitment information. The group are a vital component of the BASIL trials programme and will continue to contribute throughout the delivery of this work.

Role of funding source

This project was funded by the NIHR Programme Grants for Applied Research (PGfAR) programme (RP-PG-0217-20006). The scope of our preexisting research into multimorbidity in older people was extended at the outset of the COVID-19 pandemic with the agreement of the funder to consider loneliness and depression in this vulnerable group. The NIHR PGfAR programme had no role in the writing of this manuscript or the decision to submit it for publication.

Ethical approval

Ethical approval for the study was granted by Yorkshire and The Humber—Leeds West Research Ethics Committee on April 23, 2020, Yorkshire and The Humber—Leeds West Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8018; leedswest.rec@hra.nhs.uk), ref: 18/YH/0380 (approved as substantial amendment 02 under existing NIHR IRAS249030 research programme).

Results

Participant recruitment and characteristics

Database searches were conducted in 2 general practices within Tees, Esk and Wear Valleys NHS Foundation Trust. A total of 799 study information packs were mailed out across the 2 practices between June 17 and September 4, 2020 (initially in batches of 50, later increased to 100). Of these, 104 were screened for eligibility, and 96 were recruited out of our target of 100: 3 were not eligible as they were currently in receipt of psychological treatment, 2 eligible participants did not complete the baseline questionnaire following consent, 1 was no longer interested in the study, and for 2 more, the reason for nonparticipation was not provided.

Participants were randomised between June 23 and October 15, 2020: 47 to the BA intervention group and 49 to usual care with signposting group ([Fig 1](#)).

The mean age of participants was aged 74 years (SD 5.5) and they were mostly White ($n = 92$, 95.8%), and approximately two-thirds of the sample were female ($n = 59$, 61.5%) ([Table 1](#)). Cardiovascular conditions (49.0%) and arthritis (38.5%) were the most commonly reported long-term health conditions. The majority of participants (55.2%) were social/physical distancing and adhering to UK Government's guidance in relation to COVID-19 restrictions all of the time (65.6%). There was reasonable balance in baseline characteristics between the 2 groups, but with some differences including a larger proportion of females, and current and former smokers, and fewer participants shielding in the usual care group than the intervention group; however, given the sample size, each participant per group equates to approximately 2 percentage points, so even small numerical imbalances equate to more noticeable imbalances in proportions.

[Table 2](#) presents summaries of the clinical outcomes by time point and treatment group. Unadjusted between-group mean differences tended to favour the intervention.

Table 1. Baseline demographics of participants as randomised.

Demographic		Usual care (n = 49)	Intervention (n = 47)	Total (n = 96)
Age, years	Mean (SD)	74.1 (5.6)	74.2 (5.4)	74.2 (5.5)
Sex, n (%)	Male	17 (34.7)	20 (42.6)	37 (38.5)
	Female	32 (65.3)	27 (57.4)	59 (61.5)
Ethnicity, n (%)	White	47 (95.9)	45 (95.7)	92 (95.8)
	Black or Black British	0 (0.0)	0 (0.0)	0 (0.0)
	Asian or Asian British	0 (0.0)	0 (0.0)	0 (0.0)
	Other	2 (4.1)	2 (4.3)	4 (4.2)
[†] LTC type, n (%)	Cardiovascular condition	21 (42.9)	26 (55.3)	47 (49.0)
	Arthritis	21 (42.9)	16 (34.0)	37 (38.5)
	Respiratory condition	17 (34.7)	18 (38.3)	35 (36.5)
	Diabetes	14 (28.6)	14 (29.8)	28 (29.2)
	Stroke	5 (10.2)	4 (8.5)	9 (9.4)
	Chronic pain	2 (4.1)	3 (6.4)	5 (5.2)
	Osteoporosis	4 (8.2)	2 (4.3)	6 (6.3)
	Neurological condition	1 (2.0)	0 (0.0)	1 (1.0)
	Cancer	1 (2.0)	1 (2.1)	2 (2.1)
	Other	27 (55.1)	21 (44.7)	48 (50.0)
Smoking status, n (%)	I have never smoked	16 (32.7)	22 (46.8)	38 (39.6)
	I currently smoke	5 (10.2)	7 (14.9)	12 (12.5)
	I am an ex-smoker	28 (57.1)	18 (38.3)	46 (47.9)
Alcohol intake	Yes	7 (14.3)	6 (12.8)	13 (13.5)
(3+ units daily), n (%)	No	42 (85.7)	41 (87.2)	83 (86.5)
Post-16 education, n (%)	Yes	29 (59.2)	32 (68.1)	61 (63.5)
Degree or equivalent, n (%)	Yes	18 (36.7)	19 (40.4)	37 (38.5)
Marital status, n (%)	Single	1 (2.0)	0 (0.0)	1 (1.0)
	Divorced/separated	11 (22.4)	9 (19.1)	20 (20.8)
	Widowed	11 (22.4)	10 (21.3)	21 (21.9)
	Cohabiting	0 (0.0)	1 (2.1)	1 (1.0)
	Civil partnership	0 (0.0)	0 (0.0)	0 (0.0)
	Married	26 (53.1)	27 (57.4)	53 (55.2)
Number of children, n (%)	0	3 (6.1)	3 (6.4)	6 (6.3)
	1	7 (14.3)	8 (17.0)	15 (15.6)
	2	24 (49.0)	16 (34.0)	40 (41.7)
	3	10 (20.4)	15 (31.9)	25 (26.0)
	4+	5 (10.2)	5 (10.6)	10 (10.4)
How many people do you share your home with? n (%)	Live alone	22 (44.9)	18 (38.3)	40 (41.7)
	1 person	26 (53.1)	25 (53.2)	51 (53.1)
	2 people	1 (2.0)	3 (6.4)	4 (4.2)
	3 people	0 (0.0)	1 (2.1)	1 (1.0)
	4 or more people	0 (0.0)	0 (0.0)	0 (0.0)
Current circumstance, n (%)	Social/physical distancing	29 (59.2)	24 (51.1)	53 (55.2)
	Self-isolating without COVID-19 symptoms	10 (20.4)	4 (8.5)	14 (14.6)
	Self-isolating with COVID-19 symptoms	0 (0.0)	0 (0.0)	0 (0.0)
	Shielding*	10 (20.4)	19 (40.4)	29 (30.2)
	Other	0 (0.0)	0 (0.0)	0 (0.0)

(Continued)

Table 1. (Continued)

Demographic		Usual care (n = 49)	Intervention (n = 47)	Total (n = 96)
Adherence to UK Government's guidance in relation to COVID-19 restrictions, n (%)	All of the time	31 (63.3)	32 (68.1)	63 (65.6)
	Most of the time	15 (30.6)	15 (31.9)	30 (31.3)
	Some of the time	3 (6.1)	0 (0.0)	3 (3.1)
	A little of the time	0 (0.0)	0 (0.0)	0 (0.0)
	None of the time	0 (0.0)	0 (0.0)	0 (0.0)

[†] Conditions are not mutually exclusive so percentages not expected to sum to 100.

* Shielding was self-defined as following government guidance on shielding due to being a clinically highly vulnerable category. The definitions and list of categories changed according to shifting guidance during the course of the study.

Other conditions include (all listed for a single person unless otherwise indicated in brackets, but people may have listed more than one other condition): USUAL CARE—underactive thyroid/other thyroid problem (n = 5), high blood pressure (n = 4), high cholesterol (n = 2), sciatica (n = 2), depression (n = 2), non-chronic pain in back and legs, “tablets for bones,” autonomic neuropathic dysfunction (mainly affects bowels), brain tumour, Crohn disease, deaf in one ear from birth, flat feet, spondylitis in the spine, anxiety, kidney problems, previous stroke (n = 2), previous history of cancer, nerve problems in back, hernia in lumbar disc, Barrett disease, emphysema, sleep apnea, kidney infections/sepsis, anemia, digestive problems, pacemaker in stomach, angina, ileostomy from ulcerative colitis, glaucoma in one eye, right total hip replacement due to arthritis, raised cholesterol, some cardiovascular disease—short of breath on exertion, retinitis pigmentosa (eye sight), Reynaud syndrome, skin condition, lichen sclerosus, skin lupus; INTERVENTION—underactive thyroid or other thyroid issue (n = 7), high blood pressure (n = 3), depression (n = 3), previous cancer (n = 2), atrial fibrillation, angina (n = 2), premature ventricular contractions, emphysema, joint pain, lung function issues due to asbestos exposure, sciatica, mild bronchiectasis, eczema, IBS, Sturge–Weber syndrome, vertigo, tinnitus, chronic kidney disease, polymyalgia, high cholesterol, kidney cyst, and gall stones.

COVID-19, Coronavirus Disease 2019; IBS, irritable bowel syndrome; LTC, long-term condition; SD, standard deviation.

<https://doi.org/10.1371/journal.pmed.1003779.t001>

Engagement with the BASIL intervention

Levels of engagement with the BA intervention were high. Of the 47 intervention participants randomised to the BA intervention group, 45 (95.7%) commenced the intervention, with 44 participants completing 2 or more sessions. The number of sessions completed range from 0 to 8 (median of 6 sessions) out of a total of up to 8 sessions. Participants preferred telephone over video contact. Sessions lasted a mean of 36.7 minutes (SD 15.7). Two participants withdrew from the intervention (after completing 1 and 2 sessions, respectively); one participant stated their reason for withdrawal was that they felt “well,” and the intervention was “not for them” as they were already engaging in BA-related activities. At 1 month (the primary clinical outcome point), the median number of completed sessions for people receiving the BA intervention was 3, and almost all participants were still receiving the BA intervention.

Retention, follow-up, withdrawal, and completeness of data

Of the 96 participants randomised into the study, 90 (93.8%) completed the 1-month follow-up, and 86 (89.6%) completed the 3-month follow-up. Reasons for withdrawal include personal reasons, family bereavement, and finding the study/study questions upsetting and anxiety provoking.

Data completeness was good with all patient-reported outcome measures (PHQ-9, GAD-7, De Jong Gierveld Loneliness Scale, and SF-12v2).

Outcome data and between group comparisons at 1 and 3 months

The adjusted mean difference (AMD) between groups in the PHQ-9 indicated lower severity in the intervention group at 1 month (−0.50, 95% CI −2.01 to 1.01) and the usual care group at 3 months (0.19, 95% CI −1.36 to 1.75) (Table 3). In De Jong Gierveld score, the AMD indicated

Table 2. Patient-reported outcome measures.

Outcome measure	Control	Intervention
PHQ-9, n, mean (SD)		
Baseline	49, 7.5 (6.2)	47, 6 (5.6)
1 month	45, 6.3 (5.9)	45, 4.9 (4.6)
3 months	44, 5.7 (5.3)	42, 5.3 (5.4)
PHQ-9 categories baseline, n (%)		
Minimal depression (0 to 4)	22 (44.9)	21 (44.7)
Mild depression (5 to 9)	10 (20.4)	14 (29.8)
Moderate depression (10 to 14)	11 (22.4)	9 (19.1)
Moderately severe depression (15 to 19)	3 (6.1)	1 (2.1)
Severe depression (20 to 27)	3 (6.1)	2 (4.3)
PHQ-9 categories 1 month, n (%)		
Minimal depression (0 to 4)	22 (48.9)	24 (53.3)
Mild depression (5 to 9)	12 (26.7)	12 (26.7)
Moderate depression (10 to 14)	6 (13.3)	8 (17.8)
Moderately severe depression (15 to 19)	3 (6.7)	1 (2.2)
Severe depression (20 to 27)	2 (4.4)	0 (0.0)
PHQ-9 categories 3 months, n (%)		
Minimal depression (0 to 4)	21 (47.7)	23 (54.8)
Mild depression (5 to 9)	15 (34.1)	11 (26.2)
Moderate depression (10 to 14)	4 (9.1)	4 (9.5)
Moderately severe depression (15 to 19)	3 (6.8)	4 (9.5)
Severe depression (20 to 27)	1 (2.3)	0 (0.0)
GAD-7, n, mean (SD)		
Baseline	49, 5.2 (5.8)	47, 3.8 (4.8)
1 month	45, 4.2 (5.1)	45, 3.6 (4.2)
3 months	44, 3.7 (5.0)	42, 3.5 (3.9)
GAD-7 categories baseline, n (%)		
Anxiety (0 to 4)	31 (63.3)	35 (74.5)
Mild anxiety (5 to 9)	9 (18.4)	7 (14.9)
Moderate anxiety (10 to 14)	4 (8.2)	3 (6.4)
Severe anxiety (15 to 21)	5 (10.2)	2 (4.3)
GAD-7 categories 1 month, n (%)		
Anxiety (0 to 4)	31 (68.9)	30 (66.7)
Mild anxiety (5 to 9)	8 (17.8)	10 (22.2)
Moderate anxiety (10 to 14)	3 (6.7)	4 (8.9)
Severe anxiety (15 to 21)	3 (6.7)	1 (2.2)
GAD-7 categories 3 months, n (%)		
Anxiety (0 to 4)	31 (70.5)	28 (66.7)
Mild anxiety (5 to 9)	9 (20.5)	9 (21.4)
Moderate anxiety (10 to 14)	1 (2.3)	4 (9.5)
Severe anxiety (15 to 21)	3 (6.8)	1 (2.4)
De Jong Gierveld Loneliness Scale, n, mean (SD)		
Baseline	49, 5.1 (3.2)	47, 4.6 (3.5)
1 month	45, 4.6 (3.1)	45, 4.7 (3.0)
3 months	44, 5.0 (3.0)	42, 4.1 (2.9)
De Jong Gierveld Emotional Loneliness Subscale, n, mean (SD)		
Baseline	49, 3.1 (1.9)	47, 3.0 (2.0)

(Continued)

Table 2. (Continued)

Outcome measure	Control	Intervention
1 month	45, 3.0 (1.7)	45, 3.1 (1.9)
3 months	44, 3.4 (1.7)	42, 3.0 (1.7)
De Jong Gierveld Social Loneliness Subscale, <i>n</i> , mean (SD)		
Baseline	49, 2.0 (1.8)	47, 1.6 (1.8)
1 month	45, 1.5 (1.8)	45, 1.6 (1.8)
3 months	44, 1.6 (1.8)	42, 1.1 (1.6)
SF-12v2 (physical component score), <i>n</i> , mean (SD)		
Baseline	49, 39.4 (10.7)	47, 40.3 (11.3)
1 month	45, 40.0 (10.5)	45, 41.4 (12.4)
3 months	44, 41.0 (11.5)	42, 41.8 (11.7)
SF-12v2 (mental component score), <i>n</i> , mean (SD)		
Baseline	49, 47.0 (13.9)	47, 48.9 (10.5)
1 month	45, 48.4 (13.0)	45, 52.0 (9.5)
3 months	44, 49.0 (11.5)	42, 51.1 (9.7)

Range of possible scores: PHQ-9 0 to 27; GAD-7 0 to 21; and De Jong Gierveld total 0 to 11—emotional subscale 0 to 6, social subscale 0 to 5 (higher indicates worse outcome). SF-12v2 subscales 0 to 100 (higher indicates better outcome).

GAD-7, Generalised Anxiety Disorder 7; PHQ-9, Patient Health Questionnaire 9; SD, standard deviation; SF, Short Form.

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lower severity in the usual care group at 1 month (0.28, 95% CI –0.51 to 1.06) and the intervention group at 3 months (–0.87, 95% CI –1.56 to –0.18) when the 95% CI did not contain 0 ([Table 3](#)).

Process evaluation and changes to the intervention in light of participant feedback

Intervention participants were invited to be interviewed following completion of the 1-month follow-up and conclusion of their participation in the BASIL pilot intervention. Semi-structured interviews were conducted with 15 participants who completed the BA intervention. A study participant who did not complete the BASIL intervention was interviewed as a “non-completer.” All 9 BSWs who delivered the BASIL intervention were interviewed between August 2020 and November 2020. All interviews were conducted over the telephone, digitally recorded with consent and transcribed verbatim. Transcripts formed the basis for analysis. We summarise the key findings from a thematic analysis [37] and subsequent changes to the BASIL intervention ahead of the BASIL main trial. Analysis sensitised by the TFA [38] will be reported separately. Intervention participant and BSW demographics are reported in [S1](#) and [S2](#) Tables. Two researchers (CCG and CS) undertook the qualitative data analysis, coding transcripts, and reviewing/developing a coding frame.

Recruitment and study eligibility. Study recruitment methods appeared to be generally acceptable and clear:

“The doctor gives you a warning that this is about to happen [be contacted] and then you’re prepared when somebody phones up that it’s not a scam, a con, which is what I don’t worry about it because I know how to deal with it but to some people it could be worrying.”
(OA16)

Table 3. Unadjusted and AMD between groups at 1 and 3 months for primary and secondary outcomes measure.

	Unadjusted mean difference (95% CI)	AMD ^a (95% CI)
<i>1 month</i>		
PHQ-9	−1.44 (−3.66, 0.77)	−0.50 (−2.01, 1.01)
GAD-7	−0.54 (−2.52, 1.44)	0.20 (−1.33, 1.73)
De Jong Gierveld Scale (total)	0.13 (−1.14, 1.41)	0.28 (−0.51, 1.06)
De Jong Gierveld Emotional Loneliness Subscale	0.07 (−0.68, 0.81)	0.14 (−0.39, 0.67)
De Jong Gierveld Social Loneliness Subscale	0.07 (−0.68, 0.81)	0.14 (−0.42, 0.69)
SF-12v2 (physical component score) ^b	1.40 (−3.42, 6.22)	0.34 (−4.17, 4.85)
SF-12v2 (mental component score) ^b	3.60 (−1.17, 8.37)	1.91 (−2.64, 5.15)
<i>3 months</i>		
PHQ-9	−0.39 (−2.70, 1.91)	0.19 (−1.36, 1.75)
GAD-7	−0.16 (−2.09, 1.78)	0.31 (−1.08, 1.70)
De Jong Gierveld Scale (total)	−0.86 (−2.14, 0.43)	−0.87 (−1.56, −0.18)
De Jong Gierveld Emotional Loneliness Subscale	−0.36 (−1.09, 0.36)	−0.37 (−0.85, 0.11)
De Jong Gierveld Social Loneliness Subscale	−0.50 (−1.22, −0.23)	−0.50 (−1.00, −0.01)
SF-12v2 (physical component score) ^b	0.81 (−4.16, 5.77)	0.11 (−4.46, 4.67)
SF-12v2 (mental component score) ^b	2.09 (−2.48, 6.65)	1.26 (−2.64, 5.15)

^a Adjusted for baseline measure of the outcome as a covariate.

^b For the SF12, a positive score indicates direction of effect in favour of intervention group, and a negative score indicates direction of effect in favour of control group.

AMD, adjusted mean difference; CI, confidence interval; GAD-7, Generalised Anxiety Disorder 7; PHQ-9, Patient Health Questionnaire 9.

<https://doi.org/10.1371/journal.pmed.1003779.t003>

Some participants, generally participants without symptoms of depression at study entry and also some BSWs, raised the importance of more targeted recruitment to the BASIL intervention:

“I do think just some consideration needs to be given to who we’re targeting, maybe it’s not quite so useful for people on the threshold of depression and feel that they’re doing quite well.” (BSW 04)

“I think possibly it needs to be more targeted, so anybody who has a painful medical condition or who lives alone who is isolated. Certainly I think it would benefit [people who are isolated] a lot. I think the wide spread that you have currently can be more targeted. [it could be] more focused and more helpful.” (OA02)

Intervention delivery and content. Remote delivery of the intervention by telephone was acceptable. Although video calls were offered, these were not taken up by participants. Some participants and BSWs reported they would have preferred face-to-face intervention delivery, had this been possible. One participant suggested that those with hearing difficulties would find telephone delivery more difficult. The number and frequency of intervention sessions were acceptable, although one participant reported that they would prefer 1 session per week to allow them time to implement agreed activities and plans. Some BSWs reported that it could be difficult to stick to the 30-minute timing for more complex or isolated cases, where meetings took longer.

The BASIL BA self-help booklet was thought to be engaging, and people found the mood/behaviour cycle understandable. However, some participants—those with few depression

symptoms at study entry—found this model of limited relevance. Several participants reported that they would use the booklet after the intervention ended:

“So, in days of darkness I’ll be able to flick through it [the booklet] and say, that’s what that was all about, how to break things down and not get upset about them and not let them get you down.” (OA06)

The patient stories in the booklet were reported to be relevant, although some participants reported that booklet activity examples could ideally be more varied. Both BSWs and participants found activity planning to be sometimes difficult, especially where some services were shut under lockdown conditions. Planned activities may therefore need to be sufficiently flexible to accommodate changes in COVID-19 restrictions.

Study adaptations. The process evaluation led to intervention adaptations for the BASIL main trial, including refining the study eligibility criteria, adaptions to the self-help booklet to make reference to a wider range of example activities, making reference to modifying goals, bringing discussion of “functional activities” forward, and providing a large print version of the self-help booklet when needed.

Discussion

The BASIL trial is an external pilot trial designed to test acceptability of an adapted intervention and to refine trial procedures and design prior to undertaking a full-scale trial [22,39]. Our main finding is that higher-risk older people with LTCs living under COVID-19 restrictions were receptive to an approach to participate in a trial of a behavioural intervention. When offered BA, they preferred telephone contact rather than an offer of technology-enabled video calling. Levels of engagement with BA were high, with a greater proportion completing 6 or more planned sessions. Some people with LTCs declined the BASIL offer of telephone support.

In qualitative interviews, it was clear that those with very mild depression and good adaptation to socially-isolating restrictions were not an appropriate target group. This has led us to refine and target our intervention in a fully powered trial, and we will now only focus on older people who have some depressive symptoms above a threshold and at risk of further deterioration in mental health.

Although underpowered to test effectiveness, the between-group comparisons using CIs included benefit for BA in mitigating levels of depression at 3 months. For our measure of loneliness, there was good evidence of benefit and was unlikely to be a chance finding. Our preliminary analysis is in line with a CI approach to the interpretation of pilot trials [40], and we are keen not to overinterpret the positive finding of mitigating loneliness using BA. However, this is an encouraging finding that triangulates with the theoretical basis of BA in social isolation and the evidence of engagement and feasibility in the pilot trial. This justifies the need for a full-scale trial [41], where the consistency of this effect will be tested with greater levels of power and precision. The BASIL+ trial (the fully powered follow-on trial) is now underway and is preregistered (<https://doi.org/10.1186/ISRCTN63034289>) to reflect the design adaptations from the pilot study.

The BASIL trial and nested qualitative work adds to an emerging literature on the use of psychological interventions that incorporate cognitive or behavioural strategies to address loneliness and its causal role in depression [42]. Research to date has shown behavioural approaches to be highly effective in the treatment of depression among older people [18,20,43,44], and the preliminary results of the BASIL trial lend support to this approach in the face of COVID-19 restrictions and in mitigating loneliness [41]. A fully powered trial of

BA is now underway, and in time, this will report on the short- and long-term clinical and cost-effectiveness of a scalable behavioural psychosocial intervention. This will add to an emerging trial-based literature to establish the clinical and cost-effectiveness of interventions that target loneliness [12,45].

Our pilot trial was also undertaken rapidly and during the COVID-19 pandemic in early 2020. As such, we, along with other researchers undertaking trials during COVID-19, have had to adapt the methods used to generate randomised evidence. We have shown that it is possible to deliver trials with adaptations to minimise patient contact and streamline recruitment procedures. This makes us confident that this is an efficient method of participant engagement and follow-up for future trials, both under COVID-19 and beyond the pandemic [46]. It is of note that the time elapsed between the onset of the pandemic and the recruitment of the first participant was less than 3 months. We chose to study the impact of a plausible psychosocial intervention to mitigate depression and loneliness in an at-risk population of older people with multimorbidity. Population surveys under COVID-19 have shown that younger people are also at risk of loneliness [47] and psychological deterioration [48]. It is important that interventions to tackle the higher rates of depression and loneliness in all age groups are also developed and evaluated. Finally, we note that we worked with experts by experience at all stages of the design and delivery of the BASIL trial, and we believe the high levels of engagement reflect the positive contribution made by older people with lived experience in the BASIL programme.

The BASIL study had 2 main limitations. First, we found that the intervention was still being delivered at the prespecified primary outcome point, and this fed into the design of the main trial where a primary outcome of 3 months is now collected. Second, this was a pilot trial and was not designed to test between group differences with high levels of statistical power. Type 2 errors are likely to have occurred, and a larger trial is now underway to test for robust effects and replicate signals of effectiveness in important secondary outcomes such as loneliness. Finally, we acknowledge that we have relied on self-reported activity and social contact, and we ultimately do not know if this did in fact increase as a consequence of the intervention. The BASIL trial remains in follow-up, and we will report 12-month outcomes when these become available.

At the outset of the COVID-19 pandemic, it was predicted that there would be significant impacts on public mental health [5], including loneliness and depression, as a consequence of pandemic restrictions. This has come to pass [48], and population surveys indicate increased reports of loneliness and reports of depression [2]. The pandemic has also prompted a number of studies to understand the impacts of COVID-19 [49], but there have been very few studies to evaluate psychosocial interventions to mitigate psychological impact [46]. To our knowledge, BASIL is the first study to report trial-based evidence.

A clinical priority and policy imperative is to identify a brief and scalable intervention to prevent and mitigate loneliness, particularly in older people [50,51]. The preliminary results are in line with potential benefit for this intervention in mitigating loneliness at 3 months. We will now test the short- and long-term clinical and cost-effectiveness. This evidence may prove to be useful in improving the mental health of populations during the time of COVID-19 and also in mitigating depression and loneliness in socially isolated at-risk populations after the pandemic has passed [15].

Supporting information

S1 Table. Details of BASIL participants who did and did not complete the BASIL modules and included in qualitative analysis. BASIL, Behavioural Activation in Social Isolation. (DOCX)

S2 Table. Details of BSWs included in qualitative analysis. BSW, BASIL support worker.
(DOCX)

S1 Data. SAP. SAP, Statistical Analysis Plan.
(PDF)

S2 Data. CONSORT checklist. CONSORT, Consolidated Standards of Reporting Trials.
(DOC)

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