

Layperson-Supported, Web-based Cognitive-behavioral Therapy for Older Adults with Depression: A Randomized Controlled Trial

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Abstract

Background:

Objective:

Methods:

Results:

Conclusions:

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Introduction

Depression is the most prevalent mental health condition among older adults, particularly among those with chronic physical health conditions and functional limitations [1]. Though evidence-supported pharmacological and non-pharmacological treatments exist, not all options are readily accessible to all populations of older adults [2, 3]. Older adults with mobility difficulties, for example, face significant logistical barriers accessing office-based treatments, in addition to ~~common~~ access barriers such as cost, provider shortages, and stigma.

Web-based cognitive-behavioral therapy (wCBT), also known as internet-based cognitive-behavioral therapy (iCBT) or computerized cognitive-behavioral therapy (cCBT), is a promising option to address the unmet mental health needs of older adults. wCBT, initially introduced in the 90s via CD-ROM manuals, now typically combines audio, video, and text elements based on CBT principles hosted on websites or apps. Advantages of wCBT include low cost, efficiency, convenience, and accessibility [4]. Moreover, pre-programmed components in wCBT can minimize variability between trials and dissemination, thus maintaining greater fidelity to ~~the a~~ treatment protocol compared to the potential “drift” in face-to-face CBT sessions [5].

While wCBT holds promise, its real-world impact is often limited due to low user engagement [6]. Common drawbacks of wCBT programs include text-dense ~~and academically-leaning content~~ and a “one size fits all” approach [7]. wCBT programs intentionally designed for older adults are very limited, with only a few exceptions [8-10]. Although some generic wCBT programs have been shown to effectively reduce depression among older adults [11-13], we have found numerous usability and engagement issues with these programs when tested among underserved older adult populations, such as those with low income, limited literacy and technology competence, and disabilities [14, 15]. To realize the real-world benefits of wCBT, we need innovations to create more inclusive, user-friendly, and engaging wCBT programs to better serve older adults.

We developed Empower@Home to address the shortage of wCBT programs that fit the needs of older adults from underserved communities. The program is enhanced with “Empower Coaches”, laypersons trained to support users, considering the shortage of geriatric mental health professionals and research evidence that supported interventions is more effective than unsupported ones [16-18]. The design process of Empower@Home, detailed elsewhere [19], adopts a user-centered and community-engaged approach. The resulting program includes 9 online sessions grounded in CBT principles delivered via a custom-made website with a streamlined user interface, accompanied by a large-print user workbook containing session summaries, home practices, and wellness resources. A key innovation is the integration of entertainment elements ~~that boost user engagement~~ in the form of a character-driven storyline featuring a homebound older adult named Jackie, ~~to increase user engagement~~. Jackie, portrayed as a 74-year-old female facing health challenges common among the target demographic, appears in animated narratives favored by our stakeholders.

During usability and field tests, Empower@Home showed superior usability than comparable programs [19]. Findings from an uncontrolled trial showed a medium effect in depression reduction among older adults with mild depression and a large effect among older adults with

moderate depression [14]. However, the intervention has not yet been evaluated against a control condition. To fill this void, the present study aims to assess the efficacy of layperson-supported Empower@Home for older adults with depression in a randomized controlled trial (RCT). Potential mediators will also be explored to understand change mechanisms responsible for the expected effects.

Methods

The study protocol has been published elsewhere [3]. An abbreviated description of the study methods is provided here to inform the readers. The study is registered on ClinicalTrials.gov as NCT05593276. The University of Michigan IRB-Health Sciences and Behavioral Sciences (HSBS) approved the study as HUM00212950.

Participant Recruitment

Participants were recruited from research volunteer registries, social media advertisements, and referral from community agencies. [Participants To qualify, participants](#) needed to read and speak English, reside in Michigan, be at least 60 years old, and have elevated depressive symptoms at screening (score of ≥ 8 on the Patient Health Questionnaire [PHQ-9]). Participants were excluded if they were receiving or planning to receive psychotherapy during the trial, had probable dementia, a psychotic disorder, moderate to high risk of suicide, a terminal illness, a current substance use disorder, or uncorrected severe vision impairment (e.g., blindness). Lacking device ownership or internet access was not an exclusion criterion. Participants who lacked computer or internet were provided with a cellular tablet at no cost during the trial.

Study Design

The study adopted a parallel RCT [design](#), and participants were randomly assigned to either Empower@Home supported by trained lay coaches or a waitlist attention control group with a 1:1 allocation ratio. Allocation was made according to a computer-generated random sequence, unconcealed to the researcher but concealed to the participants. The principal investigator (XX) created the sequence, the project coordinator (ST) handled the allocation, and research staff uninformed of the sequence and allocation decision conducted screening assessments. Given the content of the intervention and study design, blinding the participant to the conditions was not feasible. Research staff who conducted follow-up assessments were blinded to conditions.

Procedures

Figure 1 shows participant flow and allocation. Potential participants sourced from volunteer registries and social media ads were guided to a web survey to complete a general screener used for multiple studies. Qualifying individuals were then contacted up to three times by the research team for further phone screening. Due to potential internet access issues, community agency referrals bypassed the web screener and directly received screening calls from the research team. Participants meeting eligibility after screening were invited to complete informed consent. Assessments were conducted over the phone at baseline (up to 2 weeks before the intervention) and post-test (up to 2 weeks after the 10-week intervention or waiting period). Participants could earn up to \$120 for completing research assessments. Compensation was not dependent on

participation in the intervention or coaching.

Participants in the waitlist control group were contacted by trained research staff, who have educational backgrounds similar to the coaches. These staff members conducted weekly friendly phone calls, which lasted about approximately 17 minutes ~~each~~, and administered depression assessments using the PHQ-9 every two weeks. Following their post-test assessment, these control participants were then allowed to participate in the intervention.

Intervention

Empower@Home has 9 sequenced online sessions tailored ~~to suit~~ to the needs of older adults. ~~Included content was informed by two, drawing from the~~ CBT manuals ~~written for clinicians for~~ working with older ~~adults, people from~~ (Gallagher-Thompson & Thompson [20] and ~~the Behavioral Activation manual from~~ Lejuez et al. [21]). The adaptations and details of the program content, including the coaching component, are documented elsewhere [14, 19]. In brief, ~~participants navigate the~~ online sessions ~~by going through~~ contain a blend of brief videos, narrated text pages, short exercises, and offline home practices. Each online session can be completed independently in ~~about approximately~~ 20 to 30 minutes. Alternatively, participants may opt to ~~undergo these complete~~ sessions during their weekly coaching calls, ~~according to their preferences~~. Participants are given 10 weeks to try the program and encouraged to do one session a week.

Each participant received support from a trained coach for up to 10 weeks. Coaches follow a structured coaching guide, developed and refined ~~from in~~ our previous studies [14, 19]. This guide is adaptable, allowing for an optimized balance between benefits and resources utilized. 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~~ participants to complete online sessions on their own and invite them to discuss the session during the weekly coaching calls. This approach, rooted in self-determination [22], ~~not only better~~ serves participants ~~better but also and~~ optimizes staff time.

The coaches participating in this RCT ~~comprised of~~ included undergraduate students in psychology (n=X), master's degree students in social work (n=X), ~~along with ana~~ and a master's-level individual holding a master's in social worker but lacking without licensure or prior psychotherapy experience. Hence, they were all considered lay coaches without specialized mental health skills. A licensed clinical social worker (JK) provided clinical backup and the coaches received group supervision and individualized support from the study's management team.

Measures

Usability, acceptability, and engagement outcomes

Usability was assessed at post-test using the System Usability Scale (SUS), a 10-item scale commonly used in evaluating the usability of websites, software, and other human-machine

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systems [23]. SUS scores range from 0 to 100, and ≥ 68 is considered above average. The SUS had good internal consistency in the study sample (Cronbach's $\alpha=.81$).

Acceptability was assessed at post-test using the Treatment Evaluation Inventory (TEI), which was developed explicitly specifically for evaluating acceptability in geriatric depression treatments [24]. We reduced the responses on the original TEI from a 7-point Likert scale to a 5-point Likert scale to ease respondents' burden during phone-based assessments. The modified TEI has a total score ranging from 11 to 55, and a score of ≥ 32 indicates favorable attitudes toward the treatment. The TEI had excellent reliability among Empower@Home participants (Cronbach's $\alpha=.89$).

Engagement was measured as the number of online sessions completed, recorded on the web portal, and verified by the coaches. These measures were administered to participants in the intervention group, as they were irrelevant to the control group at post-test.

Primary clinical outcome

Depressive symptoms ~~are~~ were assessed using the PHQ-9, the most used outcome measure in wCBT studies [25]. 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 <10 suggests a partial response, and a score of < 5 represents remission [26]. Each participant completed the PHQ-9 up to 7 times: during baseline, post-test, and five biweekly assessments during the trial. The intervention group completed the PHQ-9 on the web portal during sessions 1, 3, 5, 7, and 9, while the control group underwent the same assessment via phone calls at weeks 1, 3, 5, 7, and 9 of the waiting period.

Secondary outcomes

Secondary outcomes were measured at baseline and post-test using validated instruments. The following psychosocial outcomes were assessed. Generalized Anxiety Disorder 7-item (GAD-7) is a validated population-based survey instrument measuring anxiety symptom [27] (Cronbach's $\alpha=.81$ in this study sample). Scores 5, 10, and 15 on the GAD-7 represent thresholds of minimal, mild, moderate, and severe anxiety, respectively. The Patient Reported Outcome Measurement Information System (PROMIS) Anger 5a short form [28] assesses self-reported angry mood (e.g., irritability) (Cronbach's $\alpha=.82$). The PROMIS – Social Isolation 8a [29] contains eight items and evaluates feelings of being avoided, excluded, detached, or disconnected [29]. (Cronbach's $\alpha=.89$). For both PROMIS measures, raw scores were converted into T-scores with a mean of 50 and a standard deviation (SD) of 10, using conversion tables [30].

The following measures were used to assess physical health outcomes. Designed as a brief screening tool for insomnia, the Insomnia Severity Index (ISI) has seven questions asking about the nature and symptoms of sleep problems [31] (Cronbach's $\alpha=.78$). Scores 8, 15, and 22 on the ISI represent thresholds of subthreshold insomnia, moderate clinical insomnia, and severe clinical insomnia, respectively. The Pain, Enjoyment, General Activity (PEG) scale includes 3 items measuring the severity of pain and its interference with enjoyment of life and general

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activity (Cronbach's alpha =.93) [32].

In addition, the EuroQol 5 Dimension 5 Level (EQ-5D-5L) is a self-report survey of global health and health-related quality of life, containing questions across 5 domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression [33] (Cronbach's alpha =.76). Responses to the EQ-5D-5L were converted into utility values using an algorithm for the U.S. population [34], with a higher score corresponding to better health-related quality of life.

Potential mediators

Potential mediators include CBT-related change mechanisms. Fourteen items from the Cognitive-Behavioral Therapy Skills Questionnaire (CBTSQ) [35] were used for a general assessment of CBT skill acquisition and use of the two core CBT skills – cognitive restructuring and behavioral activation (Cronbach's alpha =.83). The 9-item Behavioral Activation for Depression Scale - Short Form (BADS-SF), which includes subscales for activation and avoidance, is often used to track changes in the behaviors hypothesized to underlie depression and specifically targeted for change by behavioral activation [36] (Cronbach's alpha =.80). In addition, the 16-item Basic Needs Satisfaction in General Scale (BNSG-S) [37] is designed to assess ~~one's~~ satisfaction with the three basic psychological needs, including autonomy, competence, and relatedness (Cronbach's alpha =.77). Autonomy pertains to an individual's desire to perceive their actions and subsequent consequences as self-determined, rather than being subject to external influences or control [38]. Competence refers to the inherent desire to experience a sense of efficacy and proficiency in the execution of tasks across a range of complexities [39]. Relatedness refers to the inherent human desire for social connection, support, and caring from others [39]. According the self-determination theory, all three needs must be fulfilled to achieve psychological well-being [38].

Statistical Analysis

Descriptive statistics were computed for demographic characteristics, psychosocial outcome measures, program usability, acceptability, and engagement measures. Between-group differences in baseline characteristics were compared using a χ^2 for categorical variables and two-sample t tests for continuous variables. Within-group differences between baseline and post-test were evaluated using paired t tests. Between-group differences in outcomes at post-test were evaluated using two-sample t tests. In addition, linear mixed modeling was used to test within-group changes over time and to compare changes between the treatment and control groups in depressive symptoms.

Causal mediation analysis [40, 41] was conducted to explore the mechanisms through which the treatment exerted its effects, specifically focusing on the role of the potential mediators described ~~previously above~~. Using the *mediate* command in Stata, each mediator was evaluated individually through separate models [42]. To account for potentially confounding factors, variables that could influence both the mediator and the outcome, namely age, gender, education, income, living arrangement, and count of chronic physical conditions, were included. Furthermore, baseline PHQ-9 score was included in the outcome equation and the baseline score of each respective mediator was included in the mediator equation, allowing for more robust estimates of

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the indirect effects.

Analyses involving depressive symptoms involved an intention-to-treat design, with missing values imputed using the last observation carried forward. Given the small sample size, low rates of missing values, and exploratory nature of the secondary aims, analyses involving secondary outcomes and potential mediators were conducted with complete data without imputing missing values. Unless otherwise specified, $\alpha = 0.05$ for two-sided tests were used to determine statistical significance. All analyses were performed using Stata SE (version 18; StataCorp LLC).

Results

Descriptive Statistics of the Study Participants

Seventy participants were enrolled and assigned to either the treatment or the waitlist attention control groups (Figure 1). Table 1 shows their baseline characteristics. Bivariate analyses did not indicate any significant differences between the treatment and the control group (all p-values > .05 for two-tailed tests). Study participants were predominately women (n=57, 81%), non-Hispanic White (n=56, 80%), with at least a college degree (n=40, 57.1%), not married (n=37, 52.9%), and earning a household income of less than \$50,000 USD a year (n=40, 58.0%). Most participants reported owning a laptop or personal computer (n=60, 85.7%). Most of them had been diagnosed with depression by a health care provider (n=44, 62.9%), but only about one-third reported taking antidepressants (n=25, 36%). All but two participants reported at least some difficulty in lower body mobility (n=68, 97%), with an average of 4 items endorsed on the mobility limitation index.

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Table 1 Baseline Characteristics of Study Sample

	Control Group		Treatment Group		Control vs. Treatment
	n	%	n	%	
Age					
Mean	67.91	(SD = 5.83)	69.80	(SD = 5.36)	t (68) = -1.41, p = .164
Range	60 to 85		61 to 86		
Gender					
Female	30	85.7	27	77.1	χ^2 (1) = 0.85, p = .356
Male	5	14.3	8	22.9	
Race/Ethnicity					
White, non-Hispanic	30	85.7	26	74.3	χ^2 (4) = 5.40, p = .249
African American or Black	4	11.4	5	14.3	
Asian or Pacific Islander	0	0	2	5.7	
Native American	1	2.9	0	0	
Mixed race or other	0	0	2	5.7	
Education					
High school or GED	4	11.4	6	17.1	χ^2 (3) = 2.91, p = .406
AA or some college	8	22.9	12	34.3	
4-year college degree	13	37.1	12	34.3	
Master's degree or above	10	28.6	5	14.3	
Household income					

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< \$20,000 USD	2	5.7	5	14.7	$\chi^2(2) = 2.51, p = .473$
\$20,000 – \$49,999 USD	17	48.6	16	47.1	
\$50,000 – \$74,999 USD	9	25.7	5	14.7	
≥ \$75,000 USD	7	20.0	8	23.5	
Living Status					
Lives with others	21	60.0	20	57.1	$\chi^2(1) = 0.06, p = .808$
Lives alone	14	40.0	15	42.9	
Marital Status					
Married	18	51.43	13	37.1	$\chi^2(4) = 4.70, p = .302$
Living with a partner	1	2.86	1	2.86	
Divorced or separated	6	17.14	14	40.0	
Widowed	8	22.86	5	14.3	
Never Married	2	5.71	2	5.71	
Count of chronic conditions^a					
Mean	2.31 (SD = .99)	2.25 (SD = 1.27)	t (68) = 0.21, p = .834		
Range	0 to 5	0 to 5			
Mobility limitation index^b					
—Mean	4.20 (SD = 2.29)	4.71 (SD = 2.76)	t (68) = -.85, p = .399		
—Range	1 to 9	0 to 10			
Device Ownership					
No device ownership	2	5.7	2	5.7	$\chi^2(2) = .73, p = .693$
Has tablet or iPad	4	11.4	2	5.7	
Has laptop or PC	29	82.9	31	88.6	
Ever received a depression diagnosis^c					
No	13	37.1	13	37.1	$\chi^2(1) = <.01, p = 1.00$
Yes	22	62.9	22	62.9	
Taking antidepressant					
No	21	60.0	24	68.6	$\chi^2(1) = .56, p = .454$
Yes	14	40.0	11	31.4	
PHQ-9 score					
Mean	11.29 (SD = 2.65)	11.49 (SD = 2.63)	t (68) = -.32, p = .752		
Range	8 to 18	8 to 19			

Notes. a. PHQ-9=Patient Health Questionnaire-9.

^a Chronic disease count was the sum of self-reported conditions including hypertension, diabetes, chronic lung disease, chronic kidney disease, heart disease, stroke, arthritis, and cancer.

^b The mobility limitation index asks if a participant has difficulty with 11 tasks: running or jogging for a mile, walking several blocks, walking one block, sitting for two hours, standing for 30 minutes, getting up from a chair after sitting for a long period, climbing several flights of stairs, climbing one flight of stairs, walking across a room, using equipment or devices when crossing a room, and getting in or out of bed. “Yeses” were summed to create a total score, ranging from 0 to 11.

^c Participants were asked, “has a doctor, therapist, psychologist, or other health care provider ever told you that you have depression?”

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Usability, Acceptability, and Engagement Outcomes

Usability, acceptability, and engagement outcomes were valid for participants in the treatment group only. Most participants completed all 9 sessions of the program ($n = 31$, 88.6%), with an average of 8.3 ($SD = 2.1$).

The average SUS score was 82 ($SD = 12.7$) with a range of 50 to 100, suggesting that the program had acceptable perceived usability among users. Moreover, an overwhelming majority ($n=30$, 88%) rated the program a SUS score of ≥ 68 . All participants ($n=34$, 100%) agreed or strongly agreed that the online program was easy to use.

The average TEI score was 45.9 ($SD = 6.6$), exceeding the benchmark score of 32, indicating favorable attitudes toward the treatment. Most participants ($n = 30$, 88%) would recommend this program to others who experience depressed moods. However, about a quarter of participants ($n = 9$, 26.5%) reported that they “experienced discomfort during this program”. Further analysis of their feedback, obtained through open-ended follow-up questions, revealed that the majority of these responses ($n = 6$) stemmed from the program evoking distressing emotions or recalling memories from their past. Interestingly, two participants clarified that they perceived this discomfort as positive (“good discomfort”), describing it as a constructive force encouraging them to change behaviors. In addition, three participants either agreed or strongly agreed that the program had undesirable side effects. An analysis of their open-ended feedback echoed sentiments expressed in the question regarding experiences of discomfort, as they felt the program made them see more clearly the issues they were facing.

Coaching

Seven coaches provided a total of 286 coaching calls to 35 participants, averaging 8.2 calls per person ($SD = 2.1$). The duration of the calls ranged from 11 to 92 minutes, with an average of 49 minutes per call ($SD = 16.9$). According to coaching notes, most participants completed the online lessons dependently prior to starting the coaching session ($n = 168$, 58.7%), while the rest did a part or an entire online lesson with the coach during the coaching session. Calls were shorter for those who completed online sessions independently, taking an average of 41 minutes ($SD = 16.6$), as compared to an average of 59 ($SD = 10.9$) minutes involving coach-guided online sessions.

According to coach self-reports, the top assistance provided by coaches was simple feedback like a word of encouragement (in 88.5% of the coaching calls), followed by facilitating understanding of lesson content (51.4%), assisting with the application of program tools (50%), reviewing or assisting with home practice (42%), and technical assistance (10.5%).

Primary Outcome

Table 2 shows the results of the linear mixed effects regression analysis for depressive symptoms. The main effect of time was significant ($b = -.49$, 95% CI $[-.73, -.26]$, $p < .001$), showing a decrease of nearly half a point on the PHQ-9 per assessment time for the control group participants. The group-by-time interaction was also significant ($b = -.68$, 95% CI $[-1.00, -.35]$, $p < .001$), indicating a faster decrease in the PHQ-score by .68 points per assessment time

for the treatment group compared to the control group. Considering both the main and interaction effects, the PHQ-9 score was predicted to decrease by 1.17 points ~~per assessment time~~ every two weeks in the treatment group.

As shown in Table 3, the treatment group had a large within-group effect size from baseline to post-test (Cohen's $d = 1.22$, $p < .001$). In contrast, the waitlist attention control group experienced a medium within-group effect (Cohen's $d = .57$, $p < .001$). All considered, the treatment was associated with a medium between-group effect size at post-test (Cohen's $d = .72$, $p < .001$).

~~Descriptives~~ Descriptive statistics were computed to describe clinically significant improvements within the treatment group. Most participants within the treatment group ($n = 21$, 60%) experienced a clinical meaningful change, defined as a change of ≥ 5 points on the PHQ-9. Among those initially scored ≥ 10 on the PHQ-9 before treatment ($n = 25$), two-thirds ($n = 19$, 76%) showed a partial response by scoring below 10 at the post treatment. Further, nearly half of the participants ($n = 16$, 45.7%) achieved a score lower than 5 on the PHQ-9 at post treatment, an indicator of remission.

Table 2 Linear Mixed Modeling Predicting PHQ-9 Scores ~~Over the Trial~~

	Estimate (SE)	95% CI	<i>t</i>	p-value
Intercept	10.48 (.50)	(9.50, 11.45)	21.14	<.001
Group allocation				
Treatment group	1.06 (.70)	(-.31, 2.43)	1.52	0.13
Time	-.49 (.12)	(-.73, -.26)	-4.09	<.001
Group \times time	-.68 (.17)	(-1.00, -.35)	-4.09	<.001

Note. CI = confidence interval; SE = standard error. Time codes represent the sequential order of assessments: 0 for the baseline, 1 for the first in-app assessment, and so on, culminating with 6 for the post-test. Each assessment occurs approximately two weeks apart.

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

Condition	Baseline	Posttest	Within-group difference	Between-group difference at posttest
Treatment (n=35)	11.49 (SD = 2.63)	6.00 (SD = 4.35)	Cohen's $d = 1.22$ $t(34) = 7.23$, $p < .001$	Cohen's $d = .72$ $t(68) = 3.00$, $p = .004$
Control (n=35)	11.29 (SD = 2.65)	8.94 (SD = 3.84)	Cohen's $d = .57$ $t(34) = 3.39$, $p = .002$	

Note. PHQ-9=Patient Health Questionnaire-9. All analyses were intention-to-treat using the last available observation carried forward. Effect sizes were calculated using pre-test scores to

subtract post-test scores so that a positive effect size indicates reduced depressive symptoms as measured by PHQ-9.

Secondary Outcomes

Table 4 presents the within-group and between-group effect sizes for secondary outcomes. Within the treatment group, significant decreases were observed at post-test from baseline in several domains: anxiety (Cohen's $d = .60$, $t_{(33)} = 3.48$, $p = .001$), anger (Cohen's $d = .65$, $t_{(33)} = 3.79$, $p < .001$), loneliness (Cohen's $d = .41$, $t_{(33)} = 2.37$, $p = .024$), insomnia severity (Cohen's $d = .49$, $t_{(33)} = 2.88$, $p = .007$), and pain intensity and interference (Cohen's $d = .39$, $t_{(33)} = 2.30$, $p = .028$). In contrast to the treatment group, the control group showed only minor absolute changes within groups, none of which were statistically significant. The between-group differences at the post-test were not statistically significant in these outcome domains. However, these results aligned with our expectations such that the treatment group showed greater improvements.

The within-group change concerning health-related quality of life, as measured by EQ-5D-5L, was not statistically significant for both the treatment and control groups. Importantly, the treatment group experienced a slight increase in quality of life, aligning with our expectations, while a decrease was noted in the control group. Despite not reaching statistical significance, the between-group effect was more pronounced than the within-group effect, owing to the divergent trends observed in each group.

Table 4 Within-group and Between-group Differences for Secondary Outcomes and Mediators

Measure	Condition	Baseline	Posttest	Within-group difference	Between-group difference at posttest
GAD-7	Treatment	7.85 (3.73)	5.06 (4.71)	Cohen's $d = .60$ $t = 3.48$, $p = .001$	Cohen's $d = .04$ $t = .17$, $p = .867$
	Control	6.17 (5.25)	5.23 (3.38)	Cohen's $d = .27$ $t = 1.48$, $p = .150$	
PROMIS-Anger	Treatment	55.20 (6.52)	50.06 (9.08)	Cohen's $d = .65$ $t = 3.79$, $p < .001$	Cohen's $d = .27$ $t = 1.10$, $p = .278$
	Control	52.67 (7.06)	52.32 (7.14)	Cohen's $d = .06$ $t = .34$, $p = .738$	
PROMIS-Social Isolation	Treatment	54.81 (8.62)	52.33 (7.98)	Cohen's $d = .41$ $t = 2.37$, $p = .024$	Cohen's $d = .31$ $t = 1.24$, $p = .221$
	Control	53.75 (6.85)	54.48 (5.52)	Cohen's $d = -.14$ $t = -.75$, $p = .462$	
Insomnia Severity Index	Treatment	13.68 (5.95)	10.74 (6.81)	Cohen's $d = .49$ $t = 2.88$, $p = .007$	Cohen's $d = .21$ $t = .83$, $p = .407$
	Control	12.33 (4.58)	12.00 (4.68)	Cohen's $d = .09$ $t = .50$, $p = .621$	
PEG	Treatment	4.44 (2.79)	3.54 (2.50)	Cohen's $d = .39$ $t = 2.30$, $p = .028$	Cohen's $d = .35$ $t = 1.40$, $p = .167$

	Control	4.36 (2.37)	4.38 (2.33)	Cohen's $d = -.02$ $t = -.10, p = .921$	
EQ-5D-5L	Treatment	.72 (.21)	.74 (.20)	Cohen's $d = .12$ $t = .68, p = .502$	Cohen's $d = .33$ $t = 1.31, p = .196$
	Control	.72 (.25)	.66 (.27)	Cohen's $d = -.26$ $t = -1.41, p = .168$	
CBTSQ	Treatment	40.85 (8.73)	50.26 (8.11)	Cohen's $d = 1.11$ $t = 6.45, p < .001$	Cohen's $d = .67$ $t = 2.69, p = .009$
	Control	44.97 (8.08)	44.90 (7.81)	Cohen's $d = -.01$ $t = -.05, p = .960$	
BADs-SF	Treatment	26.53 (12.22)	34.21 (9.98)	Cohen's $d = .64$ $t = 3.73, p < .001$	Cohen's $d = .43$ $t = 1.70, p = .094$
	Control	27.50 (10.31)	29.77 (10.93)	Cohen's $d = .19$ $t = 1.05, p = .300$	
BNSG-S	Treatment	62.18 (9.44)	66.91 (8.11)	Cohen's $d = .70$ $t = 4.11, p < .001$	Cohen's $d = .52$ $t = 2.08, p = .042$
	Control	61.0 (8.75)	62.3 (9.64)	Cohen's $d = .22$ $t = 1.23, p = .230$	

Note. N is 34 for the treatment group and 30 for the control group. Scores are reported as means with standard deviations in parentheses. Within-group differences were evaluated using paired t tests for each measure/group separately. Between-group differences were evaluated using two sample t tests for each measure separately. Analyses were conducted with complete data without imputation. Effect sizes were calculated such that a positive effect size indicates changes in the desired direction (i.e., increased quality of life, CBT skill acquisition, behavioral activation, and basic needs satisfaction, and decreased anxiety, pain, insomnia severity, anger, and loneliness). GAD-7: Generalized Anxiety Disorder 7-item. PROMIS: Patient Reported Outcome Measurement Information System. PEG: Pain, Enjoyment, General Activity. EQ-5D-5L: EuroQol 5 Dimension 5 Level. CBTSQ: Cognitive-Behavioral Therapy Skills Questionnaire. BADs-SF: Behavioral Activation for Depression Scale - Short Form. BNSG-S: Basic Needs Satisfaction in General Scale.

Mediation Analysis

As shown in Table 4, within the treatment group, significant increases were observed at post-test from baseline in all three mediators: CBT skills acquisition (Cohen's $d = 1.11, t_{(33)} = 6.45, p < .001$), behavioral activation (Cohen's $d = .64, t_{(33)} = 3.73, p < .001$), and satisfaction with basic psychological needs (Cohen's $d = .70, t_{(33)} = 4.11, p < .001$). In contrast, the control group showed only minor absolute changes within groups, none of which were statistically significant.

At posttest, significant between-group differences were observed in CBT skills acquisition (Cohen's $d = .67, t_{(33)} = 2.69, p = .009$) and basic needs satisfaction (Cohen's $d = .52, t_{(33)} = 2.08, p = .042$). Moreover, the between-group difference in behavioral activation was nearing critical value (Cohen's $d = .43, t_{(33)} = 1.70, p = .09$), reaching significance in a one-tailed test.

As illustrated in Table 5, the indirect effects associated with the three mediators were all

statistically significant. This suggests that the intervention's effect on depression was partially mediated by an increase in CBT skills acquisition ($b = -2.29$, 95% CI $[-3.58, -1.01]$, $p < .001$), behavioral activation ($b = -1.27$, 95% CI $[-2.39, -.15]$, $p = .027$), and satisfaction with basic psychological needs ($b = -1.38$, 95% CI $[-2.45, -.31]$, $p = .012$). The largest proportion of the mediation effect was observed in the CBT skills acquisition (62.9%), followed by satisfaction with basic psychological needs (46.8%), and behavioral activation (34.5%). This proportion is calculated as the ratio of the natural indirect effect to the total effect.

Table 5. Indirect and direct effects from causal mediation analysis on depressive symptoms at post-treatment ($N = 64$)

Mediator	Nature indirect effect		Nature direct effect		Proportion mediated
	b (95% CI)	p-value	b (95% CI)	p-value	
CBTSQ	-2.29 (-3.58, -1.01)	<.001	-1.35 (-3.38, .68)	.193	62.9%, $p = .005$
BADS-SF	-1.27 (-2.39, -.15)	.027	-2.41 (-4.09, -.72)	.005	34.5%, $p = .016$
BNSG-S	-1.38 (-2.45, -.31)	.012	-1.57 (-3.36, .23)	.087	46.8%, $p = .020$

Notes. The outcome was depressive symptoms as measured by the Patient Health Questionnaire–9, with a higher score indicating greater symptoms. The control group was the reference in the treatment model. Each mediator was individually evaluated in separate models. Each model included potential confounders, including age, gender, education, income, living arrangement, and count of chronic physical conditions, in both the mediator and the outcome model. Baseline depression was included in the outcome equation, and baseline score of each respective mediator was included in the mediator equation. In addition, the outcome equation includes treatment–mediator interaction. Analyses were conducted with complete data without imputation ($N = 64$, including 34 in the treatment group and 30 in the control group). CBTSQ: Cognitive-Behavioral Therapy Skills Questionnaire. BADS-SF: Behavioral Activation for Depression Scale-Short Form. BNSG-S: Basic Needs Satisfaction in General Scale. CI: Confidence Interval.

Discussion

This RCT assessed the efficacy of layperson-supported Empower@Home, a wCBT program specifically designed to alleviate depression among older adults, in comparison to a waitlist attention control group that received weekly friendly calls. The retention rate in the study was excellent, with 91% of participants engaging in the post-test interview, far surpassing the 80% benchmark. Moreover, the intervention engagement rate was high, with 89% of individuals in the treatment group completing all nine sessions of the program. To put this in perspective, the average completion rate of wCBT programs, which is typically defined as completing 80% of treatment lessons, stands at just 17% for self-administered interventions and 65% for supported interventions [43, 44]. In addition, Empower@Home demonstrated a large within-group effect [within-in](#) the treatment group (Cohen's $d = 1.22$) and a medium between-group effect [when compared to the compared-to-the](#) attention control group at post-test (Cohen's $d = .72$). These findings suggest that the novel intervention is acceptable to older adults and more efficacious than friendly calls in alleviating depression in older adults.

The findings concerning the program's usability, acceptability, and effects observed in this RCT

align with those found in a previous uncontrolled study where an initial version of the program was examined [14]. In comparison to participants in the uncontrolled study, individuals in this RCT were older by an average of 5 years (68.9 vs 63.7) and had a larger percentage of individuals with at least three physical health conditions (44.3% vs 28.2%). However, their educational background and income distribution were similar. More than half of the participants in the RCT were reached through social media advertisements, a method not utilized in the uncontrolled study. Furthermore, over half of the coaches participating in this RCT ~~were newcomers; did not have prior experience from not having~~ participated in the preceding uncontrolled study. Taking all factors into account, these consistent findings enhance the likelihood that the study results can be replicated under varied conditions.

The layperson-supported Empower@Home program showed a large within-group effect (Cohen's $d = 1.22$), aligning with previous wCBT trials with older adults, which had a pooled effect size of 1.27 as reported in a meta-analysis evaluating wCBT programs with varying levels of human support [25]. Meanwhile, its between-group effect was medium (Cohen's $d = .72$), which appears smaller than the average of 1.18 reported in the meta-analysis [25]. Notably, none of the controlled trials in the meta-analysis featured a potent attention control condition like the one utilized in this study; instead, they utilized usual care or waitlist control. The attention control group in the present study also marked a significant reduction in depressive symptoms as indicated by a medium within-group change (Cohen's $d = 0.57$). Given that empathy-oriented telephone programs administered by lay callers have been shown to improve depression and mental health among older adults [45], diminished between-group effect observed here, which results from significant improvements in the control group, is understandable. This observation is ~~in-line~~ consistent with a recent RCT involving homebound older adults with depression, where a tele-delivered behavioral activation treatment conducted by lay counselors demonstrated a medium effect ($d = .62$, 95% CI [.35 to .89]) compared to an attention control that received weekly support telephone calls [46].

Mediators [add a short discussion-optional] – can talk about CBT theory and self-determination theory and how the findings support these theories --- further evidence that this program would work.

Our study ~~furnishes-provides~~ evidence that laypersons lacking ~~prior~~ specialized mental health training can ~~be effectively trained to offer~~ offer human support in digital mental health interventions, such as wCBT programs. Supported interventions have been demonstrated to foster greater engagement and adherence and are associated with greater effects than unsupported ones [16, 47, 48]. However, the majority of currently available wCBT programs rely on therapists possessing specialized mental health qualifications or training. Given the shortage of geriatric mental health professionals, especially in underserved communities, a more practical approach might be to train laypersons to assist wCBT users. Since the primary components of therapy are pre-programmed, the training burden for wCBT supporters is considerably diminished. This makes layperson-supported wCBT a potentially more cost-effective and scalable option than therapist-supported interventions. Titov et al. [49] showed that layperson-supported wCBT for depression was equally effective as ~~a~~ clinician-supported intervention in an RCT involving adults (mean age = 44, SD = 12.3). Although research concerning older adults is still limited, Tomasino et al. [9] showed that a wCBT program,

supported by peers, was well-received and associated with a significant reduction in depressive symptoms at post-treatment in a small sample of older adults with depression. In another study that focused on low-income homebound older adults, Choi et al. [46] ~~discovered~~ found that behavioral activation treatment administered via telecommunication and led by lay counselors with bachelor's degrees was more effective than ~~the a~~ control condition, which involved weekly support calls. Although this lay counselor-led intervention was not as effective as tele-delivered problem-solving therapy conducted by clinicians in alleviating depression, it yielded comparable results in terms of secondary outcomes.

Limitations

The current study is limited by its small sample size, rendering it underpowered for the detection of small effect sizes. Power analysis indicates that a sample size of 204 is necessary to identify an effect size of .35 with a power of 80%, utilizing a two-sample t-test, as per G*Power 3.1.9.7 [50]. Moreover, without long-term follow-ups, it is unclear whether the treatment effect observed at post-test would be sustained in the long-term. In addition, generalizing the study findings should ~~consider be taken with the consideration of~~ participant recruitment sources and their characteristics. Although participants came from all parts of Michigan, including metropolitan and rural areas, participants' education levels and technology device ownership exceeded the national and state averages among older adults [51, 52]. The overrepresentation of college educated, and tech-savvy participants was not unexpected, because most participants were recruited from social media ads and a research volunteer registry that required internet access.

Conclusions

wCBT, when specifically designed for older adults and augmented with support from a trained layperson, is efficacious for reducing depressive symptoms compared to friendly telephone support. The intervention works by enhancing several change mechanisms, including facilitating the acquisition of CBT skills, promoting behavioral activation, and fostering self-determination, which manifests as a heightened sense of autonomy, competence, and relatedness. Well-designed trials are needed to test the effectiveness of the intervention for use in community and practice settings, utilizing non-clinician staff already present in these real-world settings as wCBT supporters.

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Conflicts of Interest: None

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Abbreviations

UCD: User-centered design
 iCBT: internet-based cognitive behavioral therapy
 DMHIs: digital mental health interventions
 UI: user interface