Original Research

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Effects of Cognitive Behavioral Therapy and Cash Transfers on Older Persons Living Alone in India

A Randomized Trial

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Background: A growing number of older persons in developing countries live entirely alone and are physically, mentally, and financially vulnerable.

Objective: To determine whether phone-based cognitive behavioral therapy (CBT) or a cash transfer reduce functional impairment, depression, or food insecurity in this population.

Design: Randomized controlled trial. (ClinicalTrials.gov: NCT04225845; American Economic Association RCT Registry: AEARCTR-0007582).

Setting: Tamil Nadu, India, 2021.

Participants: 1120 people aged 55 years and older and living alone.

Interventions: A 6-week, phone-based CBT and a 1-time cash transfer of 1000 rupees (U.S. \$12 at market exchange rates) were evaluated in a factorial design.

Measurements: The World Health Organization Disability Assessment Schedule (WHODAS), the Geriatric Depression Scale, and food security, all measured 3 weeks after CBT for 977 people and 3 months after for 932. Surveyors were blind to treatment assignment.

Results: The WHODAS score (scale 0 to 48, greater values representing more impairment) decreased between baseline

orldwide, many older persons, 16% by one estimate (1), live entirely alone, and the proportion is growing over time (2). The resulting isolation is of significant policy concern, as loneliness is associated with depression, cognitive decline, and reduced well-being (3, 4).

Given the low number of trained therapists in developing countries and the financial constraints their governments face, delivery of cognitive behavioral therapy (CBT) over the phone could be a promising intervention to improve the well-being of older persons living alone. Recent research has found that therapies delivered by laypeople can reduce depression in poorer countries (5-8), and video conferencingbased therapy reduces depression among homebound older persons in the United States (9). However, there is no evidence on the effectiveness of phone-based therapy among older populations in poor countries.

Research finds that CBT can effectively treat depression for older persons (10) and improve the mental health of

See also: Web-Only Supplement and the 3-week follow-up by 2.92 more (95% CI, -5.60 to -0.23) in the group assigned cash only than in the control group, and the depression score (ranging from 0 to 15, higher score indicating more depressive symptoms) decreased by 1.01 more (CI, -2.07 to 0.06). These effects did not persist to the 3-month follow-up, and CBT alone and the 2 together had no significant effects. There were no effects on food security.

Limitations: The study cannot say whether more sustained or in-person therapy would have been effective, how results would translate outside of the COVID-19 period, or whether results in the consented sample differ from those in a larger population. Primary outcomes were self-reported.

Conclusion: Among older people living alone, a small cash transfer was effective in alleviating short-term (3 weeks) functional impairment, produced a small but not clinically or statistically significant reduction in depression, and had no effect on food security. There were no short-term effects from CBT or the 2 interventions together. None of the interventions showed any effect at 3 months.

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people who are not currently mentally distressed but are at risk of becoming so (11). Behavioral components of CBT that help patients solve daily challenges and maintain relationships, or improved mental health itself, could reduce functional impairment. However, the evidence is mixed; CBT improved perceived physical health in Ghana (11), but not functional impairment of older persons in India (12). It is also possible that CBT could improve food security, a key concern in poor settings, via improved functional capabilities.

Cash transfers could have a direct effect on food security (13). They have been shown to improve mental health in many poor settings (14). They could have a direct effect on functional impairment by removing immediate constraints to carrying out daily tasks or an indirect effect through improvements in mental or physical health (15). Combining cash and CBT seems to be particularly effective for improving outcomes in some contexts (16, 17), but evidence on CBT cost-effectiveness compared with small cash payments in a poor, older population is lacking.

In a census of households in Tamil Nadu, India, used to create the sample frame for this study, we found that 8.9% of those older than age 55 years live alone, 83.4% of whom are women. In this setting, we evaluated the effects of phone-based CBT and cash transfers for older Figure 1. Study recruitment and design.



CBT = cognitive behavioral therapy; J-PAL = Abdul Latif Jameel Poverty Action Lab.

persons living alone on functional impairment, depression, and food insecurity. Our trial was conducted in 2021, during the COVID-19 pandemic.

Methods

Design Overview

We conducted a randomized controlled trial in a sample of very poor older persons living alone in Tamil Nadu during the COVID-19 pandemic. We evaluated 2 interventions using a factorial design: 1) a 6-week, phonebased CBT focused on problem-solving therapy and behavioral activation and 2) a 1-time cash transfer equal to transfers the state government provided early in the COVID-19 crisis. Figure 1 and Figure A1 of Supplement 1 (available at Annals.org) visualize the design and timeline.

Tuble 1. Descriptive Daserine characteristics of the study randopants in Each meatment choup								
Characteristics	Control (<i>n</i> = 376)	CBT Only (<i>n</i> = 377)	Cash Only (<i>n</i> = 184)	Both (<i>n</i> = 183)				
Female, n (%)	311 (83.2)	313 (83.9)	153 (83.6)	152 (83.1)				
Widow, n (%)	291 (77.8)	289 (77.5)	136 (74.3)	143 (78.1)				
Lives in rural area, <i>n</i> (%)	273 (73.0)	281 (75.3)	143 (78.1)	138 (75.4)				
Skipped or cut meals last year, n (%)	94 (26.2)	85 (23.4)	32 (17.9)	38 (21.1)				
Owns mobile phone, <i>n</i> (%)	148 (39.6)	149 (39.9)	78 (42.6)	70 (38.3)				
Not depressed: GDS < 5, n (%)	160 (42.8)	169 (45.3)	77 (42.1)	84 (45.9)				
Mildly depressed: $5 \le GDS < 9$, n (%)	82 (21.9)	85 (22.8)	41 (22.4)	42 (23.0)				
Moderately depressed: $9 \le GDS < 12$, n (%)	61 (16.3)	68 (18.2)	33 (18.0)	30 (16.4)				
Severely depressed: 12 ≤ GDS, n (%)	71 (19.0)	51 (13.7)	32 (17.5)	27 (14.8)				
Mean geriatric depression score (95% CI)	6.4 (-2.6 to 15.4)	5.9 (-2.5 to 14.3)	6.4 (-2.2 to 15.0)	6.0 (-2.3 to 14.2)				
Mean age (95% CI), <i>y</i>	67.9 (52.7 to 83.2)	67.5 (52.6 to 82.4)	67.0 (52.4 to 81.6)	66.5 (52.1 to 80.9)				
Monthly consumption in rupees, mean (95% CI)	1634.2 (-311.2 to 3579.6)	1632.1 (-257.8 to 3522.0)	1747.4 (-250.5 to 3745.3)	1863.4 (-349.6 to 4076.3)				
Self-rated finances, mean (95% CI)	2.6 (-0.7 to 5.8)	2.6 (-0.5 to 5.7)	2.7 (-0.4 to 5.7)	2.7 (-0.5 to 5.9)				
Mean WHO SAGE score (95% CI)	50.6 (17.0 to 84.3)	51.6 (17.2 to 86.1)	50.5 (13.9 to 87.1)	51.3 (14.8 to 87.8)				
Mean UCLA loneliness score (95% CI)	7.4 (3.8 to 11.0)	7.1 (3.2 to 11.0)	7.4 (4.0 to 10.8)	7.3 (3.5 to 11.0)				
Mean MMSE score (95% CI)	7.7 (-2.6 to 18.0)	7.7 (-3.2 to 18.6)	7.3 (-2.4 to 17.1)	7.7 (-3.1 to 18.5)				

Table 1. Descriptive Baseline Characteristics of the Study Participants in Each Treatment Group*

CBT = cognitive behavioral therapy; GDS = Geriatric Depression Scale; MMSE = Mini Mental State Examination; UCLA = University of California, Los Angeles; WHO SAGE = World Health Organization Study on global AGEing and adult health.

* This table presents means and 95% CIs for continuous variables, as well as counts and shares (in percentages) for binary variables from baseline surveys in control participants and in the 3 treatment groups. The 95% CIs are computed as (mean - 1.96 SD, mean + 1.96 SD), with SD being the standard deviation in the group.

The trial occurred in 3 waves, starting in January, March, and August 2021, to which potential participants had been randomly assigned in 2020. Before each wave, participants were asked for oral consent. Those who consented were randomly and evenly allocated across the trial's 4 treatment groups.

India's surge of COVID-19 in April and May 2021 prevented us from delivering cash in the second wave of our trial (there were no options for digital delivery and travel restrictions prevented in-person delivery). We therefore have just a control group and a CBT-only group in wave 2.

Follow-up data were collected through 2 rounds of phone surveys. The first took place 3 weeks after the end of CBT (the 3-week questionnaire is in **Supplement 2**, available at Annals.org) and the second 3 months after the end of CBT. Follow-up surveys were completed for the trial on 31 December 2021. Follow-up survey enumerators were blinded to treatment status.

Setting and Participants

The participants are part of an ongoing panel survey of 4739 households with persons aged 55 years and older, conducted in partnership with the Tamil Nadu state government (4). A census covering 62 000 households from 5 districts in the state was done in 2018, from which the panel sample was drawn. Older persons from the panel sample who were living alone and reachable over the phone at the time of consent were eligible for the study. We identified older persons living alone through the baseline wave of the panel in 2019 and through phone surveys with the panel sample in 2020.

Randomization

A few weeks before each wave began, we delivered phones to anyone in the wave who, based on baseline data, did not have them. Surveyors then attempted to call all persons in the wave and asked for their consent. Within each wave, an office research assistant randomly assigned the consented sample into 4 trial groups, stratifying by prior phone ownership, sex, and when first identified as living alone (2019 or 2020). Field research assistants and personnel delivering the interventions were not aware of the randomization outcome until the treatments were assigned and sent to them. All surveyors collecting followup data were blind to treatment assignment. The randomizations were done using Stata 17.0 (we detail the functions and seed used in **Appendix C of Supplement 1**).

Interventions

The therapy intervention used techniques from CBT to reduce depressive symptoms in older adults, following Dias and colleagues (12). The intervention was delivered by trained lay counselors through six 30- to 45-minute weekly calls. In the first session, counselors built rapport with the participants and introduced the intervention. Subsequent sessions used problem-solving therapy (PST) and behavioral activation (BA). In PST, participants were guided to identify problems they faced and make plans to solve them. Common problems included issues with health, pain, or sleep (Table A1 of Supplement 1). In BA, participants were guided to identify activities they enjoy and make plans to engage in them. Common activities included talking with family and/or friends and spending time with children (Table A2 of Supplement 1). Counselors were given a toolkit with information on best practices for managing various health issues the older persons might have mentioned. Participants were encouraged to involve friends or family members in the therapy to help them enact plans they made during the sessions. A booster session, delivered 2 months after the conclusion of the 6 weekly sessions and between the 2 follow-up surveys, reinforced learning.

A psychologist at Sangath (M.S.), who was involved in the organization's intervention to prevent depression late in life (12), oversaw the development of the therapy intervention and trained leaders of our field team in delivering it. The leaders in turn trained 11 lay counselors. In the 2-week training, counselors learned general counseling skills as well as the specific components of our therapy, and then practiced delivering the therapy to a few older people outside of the study sample. During the intervention, recordings of the sessions were used to monitor counselors and provide them with regular feedback. **Supplement 3** (available at Annals.org) includes intervention and counselor training materials.

Our second intervention was a 1-time cash transfer of 1000 rupees–U.S. \$12 at market exchange rates and \$43 at 2021 purchasing power parity (PPP; a conversion between currencies that accounts for purchasing power). This value represents 61.2% of average monthly control group consumption at baseline, and matches the value of emergency cash transfers the Tamil Nadu government gave to all families with ration cards for 2 months at the start of the pandemic. Our cash transfer was delivered in person 1 week after the conclusion of therapy for a given wave.

We assessed adherence to the CBT and cash interventions through records of whether each assigned counseling session was successfully completed and whether each assigned cash transfer was successfully given.

Outcomes and Follow-up

The outcomes were measured at baseline and at 2 rounds of follow-up phone surveys, 3 weeks and 3 months after the end of CBT in a given wave. To ensure the quality of the data, back-checks were done at baseline and accompaniments were done during the follow-ups.

The last version of the data-and-safety monitoring board (DSMB) protocol filed before the intervention launch specified 3 primary outcomes (Study Protocol, available at Annals.org). First is functional impairment, measured through the 0 to 48 score of the World Health Organization Disability Assessment Schedule (WHODAS). The WHODAS includes 12 items that ask how difficult it was, on a 0 to 4 scale, to perform a range of tasks related to self-care, cognition, daily life, mobility, social participation, and maintaining relationships in the last 30 days (18) with greater values representing more impairment.

The second primary outcome is depression symptoms, measured using the short-form version of the Geriatric Depression Scale (GDS) (19, 20). This scale asks participants 15 yes-no questions about their feelings in the past week, for example, whether they felt their life was empty. The GDS scores range from 0 to 15, with greater values reflecting greater depressive symptoms. Our depression and functional impairment measures have both been validated in the Indian context (19, 21).

The third primary outcome is food security, defined as an indicator equal to 1 if the participant did not have to skip or cut the size of any meal in the last week.

We also present effects on 9 secondary outcomes: health behavior; COVID-19 vaccination; health outcomes; the Mini Mental State Examination (MMSE) score; the University of California, Los Angeles (UCLA) Loneliness Scale score; consumption; social integration with family; social integration with others; and mortality.

Appendix B of Supplement 1 provides more detail on the outcomes and notes any deviations from the DSMB protocol in how they are defined.

Received	Respondents, %					
Session 1	87.5					
Session 2	82.3					
Session 3	76.3					
Session 4	72.1					
Session 5	69.5					
Session 6	67.4					
Booster session	66.1					
Received cash (if assigned cash)	91.0					

* Only respondents who complete a given session (for example, 1) are eligible to move on to the next session (for example, 2), and so on. Respondents who completed at least 1 session and did not decline consent at any point for the counseling sessions were eligible for the booster session.

Statistical Analysis

Table 2 Treatment Compliance*

Before the study began, we calculated minimum detectable effects of 0.25 SDs for all primary outcomes in a sample of 1534 participants. This effect size would correspond to 0.99 and 0.95 points in the 0 to 15 depression scale at 3 weeks and 3 months, respectively, 2.74 and 2.69 points in the 0 to 48 WHODAS score, and 11 and 10 percentage points in food security. Details are in **Appendix C of Supplement 1**. In the most closely related study, Dias and colleagues (12) found an effect of -0.81 SD 1 month after their CBT on the 12-Item General Health Questionnaire (GHQ-12) score in a sample of 181 patients.

Our tables present, for each of the 4 trial groups, the simple difference of the outcomes between follow-up and baseline, as well as an adjusted difference in difference (DiD) for each of the treatment groups relative to the control. These DiDs were computed using mixedeffect longitudinal models that controlled for stratification variables and assignment to CBT in wave 2. The models were linear for continuous variables and logistic for binary variables, and were estimated in Stata 17.0 using the *xtmixed* package. The data were analyzed as "intention to treat." We computed P values and, to adjust for multiple hypothesis testing, Q values. We also present results from specifications that account for attrition using entropy balancing (22), which reweights nonattrited observations to attain balance on baseline variables across the trial groups. See Appendix C of Supplement 1 for details on our statistical methods.

We performed exploratory subgroup analyses for the primary outcomes, splitting the sample by sex (a stratification variable), as well as baseline depression scores and baseline consumption.

Role of the Funding Source

The funding source had no direct role in the design or conduct of the trial, interpretation of the data, or preparation of the manuscript. A DSMB reviewed and approved changes in protocols and commented on the implementation of the study.

RESULTS

Trial Sample

At baseline in 2019, there were 1534 older persons living alone in the panel sample, 1499 of whom were still

Table 3.	Treatment Effects	on Primar	VOutcomes*
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Outcomes	Difference Between Follow-up and Baseline†				Effects	Difference in Difference Versus Control‡		
	Control	CBT Only	Cash Only	Both		CBT Only	Cash Only	Both
3-wk follow-up WHODAS (scale 0 to 48)								
Difference	-4.96	-6.59	-5.57	-4.62	DiD (adi.)	-2.15	-2.92	-2.22
95% CI	(-6.52 to -3.40)	(-8.17 to -5.01)	(-7.79 to -3.35)	(-6.90 to -2.33)	95% CI	(-4.82 to 0.51)	(-5.60 to -0.23)	(-5.01 to 0.56)
Observations, n	326	323	165	163	P value Q value§	0.113 0.51	0.033 0.105	0.117 0.21
GDS (scale 0 to 15)	0.10	0.00	0.11	0.71		0.00	1.01	0.20
	(0.19)	(0.09)	-0.11	0.01		-0.09	-1.01	-0.30
Observations, n	326	323	(-0.99 to 0.77) 165	(-0.24 to 1.47) 163	P value Q value	(-1.18 to 1.01) 0.88 1.00	(-2.07 to 0.08) 0.063 0.105	(-1.45 to 0.88) 0.48 0.21
(0 or 1)								
Difference	0.01	0.02	0.02	0.10	DiD (adi.)	0.03	_0.01	0.09
95% CI	(-0.05 to 0.08)	(-0.04 to 0.08)	(-0.06 to 0.10)	(0.03 to 0.18)	95% CI	(-0.07 to 0.13)	(-0.12 to 0.11)	(-0.00 to 0.18)
Observations, n	326	323	165	163	P value Q value	0.57 1.00	0.92 0.44	0.061 0.21
3-mo follow-up WHODAS (scale 0 to 48)								
Difference	-2.45	-3.04	-1.62	-1.58	DiD (adj.)	0.08	0.73	0.18
95% CI	(-4.02 to -0.88)	(-4.63 to -1.45)	(-3.94 to 0.70)	(-3.93 to 0.76)	95% CI	(-2.53 to 2.70)	(-1.81 to 3.27)	(-2.52 to 2.88)
Observations, n	314	309	159	150	P value Q value	0.95 1.00	0.57 0.62	0.89 1.00
GDS (scale 0 to 15)								
Difference	0.43	0.86	0.42	0.74	DiD (adj.)	0.44	-0.35	-0.08
95% CI	(-0.21 to 1.07)	(0.22 to 1.50)	(-0.47 to 1.30)	(-0.12 to 1.60)	95% CI	(-0.59 to 1.48)	(-1.38 to 0.68)	(-1.12 to 0.96)
Observations, <i>n</i>	314	309	159	150	P value Q value	0.40 1.00	0.51 0.62	0.88 1.00
Food security (0 or 1)								
Difference	0.07	0.04	-0.07	-0.00	DiD (adj.)	-0.01	-0.10	-0.02
95% CI	(0.00 to 0.13)	(-0.02 to 0.10)	(-0.16 to 0.01)	(-0.09 to 0.09)	95% CI	(-0.11 to 0.09)	(-0.23 to 0.02)	(-0.13 to 0.09)
Observations, n	314	309	159	150	P value Q value	0.85 1.00	0.097 0.41	0.70 1.00

CBT = cognitive behavioral therapy; DiD (adj.) = difference in difference adjusted for control variables; GDS = Geriatric Depression Scale; WHODAS = World Health Organization Disability Assessment Schedule.

* For continuous outcomes, we use a longitudinal linear mixed-effect model with random intercepts by person, and robust SEs to obtain the adjusted difference in difference (DiDs). For binary outcomes, we use a longitudinal logistic mixed-effect model with random intercepts by person, and robust SEs, with a postanalysis to obtain adjusted DiDs. More details about the statistical model can be found in the statistical appendix (Appendix C of Supplement 1).

† The first 4 columns of this table present, for each primary outcome, and within each group, the difference of the average value between the 3week (or 3-month) follow-up and the baseline, as well as the 95% CI of the difference, and the number of observations at 3 weeks (or at 3 months).

[‡] The last 3 columns of this table present, for each primary outcome and each treatment, the adjusted DiD relative to control, that is, the difference in the baseline to follow-up change between each treatment group and the control group. These DiDs are computed with a regression model that controls for stratification variables and assignment to CBT in wave 2.

§ Q values are calculated as sharpened 2-stage Q values, described in reference 23 (Anderson) and in reference 24 (Benjamini et al). We adjust for 3 hypotheses (3 outcomes) separately for each treatment at each follow-up.

alive when our study began. The phone surveys in 2020 identified 204 people in the panel sample newly living alone, for a total of 1703 people. We reached 1321 people over the phone at the time of consent, 1120 of whom consented. People who had higher depression scores and were poorer at baseline were more likely to consent, as were women, widows, and those living in rural areas (Table A5 of Supplement 1).

At the 3-week follow-up, we surveyed 977 participants (87.2%) and, at 3 months, we surveyed 932 (83.2%). Rates of attrition are the same between the control group and each treatment group (Table A6 of Supplement 1), and

our results look similar when we use entropy balancing (22) to account for attrition (Tables A16a to A16c of Supplement 1).

Table 1 presents baseline characteristics in each treatment group. The sample is predominantly female (83.4%), with an average age of 67 years. Of the sample, 77.1% were widowed and 75.0% lived in rural areas. The sample is very poor; the average person had a monthly consumption of around 1699 rupees (U.S. \$73 PPP in 2021), and 23.3% had skipped meals in the week before the survey. Forty percent owned mobile phones. The average baseline GDS was 6.14, which would be categorized as

Table 4. Treatment Effects on Primary Outcomes by Sex*								
Outcomes	Difference Between Follow-up and Baseline			Effects	Difference in Difference Versus Control			
	Control	CBT Only	Cash Only	Both		CBT Only	Cash Only	Both
Women, 3-wk follow-up								
Difference	_1 52	_7.01	_6.10	_5 15	DiD (adi.)	_3.54	_4 15	_3.24
95% Cl	(-6.23 to -2.81)	(-8.74 to -5.29)	(-8.49 to -3.71)	(-7.61 to -2.68)	95% CI	(-6.41 to -0.67)	(-7.06 to -1.24)	(-6.25 to -0.22)
Observations, n	275	275	139	135	P value O value	0.015	0.005	0.035
GDS (scale 0 to 15)								
Difference	0.60	-0.01	-0.12	0.32	DiD (adj.)	-0.54	-1.38	-0.97
95% CI	(-0.10 to 1.30)	(-0.68 to 0.66)	(-1.08 to 0.84)	(-0.63 to 1.27)	95% CI	(-1./3 to 0.65)	(-2.56 to -0.21)	(-2.11 to 0.18)
Observations, n	275	275	139	135	P value Q value	0.37	0.021	0.056
Food security (U or T)	0.00	0.02	0.01	0.11		0.07	0.01	0.11
Difference	-0.00	0.02	(0.01)	0.11 (0.02 to 0.20)	DID (adj.)	(0.06)	(0.012 ± 0.014)	0.11 (0.01 to 0.21)
95% Cl	(-0.07 to 0.07)	(-0.05 to 0.09)	(-0.08 to 0.10)	(0.03 to 0.20)	95% CI	(-0.05 to 0.17)	(-0.13 to 0.14)	(0.01 to 0.21)
Observations, II	275	275	137	155	Q value	0.33	0.46	0.028
Women, 3-mo follow-up WHODAS (scale 0 to 48)								
Difference	-1.95	-3.45	-2.21	-2.49	DiD (adj.)	-1.42	-0.69	-1.30
95% CI	(-3.65 to -0.26)	(-5.15 to -1.74)	(-4.67 to 0.26)	(-4.99 to 0.02)	95% CI	(-4.25 to 1.42)	(-3.43 to 2.06)	(-4.26 to 1.66)
Observations, n	267	260	133	123	P value Q value	0.33 1.00	0.62 0.89	0.39 1.00
GDS (scale 0 to 15)								
Difference	0.64	0.86	0.30	0.28	DiD (adj.)	0.23	-0.58	-0.65
95% CI	(-0.05 to 1.33)	(0.18 to 1.55)	(-0.66 to 1.26)	(-0.68 to 1.23)	95% CI	(-0.89 to 1.35)	(-1.70 to 0.55)	(-1.79 to 0.48)
Observations, n	267	260	133	123	P value Q value	0.69 1.00	0.31 0.89	0.26 1.00
Food security (0 or 1)								
Difference	0.05	0.04	-0.07	0.02	DiD (adj.)	0.01	-0.09	0.01
95% CI	(-0.02 to 0.12)	(-0.03 to 0.11)	(-0.17 to 0.02)	(-0.08 to 0.12)	95% CI	(-0.10 to 0.12)	(-0.22 to 0.05)	(-0.11 to 0.13)
Observations, n	267	260	133	123	P value Q value	0.87 1.00	0.20 0.89	0.89 1.00
Men, 3-wk follow-up WHODAS (scale 0 to 48)								
Difference	-7.42	-4.60	-2.99	-2.12	DiD (adj.)	6.01	3.47	2.93
95% CI	(-11.16 to -3.68)	(-8.40 to -0.79)	(-8.44 to 2.46)	(-8.02 to 3.77)	95% CI	(-0.40 to 12.41)	(-3.10 to 10.04)	(-3.87 to 9.73)
Observations, n	51	48	26	28	P value Q value	0.066 0.111	0.30 1.00	0.40 0.66
GDS (scale 0 to 15)								
Difference	-1.98	0.58	-0.10	2.04	DiD (adj.)	2.55	1.05	2.67
95% CI	(-3.54 to -0.42)	(-0.97 to 2.13)	(-2.21 to 2.01)	(0.14 to 3.94)	95% CI	(-0.03 to 5.13)	(-1.45 to 3.56)	(-0.15 to 5.49)
Observations, n	51	48	26	28	P value Q value	0.053 0.111	0.41 1.00	0.063 0.23
Food security (0 or 1)								
Difference	0.10	0.03	0.06	0.05	DiD (adj.)	-0.16	-0.04	-0.04
95% CI	(-0.06 to 0.27)	(-0.13 to 0.18)	(-0.11 to 0.22)	(-0.10 to 0.21)	95% CI	(-0.39 to 0.07)	(-0.28 to 0.19)	(-0.26 to 0.19)
Observations, n	51	48	26	28	P value Q value	0.179 0.111	0.71 1.00	0.75 0.99
Men, 3-mo follow-up WHODAS (scale 0 to 48)								
Difference	-5.42	-0.97	1.39	2.69	DiD (adj.)	8.58	8.42	/.82
95% CI	(-9.44 to -1.40)	(-5.17 to 3.23)	(-4./0 to 7.48)	(-3.67 to 9.04)	95% CI	(2.48 to 14.68)	(2.09 to 14.75)	(1./5 to 13.89)
Observations, n	47	49	26	27	P value Q value	0.006 0.018	0.009	0.012 0.037
GDS (scale 0 to 15)								
Difference	-0.72	0.83	1.02	2.97	DiD (adj.)	1.76	1.01	2.88
95% CI	(-2.41 to 0.97)	(-0.85 to 2.52)	(-1.23 to 3.26)	(1.09 to 4.85)	95% CI	(-0.95 to 4.46)	(-1.52 to 3.53)	(0.34 to 5.42)
Observations, n	47	49	26	27	P value	0.20	0.43	0.027
					Q value	0.25	0.41	0.037

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Table 4-Continued	ł							
Outcomes	Difference Between Follow-up and Baseline			Effects	Differenc	e in Difference Ver	sus Control	
	Control	CBT Only	Cash Only	Both		CBT Only	Cash Only	Both
Food security (0 or 1)								
Difference	0.15	0.05	-0.06	-0.10	DiD (adj.)	-0.12	-0.17	-0.18
95% CI	(-0.02 to 0.31)	(-0.10 to 0.20)	(-0.26 to 0.14)	(-0.30 to 0.10)	95% CI	(-0.36 to 0.13)	(-0.46 to 0.11)	(-0.45 to 0.08)
Observations, n	47	49	26	27	P value	0.35	0.24	0.176
					Q value	0.31	0.31	0.063

CBT = cognitive behavioral therapy; DiD (adj.) = difference in difference adjusted for control variables; GDS = Geriatric Depression Scale; WHODAS = World Health Organization Disability Assessment Schedule.

* This table presents effects on primary outcomes at the 3-week and 3-month follow-ups by sex. Refer to the notes for **Table 3** or to the statistical appendix (**Appendix C of Supplement 1**) for more details about the statistical methods.

mild depression; 33.3% were moderately or severely depressed. The average baseline functional impairment score implies between mild and moderate difficulty with the average task on the scale. We see balance on these characteristics by treatment (Table A4a of Supplement 1). Forty-one of the 45 standardized mean differences computed for the balance tests are between -0.1 and 0.1. Relative to the control group, the CBT-only and both groups had lower baseline GDS, and the cash-only and both groups had higher food security.

Compliance

Of those assigned therapy, 87.5% completed at least 1 session and 67.4% completed all 6 (**Table 2**). Of those assigned cash, 91.0% received the money. No persons assigned to not receive an intervention got the intervention. Only 2 participants reported being diagnosed with a mental health issue and receiving therapy for it in the year of our trial, suggesting that any concomitant therapy would have been extremely rare.

Effects on Outcomes

Primary Outcomes

Functional impairment (scale, 0 to 48) declined between baseline and 3-week follow-up in the control group (difference, -4.96 [95% CI, -6.52 to -3.40]). The decline was larger in the cash-only group (DiD, -2.92 [CI, -5.60 to -0.23], P = 0.033, Q = 0.105) (Table 3). The declines in the CBT-only and both treatment groups did not differ statistically from that in the control group.

In the control group, GDS changed little between baseline and 3-week follow-up. The changes in the CBTonly and both treatment groups did not differ statistically from that in the control group, and our estimates did not support clinically significant effects from either group (scale, 0 to 15) (CBT-only: DiD, -0.09 [CI, -1.18 to 1.01]; both: DiD, -0.38 [CI, -1.45 to 0.68]) (Table 3). The change over time was 1 point smaller in the cash-only group than in the control group (DiD, -1.01 [CI, -2.07to 0.06], P = 0.063, Q = 0.105). The baseline average score was 6.14, and scores between 5 and 8 are generally classified as mild depression, so this effect implies that the average person was brought closer to but not below the cutoff for mild depression.

For food security, there was little change between baseline and 3-week follow-up and there were no significant effects of any intervention (Table 3). The change over time was 9 percentage points higher in the both treatment group (Cl, -0.00 to 0.18, P=0.061, Q=0.21), but 1

percentage point lower in the cash-only group (CI, -0.12 to 0.11, P = 0.92, Q = 0.44).

We found no effects on any of the primary outcomes at 3 months.

Secondary Outcomes

We found no effects on any of the secondary outcomes at 3 weeks or 3 months (Table A8 of Supplement 1). For example, the UCLA score (scale 0 to 1, greater values representing more loneliness) declined between baseline and 3 weeks in all groups, but the decline was no greater with CBT (CBT only: DiD, 0.04 [CI, -0.00 to 0.09]; both: DiD, 0.02 [CI = -0.02 to 0.07]).

Exploratory Analyses: Subgroup Analyses

Although not prespecified, we performed exploratory subgroup analysis by sex. Women in each of the 3 treatment groups had larger declines in functional impairment between baseline and 3-week follow-up compared with women in the control group (for CBT only: DiD, -3.54 [CI, -6.41 to -0.67]; for cash only: DiD, -4.15 [CI, -7.06 to -1.24]; for both: DiD, -3.24 [CI, -6.25 to -0.22]) (Table 4). The effects on impairment did not persist to the 3-month follow-up. Figure 2 visualizes the steeper decline in WHODAS scores for women in 1 of the 3 treatment groups relative to the control group between baseline and 3 weeks, and the convergence of the 4 groups between 3 weeks and 3 months.

Relative to women in the control group, women in the cash-only group experienced a reduction in GDS score between baseline and 3 weeks (DiD, -1.38 [Cl, -2.56 to -0.21]) (Table 4). The average woman at baseline had a depression score of 6.28, so this effect implies that the average woman was moved just below the cutoff for mild depression. The corresponding DiDs for CBT-only and both treatments are negative but statistically insignificant. There were no effects on women's depression scores at 3 months.

Turning to men (**Table 4**), we found suggestive evidence that CBT worsened self-reported impairment and depression at 3 weeks. Between baseline and 3 months, each treatment group experienced a statistically significantly greater increase in functional impairment than the control. There were no effects on men's food security at either follow-up.

In Appendix A of Supplement 1, we analyzed effects for other subgroups (Tables A9 to A13 of Supplement 1), but the differences between sexes are most relevant.

Figure 2. Treatment effects at baseline, 3 weeks, and 3 months for WHODAS (first column) and GDS (second column) in the full (A and B), female (C and D), and male samples (E and F).



CBT = cognitive behavioral therapy; GDS = Geriatric Depression Scale; WHODAS = World Health Organization Disability Assessment Schedule.

DISCUSSION

Mental health, functional impairment, and food security are 3 areas where older persons living alone in lowincome countries may be especially vulnerable. With very few psychologists available, therapies delivered by laypeople are promising. We conducted what is to our knowledge the first large-scale randomized evaluation of a phone-based CBT among an older population in a

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poor country, and compared its effects to those of a 1time cash transfer of 1000 rupees (U.S. \$12). We found that the cash transfer was effective in reducing shortterm (3 weeks) functional impairment and had a small but not clinically or statistically significant reduction in depression. Cash did not affect short-term food security, and we saw no short-term effects from CBT or the 2 interventions together. None of the interventions showed any effect at 3 months.

The effects of CBT on depression we found were smaller than those found in previous work (12, 23). The 95% CI for the estimate of the short-run standardized mean effect (SME) of CBT only (SME, -0.02 [CI, -0.21 to 0.18]) does not include the SME of -0.73 (CI, -0.5 to -0.95) found in a meta-analysis of 27 in-person psychotherapy trials among older populations in rich countries (25), or the -0.60 SME found by Dias and colleagues (12) for a group of older people in India. This does not seem due to a lower compliance rate: 67.4% of participants assigned to he CBT group completed all 6 sessions, which is comparable to other studies delivering therapy in India (69% in Patel et al [5], 60% in Dias et al [12]). This suggests that phone administration did not work as well in this context.

The effects of the cash treatment are consistent with work in mostly younger populations showing that cash transfers can improve mental health in low-income contexts (13). Our short-run estimates of cash only (SME, -0.18 [CI, -0.37 to 0.01]) and both interventions (SME, -0.07 [CI = -0.261 to 0.122]) are larger in magnitude or comparable to the -0.069 (CI, -0.050 to -0.088) SME of cash transfers on measures of mental health including depression identified in the literature (26).

The exploratory subgroup analysis by sex found that women benefited both from the therapy and the cash in the short run. On the other hand, we found no benefits and even perverse effects for men. The results for men are surprising. They may not reproduce in other samples because the analysis was post hoc and the effects are in the opposite direction as those for women. There could also be an effect on reporting: it is possible that the CBT led men to become more aware of the difficulties they face.

At 1000 rupees (U.S. \$12) per person, our cash intervention was less expensive than our therapy intervention, which cost 1578 rupees (U.S. \$19) per person (Table A7 of Supplement 1). Given that cash seems to have produced more improvements than therapy, both for women and for the full sample, cash seems more cost-effective than therapy as delivered in the format of our study.

We view our results as indicating that the phonebased version of CBT has not conclusively demonstrated effectiveness or cost-effectiveness in this sample in Tamil Nadu. Further work is needed to understand how to obtain larger and more persistent effects. This may require more sustained or more intensive intervention than the relatively short-term and light-touch therapy studied in this paper. Indeed, prior work that exhibited success in reducing depression for longer time horizons either delivered CBT in-person (12) or via video (27). Furthermore, investigating whether the different responses to our interventions between men and women can be reproduced-and, if so, understanding potential mechanisms behind the negative effects on men-would be valuable.

The study has several limitations. First, we did not sustain therapy over time and cannot say whether sustained therapy would have produced more favorable effects. Likewise, although we documented the effects of phone-based therapy, we cannot say what the effects of a scalable in-person therapy would be in this context. Second, we do not know how the results would translate to other time periods, outside of the COVID-19 pandemic. Third, the primary outcomes were self-reported and may have reporting bias, especially as reporting itself may reflect awareness of the conditions. Fourth, our comparison is limited to those who consented, who may not be representative of a larger population of older adults.

Overall, among older people living alone in India, the small cash transfer reduced short-term (3 weeks) functional impairment and resulted in a small but not clinically or statistically significant reduction in depression in the short term. Cash had no effect on short-term food security. There were no short-term effects from CBT or the 2 interventions together. None of the interventions showed any effect at 3 months.

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Note: The study was approved by the institutional review boards (IRBs) of Massachusetts Institute of Technology (MIT), the National Bureau of Economic Research, and the Institute for Financial Management and Research (in India), with Dartmouth College ceding authority to MIT. Adherence to study protocols and protection of human subjects was overseen by a data-and-safety monitoring board (DSMB) convened by the National Institute on Aging (NIA). The trial was preregistered on ClinicalTrials.gov (NCT04225845) and the American Economic Association registry for randomized experiments (AEARCTR-0007582). There were significant changes in the protocols between the time the study was originally approved and when it was implemented because the COVID-19 pandemic precluded most of the originally planned activities. All changes to the protocol were reported to and approved by the DSMB and IRBs. A final detailed protocol was submitted to the DSMB and approved just before the launch of the interventions and is available as a supplement to this study (Study Protocol).

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Data Sharing Statement: The following data will be made available with publication: deidentified participant data, available at https://dataverse.harvard.edu/dataset.xhtml?persistentId=doi: 10.7910/DVN/SXEYFW.

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References

1. Ausubel J. Older people are more likely to live alone in the U.S. than elsewhere in the world. Pew Research Center. 10 March 2020. Accessed at www.pewresearch.org/fact-tank/2020/03/10/older-peopleare-more-likely-to-live-alone-in-the-u-s-than-elsewhere-in-the-world on 3 January 2023.

2. United Nations, Department of Economic and Social Affairs, Population Division. Living Arrangements of Older Persons: A Report on an Expanded International Dataset. 2017. Accessed at www.un.org/en/development/desa/population/publications/pdf/ ageing/LivingArrangements.pdf on 3 January 2023.

3. Hawkley LC, Cacioppo JT. Loneliness matters: a theoretical and empirical review of consequences and mechanisms. Ann Behav Med. 2010;40:218-227. [PMID: 20652462] doi:10.1007/s12160-010-9210-8

4. Banerjee A, Duflo E, Grela E, et al. Depression and Loneliness Among the Elderly Poor. National Bureau of Economic Research (NBER) Working Paper 30330. September 2022; revised February 2023. [10.3386/w30330]

5. Patel V, Weobong B, Weiss HA, et al. The Healthy Activity Program (HAP), a lay counsellor-delivered brief psychological treatment for severe depression, in primary care in India: a randomised controlled trial. Lancet. 2017;389:176-185. [PMID: 27988143] doi:10.1016/S0140-6736(16)31589-6

6. Singla DR, Kohrt BA, Murray LK, et al. Psychological treatments for the world: lessons from low- and middle-income countries. Annu Rev Clin Psychol. 2017;13:149-181. [PMID: 28482687] doi:10.1146/ annurev-clinpsy-032816-045217

7. Gureje O, Oladeji BD, Montgomery AA, et al. Effect of a steppedcare intervention delivered by lay health workers on major depressive disorder among primary care patients in Nigeria (STEPCARE): a cluster-randomised controlled trial. Lancet Glob Health. 2019;7: e951-e960. [PMID: 31097414] doi:10.1016/S2214-109X(19)30148-2 8. Bhat B, de Quidt J, Haushofer J, et al. The Long-Run Effects of Psychotherapy on Depression, Beliefs, and Economic Outcomes. National Bureau of Economic Research (NBER) Working Paper 30011. May 2022. doi:10.3386/w30011

9. Choi NG, Marti CN, Wilson NL, et al. Effect of telehealth treatment by lay counselors vs by clinicians on depressive symptoms among older adults who are homebound: a randomized clinical trial. JAMA Netw Open. 2020;3:e2015648. [PMID: 32865577] doi:10.1001/ jamanetworkopen.2020.15648

10. Peng XD, Huang CQ, Chen LJ, et al. Cognitive behavioural therapy and reminiscence techniques for the treatment of depression in the elderly: a systematic review. J Int Med Res. 2009;37:975-982. [PMID: 19761679] doi:10.1177/147323000903700401

11. Barker N, Bryan G, Karlan D, et al. Cognitive behavioral therapy among Ghana's rural poor is effective regardless of baseline mental distress. Am Econ Rev Insights. 2022;4:527-545. doi:10.1257/aeri. 20210612

12. Dias A, Azariah F, Anderson SJ, et al. Effect of a lay counselor intervention on prevention of major depression in older adults living in low- and middle-income countries: A randomized clinical trial. JAMA Psychiatry. 2019;76:13-20. [PMID: 30422259] doi:10.1001/ jamapsychiatry.2018.3048

13. Haushofer J, Shapiro J. The short-term impact of unconditional cash transfers to the poor: experimental evidence from Kenya. Q J Econ. 2016;131:1973-2042. [PMID: 33087990] doi:10.1093/qje/qjw025 14. Ridley M, Rao G, Schilbach F, et al. Poverty, depression, and anxiety: causal evidence and mechanisms. Science. 2020;370. [PMID: 33303583] doi:10.1126/science.aay0214

15. Pega F, Pabayo R, Benny C, et al. Unconditional cash transfers for reducing poverty and vulnerabilities: effect on use of health services and health outcomes in low- and middle-income countries. Cochrane Database Syst Rev. 2022;3:CD011135. [PMID: 35348196] doi:10.1002/14651858.CD011135.pub3

16. Blattman C, Jamison JC, Sheridan M. Reducing crime and violence: experimental evidence from cognitive behavioral therapy in liberia. Am Econ Rev. 2017;107:1165-1206. [PMID: 29553237] doi:10.1257/aer.20150503

17. Blattman C, Chaskel S, Jamison JC, et al. Cognitive Behavior Therapy Reduces Crime and Violence over 10 Years: Experimental Evidence. National Bureau of Economic Research (NBER) Working Paper 30049. May 2022; revised September 2022. doi:10.3386/w30049

18. Üstün T, Kostanjsek N, Chatterji S, et al, eds. Measuring Health and Disability: Manual for WHO Disability Assessment Schedule (WHODAS 2.0). World Health Organization; 2010.

19. Sarkar S, Kattimani S, Roy G, et al. Validation of the Tamil version of short form Geriatric Depression Scale-15. J Neurosci Rural Pract. 2015;6:442-446. [PMID: 26167040] doi:10.4103/0976-3147.158800

20. Yesavage JA, Brink TL, Rose TL, et al. Development and validation of a geriatric depression screening scale: a preliminary report. J Psychiatr Res. 1982-1983;17:37-49. [PMID: 7183759] doi:10.1016/ 0022-3956(82)90033-4

21. Sousa RM, Dewey ME, Acosta D, et al. Measuring disability across cultures-the psychometric properties of the WHODAS II in older people from seven low- and middle-income countries. The 10/66 Dementia Research Group population-based survey. Int J Methods Psychiatr Res. 2010;19:1-17. [PMID: 20104493] doi:10.1002/mpr.299

22. Hainmueller J. Entropy balancing for causal effects: a multivariate reweighting method to produce balanced samples in observational studies. Polit Anal. 2012;20:25-46. doi:10.1093/pan/mpr025 23. Anderson ML. Multiple inference and gender differences in the

effects of early intervention: a reevaluation of the Abecedarian, Perry Preschool, and Early Training Projects. J Am Stat Assoc. 2008;103:1481-1495. doi:10.1198/016214508000000841

24. Benjamini Y, Krieger AM, Yekutieli D. Adaptive linear step-up procedures that control the false discovery rate. Biometrika. 2006;93:491-507. doi:10.1093/biomet/93.3.491

25. Huang AX, Delucchi K, Dunn LB, et al. A systematic review and metaanalysis of psychotherapy for late-life depression. Am J Geriatr Psychiatry. 2015;23:261-273. [PMID: 24856580] doi:10.1016/j.jagp.2014.04.003

26. McGuire J, Kaiser C, Bach-Mortensen AM. A systematic review and meta-analysis of the impact of cash transfers on subjective wellbeing and mental health in low- and middle-income countries. Nat Hum Behav. 2022;6:359-370. [PMID: 35058643] doi:10.1038/ s41562-021-01252-z

27. Yeung A, Wang F, Feng F, et al. Outcomes of an online computerized cognitive behavioral treatment program for treating Chinese patients with depression: A pilot study. Asian J Psychiatr. 2018;38:102-107. [PMID: 29146042] doi:10.1016/j.ajp.2017.11.007 **Author Contributions:** Conception and design: A. Banerjee, E. Duflo, M. McKelway, F. Schilbach, M. Sequeira, G. Sharma, G. Vaidiyanathan.

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