ORIGINAL **ARTICLE**

Efficacy of a multi-component psychosocial intervention program for caregivers of persons living with neurocognitive disorders, Alexandria, Egypt: A randomized controlled trial

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ABSTRACT

Background: Unlike other chronic diseases, dementia caregiving is associated with enormous psychological burden, which stresses the need for caregivers-directed psychosocial interventions. Aim: This randomized controlled trial (RCT) was conducted to evaluate the short-term efficacy of a multi-component psychosocial intervention program for informal caregivers of persons with neurocognitive disorders in Alexandria, Egypt. **Methods:** Informal caregivers (120) were randomly assigned into intervention and control groups. The intervention group (60) participated in a multi-component program of 8 sessions, including psycho-education, group cognitive-behavioral therapy, and group social support. Program primary outcomes were assessed after program termination (post-1), and three months later (post-2). Measured outcomes included caregivers' knowledge, depression and anxiety symptoms, and perceived burden. **Results:** Caregivers' depression, anxiety, and perceived burden demonstrated significant drop at post-1, and post-2 compared to the control group ($P < 0.001$). The intervention group showed significant negative absolute change on depression, anxiety, and perceived burden measures, while on the dementia-related knowledge measure, a significant positive absolute change was found at post-1, and post-2 ($P < 0.001$), in comparison to controls. All outcome measures recorded a large effect size; the highest was for knowledge (partial eta2 = 0.98), and the least was for perceived burden (partial eta2 = 0.71). **Conclusion:** A multi-component psychosocial intervention for caregivers of persons with neurocognitive disorders demonstrated a short-term efficacy in reducing their burden, depression, and anxiety, as well as improving caregivers' knowledge. However, further research is needed to investigate long-term efficacy of the intervention.

Key words: Cognitive-behavioral therapy, dementia, informal caregivers, neurocognitive disorders, psychoeducation, psychosocial interventions, randomized controlled trial

INTRODUCTION

In 2015, the estimated worldwide prevalence of dementia was 5.2%. This number will almost double every 20 years. In North Africa and the Middle Eastern region, prevalence estimates increased from 5.9% in 2009 to 8.7% in 2015. Future projections for that region expect an increase in the number of people living with dementia by 86% in 2030.[1] In Egypt, the prevalence rate of dementia ranges from 1.4% to 21.95%.[2-4] Among the chronic diseases, dementia is

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responsible for the largest contribution to dependence,[5] as well as caregivers' burden, and psychological problems.[6-8] Psychiatric morbidity among caregivers of persons with dementia (PWD) ranged from 40% to 75% in the developing countries.[9] In Egypt, the rate of caregivers' burden was 37%.[10] Compared to caregivers of other chronic diseases, Egyptian caregivers of persons with Alzheimer's disease showed higher levels of worries, fears, distress, negative emotions, and stigma.[11] The nature of dementia care is associated with an intensity of needs, exceeding those required in other conditions, making care recipients highly dependent on their caregivers to achieve basic daily activities.[6] Meanwhile, home care is preferred by families as an essential policy for reducing the costs of long-term care in the developing countries,[12] which may exacerbate caregivers' burden.

Studies that assessed the needs of caregivers of PWD highlighted their needs to attain better knowledge about the disease, the ways of handling cognitive and behavioral problems of PWD, as well as psychological support needs such as stress management and emotional expression skills.[13,14] In Egypt, many of the older people who are ready to be discharged from hospitals are not taken home because their families cannot care for them alone. In addition, the health-care system facilities targeting the needs of older people and their caregivers are limited.[15]

A wide range of interventions supporting dementia caregivers were developed and were evaluated on different outcome measures, including psychological well-being, caregivers' burden, social outcomes, and knowledge.[16,17] Multidimensional interventions incorporating mainly psychoeducation, supportive interventions, and cognitive-behavioral therapy (CBT) are particularly effective.[6,17]

According to the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5), the term dementia has been placed under the "neurocognitive disorders" (NCDs) entity; however, "dementia" is retained in the etiological subtypes and in settings where it is more proper than the new term.[18] In the current study, both terms are used interchangeably whenever appropriate.

This study aimed at developing and evaluating the short-term efficacy of a multicomponent psychosocial intervention program for informal caregivers of persons with NCDs in Alexandria, Egypt. It is hypothesized that delivering such program will improve caregivers' knowledge and reduce their depression, anxiety, and perceived burden.

METHODS

Trial design
A randomized controlled trial (RCT) was carried out using a parallel design with 1:1 allocation ratio.

Participants
The trial took place at the psychogeriatric out-patient clinic of Al-Maamoura Psychiatric Hospital, targeting informal caregivers (principal family member/relative) of people with NCDs. This setting was chosen because the above-mentioned clinic is the largest specialized governmental clinic that serves three governorates, with an average monthly attendance rate between 100 and 150 cases and receives referral of cases from other places.

Eligibility criteria
Inclusion criteria
Informal caregivers currently living with older people diagnosed with any type of NCDs (dementia) were included. When more than one caregiver was living with the care recipient, the main primary caregiver was included.

Diagnosis of dementia
Diagnosis of dementia was carried out by the psychiatrist running the clinic (the second author). Diagnosis was made based on history taking, the criteria of DSM-4th edition-text revised (DSM-IV-TR),[19] mental status examination, and having a score <20 on the Mini-Mental State Examination (MMSE) (cognitive testing tool).[20] Laboratory investigations and neuroimaging were conducted whenever needed.

Exclusion criteria
Caregivers of patients suffering from serious diseases, e.g., terminal stage cancer, communication problems, or those who have been recently hospitalized (within last month) were excluded from the study.

The intervention program
A group psychosocial intervention program was designed with short- and long-term goals. Short-term goals included (1) improving caregivers' knowledge about dementia, (2) helping caregivers to identify different problematic behaviors of care recipients and different strategies to handle such behaviors, and (3) providing social support for caregivers. Long-term goals incorporated (1) acquiring the skills of handling problematic behaviors of care recipients, (2) enhancing caregivers' skills and strategies for managing the burden of care, and (3) improving caregivers' emotional status through acquiring skills of coping and stress management.

The program included three components: group psychoeducation (two sessions), brief group CBT (six sessions), and group support sessions that were held throughout the program covering topics similar to psychoeducation/CBT topics as illustrated in Table 1. Each session took 45–60 min. Training was conducted through a collaborative approach using illustrations, vignettes, role playing, brainstorming, group discussion, and audio-visual aids. Different methods were used to achieve different objectives of the program. An intervention protocol with all details covering the above-mentioned sessions was prepared based on caregivers' needs reported by them in the early assessment phase, and on reviewing literature for other programs directed to caregivers' of people with NCDs, worldwide. Culturally sensitive sessions were designed taking into consideration the characteristics of participants. The program was implemented by the principal investigator (second author).

Outcome measures

Evaluation of the program was conducted twice, immediately after program completion (post-1), and 3 months later (post-2) for both intervention and control groups using the following primary outcome measures: Knowledge questionnaire,[21] Arabic version of the Hamilton Depression Rating Scale (HDRS),[22] the Taylor Manifest Anxiety Scale (TMAS),[23] and the Zarit Burden Interview (ZBI).[24] No secondary outcomes were assessed in this trial.

Randomization

During the trial period (April–November 2012), caregivers accompanying their care recipients attending the clinic and fulfilling study eligibility criteria were randomly allocated into two groups (intervention and control) by simple randomization, where a single sequence of random assignments was applied using a computer software program. One author, who was situated off site, supervised the randomization process and was responsible for concealment of allocation. Allocation into intervention and control groups was concealed from the principal investigator

until all cases (120) were recruited and provided baseline data. The principal investigator (second author) was the one who enrolled intervention participants based on the sequence received from the supervisor of randomization, and participants were further assigned into six groups.

Blinding

Because of the interactive nature of the intervention program between the participants and the principal investigator (second author), they were unblinded. However, the psychometric assessment before and after program termination (outcome measures) was carried out by a psychologist, and the social support sessions were conducted by a social worker. Both psychologist and social worker belonged to the hospital staff. They were trained by the principal investigator, and they worked under her supervision.

Sample size

The sample was determined using power and sample size software,[25] and based on prior data on psychological interventions for caregivers of PWD, where the difference between pre- and post-response of the intervention group was normally distributed with standard deviation of 0.33.[26] A minimum required sample size was recommended to be fifty for each group, with probability 80% (power) at alpha level 0.05. It was estimated that the follow-up data would be unavailable for 20% of the sample, so the sample size was raised to sixty for each group.

Data were collected using the following tools

A predesigned structured interviewing questionnaire

It was used to collect demographic and socioeconomic data for PWD and their caregivers.

Psychiatric clinical assessment

All sampled care recipients were subjected to psychiatric clinical assessment to identify dementia cases fulfilling DSM-IV-TR criteria.[19] DSM-IV-TR criteria were used for this trial because DSM-5 was not yet issued at the time of the trial (2012).

The Arabic version of the Mini-Mental State Examination

It is a clinician-administered test that assesses patient's cognitive state (orientation, attention, calculation, recall, language, and motor skills). The total score is 30, a score below 25 indicates cognitive impairment, and a score below 20 indicates the presence of dementia.[20] MMSE is has been extensively used worldwide for screening of cognitive impairment. In the current study, diagnosis of cases with NCDs was not relying only on MMSE, but it included other

Table 1: Weekly program sessions	
Week number	**Sessions***
1st week	Introduction and review of dementia
2nd week	Identification and management of the challenging behaviors of dementia patients
3rd week	Analyzing cognitive distortions and irrational beliefs
4th week	Introducing CBT approach to depressed anxious mood (I)
5th week	Introducing CBT approach to depressed anxious mood (II)
6th week	The well-being module and stress management technique
7th week	Teaching caregivers assertiveness and help-seeking skills
8th week	Termination of the program

*Group support took place parallel to all sessions. CBT: Cognitive-behavioral therapy

diagnostic methods (history taking, DSM criteria, mental status examination, and investigations).

Caregivers' Dementia-related Knowledge Questionnaire

Items on this questionnaire were derived from the Alzheimer's Disease Knowledge Test,[21] a widely used tool to assess knowledge related to Alzheimer's disease. It consisted of twenty items testing the caregivers' knowledge about dementia. Each item received either a "Yes," or "No" response. A score of one was given to correct responses and zero for incorrect responses. The total score was calculated by summing the twenty items' scores.

The Arabic version of the Hamilton Depression Rating Scale

It is a clinician-administered scale, which assesses the severity of depressive symptoms. The scale included 17 items; each item received a score on a 4-point Likert scale. A total score of 0–7 was accepted to be normal, a score of 8–13 indicated mild, 14–18 moderate, and >19 indicated severe depression.[22] The 17-item version of HDRS has been viewed as the most widely used in tool for assessing depression in controlled clinical trials, which favored its use in the current study.[27]

The Arabic version of Taylor Manifest Anxiety Scale

TMAS is a 50-item scale measuring manifest anxiety symptoms. Considering the fifty items of the scale, it facilitates measuring anxiety symptoms among caregivers using a "Yes" or "No" response for each item. A total score <17 indicated no anxiety, 17–20 mild, 21–26 moderate, and ≥27 indicated severe anxiety.[23]

The Zarit Burden Interview

It is a 22-item self-report measure of caregivers' subjective burden, on a 5-point Likert scale, with a total score range of 0–88. The higher scores indicated higher burden.[24] ZBI is viewed as the most commonly used tool for assessing caregiving burden specifically among community dwellers living with Alzheimer's disease and other NCDs. Moreover, the 22-item version of ZBI showed better reliability and had been recommended for the use in clinical and research settings more than other versions.[28]

An Arabic-translated version of ZBI was developed through forward and backward translation by qualified interpreters. Then, it was subjected to a pilot study including 30 participants, showing satisfactory reliability (Cronbach's α = 0.9).

Statistical analysis

The Statistical Package for Social Sciences (SPSS, version 16; SPSS Inc., Chicago, IL, USA) was used for data analysis.

Analysis of numeric data was done using one-sample Kolmogorov–Smirnov test, a procedure that tests distributional assumption for numerical data. Since data of the current study showed skewness, this was followed by use of the Mann–Whitney U-test that compares ranks (medians) for two independent groups of cases. Ideally, for this test, the participants should be randomly assigned into two groups, so that any difference in response would be due to the treatment (or lack of treatment) and not other factors.

For categorical data, tests of significance including Pearson's Chi-square test (χ^2) and Fisher's exact test (FET) were used to assess the relationship between the categories of two independent samples (assessing differences between the intervention and control groups regarding baseline characteristics). Friedman test (χ^{2f}) was used to compare the responses for at least three related stages (baseline, post-1, and post-2) within the same group. Program effect size was measured by partial η^2 for multivariate analysis of variance. For all statistical analyses, $P \le 0.05$ was considered statistically significant.

Ethical considerations

The study was approved by the Ethics Committee of the High Institute of Public Health, Alexandria University on the basis of the Declaration of Helsinki (January 2012), and from the Ethical Committee of General Secretariat of Mental Health and Addiction Treatment. All caregivers (intervention and control) gave informed written consents to participate in the study [Consent form is displayed in Appendix 1]. Caregivers of the control group were scheduled for program sessions after termination of the second assessment phase of the program.

RESULTS

Participants' flowchart is illustrated in Figure 1. Six dropout cases were recorded throughout the program; five of them belonged to the intervention group. The only reason for dropout was death of the care recipient. Dropouts were excluded from all statistical analyses.

Baseline data

PWD aged from 61 to 86 years with a mean of 69.29 ± 6.24 years. About two-thirds of them were females (67.5%). No significant difference was revealed between the intervention and control groups regarding care recipients' age (t = 0.83, P = 0.40), sex (χ^2 = 0.74, P = 0.39), marital status (χ^2 = 4.25, P = 0.23), educational level (FET = 6.03, P = 0.29), source of income (FET = 2.54, P = 0.27), type of dementia (FET = 4.84, P = 0.16), and their mean scores on MMSE (Z = −0.08, P = 0.93).
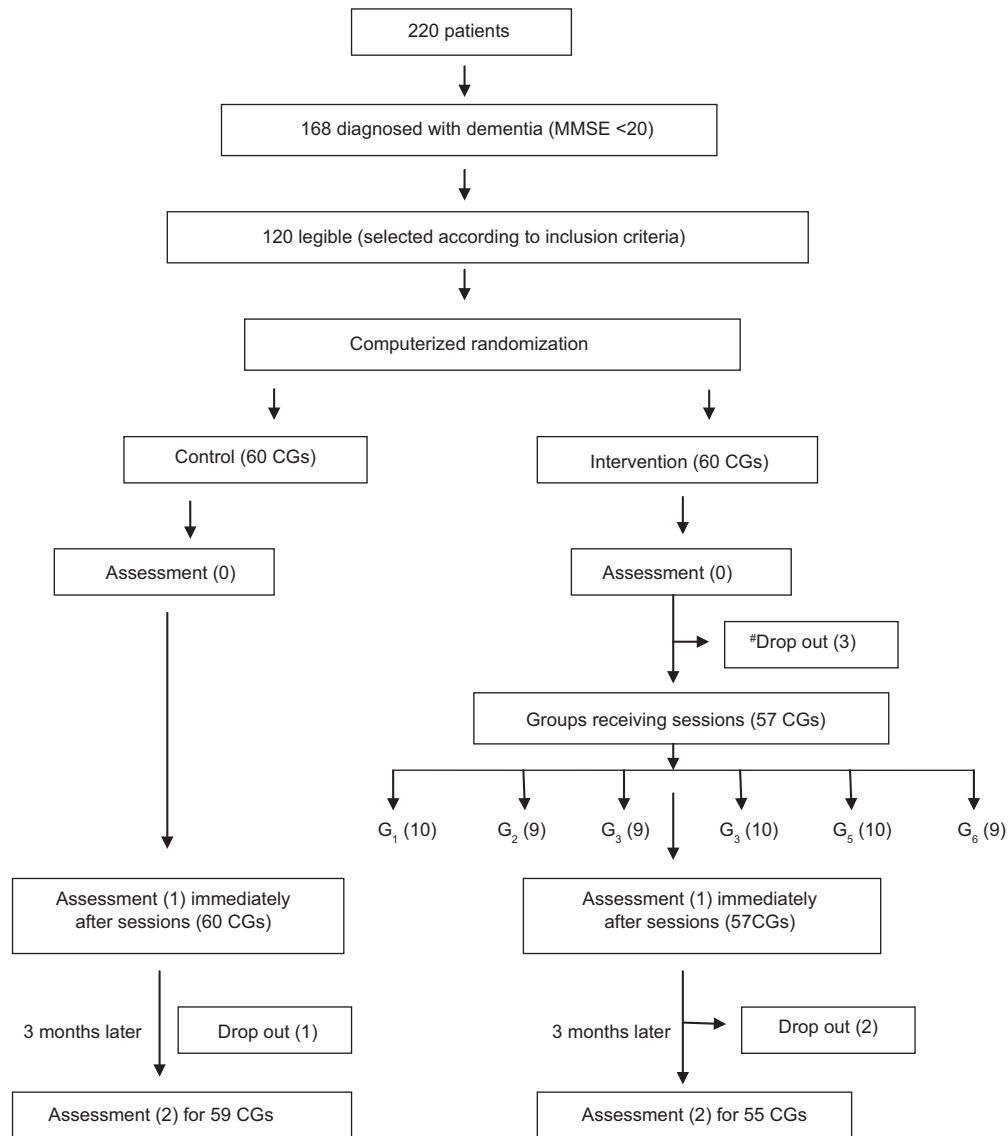
Figure 1: Flowchart of the study participants

Table 2 shows baseline data of caregivers in the intervention and control groups. The caregivers' ages ranged from 16 to 78 years with a mean of 48.63 ± 12.31 years. Female caregivers outnumbered male ones (65.8%). Caregivers in the intervention group matched their controls regarding their age, sex, marital status, education, and monthly income ($P > 0.05$). Caregivers were mainly offspring of PWD, followed by spouses and siblings, while relatives represented the least percentage of caregivers, and this was same for both groups ($P = 0.71$). The needs reported by caregivers were similar for both groups ($P > 0.05$); psychoeducation was their first priority, followed by their need for help with caregiving, and finally psychological support. At baseline, no statistically significant differences were revealed between the two groups regarding their mean scores on scales measuring depression ($P = 0.12$), anxiety ($P = 0.21$), perceived burden ($P = 0.45$), and knowledge ($P = 0.37$).

Program assessment results

The mean scores of the intervention and control groups on scales measuring depression, anxiety, perceived burden, and dementia-related knowledge at post-1 and post-2 are illustrated in Figures 2-5, respectively. Compared to controls, caregivers who participated in the program showed statistically significant drop in their depression and anxiety symptoms ($Z = -8.06$ and $Z = -8.52$, respectively, $P < 0.001$), as well as the level of perceived burden ($Z = -5.81$, $P < 0.001$), at post-1. Three months later (post-2), this drop was maintained for all outcomes: depression ($Z = -8.18$, $P < 0.001$), anxiety ($Z = -8.84$, $P < 0.001$), and perceived burden ($Z = -6.00$, $P < 0.001$). Moreover, there was a statistically significant improvement in the caregivers' dementia-related knowledge compared to controls, at post-1 ($Z = -9.25$, $P < 0.001$). This improvement was maintained at post-2 ($Z = -9.26$, $P < 0.001$).

Table 2: Baseline characteristics of the caregivers (intervention and control groups)

Baseline characteristics	Intervention (*n*=55), *n* (%)	Control (*n*=59), *n* (%)	Total (*n*=114), *n* (%)	Test of significance (*P*)
Age				
Range	31-78	16-73	16-78	*t*=0.59 (0.55)
Mean±SD	49.35±11.89	47.97±12.76	48.63±12.31	
Sex				
Male	21 (38.2)	18 (30.5)	39 (34.2)	χ^2=0.74 (0.38)
Female	34 (61.8)	41 (69.5)	75 (65.8)	
Marital status				
Married	50 (90.9)	45 (76.3)	95 (83.3)	FET=7.50 (0.052)
Widowed	2 (3.6)	5 (8.5)	7 (6.1)	
Divorced	3 (5.5)	3 (5.1)	6 (5.3)	
Single	0	6 (10.1)	6 (5.3)	
Education				
Illiterate or just read and write	14 (25.4)	18 (30.5)	32 (28.1)	χ^2=0.41 (0.81)
Basic education	15 (27.3)	16 (27.1)	31 (27.2)	
Secondary or higher	26 (47.3)	25 (42.4)	51 (44.7)	
Monthly income				
Enough	12 (21.8)	19 (32.2)	31 (27.2)	FET=2.55 (0.20)
Enough and save	43 (78.2)	39 (66.1)	82 (71.9)	
Not enough and loan	0	1 (1.7)	1 (0.9)	
Relationship to the patient				
Offspring	22 (40.0)	30 (50.8)	52 (45.6)	χ^2=1.36 (0.71)
Spouses	13 (23.6)	11 (18.6)	24 (21.1)	
Siblings	11 (20.0)	10 (17.0)	21 (18.4)	
Relatives	9 (16.4)	8 (13.6)	17 (14.9)	
Caregivers needs*				
Psychoeducation	55 (100)	58 (98.3)	113 (99.1)	FET (0.51)
Others' help with caregiving	41 (74.5)	43 (72.9)	84 (73.7)	χ^2=0.04 (0.84)
Psychological support	30 (54.5)	34 (57.6)	64 (56.1)	χ^2=0.11 (0.74)
HDRS scores				
Range	10-39	10-29	10-39	Z=−1.54 (0.12)
Mean±SD	20.89±5.11	19.12±4.36	19.97±4.80	
Median	21	20	20	
TMAS scores				
Range	17-48	20-46	17-48	Z=−1.24 (0.21)
Mean±SD	34.24±7.33	32.44±7.48	33.31±7.43	
Median	34	32	32.5	
ZBI scores				
Range	24-81	22-69	22-81	Z=−0.74 (0.45)
Mean±SD	52.1±15.1	50±12.6	50.77±13.90	
Median	56.5	52.5	53	
DRKQ score				
Range	5-12	5-11	5-12	Z=−0.88 (0.37)
Mean±SD	7.93±1.91	7.58±1.73	7.75±1.82	
Median	8	7	7.5	

*A multiple response variable. DRKQ: Dementia-related Knowledge Questionnaire, SD: Standard deviation, ZBI: Zarit Burden Interview, TMAS: Taylor Manifest Anxiety Scale, HDRS: Hamilton Depression Rating Scale, FET: Fisher's exact test

It is worth mention that within-group changes across time showed a significant drop in mean depression, anxiety, and perceived burden scores of the intervention group at post-1 compared to baseline, and it was maintained at post-2 (χ^{2f} = 106.56 depression, χ^{2f} = 101.23 anxiety, χ^{2f} = 102.25 burden, $P <$ 0.001). On the contrary, the control group showed a significant increase in their mean scores (χ^{2f} = 30.63 depression, χ^{2f} = 59.02 anxiety, χ^{2f} = 53.06 burden, $P <$ 0.001). In contrast to the control group who recorded no change in their mean knowledge scores ($P =$ 1.00), the intervention group showed a significant increase at post-1 compared to baseline, followed by a slight decrease at post-2 (χ^{2f} = 106.09, $P <$ 0.001) [Figures 2-5].

Table 3 shows the absolute changes from baseline for the intervention program outcomes among the two groups. The intervention group recorded a significant negative change compared to the control group on depression, anxiety, and perceived burden measures ($P <$ 0.001). Meanwhile, they recorded a significant positive change on knowledge measure compared to controls ($P <$ 0.001). These changes were maintained at post-2 ($P <$ 0.001).

Table 4 represents the effect size of the program for each outcome. A large effect size was recorded for all outcomes of the program, with the highest effect size for knowledge (partial η^2 = 0.98), followed by anxiety

(partial η² = 0.79), then depression (partial η² = 0.76), and the least was for perceived burden (partial η² = 0.71).

DISCUSSION

The current RCT provides evidence of support for the short-term efficacy of a multicomponent intervention
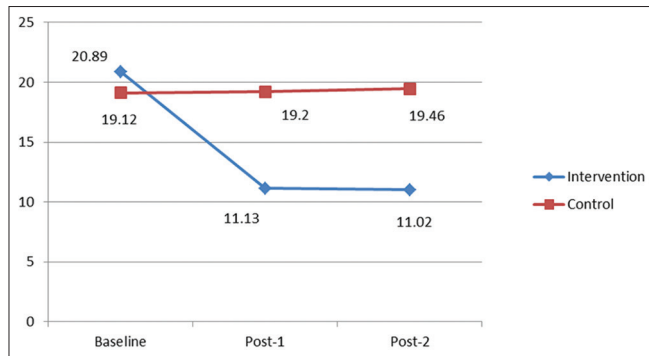

Figure 2: Mean depressive scores of intervention and control groups on the Hamilton Depression Rating Scale before and after intervention

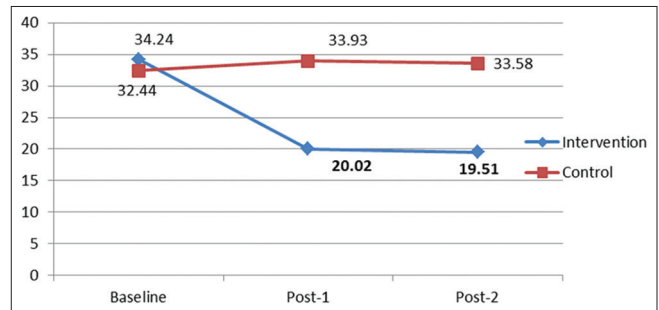| Mean Hamilton Score	Intervention	Control
Baseline	20.89	19.12
Post-1	11.13	19.2
Post-2	11.02	19.46

Figure 3: Mean anxiety scores of intervention and control groups on the Taylor Manifest Anxiety Scale before and after intervention

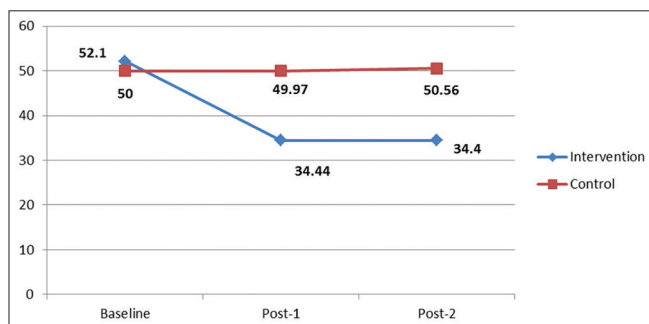| Mean Taylor score	Intervention	Control
Baseline	34.24	32.44
Post-1	20.02	33.93
Post-2	19.51	33.58

Figure 4: Mean scores of intervention and control groups on the Zarit Burden Interview before and after intervention

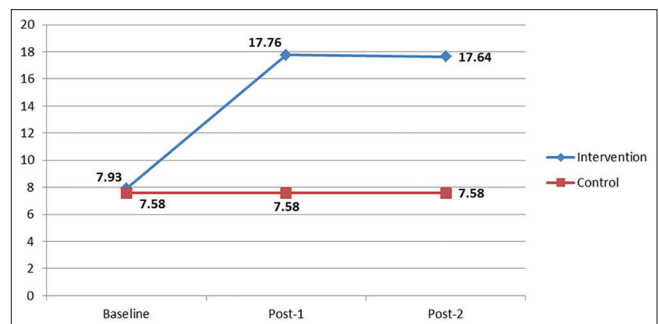| Zarit Burden Interview	Intervention	Control
Baseline	52.1	50
Post-1	34.44	49.97
Post-2	34.4	50.56

Figure 5: Total mean scores of intervention and control groups on the Dementia-related Knowledge Questionnaire before and after intervention

Knowledge	Intervention	Control
Baseline	7.93	7.58
Post-1	17.76	7.58
Post-2	17.64	7.58

Table 3: Absolute change from baseline for intervention program outcomes among the intervention and control groups

Outcomes	Change								Z (P)
	Intervention (55)				Control (59)				
	Minimum	Maximum	Median	Mean (SD)	Minimum	Maximum	Median	Mean (SD)	
Knowledge (1)*	7.00	12.00	10.00	9.83 (1.04)	0.00	0.00	0.00	0.00	−9.96 (0.000)‡
Knowledge (2)†	7.00	12.00	10.00	9.70 (1.22)	0.00	0.00	0.00	0.00	−9.95 (0.000)‡
Burden (1)*	0.00	−36.00	−19.00	−17.36 (8.34)	0.00	2.00	0.00	0.15 (0.40)	−9.52 (0.000)‡
Burden (2)†	1.00	−36.00	−19.00	−17.40 (8.38)	0.00	3.00	1.00	0.74 (0.84)	−9.08 (0.000)‡
Depression (1)*	−3.00	−24.00	−9.00	−9.76 (4.02)	0.00	1.00	0.00	0.08 (0.28)	−9.73 (0.000)‡
Depression (2)†	−3.00	−24.00	−9.00	−9.87 (4.05)	0.00	2.00	0.00	0.33 (0.51)	−9.43 (0.000)‡
Anxiety (1)*	−3.00	−25.00	−14.00	−14.21 (5.51)	0.00	2.00	0.00	0.49 (0.67)	−9.36 (0.000)‡
Anxiety (2)†	−3.00	−26.00	−15.00	−14.72 (5.68)	−2.00	3.00	1.00	1.13 (1.04)	−9.25 (0.000)‡

*Absolute difference between post-1 and baseline scores, †Absolute difference between post-2 and baseline scores. Z: Mann-Whitney U-test, ‡*P*<0.001; minimum and maximum change is based on the amount of change regardless the sign (+/−) which refers to the direction of change (positive/negative). SD: Standard deviation

Table 4: The intervention program effect size for each outcome						
Program outcomes	Multivariate tests*					
	Pillai's trace	F	df	Error df	P	Partial η²
Knowledge	0.98	3200.32	2	111	0.000†	0.98
Perceived burden	0.71	141.75	2	111	0.000†	0.71
Depression	0.76	183.20	2	111	0.000†	0.76
Anxiety	0.79	220.79	2	111	0.000†	0.79

*Design: Intercept + groups; †$P<0.001$

program in improving caregivers' perceived burden and emotional status. These findings were in agreement with other RCTs. In the UK, a program consisting of psychoeducation and cognitive-behavioral component (e.g., changing unhelpful thoughts, assertive communication, relaxation), involving carers of family members with dementia, revealed a significant reduction in their depression and anxiety symptoms.[29] In Spain, Márquez-González *et al*.[30] conducted a group CBT intervention, revealing a successful reduction in caregivers' level of depression and dysfunctional thoughts, as well as successful modification of their appraisal of the care recipient's problem behaviors. In Brazil, Fialho *et al*.[31] reported a significant reduction of caregivers' anxiety levels and improvement in their coping strategies following an eight-session CBT intervention. In a more recent study in Columbia (2014),[32] the authors delivered a group CBT to the caregivers that proved to be effective in lowering depression and burden in the intervention group compared with the controls across the posttest and 3-month follow-up.

This trial supports the effectiveness of psychoeducation in improving caregivers' knowledge. Systematic reviews that investigated studies in the area of educational interventions indicated that these studies had inconclusive evidence and focused primarily on outcome measures other than knowledge, such as emotional status and burden.[33-36] On the other hand, evidence was found for the effectiveness of interventions targeting information on improving caregivers' knowledge and ability.[37] These interventions included different forms of education about dementia such as psychoeducation,[3,38] technology-based education,[39,40] and information/support interventions.[36]

Systematic reviews showed variability of evidence for the effectiveness of multicomponent interventions in reducing caregivers' burden, depression, and anxiety.[17,37,41] A meta-analysis showed that small to medium effect sizes of caregivers support programs regarding caregivers' burden (least effect size), depression, and stress (highest effect size).[41] In partial agreement with this meta-analysis, we found large effect sizes of all program components with the least for caregivers' burden, followed by depression,

then anxiety, and the highest for knowledge. These findings provide evidence for success of the educational component of the program in satisfying some of the pressing needs of caregivers who were highly motivated to acquire the knowledge and skills necessary to handle their care recipients' problems. The relatively large effects recorded in this RCT especially for the knowledge outcome may be attributed to the low level of standard care and services directed to caregivers, as well as their baseline characteristics, which revealed that they were highly burdened, depressed, anxious, and less knowledgeable about dementia. The needs reported by the caregivers before starting the program support this explanation, where all of them reported their need for psychoeducation, and more than half indicated that they need psychological support.

The variability of evidence for the effectiveness of caregivers psychosocial interventions could be attributed to wide variations in the methodology, the intervention program content, techniques, and outcomes as well as in care recipient- and caregiver-related factors, such as presence of other life stressors, financial problems, dementia course, and emerging individual and environmental factors during the course of the program (temporal factors), which may cause deviation from the baseline recruitment data.

The evidence that can be derived from results of this study should be interpreted in light of its strengths and limitations. Being an RCT with a quite sufficient sample size is one of the strength points. Although the nature of the trial did not allow blinding, pre- and post-assessment for the outcome measures was carried out by a psychologist, and not by the principal investigator who conducted the sessions, which is another strength.

Study limitations included mainly nonassessment of secondary outcomes related to PWD and focused only on caregivers-related measures. Furthermore, the short-term follow-up makes the long-lasting effects of the intervention unpredictable. In addition, all participants in this study belonged to a specific stratum in the community, those who receive free governmental health services, while attendants of the private sector were not included.

CONCLUSIONS

The current RCT provided an evidence for the short-term efficacy of a of a culturally sensitive multicomponent psychosocial intervention program in improving dementia-related knowledge and the emotional status of informal caregivers of people with NCDs. This program is recommended to be included as an integral component of

neuropsychiatric services provided to people with NCDs and their informal caregivers, particularly those with evident perceived burden and/or emotional problems. Offering training opportunities to mental health professionals, psychologists, and nurses in such settings ensures continuity and better service quality.

Additional information

Acknowledgment

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Conflicts of interest

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REFERENCES

1. Prince M, Wimo A, Guerchet M, Ali G, Wu YT, Prina M. World Alzheimer Report 2015. The Global Impact of Dementia. An Analysis of Prevalence, Incidence, Cost and Trends. London: Alzheimer's Disease International; 2015.
2. Farrag A, Farwiz HM, Khedr EH, Mahfouz RM, Omran SM. Prevalence of Alzheimer's disease and other dementing disorders: Assiut-Upper Egypt study. Dement Geriatr Cogn Disord 1998;9:323-8.
3. El Tallawy HN, Farghaly WM, Metwaly NA, Rageh TA, Shehata GA, Elfetoh NA, *et al.* Door-to-door survey of major neurological disorders in Al Kharga District, New Valley, Egypt: Methodological aspects. Neuroepidemiology 2010;35:185-90.
4. Tallawy HN, Farghaly WM, Rageh TA, Shehata GA, Badry R, Metwally NA, *et al.* Door-to-door survey of major neurological disorders (project) in Al Quseir City, Red Sea Governorate, Egypt. Neuropsychiatr Dis Treat 2013;9:767-71.
5. Prina AM, Acosta D, Acostas I, Guerra M, Huang Y, Jotheeswaran AT, *et al.* Cohort profile: The 10/66 study. Int J Epidemiol 2016. pii: Dyw056.
6. Alzheimer's Association. 2013 Alzheimer's Facts and Figures. Chicago, IL: Alzheimer's Association; 2013.
7. Slachevsky A, Budinich M, Miranda-Castillo C, Núñez-Huasaf J, Silva JR, Muñoz-Neira C, *et al.* The CUIDEME Study: Determinants of burden in Chilean primary caregivers of patients with dementia. J Alzheimers Dis 2013;35:297-306.
8. Toribio-Díaz ME, Medrano-Martínez V, Moltó-Jordá JM, Beltrán-Blasco I. Characteristics of informal caregivers of patients with dementia in Alicante province. Neurologia 2013;28:95-102.
9. Prince M; 10/66 Dementia Research Group. Care arrangements for people with dementia in developing countries. Int J Geriatr Psychiatry 2004;19:170-7.
10. Awad MM, El Gammal HA, Fahmy MT, Imam E. Determinants of disabled elderly caregivers burden in Ismailia, Egypt. Med J Cairo Univ 2010;78:31-7.
11. El-Shinnawy H, Goueli T, Naser M. Emotional involvement and burden in caregivers of patients with Alzheimer's disease. Egypt J Psychiatr 2012;33:149-57.
12. Kaneda T. Health Care Challenges for Developing Countries with Aging Populations [Monograph on the Internet]. Population Reference Bureau; 2006. Available from: http://www.prb.org/Publications/Articles/2006/HealthCareChallengesforDevelopingCountrieswithAgingPopulations.aspx. [Last cited on 2016 Mar 15].
13. Black BS, Johnston D, Rabins PV, Morrison A, Lyketsos C, Samus QM. Unmet needs of community-residing persons with dementia and their informal caregivers: Findings from the maximizing independence at home study. J Am Geriatr Soc 2013;61:2087-95.
14. Hodgson NA, Black BS, Johnston D, Lykesos C, Samus QM. Comparison of unmet care needs across the dementia trajectory: Findings from the maximizing independence at home study. J Geriatr Palliat Care 2014;2:5.
15. Haskell DL, Haskell JH, Pottenger JJ. Harnessing values for impact beyond profit for MENA. In: Jamali D, Sidani Y, editors. CSR in the Middle East: Fresh Perspectives. Hampshire: Palgrave Macmillan UK; 2012. p. 25-48.
16. Pendergrass A, Becker C, Hautzinger M, Pfeiffer K. Dementia caregiver interventions: A systematic review of caregiver outcomes and instruments in randomized controlled trials. Int J Emerg Ment Health Human Resil 2015;17:459-68.
17. Lin S. The Effectiveness of Community Care Interventions on Caregivers of Dementia Patients: A Systematic Review [Master's thesis]. Hong Kong: University of Hong Kong; 2013. Available from: http://www.dx.doi.org/10.5353/th_b5098756. [Last accessed on 2015 Dec 14].
18. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. 5th ed. Washington, DC: American Psychiatric Association; 2013.
19. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revised. Washington, DC: American Psychiatric Association; 2000.
20. El Okl MA. Prevalence of Alzheimer Dementia and Other Causes of Dementia in Egyptian Elderly [Dissertation]. Cairo: Ain Shams University; 2002.
21. Dieckmann L, Zarit SH, Zarit JM, Gatz M. The Alzheimer's disease knowledge test. Gerontologist 1988;28:402-7.
22. Fateem L. Translation of Hamilton depression rating scale. Cairo: Al Anglo El Masrya; 1998.
23. Mostafa F, Ghaly MA. Translation of Taylor's manifest anxiety scale. Cairo: Dar El Maaref; 1962.
24. Bédard M, Molloy DW, Squire L, Dubois S, Lever JA, O'Donnell M. The Zarit Burden Interview: A new short version and screening version. Gerontologist 2001;41:652-7.
25. Dupont WD, Plummer WD Jr. Power and sample size calculations. A review and computer program. Control Clin Trials 1990;11:116-28.
26. Hébert R, Leclerc G, Bravo G, Girouard D, Lefrançois R. Efficacy of a support group programme for care-givers of demented patients in the community: A randomized controlled trial. Arch Gerontol Geriatr 1994;18:1-14.
27. Cusin C, Yang H, Yeung A, Fava M. Rating scales for depression. In: Baer L, Blais MA, editors. Handbook of Clinical Rating Scales and Assessment in Psychiatry and Mental Health. New York: Humana Press; 2010.
28. Bachner YG, O'Rourke N. Reliability generalization of responses by care providers to the Zarit Burden Interview. Aging Ment Health 2007;11:678-85.
29. Livingston G, Barber J, Rapaport P, Knapp M, Griffin M, King D, *et al.* Clinical effectiveness of a manual based coping strategy programme (START, STrAtegies for RelaTives) in promoting the mental health of carers of family members with dementia: Pragmatic randomised controlled trial. BMJ 2013;347:f6276.
30. Márquez-González M, Losada A, Izal M, Pérez-Rojo G, Montorio I. Modification of dysfunctional thoughts about caregiving in dementia

family caregivers: Description and outcomes of an intervention programme. Aging Ment Health 2007;11:616-25.

31. Fialho PP, Köenig AM, Santos MD, Barbosa MT, Caramelli P. Positive effects of a cognitive-behavioral intervention program for family caregivers of demented elderly. Arq Neuropsiquiatr 2012;70:786-92.

32. Arango-Lasprilla JC, Panyavin I, Merchán EJ, Perrin PB, Arroyo-Anlló EM, Snipes DJ, *et al.* Evaluation of a group cognitive-behavioral dementia caregiver intervention in Latin America. Am J Alzheimers Dis Other Demen 2014;29:548-55.

33. Corbett A, Stevens J, Aarsland D, Day S, Moniz-Cook E, Woods R, *et al.* Systematic review of services providing information and/or advice to people with dementia and/or their caregivers. Int J Geriatr Psychiatry 2012;27:628-36.

34. Jensen M, Agbata IN, Canavan M, McCarthy G. Effectiveness of educational interventions for informal caregivers of individuals with dementia residing in the community: Systematic review and meta-analysis of randomised controlled trials. Int J Geriatr Psychiatry 2015;30:130-43.

35. Kwok T, Wong B, Ip I, Chui K, Young D, Ho F. Telephone-delivered psychoeducational intervention for Hong Kong Chinese dementia caregivers: A single-blinded randomized controlled trial. Clin Interv Aging 2013;8:1191-7.

36. Thompson CA, Spilsbury K, Hall J, Birks Y, Barnes C, Adamson J. Systematic review of information and support interventions for caregivers of people with dementia. BMC Geriatr 2007;7:18.

37. Huis In Het Veld JG, Verkaik R, Mistiaen P, van Meijel B, Francke AL. The effectiveness of interventions in supporting self-management of informal caregivers of people with dementia; a systematic meta review. BMC Geriatr 2015;15:147.

38. Marim CM, Silva V, Taminato M, Barbosa DA. Effectiveness of educational programs on reducing the burden of caregivers of elderly individuals with dementia: A systematic review. Rev Lat Am Enfermagem 2013;21:267-75.

39. Boots LM, de Vugt ME, van Knippenberg RJ, Kempen GI, Verhey FR. A systematic review of Internet-based supportive interventions for caregivers of patients with dementia. Int J Geriatr Psychiatry 2014;29:331-44.

40. Godwin KM, Mills WL, Anderson JA, Kunik ME. Technology-driven interventions for caregivers of persons with dementia: A systematic review. Am J Alzheimers Dis Other Demen 2013;28:216-22.

41. Park S, Park M. Effects of family support programs for caregivers of people with dementia – Caregiving burden, depression, and stress: Systematic review and meta-analysis. J Korean Acad Nurs 2015;45:627-40.