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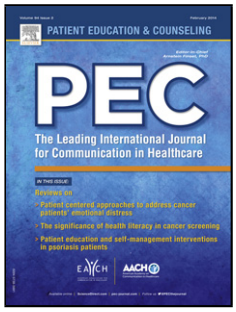

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Telephone-based Behavioral Activation Intervention for Dementia Family Caregivers: Outcomes and Mediation Effect of a Randomized Controlled Trial

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Highlights for Review

- **Both intention-to-treat and per protocol analysis conducted**
- **Intervention components elaborated and contacts for obtaining protocols given**
- **Procedures of blinding, randomization and allocation concealment discussed**
- **Attrition, nil adverse effects and monitoring of contamination bias discussed**
- **Costs of enagaging para-professionals and professional compared**

ABSTRACT

Objectives: The study examined the effects of a telephone-administered psycho-education with behavioral activation intervention (TBA) for family caregivers of person's with Alzheimer's dementia to reduce levels of depressive symptoms and burden and to enhance relationship satisfaction with the care-recipient

Methods: A double-blinded randomized trial compared TBA with telephone-based psycho-education with general monitoring (TGM). Ninety-six dementia caregivers were randomized. Both conditions received four weekly psycho-education sessions led by a social worker. TBA participants then received eight bi-weekly behavioral activation practice sessions delivered by paraprofessionals. TGM participants received eight bi-weekly monitoring sessions by paraprofessionals.

Results: As compared to TGM, TBA participants reported significantly larger reductions in depressive symptoms and burden and larger improvement in relationship satisfaction. Self-efficacy for controlling upsetting thoughts was found to have a partial meditation effect between TBA and the reduction of depressive symptoms. Qualitative feedback suggested that TBA participants expressed unique gains in awareness and developing new ways of reappraising the caregiving situation.

Conclusion: TBA was an effective intervention to reduce depressive symptoms and burden as well as to enhance relationship satisfaction in dementia caregivers.

Practice Implications: The use of telephone and trained paraprofessionals can enhance the accessibility and sustainability of behavioral activation intervention for dementia family caregivers.

KEYWORDS: psycho-education, pleasant event scheduling, communication skills, self-efficacy for controlling upsetting thoughts, cognitive reappraisal

1. Introduction

The number of persons living with dementia worldwide is expected to reach 75 million in 2030 and 131.5 million in 2050. At present, 58% of people with dementia live in low and middle income countries, but by 2050 this will rise to 68% [1]. Formal caregiving can be rewarding [2]. However, converging evidence also suggests that caring for a close relative with chronic disease or disability can have negative impact on family caregivers' well-being including the increase in depressive symptoms and chronic burden [3]. Moreover, while positive social exchanges can contribute towards beneficial experiences in caregiving, there can be cultural demands with self-sacrificial obligations to care for the family or reluctance to disclose personal difficulties that preclude caregivers from seeking support and relief [4-6]. It is thus important to develop cost-effective, accessible and sustainable interventions to reinforce sense of mastery in caregiving [7-8].

Behavioral models highlight the importance of positive reinforcement on well-being. Thompson et al. have shown that engaging in pleasant activities reduces stress and depressive symptoms in caregivers [9]. Daily pleasant experiences can bring balance between self-care and caring for others and reinforce the positive aspects of caregiving [10]. On the other hand, activity restriction has been found to be significantly associated with increased depression for both patients and caregivers over a variety of medical conditions and diverse ethnic groups [11]. It is not always easy to incorporate pleasant activities in the daily lives of caregivers due to the long-standing stress. Stressed individuals may also lack the social and communication skills to find the time and opportunity to engage in positive interactions [12].

Behavioral activation (BA) focuses on constructing reinforcement contingencies that increases functional behavior. Early reinforcement deprivation models suggested that depressive affect is produced by reduction or loss of response-contingent positive reinforcement resulting in disruption of healthy lifestyles and less engagement with the social environment. This in turn leads to further exacerbation of the depressive symptoms [13]. Later variants of this model included activity scheduling based on the notion that increase in pleasant events will increase the chance for positive reinforcement that will eventually reduce negative mood [14]. In fact, incorporation of behavioral activation into cognitive/behavioral therapy has been very effective in reducing significant depression in older adults [15].

BA utilizes a fundamentally different approach to negative thinking as compared to cognitive therapy by focusing on the individual's life circumstances and also his/her

responses to environmental changes. Using activity logs to help understand the person current level of engagement in positive activities, BA focuses on engaging in activities that bring about positive mood changes and developing communication skills to obtain reinforcements through social interactions [16-19]. Dimidjian et al. [18] found that BA was effective in treating severe depression. BA was also found to be equally effective to cognitive therapies in cases with mild to severe depression, both at the end of therapy and at 24- month follow up [20-23]. In the context of the intensifying severity of depression as the most burdensome disease in the world, the potential strengths of BA in terms of parsimony, flexibility and ease of trainability are also highlighted. In terms of treatment dissemination, Ekers et al. have also demonstrated that effective BA can be delivered by paraprofessionals like generic mental health staff after training [24]. In order to increase treatment accessibility, telephone administered and self-help BA protocols have been validated [22]. Finally, a weekly telephone-delivered BA carried out over a period of 6 weeks has been found to lower negative affect and the risk of cardiovascular diseases for dementia caregivers [25].

With its strengths as parsimonious and easily trainable intervention, the mechanism of change involved in BA has been receiving increasing interest. BA offers a structured format for individual action plans to systematically increase activation of healthy behaviors in order to empower the individual living with distress. In the study by Jacobson et al. [16], a BA stand-alone condition (BA) was compared with two other conditions: a treatment which contained both BA and restructuring of automatic thoughts (AT) and a third treatment corresponding to full cognitive therapy (CT). BA was found to be effective in reducing negative thinking and changing attribution style. Putative mediators of BA include higher levels of activation and environmental reward [26]. Losada and colleagues (27) evaluated the mechanism of change of a CBT-informed psychological intervention that included both BA and modification of dysfunctional thoughts for dementia caregivers, and found that both increasing frequency of leisure activities and reduction of dysfunctional thoughts mediated the relationship between intervention and reduction in depressive symptoms [27]. These findings echo the earlier findings of Gallagher-Thompson et al. [28] that effective skill utilization mediated between a multi-domain psycho-educational program for dementia caregivers and depressive symptoms. More recently, based on qualitative analysis, the importance of agency is underscored as a therapeutic mechanism enhancing self-determination in BA [29].

1.1 Rationale for development of the present intervention

Agency refers to the capacity to influence one's thoughts, actions and course events through intentions, goals and actions. According to Bandura (1989) [30], self-efficacy can be the most central element in personal agency. Self-efficacy refers to the person's beliefs about the abilities to exercise control on the events affecting their lives. These beliefs have an influence on sustained effort in challenging conditions and re domain-specific [31, 32]. Steffen (2018) [33] have found that caregiving self-efficacy was generalizable to cross-national populations of dementia caregivers. Au et al. [34-35] found caregiving self-efficacy for controlling negative thoughts correlated with social support and was a sensitive outcome measure for a psycho-educational intervention with Chinese dementia caregivers. In a benefit-finding intervention for dementia caregivers, Cheng et al. [36, 37] found self-efficacy for controlling negative thoughts was a partial mediator between the intervention and outcomes such as depressive symptoms and burden. Taken together these findings suggest that directly challenging negative thoughts may not be the only path for therapeutic change for distressed caregivers of persons with dementia. However, the possible role of self-efficacy as a mechanism of change of BA interventions has not been examined using quantitative methods. The present study aimed to address this research gap with reference to mechanisms of change using both quantitative and qualitative methods.

At the same time, the present study attempts to meet the global demand for accessible, sustainable, efficacious and effective interventions to enhance the well-being of caregivers. The flexible administration of BA via telephone using trained paraprofessionals contributes to its accessibility and sustainability [24]. These trained paraprofessionals can include generic mental health professionals without previous experience as interventionists or formal training in psychotherapy. While social support contributes to well-being, many caregivers may not possess social support, help-seeking skills or time to seek interventions outside their homes [38, 39]. The intervention used in the present study was entirely carried out by telephone, to facilitate caregivers to overcome these practical barriers. [40]. Telephone counseling has been found to be cost-effective in reducing depressive symptoms and burden as well as increasing self-efficacy caregivers of people with dementia [25, 41-45].

1.2 Research Hypotheses

With a double-blinded randomized trial, the present study aimed to evaluate the effects of telephone-based psycho-education with behavioral activation (TBA) against a telephone-based psycho-education with general monitoring (TGM). The study also tested whether the

intervention effects on depressive symptoms were mediated by changes in self-efficacy for controlling upsetting thoughts. Qualitative feedback on treatment gains was collected from participants. The research hypotheses tested were as follow. First, as compared to a general monitoring condition with a check-in call (TGM), TBA would produce statistically greater reductions in primary outcome in terms of level of caregivers' depressive symptoms. Second, TBA would produce statistically greater reductions in secondary outcomes in terms of decreased caregivers' burden and increased relation satisfaction with their care-recipients. Third, reduction in depressive symptoms would be mediated by gains in self-efficacy for controlling upsetting thoughts. Quantitative findings will be supplemented with qualitative feedback obtained from the participants.

2. Method

2.1 Design

This is a double-blinded randomized controlled trial. In addition to quantitative methods, qualitative feedback was obtained from participants concerning treatment gains. With randomization carried by a random number generator, both assessors and participants were blinded to intervention condition.

2.2 Protocol

The intervention protocol of the present study was an extended version of a previous pilot study on pleasant activity scheduling by the research team [45]. In view of social isolation together with the reluctance to seek help that comes with prolonged caregiving, the present study added a component to enhance assertive help-seeking skills that can help caregivers to obtain social support in the natural environment [39]. Practice with the help of the trained paraprofessionals was used to consolidate treatment gains.

2.2 Setting

Caregivers were recruited while accompanying the care-recipient attending dementia clinics of the United Christian Hospital and Prince of Wales Hospital. Written informed consent was obtained at the site of recruitment. No other clinic visits were required for the care-recipient. All interventions were carried out in the caregivers' homes via telephone.

2.3 Participants recruitment

The inclusion criteria were as follows. Caregivers were family and primary caregivers to a care-recipient with mild to moderate Alzheimer disease with physician diagnosis according to the National Institute of Neurological and Communicative Disorders and Stroke-Alzheimer's Disease and Related Disorders for possible Alzheimer Disease [46]. They needed to provide at least 14 hours of care per week for at least 3 months. Caregivers were excluded if they exhibited signs of the following conditions: severe intellectual deficits, psychotic disorders, suicidal ideation or lack of the ability to read Chinese and speak Cantonese.

Using the G*power analysis, a total sample of 68 participants is estimated to be needed to detect differences by linear regression with alpha at 0.05, power at 0.80 and medium f^2 effect size of 0.15 for two groups and four measures [47]. A total sample size of 71 would be sufficient to test mediation using bias-corrected bootstrap based on medium effect sizes for both the path from the independent variable to the mediator and the path from mediator to the dependent variable [48].

Caregiver recruitment took place from January 2015 to June 2016. A total of 129 caregivers were enrolled in the study, which is a double-blinded parallel group randomized trial. Neither the participants nor the research administrators knew about the group assignment. Allocation sequence was obtained by random number generation by a staff who was not involved in enrolling/assigning participants. The allocation was concealed in sequentially numbered sealed envelopes. Before starting the psycho-educational program, block randomization was used to achieve balance between the numbers of participants in both arms. Assessments were carried out by research assistants who were blind to the group allocation of the participants.

2.4 Intervention group: Telephone Behavioral Activation (TBA)

Delivered by telephone, there were four sessions of the sycho-education and eight sessions of BA. Adapted from the Chinese Version of the Coping with Caregiving manual [49], the themes of four weekly psycho-education sessions are listed in Table 1 and the focus of the eight biweekly BA session in Table 2 with a sample session in Table 3. After the four psycho-education sessions, participants received eight bi-weekly sessions of BA. Each session lasted about 20 minutes. Written information including the forms for pleasant event scheduling was mailed to the participants before the program started.

2.5 Control group: Telephone General Monitoring (TGM)

All TGM participants received four weekly psycho-education sessions over the phone with the same content as in the TBA group (Table 1). These caregivers were then assigned to eight bi-weekly sessions of general monitoring with no BA intervention (Table 2). Each of these sessions started with checking in with the caregiver through inviting them to update their caregiving situation. Caregivers were then guided to discuss one of the following topics at each session in this order : 1) caregiver's health, 2) care-recipient's needs, 3) caregiver's routines and 4) social support. As there were a total of eight sessions, the last four sessions repeated the order of the first four. While some caregivers might report on attempt they made on their own initiative to improve their scheduling and communication, no specific attempt was made to ask them to review these attempts. Each session lasted about 20 minutes.

2.6 Training and supervision of staff

An interventionist with a degree in social work delivered all the four sessions of psycho-education for both groups. Six paraprofessional coaches were recruited from the Institute of Active Ageing of the Hong Kong Polytechnic University. These coaches were aged between 50 and 60 years old and had an undergraduate degree in helping or service professions. They completed a 42-hour course on Psychology of Aging held at the Institute. Three paraprofessionals was assigned to deliver BA while the other three to carry out monitoring. They received an assessment of a case after 20 hours of group training on either BA or monitoring. A social worker (HY) and a clinical psychologist (AA) provided the training and facilitated weekly supervision separately for TBA and TGM coaches.

2.7 Fidelity checking

Program fidelity was assessed by a rating system built into recording form. At the end of each session, all interventionists including the paraprofessionals were asked to rate to what extent they were able to follow the protocol for each of the four PE sessions (3= fully; 2= adequately with at least 60% of the material covered; 1=slightly; 0= not at all). A similar procedure was adopted for each of the 8 sessions for both TBA and TGM. In addition, 10 cases from TBA and 10 cases from TGM were audiotaped. Interventionists' adherence to the intervention protocol was assessed by two graduate students who had received eight hours of training on the coding scheme. The sessions were coded with reference to four core TBA strategies (activity planning, review to improve on scheduling, develop new help-seeking communication skills and review to improve on communications) and four core TGM

strategies (updating on caregiving situation, overall stress and health of the care-recipient, daily routines and family communications).

2.8 Measures taken to minimize contamination bias

The following measures were taken to minimize contamination: monitoring of case-notes and reported treatment gains on completion of intervention. Furthermore, both conditions were implemented by individual telephone calls. The outpatient appointment for the care-recipient could range and vary from three to twelve months depending on assessed need. Thus, opportunities for exchanging information between the caregivers were minimal. The paraprofessionals were not informed of the other group. We scheduled them to be trained and to do their work at very different times. Both conditions require intensive work to follow the protocol assigned.

2.9 Quantitative data collection and analysis

Background information and assessments at baseline (T0) were carried out at the clinic for recruitment. Assessment for post-intervention (T1) was carried appropriately 20 weeks after T0 (after four weekly sessions of PE and eight bi-weekly sessions of TBA or TGM). Assessment questionnaires were mailed to participants with a follow-up phone call by research staff not involved in the allocation of cases or interventions. Demographic measures taken only at baseline T0 included: age, sex, gender, education, occupation, relationship to care-recipients, years of caregiving and number of hours spent in caregiving per week. The Chinese version of the Disability Assessment for Dementia [50] was used to obtain a profile of functional abilities of the care recipient in terms basic and instrumental activities of daily living.

Primary and secondary outcomes were based on measures of the caregivers only. The primary outcome measured at T0 and T1 was the level of depressive symptoms measured by the 20-item Center for Epidemiological Studies-Depression (CESD) scale [51]. This self-report measure asks caregivers to rate how often over the past week they experienced symptoms associated with depression, such as restless sleep, poor appetite, and feeling lonely. Cronbach alpha was 0.79 for this sample. Secondary outcomes included burden and relationship satisfaction. The Zarit Burden Interview (BURD) [52] contains 22 items tapping into sense of burden with response options range from 0 (Never) to 4 (Nearly Always). Cronbach alpha was 0.88 in this sample. The 7-item Relationship Assessment Scale (RAS)

was designed to measure general relationship satisfaction in close relationships. Respondents answered each item using a 5-point scale [53, 54]. The Cronbach alpha was 0.75. Self-efficacy for controlling upsetting thoughts (SE-CU) was chosen as the potential mediator for this study [55]. The 5-item self-efficacy for controlling upsetting thoughts taps the extent to which caregivers believe they can handle negative thinking including the unfairness and unpleasant aspects involved in caregiving. The Cronbach alpha was 0.83. Intention-to-treat analysis (with five multiple imputations) was compared with per-protocol analysis Separate multiple regressions were performed for each dependent variable with pre-intervention measures and group status entered as explanatory variables. SPSS Process Macro [56] was used to examine mediation effects of SE-CU with intervention as the predictor. The mediator's post-intervention value at T1 was regressed on its baseline T0 score. The residualized score (i.e., the portion of the post-intervention score that was not explained by the pre-intervention score, representing the change from before to after treatment) was entered into the above model to estimate indirect effects. The indirect effect was estimated using Hayes (2013) [56] bootstrapping method, which yields unbiased estimates using 5000 bootstrapped samples generated for each analysis.

2.10 Qualitative data collection and analysis

All qualitative data were collected at the end of program after eight bi-weekly sessions for both groups. The method of data collection of the qualitative review of the treatment gains by the caregiver was by mailed questionnaires supplemented by telephone assistance by the research staff. Participants were asked to report on up to 10 treatment gains. Two investigators (AA and HMY) developed codes after going through all the responses in order to organize the data into over-arching domains and themes. For validation, a third researcher (SN) conducted an independent review of the coded data. Discrepancies were resolved in consensus meetings involving all three coders.

3. Results

Demographics of the 111 caregivers randomized can be found in Table 4. Ninety-six caregivers completed the interventions while fifteen caregivers discontinued with the intervention with clearly defined reasons including the care recipients' admission hospital/

residential care as well as changes of personal commitment of the caregivers. No adverse effects were reported (Figure 1).

3.1 Fidelity Checking

For the implementation of the PE program, ratings were obtained from all 96 participants. The interventionist would make the initial rating to be deliberated in the supervision meeting. Over 60% of the cases obtained an overall score of 3 (fully covered). The remaining case obtained a score of 2 (adequately covered). No ratings of 1 or 0 were noted. The most common reason for deviation was the caregivers' eagerness to share their experience and frustrations. For the analysis of the audiotapes of the 20 cases, results can be found in Table 5. TBA participants were found to spend considerably more (16% to 20% of the total intervention time) on each of the four TBA core components as compared to the each of the non-core components. Kappa co-efficients between the two raters ranged from 0.74 to 0.83, suggesting a high level of consistency. Results obtained supported a clear distinction between the intervention focus of TBA and that of TGM in terms of time in each of the core components.

3.3 Contamination Bias

Three participants in the control group mentioned reviewing charts for pleasant event scheduling. No further evidence for further contamination bias was identified.

3.3 Regression

For both intention-to-treat (Table 6) and per protocol analysis (Table 7), as compared to the control condition (TGM), caregivers in the intervention condition (TBA) scored significantly lower in depressive symptoms ($p<0.001$) and burden ($p<0.001$) but higher in self-efficacy ($p<0.01$). Though significant in per-protocol analysis ($p<0.01$), the increase in relationship satisfaction was on only marginally significant in intention-to-treat ($p=0.01$).

3.4 Mediation of Self-efficacy

For both intention-to-treat with five multiple imputations (Figure 2) and per protocol analysis (Figure 3), SE-CU was found to have a significant partial mediation effect between TBA intervention and residualized change scores of depressive symptoms in CESD .

3.5 Qualitative analysis on report of treatment gains

Table 8 outlines major treatment gains for both TGM and TBA along four dimensions: skills, awareness, self-regulation and finding meaning. As compared to TGM, TBA participants had stronger appreciation of practice in adopting new strategies. Moreover, the analysis identified the following themes unique to TBA. First, there was enhanced awareness of self and also of others. Second, participants adopted new cognitive reappraisal strategies including focusing on the positive and developing new perspectives in understanding their caregiving situation.

4. Discussion and Conclusion

4.1 Discussion

This study assessed an enhanced model of psycho-education for dementia caregivers. In addition to psycho-education, the TBA group received behavioral activation training in pleasant event scheduling and help-seeking communication. On the other hand, the TGM group received psycho-education with general monitoring sessions but no specific behavioral activation training. Findings of the study showed that the integrated TBA program was effective in reducing symptoms of depression and perceived burden while enhancing relationship satisfaction between CG and CR. Effect sizes ranged from medium to large. Self-efficacy for controlling upsetting thoughts was found to have partial meditation effects for TBA on depressive symptoms. Qualitative analysis also identified the following themes unique to TBA participants: enhanced awareness of others as well as adopting new cognitive appraisal strategies like focusing on positive aspects of caregiving and taking new perspectives. These findings provided evidence that psychotherapeutic techniques can be effectively used together with psycho-education delivered over the telephone for dementia family caregivers.

4.1.1 Strengths of the study: Accessibility and sustainability of care

The flexible administration of BA via telephone and trained paraprofessionals contributes to the effective but relatively low-cost intervention [57]. A comparison of the cost of manpower

involved in engaging paraprofessionals versus professionals can be found in Table 9. The telephone-administered intervention also allowed more opportunities for addressing the individualized concerns of each caregiver. As the sessions were carried out at times convenient to the caregivers, they offered the ability to support the caregiver without the added burden of traveling outside the home. Finally, the present study also resonates with the global initiatve of moving dementia care forward from the over-reliance of health care to promoting community care to support AD caregivers [58].

4.1.2 The role of self-efficacy and culture

The present findings highlighted the significance of self-efficacy in behavioral activation. At the same time, more work would be needed in the future to examine in more detail how culture may impact on how coping with caregiving is construed. The relevance of self-efficacy may vary across cultures depending on individualistic-collectivistic concerns [33]. Familism or collectivistic values, with its emphasis on the needs of the family taking over the precedence of the needs of individual family member, may have both positive and negative effects on caregivers [4, 5]. Future work should consider incorporating cultural dimensions into activity scheduling and communication skills.

4.1.3 Limitations and Ways Forward

Future studies should include a longer period of follow-up to test if the effects of the intervention can be maintained over time. The present study did not have a non- active control group. A multiple-arm study may examine treatment effects in varying degrees/ dosage. Finally, the present study has proven to be effective for caregivers with mild depressive symptoms. Future work will be needed for caregivers with more severe levels of depressive symptoms.

4.2 Conclusion

TBA was found to be effective in reducing depressive symptoms and burden as well as in enhancing relationship satisfaction in dementia caregivers. Quantitative and qualitative analysis supported self-efficacy for controlling upsetting thoughts as a mechanism of change in the context of cognitive reappraisal.

4.3 Practice Implications

The present study contributes to the development of practical and economical interventions that can be readily accessible and provide positive behavioral and psychological changes in family caregivers. The present findings can contribute to the sustainability of long-term care for persons with dementia in the community. The use of inexpensive technology and paraprofessionals can have substantive implications for regions around the world where public services are developing and the demand for family caregiving is high due to collectivistic cultural values and beliefs [59-60].

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Ethics Approval

Obtained from the Research Ethics Committee of the Hong Kong Polytechnic University as well as the Hong Kong Hospital Authority Ethics Committee of the Kowloon East Cluster and the New Territories West Cluster

Trial Registration

The trial of the present study was registered in CliniclTrail.gov with Identifier Number NCT03552159.

Previous Presentations

1. Mental health in later life China and Hong Kong presented at Symposium on Aging and Mental Health: Global Perspectives 1st IAGG World Congress of Gerontology and Geriatrics, taking place July 23-27, 2017 in San Francisco, California.
2. Beyond Pleasant Events: The Challenge of Emotional Regulation for Caregivers. 18th Annual Updates on Dementia of Alzheimer's Association. San Francisco May 2016.

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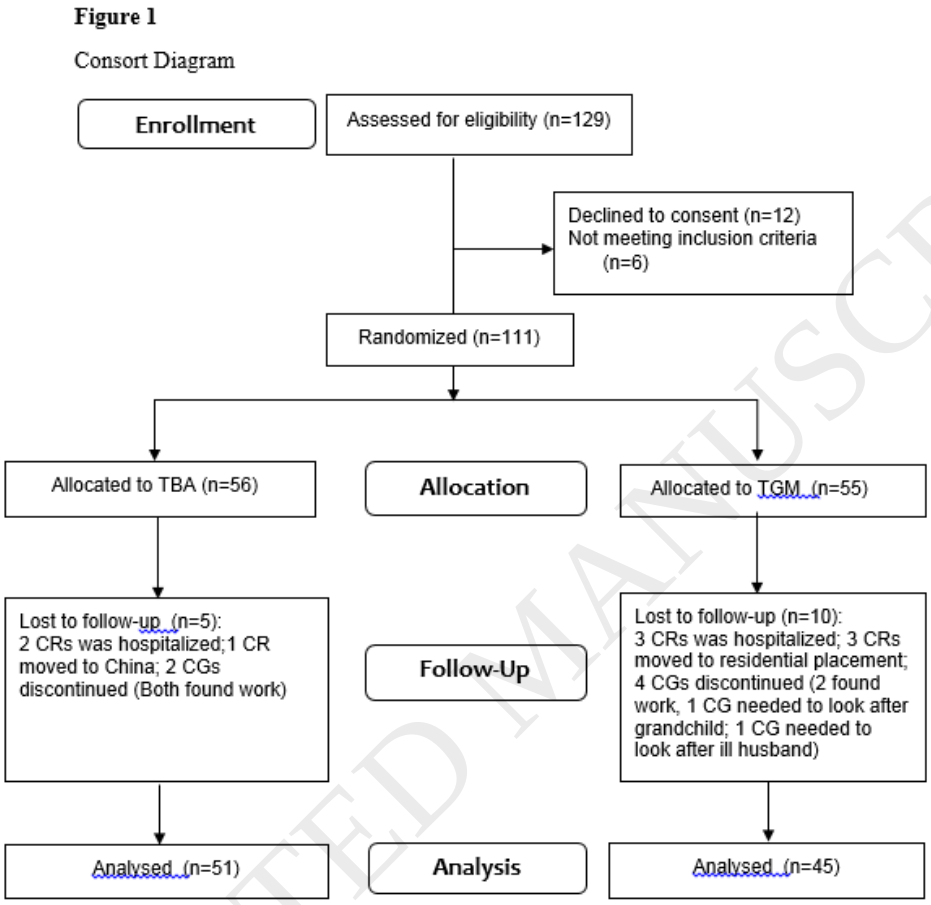
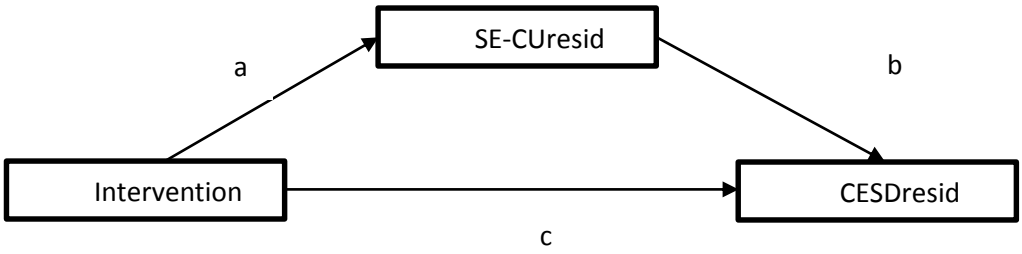
Figure 1

Consort Diagram



Note: CR: Care-recipient; CG: Caregiver ; TBA: Telephone-based Behavioral Activation; TGM: Telephone-based General Monitoring

Figure 2. Results from the mediation analysis for the effects of Self-efficacy for controlling upsetting thoughts on Center for Epidemiological Studies-Depression Scale. Unstandardized co-efficients (Intention-to-Treat)



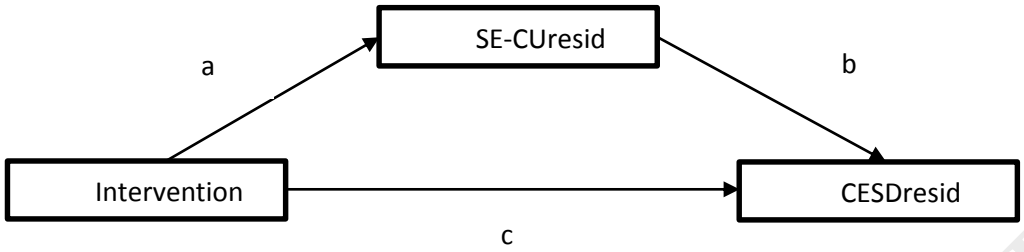
Note 1: CESDresid: Residualized change score for Center for Epidemiologic Studies Depression Scale; SE-CUresid: Residualized change score for Self-efficacy for Controlling Upsetting Thoughts

Note 2: A statistically significant mediating effect is identified when the 95% bias-corrected accelerated (BCa) confidence interval (CI) of the indirect effect does not contain the value zero.

Results of the 5 Multiple Imputations

Imputation 1
Path a from Intervention to SE-CU [β= 0.59, SE=0.18, t= 3.33, p<0.01, 95%CI= 0.24, 0.94] and Path b from SE-CU to CESD [β= -0.34. SE=0.09, t= -3.85, p<0.01, 95%CI= -0.52, -0.16] were both significant. The direct Path c between Intervention and CESD was significant [β= -0.69, SE=0.18, t= -3.92, p<0.01, 95%CI= -1.05, -0.34]. The indirect effect size was -0.24 [-0.40, -0.08], p< 0.01.
Imputation 2
Path a from Intervention to SE-CU [β= 0.48, SE=0.19, t= 2.54, p<0.01, 95%CI= 0.11, 0.85] and Path b from SE-CU to CESD [β= -0.30. SE=0.08, t= -3.68, p<0.01, 95%CI= -0.46, -0.14] were both significant. The direct Path c between Intervention and CESD was significant [β= -0.69, SE=0.16, t= -4.21, p<0.01, 95%CI= -1.01, -0.36]. The indirect effect size was -0.25 [-0.43, -0.07], p< 0.01.
Imputation 3
Path a from Intervention to SE-CU [β= 0.61, SE=0.19, t= 3.22, p<0.01, 95%CI= 0.24, 0.99] and Path b from SE-CU to CESD [β= -0.39. SE=0.08, t= -3.85, p<0.01, 95%CI= -0.56, -0.23] were both significant. The direct Path c between Intervention and CESD was significant [β= -0.45, SE=0.16, t= -2.59, p<0.01, 95%CI= -0.80, -0.10]. The indirect effect size was -0.23 [-0.46, -0.10], p< 0.01.
Imputation 4
Path a from Intervention to SE-CU [β= 0.61, SE=0.19, t= 3.22, p<0.01, 95%CI= 0.23, 0.99] and Path b from SE-CU to CESD [β= -0.50. SE=0.08, t= -4.75, p<0.01, 95%CI= -0.57, -0.23] were both significant. The direct Path c between Intervention and CESD was significant [β= -0.45, SE=0.18, t= -2.59, p<0.01, 95%CI= -0.80, -0.10]. The indirect effect size was -0.24 [-0.47, -0.11], p< 0.01.
Imputation 5
Path a from Intervention to SE-CU [β= 0.54, SE=0.18, t= 3.01, p<0.01, 95%CI= 0.18, 0.90] and Path b from SE-CU to CESD [β= -0.37. SE=0.08, t= -4.39, p<0.01, 95%CI= -0.54, -0.20] were both significant. The direct Path c between Intervention and CESD was significant [β= -0.50, SE=0.16, t= -3.06, p<0.01, 95%CI= -0.83, -0.17]. The indirect effect size was -0.24 [-0.41, -0.07], p< 0.01.

Figure 3. Results from the mediation analysis for the effects of Self-efficacy for controlling upsetting thoughts on Center for Epidemiological Studies-Depression Scale. Unstandardized co-efficients (Per Protocol: Complete Cases)



Note 1: CESDresid: Residualized change score for Center for Epidemiologic Studies Depression Scale; SE-CUresid: Residualized change score for Self-efficacy for Controlling Upsetting Thoughts

Note 2: A statistically significant mediating effect is identified when the 95% bias-corrected accelerated (BCa) confidence interval (CI) of the indirect effect does not contain the value zero.

Path a from Intervention to SE-CU [β= 0.57, SE=0.20, t= 2.93, p<0.01, 95%CI= 0.18, 0.96] and Path b from SE-CU to CESD [β= -0.36. SE=0.09, t= -3.85, p<0.01, 95%CI= -0.54, -0.17] were both significant. The direct Path c between Intervention and CESD was significant [β= -0.57, SE=0.17, t=-3.41, p<0.01, 95%CI= -0.90, -0.24]. The indirect effect size was -0.25 [-0.43, -0.07], p< 0.01

Table 1

Intervention Components (Psycho-education Program for TBA and TGM)
Four weekly sessions (Same content for both groups)
Session 1 (Week 1) Symptoms and associated behavioral changes in dementia Stages in dementia Caregiving roles and demands Effects on caregivers
Session 2 (Week2) Physical, social and psychological consequence of stress Identifying stress reactions Awareness of stress Stress and well-being
Session 3 (Week 3) The effect of life events on mood Tracking daily/ weekly events Identifying pleasant events Scheduling pleasant events
Session 4 (Week 4) Communication needs to family members Types of communications: passive, aggressive and assertive Resources available in the community Planning in the future

Note: The above components are adapted from: Gallagher-Thompson et.al. (2002). Coping with Caregiving: reducing stress and improving your quality of life [49]. Details of the Chinese version used in the study may be obtained from the first author.

Table 2

Components of the eight bi-weekly sessions delivered by paraprofessionals

	TBA	TGM
Session 1	Review the present use of time Using the monitoring form	Update caregiving situation Discuss caregivers health
Session 2	Brain-storm pleasant events Scheduling pleasant activities	Update care giving situation Discuss care-recipient's needs
Session 3	Review scheduling of events Discuss how to improve	Update caregiving situation Discuss daily/weekly routines
Session 4	Review modifications Consolidate gains on scheduling	Update caregiving situation Review support from family/ friends/ agencies
Session 5	Review present social support Explore new sources of support	Update caregiving situation Discuss caregiver's health
Session 6	Examine communication skills Explore new options	Update caregiving situation Discuss care-recipient's needs
Session 7	Review new communications Discuss how to improve	Update caregiving situation Discuss Daily/weekly routines
Session 8	Review modification Consolidate gains on support	Update caregiving situation Review social support

Note 1: TBA: Telephone-based Behavioral Activation TGM: Telephone-based General Monitoring

Note 2: The above components are adapted from the manual of Coping with Caregiving [49]. Details of the Chinese version used in the study may be obtained from the first author.

Table 3.

Outline of a sample session of TBA (The second session of a series of eight bi-weekly session focusing on brainstorming and scheduling pleasant events)

Task 1: How to Identify Pleasant Events

First, there are some rules. You need to start small and begin with simple tasks. Second, you need to choose events that we can increase in frequency and/ or intensity.

Task 2: Creating a List of Pleasant Events

Here are some examples of events that you find pleasurable and enjoyable.

1. Listen to music
2. Window shopping or buying something for yourself
3. Taking a walk
4. Going out with friends
5. Going to the cinema….

From this list of activities, choose something you think you can do on a regular basis and write them down in your work book as you own pleasant events list.

Task 3. Tracking Your Pleasant Events

On the tracking form, fill in the column marked pleasant events. Second, mark the days and dates of the week with which this event has really occurred.

Task 4: Monitoring Your Mood

In this exercise, you need to check in with yourself to ask "How do I feel right now?" You will record a number on your mood monitoring sheet at the end of each day.

Task 5: Exploring How Your Mood is Related to Events of the Day

Next to your mood score for each day, you can find several lines provided for you to write down any important events of the day that may have contributed to your mood.

Note: The above components are adapted from the manual of Coping with Caregiving Gallagher-Thompson et.al. (2002) [49].

Table 4
Baseline sample characteristics of the caregivers and care recipients of cases randomized

		TBA (N =56)	TGM (N =55)	*t*	χ^2	*p*
Caregiver						
Age	Mean (SD)	57.43 (9.69)	56.75 (10.79)	0.35		0.73
Sex	Male	9	12		0.60	0.44
	Female	47	43			
Education	Primary	17	18		0.30	0.59
	Secondary	29	26			
	Tertiary	10	11			
Married	Yes/ No	40/16	43/ 12		0.67	0.28
Employment	Unemployed	21	24		0.43	0.51
	Employed	35	31			
Relationship	Siblings	2	2		3.11	0.54
	Spouse	15	17			
	Children	34	34			
	Relatives	3	0			
	Daughter/ son-in-law	2	2			
Year of Caregiving,	Mean (SD)	4.22 (2.16)	3.75 (1.35)	1.37		0.17
Hours spent in caregiving per day Mean (SD)		10.92 (8.29)	10.93 (7.00)	-0.01		0.99
Care Recipient						
CDR	Rating of 2	32	37	1.21		0.27
	Rating or 3	24	18			
CDAD	Mean (SD)	23.64 (9.38)	25.58 (9.18)	-1.10		0.27

Note: TBA: Telephone-based Behavioral Activation TGM: Telephone-based General Monitoring; CDR: Clinical Dementia Rating Scale; CDAD: Chinese Disability

Assessment for Dementia

Table 5
Fidelity ratings of the intervention components

	TBA Mean (*SD*)*	TGM Mean (*SD*)*	Overall Kappa coefficient
Updating recent caregiving situation	1.20 (0.49)	3.85 (0.37)	0.84
Reporting overall stress and health of CR	1.10 (0.32)	3.85(0.37)	0.75
Reporting daily routines	1.05 (0.16)	3.90 (0.21)	0.74
Reporting family communication	1.15 (0.37)	3.90 (0.32)	0.75
Activity planning	3.90 (0.32)	1.15 (0.37)	0.75
Review to improve on scheduling	3.90 (0.32)	1.10 (0.32)	0.83
Develop new help-seeking skills	3.80 (0.42)	1.00 (0.16)	0.75
Reviewing to improve communication	3.95 (0.16)	1.10 (0.31)	0.74

Note 1: TBA: Telephone-based Behavioral Activation TGM: Telephone-based General Monitoring; Note 2: The total time period of 160 minutes covered eight 20-minute sessions. Ratings were based on the time spent over on each of the core components over the total time period: ranging from 0 (< 5 minutes) to 5 (20 - 25 minutes). Note 3: The percentage was based on the total intervention time of 8 sessions of 20 minutes each). The codes are as follows: 0: 5%; or less; 1: 6 to 10 %; 2: 11 to 15% ; 3: 16 to 20 % & 4: 21 to 25% .

Table 6. Mean (Standard Deviation) of Pre-Intervention and Post-Intervention Measures and Regression Results (Intention-to-Treat)

	Pre-Intervention			Post-Intervention		Regression Results		
	TBA (n=56)	TGM (n=55)	Significance	TBA (n=56)	TGM (n=55)			
	Pooled Mean (Standard Deviation)			Pooled Mean (Standard Deviation)		Pooled Unstandardized Regression Coefficient (Standard Error)	Significance	Effect Size (Cohen's d) CI Levels
CESD	13.29 (7.63)	13.92 (9.05)	t=-0.41 p=0.68	8.62 (8.53)	15.55 (11.35)	-6.55 (1.67)	t=-3.91 p<.001	-0.66 [-1.04, -0.74]
BURD	32.26 (17.43)	29.47 (17.06)	t= 0.86 p=0.38	21.82 (14.06)	37.47 (17.28)	-16.96 (2.48)	t=-6.84 p<.001	-1.14 [-1.54. -0.75]
RAS	27.78 (5.90)	27.41 (5.86)	t= 0.37 p=0.73	30.05 (4.79)	27.60 (6.08)	2.22 (0.83)	t=2.67 p=0.01	0.44 [0.82, 0.07]
SE-CU	36.08 (8.03)	33.58 (10.03)	t= 1.42 p=0.16	40.15 (9.02)	34.05 (10.07)	5.84 (1.65)	t=2.93 p<0.01	0.86 [1.24, 0.46]

Note: CESD: Center for Epidemiologic Studies Depression Scale; BURD: Zarit Burden Scale; RAS: Relationship Assessment Scale; SE-CU Self-efficacy for controlling upsetting thoughts.

Table 7. Mean (Standard Deviation) of Pre-Intervention and Post-Intervention Measures and Regression Results (Complete Data: Per Protocol)

	Pre-Intervention			Post-Intervention		Regression Results		
	TBA (n=51)	TGM (n=45)	Significance	TBA (n=51)	TGM (n=45)	Unstandardized Regression Coefficient (Standard Error)	Significance	Effect Size Cohen's d CI Levels
	Mean (Standard Deviation)			Mean (Standard Deviation)				
CESD	13.29 (7.21)	14.00 (9.19)	t=-0.42 p=0.68	8.78 (8.02)	15.76 (10.11)	-6.57 (1.60)	t=-4.12 p<.001	-0.75 [-1.16, -0.33]
BURD	31.90 (15.60)	30.07 (13.47)	t= 0.61 p=0.54	21.41 (13.77)	37.91 (15.34)	-17.36 (2.64)	t=-6.58 p<.001	-1.12 [-1.55, -0.69]
RAS	27.87 (5.21)	27.33 (5.20)	t= 0.50 p=0.62	30.16 (4.41)	27.42 (5.24)	2.41 (0.74)	t=3.26 p=002	0.56 [0.15, 0.62]
SE-CU	36.10 (7.56)	33.58 (7.25)	t= 1.66 p=0.10	40.08 (9.36)	33.53 (9.26)	5.08 (1.72)	t=2.95 p=.004	0.91 [1.33, 0.49]

Note: CESD: Center for Epidemiologic Studies Depression Scale; BURD: Zarit Burden Scale; RAS: Relationship Assessment Scale; SE-CU Self-efficacy for controlling upsetting thoughts.

Table 8.
Qualitative treatment gains (Domains and themes)

Domains	TBA (Themes)	TGM (Themes)
Skills	(Skill practice to achieve target) Practice improves my skills. Review gives me new insights.	(Knowledge of skills) I learn about timetabling. I know how to ask for help.
Awareness	(Self-awareness) I know when I cannot take it anymore and would give myself a break. (Awareness of others) I am aware of my shortcomings and am more forgiving of the faults of others	(Self- awareness) I care more for myself. I find it easier to ask for help
Self-regulation (Cognitive Reappraisal)	(Planning) Having a schedule helps me to organize my day and communicate my needs. (Communication) I accept my limitations and feel relieved about telling others. (Focusing on the positive) I learn to see the bright side of things to keep myself calm. I use humour to keep myself calm. (Taking a different perspective) It is important to see the person (care-recipient), not only the symptoms. I can now understand more about the worries and concerns of my other family members.	(Planning) Timetabling helps me to stay calm. (Communication) Good communication helps me to get things done. .
Meaning	(Responsibility) It sets a good example to the children. (Finding happiness) It is good to enjoy happy time s with my partner (CR). (Sustainability of care) The family works on future planning to sustain ourselves.	(Responsibility) It is good to pay back to my parents. (Finding happiness) I now go on interesting trips with my wife (CR).

Note: TBA: Telephone-based Behavioral Activation; TGM: Telephone-based General Monitoring;

Table 9.

Comparison of Hourly Cost of Paraprofessional and Professional

Hourly rate paid as Project Administrative Assistant for the paraprofessional*	60HKD
Hourly rate of the pay of Assistant Social Worker Officer**	640HKD

* Note 1: These estimates are based on the University rate of employing then as Project Administrative Assistant on hourly basis

** Note 2: These estimates are based on the Common Pay Scale of Non-government Organizations for an officer with undergraduate training in social work or comparable training. (Details can found in the following website: http://Salary%20Scale%20of%20Common%20Posts%20wef%2001-04-2015%20(2).pdf)

Note 3: In this study, a professional social worker was responsible for delivering all the four weekly psycho-education sessions. Para-professionals were engaged in delivering the eight bi-weekly sessions for both TBA and TGM conditions.