

## ORIGINAL RESEARCH: CLINICAL TRIAL

## A randomized controlled trial of a home-based training programme to decrease depression in family caregivers of persons with dementia

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### Abstract

**Aims.** The aim of this study was to explore distinct trajectories of caregivers' depressive symptoms and the effects of a training programme on these trajectories over 18 months after the programme.

**Background.** Overall effects of caregiver-training programmes on family caregivers' depressive symptoms have been reported, but few studies explored distinct courses of changes in caregivers' depressive symptoms and followed up intervention effects on these distinct courses.

**Design.** Randomized clinical trial.

**Methods.** Family caregivers ( $n = 116$ ) were randomly assigned into experimental ( $n = 57$ ) and control ( $n = 59$ ) groups. The experimental group received the training programme with telephone consultation and the control group received written educational materials and social telephone follow-ups. Caregivers' depressive symptoms were assessed from June 2009 – March 2012 by self-completed questionnaires before, at 2 weeks and 3, 6, 12 and 18 months after the intervention. Groups of individual trajectories were distinguished using group-based trajectory modelling.

**Results.** Caregivers' depressive symptoms fell into three stable trajectories: non-depressed, mildly blue and depressed. After controlling for covariates, caregivers who received the caregiver-training programme were less likely than those who did not experience persistent depressive symptoms ( $b = -1.92$ , odds ratio = 0.15,  $P < 0.05$ ).

**Conclusion.** Depressive symptoms of family caregivers of persons with dementia were relatively stable and followed three distinct courses: non-depressed, mildly blue and depressed. Therefore, caregivers' depressive symptoms should be assessed as early as possible. Caregivers in the experimental group had a lower probability of persistent depressive symptoms than caregivers in the control group. Therefore, this training programme can be used by healthcare providers

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**Keywords:** caregiving, dementia, depressive symptoms, family caregivers, home-based training programme, longitudinal study, nurse education, nursing home care, randomized controlled trial, trajectory group

#### Why is this research or review needed?

- Little is known regarding the distinct patterns of changes over time in the depressive symptoms of family caregivers of persons with dementia.
- The caregiver-training programme, based on the concept of partnership with family caregivers, Progressively Lowered Stress Threshold Model and Antecedent Event-Behaviour-Consequence theory, decreased caregivers' overall depressive symptoms during 6 months after the programme. However, little is known about training programme effects beyond 6 months following the programme. Specifically, little is known about effects of the training programme on caregivers with different patterns of depressive symptoms over time.

#### What are the key findings?

- Family caregivers' depressive symptoms during the 18 months following the training programme follow multiple distinct courses or trajectories that were characterized as depressive, mildly blue and non-depressive.
- All three-trajectory classes remained stable over time, i.e. those that started with high depressive symptoms stayed high and those starting with low depressive symptoms remained low.
- Caregivers who received our individualized family caregiver-training programme were less likely to be consistently depressed during the 18 months following the programme.

#### How should the findings be used to influence policy/practice/research/education?

- Nurses should assess family caregivers of persons with dementia for depressive symptoms regularly to identify high-risk groups.
- Nurses can reduce family caregivers' depressive symptoms by providing the individualized family caregiver-training programme.
- The results of this study can provide a reference for developing health education or consultation programmes that can be used by healthcare providers for persons with dementia and their caregivers.

## Introduction

Family caregivers (FCGs) of persons with dementia (PWD) have a higher prevalence of depressive symptoms than FCGs of other patient populations or the general population (Pinquart & Sörensen 2006, Hernandez & Bigatti 2010). In particular, FCGs' mental health is adversely affected by PWDs' problem behaviours and neuropsychiatric symptoms (Huang *et al.* 2009, Välimäki *et al.* 2009, Conde-Sala *et al.* 2010, Liu *et al.* 2012, Mausbach *et al.* 2012). However, little information is available on longitudinal changes in depressive symptoms of FCGs for PWD. Furthermore, apart from studies on the average course of changes in caregivers' depressive symptoms, no studies have explored whether these longitudinal changes in depressive symptoms of FCGs for PWD have different patterns. Hence, some important research questions remain unanswered. In particular, do longitudinal changes in caregivers' depressive symptoms follow distinct courses for FCGs of PWD? If so, how are these trajectories described in terms of their levels and rates of change over time? What factors affect the probabilities of following various paths of recovery?

We previously reported short-term (6-month) results showing that our home-based caregiver-training programme, which was developed from the Progressively Lowered Stress Threshold Model (PLST) model and Antecedent Event-Behaviour-Consequence (ABC) theory and used a nurse partnership with FCGs of PWD, significantly decreased caregivers' likelihood of risk for depression at least 6 months after receiving the programme (Kuo *et al.* 2013). However, whether the caregiver-training programme had different effects on caregivers with different patterns of depressive symptoms has not been studied. This information can provide a more comprehensive understanding of the effects of the training programme and how it benefits FCGs. In this paper, we extend our previous results beyond 6 months and up to 18 months after completing the caregiver-training programme by exploring its effects on distinct depressive-symptom trajectories among FCGs of older PWD. Instead of a variable-centred approach, we employed a person-centred approach to identify high-risk patients and those who can benefit from the intervention. To that end,

we used group-based trajectory modelling to describe FCGs' distinctive depressive-symptom trajectory groups (Jones *et al.* 2001, Nagin 2005, Andruff *et al.* 2009).

## Background

Family caregivers' depressive symptoms have been decreased by intervention programmes to improve FCGs' ability to manage PWD's behavioural problems. These programmes include group education (Marriott *et al.* 2000, Gallagher-Thompson *et al.* 2001, 2003, Hepburn *et al.* 2001, Márquez-González *et al.* 2007), home visits with/or telephone consultation and support (Belle *et al.* 2006, Gallagher-Thompson *et al.* 2007, Moniz-Cook *et al.* 2008, Bormann *et al.* 2009, Elliott *et al.* 2010) and support groups (Fung & Chien 2002, Chien & Lee 2008, 2011, Gavrilova *et al.* 2009, Elliott *et al.* 2010). FCGs' depressive symptoms were also significantly improved by randomized control trials of a pleasant-events programme (Moore *et al.* 2013), an individual teaching programme based on coping strategy (Knapp *et al.* 2013, Livingston *et al.* 2013), an 8-day daily telephone-monitoring stress and mood programme (Zarit *et al.* 2014), problem-solving therapy (Garand *et al.* 2014) and psychological/education interventions (Joling *et al.* 2012, Rodriguez-Sanchez *et al.* 2012).

Depressive symptoms of FCGs for patients with Alzheimer's disease were also improved relative to controls by multisite caregiver interventions (Gitlin *et al.* 2003). In that study, each site used a specific multi-component strategy that included an automated telecare intervention, behavioural skills training, long-term education in primary care, family therapy and teleconferencing among family members, psychoeducational group interventions and environmental skill-building interventions (Gitlin *et al.* 2003). However, the samples consisted of White, Hispanic and African American FCGs. Little is known about the effects of these interventions on Asian or Chinese FCGs.

In our previous randomized control trial, FCGs' risk for depression decreased after an individualized home-based caregiver-training programme for managing PWD's behavioural problems, with referrals to community services and telephone consultation (Kuo *et al.* 2013). However, these analyses focused on the overall intervention effects on the average course of changes in depressive symptoms. Little is known about the specific intervention effects on FCGs with different depressive-symptom patterns over time.

Older persons' depressive symptoms have been characterized by significant heterogeneity in how they evolve over time (Andreescu *et al.* 2008, Cui *et al.* 2008, Liang *et al.* 2011). For example, older community-dwelling persons had

trajectories of minimal-to-few depressive symptoms, a moderate level and high levels of symptoms over a 10-year period (Andreescu *et al.* 2008, Liang *et al.* 2011). Therefore, caregivers are also likely to have multiple trajectories of depressive symptoms. Accordingly, two research questions remain unanswered. First, do caregivers have multiple distinct depressive-symptom trajectories? If so, what are the levels and rates of change in these trajectories? Second, how does a caregiver-training programme affect these distinct courses of change in depressive symptoms? This research aimed to examine the long-term (18 months) effects of a home-based caregiver-training programme on multiple trajectories of FCGs' depressive symptoms. We used group-based trajectory modelling to explore FCGs' distinctive depressive-symptom trajectory groups (Jones *et al.* 2001, Nagin 2005, Andruff *et al.* 2009) and the intervention effects of the training programme on these groups.

## The study

### Aims

To extend the 6-month results of our prior study on the effects of the family caregiver-training programme (Kuo *et al.* 2013), we conducted this study to: (1) describe the multiple trajectories of family caregivers' depressive symptoms over 18 months of follow-up; and (2) report the effects of the training programme on family caregivers' distinct depressive-symptom trajectories.

### Hypotheses

We evaluated two hypotheses.

Hypothesis 1 (H<sub>1</sub>): Family caregivers' depressive symptoms during the 18 months following the training programme follow multiple distinct courses or trajectories that differ in their levels and rates of change, reflecting different patterns of depressive symptoms.

Hypothesis 2 (H<sub>2</sub>): family caregivers who receive the individualized caregiver-training programme are less likely than those without the training to be in a trajectory characterized by greater depressive symptoms, with average Centre for Epidemiological Studies Depression Scale (CES-D) scores at different times indicating risk for depression and less improvement during the follow-up.

### Design

A randomized clinical trial (Huang *et al.* 2013, Kuo *et al.* 2013) was used to explore the long-term effects of a home-

based, individualized caregiver-training programme, which was founded on the concept of partnership with FCGs (Harvath *et al.* 1994), the PLST model (Hall & Buckwalter 1987, Hall *et al.* 1995, Gerdner & Buckwalter 1996) and ABC theory (Skinner 1953). The partnership concept refers to research nurses and FCGs partnering to collaboratively develop care plans for managing patients' behavioural problems (Harvath *et al.* 1994). The PLST model, which emphasizes understanding environmental and internal stimuli that cause PWD's agitated behaviours, was used to help FCGs' identify and manage stressors leading to patients' behavioural problems causing the most trouble for FCGs. The ABC theory was employed to help FCGs alter or decrease the frequency of specific behaviours by focusing on their reasons (antecedents) and consequences.

### Participants

Participants were FCG-PWD dyads. Eligible patients were diagnosed with dementia by a neurologist,  $\geq 65$  years, living in a home setting in northern Taiwan and having behavioural problems as indicated by a Cohen-Mansfield Agitation Inventory (CMAI) (Cohen-Mansfield & Billig 1986) score  $\geq 50$ . Eligible FCGs had to assume primary caregiving responsibility and be  $\geq 20$  years old.

### Intervention

Our caregiver-training programme had two 2- to 3-hour sessions, each session 1 week apart, a 30-minute telephone consultation 2 weeks after the second session and monthly 20–30-minute telephone consultations thereafter (Huang *et al.* 2013, Kuo *et al.* 2013). At the initial visit, the research nurse conducted a structured assessment of the PWD's condition and behavioural problems as well as the family's strengths, weaknesses and resources and established a partnership with the FCG. The nurse then assisted the caregiver to identify problem behaviours; to explore the causative environmental stimuli, antecedents and consequences of each behaviour; and to develop tentative intervening strategies. In the second at-home session, the nurse further assessed PWD's condition and behavioural problems and finalized the behavioural-management plan. Suggestions to decrease environmental stimuli were re-emphasized and modified if needed. The control group received general information on dementia care.

Over the next 18 months, research nurses made follow-up phone calls to provide further assurance and consultation as well as to evaluate progress regarding behavioural management. The control group received social

contact follow-up phone calls, but without discussing management of behavioural problems.

### Sample size and determination

On the basis of our pilot study (Huang *et al.* 2003), we set the effect size at 0.50 according to power curves for multi-level modelling (Scherbaum & Ferrerter 2009), used *t*-tests and set a two-tailed  $\alpha$  of 0.05 to verify the hypothesis. Using these values, we estimated the sample size as 64 via GPower 3.1 software. Assuming an attrition rate of 20% at each time point after the first, we aimed to recruit 128 caregiver-patient dyads (Huang *et al.* 2013).

In addition, for latent-class group modelling (LCGM), this data set included a measure of depressive symptoms for 116 participants at level 2 (interpersonal differences in depressive symptoms) and at five follow-up times for 519 observations at level 1 (intrapersonal differences in depressive symptoms by time) (116, 114, 107, 97 and 85 observations at 2 weeks, 3, 6, 12 and 18 months, respectively, due to attrition by 31 participants during the follow-up period) (Figure 1). Typically, a data set of at least 300–500 observations is preferable for running LCGM, although the analysis can be applied to data sets of at least 100 cases per observations (Nagin 2005). Therefore, our observations were sufficient for LCGM. The proportion selecting the three-class model suggests that for latent class analysis at  $\alpha = 0.05$ , the power would be about 80% when *N* is slightly over 100 cases (Dziak *et al.* 2014).

### Randomization

Family caregiver-persons with dementia dyads were randomized to either the experimental or control group using Excel software. First, a random number table was created in Excel to generate the random allocation sequence (even and odd numbers were assigned to the experimental and control groups, respectively). Second, the random allocation sequence was used to assign participants to groups according to identification numbers that had been chronologically assigned by an independent research staff member. Third, study participants were blinded after group assignment, but the research nurses who delivered the training programme and assessed outcomes were not blinded. The experimental and control groups had 57 and 59 FCG-PWD dyads, respectively.

### Data collection

Data were collected on PWD's behavioural problems and all FCGs' depressive symptoms before (baseline), at 2 weeks and

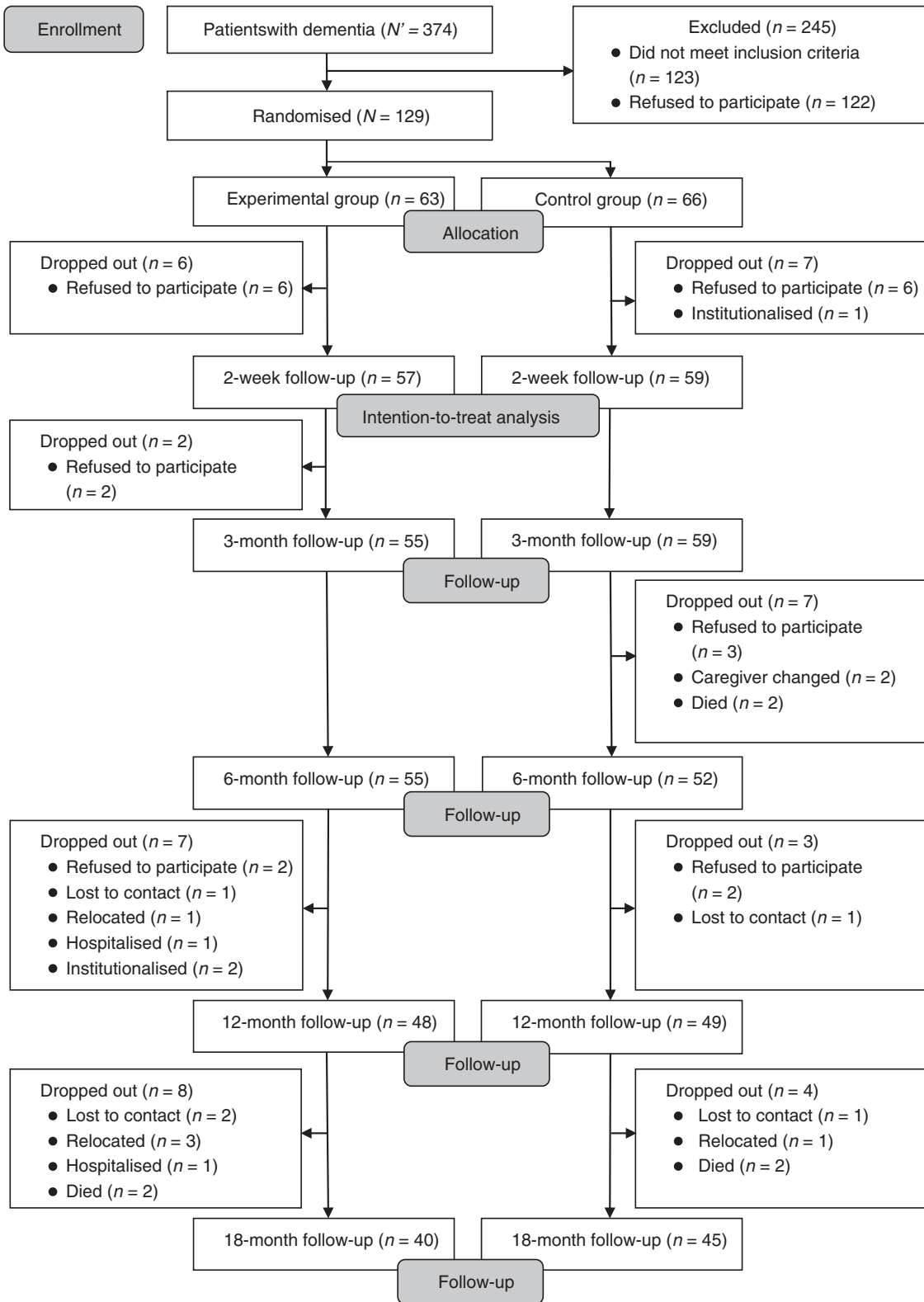


Figure 1 Flow chart of study.

3, 6, 12 and 18 months after the experimental group completed the training programme. PWD's behavioural problems were assessed by research nurses and FCGs' depressive symptoms were self-assessed by FCGs between June 2009 and March 2012. Data for the experimental group were collected at all time points by two master's degree-prepared research nurses who also delivered the intervention. Data for the control group were collected at all time points by another two research nurses who also provided general information on dementia care to this group. Cross-over contamination was avoided by research nurses not contacting participants in the other group. The completeness of data documents was checked by research nurses at each home visit. Once any incomplete data were identified, research nurses collected the missing data by phone as soon as possible. Attrition in both groups was minimized by following up with monthly telephone calls.

## Measure

### *Subjects' baseline characteristics*

Family caregivers' characteristics included gender, age (years), number of comorbidities, caregiving time/day (hours), duration of caregiving (months) and hired helper (yes/no) and PWD's characteristics included gender, age (years). Characteristics were measured by self-reported researcher-designed questionnaires at baseline. PWD's activities of daily living (ADL) performance (Chen *et al.* 1995), instrumental activities of daily living performance (Lawton & Brody 1969), cognitive status (Mini-Mental Status Examination, MMSE) (Folstein *et al.* 1975, Yip *et al.* 1992), number of comorbidities and disease severity (clinical dementia rating) (Morris 1993, Lin & Liu 2003) were assessed by research nurses.

### *Depressive symptoms*

Depressive symptoms were measured by the 20-item Chinese-version CES-D (Boey 1999, Fu *et al.* 2003, Cheng & Chan 2005a). The frequency of each symptom (item) in the last week is scored from 0 (occurred less than once per day) to 3 (occurred on 5–7 days). Total scores range from 0–60, with 0–9 indicating not depressed (Cyranski *et al.* 2007), 10–21 indicating borderline depression (Cyranski *et al.* 2007) and 22–60 indicating depressed (Cheng & Chan 2005a, Cuijpers *et al.* 2008). In this study, Cronbach's alphas for the CES-D ranged from 0.93–0.94 at different times.

### *Behavioural problems*

Persons with dementia's behavioural problems were measured by the Chinese version of the CMAI, community form

(Yang *et al.* 2007). The 42-item Chinese version CMAI, community form describes 42 behavioural problems, whose frequency over the past 2 weeks is rated from 1 (never occurred) – 7 (occurred several times per hour). Total scores range from 42 to 294; higher scores represent more frequent or more types of behavioural problems. A CMAI score  $\geq 50$  indicates behavioural problems (Cohen-Mansfield & Billig 1986); thus, it was used as an inclusion criterion for patient participants. In this study, Cronbach's alphas for the CMAI ranged from 0.84–0.87 at different time points.

## Ethical considerations

The original study was approved by the Institutional Human Subjects Protection Committee (No. 97-1850B) and all study-site administrative departments. Research nurses approached eligible FCGs at the outpatient clinics of two hospitals in the greater Taipei area and cases referred by a local care-management centre to explain the study and participants' right to withdraw at any time. Those who agreed to participate signed written consent and were randomly assigned to the experimental or control group.

## Data analysis

Distinctive groups of individual trajectories in the study sample were identified using group-based trajectory modelling or LCGM (Jones *et al.* 2001, Nagin 2005, Andruff *et al.* 2009). This approach classifies individuals into groups based on similar trajectories over time (Jones *et al.* 2001, Nagin 2005). In particular, latent class analysis was used to derive trajectory parameters through maximum likelihood estimation with the following specifications:

$$\text{Ln}Y_{iT}^{*g} = \beta_0^g + \beta_1^g \text{Time}_{iT} + \varepsilon_{iT}^* \quad (1)$$

with  $i = 1, \dots, n$ .

$\text{Ln}Y_{iT}^{*g}$  is a latent variable with a zero-inflated Poisson distribution representing the underlying depressive symptoms of FCG  $i$  at time  $T$  (e.g. baseline) given membership in group  $g$ . Time refers to assessment times from baseline to 18 months after completing the training programme. The coefficients  $\beta_0^g$  and  $\beta_1^g$  are associated with the intercept and rate of change in depressive symptoms.  $\varepsilon_{iT}^*$  is a disturbance term that is normally distributed with 0 mean and constant variance. We used the zero-inflated generalized Poisson regression model, which is useful for count data with more zeros than would be expected under the Poisson assumption (Lambert 1992). The number of trajectories (from 2–8) was tested using the Bayesian information



criterion (BIC) and the optimal number of groups was chosen to fit theoretical explanations (Andruff *et al.* 2009). The three-trajectory solution (class 3) was chosen based on its smaller BIC value, its rational percentages of class membership (Appendix S1) and its fit with the clinical meaning of depressive symptoms (CES-D scores 0–9 indicating not depressed, 10–21 indicating borderline risk for depression and 22–60 indicating risk for depression) (Cheng & Chan 2005b, Cyranowski *et al.* 2007, Cuijpers *et al.* 2008). In each group, severity of depressive symptoms was analysed as an intercept only, linear or nonlinear model of time. Parameters were estimated to define the shape of the trajectories and the probability of group membership. This analysis was conducted using an SAS software package, with accompanying Proc Trajectory (Jones *et al.* 2001).

In the second component, trajectory-group membership was subsequently treated as a dependent variable and was predicted by experimental group and caregivers' gender, age, comorbidities and direct caregiving time/day, similar to that of multinomial logistic regression analysis. Since PWDs' behavioural problems (CMAI scores), the FCG–PWD relationship and resource utilization did not

differ significantly among depressive symptom-trajectory groups (Table 1), we did not treat these variables as covariates in the final model. To examine the linkages between predictors and FCGs' depressive symptoms, we evaluated the following specifications:

$$\pi_g(z_i) = e^{z_i\theta_g} / \sum_g e^{z_i\theta_g} \quad (2)$$

where  $\theta_g$  represents the parameters of a multinomial logit model that captures the effects of time-constant covariates  $z_i$  (e.g. age, gender, group and education) on  $\pi_g$  and the probability of membership in group  $g$  (Nagin 2005). An SAS software package, with accompanying Proc Trajectory, was used to simultaneously estimate Equations 1 and 2 (Jones *et al.* 2001).

A multilevel specification such as the group-based mixture model has more than one outcome variable. First, regarding intrapersonal changes, caregiver's depressive symptoms is specified as a function of time, i.e. the trajectory of depressive symptoms, which may be characterized in several distinct groups (Equation 1). Second, in the structural part of specifications describing interpersonal variations (Equation 2), the trajectory groups identified in Equation 1 (i.e. non-depressed,

**Table 1** Sample demographics and baseline measures across depressive-symptom trajectory groups and for the total sample (N = 116).

Variable	Depressive-symptom trajectory group			Total (N = 116)	P
	Depressed (n = 22)	Mildly blue (n = 66)	Non-depressed (n = 28)		
<b>Caregivers</b>					
Experimental group, n (%)	4 (18.2)	34 (51.5)	19 (67.9)	57 (49.1)	<0.001
Female, n (%)	21 (95.5)	46 (69.7)	22 (78.6)	89 (76.7)	0.05
Age (years)	53.82 (12.70)	57.98 (14.55)	50.07 (11.28)	55.28 (13.79)	0.03
Comorbidities	1.73 (1.42)	1.30 (1.43)	0.68 (1.28)	1.23 (1.42)	0.03
Time caregiving per day (hours)	16.64 (8.76)	13.72 (8.10)	9.50 (7.57)	13.25 (8.38)	0.01
Duration of caregiving (months)	41.32 (36.93)	43.05 (32.55)	42.07 (29.46)	42.48 (32.44)	0.97
Hired helper, n (%)	5 (22.7)	21 (31.8)	15 (53.6)	41 (35.5)	0.05
Resource utilization (no), n (%)	22 (100)	65 (98.5)	28 (100)	125 (99.1)	0.68
<b>Relationship with care receivers, n (%)</b>					
Adult children	17 (77.3)	43 (65.2)	23 (82.1)	83 (71.6)	0.20
Spouse	5 (22.7)	23 (34.8)	5 (17.9)	33 (28.4)	
<b>Care receivers</b>					
Female, n (%)	7 (31.8)	39 (59.1)	15 (53.6)	61 (52.6)	0.09
Age (years)	79.41 (6.15)	79.83 (6.91)	80.86 (7.61)	80.00 (6.91)	0.73
ADL performance	70.45 (34.98)	64.70 (30.57)	72.50 (25.26)	67.67 (30.23)	0.48
IADL performance	2.05 (1.70)	1.71 (2.01)	1.82 (1.59)	1.80 (1.85)	0.77
Cognitive status (MMSE score)	11.45 (5.69)	11.18 (7.54)	10.19 (6.67)	11.00 (6.98)	0.78
Comorbidities	2.09 (1.31)	2.03 (1.35)	2.00 (1.68)	2.03 (1.41)	0.98
<b>Clinical dementia rating, n (%)</b>					
Mild	9 (40.9)	26 (39.4)	8 (28.6)	43 (37.1)	0.79
Moderate	8 (36.4)	20 (30.3)	10 (35.7)	38 (32.8)	
Severe	5 (76.3)	20 (30.3)	10 (35.7)	35 (30.2)	
CMAI score	68.36 (22.99)	68.97 (19.05)	69.71 (20.08)	69.03 (19.91)	0.97

ADL, activities of daily living; IADL, instrumental activities of daily living; MMSE, Mini-Mental Status Examination; CMAI, overall score on Cohen-Mansfield Agitation Index. Values are mean (SD) unless otherwise indicated. P values were determined by chi-square or F-test.

mildly blue and depressed) are treated as the dependent variables and assumed to depend on various covariates such as the training programme, caregivers' gender, age, comorbidities and direct caregiving time/day.

This approach differs from traditional methods of longitudinal analysis such as ANOVA, for which the data must be balanced and time-structured. That is, all participants are assessed on an identical number of occasions and each set of occasions is identical across individuals. We used multi-level models of change that are flexible because they can analyse more complex data sets, where the number of waves and spacing can vary across participants (Raudenbush & Bryk 2002, Singer & Willet 2003). Multilevel models are based on the assumption of missing at random (MAR), that is, the probability of missing data due to mortality and attrition depends only on observed data for either covariates or outcome variables, permitting valid inference (Nagin & Odgers 2010, Raudenbush & Bryk 2002). Besides using MAR to adjust for selection bias due to attrition, we included dummy variables in the level-2 equation to differentiate participants with complete data during the study period from those who dropped out ( $n = 31$ , 26.7%).

### Validity and reliability/rigour

The CONSORT guidelines were rigorously followed in this randomized clinical trial. First, a protocol was developed for the intervention as well as protocols and instructions for each instrument. The content validity of the intervention protocol was assured with three experts with specialties in gerontological nursing and community health nursing. Second, two master's degree-prepared research nurses who delivered the intervention were trained by three geriatric nurse specialists to ensure complete adherence to the intervention protocol. Protocol adherence was also ensured by supervising home visits with discussion afterwards for two cases at the beginning of the study. The quality of the intervention delivery was also ensured by monthly case conferences and research meetings. The four outcome assessors were trained by three geriatric nurse specialists to follow and adhere to instrument protocols and instructions. All assessors achieved 100% agreement in assessing two subjects before collecting data from other subjects.

## Results

### Response rate

Of 251 FCGs who met the inclusion criteria, 129 agreed to participate and were randomly assigned to the experimental

( $n = 57$ ) or control ( $n = 59$ ) group. Two weeks after starting the training programme, 116 FCGs completed the first posttest. During the follow-up period, 44 participants dropped out because of caregivers' refusal to continue ( $n = 21$ ), loss of contact with or relocation of caregiver ( $n = 10$ ), PWD death ( $n = 6$ ), institutionalization or hospitalization ( $n = 5$ ) and change in FCG ( $n = 2$ ). At 18 months, after the experimental group completed the training programme, 85 FCGs (40 in the experimental and 45 in the control group) remained in the study (Figure 1).

### Subjects' baseline characteristics

For the overall sample, slightly more than half of PWD were female (52.6%) and married (51.7%) and were on average 80.00 years old (SD 6.91). As for education, 40% were illiterate and another one-third had completed primary school. Regarding dementia diagnosis, 50% had Alzheimer's disease, 34.5% had vascular dementia and the average time since diagnosis was around 4 years. Their average MMSE score was 11.00 (SD 6.89), 37.1% had mild dementia, 32.8% had moderate dementia and 30.2% had severe dementia and they were moderately dependent in ADL (average Chinese Barthel Index score = 67.67, SD 30.23). For FCGs, the majority were female (76.7%) and married (81.9%), with an average age of 55.28 years (SD 13.79). Over one-fourth (27.6%) had completed high school and 32.8% had a college education or above. They were mostly spouses (28.4%), daughters (27.9%) or daughters-in-law (29.3%), with only 15.5% sons. These caregivers had been providing family care for around 3.5 years (42.48 months) and they reported spending on average 13.25 (SD 8.38) hours caregiving per day. Around one-third of them had a hired helper (35.5%). Patient and caregiver characteristics did not differ significantly between the experimental and control groups.

### Trajectories of depressive status

Our analyses identified three trajectories of FCGs' depressive symptoms over time from 2 weeks (first posttest) to 18 months (last posttest) after the experimental group completed the caregiver-training intervention (Table 2, Figure 2), thus supporting H1. All three trajectories were relatively stable and parallel over time, that is, none of the slopes were significant and they differed mainly in the intercepts. The only difference among these three trajectories lies in the intercept; their rates of change were very similar. In other words, all three classes remained stable over time, that is, those that started with high depressive symptoms



after receiving the training programme stayed high and those with low depressive symptoms remained low.

The first trajectory was characterized as a non-depressed group ( $n = 28, 24.1\%$ ) because its caregivers reported few depressive symptoms [mean (SD) CES-D score = 2.14 (2.70)]; Figure 1). The second trajectory was the largest and characterized as mildly blue ( $n = 66, 57.2\%$ ), based on its caregivers' mean (SD) CES-D score of 8.45 (6.86), which is close to the cut-off score of 10 for borderline depression (Table 2, Figure 2). The third trajectory was characterized as depressed ( $n = 22, 18.7\%$ ), with its caregivers' mean (SD) CES-D score of 23.64 (11.73) indicating risk for depression (Table 2, Figure 2).

**Table 2** Estimated trajectory classes and group-specific growth parameters of depressive status ( $N = 116$ ).

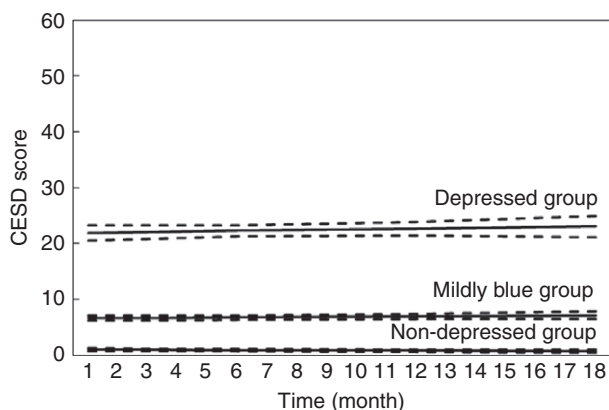
	Depressed	Mildly blue	Non-depressed
Growth parameter			
Intercept	3.12***	1.92***	0.08
Linear slope	0.00	0.01	-0.02
Group proportion	18.7	57.2	24.1
Alpha0	-3.43***		
Alpha1	0.03		
Model fit statistics			
BIC ( $N = 519$ )	-1725.06		
BIC ( $N = 116$ )	-1717.57		
AIC fit index	-1703.80		
Log likelihood	-1693.80		

BIC, Bayesian information criterion; AIC, Akaike's information criterion.

Level 1,  $N = 519$ , and Level 2,  $N = 116$ .

\*\*\* $P < 0.001$ .

$P$ -values were determined by  $t$ -test for group-based trajectory modelling.



**Figure 2** Caregiver trajectory groups for depressive status over time after completing caregiver-training programme.

Demographics and baseline measures across depressive symptom-trajectory groups were also compared (Table 1). The depressed trajectory group had a significantly higher mean (SD) CES-D score of 23.64 (11.73). These three trajectories remained distinct and robust after adjusting for several covariates, including caregivers' gender, age, comorbidities and direct caregiving time/day.

**Predictors of trajectories of depressive status**

After identifying the trajectory groups, which were classified based on their first posttest score and rate of change over time, we explored predictors for group membership. When covariates were controlled, the caregiver-training programme significantly improved FCGs' depressive symptoms, that is, using the non-depressed group as baseline, FCGs in the experimental group were significantly less likely to experience persistent depressive symptoms [ $b = -1.92$ , odds ratio (OR) = 0.15,  $P < 0.05$ ] than those in the control group (Table 3). In other words, relative to the predicted probability of being in the non-depressed group, the risk for caregivers in the experimental group becoming depressed was only 15% of that for those who did not receive the training programme. Thus, the training programme decreased 85% of the chance for non-depressed FCGs to be consistently depressed. Also, using the mildly blue group as baseline, those in the experimental group were significantly less likely to experience persistent depressive symptoms ( $b = -1.34$ , OR = 0.26,  $P < 0.05$ ) than those in the control group (Appendix S2). In other words, the training programme decreased 74% of the chance for mildly blue FCGs to be consistently depressed. Hence, our findings support the hypothesized beneficial effect of the individualized home-based caregiver-training programme on decreasing persistent depressive symptoms, particularly in decreasing the likelihood of being in the depressed group ( $H_2$ ).

In addition, caregivers' depressive-symptom trajectories were significantly associated with direct caregiving time/day. For every 1-hour increase in direct caregiving time/day, the risk of being in the depressed group ( $b = 0.11$ , OR = 1.11,  $P < 0.05$ ) increased by 11% (Table 3). On the other hand, caregivers' gender, age and comorbidities were not significantly associated with depressive-symptom trajectory groups.

**Discussion**

To the best of our knowledge, this study is the first randomized controlled trial to depict distinct trajectories of

**Table 3** Factors associated with trajectory-group membership.

Trajectory	Parameter	Estimate	Odds ratio (95% CI)
Non-depressed group	Reference group		
Mildly blue group	Constant	-0.11	
	Experimental group	-0.58	0.56 (0.19–1.62)
	Attrition	0.17	1.18 (0.36–3.86)
	Female	-0.48	0.62 (0.17–2.21)
	Age	0.02	1.02 (0.97–1.07)
	Comorbidities	0.10	1.11 (0.65–1.89)
	Time caregiving per day (hours)	0.05	1.05 (0.98–1.14)
Depressed group	Constant	-0.93	
	Experimental group	-1.92	0.15 (0.03–0.65)*
	Attrition	-0.04	0.96 (0.19–4.90)
	Female	1.92	6.79 (0.57–80.45)
	Age	-0.04	0.96 (0.90–1.03)
	Comorbidities	0.52	1.68 (0.88–3.21)
	Time caregiving per day (hours)	0.11	1.11 (1.01–1.23)*
Model fit statistics			
	BIC (N = 519)	-1744.03	
	BIC (N = 116)	-1727.54	
	AIC fit index	-1697.26	
	Log likelihood	-1675.26	

BIC, Bayesian information criterion; AIC, Akaike's information criterion.

Level 1,  $N = 519$ , and Level 2,  $N = 116$ .

\* $P < 0.05$ .

$P$ -values were determined by  $t$ -test for group-based trajectory modelling.

depressive symptoms among FCGs of PWD. A recent longitudinal study of depressive-symptom trajectories in FCGs of PWD found two trajectories, with most FCGs having a stable trajectory and a smaller subset showing a steady increase in depressive symptoms measured every 6 months for up to 6 years or until death (Ornstein *et al.* 2014). Studying depressive symptoms in FCGs of PWD is important because they have a higher prevalence of depressive symptoms than FCGs of other patient populations or the general population (Pinquart & Sørensen 2006, Hernandez & Bigatti 2010). For instance, among 206 caregivers for a PWD, 22.8% had significant depressive symptoms, vs only 11.2% for caregivers of older adults without dementia (Givens *et al.* 2014).

Our study is the also first to explore the effects of a caregiver-training programme, which we developed based on the concept of partnership with FCGs, the PLST model and ABC theory, on the distinctive prototypical trajectories of depressive symptoms among FCGs of PWD. The effects of our caregiver-training programme on decreasing depressive symptoms of FCGs of PWD are supported by previous studies (Belle *et al.* 2006, Gallagher-Thompson *et al.* 2007, Moniz-Cook *et al.* 2008, Bormann *et al.* 2009, Elliott *et al.* 2010). Furthermore, our results expand those of our previous studies (Huang *et al.* 2013, Kuo *et al.* 2013) by

following FCGs longer, by clarifying the specific intervention effects on distinct FCG groups and by providing more knowledge on how the training programme worked.

Our research revealed that caregiver participants' depressive symptoms were relatively stable and followed three distinct courses: non-depressed, mildly blue and depressed. These courses differed significantly in terms of their levels from before to 18 months after caregivers completed the training programme. Based on the suggested CES-D cut points (Chien & Cheng 1985), about one-quarter of FCGs experienced few depressive symptoms (24.1%), 57.2% were mildly blue but not yet depressed and fewer than one-fifth could be characterized as depressed (18.7%). These trajectories add to the current knowledge base by showing heterogeneity in the courses of depressive symptoms for FCGs of PWD after completing our caregiver-training programme and relatively stable depressive-symptom levels over time (Schulz & Williamson 1991, Ornstein *et al.* 2014). These trajectories of caregivers' depressive symptoms are more informative than measures of depression or depressive risk at one or two time points because a significant health difference at one time may diminish or even reverse at a later time.

Behavioural problems were common in PWD and those problems significantly impacted FCGs' subsequent

depressive symptoms (Givens *et al.* 2014). Moreover, the training included learning to understand the PWD's behavioural problems and behavioural-problem management techniques have been shown to significantly decrease FCGs' depressive symptoms (Livingston *et al.* 2013). Our caregiver-training programme might have reduced FCGs' depressive symptoms because of continually training them to manage behavioural problems based on comprehensively assessing care recipients with dementia and FCGs, suggestions and support to facilitate caregiver decision-making about using community resources and monthly telephone consultations. This study offers strong evidence that an individualized, home-based caregiver-training programme with telephone consultation and a focus on managing PWD's behavioural problems significantly benefited caregivers by decreasing persistent depressive symptoms.

Our hypotheses are also supported by our findings on three distinct depressive symptom trajectories over 18 months. These trajectories indicate that FCGs caring for older PWD had relatively stable, but distinct patterns of depressive symptoms over time. Thus, FCGs' depressive symptoms need to be assessed as early as possible. Furthermore, groups at high risk for persistent depressive symptoms, including FCGs who spend more caregiving time/day should be identified as soon as possible for early intervention.

Understanding the distinct depressive-symptom trajectories of FCGs of PWD and the effects of caregiver training on specific trajectory groups may help healthcare providers to identify and provide appropriate consultation or support for FCGs at high risk for persistent depressive symptoms.

## Limitations

One limitation of this study was its single-blinded design, that is, only PWD and their FCGs were blinded to which training programme they received. Another limitation was the small sample size that might have limited study generalizability. A third limitation was the use of a latent class-clustering method (person-centred approach) instead of a growth mixture modelling (variable-centred approach) to classify FCGs with similar trajectories in depressive symptoms, as the former approach might not capture average changes in caregivers' depressive symptoms over time. A fourth limitation was attrition, which might have reduced the validity of longitudinal changes. However, this limitation might have been minimized by controlling for attrition as a covariate in our analysis. Finally, data were not collected on potential confounding variables such as FCGs' personality type, pre-existing mental health issues and economic/social status; thus,

these variables were not controlled as covariates. Therefore, the results need to be interpreted with caution.

## Conclusion

In conclusion, depressive symptoms of FCGs of PWD were relatively stable and followed three distinct courses: non-depressed, mildly blue and depressed. FCGs who participated in our individualized, home-based training programme, which focused on enhancing FCGs' ability to handle PWD's behavioural problems, had a lower probability of having persistent depressive symptoms than their counterparts in the control group.

This theory-based training programme, which was founded on the PLST model, the concept of partnership with FCGs and ABC theory, improved mental health for FCGs of PWD in a Taiwanese sample. In particular, since the distinct trajectories in depressive symptoms of FCGs of PWD were relatively stable over time, mildly blue and FCGs at high risk for persistent depressive symptoms might benefit most and should be targeted for delivering the training programme. Our results suggest that FCGs in the depressed or mildly blue class should be identified and may need to receive more continuous support or the training intervention again. Since more daily caregiving time increased FCGs' risk of being in the depressed group, these FCGs might need more respite care and social resources. The results of this study can provide a reference for healthcare providers who regularly deal with PWD and their caregivers to identify high-risk groups and to reduce FCGs' depressive symptoms by providing the individualized FCG-training programme. Our study can also serve as a model for future studies on trajectories and related interventions for FCGs' depressive symptoms.

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## Conflict of interest

The authors have no financial or any other kind of personal conflicts with this paper.

## Author contributions

All authors have agreed on the final version and meet at least one of the following criteria [recommended by the ICMJE (<http://www.icmje.org/recommendations/>)]:

- substantial contributions to conception and design, acquisition of data or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content.

## Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site.

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