Trajectories of health-related quality of life among family caregivers of individuals with dementia: A home-based caregiver-training program matters

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To determine distinct courses of change in health-related quality of life (HRQoL) among family caregivers of individuals with dementia and how participating in a home-based caregiver-training program affects the probability of belonging to each course. Sixty three caregivers were in the intervention group, and 66 caregivers were in the control group of a single-blinded randomized clinical trial. Two distinct trajectories of HRQoL were identified: a well-functioning trajectory and a poor-functioning trajectory. Caregivers who received the training program were more likely than those who did not have a well-functioning trajectory of HRQoL over 18 months. This trajectory included bodily pain ($b = 1.02$, odds ratio $[\text{OR}] = 2.76$), general health perception ($b = 1.28$, OR $= 3.60$), social functioning ($b = 1.08$, OR $= 2.94$), and mental component summary ($b = 1.27$, OR $= 3.55$). Home-based caregiver training can be considered as part of the protocol for managing patients with dementia and their caregivers.

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**Introduction**

The number of patients with dementia is increasing in Taiwan, creating a major caregiving burden for family caregivers, as in many other developed nations. The age-adjusted prevalence of all-cause dementia in Taiwan was recently estimated to be 8.0%, significantly higher than previous estimates.\textsuperscript{1} Among patients with dementia, 90% have at least one behavioral and psychological symptom, 30%–79% have neuropsychiatric symptoms, and 9%–58% exhibit agitation, delusions of persecution, wandering, or aggression.\textsuperscript{2}–\textsuperscript{6}

Behavioral problems and neuropsychiatric symptoms of patients with dementia have significant, negative effects on family caregivers that seriously impact their health outcomes and quality of life.\textsuperscript{7,8} However, little information is available on heterogeneity in caregivers who seriously impact their health outcomes and quality of life.

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patients with dementia are likely to be heterogeneous, containing both good and poor trajectories.

Intervention programs to enhance family caregivers’ ability to manage dementia care have been shown to improve their quality of life and mental health. For example, caregiving burden and quality of life improved in a randomized controlled trial of an information-and-psychological-support system linking case managers, dementia care services, health professionals, and referrals for Chinese caregivers of patients with dementia. The program prioritized problem areas for each family and formulated an individualized multidisciplinary education program on effective dementia care. Similarly, a structured multi-component intervention addressing caregiver depression, burden, self-care, social support and care recipient problem behaviors through 12 in-home and telephone sessions over 6 months improved the HRQoL of ethnically diverse (Hispanic, Caucasian, and African-American) caregivers.

Most studies of intervention effects on HRQoL of family caregivers of patients with dementia have assessed HRQoL at discrete time points or averaged its changes over time. Family caregivers who received an individualized home-based training program were found to have better HRQoL in bodily pain, role disability due to emotional problems, vitality, and better mental summary score at least 6 months after receiving the program than those who did not. However, only average effects of the training program were shown on HRQoL. No studies were found on whether these family caregivers’ HRQoL follows multiple distinct trajectories, and whether the effects of a given intervention vary across different trajectories. One statistical approach to approximating unknown trajectories across members of a population is group-based trajectory modeling, also known as group-based mixture modeling or latent-class growth modeling (LCGM). This approach was used in the current study to identify clusters of caregivers following similar trajectories of HRQoL over time. Thus, the purpose of this study was to 1) identify distinct courses of change in HRQoL over 18 months among family caregivers of patients with dementia, and 2) evaluate the effect of caregiving training on the probability that family caregivers would experience various HRQoL trajectories. Two hypotheses were tested as follows:

Hypothesis 1. Family caregivers’ HRQoL during the 18 months after the training program will follow distinct courses or trajectories that can be characterized as well-functioning and poor-functioning.

Hypothesis 2. Caregivers who receive the individualized caregiver-training program will be more likely than those who receive no training to have HRQoL that follows a well-functioning trajectory.

Methods
Design
A single-blinded randomized clinical trial was used to evaluate the effects of a home-based training program for family caregivers of patients with dementia. After completing the training program, caregivers were followed for 18 months to assess their HRQoL and caring outcomes.

Participants
To be included in the study, family caregivers had to be (1) at least 20 years old, and (2) have primary care responsibility for the patient with dementia. Caregivers were excluded by these criteria: (1) suffering from critical illness or psychosis or a (2) paid caretaker. Patients with dementia were included by these criteria: (1) at least 65 years old, (2) living in a home setting in northern Taiwan, (3) diagnosed with dementia by a neurologist, and (4) exhibiting behavioral problems that scored at least 50 points on the Cohen-Mansfield Agitation Inventory (CMAI). Patients with dementia were excluded if they suffered from critical illness or psychosis.

Among the 251 family caregivers who met the inclusion criteria, 129 (51.4%) consented to participate in the study and were randomly assigned to the training program intervention (n = 63) or control (n = 66) group (Fig. 1). 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), patients’ death (n = 6), institutionalization or hospitalization (n = 5), and change in family caregiver (n = 2). As the participants who dropped out still provided partial data, they were included in the analysis based on the assumption of missing at random. However, dropouts were flagged in the multivariate analysis to minimize the bias of selective attrition. At the end of the 18-month follow-up after completing the training program, 85 family caregivers remained in the study (40 in the intervention and 45 in the control group).

Since group-based trajectory modeling, group-based mixture modeling or LCGM was used in this study to identify HRQoL trajectories, a data set of at least 300 to 500 observations was preferable. In this data set, HRQoL dimensions were measured 6 times; for 129 participants, 649 measurements were included in the analysis. Therefore, this sample size was sufficient for the current analysis.

Caregiver-training program
The training program was an individualized, home-based consultation and education program delivered by an experienced geriatric nurse via home visits. This program stressed the importance for the nurse to establish a partnership with the family caregiver to collaboratively develop a care plan. The program also aimed to help family caregivers detect and decrease environmental stimuli for a specific dementia-related behavioral problem based on the theory of Progressively Lowered Stress Threshold (PLST). The PLST model assumes that the agitated behaviors of patients with dementia are caused by excessive demands from environmental and internal stimuli. Thus, appropriate control of excessive stimuli would decrease the agitated behavior.

This training program consisted of two weekly sessions, each lasting 2–3 h. Following the training sessions, further assurance and consultation were provided in monthly telephone follow-ups, and progress in behavior management was evaluated. During the first home visit, a geriatric nurse made a structured assessment and helped the family caregiver identify specific dementia-related problem behaviors and explored the causative environmental stimuli with the caregiver to develop tentative intervention strategies. In the second session, the nurse followed up on the outcomes of the behavior problem-management strategies and revised the management plan. In contrast, the control group received general information on dementia care and follow-up phone calls simply to maintain contact, but without any training for developing a behavioral problem-management plan and strategies.

Measures
Family caregivers’ HRQoL was measured using the Taiwan-version Medical Outcomes Study 36-Item Short Form Survey (SF-36). Items on the SF-36 represent eight generic health concepts: physical functioning (PF), role disability due to physical health problems (RP); bodily pain (BP); vitality (energy/fatigue) (VT); general health perceptions (GH); social functioning (SF); role disability...
due to emotional problems (RE); and general mental health (MH). In addition, scores are calculated for the mental component summary (MCS) and physical component summary (PCS) using norm-based (50, 10) scoring methods with Taiwan-specific SF-36 algorithms.27 Scores for each subscale, mental component summary, and physical component summary range from 0 to 100, with higher scores representing better health outcomes. In this study, Cronbach’s alphas for the eight scales ranged from 0.84 to 0.89.

Behavioral problems of patients with dementia were identified using a score >50 on the Chinese-version CMAI, community form.20 This scale contains 42 behavioral problems, whose frequency over the past week is rated by the caregiver from 1 (never) to 7 (several times per hour). Total scores range from 42 to 294, with higher scores representing more frequent or more types of behavioral problems.

### Procedure

Study approval was obtained from the Institutional Review Board for Human Subjects Protection Committee (97–1850B) of Chang Gung Memorial Hospital. Potential participants were approached in the outpatient clinics of two hospitals and one community-based long-term care center in the greater Taipei area. Research nurses explained the study aims and participants’ right to withdraw from the study. After the family caregivers gave their informed consent, they were randomly assigned to the intervention or control group. Microsoft Excel was used to generate random numbers, with even numbers assigned to the intervention group and odd numbers to the control group. Family caregivers were blinded to their group assignment. The intervention group received the training program with telephone follow-ups; at the same time,
the control group received only written educational materials and telephone follow-ups for social contact. HRQoL of family caregivers in both groups was then assessed at 2 weeks, and 3, 6, 12, and 18 months after completion of caregiving training.

All assessment nurses used standardized guidelines to collect data and were trained by three gerontological nursing experts to reach 100% inter-rater consistency before data collection. Assessment nurses were trained to immediately check the completeness and correctness of the data before leaving the participant’s home after each visit, thus avoiding missing data and incorrect answers. The intervention program was administered by two different registered nurses with specialties in community and geriatric nursing under the supervision of three gerontological nursing specialists. The quality of the data collected was ensured by holding regular research meetings once a month to monitor the progress of the study and discuss related issues.

Data analysis

Distinct trajectories of change in each HRQoL subscale for family caregivers were identified using group-based mixture modeling with maximum likelihood estimation.20 The best-fitting model with optimal number of trajectory groups was chosen based on the Bayesian information criterion scores and examination of 95% confidence intervals (CIs). These models were estimated using the SAS PROC TRAJ package.19

Posterior probabilities derived from the best fitting model for each HRQoL subscale were used to assign each caregiver to a trajectory group to which this individual had the highest probability of belonging. Membership in the distinct trajectory groups was then treated as a dependent variable in logistic regression analysis to evaluate the effects of caregiving training on changes in a given HRQoL dimension (subscale score).

Trajectory parameters were derived using latent class analysis through maximum likelihood estimation with the following specifications:

\[
\ln Y^i_T = \beta_0g + \beta_1 g \text{ Time}_{iT} + \epsilon^i_T \text{ with } i = 1, \ldots n
\]

\[
\ln Y^i_T \text{ is a latent variable with a zero-inflated Poisson distribution representing the underlying HRQoL of family caregiver } i \text{ at time } T \text{ (e.g., baseline) given membership in group } g. \text{ Time refers to assessment times from baseline to 18 months after completing the training program. The coefficients } \beta_0g \text{ and } \beta_1 g \text{ are associated with the intercept and rate of change in HRQoL. } \epsilon^i_T \text{ is a normally distributed disturbance term with 0 mean and constant variance. The zero-inflated generalized Poisson regression model was used because it is useful for count data with more zeros than would be expected under the Poisson assumption.21} \text{ Within each group, HRQoL status was analyzed as an intercept only, a linear, or a nonlinear model of time. Parameters were estimated to define the shape of the trajectories and the probability of group membership.}

The trajectory-group membership was subsequently treated as a dependent variable and was predicted by experimental group and attrition, similar to that of multinomial logistic regression analysis. Linkages between predictors and family caregivers’ HRQoL were examined by evaluating the following specifications:

\[
\pi_g(z_i) = e^{\theta_g} / \sum_g e^{\theta_g} \quad \text{with } \pi_g \text{ and the probability of membership in group } g. \quad \text{18}
\]

A multilevel specification such as the group-based mixture model has more than one outcome variable. First, regarding intrapersonal changes, caregivers’ HRQoL is specified as a function of time, i.e., the trajectory of HRQoL, 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., poor-functioning and well-functioning groups) are treated as dependent variables and assumed to depend on various covariates such as the training program and attrition.

Covariates in the zero-inflated Poisson model included not only the training program, but also the patient’s dementia severity, caregiver’s chronic diseases, and the amount of caregiving time each day, as these variables may be significantly correlated with HRQoL. Finally, the bias for selective attrition was minimized by flagging participants who dropped out via a control variable in the zero-inflated Poisson model.

Results

Subjects’ characteristics

Of the 129 patients with dementia, 54.3% were female, with an average age of 80.26 years (SD = 6.95). The majority of patients had Alzheimer’s disease (n = 68, 52.7%), and 46 (35.7%) had vascular dementia. Their mean Chinese Mini-Mental State Examination29 score was 10.95 (SD = 7.07), indicating moderately demented. Their dementia severity, rated by the Clinical Dementia Rating Scale,30 was mild for 36.4% of patients, moderate for 34.1%, and severe for 29.5%. These characteristics of patients with dementia did not differ significantly by group.

Of the family caregivers, 75.2% were female, with a mean age of 55.47 years (SD = 13.69), and the largest proportion had completed high school (35.7%). Similar percentages of caregivers were spouses (28.7%), daughters (27.9%), and sons-in-law (27.1%) and the rest were sons (16.3%). They had been family caregivers for an average of 42.63 months (SD = 36.16) and they spent on average 13.45 h per day providing care. Only 34.9% hired a home helper.

No significant differences were found in these variables and most HRQoL outcome variables (Appendix 1). However, baseline differences were found in bodily pain, general health perceptions, social functioning, vitality, and mental component summary (Appendix 1). Therefore, baseline and follow-up data at all five data-collection times were treated as outcomes and included in the LCGM analysis.

Trajectories of HRQoL

For all eight SF-36 dimensions, the authors identified two distinct trajectories, a well-functioning group, with most of the SF-36 scores being over 50, and a poor-functioning group, with most of the SF-36 scores being under 50. A cutoff score of 50 was used because it reflects the mean of the standardized combined SF-36 scores that are transformed from individual scores into z-scores.27 Most of the two distinct trajectories in each SF-36 dimension remained stable over time (Fig. 2). The data were analyzed with quadratic and cubic models, but the results were quite similar to those based on linear functions. Hence, only results based on linear models are presented herein. Consistent with Hypothesis 1, these results showed two distinct trajectories for each of the eight dimensions of HRQoL.

More specifically, all five dimensions of physical HRQoL evolved along two trajectories, with the well-functioning group at a higher level of functioning than the poor-functioning group. In addition, HRQoL dimensions changed little over time except for the bodily pain well-functioning and general health perceptions poor-
functioning groups, which both showed a very slight linear decrement during the 18-month period. For instance, the mean physical functioning scores for the well-functioning group were 89.42 at baseline and 88.29 at 18 months following completion of the training program. In contrast, caregivers in the poor-functioning group reported mean physical functioning scores of 32.37 at baseline and 26.11 at 18 months. Finally, the vast majority of caregivers (66%–92%) could be classified as well-functioning in terms of physical functioning, role disability due to physical health problems, bodily pain, general health perceptions, and physical component summary (Fig. 2).

Similar results were obtained for the mental health-related subscales. Changes in each dimension of mental health-related quality of life were characterized by two trajectories: a well-functioning group and a poor-functioning group. The well-functioning group showed higher role disability due to emotional problems, social functioning, vitality, general mental health, and mental component summary scores than the poor-functioning group. Although the well-functioning group remained stable over the 18-month period, the poor-functioning group showed a slight decline in social functioning and vitality. Like the results for the physical health-related subscales, the majority of caregivers (51%–

Fig. 2. Caregiver trajectory groups for health-related HRQoL dimensions over time after completing the caregiver-training program. (A) BP; (B) GH; (C) SF; (D) VT; (E) MH; (F) MCS. BP = bodily pain, GH = general health perception, SF = social functioning, VT = vitality, MH = general mental health, MCS = mental component summary. Scores for each SF-36 subscale range from 0 to 100; higher scores indicate better HRQoL. N = 129.
The home-based caregiver-training program improved caregivers’ HRQoL in that it increased their odds of being in a well-functioning group on two physical health-related components (i.e., bodily pain, BP and general health, GH), three of four mental health-related components (i.e., social function, SF; vitality, VT; mental health, MH), and overall mental component summary score (MCS). In particular, caregivers who received the intervention were 2.76 times more likely than those in the control group to experience a well-functioning trajectory in bodily pain \( (b = 1.06, \text{OR} = 2.76, \text{CI} = 1.24–6.16, p < 0.05) \) and 3.60 times more likely to have a well-functioning trajectory in general health perceptions \( (b = 1.28, \text{OR} = 3.60, \text{CI} = 1.63–7.95, p < 0.05) \) (Table 1).

Furthermore, caregivers who completed the training program were 3.05 times more likely than those in the control group to be well-functioning in social functioning \( (b = 1.12, \text{OR} = 3.05, \text{CI} = 1.26–7.37, p < 0.05) \), 4.49 times more likely to be well-functioning in vitality \( (b = 1.51, \text{OR} = 4.49, \text{CI} = 2.06–9.79, p < 0.001) \), and 2.94 times more likely to be well-functioning in general mental health \( (b = 1.08, \text{OR} = 2.94, \text{CI} = 1.15–7.53, p < 0.05) \). In addition, relative to caregivers in the control group, those who had the training were 3.55 times more likely to be well-functioning in overall mental health outcomes, i.e., the mental component summary \( (b = 1.27, \text{OR} = 3.55, \text{CI} = 1.39–9.08, p < 0.01) \) (Table 2).

### Discussion

To the best of the authors’ knowledge, this study is the first to evaluate the effects of an individualized, home-based family caregiver-training program on distinctive prototypical trajectories of HRQoL dimensions among family caregivers of patients with dementia. These findings expand existing knowledge on the effects of family caregiver-training on HRQoL, at discrete points in time\(^9,12–14\) or averaged over time.\(^{16,21}\) The current study results present evidence that changes in all eight dimensions of HRQoL evolved in two distinct courses: a well-functioning trajectory and a poor-functioning trajectory. These trajectories remained largely stable over an 18-month period, with small changes in several dimensions. These findings are similar to those reported for caregivers of patients with dementia who continued caregiving rather than yielding to formal care; their physical functioning was stable over 2 years, but general mental health improved over 2 years.\(^{31}\) Stable patterns of HRQoL were also found for family caregivers of patients with spinal cord injury\(^7,15\) and stroke.\(^{33}\) Health trajectories are useful outcome measures, as they dynamically depict the natural history of health and disease. They are more informative than health-related measures at one or more time points because a significant health difference at a given time may disappear or even reverse at a later time. Moreover, multiple trajectories depict heterogeneous changes in health outcomes. Knowledge of health trajectories facilitates not only disease management, but also the development of new initiatives for health promotion and disease prevention.

This study was found that \(8\%–49\%\) of family caregivers of patients with dementia were categorized as having poor-functioning trajectories in the HRQoL dimensions. To understand the clinical significance of the distinction between a well-functioning and a poor-functioning trajectory and refer to the minimal clinically importance difference (MCID). The MCID is a model for identifying the smallest change in HRQoL that would
Significantly increase the risk of negative outcomes. For HRQoL subscales, the MCID for the physical component summary is suggested to be 5 points and for the mental component summary it is 2.5–7.8 points. These criteria indicate that the distinction between well- and poor-functioning trajectories is quite meaningful clinically. In particular, the mean differences between the poor- and well-functioning trajectory groups for the HRQoL subscales were all greater than 30, whereas for the physical component summary and mental component summary, they were greater than 15. The result was found that the training program effectively enhanced bodily pain, general health perceptions, social functioning, vitality, general mental health, and mental component summary for family caregivers of patients with dementia and had a medium effect (effect sizes = 0.44, 0.57, 0.44, 0.67, 0.40, and 0.47, respectively).

These differences clearly reinforce the clinical significance of distinguishing between the poor- and well-functioning trajectories in each SF-36 dimension. More importantly, most trajectories of good HRQoL in this study reflected scores above 70, indicating relatively good HRQoL and most poor HRQoL trajectories found in this study reflected scores around 30, indicating poor HRQoL. These findings indicate that the good and poor HRQoL trajectories identified in this study had dramatic clinical differences, adding to the current knowledge base by demonstrating that family caregivers of patients with dementia had heterogeneous, but stable courses of HRQoL.

In terms of the intervention effects on different HRQoL dimensions, the probability of a caregiver being in a well-functioning trajectory for mental health-related subscales was enhanced more than for physical health-related subscales during the 18 months after receiving the training program. This conclusion is further supported by our finding that after controlling for covariates (treatment, attrition, patients’ dementia severity, caregivers’ chronic diseases, and direct caregiving time per day), the intervention effects on mental health-related HRQoL (social functioning, vitality, general mental health, and mental component summary) remained robust, but the intervention effects on physical health-related HRQoL disappeared (data not shown). Similar results were found in the short-term (6 months) outcomes of this caregiver-training program.

This study’s findings are also consistent with a report that female primary informal caregivers in Hong Kong were more likely to report chronic diseases and scored significantly lower in all eight SF-36 dimensions and that longer hours of caregiving (per quartile) were inversely, partially correlated with mental health-related HRQoL. Furthermore, the findings of the current study agree with prior results that caring for a patient with more severe Alzheimer’s disease predicted caregivers’ poor physical health-related outcomes in role disability due to physical health problems, but better mental component summary.

Limitations

Like all research endeavors, this study has several limitations. First, the study design was single-blinded, i.e., only patients with dementia and their family caregivers did not know which intervention they received, but not the interviewers. Second, participants were recruited in northern Taiwan and care recipients were limited to those diagnosed with dementia. Replication studies are warranted in patient populations living in other countries. Third, the sample size ($N = 129$) was somewhat limited, which may have prevented us from identifying other trajectories for each SF-36 dimension. Last, the same sample was used to explore the HRQoL trajectories and the effect of the caregiver-training intervention on those trajectories, which might have limited the generalizability of the findings.
the current findings on the trajectories. This limitation is minimized by finding similar trajectory results when examining the trajectory modeling for the control group (data not shown). Nonetheless, the authors recommend that this study’s findings on the trajectories be validated by future studies using a different sample without any intervention.

Conclusion and implications

The results of this study support the existence of multiple trajectories of HRQoL among family caregivers in Taiwan. These results also show that an individualized, home-based caregiver-training program effectively enhanced family caregivers’ odds of being in a well-functioning trajectory, especially in mental health-related outcomes. This training program, which emphasized partnership with family caregivers and was based on the PLST theory to help family caregivers detect and decrease environmental stimuli for a specific dementia-related behavioral problem, effectively enhanced two dimensions of physical HRQoL and four dimensions of mental HRQoL by achieving a medium effect and MCID. The program can be used by healthcare providers and case managers for persons with dementia and their caregivers in clinical settings. This intervention was effective in a Taiwanese sample and might be used in other countries with Chinese populations. Policies can be developed to implement similar programs in the community to support family caregivers of patients with dementia. Further replications of this clinical trial are needed in different care-recipient populations, preferably with larger samples.

Author contributions

Yea-Ing L. Shyu, Li-Min Kuo, and Huei-Ling Huang: study concept and design, acquisition of subjects and data, analysis and interpretation of data, and preparation of manuscript. Jersey Liang: analysis and interpretation of data, and preparation of manuscript. Yam-Ting Kwok and Wen-Chuin Hsu: study concept and design, analysis and interpretation of data, and preparation of manuscript. Jin-Yi, Liu: acquisition of subjects and data.

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Appendix.

Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.gerinurse.2016.08.017.


