*International Psychogeriatrics* (2004), 16:1, 33–49 © 2004 International Psychogeriatric Association
DOI: 10.1017/S1041610204000055 Printed in the United Kingdom

2003 IPA RESEARCH AWARDS SECOND-PRIZE WINNER

# A randomized controlled trial of a specific reminiscence approach to promote the well-being of nursing home residents with dementia

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## ABSTRACT

**Background:** To date, no firm conclusions can be reached regarding the effectiveness of reminiscence for dementia. Researchers have emphasized that there is an urgent need for more systematic research in the area.

**Objective and Method:** A single-blinded, parallel-groups (one intervention, one comparison, and one no-intervention group) randomized controlled trial (RCT) was adopted to investigate whether a specific reminiscence program leads to higher levels of psychosocial well-being in nursing home residents with dementia. The intervention adopted a life-story approach, while the comparison group provided friendly discussions to control for any changes in outcome as a result of social contacts and attention. The Social Engagement Scale (SES) and Well-being/Ill-being Scale (WIB) were the outcome measures used. The outcomes of the groups were examined with reference to the baseline ($T_0$), immediately ($T_1$), and six weeks ($T_2$) after intervention. The final sample had 101 subjects (control group: $n = 30$; comparison group: $n = 35$; intervention group: $n = 36$). Using multivariate analysis with repeated measures, no significant differences in outcome were found between groups at either $T_1$ or $T_2$. Wilcoxon signed rank tests were performed for each group comparing outcomes between $T_1$ and $T_0$, $T_2$ and $T_1$, and $T_2$ and $T_0$. Significant differences were observed in the intervention group when comparing $T_1$ and $T_0$ WIB ($p = .014$), but not for the other groups.

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**Conclusion:** Although the intervention did not lead to significant differences between the three groups over time, there was a significant improvement in psychosocial well-being for the intervention group.

**Key words:** Dementia, reminiscence, life-story book, randomized controlled trial, nursing home care

## Introduction

Over the past decades various psychosocial treatments have been developed for people suffering from Alzheimer's disease (AD) (Woods, 1996). Among the psychosocial approaches, the more popular studied is reminiscence therapy (Webster and Haight, 2002). A comprehensive systematic review assessing the effects of reminiscence therapy on dementia by Spector and colleagues (2002) determined that no firm conclusions could be reached regarding its effectiveness, yet there was a trend in favor of treatment in terms of behavior but not cognition. Pusey (2000) also found limited evidence upon which to draw conclusions about the effects of reminiscence on cognition and behavior in her systematic review. However, she commented that perhaps measuring efficacy purely in terms of cognition and behavior would not address the potential benefits that a person with dementia might experience, and suggested variables such as pleasure and well-being should be examined. Owing to the inconclusive results, more rigorous studies are required to explicate the benefits of reminiscence before any conclusions can be drawn. This study is a randomized controlled trial aimed at finding out whether a specific reminiscence program would lead to any changes in social well-being for nursing home residents with dementia.

## Method

This study adopted a single-blinded, parallel-group (one intervention, one comparison, and one control [no-intervention] group) design to address the following research questions:

- Is specific reminiscence adopting a life-story approach a useful intervention for promoting social well-being in people with dementia in nursing homes?
- If it is useful, can its effects be sustained for six weeks after the intervention?

A positive correlation between intervention and outcome is hypothesized. The overall assumption is that the intervention group will be more likely to experience a higher level of well-being in the post-intervention period than the comparison and control groups. Residents recruited from two publicly funded nursing homes

(Facilities A and B), sharing similar characteristics were randomly assigned to the control, comparison and intervention groups. Data was collected at baseline ($T_0$), immediately ($T_1$), and six weeks post-intervention ($T_2$). Subjects included were residents diagnosed as suffering from dementia (DSM-IV); able to communicate most of the time (according to the Resident Assessment Instrument [RAI] communication scale); and able to understand and speak Cantonese. Excluded were residents with any active major psychiatric disorders (schizophrenia, major affective disorders); any acute or unstable chronic medical conditions including cardiac or lung diseases; blindness (RAI – vision scale); and inability to hear even with hearing aids (deafness) (RAI – hearing scale).

The intervention was designed as an individual treatment condition. Specific reminiscence refers to the highly focused use of triggers that approximate the life history of an individual, and efforts to stimulate recall during conversations (Gibson, 1994). The term 'life story' was used in a generic and global sense, referring to glimpses of an individual's life, rather than to a biography or an entire life story (Wacks Jr., 1989). The contents of an LSB as proposed by Hellen (1998) were adopted. Several concepts in Hellen's LSB categories were modified because the concepts were either too broad or too vague. For example, "genealogy" was too broad a construct and was changed to "family and roots." To control for the possibility that a resident's improvement might have been the result of the attention and social contacts resulting from the intervention itself, the comparison program was designed to provide social contacts. All features in the design of the two protocols were the same, except that residents assigned to the intervention group would discuss their life experiences and events of the past, while those assigned to the comparison group were facilitated to do otherwise. Themes of the comparison protocol, for example, included "diet and health" and "social security for the elderly." The development, testing and refining of both the intervention and comparison programs took place in five cycles in four different old age homes over nine months, beginning in June 2001. The final program was a weekly 30-minute session for six weeks. Subjects assigned to the control group received no intervention. No pilot testing site was involved in any of the research activities undertaken in the main study. The study was approved by the Ethics Review Committee, School of Nursing, The Hong Kong Polytechnic University.

## Measures

Data regarding the demographic and clinical characteristics of individual residents, including their age, gender, marital status, education, religion, year of diagnosis of dementia, coexisting medical problems, Mini-mental State

Examination (MMSE) score, functional abilities, whether they were being restrained, use of psychotropic medications, regular programs and activities per month, and the number of visits per month from families and friends, were collected.

The Cantonese version of the Mini-mental State Examination (C-MMSE) was validated by Chiu and colleagues (1994). It has a Cronbach's alpha of 0.86, a reliability of 97.5%, a validity of 97.3%, and an inter-rater correlation coefficient of 0.99. The functional performance of the residents was ascertained by the activities of daily living assessment protocol (MDS-ADL) of the local version of the Minimal Data Set – Home Care (MDS-HC). Scores of the MDS-ADL range from 0 to 46, with "0" meaning total independence and "46" indicating complete dependency. The MDS-HC was derived from the original RAI, and has been validated in many nations (Hirdes, 1996; Morris *et al.*, 1997) as well as in Hong Kong (Chou *et al.*, 2001), who reported an inter-rater reliability of 60–70% agreement for two raters.

The Social Engagement Scale (SES, Mor *et al.*, 1995; Schroll *et al.*, 1997) is a caregiver rating scale that evaluates the status of the resident in the past seven days. Items include for example, "at ease interacting with others" and "at ease doing planned or structured activities." Each item is rated as yes (1) and no (0). The highest score attainable for an individual resident is 6 and the lowest score is 0. It showed a high internal consistency (intra-class correlation: 0.51–0.64), with its items shown to be relevant across groups of residents with a variety of functional and cognitive statuses. The same six items of the SES are also part of the MDS-HC.

The Well-being/Ill-being Scale (WIB) is one of the three measures in the tool Dementia Care Mapping (DCM) developed and tested by the Bradford Dementia Group (1997). DCM is used extensively in research in the United Kingdom (U.K.) (Beavis, 1998; Brooker *et al.*, 1998; Perrin, 1997), and other parts of the world, including North American and European countries (Moore, 2002). Indicators of well-being in the WIB include, for example, "being able to express wishes in an acceptable way," "bodily relaxation," and "creative self-expression" (such as singing, dancing or painting) while indicators of ill-being include examples such as "unattended sadness or grief," "sustained anger," or "anxiety." The WIB scale rates each category of behavior observed every five minutes for a minimum of six hours (Brooker and Duce, 2000). After five minutes, the rater quantifies the nature of the observed behavior category by assigning a WIB value to it. The six-point WIB scale ranges from very negative to very positive ($-5, -3, -1, +1, +3, +5$). The values were calculated at the end of an observation period to form a mean score. Because studies validating WIB in Hong Kong could not be located in the literature, a 15-member panel consisting of nurses, social workers, occupational therapists, clinical psychologists, and

family caregivers rated the validity of the tool for local use on a four-point Likert Scale. The result showed a high content validity index of 0.95.

**Sameness of approach by intervention RAs**

The group of Research Assistants (RAs) who delivered the intervention and comparison conditions included three social workers and one occupational therapist. All of them have substantial work experience, either with older people, mentally handicapped individuals, or nursing home residents with dementia. The mean number of times of training provided was 10.3 (Standard Deviation [SD] 3.2), and the mean number of hours of training was 19.3 (SD 6.9). To ascertain that the team of RAs would conduct the intervention and comparison protocols in the same manner, a panel of two experts was asked to review the videotaped records of both the intervention and comparison programs conducted by each RA. Evaluations were conducted according to a structured checklist adopting Donabedian's (1988) structure-process-outcome model developed by the first author. The panel concluded that the team of RAs was conducting both protocols in a fashion similar to one another, and that further training was not required.

**Training of the data collection RAs**

The group of RAs who collected data on the participants included both raters (who rated only the WIB of the DCM) and assessors (who performed the rest of the assessments), and both groups were blinded to subject assignment. A total of five assessors, three registered nurses and two social workers were trained. The mean number of training sessions provided for the assessors was 10 (SD 1.8), and the mean number of hours of training was 25 (SD 3.6). Nine raters who were graduate nurses or registered nurses were recruited for the rating of the WIB. The mean number of training sessions provided for the team of raters was 7.1 (SD 1.7), and the mean number of hours of training for the raters was 13.9 (SD 2.9).

Intra-class correlations to test for test-retest reliabilities and inter-rater reliabilities were conducted after training. The alpha for the inter-rater reliability of both the C-MMSE and RAI-ADL was .99. The mean alpha value for the test-retest reliability of each individual rater of the C-MMSE was .87, and for RAI-ADL .98. As for the inter-rater reliability of the WIB and the SES, the alphas were .93 and 1.00, respectively. Mid-study inter-rater reliability tests also reached comparable levels. Studies of test-retest reliability for the WIB and the SES were not conducted because behavioral presentations are context-based and dynamic in nature, and may be different from day to day, thus affecting the validity of the comparison.

### Preparation of nursing home staff

The Personal Care Workers (PCW, synonymous to health care aides) that participated in the intervention and comparison conditions were required to have at least four hours of training on dementia care prior to participating. In-service education programs on dementia care were offered by the first author for those who did not meet this criterion. Subsequently, all but one staff member in Facility A met this requirement. To ensure that all PCWs participating in the group sessions understood the study and their roles in the same way, each staff member was briefed in person by the first author, and was given an information sheet prior to the commencement of his/her first group session.

### Procedures

The first author met with different levels of staff in both facilities to explain the study and its operational logistics and subject selection criteria. During explanations, care was taken not to emphasize the intervention as a novel way preferred over the comparison condition. The physicians in charge of the homes confirmed that those residents diagnosed as having dementia met the criteria as specified by the DSM-IV. All recruited subjects had the informed consent of their families or proxies and were randomly assigned to the three groups. Fixed allocation (Byar *et al.*, 1976) was practiced.

Fifty-four out of 67 (i.e., 80.6%) eligible cases were recruited in Facility A. There were 10 residents whose families the nurses were unable to reach or whose participation their families refused to allow. One resident refused to participate herself, and two residents were hospitalized during recruitment. Three of the 54 participants were later found to be ineligible – two had severe visual impairment, and the other did not meet the criterion of being able to communicate most of the time. Two participants died after the commencement of the study and two others explicitly stated after the sessions had begun that they no longer wished to participate. Another resident experienced excessive sleepiness during the sessions. The final number of subjects in Facility A who were able to complete the $T_0$ and $T_1$ data collections, therefore, consisted of 46 out of the 54 (i.e., 85.2%) recruited residents. Five out of the 46 subjects were hospitalized during $T_2$; therefore measurements for these five residents were not collected at $T_2$.

Forty-seven out of a total of 60 (78.3%) eligible cases in Facility B were recruited at the commencement of the study. The families of three eligible residents were unable to be reached even after repeated attempts and the families/guardians of five residents did not give their consent. One family withdrew their relative from the study after having initially approved of the relative's participation. According to the nurse manager, the family member of

one resident was mentally incompetent, and therefore, was not approached. One resident had a stroke before the family was contacted and suffered a significant loss in the ability to speak, thus becoming ineligible. Two residents died in the process of contacting the families. During the baseline data collection period, seven participants out of the 47 cases dropped out of the study. Two of them were found to have been wrongly included – one had a severe visual impairment and the other had serious auditory impairment. One participant was admitted into hospital for a sustained period of time, and one died prior to the commencement of the study. Two other residents refused to take part in the sessions. Lastly, one resident was excluded from the study because she was found to be depressed during the sessions, but showed no signs of distress and behaved as usual outside of the group sessions. Group sessions of the nature of this study were considered unsuitable for her and sessions were terminated. No participants dropped out during $T_1$; therefore, 40 out of 47 (85.1%) participants successfully completed the intervention phase. Two residents were hospitalized during $T_2$, therefore only 38 participants were included in data collection for $T_2$. Data was collected from February to October 2002. Care was taken that the assessors and the raters would not be scheduled to collect data at the same time.

**Statistical analyses**

SPSS 11.0 for Windows was used for data entry and statistical computation. Descriptive statistics were generated for the demographic and clinical variables, and then compared by groups using a $\chi^2$ test and a Mann-Whitney U test. The normality test for all outcome variables was applied and non-parametric tests were used as indicated. A General Linear Model (GLM) with repeated measures was used to determine differences between groups and within groups. The level of significance for all of the statistical tests was selected as .05. All statistical tests were set as two-tailed. Data were analyzed using the intention-to-treat (ITT) principle (Fisher *et al.*, 1990).

**Missing data**

In the ITT sample, (Table 1) the percentage of data missing for the outcome variables of $T_0$, $T_1$, and $T_2$ was 0.5%, whereas the missing data for two controlling variables, the MMSE and the MDS-ADL, was 0.9%. Missing data for all other variables constituted 1.1%. In total, 2.5% of the data was missing in this dataset. For the per protocol sample, the percentages of missing data for the outcome variables was 0.2%, the MMSE and the MDS-ADL–0.5%, and all other variables –0.8%. The total percentage of missing data for the per protocol sample was 1.5%. The mean value of the outcome variables for each respective group was used as a replacement for the missing data.

**Table 1.** The intention-to-treat sample profile

| | RECRUITED PARTICIPANTS $N=101$ | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | CONTROL GROUP | | COMPARISON GROUP | | INTERVENTION GROUP | | KRUSKAL-WALLIS TEST | |
| CHARACTERISTICS | $n=30$ | (%) | $n=35$ | (%) | $n=36$ | (%) | STATISTICS | SIG. |
| Age | 86.8 | (7.3) | 84.1 | (7.4) | 86.2 | (6.3) | 2.974 | $p=0.224$ |
| Gender | | | | | | | | |
| • Male | 11 | (35.7) | 11 | (31.4) | 10 | (27.8) | 0.599[a] | $p=0.741$ |
| • Female | 19 | (63.3) | 24 | (68.6) | 26 | (72.2) | | |
| Marital status | | | | | | | | |
| • Married | 8 | (26.7) | 8 | (22.9) | 8 | (22.2) | 0.968[a] | $p=0.915$ |
| • Widowed | 20 | (66.7) | 25 | (71.4) | 24 | (66.7) | | |
| • Single | 2 | (6.7) | 2 | (5.7) | 4 | (11.1) | | |
| Years of education | 2.7 | (3.67) | 1.8 | (3.4) | 2.4 | (3.9) | 1.456 | $p=0.483$ |
| Religion | | | | | | | | |
| • Yes | 7 | (23.3) | 16 | (45.7) | 9 | (25.0) | 4.696[a] | $p=0.096$ |
| • No | 23 | (76.7) | 19 | (54.3) | 26 | (72.2) | | |
| Missing data | 0 | (0) | 0 | (0) | 1 | (2.8) | | |
| Length of stay (months) | 280. | (9.2) | 25.4 | (10.4) | 23.7 | (10.8) | 4.663 | $p=0.097$ |
| No. of diagnoses other than dementia | 4.5 | (1.9) | 3.7 | (1.7) | 4.2 | (1.4) | 4.707 | $p=0.095$ |
| Sedatives/Hypnotics prescribed | 0.0 | (0) | 0.1 | (0.3) | 0.1 | (0.3) | 2.670 | $p=0.263$ |
| Psychotropics prescribed | 0.2 | (0.5) | 0.1 | (0.4) | 0.3 | (0.5) | 2.842 | $p=0.241$ |
| Restrained | | | | | | | | |
| • Never | 12 | (40.0) | 14 | (40.0) | 7 | (19.4) | 5.032[a] | $p=0.284$ |
| • Intermittently | 4 | (13.3) | 7 | (20.0) | 9 | (25.0) | | |
| • Continually | 14 | (46.7) | 14 | (40.0) | 20 | (55.6) | | |
| Regular programs | | | | | | | | |
| • Yes | 9 | (30.0) | 20 | (57.1) | 15 | (41.7) | 4.923 | $p=0.085$ |
| • No | 21 | (70.0) | 15 | (42.9) | 21 | (58.3) | | |
| Total no. of visits/ month | 10.4 | (16.2) | 6.5 | (10.6) | 6.4 | (10.7) | 0.050 | $p=0.975$ |
| C-MMSE | 10.7 | (6.1) | 9.3 | (5.1) | 8.3 | (5.1) | 3.160 | $p=0.206$ |
| MDS-ADL | 20.9 | (7.7) | 21.6 | (8.1) | 22.2 | (8.7) | 0.431 | $p=0.807$ |
| Social Engagement Scale | 3.6 | (1.6) | 3.4 | (2.0) | 3.6 | (1.7) | 0.281 | $p=0.869$ |
| Well-being/Ill-being Scale | 1.3 | (0.3) | 1.3 | (0.2) | 1.3 | (0.2) | 0.778 | $p=0.678$ |

[a] $\chi^2$ test.

## Results

The final sample of all randomly assigned cases was 101, with 54 (53.5%) from Facility A and 47 (46.5%) from Facility B. There were 30 subjects in the

control group, 35 in the comparison group, and 36 in the intervention group. The completed cases, defined as residents who had completed the intervention phase of the study, consisted of 86 participants. The number of completed cases included 46 (54.0%) in Facility A and 40 (46.0%) in Facility B, with 26 subjects in the control group, 29 in the comparison group, and 30 subjects in the intervention group.

### The ITT sample

The mean age of the ITT sample ($N = 101$) was 85.6 (Standard Deviation [SD] = 7.0). Sixty-eight percent were female. The majority had lost a spouse (68.3%). Most had received no education (61.4%) or only primary education (28.7%). The majority of them did not have any religion (67.3%). Their mean length of stay at the nursing homes was 25.5 months (SD = 10.3). The mean number of medical diagnoses they had other than dementia was 4.1 (SD = 1.7). Few were being prescribed sedatives/hypnotics (mean number prescribed 0.1, SD = 0.2) and psychotropic medications (mean number prescribed 0.2, SD = 0.5). Almost half of them were put on continual restraints (47.5%). Forty-four percent of them had some kind of regular program per month. The mean number of visits they received per month from families, friends or maids was 7.6 (SD = 12.6). The majority of them did not participate in any exercise programs (95.0%) or religious activities (83.2%). Their mean baseline ($T_0$) C-MMSE score was 9.3 (SD = 5.4) and baseline MDS-ADL score was 21.7 (SD = 8.1). There were no significant differences between the control, comparison and treatment groups in all clinical and demographic variables.

The two controlling variables, C-MMSE and MDS-ADL, were tested for any significant changes in $T_1$ and $T_2$ using the Kruskal-Wallis test. There were no significant differences between the three groups for both post-intervention measurements. Each group was also examined for changes in their C-MMSE and MDS-ADL over time using the Wilcoxon signed rank test. No significant changes were found when comparing the time periods $T_1$ and $T_0$, $T_2$ and $T_1$, and $T_2$ and $T_0$.

A general linear model (GLM) with repeated measures was constructed to examine whether the intervention could bring about any significant differences in outcome between the groups over time. The result showed that there were no significant differences within subject effects ($F = 0.581$, $p = 0.794$). When grouping was examined for any between-subject effects, no significant differences were found in both the SES ($F = 0.049$, $p = 0.952$) and WIB scores ($F = 0.270$, $p = 0.764$).

Wilcoxon signed rank tests were performed for each of the groups comparing the scores of their outcome variables (SES and WIB) between $T_1$ and $T_0$, $T_2$ and $T_1$, and $T_2$ and $T_0$ (Table 2). No significant differences were noted between

**Table 2.** Intention-to-treat sample mean scores for outcome variables of the control, comparison and intervention groups

| | $T_0$ SES | $T_1$ SES | $T_2$ SES | $T_0$ WIB | $T_1$ WIB | $T_2$ WIB |
|---|---|---|---|---|---|---|
| | MEAN (SD) | MEAN (SD) | MEAN (SD) | MEAN (SD) | MEAN (SD) | MEAN (SD) |
| Control group | 3.62 (1.63) | 4.17 (1.56) | 3.83 (1.51) | 1.37 (0.29) | 1.44 (0.32) | 1.42 (0.37) |
| Comparison group | 3.40 (2.02) | 4.09 (1.46) | 4.37 (1.39) | 1.33 (0.22) | 1.42 (0.27) | 1.41 (0.26) |
| Intervention group | 3.61 (1.71) | 4.03 (1.73) | 4.25 (1.11) | 1.30 (0.20) | 1.41 (0.24) | 1.41 (0.22) |

SES-Social Engagement Scale
WIB-Well-being/Ill-being Scale

the control and comparison groups. In the intervention group, there were also no significant differences when comparing $T_1$ and $T_0$, and $T_2$ and $T_1$ SES and WIB. A significant difference was observed, however, between $T_2$ SES and $T_0$ SES ($p = 0.032$). The mean SES score for $T_0$ was 3.610 and the mean score for $T_2$ was 4.250. The difference in mean for the two measurement points was 0.640, with an SD of 1.710. The intervention, therefore, has an effect size of 0.374 on the SES scale. Yet, using nQuery Advisor software (2000), a sample size of 36 has only a 60% power. A significant difference was observed, too, between $T_1$ and $T_0$ WIB ($p = 0.014$). The mean WIB score for $T_0$ was 1.300 and for $T_1$ was 1.413. The difference in mean was 0.113, with an SD of 0.237. The intervention, therefore, had an effect size of 0.476 on the dependent variable WIB. The power of this test reached 80% for a sample size of 36. Table 2 lists the *p*-values showing the results of testing for significant differences in outcome measures.

### The per protocol sample

Eighty-six (85.1%) subjects in the ITT sample completed the intervention protocol. There were no significant differences in the clinical and demographic characteristics of those who had completed, versus those who had not completed, the study protocols, except for the baseline ($T_0$) SES score ($p = 0.032$).

The control, comparison and intervention groups in the per protocol sample Table 3) were only significantly different from one another in that there was a difference between the control and comparison groups in the number of medical diagnoses they had other than dementia ($p = 0.041$), and in whether they had any regular programs ($p = 0.050$). No significant differences were noted between the control and the intervention groups, or between the comparison and intervention groups in any of the variables. A repeated-measures analysis showed no significant difference within subject effects for the interaction between time and group

**Table 3.** The per protocol sample profile

| | RECRUITED PARTICIPANTS $N=86$ | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | CONTROL GROUP | | COMPARISON GROUP | | INTERVENTION GROUP | | KRUSKAL-WALLIS TEST | |
| CHARACTERISTICS | $n=27$ | (%) | $n=29$ | (%) | $n=30$ | (%) | STATISTICS | SIG. |
| Age | 87.2 | (7.5) | 83.1 | (7.7) | 85.7 | (6.6) | 5.006 | $p=0.082$ |
| Gender | | | | | | | | |
| • Male | 9 | (33.3) | 10 | (34.5) | 9 | (30.0) | 0.146[a] | $p=0.930$ |
| • Female | 18 | (66.7) | 19 | (65.5) | 21 | (70.0) | | |
| Marital status | | | | | | | | |
| • Married | 7 | (25.9) | 7 | (24.1) | 7 | (23.3) | 0.256[a] | $p=0.992$ |
| • Widowed | 18 | (66.7) | 20 | (69.0) | 20 | (66.7) | | |
| • Single | 2 | (7.4) | 2 | (6.9) | 3 | (10.0) | | |
| Years of education | 2.5 | (3.5) | 2.1 | (3.6) | 2.7 | (4.1) | 0.343 | $p=0.842$ |
| Religion | | | | | | | | |
| • Yes | 7 | (25.9) | 12 | (41.4) | 7 | (23.3) | 2.435[a] | $p=0.296$ |
| • No | 20 | (74.1) | 17 | (58.6) | 22 | (73.3) | | |
| Missing data | 0 | (0) | 0 | (0) | 1 | (3.3) | | |
| Length of stay (months) | 27.3 | (9.4) | 24.8 | (10.7) | 24.0 | (10.1) | 3.129 | $p=0.209$ |
| No. of diagnoses other than dementia[b] | 4.7 | (1.8) | 3.6 | (1.5) | 4.3 | (1.4) | 6.376 | $p=0.041$* |
| Sedatives/Hypnotics prescribed | 0.0 | (0) | 0.1 | (0.3) | 0.1 | (0.3) | 2.920 | $p=0.232$ |
| Psychotropics prescribed | 0.2 | (0.5) | 0.1 | (0.4) | 0.3 | (0.5) | 2.517 | $p=0.284$ |
| Restrained | | | | | | | | |
| • Never | 10 | (37.0) | 11 | (37.9) | 6 | (20.0) | 2.947[a] | $p=0.567$ |
| • Intermittently | 4 | (14.8) | 5 | (17.2) | 7 | (23.3) | | |
| • Continually | 13 | (48.1) | 13 | (44.8) | 17 | (56.7) | | |
| Regular programs[c] | | | | | | | | |
| • Yes | 8 | (29.6) | 18 | (62.1) | 15 | (50.0) | 5.998[a] | $p=0.050$* |
| • No | 19 | (70.4) | 11 | (37.9) | 15 | (50.0) | | |
| Total no. of visits/ month | 11.2 | (17.0) | 7.5 | (11.5) | 4.8 | (5.6) | 1.254 | $p=0.534$ |
| C-MMSE | 10.5 | (6.1) | 9.1 | (4.4) | 8.4 | (5.0) | 2.299 | $p=0.317$ |
| MDS-ADL | 20.6 | (7.8) | 21.2 | (8.2) | 22.8 | (7.9) | 1.110 | $p=0.574$ |
| Social Engagement Scale | 3.6 | (1.6) | 3.9 | (1.8) | 3.7 | (1.7) | 0.410 | $p=0.815$ |
| Well-being/Ill-being Scale | 1.4 | (0.3) | 1.3 | (0.2) | 1.3 | (0.2) | 0.394 | $p=0.821$ |

[a] $\chi^2$ test.
[b] Significant difference between control and comparison group, Mann-Whitney U test statistic = 255.5, $p=0.023$.
[c] Significant difference between control and comparison group, $\chi^2$ statistic = 5.916, $p=0.015$.
* $p<0.05$.

($F = 0.353$, $p = 0.944$), between time and regular program ($F = 2.117$, $p = 0.078$), and between time and the number of medical diagnoses other than dementia ($F = 0.696$, $p = 0.595$). When grouping was examined for any between-subject effects, no significant differences were found. Also, no significant differences were found when comparing the outcome variables between $T_1$ and $T_0$, $T_2$ and $T_1$, and $T_2$ and $T_0$ for each individual group.

## Discussion

Because the intervention did not bring about any significant differences in the outcomes of the participants over time, the null hypotheses of the study cannot be rejected. However, significant changes in the outcomes of the intervention group of the ITT sample were noted when comparing the $T_1$ and $T_0$ WIB scores and the $T_2$ and $T_0$ SES scores. Because the test for significant change in the subjects' WIB score reached a power of 80%, the finding that the intervention did produce significant improvements in the well-being of the subjects can be regarded as fairly convincing.

The observed difference in the two outcome variables could be related to the nature of the two instruments. The WIB scale of the DCM captures micro-changes in the resident on a moment-to-moment basis (rating behaviors every five minutes) while the SES captures the more global changes in the behavior of the residents over time (in the past seven days). The changes in outcomes could have been small enough that it took some time for the staff to recognize differences in behavior. Therefore, it can be concluded that although the intervention did not bring about significant changes between the three groups, it did bring about significant changes within the intervention group itself. The comparison group in the ITT sample, which had been offered a social program, also showed a significant difference when their $T_2$ and $T_0$ SES scores were compared. Such a change was not observed in the no-intervention group, indicating that some kind of activity was better than none.

Caution is needed when interpreting the benefits of the intervention program because significant changes were not observed in all of the groups in the per protocol sample. It is interesting to see that positive changes are observed in the ITT sample but not in the per protocol sample, because the ITT analysis usually dilutes the experimental effect and will likely yield a downward-biased estimate of treatment difference, whereas the per protocol analysis tends to yield an upward-biased treatment difference (Sheiner and Rubin, 1995). One possible explanation is that the participants needed to complete the intervention program in order to benefit from it. Another possibility is that the ITT sample had a slightly larger sub-sample, with six more subjects in the intervention group.

There were no significant differences between those who had completed and those who had not completed the study protocol except for their mean SES score. It probably should not come as a surprise that many of those who did not complete the protocol had either died before or after the commencement of the study, refused to continue, or verbalized a depressed mood during sessions.

Concerning the per protocol population, significant differences were found between the control and comparison group in the number of medical diagnoses other than dementia and in whether they had any regular programs. It was difficult to explain the meaning of the differences, as these two groups were not significantly different in terms of their baseline ($T_0$) and $T_1$, C-MMSE and MDS-ADL scores. It is likely that their difference in the number of medical diagnoses other than dementia had no impact on their cognitive and functional levels. Whether residents had any regular programs also had no impact on their outcome.

In answering the research question whether a specific reminiscence using a life-story approach is a useful intervention for promoting social well-being in nursing home residents with dementia, a straightforward answer is "no," as indicated by the results from the use of the GLM with repeated measures. However, judging from the statistical analysis that examined the degree of change for the intervention group, the answer to the same question would be "yes." Concerning the second research question – If the LSB was a useful intervention, would the effect be sustained six weeks after the intervention? – the answer is "yes" when the degree of change for the intervention group itself is examined. There was some improvement in the subjects' level of well-being as reflected in the WIB scores six-weeks post-intervention, but not to a statistically significant level. An upward trend of improvement was noted in the SES score in $T_1$, which rose to a significantly different level in $T_2$. Because of the differences in the results generated from the ITT and per protocol analysis, it can only be said that the results are promising but not definitive.

Goldwasser and co-workers (1987) found that any benefits immediately after reminiscence therapy were quickly lost in a five-week follow-up. The short-term nature of the effect of reminiscence was also noted by Orten and colleagues (1989). In this study, the positive changes in outcome could still be observed for one of the measures– the SES – in the six-week post-intervention period. This test has only a 60% power and the result cannot be regarded as conclusive. Apparently, our finding seems to support the suggestion of Spector and his team (2002) that, if specific reminiscence is to be beneficial, perhaps it needs to be part of a continuous, ongoing program.

Even though it could be said that the result of our intervention is, in a way, promising, the clinical significance of the degree of change as observed in the intervention group of our ITT sample must be considered. The intervention

produced an effect size of 0.374 for the SES score, and an effect size of 0.476 for the WIB score. Forty-seven percent of the subjects had a WIB score of between 1.3 and 1.4, and 45.6% of the subjects had a SES score of between 3 and 4 in $T_1$. One possible reason accounting for the narrow spread of scores was the monotony of nursing home life, as attested to by our raters, who spent hours making on-site observations. In view of the narrow spread of the scores, the changes in the scores may be interpreted as having some clinical significance.

It is difficult to compare the results of this study with other RCTs because there are fewer than a handful of RCTs on reminiscence. Reddin (1996) studied the use of a structured life review as a therapeutic process for elderly nursing home residents as opposed to the use of simple reminiscence (unstructured) and friendly visits. Reddin's study hypothesized that overall well-being will be higher in those elderly nursing home residents (not residents with dementia in particular) who participated in a structured life-review group process than in those who participated in a simple reminiscence group process or those who participated in a friendly visit group. The intervention protocol consisted of seven weekly one-hour sessions conducted in a group format. The findings did not confirm any of her hypotheses.

Another study that is fairly similar in design is the research of Beck and co-workers (2002) that tested two interventions – an ADL program and a psychosocial activity intervention – to determine their efficacy in reducing disruptive behavior and improving affect in nursing home residents with dementia. Although their sample consisted of people with dementia, their focus was on reducing disruptive behavior rather than on promoting well-being. It was also unclear whether a random assignment was used in group allocation. Their findings indicated significantly more positive affect but not a reduction in disruptive behavior in treatment groups compared to control groups. Still, we agree with their proposition that treatments that produce even a brief improvement in affect, are indicative of an improved quality of mental health.

In studying the use of psychosocial treatments for managing disruptive vocalizations made by residents with severe dementia, Doyle and colleagues (1997) concluded that psychosocial interventions might be more successful for patients in earlier stages of dementia, when their remaining ability to learn is higher than those with severe dementia. Our results did not converge with their observation. The mean C-MMSE of the subjects in the intervention group of the ITT sample of this study was 9.3 (SD 5.1), which many studies would classify as suffering from severe dementia. Doyle and colleagues (1997) also suggested that the physical health of their participants might have mitigated the stronger effect of their interventions, reducing the subjects' ability to attend to environmental

changes. Again, this was not observed in this study. In the ITT sample, the mean MDS-ADL score was 21.7 (SD 8.1). Our subjects were fairly dependent on others for their activities of daily living. Their physical abilities remained stable throughout the pre- and post-intervention periods, and had no impact on the outcome variables.

Several factors could have confounded our results. First, the sample size was too small for a repeated-measures multivariate analysis. Only two nursing homes were used as study sites. Indeed the use of a few study settings facilitated standardized sampling, data collection, protocol adherence and control for a number of confounding variables; however, it also posed restrictions on the adequate recruitment of subjects. Second, the "dosage" of the intervention might have been weak. The intervention program consisted of only six 30-minute weekly sessions. Third, regardless of the number of precautionary steps that had been exercised, it would be impossible to prevent people from having preconceived notions about the intervention and comparison programs. Last, it was likely that the measures were not sensitive enough.

Numerous methodological problems in psychosocial studies have been noted by reviewers (e.g., Finnema *et al.*, 2000; Marshall and Hutchinson, 2001): sampling problems such as unclear selection criteria and diagnostic difficulties, design and measurement problems such as the lack of rigor, the use of instruments without reporting reliability and validity in the populations of concern, and the inadequate description of interventions and measurement of outcomes. The contribution of our study is that it was an RCT that addressed many of the methodological issues mentioned in the literature. One particular improvement that can be made when designing a future study is to include the staging of dementing illness with subjects. Staging will enable researchers to gain an understanding of the differential impact on subjects when various therapeutic modalities are being tested. More focussed research will be needed to determine which features of reminiscence (such as sensory input or interpersonal communications skills), and under what circumstances (such as group size or combination), will have greater or lesser benefits. Another aspect that warrants our consideration is the inclusion of intra-intervention observations or measures. Triangulation of quantitative and qualitative methods for the evaluation of process and outcome will provide valuable insights. Studies that are of longer duration or that are longitudinal in nature are needed.

To date, our current knowledge about dementing disorders may be unlikely to lead to treatments with an impact on the onset and progression of these illnesses (Ferris and Mittleman, 1996). For now, it is essential to develop effective psychosocial interventions that can promote the well-being of people with dementia. Reminiscence using a life story approach showed some promising effects on the well-being of people with dementia.

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