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Article type : Original Article

Title: Effect of a mindfulness program for long-term care residents with type 2 diabetes: A cluster randomized controlled trial measuring outcomes of glycemic control, relocation stress and depression

ABSTRACT

Aims: The aim of this study was to determine physical, behavioral and psychosocial effects of a newly developed mindfulness program for older adults with type 2 diabetes relocating to long-term care facility (LTCF).

Background: Taiwan is viewed as an 'aged society' with significant proportion of the population living in a long-term care facility (LTCF). Approximately one third of residents living in LTCFs have been diagnosed with type 2 diabetes and disruption to management of their glycemic levels is at risk for up to one year after relocating to a LTCF.

Design: A cluster randomized controlled trial was used to examine the effects of a newly developed mindfulness program on outcomes of glycemic levels, relocation stress and depression.

Methods: A total of 140 participants were recruited from six LTCFs in Southern Taiwan. A mindfulness program was delivered over nine weeks and consisted of meditations, education and exercise techniques that were delivered by a Registered Nurse trained in mindfulness strategies. Participants in the control group received routine care as provided in the facilities, including routine check-ups at diabetes clinics as necessary. Data were analyzed by Johnson-Neyman Technique and Generalized Estimating Equations.

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Results: In total, 120 residents completed the study. The majority of patients were female (64.8%), and 83.5% of the sample were financially supported by their children. The results showed significant improvements in glycated hemoglobin (HbA1c), relocation stress (Waldχ^2 = 78.91), depression (Waldχ^2 = 45.70) between groups. In the intervention group, the mean of HbA1c levels showed 16.4% reduction (Mean differences = 1.3; SD = 0.3). However, there were no significant differences in relocation stress and depression within groups.

Conclusion: The results provided positive effects of the mindfulness program for older diabetes people moving into LTCFs. The program will assist in future planning for diabetes care in LTCFs.

Implications for practice:

- To incorporate the mindfulness program into existing diabetes education programs for older people living in LTCFs.
- Further investigation on the sustainability of the mindfulness program is warranted.

What does this research add to existing knowledge in gerontology?

- This is the first RCT study to develop and evaluate a mindfulness program for older people with type 2 diabetes living in a long-term facility.
- This study addressed physical and psychological aspects for older people with type 2 diabetes.

What are the implications of this new knowledge for nursing care with older people?

- The newly developed mindfulness program demonstrates potential for improving glycemic levels and reducing relocation stress and depressive symptoms for older adults with type 2 diabetes living in long-term care facilities.
- Health professionals could carefully consider how relocation stress impacts glycemic levels and depression for older adults with type 2 diabetes moving into long-term care facilities.

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How could the findings be used to influence policy or practice or research or education?

The findings provide valuable information to support policy makers and clinicians considering implementing or incorporating mindfulness mediations and exercise techniques into current care for older people with type 2 diabetes in long-term care facilities

Clinical Trial Registry number (Retrospectively): NCT03950713 (registered on May 15, 2019)

Key words: Mindfulness; diabetes; long-term care; glycemic control; relocation stress; depression

1. INTRODUCTION

In 2016, the Taiwanese population aged over 65 years old reached 14.05% (3.2 million) (Social and Family Affairs administration, 2016), and subsequently, the country is now viewed as an 'aged society' (Lin & Huang, 2016; Ministry of the Interior Taiwan, 2017). According to Government reports, approximately 12.5% of the elderly population also had a physical disability and 1.5% of this cohort were living in long-term care facilities (LTCFs) (Social and Family Affairs administration, 2016). Additionally, approximately one third of residents living in LTCFs in Taiwan are diagnosed with type 2 diabetes, and this figure continues to grow (Liu et al, 2014). Furthermore, elderly patients in Taiwanese LTCFs are reported to have moderate to severe functional impairments and diminished physical ability, with concomitant loss of independence (Bekhet & Zauszniewski, 2014; Retornaz, Grino, Mari, & Oliver, 2017; Gadsby, 2018; Schmitt et al., 2015; Katarzyna et al., 2015). It is therefore recognized that relocating to a LTCF may have significant impact to an elderly person's quality of life.

Relocation has been defined as a "passage from one life phase, condition or status to another, a multiple concept embracing the elements of process, time span, and perception" (Chick & Meleis, 2010, p. 25-26). Relocation to a LTCF is a significant stressful life event for older adults and has potentially caused negative psychological outcomes (Fitzpatrick &Tzouvara, 2017). The impact of

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this type of relocation is more significant for older adults with type 2 diabetes. It is reported that within one year of moving into a LTCF residents with type 2 diabetes develop persistently higher blood sugar levels and are more likely to be hospitalized than people who have been living in the LTC over one year (Lin, Tsai, Chiang, & Koo, 2010; Newton et al., 2013; Yang, Chen, Kuo, &Lee, 2014). According to Mello & O'Connor (2016), approximately 18.4% of residents who were suddenly and involuntarily relocated to a LTCF died within the first year. Residents relocating from a comfortable and familiar home to a nursing home or LTCF are reported likely to experience a variety of issues at different times. For example, prior to moving into a LTCF, residents may feel the desire to give up, and experience stages of grief and/or loss; During the move into a LTCF (also known as the transition phase), residents may feel abandonment and vulnerability and after moving into a LTCF, residents may require up to a year to make necessary adjustments and settle in to their new normality. Although residents, family members and caregivers may expect the stress of relocation to diminish soon after the resident has become oriented to their new home, clinical symptoms may continue throughout the first year (Fitzpatrick & Tzouvara, 2019).

Furthermore, studies show negative psychosocial impact on people with type 2 diabetes relocating to LTCFs (Andreassen, Sandbery, Kristensen, Solvik, Kjome, 2014; Garcia & Brown, 2011). Such impacts include increased stress, anxiety, depression, confusion, feelings of loneliness and hopelessness (Yang, Chen, Kuo, & Lee, 2014; Fitzpatrick & Tzouvara, 2018). More than 30% of residents present with depressive symptoms and decreased physical, cognitive and social function (Fiocco & Mallya, 2015). Consequently residents are less likely to adhere to treatment regimens and physical activity recommendations, which can result in poor management of blood sugar levels (Khullar et al., 2016; Asuzu, Walker, Williams, & Egede, 2017; Indelicato et al., 2017; Gonzalez et al., 2018; Retornaz, Grino, Mari,& Oliver, 2017; Brownley, Boettiger, Young, & Cefalu, 2015).

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Literature reveals the relationships between glycemic levels and micro- and macro-vascular diabetic complications. HbA1c levels >8.0% increase risk of all-cause mortality in older adults with diabetes and are associated with poor cardiovascular outcomes (Palta, Huang, Kalyani, Golden, Yeh, 2017; Schmitt et al., 2015; Asuzu, Walker, Williams, & Egede, 2017; Indelicato et al., 2017). However, given greater concerns about hypoglycemia episodes with asymptomatic symptoms (Abdelhafiz, Rodríguez-Mañas, Morley, & Sinclair, 2015), studies urge that along with carefully monitoring hyperglycemic episodes, it is also important to consider a more appropriate blood sugar level for this at-risk group (Retornaz, Grino, Mari, & Oliver, 2017; Brownley, Boettiger, Young, & Cefalu, 2015). Thus, less stringent HbA1c levels of 7.0% (53 mmol/mol) for older adults are recommended (American Diabetes Association, 2019; Inzucchi et al., 2015).

Previous research has demonstrated reduced psychological distress, anxiety, depression, and improved quality of life, well-being and glycemic control for patients with chronic conditions such as type 2 diabetes, cancer, chronic pain, and eating disorders, following implementation of a mindfulness program (Hartmann et al., 2012; Alsubaie et al., 2017; Dinardo et al., 2017; Pascoe, Thompson & Chantal, 2017). Mind-body approaches for stress control and depression treatment can employ imagery, biofeedback, yoga, and/or meditation. The key feature of a mindfulness program is self-regulation of one's experience, including thoughts, feelings and attitudes toward an experience (Pascoe, Thompson, & Chantal, 2017; Alsubaie et al., 2017). Mindfulness programs can also provide training in body scan meditations, yoga stretches and postures, mindful meditation, awareness and use of a nonjudgmental perspective (Whitebird, Kreitzer, Vazquez, & Enstad, 2018; Gallegos, Hoerger, Talbot, Moynihan, & Duberstein, 2013). Despite the apparent benefits of mindfulness programs, limited evidence is found for such programs designed specifically for older adults with type 2 diabetes and living in a LTCF.

2. AIM

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This study aimed to evaluate the effectiveness of a newly developed mindfulness program for older adults with type 2 diabetes living in LTCFs. The primary outcome was glycemic level, with secondary outcomes being relocation stress and depression.

3. METHOD

3.1. Study design

A cluster randomized controlled, single blinded trial was used to examine the effect of the mindfulness program. Participants in the intervention group received the mindfulness program in addition to usual care. The control group received usual care provided in facilities, including routine check-ups at diabetes clinics, but no mindfulness related activities.

3.2. Settings

The study was undertaken across six hospital-affiliated LTCFs in Southern Taiwan. Each LTCF provided similar diabetes care programs and had capacity for 200 to 250 residents of similar ethnicities, age groups, and nurse-resident ratios.

3.3. Sample

After obtaining agreements from facility authorities to participate to the study, six centers were randomly allocated into the intervention group (3 facilities, n=66) or control group (3 facilities, n=74) (Figure 1). Across the facilities, were 1298 residents identified with chronic diseases, and 152 of these met the selection criteria. Potential participants were invited to take part in the study however, 12 residents declined at this stage due to “not having interest” or “feeling no need for an intervention.” Inclusion criteria comprised: resident’s age over 65 years old, being diagnosed with type 2 diabetes, moving into the facility within 12 months, no obvious delirium, confusion or current psychiatric illness as determined by the residents’ treating physician, and being able to communicate in Chinese. Participants were excluded if they were terminally ill.

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3.4. Sample size calculation and randomization

To identify significant differences between groups, it was determined that 60 participants per group were required. This was calculated on a total sample of 140, allowing for attrition rate of 20% on primary outcome of HbA1c, with 90% power and an α of .05 (Cohen, 1988; Tovote et al., 2014). Eight participants (2 in intervention; 6 in control group) had to subsequently withdraw from the study due to moving out of their facility or being hospitalized before completion of the intervention. In total therefore, 60 participants in the experimental group and 60 participants in the control group completed the study and were included in the data analyses (Figure 1). All sessions in the mindfulness program were delivered by a Registered Nurse who had received additional training qualifications teaching mindfulness. A research assistant, blinded to the study protocol, was employed to undertake data collection at baseline (T0), three (T1), six (T2) and nine (T3) weeks.

Insert Figure 1 here

3.5. Mindfulness program

The content of the intervention was adapted from a mindfulness program developed by the Taiwan Mindfulness Association for people with mental illness (Huang, Li, Huang & Tang, 2015). For this study, the program consisted of nine weekly sessions, each of 1.5-hour duration and was undertaken by groups of 8 to 10 participants. Each session was held in an indoor social activity space at each LTCF and included 30 minutes of mindful deep breathing relaxation and 60 minutes of practicing mindfulness activities. The nine sessions also included content as follows: 1) What is mindfulness, 2) Cognitive and creative responses to stress, moving, 3) The happiness and strength of living, 4) How the restrictive effects and cognition shape our experience, 5) Stress reaction / automation / missing, 6) Communication and interpersonal relationships of mindfulness, 7) Full day of mindfulness exercises, 8) Fully integrated mindfulness into life, 9) Living mindfully in a new “home”.

The mindfulness program focused on strategies that can assist managing diabetes distress for participants using three new techniques. Firstly, through practicing body and meditation exercises

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which encourage being open to the awareness and acceptance of transferred life experiences. More specifically, this encourages a moment-to-moment awareness of one's experience without judgment. For example, mindful attention exercises allow the residents to behave in a less reactive and more reflective manner when confronted with transferred life stressors. Secondly, mindfulness meditation techniques were provided to allow residents to cope with difficult thoughts and feelings related to diabetes, such as encouraging attention to the present moment and choosing to respond skillfully rather than reacting automatically to external events, thoughts or emotions as they arise. Thirdly, a specific topic was provided for each session, for example how to stay mindful when life style is changed, or how to pay attention to the present moment in a manner aligned to Chinese value of peacefulness.

3.6. Measurements

The primary outcome of glycemic control was measured by HbA1c, with data were collected from the participants' medical records at baseline and at 3 months. Secondary outcomes of depression and relocation stress were measured by the Chinese version of the Depression and Anxiety Stress Scale (DASS-21) and Relocation Stress Scale (Yang, Chen, Kuo, & Lee, 2014; Moussa, Lovibond, & Laube, 2003). Except HbA1c, depression and relocation stress data were collected at baseline, 3, 6 and 9 weeks by the research assistant who was blinded to group allocations.

The DASS-21 (Chinese version) consists of 21 items with a 4-point Likert scale with good internal consistency of .92 for depression, .94 for anxiety, and .91 for stress subscales (Moussa, Lovibond, & Laube, 2003). The Relocation Stress Scale (Chinese version) consists of a 29-item functional assessment of health status with a 5-point Likert scale (5 is the highest, 1 is the lowest), and has good internal consistency of .72 (Yang, Chen, Kuo, & Lee, 2014).

3.7. Data analysis

The Statistical Package for the Social Sciences (SPSS) Version 22.0 was used to analyze the data

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(IBM Corp 2016). Following Intention-to-Treat (ITT) principles, analysis was undertaken at TI to compare differences between participants who completed the study and those who withdrew. No significant differences were identified therefore further data analyses were performed only on participants who completed the study. Descriptive statistics such as χ^2 test or t-test were used to examine differences in demographic data. The generalized estimating equation (GEE) approach was the appropriate statistical test for analyzing depression and relocation outcome variables, as well as time and interaction effects between- and within-groups (Diggle, Heagerty, Liang, & Zeger, 2002). 'Time' was treated as a categorical variable in the GEE. The GEE can be used to analyze data regardless the normality of distributions and can take within subject correlations into account, hence it was determined to be appropriate and precise for analyzing the longitudinal data in this study. Repeated measure ANOVA approaches were deemed inadequate because they do not use a model of the covariance among repeated observations to increase the efficiency of analysis on parameter estimates, they generally require balanced and completed datasets and are restricted to analysis of normally distributed response variables, not allowing for analysis of covariates that may change over time. The objectives of the study were to explore the population average effect (using GEE) rather than the individual specific effect (using latent growth curve); several types of within-subject correlation can be specified in GEE, whereas compound-symmetry correlation is assumed in latent growth curve analysis (i.e. variances and co-variances are assumed equal). Therefore, we believe GEE was the most appropriate analysis for depression and relocation outcome variables across the four time points post-test (Diggle, et al., 2002). Johnson-Neyman Technique was conducted on HbA1c if time and group interaction effects were identified. A p-value of less than .05 was regarded as a statistically significant.

3.8. Ethical considerations

Full ethics approvals from the Institutional Review Board (IRB) of the human research ethics committees were obtained from University Hospital (approval number: FYH-IRB-104-06-02). The Helsinki Declaration was adhered to also. Individual resident's informed consent was obtained.

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Privacy, confidentiality, and voluntary participation were ensured. Data were kept in a university secure drive, protected by password, and only authorized researchers had access to the data.

4. RESULTS

4.1. Participants' demographic profiles

A total of 140 participants were recruited; 120 of them completed the study (n= 60 per group). Most participants reported the decision of moving into the facility was not self-made (95.3%). The majority were female (64.8%), were married (90.6%), and received financial support from their children (83.5%), 46.2% of participants moved into the facility within 12 months. The mean age was 78.9 years (SD =7.3; ranged from 65-84 years). There were no significant differences in control and intervention groups, indicating similar demographic profiles of the participants (Table 1).

Insert Table 1 here

4.2. Glycemic levels

The levels were measured by glycated hemoglobin (HbA1c) at baseline and at 3 months. The mean HbA1c levels in the intervention group showed 1.1% reduction (M = 8.0; SD =1.8) to (M = 6.9; SD = 1.3) (t= 5.6; p <.001) over time. In comparison, the control group reported a non-significant HbA1c level increase of by 0.1% from baseline to 12-week respectively (M = 6.6; SD = 1.9) to (M = 6.7; SD = 1.9) (t= -0.31, p=.75). However, because the interaction of group and baseline HbA1c was significant (F= 9.47; p=.003), Johnson-Neyman-Technique rather than independent samples one-way ANCOVA was used to explore the intervention effect on HbA1c. The result showed mindfulness program did significantly improve HbA1c among residents with baseline values greater than 6.75%. There were more improvements in mindfulness program group compared to the control group (Figure 2).

Insert Figure 2 here

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4.3. Relocation stress

4.3.1. Interaction effect between different time points and different groups

Results of GEE indicated that there were significant interaction effects between four-time points and two different groups in the relocation stress score (Waldχ^2= 78.91; p<.001) (see Figure 3A).

4.3.2. Differences between groups at each post-test

Controlling for baseline measures, two-group differences in each post-test indicated that both the intervention group (IG) and control group (CG) had significant differences in relocation stress scores after 3 weeks (T1 adjusted mean: IG =72.68; CG = 78.27), 6 weeks (T2 adjusted mean: IG = 66.71; CG = 74.54) and 9 weeks (T3 adjusted mean: IG= 54.39; CG = 78.71) of the study, respectively. The adjusted relocation stress scores of participants in the intervention group were significantly lowered than those in the control group at T1 (Waldχ^2= 9.45; p <.01), T2(Waldχ^2 = 25.28; p <.001) and T3 tests, respectively (Waldχ^2= 82.51; p<.001).

4.3.3. Differences across four time points within each group

Results indicated that relocation stress scores across four time points were statistically significant in the intervention group (Waldχ^2 = 209.75; p<.001). The scores in the post-tests were all smaller than the pretest scores (Table 2), indicating that after the mindfulness intervention, participants' relocation stress decreased significantly and had improved at the 9th week (T3). Unlike results were found in the control group, their location stress mean scores decreased at T2 (M =73.33; SD =9.26) but increased slightly at T3 (M =78.25; SD = 17.17). However, the control group participants showed no significant differences in relocation stress scores across four waves of time (Waldχ^2 = 12.60; p>.05) (See Table 2).

Insert Table 2 here

4.4. Depression

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4.4.1. Interaction effect between different time points and different groups

Results identified a significant interaction effect between the four-time points and two different groups in the depression scores (controlling for baseline test) (Waldχ^2 = 45.70; p <.001) (Figure 3B).

Insert Figure 3B here

4.4.2. The differences between the two groups at each post-test

Controlling for baseline test, two-group differences in each post-test of depression scores showed that intervention and control groups had significant differences in depression scores (T1 adjusted mean: IG = 32.85; CG = 40.27) (T2 adjusted mean: IG = 29.53; CG = 37.82) (T3 adjusted mean: IG = 23.01; CG = 41.09) respectively. The adjusted depression scores of participants in the intervention group were significantly lower than those in the control group at T1 (Waldχ^2 = 17.86; p <.001), T2 (Waldχ^2= 26.40; p <.001) and T3 (Waldχ^2 = 138.63; p<.001) respectively.

4.4.3. The difference among four time points within each group

Results indicated that depression scores among four-time points were significantly decreased in the intervention group (Waldχ^2=116.94; p<.001). The scores in the post-tests were all smaller than the pre-test scores (Table 2), indicating that after the intervention, participants' depression scores decreased significantly by the 9th week of intervention. This was not significant in the control group (Waldχ^2=6.69; p >.05), although there was a decrease at T1and T2, but an increase at T3 (See Table 2).

5. DISCUSSION

The improved results in relocation stress, depression and HbA1c levels showed that the mindfulness program was an effective approach for older adults with type 2 diabetes living in a residential care facility. A progressive reduction in HbA1c levels was seen in intervention groups, from 8.0% to

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6.9% (a reduction of 1.1%) in the intervention group and from 6.6% to 6.7% (an increase of 0.1%) in the control group. The decrease in the HbA1c from baseline was significant ($p<.001$) in the intervention group and a non-significant increase was seen in the control group ($p =.75$).

The findings confirm a previous study suggesting mindfulness programs can improve glycemic control (Whitebird, Kreitzer, Vazquez, & Enstad, 2018). This finding is also consistent with previous studies of the importance of HbA1c levels in diabetes care. A 1% decrease in HbA1c has been estimated to lead to a 21% decrease of mortality (Chiang et al., 2018; Palta et al., 2017). Residents in the intervention group achieved a 1.1% reduction in HbA1c levels, which proposes significant health benefits. A significant HbA1c reduction in older adults with diabetes could lead to less complications, such as retinopathy and other microvascular conditions (Nathan, McGee, Steffes, & Lachin, 2014; Yun et al., 2016). Furthermore, the benefits of HbA1c reductions have been reported in a previous study demonstrating that a percentage point decrease in HbA1c (from 8% to 6.9%) was associated with a 40% reduction in the risk of complications (Nicholas, Charlton, Dregan, & Gulliford, 2013).

The secondary outcomes showed a positive response to the mindfulness program when compared with baseline data. Statistically significant results were found in relocation stress and depression scores between the intervention and control groups. These findings were consistent with previous studies reporting on a mindfulness program where increased engagement in the practice of a series of meditative strategies, (such as awareness of individual sensations, bodily states, thoughts, consciousness and nonjudgmental awareness of present moment experience) were found to be a viable protective factor to curtail the hazards of stress (de Frias & Whyne, 2015; Li & Bressington, 2019; Van Son et al., 2013). The learnt skills of a mindfulness program are reported to effectively reduce negative mood states (Van Son et al., 2013), with improvements noted in patients with type 2 diabetes and their levels of emotional distress, quality of life, and individual ability to change

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stress perceptions (Van Son et al. (2013).

Although evidence shows the benefits of mindfulness program for a range of clinical populations on depression, anxiety and stress in older adults (Li & Bressington, 2019). the present study is the first cluster randomized controlled trial for older people with diabetes living in LTCFs. The mindfulness program in this present study conducted specific sessions which were specific to the resident's situation which may have been crucial to influencing the significant results of reducing relocation stress and depression specifically for older adult with diabetes in LTCFs (Wetherell et al., 2017; Nykicek, Dijksman, Lenders, Fonteijn, & Koolen, 2014; Chen, Yang, Wang, &Zhang, 2013). Research suggests that stress and depression in older adults with chronic diseases might differ to presentation of stress and depression in younger adults (Fitzpatrick &Tzouvara, 2018; Li & Bressington, 2019; Geiger et al., 2016; Karlin, et al., 2013; Mallya & Fiocco, 2016; Dinardo et al., 2017). The findings of this study support the mindfulness intervention as a way of minimizing the relocation stress and depression in this specific cohort.

5.1. Strengths and limitations

The major strengths of this study were the contexts of sessions used to implement friendly customized-training elements of the mindfulness program for participated residents. However, limitations are acknowledged. One limitation is that the study focused on a specific cultural Taiwanese population, thus the generalizability of findings is restricted. Also due to time constraints results may not support longitudinal effects, after 9 weeks, of the program on the same outcomes.

5.2. Future research

Implications for clinical practice for long-term care facilities include incorporating the mindfulness program into existing diabetes education programs. A longitudinal study on changes in HbA1c, and psychosocial outcomes (such as relocation stress, depression) is recommended. Future research is

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also suggested to investigate the potential time for training for healthcare providers to determine any cost benefits of the program.

5.3. Conclusion

This present study reported the first randomized controlled trial of a mindfulness program for residents with type 2 diabetes within one year of moving into a LTCFs on glycemic control, relocation stress, and depression. The results highlighted the benefits of using strategies in the mindfulness program to promote quality diabetes care for residents in long-term care facilities.

CONFLICT OF INTEREST

The authors declare that they have no competing interests.

AUTHOR CONTRIBUTIONS

Concept develop and study design: SMC, HSL, C-JW; data collection and analysis: SMC, HSL, C--JW; manuscript preparation: SMC, C-JW, HSL, JA.; manuscript appraisal and editing: SMC, C-JW, HSL, JA; All revisions: SMC, C-JW equally. Final approvals: SMC, C-JW, HSL, JA, RM.

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TABLE 1. Demographic and clinical characteristics in baseline

Variable	All		IG(n=62)		CG (n=66)		t/χ^2	p
	n	%	n	%	n	%		
		Mean(SD)		Mean(SD)		Mean(SD)		
Age	128	78.91(7.34)	62	78.85(7.62)	66	78.95(7.12)	.07	.93
Gender							.38	.71
Male	45	35.2	22	35.4	23	34.8		
Female	83	64.8	40	64.6	43	65.2		
Financial support							.50	.48
Self	9	7.1	7	11.1	2	3.0		
Children	107	83.5	49	79.2	58	87.8		
Spouse	2	1.6	1	1.6	1	1.5		
Others	10	7.8	5	8.1	5	7.7		
Marital status							.03	.87
Single	9	7.0	2	3.2	7	10.6		
Married	116	90.6	58	93.6	58	87.9		
Divorced	3	2.4	2	3.2	1	1.5		
Moved in facility time							.37	.54
1month	18	14.1	9	14.5	9	13.6		
3months	23	17.9	11	17.7	12	18.2		
6months	28	21.8	14	22.6	14	21.3		
1year	59	46.2	28	45.2	31	46.9		
Decision of moving into the facilities (self made)							.69	.41
Yes	6	4.7	2	3.3	4	6.0		
No	122	95.3	60	96.7	62	94.0		

*p < .05

IG, intervention group; CG, control group

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TABLE 2. Comparisons of score's levels between groups at different posttests and across four waves of times in individual groups

Time / Group	**T0** **M (SD)**	**T1** **M (SD)**	**T2** **M (SD)**	**T3** **M (SD)**	**Wald$\chi^{2,b}$**	***Bonferroni's*** **Post hoc test**
Relocation stress						
Intervention	80.17(12.77)	74.55(12.82)	67.91(12.82)	54.85(11.91)	209.75***	T0>T1>T2>T3
Control	73.90(14.49)	76.40(14.03)	73.33(9.26)	78.25(17.17)	12.60**	n.s.
Wald$\chi^{2,a}$		9.45**	25.28***	82.51***		
Depression						

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Intervention	44.20(16.57)	33.77(12.55)	30.20(11.89)	23.17(5.35)	116.94***	T0>T1>T2>T3
Control	39.78(11.15)	39.35(10.22)	37.15(12.39)	40.93(18.12)	6.69	n.s.
Wald$\chi^{2,a}$		17.86***	26.40***	138.63***		

T0, baseline test; T1, 3 week test; T2, 6 week test; T3, 9 week test.

*p < .05; **p <.01; ***p < .001; .n.s.: non-significant (p > .05)

[a] GEE of the differences between the two group at each posttest (controlling for baseline)

[b] GEE of the difference among four time points within each group

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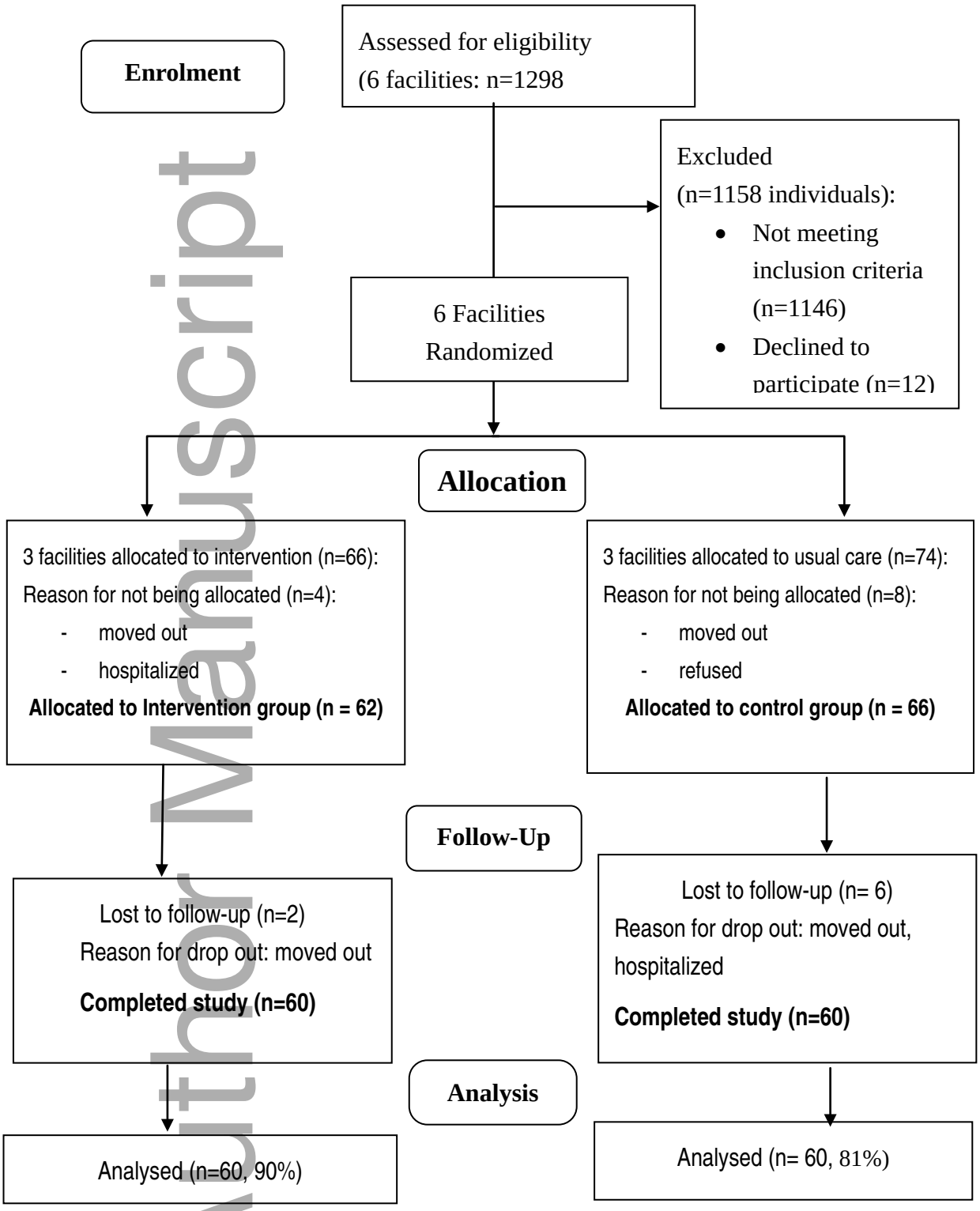

Figure 1. CONSORT flow diagram of the trial

**140 individuals stayed within their allocated facility, randomization applied at facility level only*

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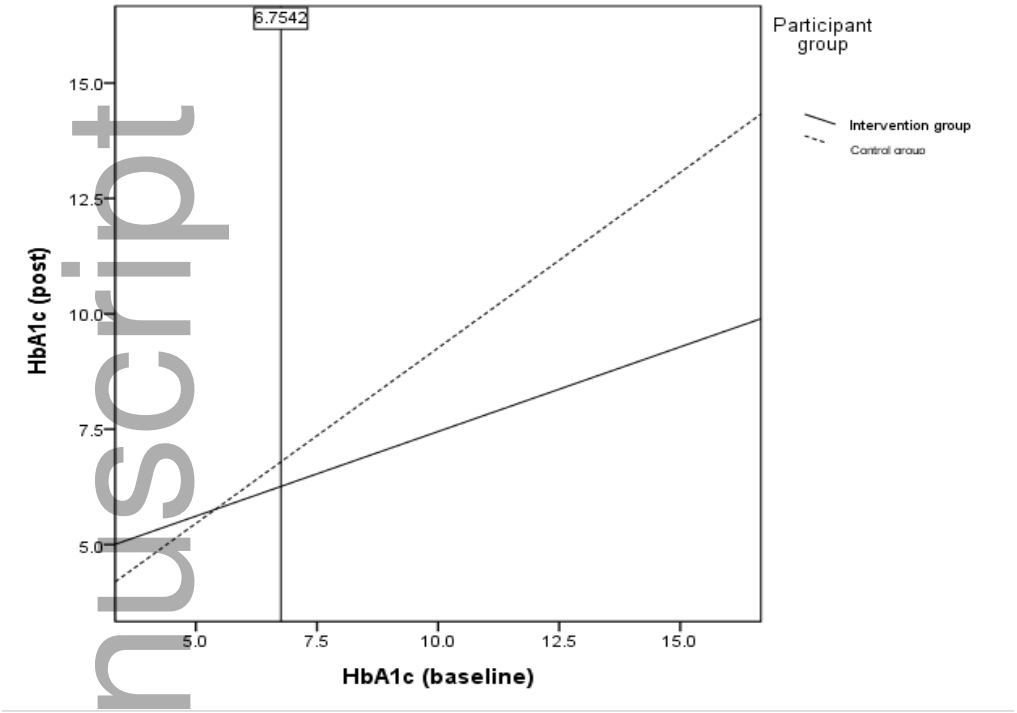

FIGURE 2. The regression line of HbA1c outcome measure against baseline data in each group and the cut points of significant differences between two groups.

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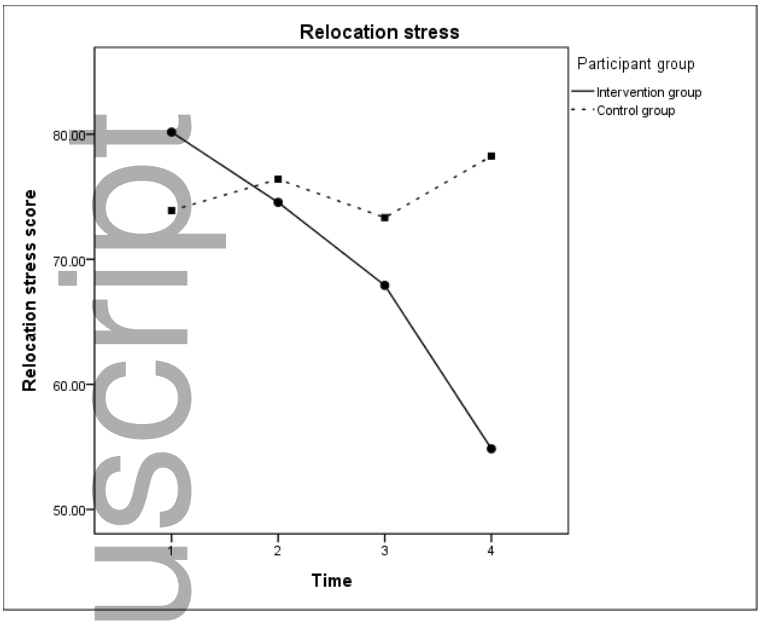
(A)



(B)

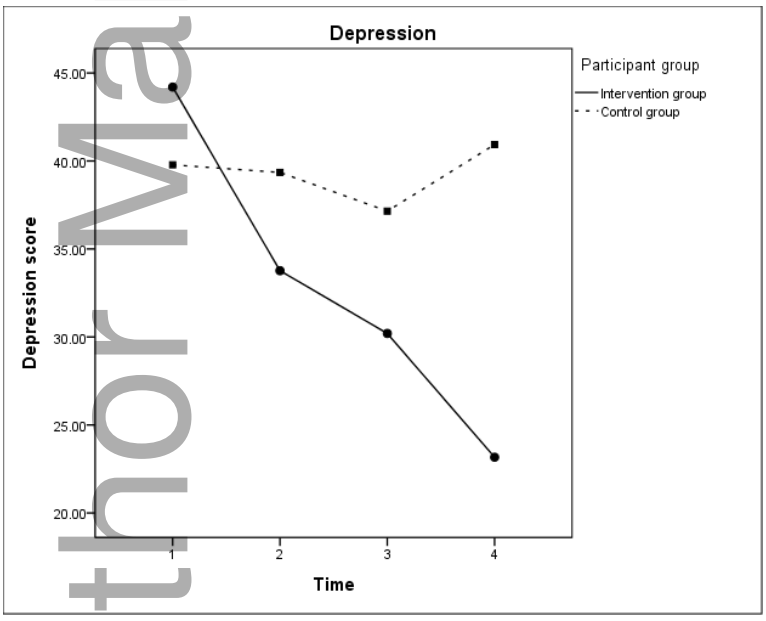


Figure 3. Mean values of the relocation stress (A) and depression (B) scores in the two groups across four timepoints.

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