INTRODUCTION

Diabetes has reduced life expectancy, and it is estimated that more than one third of Americans born in 2000 have the risk of developing diabetes in their lifetime (Narayan, Boyle, Thompson, Sorensen, & Williamson, 2003). The New York Times recently carried an editorial about this crisis (Kleinfield, 2006).
Korea has also seen a sharp increase in diabetes in adults in recent decades. The prevalence of diabetes rose from 1% of the general population in the 1970s to approximately 3% in the late 1980s. In 2000, 13.5% of males and 10.7% of females aged 30 years or older had diabetes (Chae et al., 1998).

Strict glycemic control has proven to be beneficial in preventing and delaying complications related to diabetes (Stratton et al., 2000). However, controlling blood glucose without lifestyle change has not been effective because unhealthy lifestyle choices such as overeating, lack of exercise and stress are known to influence glycemic control (Matsumoto, Ohno, Noguchi, Kikuchi, & Kurihara, 2006).

Studies that focused on education programs about diet and/or exercise in patients with type 2 diabetes have shown generally positive effects in the short term (i.e., 3–6 months) (Norris, Engelgau, & Narayan, 2001). However, maintenance of the positive effects requires more than a physical regimen. Behavior change and health outcomes are known to be influenced by reciprocal relationships between metabolic control and psychosocial variables such as anxiety and social support (Jirkovská & Hrachovinová, 2005). Therefore, adding a behavior modification program to the physical regimen would add more potency to the intervention for glycemic control. In addition, patient success in adhering to the regimens is associated with interaction and relationship with health care professionals including nurses (Bernard & Krupat, 1994; Lo, 1999). Hence, comprehensive interventions in the clinic for patients with diabetes are important for changing their behaviors.

Yet, only a few studies to date have examined the combined effects of physical and behavioral interventions that are relevant to patients with diabetes (Bijlan et al., 2005), nurse-led comprehensive interventions (Clarke, Crawford, & Nash, 2002) and the long-term effect of diabetes control interventions (Norris et al., 2001).

Among chronic diseases, diabetes is one of the most demanding in terms of behavioral changes (Cox & Gonder-Frederick, 1992). The outcome of diabetes treatment is highly dependent on the patient having a healthy lifestyle. Lifestyle, including an appropriate diet and regular exercise, has been reported to control diabetes effectively (Klein et al., 2004). However, substantial patience and effort are required to form healthy eating habits and to continue regular exercise. Hwang, Yoo, and Kim (2001) reported that the compliance level of patients with type 2 diabetes diminished over a 4-month period following intervention by nurse researchers. Wing, Venditti, Jakicic, Polley, and Lang (1998) and Aas, Bergstad, Thorsby, Johannesen, and Birkeland (2005) reported that patients with diabetes could not maintain the effects of glucose control over a 9-month period following intervention. These findings suggest that good lifestyle habits and glucose control are difficult to maintain 4–9 months after the intervention, even though they showed positive effects during the intervention. Previous lifestyle modification studies (Yoo et al., 2004; Yoo, Kim, & Lee, 2006) showed short-term effect (0–2 months after finishing the program) of glycemic control; they have not yet reported the effect 6 months after finishing the program.

For long-term effects, patients were required to sustain their efforts to continue self-management with increasing self-efficacy for control of diabetes (Rapley & Fruin, 1999). Nurses should reinforce the principle of self-efficacy when they teach patients how to maintain a healthy lifestyle. Initially, nurses should focus on behavior change based on the general sense of self-efficacy as suggested by Bandura (1986), however, they should shift the focus to task-specific efficacy to maintain the learned behaviors and sustain various new skills (Raply & Fruin). For example, nurses should help patients build up their self-confidence in managing healthy lifestyle for controlling diabetes (general self-efficacy) and then teach them about balanced diet and daily exercise (task-specific efficacy) so that patients can continue to practice newly acquired behaviors.

Therefore, we developed a comprehensive lifestyle modification program (CLMP), which was a nurse-led education and counseling program incorporating key components of self-efficacy (Bandura, 1986) in addition to well-known variables such as diet and exercise.
The aim of this study was to describe the effectiveness of the CLMP on glycemic control and body composition in patients with type 2 diabetes and to analyze the long-term effects of the CLMP.

METHODS

Design
This study used a two-group experimental design with repeated measures and a random assignment on a convenience sample of patients in a clinic.

Subjects
The study subjects consisted of 48 adult patients with type 2 diabetes who had visited the diabetic center of one of the university medical centers in Korea. The study was conducted from October 2003 to April 2005. Inclusion criteria were: adults aged over 35 years, diagnosed with type 2 diabetes, not receiving insulin therapy, not having any change in their therapy (e.g., drug dosage or any additional drugs) for at least 3 months prior to the start of the study, not having a history of psychiatric disorders or eating disorder, and able to participate in regular walking exercise or swimming.

Sample size was estimated using a power table (Machin, Campbell, Fayers, & Pinol Alain, 1997), and it showed that 32 was sufficient in both groups for repeated measures, at a significance level of .05, correlation of .60, effect size of .60, and power of 80%. However, we recruited 60 to accommodate possible attrition. The effect size was calculated based on a major outcome variable, such as glycosylated hemoglobin (HbA1c), in a previous study that examined the effect of an exercise and diet program on improving glucose index (difference between the means = 0.6, SD = 1) (Boule, Haddad, Kenny, Wells, & Sigal, 2001).

Due to the nurse researchers’ schedule and availability of space for group meetings, patients were recruited in eight phases over 8 months. The number of patients ranged from 5–8 per phase. Five patients in the experimental group were excluded because they had a change in drug regimen (3 patients) or they participated in less than 50% of the 4-month CLMP (2 patients). A total of 7 patients in the control group were excluded because 4 patients changed drug regimen and 3 patients did not complete follow-up tests. Thus, the experimental group had 25 patients, and the control group had 23 patients, for a total of 16 males and 32 females.

Procedure
Patients were recruited from a diabetes clinic which they visited every 3 months for a doctor’s check-up. Researchers approached patients while they were waiting in the clinic and asked if they would be interested in participating in a research project. With their initial agreement, researchers then explained the study purpose and procedure. Researchers assured patients that their anonymity and the confidentiality of their responses throughout the study and in the publication would be maintained. Once written consent was received, patients were assigned to the experimental or control group per phase by tossing a coin. Researchers obtained demographic information and made an appointment with all patients for the following measurements: fasting blood glucose, HgA1c, body weight and height, and visceral fat thickness (VFT). Medical history and medication profile were obtained from the patients’ medical records.

Two endocrinologists and one nursing professor who had expertise in researching patients with diabetes established the content validity of the CLMP. In addition, a pilot study was carried out to test the feasibility of the study using the CLMP (see below). Three nurse researchers carried out the pilot study upon completion of group training of 3 hours on the protocol. The results finalized the CLMP content and protocol.

Pilot study
Ten participants with type 2 diabetes were enrolled in the pilot study of the CLMP for 2 months. Education on exercise and diet was carried out on a one-to-one basis, and it included walking 150 minutes per week and consuming a calorie level that was determined by the goal of 7% reduction in weight in 6 months (Diabetes Prevention Program Research Group, 2003) on an individual basis.
The results of the pilot study: glucose level was reduced to $195 \pm 61.47$ mg/dl from the baseline level of $230 \pm 83.36$ mg/dl; body weight was reduced by 1.04% from the baseline of $60.03 \pm 5.53$ kg to $59.4 \pm 5.93$ kg. However, the changes were not statistically significant ($p > .05$).

Hence, the CLMP protocol was modified to increase the effect of the CLMP. First, exercise time was lengthened to 360 minutes/week (i.e., a 1-hour walk per day for 6 days per week), which is more in line with recent guidelines (Wing & Hill, 2001). Second, instead of one-to-one sessions, small group discussion sessions were planned to facilitate peer group support. Third, participants were asked to report twice weekly instead of daily on their diet and exercise activities, because most expressed difficulty in performing the tasks daily. Fourth, the goal of reducing body weight by 7% in 6 months (or 1.75% in 2 months during the pilot study) was considered ideal as a long-term goal over a 12-month period.

**Intervention: CLMP**

**Theoretical basis for the CLMP**

We developed a CLMP based on the key components of self-efficacy (Bandura, 1986), and the *Lifestyle Balance Program* (Diabetes Prevention Program Research Group, 2003). The CLMP focused on improving self-efficacy, including mastery of experience, vicarious experience, social persuasion, and reducing stress reactions (Bandura). The *Lifestyle Balance Program* served as a guide to the 4-month diet and exercise program of the CLMP.

**Contents of the CLMP**

Table 1 shows the content of the CLMP intervention. It was composed of education on diet and exercise regimen, self-recording of regimens, counseling, stress management, and support using the principles of self-efficacy. Sixteen weekly meetings were composed of 60-minute sessions. These included measurement and explanation about body composition and glucose level for 10 minutes; discussion about participants’ recording on diet consumption and exercise for 10 minutes; lecture and discussion about main topics for 30 minutes; and finally, explanation about the tasks to be performed until the subsequent meeting for 10 minutes. Following the weekly intervention period, nine monthly follow-up sessions were provided to the experimental group. Each follow-up session lasted 60 minutes, and the content was the same as that of the CLMP, but the lectures and discussion were more focused on participants’ questions and concerns, and counseling about difficulties that they had experienced during the previous month. The experimental group participated in the CLMP for 1 hour per week for 4 months, and the follow-up study continued for 9 months, which was a monthly visit, after intervention. The control group participated in a 1-hour educational group session on diabetic diet that is routinely taught by a dietitian in the clinic at the beginning of the study. Patients in both groups participated in a total of five measurements, four of which were post intervention.

**Dependent variables**

Glycemic indices were measured by fasting blood sugar (FBS) and HbA$_{1c}$. Body composition was measured by body weight, body mass index (BMI) and VFT. VFT was defined as the distance between the anterior wall of the aorta and the internal face of the rectoabdominal muscle perpendicular to the aorta (Kim et al., 2004). VFT was calculated by sonography (Logiq 9; GE Medical Systems, Milwaukee, WI, USA). Patients were examined in the supine position. Frozen images were obtained immediately after expiration to avoid the influence of respiratory status or abdominal wall tension.

**Ethical considerations**

Approval from the hospitals’ research and ethics committees was obtained before initiation of the study. Following the explanation about the purpose, procedure, and confidentiality and anonymity of the study by the researchers, patients were asked to sign the consent form.

**Data analysis**

Data were analyzed using SPSS version 11.0 (SPSS Inc., Chicago, IL, USA) for Windows. Patient characteristics are summarized using mean and standard
The Mann-Whitney $U$ test and $\chi^2$ test were used to test the homogeneity of the two groups. Changes in study outcomes (FBS, HbA1c, body composition) from baseline to 9 months post intervention were analyzed by repeated-measures ANOVA, in which main effect (group difference), time effect, and interaction effect were examined. A $p$ value of less than .05 was considered statistically significant.
RESULTS

Patient characteristics
The mean age of the 48 patients was 55.2 ± 7.31 years (range = 38–75 years), and the mean duration of diabetes was 9.8 ± 6.49 years (range = 1–23 years). There were no statistically significant differences between the experimental and control groups (Table 2). No statistically significant differences were found at baseline between the two groups with regard to the glycemic indices and body composition (p > .05).

Glycemic indices
Immediately after intervention, the experimental group showed a 16.6 mg/dl reduction in FBS, while the control group showed a 3.3 mg/dl reduction. At 9 months post intervention, there was a 25.6 mg/dl reduction in FBS in the experimental group, while the control group showed a 0.6 mg/dl increase. Analysis of FBS showed a time and group interaction that was statistically significant (F = 3.142, p = .016), but no effect of time (F = 1.704, p = .151), and a statistically significant difference between the two groups (F = 8.827, p = .005). The results demonstrated statistically significant differences in FBS change pattern between the two groups.

HbA1c in the experimental group showed a decrease of 0.91% at 6 months post intervention and decrease of 0.65% at 9 months from baseline. The control group showed an increase of 0.6% at 6 months post intervention and an increase of 0.25% at 9 months. HbA1c showed a time and group interaction (F = 3.088, p = .031), an effect of time (F = 2.742, p = .047), and a difference between the two groups that was statistically significant (F = 10.114, p = .003). The results demonstrated statistically significant changes in HbA1c over time, and significant differences in HbA1c change pattern between the two groups. These are shown in Table 3.

Body composition indices
Repeated measures analysis of BMI and waist circumference showed no significant time and group interaction, and between group differences (both p > .05); however, the effect of time was statistically significant (both p < .05). The results indicate that both groups demonstrated statistically significant changes in BMI and waist circumference over time, but there was no significant difference in the pattern of change between the two groups (Table 3).

DISCUSSION

Nurse researchers led the CLMP for patients with type 2 diabetes. The nurse’s role in the care of
patients with diabetes is diverse and includes not only providing physical care but also educating and counseling on what constitutes a healthy lifestyle. The significant improvement shown in the experimental group compared with the control group with regard to glycemic indices such as HbA1c and FBS over the 9-month follow-up period suggests that nurses’ education and counseling on diet and exercise had a significant impact. All of the elements of the CLMP integrated together may have provided

<table>
<thead>
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<td></td>
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<tr>
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<tr>
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<td>HbA1c (%)</td>
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<td>BMI (kg/m²)</td>
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Note. Post 0 month = immediately after intervention; Post 3 mo (6 mo, 9 mo) = 3 months (6 months, 9 months) post intervention; FBS = fasting blood sugar; HbA1c = glycosylated hemoglobin; BMI = body mass index; VFT = visceral fat thickness; Δbase = difference from baseline.
a synergistic effect on glycemic control and body composition.

Our results showed more improvement in HbA1c than the results of the meta-analysis reported by Norris, Lau, Smith, Schmid, and Engelgau (2002), which showed a decrease in HbA1c of 0.28% at the 1–3-month follow-up and of 0.28% at 4 months and beyond. Additionally, a 0.97% decrease and 0.9% decrease at 6 and 9 months post intervention are similar to the 1% reduction in HbA1c level noted by Norris et al. Our findings showed, in general, more improvement in HbA1c levels than previous studies that showed statistically significant reductions among participants with diabetes (Boule et al., 2001; Norris et al., 2001). For a 1% reduction in HbA1c, there was a 14% reduction in the mortality of patients with diabetes in the United Kingdom (Stratton et al., 2000). This suggests that our finding of 0.90–0.97% reduction in HbA1c at 6 and 9 months post intervention could have a similar impact on patient mortality. In addition, the statistically significant differences in repeated measures analysis found in glycemic indices between the two groups indicate that the effect of the CLMP in our study was real and sustainable up to 9 months post intervention.

A few studies have shown that a lifestyle change program is as effective as other treatments such as drugs. For example, lifestyle changes were almost twice as effective as metformin therapy in those with impaired glucose tolerance (Knowler et al., 2002). Lifestyle changes were as effective as insulin treatment in improving glycemic indices in patients with poorly controlled type 2 diabetes (Aas et al., 2005). However, it is important to take prescribed medication consistently so that behavioral intervention can be effective (Lauritzen et al., 2000). Our results suggest that CLMP is an added factor to pharmacological treatment because 68% of patients in the experimental group were still taking medication to control glucose levels.

In our study, weight loss in the experimental group was 1.03 kg (1.6%) at 9 months post intervention, and this was of a smaller magnitude than that found in other studies (Agurs-Collins, Kumanyika, Ten Have, & Adams-Campbell, 1997; Wing & Hill, 2001). This might have been due to a lower mean BMI in our participants than in the participants of the other studies (i.e., mean BMI in our study was 25.7, versus more than 33 in the other studies). It could also have been due to the dietary habits of our participants, who tended to overeat, particularly when eating away from home. The median exercise time of our participants was 6 hours per week (range = 2–15 hours) at 3 months post intervention. This exercise time is usually considered necessary for successful long-term weight loss (Klein et al., 2004). When these two factors (dietary habits, exercise time) are considered together, the lower reduction in weight loss found in our study was probably due to excess food intake rather than insufficient exercise.

Patients with type 2 diabetes with excess visceral fat are at increased risk for negative health consequences. VFT as measured by sonography has proved to be strongly correlated with metabolic syndrome and cardiovascular disease (Kim et al., 2004); hence, the reduced VFT found in this study could contribute to the prevention of cardiovascular disease.

The control group in our study showed weight reduction at 6 months post intervention and reduction in VFT at 3 months post intervention compared with baseline measurements, but these differences were not statistically significant. This may be related to the education (given at the beginning only) and feedback on the measurements of the same variables (5 times) given to the control group patients. Given the increasing prevalence of diabetes in Korea as well as in the rest of the world, nurses should provide comprehensive care that addresses both the physical and behavioral aspects of diabetes and coordinate multidisciplinary therapeutic regimens. This care approach should be used in all clinical settings, including community health centers.

The major weaknesses of this study are that the results cannot be generalized to diabetes patients in other clinical settings, and the patients who participated in this CLMP might have been more motivated for the treatment than the average patient with type 2 diabetes, which may therefore have contributed to the positive outcome in this study. One could also question which particular element of the CLMP
contributed to the positive results of this intervention? Although participants were educated about monitoring the intensity of exercise, we could not detect the influence of exercise intensity because participants were not required to check their exercise intensity consistently.

Although diet and exercise interventions have been found to be effective in improving diabetes in previous studies, its long-term effects are inconclusive. The CLMP was designed for nurses to provide comprehensive care to patients with type 2 diabetes so that the positive impact can be sustained for a long period of time. It was reasoned that providing care that integrates both education and counseling using the principles of self-efficacy, rather than using a fragmented approach, would bring forth positive synergistic effects on the long-term maintenance of glycemic control and body composition. Hence, what could be considered a weakness is in fact the unique feature and strength of this study.

CONCLUSION

Given the increasing prevalence of diabetes in Korea as well as in the rest of the world, nurses should provide comprehensive care that addresses both the physical and behavioral aspects of diabetes and coordinate multidisciplinary therapeutic regimens. A nurse-led comprehensive intervention such as the CLMP can help patients with type 2 diabetes maintain healthy lifestyles and lead to glycemic control. It is recommended that our intervention be tailored according to individual readiness for more successful glycemic control in patients with type 2 diabetes, and this needs to be tested in multiple clinical settings where nurses around the world practice.

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REFERENCES


