The Effectiveness of Intervention on Insulin Injection in Insulin-naive Patients With Type 2 Diabetes: Application of the Transtheoretical Model

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Introduction

If not well controlled, diabetes can easily trigger various complications. Maintaining a glycosylated hemoglobin (HbA1c) level lower than 7% has been established as the standard for diabetes control. Insulin treatment has been regarded as an effective method, and treating diabetes with insulin early on is widely considered as an important principle for treating patients with type 2 diabetes mellitus (T2DM) in the US and Europe. However, many studies have shown that patients with T2DM are often reluctant to change from oral medication to insulin treatment. Research has also found that patients with T2DM whose glycemic control was poor delayed insulin treatment by 7 to 8 years. Therefore, it is necessary for healthcare professionals to establish a comprehensive intervention plan to help patients with poor glycemic control to initiate insulin injection early and adhere to the treatment. However, as far as is known, little research has been done on this topic in Taiwan.

According to the Transtheoretical Model (TTM) proposed by Prochaska and Diclemente, people will experience different stages of change before the actual behavioral change takes place. Ineffectiveness of intervention to instigate behavioral change is largely due to failure to take into account the stage of change in which individuals are. The TTM suggests that decisional balance, which reflects the relative difference between pros and cons, is important for influencing the stage of change. In order to achieve behavioral change, the perceived pros of changing must be strengthened to outweigh the cons. In addition, individual must be self-convinced that the behavioral change is important for themselves. Subsequently, the process for behavioral change can be provided to facilitate behavioral change in individuals. The theory of TTM has

been applied to change various problematic behaviors, but so far, it has yet been used to improve the behavior of insulin initiation in insulin-naïve patients with T2DM. Thus, this study aims to assess the effectiveness of an intervention for insulin injection initiation based on the TTM in insulin-naïve patients with T2DM.

Methods

Study design

The present study adopts quasi-experimental design. To avoid contamination between participants in two study arms, cluster sampling is used. Patients with T2DM of an endocrinology clinic in southern Taiwan are assigned to the intervention arm, whereas patients at another endocrinology clinic in southern Taiwan are placed in the control arm. Eligible patients that match the inclusion criteria are recommended by doctors to initiate insulin treatment after getting the consent forms from eligible participants. Research assistants will subsequently collect baseline data from eligible participants. Afterwards, the participants in the intervention arm will receive the intervention. For the control arm, the participants will receive regular patient education originally administered at the hospital. Data for the participants in both study arms will be collected by research assistants at baseline, 3 months, 6 months, and 12 months post-intervention. The main outcome variable is change in HbA1c levels, while the change in stage of change, in insulin injection adherence, in appraisal of insulin injection, in patient empowerment, in self-efficacy for insulin injection, in diabetes distress, in quality of life, in triglyceride(TG), in total cholesterol (TC), in high-density lipoprotein cholesterol(HDL-C), in low density lipoprotein cholesterol(LDL-C), in urine albumin creatinine ratio (UACR), in estimated glomerular filtration rate(GFR) are secondary outcome variables. The outcome

variables and collection time points are summarized in Table 1.

Samples

The inclusion criteria of eligible participants are: (1) diagnosed with T2DM for at least half a year; (2) aged 20-70 years old; (3) controlling diabetes only through oral medication, without previous experience in insulin injection; (4) HbA1c≧8.5% as measured more than twice in the most recent year. Exclusion criteria were: (1) unable to communicate with language; (2) incapable of self-administering insulin injection due to visual or muscular impairment. Eligible participants who have been assessed and considered suitable for changing to insulin treatment by doctor will be included in this study.

Sample size estimation was done according to previous literature. An estimation of 63 participants in each study arm was calculated through setting a middle effect size of 0.5 between the two study arms in HbA1c levels, α of 0.05, and power of 0.8. Furthermore, an attrition rate of 20% was expected. Therefore, each study arm should include at least 76 participants.

Measurements

Biomedical indicator measurement

The HbA1c levels, triglyceride(TG), total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C), low density lipoprotein cholesterol(LDL-C), urine albumin creatinine ratio (UACR) will be collected through blood test. Estimated glomerular filtration rate(GFR) will be collected through urine test. Height and weight will be collected through body weight and height scales, and will be converted to body mass index (weight (kg)/ height(m) ^{2}.

Self-reported questionnaire

The other outcome variables will be collected by self-report questionnaire. The questionnaire will include following contents.

Demographic data & disease characteristics

Age, sex, educational level, duration of diabetes, duration of taking oral drug before insulin therapy will be collected at baseline. Insulin treatment regimen including type of insulin, dose, frequency of injection and blood sugar self-monitoring will be collected after participants receiving insulin injection.

Stage of change for insulin injection. A question of stages of change for insulin injection was developed. At baseline, the question was "If the doctor recommends that you initiate insulin treatment right now, what would be your opinion?" Three responses to this question included "never considered", "under consideration and might start within the next 6 months", and "likely to start immediately", which respectively represented three early stages of change — precontemplation, contemplation, and preparation. At the 3, 6, and 12 months post-intervention, the question was "what's the status of your insulin injection?" The responses were "taking insulin injection previously, but now is stop insulin injection and never consider to receive insulin injection again, "taking insulin injection previously, but now is stop insulin injection, consider to start insulin injection again within next 6 months", "still receive insulin injection but sometimes forget to inject" , "Continuously inject insulin but less than 6 months", "Continuously injected insulin and more than 6 months".

Insulin injection adherence. An 8-item Morisky Medication Adherence Scale was used to assess insulin injection adherence behaviors of participants. The total scores ranged from 7 to 11. The higher scores indicate, the better insulin injection adherence behaviors

Appraisal of insulin injection. A 13-item Decisional Balance for Inulin Injection scale was used in the study to assess the appraisal of insulin injection. The scale comprised subscales of positive and negative appraisal. Each item was rated from 1 (strongly

disagree) to 5 (strongly agree). Decisional balance for insulin injection was calculated by deducting the mean score of positive appraisal with that of negative appraisal. The higher score indicated the higher decisional balance for insulin injection.

Empowerment perception. A 13-item Chinese version of the Diabetes Empowerment Process Scale was used to assess the perceived level of empowerment by healthcare providers in participants. Each item was rated on a 5-point scale with scores ranging from 0 (strongly disagree) to 4 (strongly agree). The total score range from 13 to 65. A higher score indicated higher perceived patient empowerment.

Self-efficacy for insulin injection. A 4-item scale was used to assess self-efficacy for insulin injection in participants. Each item was rated on a scale from 0 to 4 with 0 indicating "no confidence", 1 indicating "20-30% confidence", 2 indicating "40-50% confidence", 3 indicating "60-70% confidence", 4 indicating "over 80% confidence". A higher score represented higher confidence in performing insulin injection.

Diabetes distress. An 8-item Chinese version of the short-form Problem Areas in Diabetes Scale was used to assess the levels of diabetes distress in participants. The response of each item was rated from 0 (not a problem) to 4 (serious problem). The total score ranged from 8 to 32. A higher score represented severer diabetes distress.

Quality of life. A 15-item Diabetes-Specific Quality-of-Life Scale was used to assess the subjective appraisal of participants in their perceived degree to which their current health-related aspects in life were affected by emotional suffering, social functioning, adherence to treatment regimen, and diabetic-specific symptoms. Each item was rated from "very much" (0 point) to "not at all" (4 points). The total score ranged from 0 to 60. A higher score indicated better quality of life.

Intervention plan of the intervention arm

The intervention plan contains three parts: (1) individual intervention; (2) insulin injection follow-up management; (3) motivational group activities. Different

intervention strategies are applied to patients according to their stages of change. In addition, a computerized information system will be applied to facilitate data management and recording by interveners. The strategies for individual intervention designed according to the stage of change and the corresponding process of change are shown in Table 2. Details of insulin injection follow-up management from preparation stage to maintenance stage are shown in Table 3. The motivational group activities from precontemplation stage to maintenance stage are shown in Table 4.

Usual care of the control arm

Participants in the control arm attend regular patient education at the hospital. The contents of the education plan are as follows:

1. Teach participants the method of injection following the standard procedure, including gathering insulin supplies, the steps of injection, and so on.
2. Hand out a step-by-step pictorial guide to participants after teaching them the techniques and supply preparation for using insulin pen. Fill in the type and dose of insulin and the site and time of injection on a sheet for participants and their family to refer to after they return home.
3. Recommend patients to administer blood-glucose self-monitoring and record the results.
4. Conduct a telephone follow-up 3 days after patient education to check on the condition of insulin injection. Schedule a return visit after a week, during which the doctor adjusts the medication according to the results of SMBG and instructs the rule for dose adjustment at home.
5. Provide a hotline for patients to seek consultation when they encounter difficulties or problems.
6. Play patient education video clips on insulin injection in the waiting room when patients come for return visits.

7. Provide patient education in small groups occasionally, in which insulin-treated patients are invited to share their experience and clarify questions.

Ethical consideration

The study is approved by the Human Experiment and Ethics Committee of two hospitals (NO. KMUHI-E(I)-20150262, TSGHIRB-1-105-05-163). Participants are informed of their rights to refuse participation in the study without any penalty. Only after the participants have signed the consent forms will data be collected from participants.

Data Analysis

The statistical software program SPSS 17.0 was used for data analysis. The Chi-squared test and independent t-test were used to compare differences in personal characteristics and outcome variables between the two groups before and after intervention. Paired t-tests were used to examine within-group differences at baseline, 3 months, 6 months, and 12 months post-intervention. A linear mixed-effect model that adjusted for the demographic data and baseline outcome variables was used to examine the changing amount of outcome variables from baseline to 3 months, to 6 months, and to 12 months post-intervention between the intervention and control arms. Participants were considered as a random effect. First-order autoregressive was used in the mixed-effect model analysis with the restricted maximum likelihood (REML) approach. A p-value < .05 was considered statistically significant.

Table 1. Outcome measures and collection time points

Measures	Baseline	3rd month	6th month	12th month
Demographic data & disease characteristics	✓	✓	✓	✓
Body mass index	✓	-	✓	✓
HbA1c	✓	✓	✓	✓
Lipids (TC, HDL-C, LDL-C, TG)	✓	✓	✓	✓
Renal function: UACR, GFR	✓	✓	✓	✓
Stage of change for insulin injection	✓	✓	✓	✓
Insulin injection adherence	-	✓	✓	✓
Appraisal of insulin injection	✓	✓	✓	✓
Empowerment	✓	-	✓	✓
Self-efficacy	-	✓	✓	✓
Diabetes distress	✓	-	✓	✓
Quality of life	✓	-	✓	✓

Table 2. Individual intervention plan

Stage of Change	Strategy	Process of Change
Precontemplation	• Use examples in which good/bad glycemic control has a positive/negative impact on significant others to help patients reflect on their own HbA1c control • Explain current health condition to patients through the changes in the curves of the their data • Use UKPDS Risk Engine to predict the risk of cardiovascular disease and cerebrovascular event in the future 10 to 20 years in individual patients	Consciousness raising
	• Build a well-established trusting relationship • Use empathic skills to recognize the feelings of patients (fear, worry, guilt, etc.) • Guide patients to explore the influence of glycemic control and physical health on their lives • Explain that accepting insulin injection does not mean failure of treatment or advancement of disease but the natural progression of diabetes • Assess the decisional balance for insulin injection and provide clarification • Guide patients to think about possible benefits brought about by insulin injection to themselves and their family	Dramatic relief
Contemplation	• Invite patients to compare the perceived pros and cons	Self-reevaluation

	• List all medications for treating diabetes and their mechanisms, maximum dose, expected range of improvement in HbA1c, possible side effects, and costs	
	• Enhance the positive effects of insulin injection • Guide patients to consider the importance of good glycemic control	Dramatic relief
Preparation	• Assess the decisional balance for insulin injection and provide guidance	Dramatic relief
	• Set short-term targets for glycemic control and insulin injection with patients	Self-reevaluation
	• Assess family support and provide patient education • Provide resources that give instant feedback and build a platform for instant interaction	Helping relationship
	• Systematic desensitization—Gradual self-administered insulin injection. Patients first receive insulin injection given by healthcare professionals at medical institutions, and then slowly perform injection by themselves from withdrawing insulin, pushing away air bubbles, and injecting. Give rewards for each progress made • Instruct patients in the techniques for insulin injection and medicine preservation • Use the results of blood-glucose self-monitoring to guide patients to	Counterconditioning

	think about the relationship between insulin injection, diet, and physical activity • Provide patient education on blood-glucose self-monitoring and assessment on the ability to deal with hypoglycemia • Ask patients to continuously keep a daily record of the dose, time, site of injection, administration of blood-glucose self-monitoring, and incidents of hypo/hyperglycemia in the "Health Guardian Pamphlet"	
Action	• Educate family members to provide support for patients • Build an instant online interactive system with professionals to provide feedback to patients	Helping relationship
	• Encourage patients to adhere to the insulin injection plan • Healthcare professionals conduct telephone interviews and schedule return visits for patients on a regular basis • Instruct patients how to adjust their diet and exercise flexibly according to insulin injection so as to decrease the chance of termination caused by barriers • Teach patients to adjust the dose of insulin according to the results of blood-glucose self-monitoring	Reinforcement management
	• Patients promise to set mid-term and long-term goals	Self-liberation

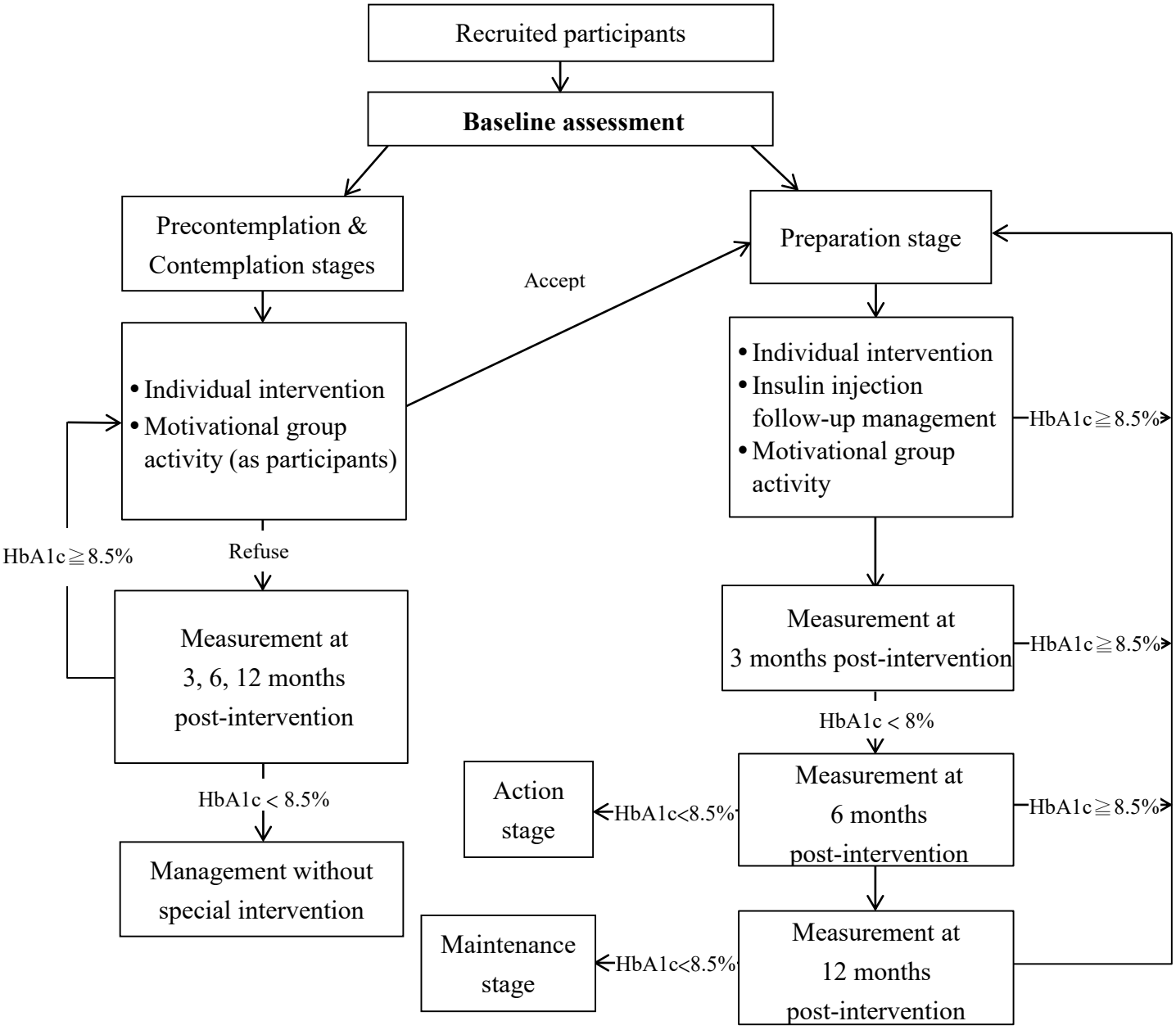
Table 3. Motivational group activity

Stage of Change	Strategy	Process of Change
Precontemplation	• Listen to fellow patients in the stages of action and maintenance share the benefits of insulin injection and the ways to overcome obstacles • Try out insulin injection • Use pictorial or multimedia materials to illustrate the relationship between insulin and blood-glucose	Self-reevaluation
Preparation	• Listen to fellow patients in the stages of action and maintenance share the benefits of insulin injection and the ways to overcome obstacles • Try out insulin injection • Use pictorial or multimedia materials to illustrate the relationship between insulin and blood-glucose	Self-reevaluation
Action	• Share experience in insulin injection and provide support and solution • Build mutually supportive partnerships with fellow patients	Reinforcement management
Maintenance	• Share successful experience with other patients to enhance the motivation of the patient to continue insulin injection	Reinforcement management

Table 4. Insulin injection follow-up management

Stage of Change	Strategy	Process of Change
Preparation	• Follow up problems with insulin injection, e.g. dose, site of injection, and technique	Reinforcement management
Action	• Guide patients to examine the relationship between insulin injection and changes in blood-glucose to strengthen their self-efficacy	Self-reevaluation
	• Ask patients to continuously keep a daily record of the dose, time, site of injection, administration of blood-glucose self-monitoring, and incidents of hypo/hyperglycemia in the “Health Guardian Pamphlet”	Counterconditioning
Maintenance	• Encourage patients regularly when HbA1c level decreases • Provide care and support	Reinforcement management

Figure 1. Intervention flowchart of the intervention arm



* Motivational group activities are held once every two months. Patients in the stages of action and maintenance will be invited to share their experiences during the activity.