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Original Article

Dissemination of evidence-base minimal psychological intervention for diabetes management in Taiwan adults with type 2 diabetes

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Abstract: This study evaluated the impact of minimal psychological intervention (MPI) on improving psychological well-being and glycemic control in patients with type 2 diabetes in Taiwan. A randomized controlled trial was conducted, comparing the MPI with usual care in 182 primary care type 2 diabetes patients 50 and older in Taiwan. Nurses called patients at home over a period of 6 weeks. Questionnaire data were obtained from 174 participants at baseline, immediately post intervention, and 1-month after intervention. Hemoglobin A1c levels (HbA1c) from baseline to eight months after the interventions were assessed from medical charts. The telephone-delivered MPI significantly reduced patients' diabetes-specific distress ($\beta_{MPI*time}$ = -3.24, P = 0.03), but not depressive symptoms, in those who have more than one complications. We also observed there is a trend suggesting those who diagnosed with diabetes within the last 10 years had greater reduction in diabetes-specific distress ($\beta_{MPI*time}$ = -1.58, P = 0.05). In patients whose baseline HbA1c were less than 8%, an improvement on the blood glucose level was observed 3 months after the intervention ($\beta_{MPI*period\ 3}$ = -0.18, P = 0.02). A telephone-delivered MPI might be a feasible and effective method for decreasing diabetes-specific distress and achieving better glycemic control in non-Western populations, especially in those who were at the early stage of diagnosis but had poor glycemic control.

Keywords: Type 2 diabetes, minimal psychological intervention, glycemic control, depressive symptoms, problem area in diabetes, middle-aged and older adults

Introduction

Adults living with type 2 diabetes often experience emotional distress [1], which can undermine their adherence to medications or other self-management activities and, in turn, to poor glycemic control [2-6]. Conventional diabetes education focuses primarily on increasing diabetes-related knowledge or self-care behaviors, and less so on psychological interventions that can improve patients' outcomes and self-efficacy for managing their diabetes. Existing interventions that focus on psychological interventions [7-10] are generally intensive and time-consuming, lessening their applicability to clinical settings.

A minimal psychological intervention (MPI), developed by Lamers and Jonkers for patients in the Netherlands, was used to help adults with a variety of chronic illnesses (including diabetes) manage the psychological burden of those illnesses by breaking through negative spirals between thoughts and behaviors. On average, an MPI program consisted of 4 door-to-door interventions, over a period of 3 months, with each intervention lasting less than 1 hour. This time-efficient program has been tested widely in Western populations of adults with type 2 diabetes or chronic obstructive pulmonary disease (COPD) and found to reduce depressive symptoms [11-15]. Currently, however, the effectiveness of MPI on non-Western population is unknown.

The present study evaluated the immediate impacts of MPI on depressive symptoms and diabetes-related distress in middle-aged and

older diabetes patients. We also employed piecewise growth curve modeling to assess its long-term impact on glycemic control. The piecewise growth curve modeling (also known as linear spline modeling) [16] estimates slopes of the linear trend within each segment, and identifies blood glucose levels at different steps of and intervention and post-intervention follow-ups. To inform the effectiveness of the MPI program for different subgroups, we also assessed the effects of MPI on participants by different siociodemographic or clinical characteristics. We hypothesized that (1) the MPI improves diabetes patients' psychological well-being and blood glucose levels, and that these effects change over time; (2) the impact of MPI varies by patients of different soiciodemographic or clinical characteristics. Specifically, MPI is more effective for newly diagnosed patients in poor glycemic control. Finally, to decrease travel and time burden of the nurses and research assistants for this and future interventions [17], we modified the original MPI program to be delivered via telephone.

Materials and methods

Design and participants

This study is a two-arm randomized control trial. Initiated in September 2012, we recruited type 2 diabetes patients aged 50 years and older with occasional distress or minor depressive symptoms from a medical center in Southern Taiwan. Participants were excluded if they were using anti-depression medications, receiving ongoing psychological/psychiatric treatment, had been diagnosed with psychosis (e.g., schizophrenia or bipolar disorder), had severe cognitive problem or hearing impairment, or lost their partner within the past three months (see **Figure 1**). A consent form that was approved by the Institutional Review Board of National Cheng Kung University Hospital (IRB Approval No.B-ER-101-022) was signed by all the participants. This study was listed in the ClinicalTrials.gov with Identifier: NCT02473081.

Randomization

After signing informed consent forms and completing baseline questionnaires, 182 enrolled patients were randomly assigned to the MPI program or to the usual care group. Among the 182 participants recruited in our study, 176 received the entire intervention and 174 (95.6%) had complete data on all the questionnaire evaluations, including 85 in the Intervention group and 89 in the control group, respectively. Comparisons between participants who completed all the evaluations and those who did not (174 v.s. 8) showed that participants who completed the study had higher PAID scores than those who did not (5.5 points compared to 2.2 points, $P < 0.01$). There were no significant difference between these two groups on any other sociodemographic and clinical characteristics.

The minimal psychological intervention (MPI) and the usual care

In addition to receiving the usual care as given by their family physicians, participants in the MPI group received 3-4 phone calls lasting 30-60 minutes each time. The phone calls were made by two assistants whose academic backgrounds were nursing and psychology and who were trained by a certified diabetes educator to communicate with diabetes patients through role-playing exercises.

In the first call, research assistants explored patients' diet, sleeping, exercise, and blood glucose control, as well as general and diabetes-specific health conditions. In addition, patients were asked to talk about their feelings and lifestyle changes after they were diagnosed with diabetes. The goal was for the assistants to understand daily routines, as well as thoughts, worries, and related feelings and behaviors of the patient. Based on the information collected in the first phone call, the assistants talked with the patients in the second call about their thoughts and possible solutions for the issues they raised, and discussed plans tailored to their particular issues. Some patients implemented self-management skills (such as changing diet and exercise plans), only to discover new emotional distresses associated with executing those plans since the first or second call. In the third or fourth calls, the assistants utilized reattribution therapy, which encourages patients to consider alternate reasons for outcomes so as to not blame themselves for their diabetes. Also, assistants utilized role-playing exercises to help patients' consider alternate ways of executing theirself-management behaviors with less distress.

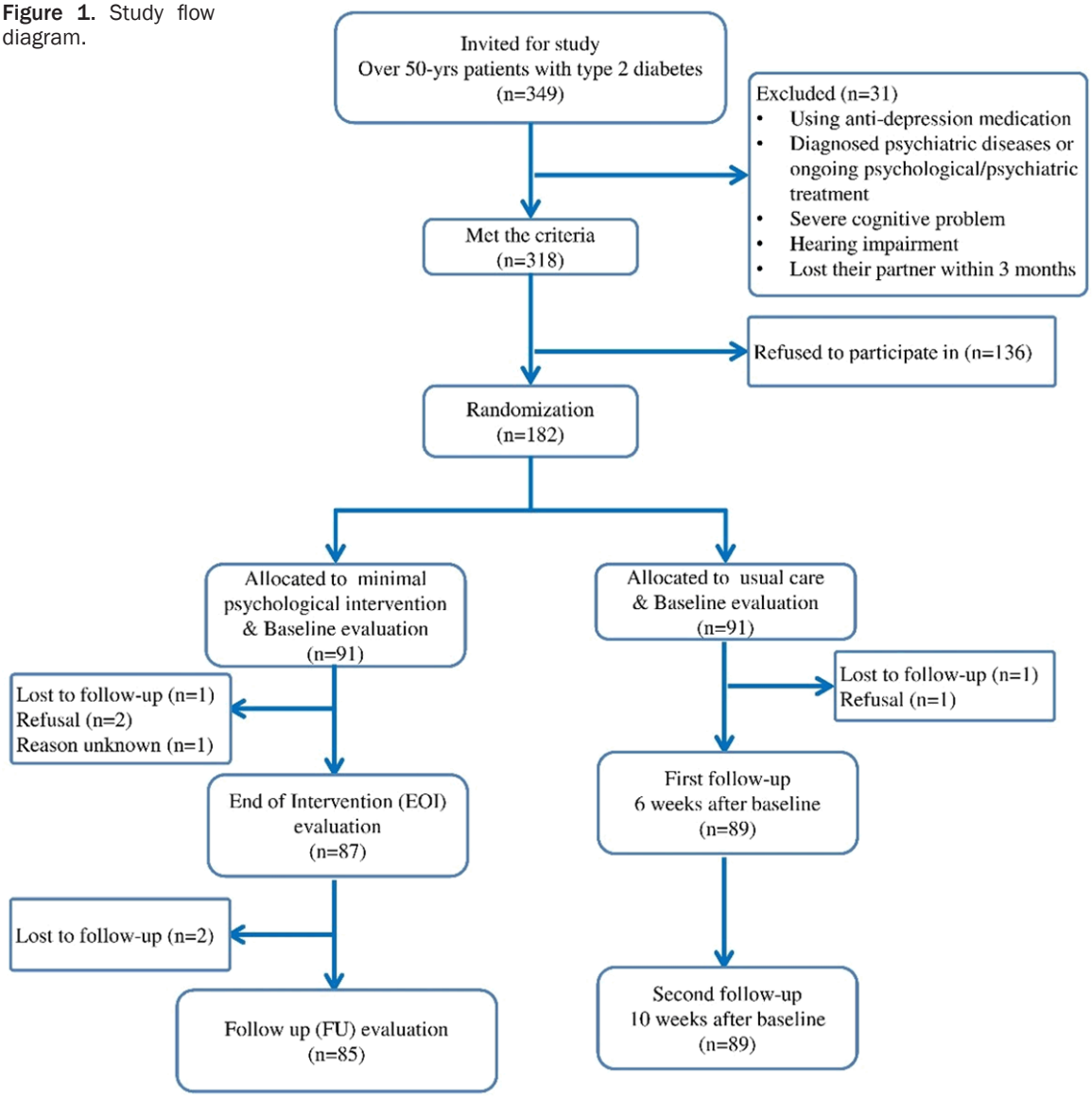

Figure 1. Study flow diagram.

Measurements

Interview surveys were scheduled at three points in time in both the intervention and the control groups: at baseline, immediately after completing the MPI program (6 weeks from baseline), and 1-month after the intervention (10 weeks from baseline). The baseline survey was completed by face-to-face interviews at the outpatient Family Medicine Clinic, and the follow-up surveys were completed primarily by telephone.

The survey collected data on sociodemographic characteristics, lifestyle (such as smoking, drinking, and exercise), health conditions (such as chronic diseases and complication of diabetes), duration of diabetes and medical treatments for diabetes. Depressive symptoms were assessed using the 10-item Center for Epidemiologic Studies Depression Scale (CES-D 10) [18], with each symptom ranging from 0-3 points (Cronbach's α between 0.79-0.83). Respondents were asked to indicate the frequency with which they experienced specific symptoms of depression within the preceding week. Scores ranged from 0 to 30, with scores ≥ 8 representing high depressive symptoms [19]. Diabetes-specific emotional distress was assessed with the self-reported 20-item Problem Areas in Diabetes (PAID) scale [20]. Negative emotions related to coping with diabe-

Table 1. The socio-demographic and clinical characteristics between intervention and control groups at baseline

	Overall (*N* = 174)	Intervention (*n* = 85)	Control (*n* = 89)	*p*-value[a]
Mean Age (years)	64.68.9	64.78.3	64.59.4	0.77
Male, %	51.7	54.1	49.4	0.54
Education level, %				
6 grades and below	39.7	40.0	39.3	0.97
7-12 grades	37.4	36.5	38.2	
13 grades and above	23.0	23.5	22.5	
Married or partnered, %	80.5	77.7	83.2	0.36
Smoking, %	8.6	12.9	4.5	0.05
Drinking alcohol, %	20.1	23.5	16.9	0.27
Exercising, %				
Never	17.8	18.8	16.9	0.85
1-2 times or less than 90 minutes per week	23.4	24.7	22.5	
More than 3 times and > 90 minutes per week	58.6	56.5	60.7	
Mean duration of diabetes (years)	10.58.3	10.6	10.58.2	0.99
Diabetes treatment, %				
Diet & Exercises	8.6	5.9	11.2	0.41
Oral medication	78.7	80.0	77.5	
Insulin	12.6	14.1	11.2	
Mean HbA1c level, %	7.61.4	7.6	7.71.3	0.14
Mean BMI	25.83.9	25.83.4	25.94.3	0.61
Diabetes complications, %				
Eye problems	9.2	7.1	11.2	0.34
Foot problems[b]	8.1	10.6	5.6	0.23
Kidney diseases	6.3	4.7	7.9	0.39
Comorbidity, %				
Hypertension	51.7	54.1	49.4	0.54
Lung diseases	2.3	2.4	2.3	0.96
Heart diseases	9.8	11.8	7.9	0.39
Cancer	6.9	7.1	6.7	0.93
Arthritis	9.8	10.6	9.0	0.72
Mean depressive symptoms (CES-D, range: 0-30)	3.44.4	3.2	3.74.8	0.77
Mean diabetes-specific emotional distress (PAID, range: 0-100)	5.5	5.67.6	5.4	0.30

Data are expressed as means ± SD or %. a: *p*-value based on chi-square or Wilcoxon two-sample tests. b: Foot problems including feeling numbness or tingling.

tes were rated on a 5-point Likert scale, ranging from 0 (not a problem) to 4 (a serious problem). To facilitate interpretation, sum scores are converted to a 0-100 scale by multiplying scores by 1.25 [5].

Hemoglobin A1c (HbA1c) data from enrollment to the end of the study (maximum HbA1c follow-up period was 8 months) were collected from medical charts. Patients in both groups visited the outpatient clinic every 2-3 months, during which glycosylated hemoglobin (HbA1c) was measured. Patients who did not have at least three records on HbA1c data (including baseline) were not analyzed in the piecewise growth curve model. For the piecewise growth curve model, a total of 109patientswere analyzed (57 MPI and 52 control participants). The comparability of patients with and without HbA1c data available was examined. Patients who had at least three HbA1c data points had fewer complications than those who did not; however, these groups did not differ by either demographic or other outcome variables. Poor glyce-

Table 2. Diabetes-specific emotional distress (PAID) by follow-up times and stratified by gender, complication, basal HbA1c level, basal depression score or duration of diabetes, raw score and MLM results[a]

	Intervention group (*N* = 85)	Control group (*N* = 89)	Mixed model analysis summary		
	Mean ± SD	Mean ± SD	Effect	Coefficient	*p*-value
Overall					
Baseline	5.6	5.4	MPI	0.04	0.97
EOI	2.2	2.9	Time	-1.67	< 0.01
FU	1.6	2.0	MPI*time	-0.36	0.64
Male					
Baseline	5.4	3.4	MPI	1.39	0.17
EOI	1.7	2.8	Time	-0.67	0.24
FU	1.4	2.1	MPI*time	-1.33	0.10
Female					
Baseline	5.9	7.3	MPI	-1.20	0.54
EOI	2.7	3.1	Time	-2.64	< 0.01
FU	1.8	2.0	MPI*time	0.56	0.68
Have 1 complication[b]					
Baseline	9.9	4.1	MPI	4.61	0.06
EOI	1.1	2.1	Time	-1.51	0.16
FU	0.4	1.1	MPI*time	-3.24	0.03
No complication[b]					
Baseline	4.5	5.7	MPI	-1.16	0.34
EOI	2.5	3.1	Time	-1.71	< 0.01
FU	1.9	2.3	MPI*time	0.42	0.63
Basal HbA1c ≥ 8%					
Baseline	8.1	6.6	MPI	1.09	0.62
EOI	1.1	2.1	Time	-2.37	< 0.01
FU	0.4	1.9	MPI*time	-1.46	0.27
Basal HbA1c < 8%					
Baseline	4.8	4.6	MPI	-0.15	0.90
EOI	2.6	3.4	Time	-1.27	0.06
FU	2.0	2.1	MPI*time	-0.11	0.91
Depression score ≥ 8[c]					
Baseline	8.3	13.8	MPI	-5.05	0.21
EOI	1.8	4.0	Time	-5.33	< 0.01
FU	1.0	3.2	MPI*time	1.71	0.51
Depression score < 8					
Baseline	5.1	3.4	MPI	1.29	0.15
EOI	2.3	2.7	Time	-0.81	0.11
FU	1.7	1.8	MPI*time	-0.88	0.22
Diabetes duration ≥ 10					
Baseline	5.8	7.2	MPI	-1.18	0.51
EOI	2.9	2.9	Time	-2.59	< 0.01
FU	2.0	2.0	MPI*time	0.69	0.59
Diabetes duration < 10					
Baseline	5.4	3.2	MPI	1.53	0.21
EOI	1.5	3.0	Time	-0.59	0.32
FU	1.2	2.0	MPI*time	-1.58	0.05

Note: PAID, Problem Area in Diabetes; EOI, End of intervention; FU, 1 month after intervention. a: MLM, multilevel modeling. The model equation as follows: $PAID_{ij} = [\beta_{00} + \beta_{01} MPI + \beta_{10} Time_{ij} + \beta_{11} (MPI \times Time_{ij})] + [u_{0j} + u_{1j} Time_{ij} + r_{ij}]$, where i is the subject, and j is the time of measurement. The variables represent random effects and is the random error. b: Diabetes complications, such as eye, foot and kidney diseases. c: The number of participants which basal depression score ≥ 8 were 32 (intervention and control group were 15 and 17, respectively).

Table 3. Comparisons of HbA1c level over time between MPI and control groups and stratified by baseline HbA1c level[a]

	Overall (*n* = 109)		Baseline HbA1c ≥ 8% (*n* = 33)		Baseline HbA1c < 8% (*n* = 76)	
	β (SE)	*p*-value	β (SE)	*p*-value	B (SE)	*p*-value
Intercept	7.55 (0.17)	< 0.001	8.73 (0.25)	< 0.001	6.93 (0.10)	< 0.001
MPI program	-0.09 (0.24)	0.71	0.62 (0.37)	0.10	-0.14 (0.13)	0.29
Period 1[b]	0.002 (0.05)	0.96	-0.14 (0.10)	0.18	0.10 (0.05)	0.05
Period 2[c]	0.01 (0.08)	0.94	0.19 (0.17)	0.25	-0.15 (0.08)	0.06
Period 3[d]	-0.03 (0.07)	0.73	-0.14 (0.15)	0.35	0.09 (0.06)	0.11
MPI*Period 1	0.02 (0.07)	0.80	0.02 (0.15)	0.90	-0.06 (0.07)	0.42
MPI*Period 2	0.003 (0.12)	0.98	-0.09 (0.25)	0.71	0.16 (0.11)	0.14
MPI*Period 3	-0.04 (0.10)	0.71	0.11 (0.21)	0.62	-0.18 (0.08)	0.02

a: Estimated from piecewise growth curve modeling with the equation as follows:

$$HbA1c_{ij} = \left[\begin{array}{l}\beta_{00} + \beta_{01} MPI + \beta_{10} Time_{ij} + \beta_{11} MPI \times Time_{ij} + \beta_{20} D_{1i}(Time_{ij} - 1.5 \text{ months}) + \beta_{21} MPI \times D_{1i}(Time_{ij} - 1.5 \text{ months}) \\ + \beta_{30} D_{2i}(Time_{ij} - 4.5 \text{ months}) + \beta_{31} MPI \times D_{2i}(Time_{ij} - 4.5 \text{ months})\end{array}\right]$$

$$+\left[u_{0j} + u_{1j} Time_{ij} + u_{2j} D_{1i}\left(Time_{ij} - 1.5 \text{ months}\right) + u_{3j} D_{2i}(Time_{ij} - 4.5 \text{ months}) + r_{ij}\right]$$

, where i is the subject, and j is the time of measurement. The D variables are dummy variables equal to 0 when the amount of time from the origin, is less than 1.5 months and 4.5 months respectively, and equal to 1 when Time is greater than i_1 and i_2 respectively. The u_{ij} variables represent random effects and r_{ij} is the random error. b: The period was baseline to end of intervention; c: The period was end of intervention to 3 months after intervention; d: The period was 3 months after intervention to 8 month after intervention.

mic control was defined as HbA1c ≥ 8%, a value indicated to be associated with more diabetes complications [21].

Statistical analysis

The data were analyzed per protocol principles with the 174 participants with complete data across the entire intervention duration. We used chi-square and Wilcoxon two-sample tests to check the comparability of the two groups at baseline. Multilevel modeling (MLM) tested the differences in PAID scores between groups at follow-ups. In addition, to estimate the long-term effects of MPI on glycemic control at different follow-up periods, piecewise growth curve model [22] with 2 knots at 1.5 months and at 4.5 months, which represented the period of post-intervention and 3-month after intervention respectively, was used. We used SAS 9.3 to perform all analyses, with a significance level $\alpha = 0.05$.

Results

Participant characteristics

The sociodemographic and clinical characteristics of the 174 participants are presented in **Table 1**. Overall, there were no significant differences between the intervention and control groups on age, gender, educational level, clinical characteristics, baseline depressive symptoms, or distress scores. The participants' mean age was 64.6 years (SD = 8.9); 51.7% of them were male, and 60% of participants had received more than 6 years of education. The average duration since diabetes diagnosis was 10.5 years (SD = 8.3). About 12.6% of patients were treated with insulin and 78.7% received oral medication. Participants' HbAlc level were 7.6 (SD = 1.4) and the mean BMI was 25.8 (SD = 3.9). The average depressive symptoms score was 3.4 (SD = 4.4) on a 0-30 scale; and the average PAID score was 5.5 (SD = 8.5) on 0-100 scale. There was a trend that more participants in the intervention group smoked than did participants in the control group (12.9% compared to 4.5%, $P = 0.05$); thus, to be conservative, smoking status was controlled as a covariate in subsequent regression models.

Change in depressive symptoms and diabetes specific distress

Multilevel modeling analyses tested the difference between MPI and usual care groups on changes in CESD and PAID scores. The

telephone-delivered MPI did not significantly improve the participants' CESD depressive symptoms score, but did improve the patients' diabetes-related distress. As shown in **Table 2**, the baseline PAID scores were 5.6 and 5.4 in the intervention and control groups, respectively. One month after completion of the intervention, both intervention and control group participants experienced significant decreases in diabetes-specific emotional distress (the PAID scores were 2.2 and 2.9, respectively. β_{time} = -1.67, $P < 0.01$). Although the decreases did not differ between the two groups ($\beta_{MPI*time}$ = -0.36, $P = 0.64$), we found that there was a significant decrease in the PAID scores of patients with more than 1 complications ($\beta_{MPI*time}$ = -3.24, $P = 0.03$) or in patients with diabetes durations of less than ten years ($\beta_{MPI*time}$ = -1.58, $P = 0.05$) in the MPI group compared to the control group.

The long-term effects of MPI on glycemic control

Finally, in order to evaluate the impact of MPI on longer-term glycemic and whether the intervention had different impacts at each follow-up period, we used piecewise growth curve modeling. **Table 3** presents the HbA1c level between the MPI and control groups from baseline to end of intervention (period 1), from end of intervention to 3 months after intervention (period 2), and during the 3- to 8- month follow-up (period 3). For the analysis with the entire sample who had complete data on HbA1c levels over the four measurement occasions, regression models revealed an average HbA1C level of 7.55 (SD = 0.17), with no difference between the MPI or control group, nor any time trend. However, in the subgroup analyses that grouped participants by glycaemia levels at baseline, we found that the HbA1c level of participants in experimental group with HbA1c < 8% at base line declined significantly ($\beta_{MPI*period\ 3}$ = -0.18, $P = 0.02$) during the 3- to 8-month follow-ups. In other words, the impact of MPI on glycemic improvement was most evident for diabetes patients with HbA1c < 8% after 3 months post-intervention.

Discussion

In this study, we examined the effectiveness of a telephone-based version of minimal psychological intervention (MPI) on type 2 diabetes patients' psychological well-being and glycemic control in Taiwan. The present study found that the 6-week MPI program was successful in improving diabetes patients' diabetes-related distress, especially in those reporting more than one complication. In addition, in those with baseline HbA1c levels of less than 8%, blood glucose levels decreased 3 months after intervention.

Previous MPI research indicated significant impacts of MPI on lessening depressive symptoms in older adults with chronic illness [11, 14]. Although our telephone-delivered MPI did not markedly improve the participants' depressive symptoms as indicated with the CESD score, we found that MPI improved the patients' diabetes-related distress. Previous studies indicated diabetes distress, rather than depressive symptoms, was significantly associated with HbA1c level [23, 24]; and one study indicated that diabetes-related emotional distress mediated the association between depressive symptoms and glycemic control [25], suggesting that MPI might be effective for patients' glycemic control. This conjecture was supported in our analysis examining HbA1c change after intervention.

We also examined if the effect of MPI on diabetes patients' emotional distress differed by patients' characteristics, such as gender, and diabetes duration, as well as HbA1c level, depressive symptoms and complications at baseline. Our analyses revealed that patients who received MPI improved their diabetes-related distress regardless of their gender, baseline HbA1c level or depressive symptoms, but that the effect differed by patients' diabetes duration and baseline complication status: in those with more than one complications or who were diagnosed with diabetes less than 10 years prior, the MPI intervention significantly decreased the PAID scores of the participants. These findings suggest that a telephone-delivered MPI might be a feasible and effective method for decreasing diabetes-specific distress and achieving better glycemic control in non-Western populations, especially in those who were at the early stage of diagnosis but had poor glycemic control.

Previous studies indicated that diabetes patients with minor to moderate depression receiving MPI improved their HbA1c level up to

9 months after intervention [12]. Our results support and extend those findings. Our analyses indicated that the MPI impact on clinical indicators may have a lagged effect: in those-withHbA1c level less than 8% at baseline, the MPI did not significantly improve their HbA1c levels until 3 months after intervention. Because the HbA1c is a "weighted" average of blood glucose levels during the preceding 3 months, this finding implies that patients receiving our intervention may gradually change their behaviors, and resulted in a lower HbA1c level 3 months after the Intervention.

This study has two key strengths. First, we adjusted the original MPI approach by changing the intervention to be delivered via telephone, a more convenient and cost-effective mode. Second, we tested the MPI effects on HbA1c using piecewise growth curve modeling, which enabled us to explore whether the slope of linear trends changed within each period [16, 26], which helped to clarify the impact of MPI on glycemic control at different stages over a long-term follow-up.

Several limitations should also be taken into account in this study. First, our follow-up interviews were conducted by telephone survey rather than in face-to-face interviews in the outpatient clinic, as conducted when the participants were first recruited and completed their baseline assessment. It is possible that when patients were interviewed at home, their families affected their reports about depressive symptoms or diabetes-reported distress; thus, differences observed at follow-ups may have arisen simply from a different measurement approach. Second, the average PAID score of our participants was relatively lower than other studies. As a result, the findings from this study are conservative with inference to the diabetes patients with minor to moderate depression. The effects of higher PAID score on different level of depression remains unclear. Future researchers should attempt to use larger samples and recruit a broader range of older adults for increased generalizability. Third, based on the comparability examination between patients who provided data on piecewise growth curve model for evaluating the long-term impact of MPI on glycemic control (e.g., those who had more than three records on HbA1c data) and those who did not, we found that patients who had more than three HbA1c data had less complications than those who did not. Thus, our results showing the positive impact of telephone-delivered MPI on glycemic control might only be generalized to those with fewer complications. In addition, compared to prior diabetes-related research using nationally representative data in Taiwan [27], participants in this study had higher educational levels. Thus, our results may only be generalized to those who have higher education levels.

Conclusion

In conclusion, this study aimed to test a convenient and well-executed intervention in type 2 diabetes patients in Taiwan. To our knowledge, this is the first study to test MPI in a non-Western population. Our results showed that the 6-week telephone-delivered MPI may be effective in mitigating patients' diabetes-related distress but not depressive symptoms. Further, its impact was more evident in those who were in earlier stages of diabetes diagnosis, had normal or marginally poor glycemic control (HbA1c < 8%), or who had complications such as eye, foot or kidney disease. We also found that the effect on glycemic may not be immediate, but rather observed 3 or more months after the intervention. These results support that a telephone-delivered MPI is a feasible and a moderately effective method for improving diabetes patients' self-management.

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Disclosure of conflict of interest

None.

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