Impact of an IMB theory-based health education intervention on hypoglycemic coping in patients with type 2 diabetes: a pilot study

August 01, 2023

Study Protocol

1. Integrity Statement

(1) Ensure that the operation is in strict accordance with the test protocol and the authenticity of the data records; (2) No conflict of interest with other projects.

2. Title of the study

Impact of an IMB theory-based health education intervention on hypoglycemic coping in patients with type 2 diabetes: a pilot study

3. Flow chart of the implementation of the study

Specific intervention program for T2DM hypoglycemic coping styles based on IMB modeling

Level 1 indicators	Level 1 indicators	Level 1 indicators（Content of the intervention）	Objectives of intervention	Forms of intervention	intervention time	implementers
information	base case	Patients completed the questionnaire within 3 hours of admission.	1、Perfect hypoglycemic cognition. 2 、 Correct incorrect hypoglycemic cognition and rebuild the hypoglycemic cognitive system. 3 、 Re-understand the different outcomes of different hypoglycemic coping styles. 4、Master the skills of hypoglycemic coping styles. 5、Improve the negative cognition, positive coping.	poll	Within 3 hours of admission	nurse practitioner-in-charge
	Hypoglycemia Handbook	Distribute hypoglycemia brochures and assist patients in developing individualized blood glucose management plans.		written form	Day 1 of admission	nurse practitioner-in-charge
	Specialized Lectures	Centralized in-departmental hypoglycemia education in the form of a PowerPoint presentation by a specialist nurse.		PPT (location: demonstration room, time: 8 minutes)	Day 2 of admission	Principal Investigator
	peer education	Introduce patients to recognize the pre-symptoms of hypoglycemia and how to deal with them, and show the dangers of wrong ways of coping with hypoglycemia with examples. Utilize the peer effect to allow people to share their experiences of hypoglycemia management and exchange experiences.		PPT presentation (15min) Peer exchange (20min)	3rd day of admission (and every Friday afternoon thereafter, after the end of treatment)	Principal Investigator
	WeChat Information Dissemination	Patients and their families join the WeChat group on admission, and every Tuesday and Thursday, we push out the graphic and video knowledge related to diabetes mellitus hypoglycemia (the content involves diabetes mellitus specialty knowledge, diet, exercise, blood glucose testing, hypoglycemia coping, psychological debugging, etc.).		WeChat form	From the first week of admission	Principal Investigator and Charge Nurse

	Knowledge Contest with Prizes	Conduct a contest on knowledge related to coping with hypoglycemia, with small gifts awarded to the top three winners.		In the form of a group activity (duration: 30 minutes)	1 day before discharge	Principal Investigator
motives	Health belief formation	Based on the results of the patient's hypoglycemic coping style questionnaire on admission, the intervener will give corrections for the diabetic patient's misperceptions, assist in setting goals for the next week, and give positive psychological interventions	1、(No-intention period) Change their negative hypoglycemia coping mentality and establish correct health beliefs. 2、(Intentional period) Enhance their confidence in coping with hypoglycemia positively and recognize the harm of negative coping.	Questionnaires, one-on-one exchanges (20 minutes long)	Day 1 of admission	nurse practitioner-in-charge
	Family member support	Face-to-face communication with patients and their families was conducted 1 day before discharge to understand the family status of the patients after discharge and inform their families of the importance of family support in coping with diabetes mellitus, instructing the patients' families to control their diets and their behaviors, to do a good job of family support, to play a good supervisory and nursing care, and at the same time, informing the patients of the path of professional counseling and the convenience of the community resources and so on.	1、(Preparation period) Include family members and act together to provide family support for patients 2、(Change period) Make full use of resources at home, hospitals, communities, pharmacies, etc. to promote behavioral change 3、(Sustainability Period) Guide patients to think about the benefits gained from healthy behaviors, instruct them	Face-to-face exchanges (20 minutes in length)	1 day before discharge	nurse practitioner-in-charge
	Medical staff support	1, 2, 3 weeks after discharge, every Tuesday and Thursday through the WeChat group to push the knowledge related to diabetic hypoglycemia, and encourage patients to actively share their own experience of successfully coping with hypoglycemia in the group, in order to play the role		WeChat or Phone	1, 2, 3 weeks after discharge	Principal Investigator

		of an example. For patients with difficulties in coping, contact them by phone or WeChat, and according to the actual situation of the patients, analyze the reasons and assist in the development of a coping plan, and modify the plan in a timely manner according to the actual situation of the patients during the implementation of the plan.	to effectively use social and family resources, and establish internal and external environments conducive to the long-term implementation of the program to encourage patients to continue to adhere to it.			
	social security (pensions, medical insurance)	The group education and feedback were conducted in the 4th week after discharge from the hospital at the Diabetes Clinic of Chuzhou First People's Hospital.		Group offline lectures (duration: 1 hour)	4th week after discharge	Principal Investigator
behavioral skill	Health Information Access Skills	Patients are admitted to the hospital for an explanation of ways to acquire knowledge about diabetes, and the WeChat group pushes out specialized websites for patients to view, or they can go to the hospital's diabetes specialist clinic for consultation.	1、Guide them to adopt a correct and scientific way of obtaining disease information. 2、Enhance the coping ability to deal with hypoglycemia. 3、Perform diabetes outpatient information consultation and sensitization, so that they can obtain professional knowledge in the professional window. 4、Guide patients with psychological disorder to moderate psychological counseling in order to enhance confidence.	Questionnaire, PPT presentation, WeChat	Day 2 of admission	nurse practitioner-in-charge
	Self-conditioning skills	Post-discharge WeChat pushes examples of the dangers of incorrect response to hypoglycemia on Tuesdays and Thursdays, as well as knowledge of insulin injection techniques, diet, exercise skills, and blood glucose testing; patients are asked to keep a diabetes diary every month.		WeChat, written	1, 2, 3 months after discharge	nurse practitioner-in-charge
	Peer experience sharing	Regular monthly communication with discharged patients, patients with more serious problems, one-on-one communication at the end of the lecture, weekly and monthly plans; praise for better performance and let them talk about their coping experience.		Lecture (duration: 1 hour)	1, 2, 3 months after discharge	Principal Investigator

4.Background

Hypoglycemia, as one of the common complications in patients with diabetes mellitus, not only leads to an increase in the incidence of cardiovascular events and all-cause mortality, but also imposes a serious psychological burden on them, so much so that patients make behavioral changes such as increasing food intake, decreasing insulin dosage, and restricting physical activity in order to prevent hypoglycemia, which are not conducive to the management of the disease and accelerate the adverse regression of the disease, therefore, it is urgent to change the erroneous Hypoglycemic coping is urgent, and IMB theory, which states that individuals must have three behavioral components, namely information, motivation, and behavioral skills, in order to produce behavioral change, can help interveners to analyze the behavioral components that are lacking in order to determine the focus of the intervention, select appropriate interventions, and implement them. The purpose of this study was to develop a health education intervention program based on the IMB theory to change erroneous hypoglycemic coping styles and to validate the feasibility, acceptability, and initial effectiveness of the program.

5. Research purpose

The purpose of this study was to develop a health education intervention program based on the IMB theory to change the erroneous hypoglycemic coping styles of patients with type 2 diabetes and to validate the feasibility, acceptability, and initial effectiveness of the program.

6. Inclusion and Exclusion Criteria

Inclusion criteria: (1) meet the 2018 edition of ADA Diabetes Medical Diagnosis and Treatment Criteria and diagnosed with T2DM; (2) patients using insulin or sulfonylureas; (3) disease duration ≥1 year, age ≥18 years; (4) history of hypoglycemia occurrence in the past 6 months; (5)

patients with a tendency of avoidance and compromise in T2DM Hypoglycemic Coping Styles Inventory; (6) good communication and verbal skills; (7) have a smartphone and know how to use it; and (8) voluntarily participate in this study. Exclusion Criteria: (1) patients with type 1 diabetes mellitus; (2) patients with severe complications in combination with T2DM; and (3) patients who are participating in studies on other topics.

7. Intervention process

From August 2023 to January 2024, T2DM patients who met the inclusion and exclusion criteria were selected from 1 tertiary hospital in Chuzhou City. The control group implemented conventional diabetes health education, and the intervention group implemented health education based on IMB theory on the basis of the control group.

8. Sample size estimation

In this study, a randomized controlled trial was conducted to investigate the effect of intervention based on IMB model on the hypoglycemic coping style of T2DM patients, which was randomly divided into the control group and the intervention group, and the main observation index was the hypoglycemic coping style after the intervention. According to previous studies in similar literature, the control group was 30.14±5.08, and the intervention group was 34.40±5.36, with $\alpha = 0.05$, power = 0.95, and 1:1 parallel control. According to the formula for calculating the sample size of the mean value of the two groups, the sample size of the two groups was calculated to be 41 cases in each group, and at least 50 cases should be included in each group at the baseline, taking into account the 15% dropout rate, which made the total number of cases to be 100 in total.

9. Randomisation

Participants were identified through screening of medical records and face-to-face interviews, and participants signed a written consent form to participate in the study. After the baseline assessment, participants were randomly assigned to either the intervention or control group using a lottery method after drawing a labelled card in an opaque sealed envelope from an independent research assistant who was not involved in the recruitment and implementation of the study.

10. Measurement index

General information questionnaire: day 1 of admission; Hypoglycemia Coping Styles Scale for Patients with Type 2 Diabetes Mellitus (primary indicator): day 1 of admission, 4 weeks post-intervention, 8 weeks post-intervention, and 12 weeks post-intervention; Fear of Hypoglycemia Scale Score (secondary indicator): day 1 of admission, 4 weeks post-intervention, 8 weeks post-intervention, and 12 weeks post-intervention; Health Information Acquisition Behavior Scale (secondary indicator): day 1 of admission, 4 weeks post-intervention Day 1, 4 weeks post-intervention, 8 weeks post-intervention, 12 weeks post-intervention; Type 2 Diabetes Knowledge Scale (secondary indicator). Day 1 of admission, 4 weeks post-intervention, 8 weeks post-intervention, and 12 weeks post-intervention.

11. Ethical consideration

The study was ethically approved by the Ethics Committee of the College of Nursing of Yangzhou University (YZUHL20220047).

12. Statistical analysis of data

SPSS 26.0 software was applied for data analysis. Describing the general demographic characteristics of the study population: Mean ± standard deviation (±s) was used to describe measures that conformed to normal distribution, and median and interquartile spacing M (QR) were used to describe skewed distribution; count data were expressed as frequencies and constitutive ratios. Homogeneity test: the chi-square test or Fisher's

exact test was used for the count data of the two groups at baseline, non-parametric test was used for the rank count data, and t-test or non-parametric test was used for the measurement data. Repeated measures ANOVA was used to analyse the intervention effect of each indicator within groups, and two independent samples t-test was used to compare between groups at different time points before and after the intervention. The significance level $P < 0.05$ indicated that the difference was statistically significant.