Effects of a health education intervention based on the behaviour change wheel on fear of hypoglycemia in patients with type 2 diabetes mellitus: a pilot study

January 14, 2021

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

Effects of a health education intervention based on the behaviour change wheel on fear of hypoglycemia in patients with type 2 diabetes mellitus: a pilot study

3. Flow chart of the implementation of the study

Specific implementation elements of the Intervention programme

Behavioural analysis with the BCW theory		Intervention function	Specific interventions	Implementation modalities	Implementation time
Motivations	**Spontaneous motivation** Intensive daily diabetes management to change attitudes and habits.	**Education, training, persuasion, modelling**	1. Fill in the hypoglycaemia fear scale on the first day of admission, grasp the obstacles in blood glucose management and hypoglycaemia cognition, correct the wrong cognition on a one-to-one basis, and establish the scientific concept of blood glucose management.	Questionnaires, face-to-face interviews	Day 1 of admission, duration 15min
			2. Introduce the knowledge of diabetes, hypoglycaemia and fear of hypoglycaemia to patients through PPT teaching.	PPT lectures and video learning	Days 2, 4 and 6 of admission, each 60 min long
			3. 1-3 weeks after discharge, describe blood glucose management management and how to respond when hypoglycaemia occurs through patient diaries. Encourage patients to upload and share their hypoglycaemic fear and diet and exercise diaries in WeChat group, and patients with good psychological status to share their feelings.	WeChat or telephone communication	Weeks 1, 2 and 3 after discharge, 1 time per week, 15min each time
	Introspective motivation Understand the negative consequences of fear of hypoglycaemia, improve hypoglycaemia awareness and self-regulation skills, set blood glucose control goals to maintain stable blood glucose and reduce the occurrence of abnormal blood glucose.		1. Personalised guidance on knowledge about hypoglycaemia was pushed through WeChat to reshape, as far as possible, their sense of self-efficacy in relation to glycaemic control.	WeChat	Every Monday of the 1st, 2nd and 3rd week after discharge
			2. Use examples to illustrate the dangers of excessive avoidance behaviours caused by the fear of hypoglycaemia.	WeChat	60min on the 6th day of admission
			3. Encourage patients with stable glycaemic management to share their experiences and set an example for other patients.	WeChat or telephone communication	Every 3rd week after discharge 15min duration

(Continued)

Behavioural analysis with the BCW theory		Intervention function	Specific interventions	Implementation modalities	Implementation time
Capability	**Mental capacity** Raise awareness of hypoglycaemia, detect hypoglycaemia in a timely manner, acquire scientific knowledge about hypoglycaemia, and understand the health problems associated with the fear of hypoglycaemia.	**Education, training, realisation**	1. Fill in the questionnaire on the first day of admission to understand the patient's psychological state and knowledge of hypoglycaemia fear.	Questionnaire	Day 1 of admission, duration 15min
			2. Introduce patients to diabetes mellitus as well as knowledge about hypoglycaemia and hypoglycaemia fear and the impact it has on diabetes mellitus.	Interpretation of the Type 2 Diabetes Hypoglycaemia Health Education Manual	Day 1 of admission, duration 15min
			3. Help patients to look for clues to the occurrence of hypoglycaemia and the causes and consequences of impaired awareness of hypoglycaemia, and instruct patients on how to reduce hypoglycaemia exposure.	Face-to-face Interview	Day 1 of admission, duration 15min
			4. Re-completion of the questionnaire to understand the patient's knowledge of hypoglycaemia and fear of hypoglycaemia	Questionnaire Survey	Day 1 before discharge, duration 15min
	Physical capability In the event of a hypoglycaemic event, patients know how to deal with it, how to monitor their blood glucose appropriately and how to calculate the amount of diet and exercise to maintain a stable blood glucose level.		1. Introduce patients to proper diet, moderate exercise and rational use of medication, the correct way of monitoring blood glucose, identifying the pre-symptoms of hypoglycaemia, and how to deal with them.	PPT lectures and video learning	Days 2, 4 and 6 of admission, each lasting 60 min.

(Continued)

Behavioural analysis with the BCW theory		Intervention function	Specific interventions	Implementation modalities	Implementation time
Opportunity	**Social opportunities** The external environment and medical support are facilitators of change in patients' hypoglycaemic fear-avoidance behaviour, and reasonable and effective diabetes support is provided with due consideration of external factors and their own opportunities.	**Environmental reconstruction, realisation**	1. Develop an individualised self-management plan based on the patient's glycaemic control, and commit the patient to follow this plan for self-management.	Face-to-face interviews	Day 1 before discharge, duration 15min
			2. Instruct the patient's family members to control their diet and behaviour, provide family support and play a good role in supervision and care.	Face-to-face interviews	Day 1 before discharge, duration 15min
			3. Discharged patients can join the WeChat group to push diabetes-related counselling.	Wechat	Every Monday of the 1st, 2nd and 3rd weeks after discharge
			4. Regular nursing visits to the patients, recalling the recent life with the patients, finding out whether the patients have hypoglycemia and analysing the causes of hypoglycemia.	WeChat or telephone communication	Weeks 1, 2 and 3 after discharge, 1 time per week, duration 15min
	Physical opportunity Glucose management through WeChat platform, on-site teaching and guidance by specialist nurses to create opportunities for patients who can change excessive/avoidant behaviours.		1. Specialist nurses on-site instructed patients on how to correctly monitor blood glucose, how to calculate daily diet and exercise, and how to correctly deal with abnormal blood glucose.	On-site Practical Teaching	Day 4 of admission, 60min per session
			2. Through the WeChat group peer communication, exchange insights and tips with patients who have ideal blood glucose control on-site, through the exchange of knowledge and provide assistance.	WeChat group communication Questionnaire	Week 3 after discharge, 15min duration

4.Background

Fear of hypoglycemia (FoH) is becoming an important barrier to achieving good glycemic control in patients with type 2 diabetes. Clinical care professionals have been working to address FoH in patients with diabetes mellitus, and the behaviour change wheel (BCW) theory, which states that individuals must possess the three behavioral components of ability, opportunity, and motivation in order to develop behavioral change, helps interventionists analyze the behavioral components that are lacking in order to determine the focus of the intervention, and then select the most appropriate intervention based on the combination of the nine functions of the intervention and implement it. The purpose of this study was to develop a health education intervention program based on the BCW theory to reduce the level of fear of hypoglycemia in patients with type 2 diabetes and to investigate the feasibility, acceptability, and preliminary effects of the program.

5. Research purpose

The purpose of this study was to develop a health education intervention program based on the BCW theory to reduce the level of fear of hypoglycemia in patients with type 2 diabetes and to investigate the feasibility, acceptability, and preliminary effects of the program.

6. Inclusion and Exclusion Criteria

Inclusion criteria: (1) Compliance with the 2020 Chinese guidelines for the prevention and treatment of type 2 diabetes mellitus patients[24] ; (2) Age ≥ 18 years; (3) Duration of diabetes mellitus ≥ 1 year; (4) According to the elevated item endorsement criterion (EI criterion) : Hypoglycaemic Fear-Worry Scale (HFS-WS) Any item ≥ 3 points was judged as FoH; (5) Have the ability to listen, read, write and walk, and be able to cooperate with the completion of the study; (6) Have a smart phone, and be able to use WeChat or phone to communicate proficiently; (7) Voluntarily participate in this study and sign the informed consent form. Exclusion Criteria: (1) Those who are combined with acute complications or other serious diseases or disorders of consciousness, such as diabetic hypertonic state, tumour, coma, etc.; (2) Those who are combined with psychiatric diseases or taking psychotropic drugs. (3) Patients who have recently or are

participating in other studies on similar topics.

7. Intervention process

From August 2021 to January 2022, T2DM patients who met the inclusion and exclusion criteria were selected from 2 tertiary hospitals in Yangzhou City. The control group implemented conventional diabetes health education, and the intervention group implemented health education based on BCW theory on top of the control group.

8. Sample size estimation

According to the formula for calculating the sample content: $n1=n2=2[(Z_\alpha+Z_\beta)\ \sigma/\delta]^2$, n1, n2 are the required sample contents of the two groups, set $\alpha=0.05$, $\beta=0.1$, check the boundary table $Z\alpha/2=1.96$, $Z\beta=1.282$. $n1=n2 \approx 22$ cases according to the sample size estimation formula of the pre-experimental results substituted into the comparison of the two sample means, considering a 15% attrition rate, expert opinion and clinical situation, 25 patients in each group were finally determined.

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: admission day 1; hypoglycaemia fear scale (primary indicator): admission day 1, 4 weeks post intervention, 8 weeks post intervention; impaired hypoglycaemia awareness score (secondary indicator): admission day 1, 4 weeks post intervention, 8 weeks post intervention; medical support scale (secondary indicator): admission day 1, 4 weeks post intervention, 8 weeks post intervention; diabetes self-management attitude scale (secondary indicator). Day 1 of admission, 4 weeks post-intervention, 8 weeks post-intervention.

11. Ethical consideration

The study was ethically approved by the Ethics Committee of the College of Nursing

of Yangzhou University (YZUHL20210088).

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.