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Original research article

The effects of a hypoglycaemia education programme on the outcomes in patients with type 2 diabetes

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Abstract
Aim: This study aims to evaluate how a Hypoglycaemia Education Programme (HEP) affects the hypoglycaemia outcomes of patients with Type 2 Diabetes Mellitus (T2DM).
Methods: This study which included a six-month follow-up was conducted with 101 patients with T2DM receiving insulin in the outpatient diabetes clinic. The patients were assigned to the HEP group (n = 51) and the control (n = 50) group. Patients in the HEP group participated in the Hypoglycaemia Education Programme. The patients in both groups were assessed at baseline, and one, three, and six months after HEP using the Clarke Hypoglycaemia Awareness Scale and the Hypoglycaemia Fear Survey in terms of frequency, self-management behaviours of hypoglycaemia, fasting and postprandial blood glucose levels, and haemoglobin A1c (HbA_{1c}) levels.
Results: The HEP group had a higher score of hypoglycaemia awareness in six months compared to the control group (p = 0.006). Fear of hypoglycaemia decreased significantly (p < 0.001) but the frequency of hypoglycaemia did not change in the HEP group compared to the control group (p > 0.05). While self-management behaviours for hypoglycaemia improved in the HEP group, no change was observed in the control group (p = 0.005). Moreover, HbA_{1c} lowered significantly in the HEP group (p < 0.01).
Conclusion: As a unique first programme on hypoglycaemia management in T2DM in Turkey, HEP is effective for improving self-management behaviours for hypoglycaemia, hypoglycaemia awareness, and glycaemic control.

Keywords: Fear of hypoglycaemia; Hypoglycaemia; Hypoglycaemia awareness; Patient education; Type 2 diabetes mellitus

Introduction

Hypoglycaemia education is recommended as part of routine diabetes education but is often limited in the general education programmes for type 1 diabetes mellitus (T2DM) (Iqbal and Heller, 2018). Hypoglycaemia-focused education models improve glycaemic control, reduce hypoglycaemia events and severity, and improve hypoglycaemia management in patients with type 1 diabetes mellitus (T1DM) (Iqbal and Heller, 2018; LaManna et al., 2019). The DAFNE-HART study, with its 6-week intervention using motivational interviewing and cognitive-behavioural techniques, revealed that motivational interviewing and cognitive-behavioural techniques were effective in improving hypoglycaemia awareness and decreasing the rates of severe hypoglycaemia (de Zoysa et al., 2014). In their study, Demir et al. (2019) reported that impaired hypoglycaemia awareness improved in children with T1DM who received structured education and were constantly monitored with glucose control systems. Speight et al. (2016) reported that structured education, provided within routine care implemented at the national level, resulted in a decrease in severe hypoglycaemia events in patients with T1DM.

However, these programmes were created for patients with T1DM and intensive insulin users. There is a lack of published evidence focusing on hypoglycaemia education programmes for patients with T2DM. Unlike individuals with T1DM, it has been reported that individuals with T2DM experience mild and moderate hypoglycaemia episodes more frequently than severe hypoglycaemia. This difference should be taken into consideration when creating the education plan. In addition, other factors such as oral antidiabetics or lifestyle-related causes should be intensively addressed in its aetiology and prevention (Iqbal and Heller, 2018). This study was conducted based on the need for an education programme focusing on the prevention and management of hypoglycaemia in patients with T2DM.

Materials and methods

Aim

This study was conducted to evaluate how the Hypoglycaemia Education Programme (HEP) affects the characteristics, fear, awareness, and management of hypoglycaemia in patients with T2DM.

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Objectives of the study were determined as follows:
1. The HEP decreases frequency of hypoglycaemia in patients with T2DM.
2. The HEP improves self-management behaviours for hypoglycaemia in patients with T2DM.
3. The HEP decreases the fear of hypoglycaemia in patients with T2DM.
4. The HEP raises awareness on hypoglycaemia in patients with T2DM.

Subjects
The inclusion criteria for the participants were determined as follows: diagnosed with T2DM, aged between 18–65 years, have used insulin for at least three months, have experienced hypoglycaemia (blood glucose <70 mg/dl) at least once after diagnosis, are literate, and agree to self-monitor blood glucose at home.

Upon calculation of the sample size by power analysis, the number of target participants was determined to be 50 patients in the HEP group and 50 patients in the control group, assuming that the rate of hypoglycaemia could be reduced by 50% through education (Iqbal and Heller, 2018). Since the HEP applied to the HEP group was conducted as a group education and it was recommended that each group should include 6–10 people for the best group dynamics, the education continued until the target sample size was reached. As a result, 51 patients were assigned to the HEP group and 50 to the control group. A total of 44 patients in the HEP group and 36 in the control group completed the six-month follow-up. The drop-out ratio of the sample was 21%.

Study design and setting
This experimental study with a six-month follow-up was conducted at an outpatient diabetes clinic of a leading state hospital in Turkey.

Data collection tools and measures
The patient questionnaire was used to collect data about the patients' socio-demographic characteristics, duration of diabetes, and characteristics of treatment. Glycaemic control was assessed by haemoglobin A_{1c} (HbA_{1c}), fasting, and postprandial blood glucose measurements.

Hypoglycaemia was assessed based on several parameters: (1) experiencing hypoglycaemia at least once, (2) number of hypoglycaemic episodes, (3) self-management of hypoglycaemia, (4) impaired awareness of hypoglycaemia, and (5) fear of hypoglycaemia. A glucose meter, a sufficient amount of strips for self-monitoring blood glucose, and a diary to note the results were given to each patient in both groups in order to determine the level of glycaemia and real-time hypoglycaemia. The frequency of hypoglycaemia was determined based on glucose results from the glucometer and the patients' diary entries. In the follow-ups, the patients in both groups were asked whether or not they had experienced any hypoglycaemic episode, and any interventions based on the hypoglycaemia protocol were evaluated. In addition, whether or not the patients had hypoglycaemia in the one to six months prior to the onset of the study was also retrospectively investigated in the baseline evaluation.

Impaired awareness of hypoglycaemia was assessed using the Clarke Hypoglycaemia Awareness Scale, developed by Clarke et al. (1995), to assess hypoglycaemia and hypoglycaemia awareness in patients with diabetes. This scale consisted of eight items (Clarke et al., 1995).

The fear of hypoglycaemia was assessed using the Hypoglycaemia Fear Scale which was developed by Cox et al. (1987) and adapted to Turkish by Erol and Enç (2011). The scale consists of two subscales and 32 items that assess an individual's behaviours and worry levels related to the fear of hypoglycaemia.

Patients' self-management behaviours for hypoglycaemia were evaluated by interviewing them through the Hypoglycaemia Management Protocol. This protocol was prepared based on the national hypoglycaemia management recommendations (Republic of Turkey Ministry of Health, 2015; Turkish Endocrinology and Metabolism Society, 2020). When patients explained hypoglycaemia management steps correctly according to the protocol, hypoglycaemia self-management for those patients was coded as 'correct' while other responses were coded as 'incorrect'.

Hypoglycaemia education programme
The HEP was developed by the researchers and consisted of seven modules, each of which were associated with the prevention of hypoglycaemia and its effective management in patients with T2DM using insulin: (1) what T2DM is and how it is managed; (2) nutritional therapy; (3) regular exercise in diabetes management; (4) insulin therapy; (5) hypoglycaemia and its treatment; (6) self-monitoring and action planning; (7) acute health problems and glycaemic control. The content of each module was discussed by associating it with hypoglycaemia. Interactive and visual education methods were used for designing the programme by following the principles of the empowerment model (Anderson and Funnell, 2005), and the Diabetes Conversation Maps (Healthy Interactions, 2015).

Study process
In the HEP group, the baseline evaluation of the patients was conducted and the one-day, eight-hour programme was scheduled for groups of five to eight patients. The patients in both groups were invited for one-, three-, and six-month follow-ups.

Statistical analysis
Primary results of the study were hypoglycaemia frequency, hypoglycaemia self-management, impaired awareness of hypoglycaemia, and fear of hypoglycaemia. Secondary result was the change in HbA_{1c} levels. The data were analysed using SPSS (v.24.0), and the value of $p < 0.05$ was accepted as statistically significant (Griffiths and Needleman, 2019). Mean, standard deviation, median, minimum and maximum values were used as descriptive statistics for continuous data. For discrete data, numbers and percentages were used. In the group comparisons, the *t*-test was used for normally distributed data. The Mann–Whitney *U* test was used for non-normally distributed data. When comparing the HEP and control groups, the chi-square test and Fisher's exact test were used for nominal and discrete variables. Repeated measures analysis of variance was used to compare the variables that fit the normal distribution. The Wilcoxon test was used to compare data that were continuous and were not normally distributed.

Ethical considerations
For the study, ethics committee approval was obtained from the Clinical Trials Ethics Committee (Approval no: 12/2013) and institutional permission was obtained from the Institute of State Hospitals (no: 016638-06052013). The study adhered to the code of ethics of the World Medical Association for experiments involving humans (Declaration of Helsinki). Informed consent forms were signed by the patients. Permission to use the Hypoglycaemia Fear Scale and the Clarke Hypoglycaemia Awareness Scale was received from the authors who developed them.

Results

Socio-demographic and diabetes management characteristics of the participants

There was no difference between the HEP and control groups in terms of socio-demographic characteristics of the participants ($p > 0.05$). In the HEP and control groups, their mean age was 53.37 (±7.15) and 53.56 (±6.47) years, respectively. Of the patients, 74.5% ($n = 38$) in the HEP group and 72% ($n = 36$) in the control group were female.

There was no statistically significant difference between the HEP and control groups in terms of duration of diabetes, treatment, total daily insulin doses, and HbA_{1c} levels ($p > 0.05$). In both groups, the majority of patients had diabetes for over five years (90.2% of the HEP group; 88% of the control group). Use of oral antidiabetic drugs (metformin, glitazone) was 47.1% ($n = 24$) in the HEP group and 52.9% ($n = 27$) in the control group. Moreover, 23.5% ($n = 12$) of the HEP group and 32% ($n = 16$) of the control group had been using insulin for more than five years. The mean daily insulin dose (units) at the baseline evaluation was 44.61 (±23.76) in the HEP group and 53.14 (±30.11) in the control group. During the follow-ups, there was no significant difference between the groups in terms of the change in insulin doses. At the six-month follow-up, the mean insulin dose was 47.30 (±24.17) in the HEP group and 59.83 (±35.51) in the control group.

In the baseline evaluation, the mean HbA_{1c} was 9.09% (±1.84) and 9.27% (±2.26) in the HEP and control groups, respectively ($p > 0.05$). During the follow-up period, HbA_{1c} levels decreased gradually in the HEP group, and a significant difference was found between the two groups ($p = 0.000$). For the HEP group, the mean HbA_{1c} value was 8.04% (±1.33) in three months and 7.77 (±1.21) in six months. It was 9.49% (±2.20) in three months and 9.73 (±2.18) in six months for the control group (Chart 1).

The mean fasting blood glucose concentration was 217.50 mg/dl (±85.19) in the HEP group and 228.28 mg/dl (±81.61) in the control group at the baseline evaluation ($p > 0.05$). During the follow-up period, fasting blood glucose levels lowered significantly in the HEP group, and there was a significant difference between the groups ($p = 0.000$). The mean fasting blood glucose concentration in the HEP group was 172.34 mg/dl (±62.97) in one month, 164.55 mg/dl (±61.62) in three months, and 150.58 mg/dl (±49.85) in six months; whereas, these values were 212.68 mg/dl (±90.14), 211.76 mg/dl (±81.96), and 230.76 mg/dl (±86.16) in the control group, respectively.

Mean postprandial blood glucose concentration was 306.55 mg/dl (±110.97) in the HEP group and 294.44 mg/dl (±117.65) in the control group ($p > 0.05$). During the follow-up period, postprandial blood glucose levels lowered significantly in the HEP group and a significant difference was detected between the groups ($p = 0.000$). The mean postprandial blood glucose concentration in the HEP group was 238.34 mg/dl (±90.02) in one month, 202.82 mg/dl (±70.65) in three months, and 205.71 mg/dl (±84.69) in six months; whereas in the control group the values were 277.76 mg/dl (±93.15), 274.28 mg/dl (±131.63), and 299.96 mg/dl (±128.16), respectively.

Results on hypoglycaemia and its management

The rate of patients experiencing hypoglycaemia in the six months before the study was 82.4% ($n = 42$) in the HEP group and 74% ($n = 37$) in the control group ($p > 0.05$), while these rates were 36.4% ($n = 16$) and 30.6% ($n = 11$) in the six-month follow-up, respectively ($p > 0.05$).

The mean number of hypoglycaemic events experienced by the patients in the six months before the study was

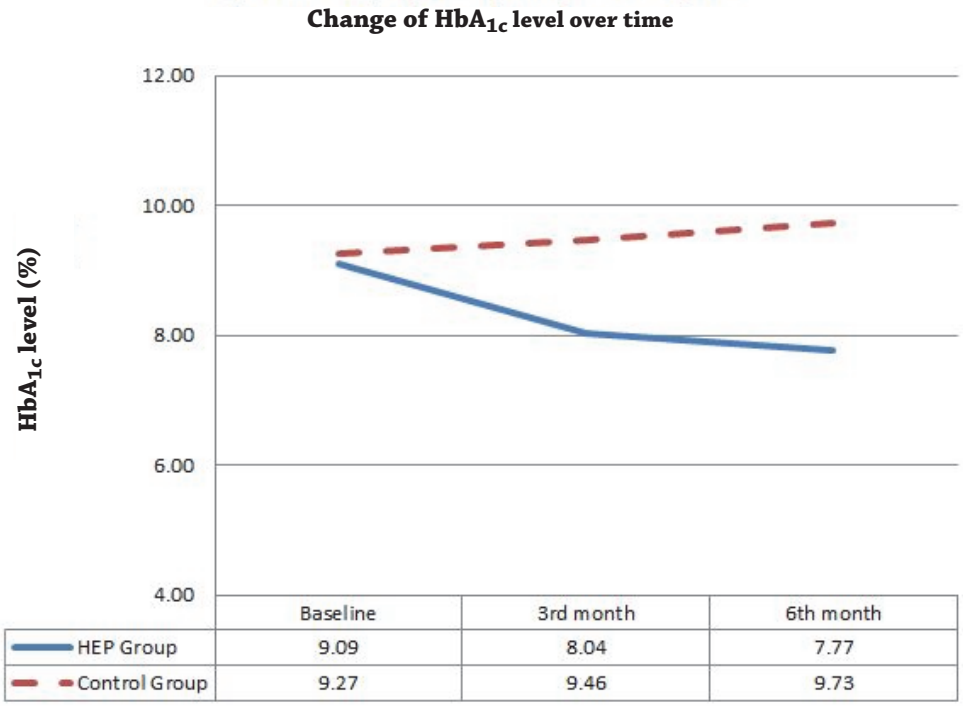

Chart 1. Change of HbA_{1c} level over time. Repeated measures analysis of variance. Group $F(1.63) = 7.696$, $p = 0.007$, $p < 0.01$, there was a difference between the groups. Time $F(1.574, 99.175) = 6.915$, $p = 0.003$, there was a difference between the time measurements, $p < 0,01$. Group*Time $F(1.574, 102.894) = 19.152$, $p = 0.000$, interaction was significant, $p < 0.001$.

3.82 (±4.18) in the HEP group and 4.64 (±7.53) in the control group, and no significant difference was observed between the groups ($p > 0.05$). During the follow-ups, the number of hypoglycaemic episodes decreased significantly in six months in both groups ($p = 0.01$ in the HEP group, $p = 0.008$ in the control group), but no difference was observed between the groups ($p > 0.05$). The number of hypoglycaemic events in six months was 2.23 (±3.04) in the HEP group and 2.44 (±4.59) in the control group.

The rate of managing hypoglycaemia correctly in patients with hypoglycaemia in the HEP and control groups was similar at baseline. During the follow-up period, the number of patients in the HEP group who were able to manage hypoglycaemia increased (Table 1).

Table 1. Distribution of data on the self-management of hypoglycaemia [a]

Self-management of hypoglycaemia	HEP group		Control group		*p* [b]
	n	%	*n*	%	
Baseline					
Correct	13	28.9	12	31.6	0.790
Incorrect	32	71.1	26	68.4	
In one month					
Correct	10	66.7	5	45.5	0.426
Incorrect	5	33.3	6	54.5	
In three months					
Correct	14	93.3	3	37.5	**0.009**
Incorrect	1	6.7	5	62.5	
In six months					
Correct	13	92.9	3	33.3	**0.005**
Incorrect	1	7.1	6	66.7	

Note: [a] Only patients with T2DM who had hypoglycaemia were evaluated. [b] Chi-square test/Fisher's exact test.

Results on impaired awareness of hypoglycaemia and fear of hypoglycaemia

According to the Clarke Hypoglycaemia Awareness Scale, the impaired awareness of hypoglycaemia at baseline was 11.8% in the HEP group and 10% in the control group ($p > 0.05$). In the six-month follow-up, no patients with impaired awareness of hypoglycaemia were identified in the HEP group; however, patients with impaired awareness of hypoglycaemia were identified in the control group (8.3%) ($p < 0.01$) (Table 2).

Table 2. Change of the clarke hypoglycaemia awareness scale results

Classification of hypoglycaemia awareness	HEP group		Control group		*p* [a]
	n	%	*n*	%	
Baseline					
Normal awareness	45	88.2	45	90.0	0.776
Unclassified	0	0.0	0	0.0	
Impaired awareness	6	11.8	5	10.0	
In six months					
Normal awareness	38	86.4	33	91.7	**0.006**
Unclassified	6	13.6	0	0.0	
Impaired awareness	0	0.0	3	8.3	

Note: [a] Chi-square test/Fisher's exact test.

Before the education programme, the behaviour subscale score, worry subscale score, and total score of the Hypoglycaemia Fear Scale were similar in both groups. In the six-month follow-up, both the subscale scores and total scale score changed significantly in the HEP group. The hypoglycaemia fear score showed a significant decrease in the HEP group ($p < 0.05$) (Table 3).

Table 3. Comparison of differences between baseline and sixth month scores of hypoglycaemia fear scale in two groups

Subscales of the scale	HEP group		Control group		*p* [a]
	Mean ± sd	Median (min–max)	Mean ± sd	Median (min–max)	
Behaviour subscale	–7.75 ± 8.98	–5.5 (–34/3)	–1.11 ± 4.28	0 (–13/12)	**0.001**
Worry subscale	–9.25 ± 11.11	–4.5 (–39/3)	–0.81 ± 5.13	0 (–17/16)	**<0.001**
Total scale score	–17.0 ± 19.24	–11 (–69/3)	–1.92 ± 8.53	0 (–30/28)	**<0.001**

Note: [a] Mann–Whitney *U* test.

Discussion

Hypoglycaemia is a common problem in patients with T2DM and increases in insulin users (Aronson et al., 2018; Zhong et al., 2017). At baseline assessment, the present study revealed that more than half of the patients in both groups experienced at least one episode of hypoglycaemia in the six months before the study.

In this study, the frequency of hypoglycaemia decreased in both groups compared to the baseline values, but there was no statistically significant difference between the groups. Ehrmann et al. (2018) reported that education programmes decreased the number of hypoglycaemic events in diabetic patients who were using insulin pump. De Zoysa et al. (2014) reported that the education programmes reduced the frequency of hypoglycaemia in patients with T1DM and patients with T2DM. Longer follow-ups may be needed to show the effect of patient education in decreasing the frequency of hypoglycaemia.

In the HEP group, fasting blood glucose, postprandial blood glucose, and HbA1c levels decreased significantly in the follow-ups compared to the baseline, while these values remained high in the control group. The related studies reported that intensive glycaemic control increased the frequency of severe hypoglycaemia (Chow et al., 2018; DCCT, 1993; UKPDS, 1998). Despite the significant improvement in glycaemic control in the HEP group in the present study, the frequency of hypoglycaemia in this group was similar to the value in the control group.

Effective hypoglycaemia management reduces the duration of a hypoglycaemic episode, as well as the number of prolonged and recurrent episodes. In this study, the effective management of hypoglycaemia was similar in both groups at the baseline. During the follow-up period, the management of hypoglycaemia showed a significant improvement in the HEP group compared to the control group. In the literature, it is stated that there has been a decrease in the frequency of hypoglycaemia and an improvement in the management of hypoglycaemia with education programmes offered to patients with diabetes (Iqbal and Heller, 2018).

In the literature, it is reported that symptoms felt at the time of a hypoglycaemic episode changed over time, and awareness of hypoglycaemia was impaired (Seaquist et al., 2022). However, it is important that diabetic patients feel the symptoms of hypoglycaemia so that it can be recognised earlier for the necessary intervention. Therefore, it is important to identify diabetic patients who show impaired awareness of hypoglycaemia. Impaired awareness of hypoglycaemia can be defined using different methods. Data from self-monitoring of blood glucose and measurements from continuous glucose monitoring, as well as proven, research-based scales and scoring systems, can be used to identify awareness levels.

In this study, the Clarke Hypoglycaemia Awareness scale was used to identify impaired awareness of hypoglycaemia. In the measurements performed with the scale, the awareness of hypoglycaemia improved in the HEP group. The improvement in patients' hypoglycaemia awareness, which was determined by the scale during the HEP, can be explained as a positive result of the education. The studies reported that structured educational opportunities showed an improvement in the awareness of hypoglycaemia in patients with T1DM (de Zoysa et al., 2014; Demir et al., 2019; Little et al., 2018).

A patient's fear of hypoglycaemia is associated with frequent and severe hypoglycaemic events. Fear of hypoglycaemia disrupts treatment adherence and negatively affects glycaemic control (Rossi et al., 2019; Sakane et al., 2015; Zhang et al., 2021). In this study, fear of hypoglycaemia decreased in the HEP group. The studies on education interventions also showed a decrease in the fear of hypoglycaemia after education; however, these studies were conducted either using general diabetes education programmes or with patients with T1DM (LaManna et al., 2019).

The present study revealed that both the frequency and fear of hypoglycaemia decreased in the HEP group. Although the frequency of hypoglycaemia decreased in the control group, the fear of hypoglycaemia did not decrease. Considering that the patients' efforts to control hypoglycaemia were insufficient in the control group, the results also showed that the patients' fear of hypoglycaemia was high. The study by Speight et al. (2016) revealed that in patients with T1DM, education reduced the hypoglycaemia event and distress associated with hypoglycaemia, and improved glycaemic control, sense of well-being, and self-control.

Education plays an important role in reducing the frequency of hypoglycaemia, improving hypoglycaemia management, reducing hypoglycaemia fear, and improving hypoglycaemia awareness in diabetic patients (Brennan et al., 2021; LaManna et al., 2019; Speight et al., 2016; Zhang et al., 2021). In this study, HEP improved self-management, reduced impaired awareness and fear of hypoglycaemia, and improved glycaemic control. Thus, the desired primary and secondary benefits could be achieved.

Structured education programmes have become increasingly widespread in patient education and have increased success of treatment (Iqbal and Heller, 2018). However, the most important aim in patient education is to motivate and empower patients for better self-management and develop behavioural changes. Education programmes prepared using active teaching and learning methods make it possible for patients with diabetes to become more empowered, learn how to live with diabetes, and change self-management behaviours. The integration of interactive techniques into diabetes education can enable the elimination of cognitive and motivational barriers to restore awareness and optimal diabetes management (Shuttlewood et al., 2015).

Strengths and limitations

The present study revealed that the HEP designed to address the needs of patients with T2DM for preventing and managing hypoglycaemia was effective. Hypoglycaemia events were objectively determined by the self-monitoring of blood glucose levels in addition to subjective evaluations using reliable scales. Another strength of the study was the similarities of the HEP and control groups at baseline.

The present study did not examine illiterate patients; thus its results could not be generalised to those patients. As the follow-up period of the study became longer, the number of participants decreased over time. For this reason, the follow-up period of the study was limited to 6 months.

Conclusion

This study was conducted with an experimental design to evaluate the effect of the HEP on preventing hypoglycaemia, reducing its frequency, and improving its management in patients with T2DM. It was found that the frequency of hypoglycaemia decreased in both groups but there was no significant difference between groups; management and impaired aware-

ness of hypoglycaemia improved and fear of hypoglycaemia decreased in the HEP group compared to the control group.

Practice implications

As a first and unique education programme focusing on hypoglycaemia in the management of T2DM in Turkey, the HEP was developed and found to be effective in patient education in clinical practice. It has a structured curriculum and uses an active, group-based education model with active teaching materials. Therefore, diabetes education nurses could use the HEP more in clinical practice and thus its information could be disseminated.

It is recommended to conduct further studies with a larger sample and over a longer period in order to evaluate the education programme presented in this study. In addition, it is recommended to conduct further randomised controlled experimental studies to improve hypoglycaemia and related conditions by developing models based on different training methods.

Authors' contributions

Study conception and design: *ATÖ, ŞÖ*; Developing the education programme: *ATÖ, ŞÖ*; Data collection: *ATÖ*; Data analysis and interpretation: *ATÖ, ŞÖ*; Drafting of the article: *ATÖ, ŞÖ*; Critical revision of the article: *ATÖ, ŞÖ*.

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Ethical aspects and conflict of interest

The authors declare no conflicts of interest, including any financial, personal, or other relationships with other people or organisations within three years of beginning the submitted work that could inappropriately influence, or be perceived to influence, their work.

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