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Intervention in emotional abilities for adolescents with type 1 diabetes mellitus in a hospital setting: a study protocol for a randomised controlled trial

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ABSTRACT

Introduction Type 1 diabetes mellitus (T1DM) is one of the most frequent chronic endocrine diseases in the paediatric population. As a result, this disease has a strong impact on psychological well-being. In line with this, emotional factors play an important role in adaptation. The aim of the present study protocol is to design an emotional abilities programme to improve metabolic control assessed by haemoglobin A1c (HbA1c) samples. Specifically, this intervention will be focused on adaptive coping strategies to deal with unpleasant emotions associated with T1DM. The primary aim of this project is to assess whether the employment of this new psychological intervention improves the emotional abilities of adolescents with T1DM.

Methods and analysis Two focus groups will be carried out for the design and evaluation of the programme following the APEASE criteria (affordability, practicability, effectiveness, acceptability, side effects/safety and equity). Behavioural change will be based on the Behaviour Change Wheel. Sixty-two participants from 12 to 18 years of age will be recruited at a public hospital and randomised to either an intervention or a control group. The intervention group will receive an emotional abilities training programme. The control group will receive usual educational intervention. The primary outcomes are metabolic control and emotional abilities. The secondary outcomes include emotional distress control, positive and negative affect, healthy habits, and quality of life. Data will be collected at baseline, immediately postintervention, and at follow-up visits at 6 and 12 months. A feasibility analysis will be conducted.

Ethics and dissemination The study has been approved by the Ethics Committee of Universidad Loyola Andalucía. Results will be submitted for publication in peer-reviewed journals and disseminated across the scientific community.

Trial registration number NCT03734367.

Strengths and limitations of this study

► A strength of this study is its design and implementation of an emotional intelligence educational programme adapted to the needs of adolescents with type 1 diabetes mellitus (T1DM).
► This trial is the first randomised controlled trial to evaluate the effectiveness of a programme for adolescents with T1DM.
► This programme will include training for adolescents and their parents.
► It may be difficult to have access to participants due to their specific characteristics.

and avoid hypoglycaemia. This has a major influence on the psychological and psychosocial functioning of this population and on the resources of health systems.[2 3]

Recent research indicates that emotional factors play an important role in the control of diabetes.[4 5] According to the literature, the burden of diabetes and its treatment contributes to emotional distress.[6 7] The emotional distress associated with diabetes can influence blood glucose control because it is related to a decrease in self-care behaviours and adherence to protocols and care routines. Some studies show that, even at low levels, the distress associated with diabetes is significantly related to glycaemic control, even after controlling for other emotional and clinical factors such as clinical depression.[8] Specifically, the scientific literature shows that levels of anxiety and depression affect adherence to diabetes treatment as individuals are less likely to comply with the recommendations of their healthcare providers due to the difficulty involved with adhering to lifestyle restrictions.[9]

For many patients, the need for lifelong medical care can generate high levels of frustration. The impact of long-term

INTRODUCTION
Background

Type 1 diabetes mellitus (T1DM) is one of the most frequent endocrine diseases in childhood and adolescence and the main health problem of the paediatric population worldwide.[1] This chronic disease requires changes in lifestyle to maintain tight glycaemic control

complications leads to important changes in the ability of the patient to function in daily life, especially in adolescents.[10] Adapting to the illness frequently involves increased emotional distress and is often accompanied by a variety of negative emotional responses such as anger, guilt, isolation or pessimism.[7] Therefore, certain cognitive and emotional characteristics of patients with diabetes can have a dampening effect on emotional well-being.

Emotional abilities are a psychological resource that has been consistently linked to better physical and mental health.[11] Previous studies indicate that the ability of people to process emotional information adequately is related to effective social functioning, resilience to emotional and social pressures, and a lower emotional impact when faced with certain health problems.[12 13] Emotional intelligence (EI) is a set of abilities that include the identification, processing and use of simple and complex emotions to facilitate effective responses to problem solving.[14] EI is defined as 'the ability to accurately perceive, evaluate and express emotions; the ability to access and/or generate feelings that facilitate thinking; the ability to understand emotions and emotional knowledge; and the ability to regulate emotions promoting emotional and intellectual growth'.[14] The model is based on the hypothesis that people who perceive, understand and adequately regulate their emotions have greater mental health and report fewer physical symptoms, less stress and less illness. Based on the definition of EI, it seems logical that this combination of abilities may be negatively associated with the symptoms of T1DM because it provides resources to improve self-management when faced with the challenges of the condition.[15] Some studies have found that people with diabetes have significantly lower levels of intrapersonal and interpersonal EI than non-diabetic individuals.[16] Preliminary results suggest a negative association between levels of EI and poor management of diabetes (haemoglobin A1c (HbA1c)).[5] Moreover, adolescents with limited emotional abilities have higher levels of emotional distress and poorer management of emotional reactions associated with the condition and its treatment.[5 16] Indeed, recent studies show that adolescents with better emotional regulation strategies can handle the negative emotions associated with their condition, buffering the impact that the disease has on them.[17]

The ability of these patients to process and manage emotional states can affect the relationship between the negative emotions they experience and the impact of diabetes.[18] Therefore, EI can buffer the negative emotions produced by this chronic disease. Research has shown that EI is associated with less negative emotionality, less emotional discomfort when people face stressful situations and even with a lower perception of pain.[19]

According to the ability model of EI, the emotional knowledge and abilities it comprises can be taught and developed.[20] Teaching these abilities depends primarily on practice and training and to a lesser extent on verbal instruction. These abilities must be practised so that they become a more adaptive response in the natural repertoire of the individual. Studies support the effectiveness of specific EI training programme.[21] Improving emotional abilities in patients with diabetes can be an adequate framework to improve emotional well-being. In fact, there is empirical evidence of the effect of EI training in patients with diabetes. One example is the study carried out by Yalcin et al,[22] in which patients with type 2 diabetes who participated in an emotional abilities programme achieved higher levels of well-being and quality of life. Similarly, previous studies have indicated that better emotional abilities of parents are also associated with better disease management in their children. This relationship remains significant even when controlling for variables such as socioeconomic status, which has been associated with the management of diabetes in the medical literature.[22] Accordingly, the protocol will include a specific intervention module on the emotional abilities of parents. This will serve as reinforcement and as an aid in transferring to daily life the emotional abilities learnt by the adolescents.

This research aims to (1) design an EI educational programme based on the EI ability model and on the Behaviour Change Wheel (BCW)[23] adapted to the needs of adolescents with T1DM, and (2) analyse the effectiveness of this programme on diabetes management indicators and well-being immediately after completion of the training and at 6 and 12 months. The study hypotheses are the following: (1) adolescents in the emotional ability programme will show an improvement in metabolic control evaluated through HbA1c, healthy lifestyle habits and better emotional well-being than adolescents in the control group; and (2) behaviour change will be maintained 6 and 12 months after completing the programme.

METHODS: PARTICIPANTS, INTERVENTIONS AND OUTCOMES

Following the Standard Protocol Items: Recommendations for Interventional Trials statement, the current study protocol describes the details of the study rationale, proposed methods, organisation and ethical considerations.[24] This protocol describes a quasi-experimental study. The development of the study will have three phases: phase I: design of an EI educational programme for adolescents with T1DM; phase II: implementation of an intervention based on the programme; and phase III: assessment of the effectiveness of this programme.

Study setting
This study will be carried out at Hospital Universitario Virgen Macarena (Seville) in Spain.

Eligibility criteria
Participants will be recruited when they receive care at the hospital. The inclusion criteria will be (1) adolescents 12–18 years of age, (2) diagnosis of T1DM within the previous 12 months and (3) type of treatment, IU insulin/kg. The exclusion criteria will be (1) presentation of a psychiatric disorder or other chronic illness and (2)

not understanding the Spanish language. All the parents of recruited adolescents will be offered the opportunity to participate in a brief, specific training in emotional abilities. This training will help to strengthen and transfer the emotional abilities learnt by the adolescents to daily life. The training for parents will be carried out in two 2-hour sessions. The trainers will be psychologists specialised in T1DM who, prior to the start of the programme, will have received 16 hours of emotional abilities training over 2 days.

Interventions

In phase I, the design of the programme, theoretical materials and practical dynamics will be formulated. The International Society for Pediatric and Adolescent Diabetes recommends that (1) diabetes education should be person-centred and thus adaptable to individual needs; (2) diabetes management is unlikely to be successful without some degree of behavioural change in the patients; and (3) resources should be made available to the interdisciplinary paediatric diabetes team, to provide easy access to professionals with expertise in the mental and behavioural health of children and adolescents.[23] To elicit a change in behaviour, the emotional abilities programme will be based on the BCW.[25] This method synthesises 19 different behaviour change frameworks, providing a systematic approach for the design and evaluation of interventions connecting outcomes and action mechanisms. The overall desired behaviours are associated with glycaemic control and emotional abilities. In the pursuit of this achievement, we will conduct a behavioural analysis using qualitative research, scientific evidence and stakeholder consultation to determine what should change in the person and/or environment. This analysis will be guided by the capability-opportunity-motivation-behaviour (COM-B) model (eg, capability: 'Does the patient know how to use the handheld device for self-monitoring of blood sugar?' No change is needed as patients are shown in hospital how to use the device).

In bringing about the change, the BCW identifies different intervention functions (education, persuasion, incentivisation, coercion, training, restriction, environmental restructuring, modelling, enablement) that are connected to the COM-B components and will be applied in the development of the programme. These intervention functions can be delivered by a variety of techniques and vice versa. Techniques will be categorised using the Behaviour Change Technique Taxonomy.[26]

In order to ensure the suitability of the contents and methodology, a focus group will be conducted. Intentional sampling will be used to recruit the professionals in a multistep process. First, one of the authors (MAM-B) will propose a list of stakeholders and experts in the field. Second, another author will contact them by email and will schedule a meeting convenient for all the participants. For the focus group, the moderator will use a semi-structured interview guide. Questions will focus on the identification of target behaviours, intervention functions

that could alter these behaviours and the most appropriate techniques to be considered within an emotional abilities training programme. In addition, the APEASE criteria (affordability, practicability, effectiveness, acceptability, side effects/safety and equity) will be applied to the identified interventions and techniques for the final selection.[27] In this preintervention phase, another focus group will be held with the potential participants in the programme recruited during their routine medical visits at the hospital to address the subjective perception of their emotional needs.

Additionally, after the intervention, a second round of focus group will take place involving different subgroups (healthcare professionals and participants in the programme) to evaluate their experience. Topics will include components of the programme enjoyed, barriers to adherence and so on.

A feasibility analysis will be conducted simultaneously to evaluate the suitability of the programme for its use in practice. For this, we will use an adapted version of the questionnaire by Zeilinger et al,[28] including items related to the APEASE criteria (eg, practicability: 'From your point of view, is the complexity of program content appropriate?'). Participants in the focus groups will be asked to complete the questionnaire.

The emotional abilities training programme will focus on practising and improving emotional abilities so they can become habitual adaptive responses in the adolescent's repertoire.[21] Adolescents will participate in a 10-hour emotional abilities training programme to be carried out over 5 weeks, in sessions of 2.5 hours. The work methodology will be eminently practical, working in groups including analysis of real situations and interactive simulation. Parents of adolescents recruited for the training programme will receive two training sessions in emotional abilities (2 hours each) with the aim of helping adolescents to assimilate the contents and strengthen the abilities acquired during the training programme. To improve adherence to the intervention, texts will be sent to the parents and adolescents participating in the programme. Participants in the control group will receive usual educational intervention with a duration of 10 hours distributed over 5 weeks, in sessions of 2.5 hours. The aim will be improving knowledge and skills for the proper control of diabetes to prevent acute and chronic complications. In the event the intervention produces clinically meaningful results, the control group will receive the intervention once the study is complete.

Outcomes

The primary outcomes are glycaemic control and emotional abilities. The secondary outcomes are emotional distress control, positive and negative affect management, healthy habits, and quality of life. All outcomes will be assessed at baseline, immediately postintervention, and at the 6-month and 12-month follow-up visits.

	STUDY PERIOD					
	Enrollment	Allocation	Post-allocation			
TIMEPOINT	-t₁	0	Baseline (week 0)	Post-treatment (week 16)	6-month follow-up	12-month follow-up
ENROLLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
Intervention group			●———————●			
Control group			X			
ASSESSMENTS:						
			X	X	X	X
Glycemic control			X	X	X	X
Difficulties in Emotion Regulation Scale (DERS)			X	X	X	X
Diabetes Distress Scale (DDS-17)			X	X	X	X
Positive and Negative Affect Schedule (PANAS)			X	X	X	X
eVITAL toolkit8			X	X	X	X
Quality of life (SF-36)			X	X	X	X

Figure 1 Time schedule for enrolment, interventions and assessments.

Participant timeline

The study is planned to take place from January 2020 until December 2022. The time schedule for enrolment, interventions and assessments is presented in figure 1. Phase III will begin following completion of the intervention, with the post-treatment assessment. In addition, to evaluate the effects of our programme over time, follow-up assessments will be performed 6 and 12 months later.

Sample size

Thirty-one participants will be needed per group (n=62) to achieve an 80% probability of detecting a 1% (11 mmol/mol) difference in mean HbA1c between the two groups with a 5% significance in adolescents who initially have HbA1c above a high range of 8%–8.5%.[29] In adolescents with reduced HbA1c (less than 8%), the goal will be combined taking into account the reduction of HbA1c and the reduction of the hypoglycaemic rate.

For the evaluation of hypoglycaemia, the aim is to reduce the number of episodes of hypoglycaemia (<70 mg/dL) by 20% and/or to obtain a number of hypoglycaemia less than four episodes per week, ensuring the evaluation of records of six capillary glycaemia a day. The estimation for the sample size is based on a mean (SD) HbA1c of 8.84% (1.39) (73.1±15.3 mmol/mol) in adolescents 11–16 years of age diagnosed within the previous 12 months.

Recruitment

Phase II will begin with the recruitment of participants. The endocrinologists will be the gatekeepers for recruitment, which will take place in the hospital during routine endocrinology visits. Participants will be asked to complete a battery of psychological and physical health status questionnaires in a single session. After that, they will be assigned randomly to each group. Randomisation and allocation will be performed by one of the researchers (MRG-C). The allocation sequence will be computer-generated, using a simple random assignment with the procedure 'Assignment of subjects to treatments' available in Epidat V.4.2 software.[30] Within the course of the intervention, the trainers will be unblinded to group allocation. The collection of outcome measures will be performed by the endocrinologists who will be blinded to the group allocation of the participants.

METHODS: DATA COLLECTION, MANAGEMENT AND ANALYSIS

Assessments at baseline and at follow-up will be performed by the endocrinologists who will be blinded to the group allocation of the participants.

Glycaemic control

Participants report their HbA1c level from their last blood test. The American Diabetes Association recommends a target HbA1c of 7.5% for children and adolescents.[31] Moreover, mean glucose, SD, percentage of glucose in normoglycaemia (time in range, according to individualised target), per cent of time in hypoglycaemia (below 70), per cent of time in hyperglycaemia (according to an individualised target) and the number of hypoglycaemic episodes will be collected. Variables will be analysed from the last 15 days prior to evaluation. Metabolic variables will be obtained using a flash glucose monitoring device (FreeStyle Libre) as it has become the standard glucose monitoring system in the Andalusian Public Health System for the paediatric population. For non-flash glucose monitoring users, metabolic variables will be obtained by glucometers through their specific software.

Difficulties in Emotion Regulation Scale

The Difficulties in Emotion Regulation Scale[15 32] is a 28-item, self-report questionnaire measuring clinically relevant difficulties in emotion regulation. In the Spanish adaptation, the items are grouped into five subscales: impulse control difficulties, non-acceptance of emotional response, difficulties engaging in goal-directed behaviour, lack of emotional awareness and lack of emotional clarity. Subscales are scored on a 5-point scale ranging from 1 (never) to 5 (always). Higher scores indicate greater difficulty with emotion regulation. This scale has been shown to have adequate psychometric properties.[33]

Diabetes Distress Scale

The Diabetes Distress Scale-17[34] assesses the emotional distress associated with diabetes and includes four dimensions: emotional burden, physician-related distress, regimen-related distress and diabetes-related interpersonal distress. Higher scores indicate greater stress related to the disease. This scale has been shown to have adequate internal consistency and validity. Cronbach's alpha ranged from 0.88 to 0.93.[34]

Positive and Negative Affect Schedule

The Positive and Negative Affect Schedule[35 36] is a self-reported adjective checklist that contains two 20-item subscales designed for the assessment of positive and negative affect. Respondents use a 5-point Likert scale to rate the extent to which they usually feel each of the 20 emotion-related words. Reliability and validity reported by Watson and colleagues[36] were moderately good. Cronbach's alpha ranged from 0.87 to 0.90.

eVITAL toolkit8

The eVITAL toolkit8[37] is an adaptation of the Macrodomain Diet and Exercise 4.1 Diet and nutrition domain and 4.2 Exercise domain from the eVITAL toolkit for measuring healthy habits in diabetes.

PedsQL 4.0 Generic Core Scales

The 23-item PedsQL 4.0 Generic Core Scales[38] comprise four multi-item scales that explore dimensions of health-related quality of life: (1) physical functioning (eight items), (2) emotional functioning (five items), (3) social functioning (five items) and (4) school functioning (five items). This scale has shown an acceptable level of reliability.

Patient and public involvement

Patients and parents will not be involved in formulating the research question or the outcome measures, but they will participate in the design and evaluation of the programme. A focus group with adolescents will be undertaken to enable the programme to respond to their emotional needs. Following completion of the intervention, a second focus group will gather all the study participants to provide feedback on the results of the study.

Statistical methods

The results will be analysed according to the objectives proposed in the project. For the first aim of the study, to design an EI educational programme based on the EI ability model and on the BCW adapted to the needs of adolescents with T1DM, focus groups will be examined using thematic analysis. Following the reflexivity principle, changes in the programme will be implemented if any discrepancy or difficulty is reported by the participants. All focus groups will be digitally audio-recorded and transcribed verbatim by one of the authors. Based on an inductive approach, thematic analysis will be conducted following an iterative and reflexive process, with the findings emerging directly from the data. Focus groups will be analysed independently by two researchers with the aim of identifying meaningful segments related to the needs of the intervention programme design, identifying major themes and subthemes.

For the second aim of the study, which is to examine the effectiveness of the intervention on the improvement in emotional abilities, metabolic control, lifestyle habits and emotional well-being, a comparison of the means will be performed. First, in order to determine if there are significant differences between groups at baseline, scores will be compared via t-test for independent samples. Second, pre-follow-up and post-follow-up measurements will be compared using t-test for repeated measures. Considering the design of the research, analysis of covariance will be used to separate the effect of the intervention from the effect of the differences in the selected participants. Following the guidelines of Cook et al,[39] the effectiveness of the intervention will be assessed using an analysis of the post-test covariance for groups (both intervention and control) including the pretest scores as a covariate. In addition to the quantitative analyses, focus groups of participants and healthcare professionals to be undertaken following the intervention will provide a deeper understanding of the experience and the acceptability of the intervention. A feasibility analysis will be conducted considering the APEASE criteria.

ETHICS AND DISSEMINATION

Each participant will receive information about the aim and procedures of the study and will provide written consent for participation. Consent and assent will be obtained by the endocrinologist. The data will be confidential and anonymised and used solely for the objectives of the study (Organic Law 15/1999 on the Protection of Personal Data). Numerical codes will link each participant's identification information. Data collected will be stored in a locker in the place of work of the principal investigator, and electronic data will be protected by password on the university network computer. Any protocol amendments will be registered at ClinicalTrials.gov.

The results of this protocol will be disseminated in different high-impact, peer-reviewed scientific journals, as well as national and international academic forums. The researchers will provide feedback to key stakeholders and associations dedicated to interventions with adolescents with diabetes.

DISCUSSION

The first aim of this study is to design an emotional abilities educational programme based on the EI ability model and on the BCW adapted to the needs of adolescents with T1DM. The anticipated results of this study could incorporate improvements in routine clinical practice. This programme will offer an effective tool to improve health and general well-being.

The second aim is to analyse the effectiveness of this programme on diabetes management indicators and well-being immediately after completion of the training and at 6 and 12 months. We anticipate finding that the improvement in emotional abilities through training will improve well-being, quality of life and glycaemic control in these adolescent patients with T1DM as demonstrated by previous studies in patients with type 2 diabetes.[22 40] These results show successful emotional abilities training, underlining the importance of emotional abilities interventions in this population. Moreover, family support is an

important protective factor,[41] and there is evidence associating the emotional abilities of parents with the diabetes management outcomes of their children. For this reason, this intervention programme will include two training sessions in emotional abilities for parents. We expect that this parent-focused intervention will strengthen the abilities acquired in the adolescents.

Despite every effort to control for confounding variables, this study will have some limitations. Access to participants may be difficult because they have very specific characteristics. This will be minimised by using gatekeepers who have direct access. Motivation for participation will be encouraged by taking into account intervention scheduling needs.

CONCLUSION

To the best of our knowledge, this would be the first programme specifically designed to improve the emotional abilities of adolescents. Although efforts have been made to develop and evaluate educational programmes for children and adolescents with T1DM, few seem to affect their emotional competencies. Many programmes evaluate emotional problems as outcomes; however, they do not provide explicit training in emotional abilities.[42] Working with adolescents and young adults on emotional ability development and utilisation may be a useful strategy in helping patients with T1DM effectively cope with their condition. Using effective emotional regulation strategies can help them feel more in control of their condition, a state associated with greater well-being.

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