

Protocol of Reducing Emotional Distress for Childhood Hypoglycemia in Parents (REDCHiP): A feasibility randomized controlled trial in the Portuguese context

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Abstract: Type 1 diabetes (T1D) in early childhood presents unique challenges, especially for parents who are mainly responsible for T1D treatment. Fear of Hypoglycemia (FH) is a major concern, as young children often cannot identify or communicate symptoms, increasing the risk of severe consequences. Reducing Emotional Distress for Childhood Hypoglycemia in Parents (REDCHiP) is the only validated psychological intervention specifically developed to target parental FH in early childhood. This protocol outlines plans to translate, adapt and implement REDCHiP in Portugal. A Feasibility Randomized Controlled Trial (FRCT) will be conducted using a two-arm, open-label design and a mixed-method approach among parents of children up to 8 years old. Participants will be randomly allocated (1:1) to the intervention or treatment as usual (TAU) and assessed at baseline, post-intervention, and three-month follow-up. Primary outcomes will focus on parental psychological adjustment, including FH and diabetes distress. Secondary outcomes will evaluate children’s Glycated Hemoglobin (HbA1c), via Glucose Management Indicator (GMI) and Blood Glucose Sample Test, and Time Below Range (TBR), Time In Range (TIR), and Time Above Range (TAR). Semi-structured interviews will explore participants’ experiences with this intervention. This study represents the first international adaptation and implementation of REDCHiP and the first evaluation of its feasibility and acceptability in a European context. Findings may inform the integration of culturally adapted psychological support and digital interventions into pediatric diabetes care.

Keywords: Protocol, Psychological intervention, REDCHiP, Parents, fear of hypoglycemia, Type 1 diabetes.

Background

For young children living with a chronic disease such as Type 1 diabetes (T1D), and their caregivers, health development is both critical and uniquely vulnerable (Haegele et al., 2022;

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Jeppesen et al., 2026). Throughout early childhood, parents play a vital role in shaping children's well-being outcomes (Baş et al., 2025). However, the demands of T1D management can impose substantial challenges on families, making this a particularly sensitive period.

While young children may not fully understand the complexity of T1D, this experience is often frightening for caregivers (e.g., especially those whose children were recently diagnosed with T1D), requiring tailored care and continuous vigilance (Smaldone & Ritholz, 2011; Streisand & Monaghan, 2014; Sullivan-Bolyai et al., 2003). The exhaustive management of T1D (i.e., insulin administration, monitoring blood glucose levels, counting carbohydrates and treating hypoglycemia and hyperglycemia) is typically the responsibility of parents during early childhood (Monaghan et al., 2022). Some children may begin to engage in simple tasks of T1D around the time that they enter elementary school, although this would occur under full parental supervision and with support from others (e.g., school staff) (American Diabetes Association [ADA], 2002).

According to Aalders et al. (2025), sharing responsibilities and tasks associated with T1D management might be influenced by contextual and individual factors such as the school and health care team, child diabetes self-efficacy and emotional well-being, and parents' personality and parenting behaviors. Given the considerable dependence of young children on their parents to carry out all tasks of T1D management, this substantial responsibility frequently triggers parental fears and concerns (Commissariat et al., 2020; Kimbell et al., 2021). Consequently, the demands inherent to T1D exert a significant psychological impact on parents' everyday life, commonly manifesting feelings and symptoms of anxiety, depression, burnout and distress (Bassi et al., 2021; Lindström et al., 2017).

One of the principal fears experienced by parents of young children with T1D is related to the occurrence of hypoglycemia episodes (Barnard et al., 2010; Zhang et al., 2022). These events may occur daily and could be associated with factors such as increased physical activity or prolonged periods without eating, within the context of common developmental variation and can lead to serious immediate effects (i.e., seizures and coma) as well as long-term complications (i.e., cognitive decline (Kalra et al., 2013; Yale et al., 2018). Moreover, young children often demonstrate reduced awareness for hypoglycemia and a limited ability to report its symptoms (i.e., weakness sensation, shaking and dizziness) making it challenging for parents and other adult caregivers to detect and treat a hypoglycemic event (Gonder-Frederick et al., 2013; Jensen et al., 2022). Taken together, these circumstances substantially increase parental FH, and in certain instances, may progress to clinical phobia (Cox et al., 1987). In line with the theoretical model of caregiver fear of hypoglycemia (Patton, McConville et al., 2020), higher parental FH is frequently associated with avoidant behaviors and maladaptive coping strategies related to hypoglycemia. These patterns may contribute to persistently higher glycemic levels and increased variability, which, in turn, can serve as a catalyst for the development of T1D complications (Patton, McConville et al., 2020).

The literature has highlighted the potential impact of parental FH on children's glycemic outcomes and T1D management (Costa, Pereira et al., 2025; Monzon et al., 2024). It is also unclear whether routine use of an insulin pump or continuous glucose monitor can help to reduce FH in parents of very young children with T1D without the addition of psychological support, suggesting it is a high priority to design and test interventions to effectively treat parental FH, enhance parental well-being, and promote their T1D treatment engagement (Patton, McConville et al., 2020).

The benefits of group interventions, as well as telehealth and digital delivery formats (i.e., potentially mitigating travel, time and physical costs), have been supported by research in various healthcare contexts (Balkhi, 2015; Tully et al., 2017). These advantages are further reinforced by well-established therapeutic factors (e.g., universality and interpersonal learning) associated with group therapy (Skinner & van der Ven, 2005; Snoek et al., 2001; Yalom et al., 2005). To the best of our knowledge, only two psychological interventions targeting parental FH have been developed in the United States (US). REDCHiP (Patton, Clements et al., 2020), designed for parents of young children with T1D, is currently the only intervention that has been fully evaluated, demonstrating improvements in parental FH, coping strategies, and children's glycemic outcomes. A second

intervention targeting parents of adolescents with T1D has been described in a protocol paper (O'Donnell et al., 2022). However, unlike REDCHiP, findings from its evaluation have not yet been published. Therefore, REDCHiP was selected for adaptation and validation in the Portuguese context because it is currently the only intervention with demonstrated efficacy in reducing parental FH among parents' of young children with T1D.

Despite these promising findings, REDCHiP has only been evaluated in the United States, limiting current understanding of its feasibility, acceptability and potential effectiveness across different cultural contexts of families with a child with T1D. Variations in healthcare system, access to psychological support, family roles in T1D management and cultural beliefs about their child condition, may all influence intervention engagement and outcomes. These efforts highlight the limited number and cultural scope of interventions addressing FH. Consequently, validation of REDCHiP in Portuguese families is an essential step to determine its transferability and implementation potential beyond its original context, addressing a key gap in the literature on digital psychological interventions targeting parental FH.

Present study

The objective of this Feasibility Randomized Controlled Trial (FRCT) is to assess the acceptability and effectiveness of the REDCHiP intervention among parents of young children with T1D in the Portuguese context. Beyond evaluating intervention outcomes, this study seeks to determine whether REDCHiP can be effectively translated, adapted and implemented in a European context, more explicitly among parents of children with T1D in Portugal. As the first international adaptation of REDCHiP, this protocol will provide novel evidence regarding the feasibility of disseminating a validated intervention for parental FH beyond its original US setting. Aims are to evaluate: (1) acceptability and feasibility by assessing recruitment and retention rates, sessions attendance, and parental satisfaction; (2) effectiveness by analyzing changes in parents' FH, diabetes distress (DD), emotional regulation (ER), resilient coping skills (RC), and anxiety and depression as well as changes in child glycemic outcomes (HbA1c, GMI, TBR, TIR, TAR) across three time points between intervention and TAU group; and (3) participants experiences and feedback regarding the REDCHiP intervention through qualitative interviews.

In line with previous REDCHiP findings (Patton, Clements et al., 2020), and reported feasibility and acceptability study (Marker et al., 2020), we hypothesize that participants in the intervention group will report lower levels of FH and better glycemic outcomes at immediate post-intervention compared to TAU group. We anticipate between-group differences at three-month follow-up. Furthermore, we expect that REDCHiP will lead to greater improvements in all psychosocial adjustment factors (i.e., FH, DD, ER, RC, anxiety and depression) among parents in the REDCHiP intervention compared to the TAU group, from baseline to post-intervention.

Method

Study design

The implementation of REDCHiP in the Portuguese context will involve a two-arm, parallel-group, open label, mix-method FRCT, with a 1:1 allocation ratio. The present protocol was developed in accordance with Standard Protocol Items Recommendations for Interventional Trials (SPIRIT) (Chan et al., 2025). Furthermore, our investigation follows the ORBIT model for Randomized Controlled Trials (Czajkowski et al., 2015), specifically Phase 2 – Preliminary Testing, paving the way for potentially progressing to Phases 3 and 4, which involve future large-scale efficacy trials.

Participants, recruitment and randomization

A clinical and convenience sample of parents of young children up to 8 years of age with T1D, receiving care at two major hospitals in Lisbon, Santa Maria Hospital (Local Health Unit of Santa Maria) and Dona Estefânia Hospital (Local Health Unit of São José), will be recruited. Participant enrollment is expected to take place online or in person between January and April 2026, with the intervention anticipated to be delivered between April and December 2026. Informed consent will be obtained from all participants (i.e., online or in person) and instruments will be completed online. Recruitment will comprise direct and indirect approaches. First, indirect recruitment will occur through contacts with doctors and nurses from these hospitals, who may refer to parents potentially interested in this study. Second, we will announce that we are recruiting for the trial from these two hospitals on our project website and using social media. Third, we will interact with parents in person at daily diabetes consultations and contact them via email and phone.

Participants will complete study outcomes measures at three times: (1) pre-intervention, (2) immediate post-intervention and (3) 3-month follow-up (see Figure 1). We will randomly allocate participants to their treatment arm after they complete the pre-intervention assessment using specialized software incorporating automated blocking with fixed block sizes and stratification based on pre-determined factors (i.e., child T1D diagnosis length, type of insulin treatment and child age) to achieve control group size and mitigate potential confounding factors. REDCHiP will be delivered to parents by a psychologist, registered as an effective member of the Portuguese Order of Psychologists, with 11 years of experience, training in group therapy, and qualified to deliver this CBT-based manualized intervention. Participants allocated to the TAU group will not receive REDCHiP intervention. We anticipate having at least 44 parents enrolled in this study, with 22 parents assigned to each group (i.e., intervention and TAU group) due to the limited number of hospital cases involving children aged up to 8 years. Power analysis demonstrated that we would have sufficient statistical power (i.e., $f \geq 0.25$, $\alpha = 0.05$; $1-\beta \approx 0.80$) in group by time interactions. Additionally, following the final REDCHiP session, we plan to conduct interviews with participants that will be audio recorded to gather qualitative insights on the efficacy and other aspects of REDCHiP (see Figure 1).

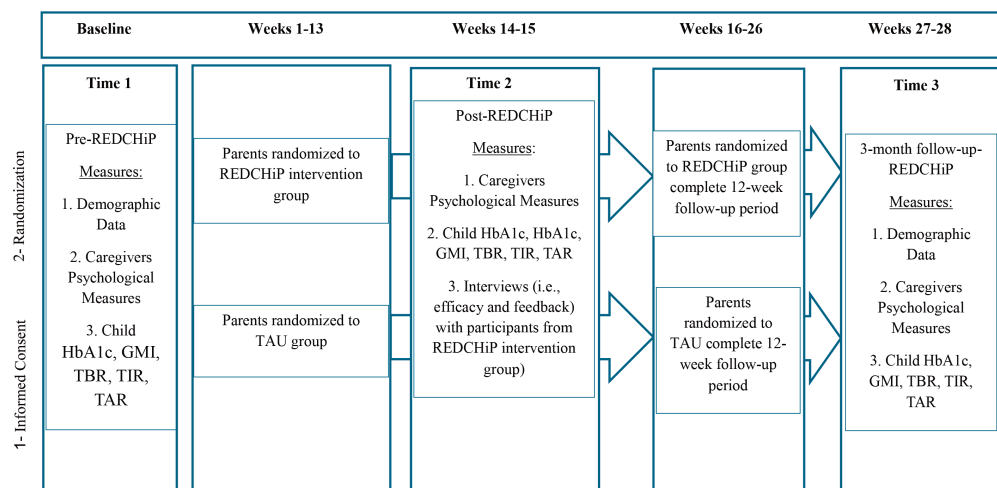


Figure 1. Participants flow diagram data collection and timeline

Note. Adapted from Patton, McConville et al., 2020. REDCHiP: Reducing Emotional Distress for Childhood Hypoglycemia in Parents; HbA1c: glycated hemoglobin; GMI: Glucose Management Indicator; TAU: Treatment As Usual; Time Bellow Range: TBR; Time In Range: TIR; Time Above Range: TAR.

Inclusion and exclusion criteria

For our inclusion criteria, (1) primary caregivers must have a young child aged ≤ 8 years with a confirmed diagnosis of T1D for at least three months, (2) young children must be using either a continuous subcutaneous insulin infusion (CSII) or multiple daily insulin injections (MDI) and continuous glucose monitoring (CGM) for daily T1D treatment, and (3) parents must have internet access and a computer, tablet or smartphone that connects to the internet. We will exclude, (1) parents with severe psychiatric diagnosis, (2) families of children with another severe chronic condition (e.g., chronic kidney disease and Crohn's disease), and (3) parents who are not fluent in Portuguese.

Ethics and dissemination

Ethics committee approval was obtained from Santa Maria Hospital (Lisbon, Portugal) with the Reference No. 114/24 and Dona Estefânia Hospital with the Reference No. Inv 632.

Also, this investigation is registered at Clinical Trials.gov with reference No. NCT07201779 (Registered on September 30, 2025). Informed consent will be obtained from parents by the principal researcher, aiming to ensure that participants are fully aware of the procedures, risks, benefits, and their free will to withdraw. Personal data will be treated in accordance with data protection regulations. Any relevant modifications and amendments to the protocol will be promptly communicated to the Ethics Committee of both healthcare institutions and updated at Clinical Trials.gov. Parents' psychological state will be monitored and managed through all sessions by the principal investigator or intervention facilitators to prevent severe emotional activation. Results will be systematically disseminated to participants, healthcare practitioners and the scientific community following the completion of the trial. Dissemination will occur through our project website, social media channels, and scientific outputs (i.e., peer-reviewed publications and presentations at international and national conferences). All findings will be properly de-identified to ensure participant confidentiality is maintained.

Translation and structure of REDCHIP intervention

To ensure cultural sensitivity in the adaptation process and translation of this manualized intervention and its materials (i.e., power point slides) the ecology validity model will be followed (Bernal et al., 1995, 2009). This framework comprises eight relevant factors: language (i.e., appropriate expressions and terms); metaphors (i.e., culturally important examples); persons (i.e., cultural knowledge of the psychologist delivering the intervention); content (i.e., integration of cultural values); concepts (i.e., ideas adjustable to the new environment); goals (i.e., cultural alignment of intervention objectives); methods (i.e., intervention delivery strategies) and context (i.e., suitability of social, economic and political variables) The translation process of this intervention will guarantee linguistic and cultural appropriateness (Beaton et al., 2000; Guillemin et al., 1993). Two translators will independently translate the manual and materials into European Portuguese and then work through consensus to attain a single and final translated version of the treatment manual and materials.

The original structure of the manualized REDCHiP intervention is 10 video-based telehealth sessions (i.e., 7 group and 3 individual sessions with the duration of 30 to 60 minutes) (Patton, McConville et al., 2020). The current Portuguese REDCHiP intervention will consist of 10 video-based telehealth group sessions, targeting parents of young children (≤ 8 years old). This format aligns with emerging recommendations to evaluate alternative trials delivery formats, which may enhance the intervention's accessibility and scalability (Kahhan et al., 2025). This intervention is

grounded in Cognitive Behavioral Therapy (CBT) principles, and is designed to address parents FH, and their avoidant coping behaviors related to FH. In addition, the sessions also focus on strengthening parents' coping strategies associated with T1D management and helping them to reduce feelings of diabetes distress (see Table 1 for intervention key themes).

Table 1

REDCHiP Intervention key points content

Session number	Key points content
1	Introduction to REDCHiP intervention, and to Cognitive Behavioral Therapy (CBT) (e.g., cognitive triangle for fear of hypoglycemia and cognitive distortions);
2	Contingent Attention and Parenting (e.g., the relevance and strategies of praise and planned ignoring).
3	Cognitive Reframing (e.g., addressing negative thoughts) and healthy coping strategies in diabetes management.
4	Fear Hierarchy, Imaginal and In Vivo Exposure (e.g., practical exercises based on parents' real fears and strategies to address and reduce them).
5	Glycemia pattern analysis relevance (e.g., expectations and strategies) and SMART Goals;
6	Number Fear (e.g., deconstructing fear related to glycemic values) and CBT-based strategies (e.g., coping techniques to manage this fear);
7	High and Low Blood Glucose Symptoms & Type 1 Diabetes Management (e.g., exploring parents' emotions and providing strategies to implement with their child);
8	Behavioral Parenting Strategies and Tools (e.g., establishing family rules and practical tools for Type 1 Diabetes management).
9	Sticky Fears Related to T1D and Problem-Solving (e.g., defining fears, exploring parents' thoughts, and developing practical coping strategies).
10	Review of all sessions and Maintenance

Note. Adapted from Patton, McConville et al., 2020 and REDCHiP Manual.

More specifically, REDCHiP uses CBT strategies to increase parents' awareness of any maladaptive thoughts and behaviors they may have related to FH (e.g., fear associated with in target glucose levels, reducing insulin to maintain higher glucose levels) and helps them to adopt more adaptive coping skills. REDCHiP also includes content to improve participants' parenting skills and some T1D education to promote parents' knowledge and skills related to managing their young child's T1D. We will conduct sessions online via the Teams platform and all participants will be able to access the sessions using an electronic device (i.e., tablet or computer). The sessions will not be recorded. However, the accredited psychologist will register notes from every session to provide important information for future sessions and interventions. TAU group will not receive the REDCHiP intervention.

Following the REDCHiP intervention, audio-recorded interviews will be conducted with parents either online or in-person, depending on availability (see Figure 1) to gather qualitative data regarding the intervention's feasibility and acceptability.

Instruments

Sociodemographic assessment. Information on parent and child age, gender, academic levels and district of residence will be collected. Data on parents' socioeconomic status, marital status, CGM monitoring (i.e., per day, how many times, on average, do you monitor/verify your child's diabetes?), T1D treatment (i.e., insulin pump or pens) and any diagnosis of mental health disorder will also be gathered. In addition, information on T1D duration and any diagnosis of other chronic conditions will be obtained.

Parents' psychological measures

The Hypoglycemia Fear Survey – Parents (HFS-P) (Clarke et al., 1998; Costa, Patton et al., 2025), is an 18-item self-report measure that assesses parents FH via total score and two subscales: Behavior (“*Have my child eat large snacks at bedtime*”) and Worry (“*No one being around to help my child during a low*”). Items are rated on a 5-point Likert scale ranging from 0 (Never) to 4 (Almost always). Scores for each subscale and total scale are computed by summing the respective items.

The Problem Areas in Diabetes – Parent Revised (PAID-PR) (Markowitz et al., 2012; Costa, & Brandão, 2024) is an 18-item self-report measure designed to evaluate parents' diabetes-related distress when caring for a child with T1D. It comprises two subscales: Immediate Burden (“*I feel that my child is excluded from activities/events because of his/her diabetes*”) and Theoretical Burden (“*I worry about my child having a low blood sugar*”). Items are rated on a 5-point Likert scale from 0 (Agree) to 4 (Disagree), with all items reversed-scored. Total scores range from 0 to 100.

The Depression Anxiety Stress Scales (DASS-21) (Lovibond & Lovibond, 1995; Pais-Ribeiro et al., 2004) is a 21-item measure that assesses the severity of symptoms across three dimensions: anxiety (“*I was aware of dryness of my mouth*”), depression (“*I felt down-hearted and blue*”) and stress (“*I found it hard to wind down*”) scales. Each item is rated on a 4-point Likert scale from 0 (Does not apply to me at all) to 3 (Applies to me most of the time). Total scores for the three scales are obtained by calculating the respective items, resulting in total scores ranging from 0 to 21 for each dimension.

The Brief Resilient Coping Scale (BRCS) (Pais-Ribeiro & Morais, 2010; Sinclair & Wallston, 2004) is a 4-item self-report measure designed to assess resilience as a coping mechanism, reflecting an individuals' capacity to adapt and manage stress (“*I look for creative way to alter difficult situations*”). Participants respond to each item using a 5-point Likert scale ranging from 1 (Almost never) to 5 (Almost always). Total score can range from 4 to 20.

The Emotion Regulation Questionnaire (ERQ) (Gross & John et al., 2003; Vaz & Martins, 2008) is a 10-item scale designed to examine two key emotion regulation strategies: (I) Cognitive Reappraisal (“*I control my emotions by changing the way I think about the situation I'm in*”) and (II) Expressive Suppression (“*I keep my emotions to myself*”). Items are rated in a 7-point Likert-scale ranging from 1 (strongly disagree) to 7 (strongly agree).

Interviews qualitative measure

The Client Change Interview (CCI) (Elliott et al., 2008; Sales et al., 2007) is a semi-structured qualitative measure aimed at understanding clients' (i.e., in this case, REDCHiP participants) perspectives and experiences on any personal changes (e.g., positive and negative situations) associated with ending a therapeutic process (i.e., participants feedback from group intervention).

For the present study, an adaptation of this instrument (Brandão, 2017) will be employed containing several important domains: (1) Change (“*Has anything changed for the worse for you since group therapy started*”); (2) change ratings (“*How important or significant to you personally do you consider this change to be*”); (3) attributions (“*In general, what do you think has caused these various changes*”); (4) resources (“*What things in your current life situation have helped you make use of group therapy to deal with your problems*”); (5) limitations (“*What things in your current life situation have made it harder for you to use group therapy to deal with your problems*”); (6) helpful aspects (“*Can you sum up what has been helpful about the group therapy so far*”); (7)

problematic aspects (“*Has anything been missing from your group therapy*”); (8) the investigation (“*What has it been like to be involved in this research*”); Part two is divided into four topics:

- Motivations and expectations to collaborate in the group intervention (“*Why did you decide to participate in group therapy*; “*What did you expect by participating in the group*”);
- Involvement in group intervention (“*What did this group mean to you, and what does it mean to you now*”);
- Group design (“*What did you think of the group’s organization*”);
- Therapeutic relationships (“*What did you like most and least about your relationship with the therapist*”).

Children T1D biological measures

Child HbA1c will be measured through point-of-care HbA1c test (i.e., Dona Estefânia Hospital) and laboratory blood sample (i.e., Santa Maria Hospital). GMI, TBR, TIR and TAR will be computed using children’s personal CGM data (i.e., Dexcom®, Freestyle Libre® or Guardian®). These measures will be shared upon parental authorization and collected in close collaboration with the hospital team (i.e., physicians or nurses), through the respective monitoring platforms, thereby ensuring data feasibility.

Data analyses

Quantitative data analysis will be conducted using Jamovi software. First, descriptive statistics will be used to summarize sample characteristics. Second, Spearman’s correlations will assess associations between demographic variables (e.g., child age and sex) and clinical covariates (e.g., insulin treatment) with the primary outcomes (e.g., FH). Third, between-group differences (i.e., intervention vs. TAU) over three time points (i.e., pre-, post-intervention and three months follow-up) will be examined using repeated measures ANOVA. Fourth, within-group changes will be evaluated using paired sample *t*-tests for parents’ psychological factors and children’s glycemic outcomes (i.e., GMI, TBR, TIR, TAR and HbA1c). Finally, effect sizes (e.g., Cohen’s *d*, partial eta squared) and *p*-values will be reported to determine effect significance.

Qualitative data from interviews with REDCHiP participants will be analyzed using NVivo software. Content analysis will be conducted following the three core phases described by Krippendorff (2004): (1) Pre-analysis, involving transcription of the interviews and preliminary familiarity and immersion of participants perspectives; (2) Exploration, where transcripts will be systematically coded and categorized to identify patterns and recurring themes; (3) Results management, in which the coded data will be interpreted, focusing on the perceived feasibility and acceptability of the REDCHiP intervention. Two independent coders will perform the coding procedure. Inter-coder reliability will be evaluated using Cohen’s Kappa coefficient to ensure consistency with any discrepancies resolved through deliberation until consensus is attained.

Discussion

This protocol describes the implementation of the pioneering REDCHiP intervention for parents of young children with T1D in Portugal. Similarly, to Patton, Clements et al. (2020) findings, we expect that parental FH, DD, and children’s glycemic control will improve post-intervention. Thus, addressing the scarcity of psychological interventions for this population and the limited

implementation of REDCHiP outside the United States, this study may emphasize the importance of working towards greater integration of evidence-based psychosocial interventions in routine T1D care.

Limitations

The present FRCT has both anticipated limitations and strengths. One of the limitations is the relatively small, estimated sample size, which may restrict the generalizability of the results. Logistical concerns (i.e., scheduling conflicts and time commitment), could lead to participants dropping out. Furthermore, self-report data may constitute a limitation, as it is potentially subject to response bias.

Strengths and clinical implications

Several key strengths of this study include its innovation and potential scalability. This trial represents the only cross-cultural adaptation of the REDCHIP intervention for the Portuguese context. In the original intervention, parents with children older than 7 years old were excluded, while the Portuguese REDCHiP intervention will extend the age range to include parents of children up to 8 years old, which may promote greater accessibility of the intervention. The trial will use a video-based telehealth group design and a manualized format which may facilitate scalability across different healthcare settings. The results of this trial may reflect an indirect effect among policymakers and healthcare professionals by raising awareness of the importance of integrated continuous psychological care on diabetes consultations.

Conclusion

In summary, the REDCHiP intervention trial primarily aims at reducing parental FH, DD and improving young children's glycemic outcomes (i.e., HbA1c, GMI, TBR, TIR, TAR). Moreover, qualitative data collection will provide essential insights to guide future refinements and intervention optimization. Furthermore, these findings may provide preliminary support for the potential applicability and replicability of the REDCHiP intervention beyond the United States context.

Declaration of conflicting of interests

The author(s) declares no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical approval

Ethics approval for the present investigation was provided by Santa Maria Hospital (Lisbon, Portugal) with the Reference No. 114/24 and Dona Estefânia Hospital with the Reference No. Inv 632. The present research is registered at Clinical Trials.gov with the Reference No. NCT07201779 (Registered on September 30, 2025).

Informed consent

All participants in this study were informed of the purpose of the study and how data will be used. They were assured that their identities would remain anonymous across the study.

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Authors' contribution

Conceptualization: VC; TB; Methodology: VC; Supervision: SRP, SV, LS, CL, TB; Writing – Original draft: VC; Writing – Review and editing: VC, SRP, SV, LS, CL, TB.

All the authors read and approved the final manuscript.

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Protocolo de Redução do Sofrimento Emocional face à Hipoglicemia na Infância para Pais (REDCHiP): Um ensaio clínico aleatorizado de viabilidade no contexto português

Resumo: A diabetes tipo 1 (DT1) na primeira infância apresenta desafios únicos, especialmente para os pais, que assumem a principal responsabilidade pelo tratamento da criança. O medo da hipoglicemia (MH) constitui uma preocupação significativa, uma vez que as crianças pequenas, frequentemente, não conseguem identificar ou comunicar os sintomas, aumentando o risco de consequências graves. O programa Reducing Emotional Distress for Childhood Hypoglycemia in Parents (REDCHiP) é a

única intervenção psicológica validada, direcionada ao MH parental em crianças pequenas com DT1. Este protocolo descreve os planos para traduzir, adaptar e implementar o REDCHiP em Portugal. Será conduzido um ensaio clínico randomizado de viabilidade (FRCT) com rótulo aberto de dois grupos e abordagem mista, envolvendo pais de crianças até 8 anos. Os participantes serão randomizados (1:1) para o grupo de intervenção ou para o de tratamento habitual (TAU) e avaliados nos momentos, antes da intervenção, pós-intervenção e aos três meses de seguimento. Os resultados primários focar-se-ão no ajustamento psicológico parental, incluindo MH e sofrimento psicológico relacionado com a gestão da diabetes. Os resultados secundários avaliarão a Hemoglobina Glicada (HbA1c) através do Glucose Management Indicator (GMI) e de um teste de glicose no sangue, e ainda, o tempo abaixo do intervalo (TBR), o tempo dentro do intervalo (TIR) e o tempo acima do intervalo (TAR). Entrevistas semiestruturadas explorarão as experiências dos participantes com a intervenção. Este estudo representa a primeira adaptação e implementação internacional do REDCHiP, e a primeira avaliação da sua viabilidade e aceitabilidade num contexto europeu. Os resultados poderão contribuir para apoiar a integração do suporte psicológico e de intervenções digitais adaptadas culturalmente para os cuidados pediátricos de diabetes.

Palavras-chave: Protocolo, Intervenção psicológica, REDCHiP, Pais, Medo da hipoglicemia, Diabetes tipo 1.

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