

Feasibility Study of a Behavioral Parent Intervention to Support Self-management in Pediatric Typ 1 Diabetes: Statistical Analysis Plan

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ClinicalTrials.gov registration:

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Ethics consent:

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Feasibility criteria

- 1) Participation: at least 70% of participants or their partners attend at least four of the six initial sessions.
- 2) Satisfaction: participants are satisfied with the program's structure and content by scoring a mean of at least 24 points on the Client Satisfaction Questionnaire.
- 3) Engagement in the six behavioral assignments that are presented at each of the first six weeks' sessions as "this week's tool". Engagement is measured by weekly parent reports of 1) **frequency**: how often they used it (0-7 points reflecting number of days used), 2) **intensity**: how much effort they have put down in using it (0 = none, to 5 = a lot) and 3) **usability**: how helpful they perceive the strategy to be for them (0 = not at all, to 5 = very). We have chosen feasibility criteria to be met if mean scores for the whole group and all the components exceed 2 points in each of the three domains. The score will also be calculated separately for each component to investigate need of adjustments or removal of specific modules.
- 4) Whether the set of questionnaires is of reasonable size and capture relevant parameters according to the participants. Perception of questionnaire size is measured by asking participating parents to score how much time they perceived the questionnaires took ranging from 1-4 points (1 = a short while, 2 = reasonably long time, 3 = long time but it felt OK, 4 = too much time) after finishing the T2 questionnaires. This is followed by the same question regarding the weekly questionnaires. Children will answer the same question at the end of the T2 questionnaires. A mean score will be calculated for each of the assessments (T2 for parents, T2 for children, and weekly measurements for parents) and a score below 3 will be considered as reasonable questionnaire size. Perception of relevance is measured by asking participating parents whether the questions have captured relevant aspects rated from 1-4 (1 = yes totally, 2 = to a large extent, 3 = to some extent, 4 = not at all). This question is not posed to the children as it is considered difficult for a child to answer. If the mean score is 2,5 or less the questionnaires is considered to capture relevant aspects according to the participants.

Assessments

Outcome measures are assessed at three main time points: T1) baseline: one week before the intervention starts, T2) primary end point: four weeks after the last session, and T3) at 3-month follow-up: three months after primary end point. To explore change over the course of the intervention and mediators of change, a subset of the outcome variables are assessed weekly or every second week during the 15 weeks between baseline and primary endpoint. See table 1 for a full list of variables.

Statistical analysis of potential effects

Analysis of outcomes are performed using linear mixed models with time as independent variable, coded as a factor with two levels (T2 and T3) and baseline (T1) as the reference value. Secondary moderation analyses will be conducted to explore if ADHD symptoms in children and participating parents predict change on the primary outcome variable. The moderation analysis will be performed on the weekly collected outcome during treatment to optimize statistical power.

Within-group mediation analysis will be conducted using linear mixed models to investigate whether changes over time in diabetes treatment satisfaction, TiT and the parent-reported percentage of times their children have taken insulin and reacted to low / high blood glucose levels out of all the times it has been needed during the last week (“Getting Self-Management Routines Done”) are mediated by a change in parent-reported behavioral challenges in diabetes self-management, as measured by a non-validated questionnaire newly developed by the research group (Parental Challenges in Diabetes Self-Management).

Thematic analysis of interview data

Shortly after the sixth session, parents will be asked to participate in a short telephone interview conducted by psychology students with T1D knowledge, answering open-ended questions on their experiences of the intervention. Qualitative analysis of interview data will be performed with reflexive thematic analysis.

Table 1. Variables, measurements, and their assessment time points.

	Variable	Measurement	Assessment time points
Parent-reported data	Diabetes treatment satisfaction (primary outcome measure)	Diabetes Treatment Satisfaction Questionnaire (DTSQ)	T1, T2, T3, weekly assessments between T1-T2
	Self-management behaviors (proxy)	Getting Self-Management Routines Done	
	Parental challenges in diabetes self-management	Parental Challenges in Diabetes Self-Management	
	Parents' symptoms of anxiety	General Anxiety Disorder – 7 (GAD-7)	
	Child ADHD symptoms	ADHD Self Report Scale for Parents (ASRS)	T1
	Parent ADHD symptoms	Adult ADHD Self-Report Scale (A-ASRS)	
	Satisfaction with intervention	Client Satisfaction Questionnaire (CSQ)	T2
	Diabetes related family conflicts	Diabetes Family Conflict Scale (DFCS) – parent report	T1, T2, T3
	Parents' symptoms of stress	Perceived Stress Scale (PSS)	
	Parenting behaviors	Parenting Practices Scale	
	Parent self-efficacy	Me As Parent	
	Parent quality of life	Peds Quality of Life - Family Impact Measure (PedsQL-FIM)	
	Child health related quality of life	DISABKIDS – generic module, parent report	
Child-reported data	Child health related quality of life	DISABKIDS – generic module and diabetes module, child report	T1, T2
	Diabetes related family conflicts	Diabetes Family Conflict Scale (DFCS), youth report	
Medical data from NDR	Glycemic control	Glycated haemoglobin (HbA1c)	Closest before T1, after T2 and T3
	Physical activity	Number of days a week being physically active	Closest before T1, after T3
	Appointments at the diabetes clinic	Number of diabetes clinic appointments	
	Ketoacidosis	Incidents of ketoacidosis	
	Severe hypoglycaemia	Incidents of severe hypoglycaemia	
Medical data from online glucose system Glooko	Time in target	% time blood glucose values are within the target interval 4-8 mmol/mol the last 2 weeks	T1, T2, T3, assessments every second week between T1-T2
	Time with low blood glucose	% time blood glucose values are below 3 mmol/mol the last 2 weeks	
	Time with high blood glucose	% time blood glucose values are above 12,9 mmol/mol the last 2 weeks	
	Mean blood glucose	Mean blood glucose value the last 2 weeks	
	Blood glucose variation	Standard deviation of blood glucose values the last 2 weeks	

T1: baseline assessment, T2: primary end point assessment, T3: three months follow-up assessment.