

BMJ Open Disordered eating behaviours and eating disorders in adults with type 1 diabetes (DEBBI): rational and design of an observational longitudinal online study

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ABSTRACT

Introduction Disordered eating behaviours (DEB) and eating disorders (ED) are among the most common mental health comorbidities of type 1 diabetes. However, research on diabetes-specific risk and protective factors is limited. To this end, comprehensive characterisations of DEB and ED in type 1 diabetes, as well as longitudinal research on the course of DEB and ED, are needed to gain more insight. The 'Disordered eating behaviours and eating disorders in diabetes type 1' (DEBBI) study aims to describe DEB/ED and their correlates in people with type 1 diabetes, to identify key diabetes-specific, psychosocial risk and protective factors, and to describe the course of DEB over time.

Methods and analysis The DEBBI study is a longitudinal online survey with follow-up assessments after 6, 12 and 18 months, targeted at adults who have been diagnosed with type 1 diabetes for at least 12 months. The survey covers data on diabetes diagnosis and self-management (eg, diabetes treatment and complications), lifestyle (eg, eating habits, physical activity), psychosocial well-being (eg, anxiety, depressive symptoms) and demographic and medical information. It includes validated instruments and self-generated items. One key aspect of the data analysis will be latent profile analyses to determine latent subtypes of DEB manifestation in people with type 1 diabetes and their courses over time, including data on the clinical picture and symptoms, behaviours and diabetes-specific complications.

Ethics and dissemination The study protocol was approved by the Ethics Committee of the State Medical Chamber of Rhineland-Palatine, Germany (ID 2021-16040). Participants give informed written consent before starting the survey. The DEBBI study will provide more clarity in the so far inconsistent empirical evidence base and will help to inform research on prevention and intervention strategies that are tailored to diabetes-specific needs.

Trial registration number The study is registered with DRKS German Clinical Trials Register (DRKS00028833).

INTRODUCTION

Type 1 diabetes is a chronic autoimmune condition where β -cells in the pancreas do not produce insulin. Type 1 diabetes

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The 'Disordered eating behaviours and eating disorders in diabetes type 1' (DEBBI) study is an online survey easy to disseminate; it can achieve high statistical power, and participant burden is expected to be low.
- ⇒ With four assessment points, we will be able to capture steady symptoms and behaviours as well as medium-term changes, and to identify risk and protective factors for disordered eating.
- ⇒ Latent profile analyses will be used to identify distinguishable disordered eating behaviour subtypes.
- ⇒ While disordered eating behaviour is measured with validated questionnaires, we will not be able to validate self-reports of a current or former diagnosis of a (clinical) eating disorder.
- ⇒ We expect some degree of selection bias among online survey participants but believe that dissemination of the survey through online channels combined with analogue promotion of the study in diabetes centres and clinics could compensate this.

self-management requires careful monitoring of dietary intake to align insulin administration, to keep glucose levels in a desirable range and avoid hypoglycaemia and hyperglycaemia. Disordered eating behaviours (DEB) and eating disorders (ED) are among the most dangerous mental health comorbidities of type 1 diabetes and put people with type 1 diabetes at higher risk of acute and early-onset diabetes complications and mortality.¹⁻⁴ Recent data indicate a 10.8% prevalence of DEB among 11–27 years old people with type 1 diabetes in Germany, with high persistence of DEB.⁵

A formal diagnosis of disordered eating according to the international classification systems can be difficult, as DEB in type 1 diabetes often does not meet the formal



criteria of an ED (eg, in its intensity and frequency). Furthermore, DEB in type 1 diabetes may come with distinct behaviours, for example, the underdosing or omission of insulin ('insulin purging', sometime referred to as 'diabulimia'). The underdosing or omission of insulin and subsequent glucosuria to purge calories is a DEB unique to people with type 1 diabetes and has been found to be a common feature.^{6,7} Omitting insulin doses will almost inevitably result in a deterioration of glucose control, thus increasing the risk of serious health consequences, like hyperglycaemic crisis, ketoacidosis and early-onset diabetes complications, as evidenced by a threefold increase in mortality compared with people with type 1 diabetes who have never engaged in this particular method to compensate calorie intake.²

Theoretical models like the Transdiagnostic Model of Disordered Eating in Type 1 Diabetes⁶ describe how the adverse combination of diabetes-specific vulnerability and self-management distress paves the way to DEB and ED. There appear to be several diabetes-specific factors promoting DEB and ED, including insulin-related weight gain with subsequent weight concerns, the availability of a 'low-threshold' purging method (underdosing of insulin with subsequent glucosuria), perceived dietary restrictions, preoccupation with food, physiological changes in hunger and satiety and pressure of diabetes management.^{6,8} Studies on psychosocial risk factors indicate a link between DEB/ED in type 1 diabetes and depressive symptoms, anxiety symptoms, low self-esteem, perfectionism, avoidance-oriented coping, family relationships and diabetes-related distress.^{6,9,10} However, characterisations of people with type 1 diabetes and DEB or ED are inconsistent, with studies noticing lower symptom burden as well as similar or lower prevalence of DEB and ED in type 1 diabetes, compared with people without diabetes, eg.^{5,11-13} These inconsistencies may be of a methodological nature; however, more studies characterising the features and course of DEB and ED in type 1 diabetes are needed.^{4,8} There are limited cross-sectional characterisation of the population with type 1 diabetes and DEB or ED (eg, regarding to age, gender, symptom severity, occurrence of other psychopathologies), and a lack of longitudinal studies identifying potential, so far understudied diabetes-specific risk factors (eg, diabetes-related distress, fear of hypoglycaemia) and potential diabetes-specific protective factors (eg, patient education programmes, support from the diabetes team), that could provide to more clarity in the inconsistent evidence base.

Broadley *et al*⁴ suggest that due to the complexity of DEB and ED and type 1 diabetes, it may be helpful for researchers and clinicians to further characterise disordered eating differently in people with type 1 diabetes. They suggest examining and integrating the medical risk (eg, for diabetes complications), clinical features (eg, weight) and behaviours (eg, different compensatory behaviours) which could help to identify clinically meaningful subtypes of disordered eating in type 1 diabetes

which, in turn, may open novel avenues for tailored interventions and preventive measures.

Therefore, the 'Disordered eating behaviours and eating disorders in diabetes type 1' (DEBBI) study has four aims: first, to characterise disturbed eating behaviours in people with type 1 diabetes, using a combination of clinical features (eg, weight), behavioural patterns (eg, insulin purging, restrictive eating behaviour) and diabetes-associated complications (eg, occurrence of ketoacidosis), and to identify potential subtypes. Second, to identify key diabetes-specific, psychosocial risk factors and protective factors for dysfunctional eating behaviours and ED. Third, to describe the course of DEB over time, and finally, to collect data that will help to develop and guide tailored interventions and preventive measures that consider possible subtypes and constellations of risk factors.

Research questions and hypotheses

We seek to answer the following research questions:

1. Are there distinguishable DEB manifestations (subtypes) in people with type 1 diabetes, regarding (a) the clinical picture and psychosocial symptoms, (b) behaviours and (c) diabetes-specific acute and long-term complications?
2. What are diabetes-specific, psychosocial risk factors and protective factors for DEB and ED?
3. What is the course of DEB over time? Do potential DEB subtypes develop differently? Does the risk for a manifest ED differ between subtypes?
4. Are there hints towards diabetes-specific intervention strategies? Can different strategies be derived for different subtypes?

With regard to research question number 2 and based on previous research on DEB/ED in type 1 diabetes,^{6,8} we hypothesise that the following factors are positively associated with DEB: female gender, body mass index (BMI), weight fluctuations, depressive symptoms, anxiety, perfectionism, dysfunctional emotional regulation and coping strategies and haemoglobin A1c (HbA1c) levels. The following factors should be negatively associated with DEB: age, self-esteem, (moderate) physical activity, regular meals, positive attitude towards healthy eating, diabetes knowledge and careful diabetes self-management. Research question numbers 1, 3 and 4 will be answered exploratively (see Planned statistical analyses).

METHODS AND ANALYSIS

This article presents the protocol of the Disordered eating behaviours and eating disorders in diabetes type 1 (DEBBI) online study.

Study design and sample size

The DEBBI study is realised as a longitudinal online survey, with baseline assessment and three follow-up assessments (after 6, 12 and 18 months) to investigate diabetes-specific risk and protective factors for DEB and

describe the course of DEB over time. We chose a 6-month interval to capture both steady symptoms and behaviours as well as possible medium-term changes. An extension of the protocol beyond 18 months is projected to cover longer term development (funding pending).

To determine the sample size for our study, we followed guidelines on sample size calculations for latent profile analyses (LPA; see also Planned statistical analyses). LPA can be conducted at a Cohen's *d* of 0.8 if the sample size is at least $N=500$, given a minimum of 10 indicators of latent class membership.¹⁴ To surpass this estimated minimum and to have more freedom in exploratory subgroup analyses, our aim is to recruit $N=600$ participants.

Participants and recruitment

The online survey is targeted at adults with type 1 diabetes with and without DEB/ED. We defined the following inclusion criteria: people with type 1 diabetes >12 months since diagnosis of diabetes, age ≥18 years, with sufficient German language skills to participate in the online survey. The online survey will be disseminated using social media channels, for example, Facebook groups for people with type 1 diabetes. Additionally, local outpatient diabetes clinics and other diabetes care facilities with interest in the study will receive written DEBBI study information materials to distribute to their patients.

DEBBI online survey

The DEBBI study will be implemented as an online survey with SoSci Survey (SoSci Survey GmbH, Munich, Germany). Survey completion takes about 30–45 min. At the end of the baseline survey, participants are asked to enter their email address to be invited to the follow-up assessments. Follow-up email invitations are to be automatically sent 6 months after completing the previous survey. Participants who do not start the follow-up survey right away receive an automated email reminder after 10 days. The online survey platform complies with European privacy and data protection regulations.

To be able to identify distinguishable DEB subtypes as well as diabetes-specific, psychosocial risk and protective factors, the variables and constructs assessed in the four survey parts were derived from either theoretical models or empirical studies on DEB in type 1 diabetes (see Instruments and measures). The DEBBI online survey consists of four sections, covering data on (1) diabetes and self-management, (2) lifestyle, (3) psychosocial well-being and (4) demographics and medical information. **Table 1** gives an overview over the contents of the survey parts. Some information in the first part and most of the information in the fourth part may be provided on a voluntary basis; participants are not required to provide medical details (eg, comorbid diagnoses) to complete the questionnaire. The survey includes validated instruments as well as self-generated items.

Table 1 Contents of the 'Disordered eating behaviours and eating disorders in diabetes type I' (DEBBI) online survey

Part 1: diabetes and self-management	Diabetes duration, insulin therapy, insulin doses, HbA1c levels, diabetes technology use, glucose fluctuation, acute/long-term complications, self-management activities and adherence, hypoglycaemia awareness, hypoglycaemia-related disinhibited eating, insulin overdosing, fear of hypoglycaemia, diabetes-related distress, diabetes-specific DEB
Part 2: lifestyle	Physical activity, eating habits (meal frequency, food choice, diets, snacking) alcohol and nicotine consumption
Part 3: psychosocial well-being	ED symptoms (diabetes unspecific), intuitive eating, stress, emotion regulation, coping style, locus of control, depressive symptoms, anxiety, self-esteem, perfectionism
Part 4: demographics and medical information	Age, gender, education, job and family situation, height, weight, physical/mental health comorbidities (diagnoses, treatment details)
DEB, disordered eating behaviours; ED, eating disorders; HbA1c, haemoglobin A1c.	

Instruments and measures

The instruments and measures included in the DEBBI survey are presented below with details on (sub)scales, scoring and psychometric quality.

Diabetes Self-Management Questionnaire (DSMQ)

Disordered eating in type 1 diabetes has been associated with ineffective self-management.⁸ We use the DSMQ to assess diabetes self-care activities on four subscales: Glucose Management, Dietary Control, Physical Activity, and Healthcare Use. Respondents rate how 16 different statements apply to their self-management regarding the last 8 weeks on a 4-point Likert scale. Higher scores indicate more effective diabetes self-management (range 0–48). The DSMQ (German version) was attested good psychometric qualities (eg, Cronbach's $\alpha=0.84$).¹⁵

GOLD score and Hypoglycaemia Fear Survey-II (HFS-II), short form

Episodes of hypoglycaemia can trigger disinhibited eating, which might be accompanied by feelings of guilt and shame.¹⁶ Unimpaired awareness of hypoglycaemia onset might prevent disinhibited eating as well as fear of hypoglycaemia, which is a diabetes-related psychosocial factor that has received limited attention in DEB research.⁴ To assess hypoglycaemia awareness, we use the GOLD score, which is a one-item self-report scale. Respondents are asked to rate their awareness of hypoglycaemia onset on a 7-point Likert scale from 1, 'always aware of the onset of hypoglycaemia' to 7, 'never aware of the onset of hypoglycaemia'. A GOLD score ≥4 indicates impaired hypoglycaemia awareness.¹⁷ To assess fear of hypoglycaemia,

we use the Hypoglycaemia Fear Survey that comprises 33 items on two subscales (Worry and Avoidance). The German translation showed good psychometric qualities (eg, Cronbach's $\alpha=0.96$ for Worry subscale and Cronbach's $\alpha=0.86$ for Avoidance subscale).¹⁸ We decided to use the more economic HFS-II short form, a reliable and valid measure to assess the level of fear of hypoglycaemia with 11 items referring to the last 4 weeks.¹⁹ Answers are scored on a 5-point Likert scale, with higher sum scores representing higher levels of fear of hypoglycaemia (range 0–44).

Problem Areas in Diabetes Scale (PAID)

The PAID is a 20-item questionnaire assessing current diabetes-related distress, a key diabetes-related psychosocial factor that has been associated with DEB^{10 20} but has received limited research attention.⁴ The PAID items are rated on 5-point Likert scale and scores are summed and transformed into a total score (range 0–100). A higher total score indicates more severe diabetes-related distress, with a cut-off criterion of ≥ 40 for elevated diabetes-related distress. The German PAID translation was attested good psychometric quality (eg, Cronbach's $\alpha=0.92$).²¹

Diabetes Eating Problem Survey-Revised (DEPS-R)

The DEPS-R is a 16-item screening instrument for ED in type 1 diabetes, also covering underdosing or omission of insulin. The items are answered on a 6-point Likert scale, with higher sum scores indicating more frequent DEB in the last 4 weeks (range 0–80). A sum score ≥ 20 indicates high ED risk. The German DEPS-R version was attested good internal consistency (Cronbach's $\alpha=0.84$) and showed significant correlations with HbA1c levels, Body Mass Index standard deviation scores and expert clinician reports.²² In addition to the DEPS-R sum score, we will use two single-item scores (item 4, 'When I overeat, I don't take enough insulin to cover the food' and item 13, 'After I overeat, I skip my next insulin dose') to investigate the frequency of underdosing and omission of insulin.

International Physical Activity Questionnaire (IPAQ), short form

Physical activity has been shown to improve physical health and well-being in type 1 diabetes,²³ thus might functioning as a protective factor for DEB. However, excessive exercise has also been associated with DEB in type 1 diabetes.²⁴ We chose the IPAQ because it captures both physical activity in general as well as more intense exercise. The short IPAQ version consists of nine items, measuring the intensity (sedentary activity, walking, moderate activity, vigorous activity), duration (minutes) and frequency (days per week) of physical activity in the last 7 days or a regular week. A minimum of 150 min of activity per week indicates sufficient physical activity. The IPAQ was developed to obtain internationally comparable self-report data on physical activity and has acceptable psychometric properties (eg, test-retest reliability $r=0.80$).²⁵

Eating habits

Strict dieting, dietary restrictions (eg, only 'healthy' foods are allowed) and emotional dysregulation are central components in models for development and maintenance of DEB in type 1 diabetes (eg,⁶). Therefore, we chose to include pattern of eating (ie, frequency of meals and snacks), eating style, as well as emotional eating (eating as a strategy to cope with emotional distress) in the DEBBI study. We further plan to use these variables to identify possible DEB subtypes. To assess pattern of eating, two questions of the German version of the Eating Disorder Examination (EDE) interview²⁶ were adapted. Participants are asked to rate meals and snacks of the last 4 weeks (breakfast, mid-morning snack, lunch, mid-afternoon snack, evening meal, evening snack, nocturnal eating) on a 7-point Likert scale (0, 'meal/snack not eaten' to 6, 'meal/snack eating every day'). In case of nocturnal eating episodes, participants are further asked if impairment of awareness or recall occurred. To assess healthy eating style, we use a 16-item questionnaire by König *et al.*²⁷ The questionnaire presents statements on food preferences and healthy eating behaviours (eg, 'I do not eat fast food', 'I eat a lot of fruit and fresh vegetables'). Items are answered on a 7-point Likert scale, with a higher total score representing a healthier eating style (range 16–112).²⁷ To assess emotional eating, we use a subscale of the Intuitive Eating Scale-2 (IES-2). The IES-2 examines intuitive eating, which has been described as reliance on internal cues of hunger and satiety and low preoccupation with food.²⁸ The subscale 'Eating for physical rather than emotional reasons' (EPR) consists of eight items which are answered on a 5-point Likert scale. Higher mean values indicate less emotional eating (range 1–5). The EPR subscale was attested good psychometric properties (eg, Cronbach's $\alpha=0.91$).²⁸

Eating Disorder Examination-Questionnaire (EDE-Q), short form

The EDE-Q is a reliable and valid ED questionnaire based on the EDE interview. It complements the diabetes-specific DEPS-R questionnaire by measuring the frequency and severity of (diabetes unspecific) ED symptoms, for example body dissatisfaction, which has been associated with DEB.^{20 29} The short form (EDE-Q8) consists of eight items, two from each of the subscales Restraint, Eating Concern, Weight Concern and Shape Concern. The items refer to the last 28 days and are scored on a 7-point Likert scale. A mean global ED psychopathology score and mean subscale scores can be calculated (range 0–6). Higher mean scores indicate more frequent and/or severe ED symptoms. The German EDE-Q8 version was attested good psychometric properties (global score; eg, Cronbach's $\alpha=0.93$).³⁰

Perceived Stress Scale (PSS-10) and locus of control (IE-4)

It is hypothesised that the psychological burden associated with a chronic medical condition like type 1 diabetes enhances vulnerability for DEB and feelings of loss of control.^{4 31} The latter may lead to insulin misuse

as a mean to regain control,⁴ which may also be associated with locus of control. We include perceived stress and locus of control as a way to picture psychological burden, and to inform possible subtypes. We will further be able to differentiate between diabetes-specific and diabetes-unspecific levels of stress associated with DEB. We use a German adaption of the PSS-10³² to measure diabetes-unspecific levels of stress, comprising 10 items (on two subscales, Perceived Helplessness and Perceived Self-Efficacy) referring to the last month. Respondents are asked to rate their feelings and thoughts on a 5-point Likert scale. Higher total scores reflect greater stress levels (range 10–50). The German adaption was attested good psychometric quality (total score; eg, Cronbach's $\alpha=0.88$ in a nonclinical and $\alpha=0.89$ in a clinical sample).³² To assess internal and external locus of control, we use the German IE-4 scale that comprises four items on two subscales (Internal vs External Locus of Control).³³ The items are answered on a 5-point Likert scale. Mean scores for each subscale can be computed and compared with reference values for the German population (range 1–5). The questionnaire was attested satisfactory psychometric properties (eg, test–retest reliability $r=0.56$ for Internal and $r=0.64$ for External Locus of Control).³³

Brief COPE

A relationship between dysfunctional coping strategies, like avoidance, and DEB in type 1 diabetes has been demonstrated.⁹ We assess coping strategies with a German adaption of the Brief COPE,³⁴ a 28-item questionnaire comprising 14 scales that can be summarised into four latent coping scales (Focus on Positive, Support Coping, Active Coping, Evasive Coping). The items refer to usual thoughts and actions while facing a difficult situation. Items are answered on a 4-point Likert scale. Mean coping scale scores represent the degree to which the participant has been engaging in that coping strategy (range 1–4). The German adaption showed satisfactory psychometric properties (eg, Cronbach's $\alpha=0.76$ for Focus on Positive, $\alpha=0.81$ for Active Coping, $\alpha=0.76$ for Support Coping, $\alpha=0.70$ for Evasive Coping).³⁴

Brief Patient Health Questionnaire (PHQ-9) and Staite-Trait-Anxiety Inventory (STAI), subscale trait anxiety

Mood dysregulation and negative affect are central components of models in DEB in type 1 diabetes,^{8 20 29} and bidirectional associations between depressive symptoms, anxiety and DEB have been demonstrated.^{35 36} In the DEBBI study, depressive symptoms are assessed with the German version of the 9-item depression module from the Patient Health Questionnaire.³⁷ The items are scored on a 4-point Likert scale, referring to the frequency of depressive symptoms in the last 2 weeks. Higher total scores represent more frequent/severe depressive symptoms (total score range 0–27). A total score ≥ 5 , ≥ 10 , ≥ 15 represents mild, moderate and severe depression, respectively. The German PHQ-9 version was attested satisfactory psychometric properties (eg, Cronbach's $\alpha=0.87$).³⁷

To assess anxiety, we use the trait subscale of the well-established German version of the STAI.³⁸ The trait questionnaire consists of 20 items and asks respondents to rate how they generally feel on a 4-point Likert scale. Higher total scores represent greater trait anxiety (range 20–80). The trait subscale has good psychometric quality (eg, Cronbach's $\alpha=0.90$).³⁸

Rosenberg's Self-Esteem Scale

To measure self-esteem, a factor that has been proposed to endorse the development and maintenance of DEB in type 1 diabetes,^{6 8} we use the revised German adaptation of Rosenberg's Self-Esteem Scale.³⁹ Participants are asked to rate 10 items on a 4-point Likert scale. Higher total scores (range 0–30) indicate higher global self-esteem. The German revised version was attested good psychometric properties (eg, Cronbach's $\alpha=0.84$).³⁹

Multidimensional Perfectionism Scale (MPS-F)

Perfectionism has been discussed to promote frustration in diabetes self-management and, thus, as a part of a dysfunctional scheme for self-evaluation, can lead to DEB like dietary restriction, binge-eating and insulin omission.^{6 29} To measure perfectionism, we use three subscales of the German version of the MPS-F that were attested satisfactory construct validity.⁴⁰ Our adaption consists of 20 items measuring perfectionisms on the subscales Personal Standards, Concern over Mistakes and Doubts about Action. Participants indicate their answers on a 6-point Likert scale. Higher total scores represent greater perfectionism (range 20–120). The three selected subscales were attested satisfactory internal consistency (Personal standards, Cronbach's $\alpha=0.84$; Concern over Mistakes, Cronbach's $\alpha=0.89$; Doubts about Action, Cronbach's $\alpha=0.70$).⁴⁰

Self-generated items

We use self-generated items to gather information on diabetes duration, insulin therapy, insulin doses, HbA1c levels, diabetes technology use, glucose fluctuation, participation in structured patient education programmes, acute and long-term diabetes complications, hypoglycaemia-related disinhibited eating (four questions adapted after¹⁶), insulin overdosing (which might be practiced to be 'allowed' to eat sweets to treat hypoglycaemia), number of diets, snacking, tobacco and alcohol consumption, demographics, weight, height and comorbid physical/mental health diagnosis and treatment.

To investigate glucose fluctuation, participants using continuous glucose monitoring are asked to enter the mean time they spent in moderate-to-severe hypoglycaemia (% of glucose values <55 mg/dL or 3.1 mmol/L), in mild hypoglycaemia (% of glucose values 55–70 mg/dL or 3.1–3.9 mmol/L), in range (% of glucose values 70–180 mg/dL or 3.9–10 mmol/L) and in hyperglycaemia (% of glucose values >180 mg/dL or 10 mmol/L) in the last 30 days.



Planned statistical analyses

Data will be analysed using SPSS Statistics V.27 and R V.4.1.2. Descriptive statistics will be presented for all measures. Continuous data will be summarised using the number of observations, minimum, maximum, median, mean and standard deviation. Categorical data will be summarised with counts and percentages.

One key aspect of the data analysis will be LPA to determine latent subtypes of DEB manifestation in people with type 1 diabetes, including data on the clinical picture and symptoms, behaviours and diabetes-specific complications (research question 1). Associations between sociodemographic, diabetes, lifestyle and psychosocial predictors and DEB will be analysed with correlation analyses and multiple regression models (research question 2). Comparisons between a priori assumed subgroups, people with DEPS-R²² scores <20 (low risk for ED) vs ≥20 (at risk for ED), will be realised with χ^2 tests for categorical variables, Wilcoxon's rank-sum test for non-normally distributed continuous variables, independent sample t-tests for normally distributed continuous variables, and multivariate analysis of variance (ANOVA) models. Risk factors and protective factors for DEB and ED will be indicated with odds ratios (research questions 2, 3). Differences over time will be examined with mixed ANOVA models and latent growth modelling (research question 2, 3). $P < 0.05$ will be considered statistically significant.

Research question 4 will be discussed in a clinical expert committee. Taking latent DEB manifestations and their course into account, we hope to reach a consensus on promising strategies that could inform further guidance for research on diabetes-specific DEB/ED interventions.

Patient and public involvement statement

Patients were not involved in the planning and design of the study.

ETHICS AND DISSEMINATION

The study protocol was approved by the Ethics Committee of the State Medical Chamber of Rhineland-Palatine, Germany (ID 2021-16040). Participants give informed written consent before starting the survey. Participants do not receive a financial compensation for the survey completion but are eligible to receive a free report on the aggregated study results.

The study is registered with DRKS German Clinical Trials Register (DRKS00028833). The status of the study will be updated regularly. We aim to publish results of the baseline assessment and follow-up assessments in peer-reviewed journals in the field of psychosocial diabetes mellitus research. The results of the DEBBI study will provide more clarity in the so far inconsistent empirical evidence base on DEB and ED in type 1 diabetes and help to inform research on prevention and intervention strategies that are tailored to type 1 diabetes-specific needs. Results will further be presented at national and

international conferences, facilitating dissemination into clinical and research practice.

Contributors LP conceptualised the study and wrote the original manuscript draft. JG supported the study conceptualisation and reviewed and edited the manuscript. EAS supported the study conceptualisation and project administration. TK supervised the project, supported the study conceptualisation and reviewed and edited the manuscript. All authors approved the submitted manuscript version.

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Competing interests LP received speaking honoraria from Ypsomed GmbH. JG received speaking honoraria from Novo Nordisk Pharma GmbH, Eli Lilly and MSD Sharp & Dohme GmbH. TK received speaking honoraria from Dexcom and Novo Nordisk Pharma GmbH. The authors declare that they have no competing interests regarding this article.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Ethics Committee of the State Medical Chamber of Rhineland-Palatine, Germany, ID 2021-16040. Participants give informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

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