STUDY PROTOCOL

Dietary changes in adults in the family unit in newly diagnosed pediatric cases of type 1 diabetes: impact of educational actions on routine practice

Protocol version and date	Version: 4.0 Date: 27/06/2024
Protocol code	IIBSP-DDM-2023-166
Promotor	Institut de Recerca Sant Pau (IR SANT PAU) C/ de Sant Quintí, 77, 08041 Barcelona Tel: 93 556 56 17
Coordinador Researcher	Dídac Mauricio Puente, Chief of nutrition and endocrinology department Hospital de la Santa Creu i Sant Pau c/ Sant Antoni Maria Claret, 167 08025 Barcelona Tel: 627953473 e-mail: dmauricio@santpau.cat
Principal investigator	Joana Rossell Rusiñol, IR SANT PAU e-mail: jrossell@santpau.cat c/ Sant Sant Quintí 77-79 08041 Barcelona
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SUMMARY

List of abbreviations

aMED - Mediterranean Diet Adherence Index

aHEI - Healthy Eating Index

BEDCA - Spanish Food Composition Database

EDC - Electronic data collection

FFQ - Semi-quantitative food frequency questionnaire

HADS - Hospital Anxiety and Depression Scale

HSCSP - Hospital de la Santa Creu i de Sant Pau

HUAV - Hospital Universitari Arnau de Vilanova

IPAQ - International Physical Activity Questionnaire

IR SANT PAU – Institut de Recerca Sant Pau

MEDAS - Mediterranean Diet Adherence Screener

MET - Metabolic equivalent task

PIP - Pediatric Inventory for Parents

T1D - Type 1 diabetes mellitus

1. RESUME

Promoter identification	Institut de Recerca Sant Pau (IR SANT PAU) C/ de Sant Quintí, 77, 08041 Barcelona Tel : 93 556 56 17
Study title	Dietary changes in adults in the family unit in newly diagnosed pediatric cases of type 1 diabetes: impact of educational actions on routine practice
Code	IIBSP-DDM-2023-166
Protocol version and date	Version: 2.0 Approval date: 19/02/2024
Coordinator investigator	Dídac Mauricio Puente, Endocrinology and Nutrition service Hospital de la Santa Creu i Sant Pau c/ Sant Antoni Maria Claret, 167 08025 Barcelona Tel: 935565661 e-mail: dmauricio@santpau.cat
Principal investigator	Joana Rossell Rusiñol, IR SANT PAU e-mail: jrossell@santpau.cat
Collaborator researchers	Marta Hernández Mireia Tirado Laura Franquesa Marina I. Rojo Minerva Granado Jordi Bosch Priscila Llena Imma Sans Bogdan Vlacho Idoida Genua Berta Fernández Roque Cardona Serafin Murillo Marina Llobet
Centros participantes	Hospital de la Santa Creu i Sant Pau, Barcelona Hospital Universitari Arnau de Vilanova, Lleida Hospital Sant Joan de Déu, Esplugues de Llobregat
Reference ethics comitee	CEI Sant Pau
Principal Aim	To characterize dietary patterns in the family (parents or guardians) of people newly diagnosed with type 1 diabetes mellitus at the time of diagnosis, and to evaluate their evolution and the effect on health indicators after one year of evolution.
Design	Observational study on a prospective cohort

Disease of study	Type 1 Diabetes mellitus
Methods	Recruitment of 26 family units of newly diagnosed patients with T1D (pre-screened upon hospital admission). Inclusion visit (within the first week of diagnosis). Follow-up visits at 6 months. Final visit at 12 months.
Study population and total number of subjects	26 family units (parents or guardians) of newly diagnosed T1D patients.
Timeline. Study expected duration.	The expected duration will be 3 years, including a 2-year recruitment period, and a one-year study period: - Recruitment start: April 2024. - Recruitment end: April 2026. - Study end: April 2027.
Key words	T1D, feeding patterns, family setting, diet, pediatric

2. ABSTRACT

Type 1 diabetes (T1D) is a chronic disease that often manifests at a young age and requires exogenous insulin administration to ensure adequate glycemic control, in addition to dietary education focused on carbohydrate intake control and healthy eating habits. Diabetic education is carried out in the close family (parents or guardians), whose involvement is necessary to ensure optimal glycemic control and the successful adaptation to a healthy dietary pattern in children and young adolescents. In this sense, parents (or guardians) of children and young adolescents with T1D receive diabetic education too to guarantee the successful adaptation to a healthy dietary pattern. Nevertheless, the modifications in dietary habits within the family unit remain relatively unexplored.

We hypothesize that implementing healthier dietary patterns in the management of newly diagnosed T1D in children and young adolescents has a significant impact on the eating habits of the entire family environment. Therefore, in this study, we aimed at characterizing the dietary patterns of parents or guardians of individuals with newly diagnosed T1D at the time of diabetes diagnosis and at follow-up to assess the impact of routine diet and nutrition education within the family unit, regardless of the changes occurring in the index case itself.

We expect to identify significant changes in the eating habits of the entire family in the first year after the diagnosis of T1D of a family member. These changes, derived from the diabetic education received, offer a potential intervention opportunity for a dietary improvement for the whole family.

Keywords: Type 1 diabetes, alimentary patterns, family, diet

3. BACKGROUND

Type 1 diabetes mellitus (T1D) is a chronic disease characterized by the autoimmune destruction of pancreatic beta cells, resulting in severely impaired insulin production. Unlike type 2 diabetes, in which insulin resistance plays a predominant role, T1D frequently presents at an early age, requiring exogenous insulin administration to achieve adequate glycemic control (1,2). In addition to insulin administration, choosing an appropriate diet, including carbohydrate counting and establishing good eating habits, is an important pillar in the management of T1D. The goal of dietary change is to ensure the child's proper development, help maintain blood glucose levels within optimal ranges, prevent the development of acute and chronic complications, and improve the quality of life with T1D (1–3). General recommendations for patients with diabetes are similar to those for the general population, based on a balanced diet with a caloric distribution within the range of 50-55% slow-absorbing carbohydrates, 30-35% fats, and 10-15% proteins, limiting the consumption of snacks between meals (2,3). However, the relationship between dietary habits and T1D is inherently complex and multifaceted. Different dietary patterns can influence food absorption and insulin utilization, as well as the postprandial glycemic response (4). Advances in research have led to a better understanding of how food selection and macronutrient distribution are essential for their relationship with glycemic control and insulin requirements in people with T1D (4). In a systematic review we recently published to analyze the effectiveness of medical-nutritional therapy in adolescents with T1D, we observed that dietary interventions delivered to children and adolescents and their families using carbohydrate counting, the use of multimedia applications, and diets rich in vegetables and/or vegetarians have a positive impact on glycemic control and lipid profile of adolescents with T1D (5). However, studies analyzing the effectiveness of medical-nutritional therapy in adolescents with T1D are scarce and of low reliability due to a large number of biases and limitations. On the other hand, we have explored the dietary patterns of adults with T1D in our population, observing that they exhibit healthier eating habits and greater adherence to the Mediterranean Diet than people without diabetes (6).

Due to the individualized nature of diabetes management and the interindividual variability in glycemic response, there is no single dietary strategy that suits all individuals with T1D (3, 7, 8). In fact, implementing new eating habits requires a high degree of self-care on the part of the patient (9). In people with T1D, since they are usually diagnosed in childhood, an additional effort is required by the family unit, which ideally also receives the impact of behavioral interventions to make the necessary dietary changes (10). Thus, with a new diagnosis of a chronic disease such as T1D, not only the individual is exposed to a lifestyle change, but also their family environment. In this regard, it has been documented that parents are willing to make an effort to dedicate more time, as well as increase family financial spending, and adopt organizational changes aimed at maintaining a carbohydrate-controlled diet to maintain adequate blood glucose levels (11). However, these types of changes pose sources of emotional stress, especially related to the patient's glycemic control (12, 13). Additionally, the stress experienced by parents of a child with T1D can negatively impact the patient's glycemic control (13). In very young patients (under 6 years of age), behavioral problems related to eating have been described, which increase the stress perceived by families and are associated with lower adherence to dietary recommendations and worse glycemic control (12).

Diet in a family is shaped by multiple internal and external factors. Therefore, a child's food choices are strongly influenced by those of parents and siblings (14). Thus, parents' dietary patterns shape the home food environment, influence the way the child thinks about food, and consequently influence the children's eating behavior (15, 16). Even the presence of other siblings influences dietary habits, as it has been reported that only children tend to have less healthy dietary patterns compared to families with a larger number of children (17). A recent diagnosis of T1D is one of the external factors that influence the family unit's dietary habits. However, there are very few scientific studies that evaluate the dietary patterns of families with children or adolescents with T1D. Most families with a child with T1D report that the affected child eats the same foods as non-diabetic family members (14). Furthermore, some dietary modifications have been reported based on the dietary guidelines at the time of diagnosis, such as relatives of children with T1D changing their choice of fats

and milk (18). A randomized controlled trial of a behavioral nutrition intervention conducted in families of young people with T1D showed that the dietary pattern measured in terms of diet quality was similar to that observed in the general population (19). However, these studies never evaluate the impact beyond the change in the patient themselves, and not in the family members. To the best of our knowledge, there are no scientific studies evaluating the impact of medical-nutritional therapy on the eating habits and lifestyle of other family members of children and adolescents newly diagnosed with T1D.

4. HYPOTHESIS, PRIMARY AND SECONDARY OBJECTIVE

4.1 Hypothesis

Given the importance of the family environment in the evolution and management of T1D in children, and that the environment and the patient exert a bidirectional influence, there are no studies focused on studying the impact of diagnosis and management measures on potential changes in the diet and food choices of family members of children/adolescents with T1D. Studies focusing on dietary changes in patients provide insights into dietary recommendations for individuals with T1D, highlighting the importance of individualization and nutritional education in disease management. In this context, we firmly believe that adequately characterizing dietary patterns in adults in families with children with T1D is a very important aspect that has never been previously addressed.

Our initial hypothesis is that the implementation of medical-nutritional therapy in terms of healthy eating for newly diagnosed individuals with T1D has a significant impact on the eating habits and lifestyle of the family members living with the patient.

Furthermore, scientific studies focus solely on analyzing the impact of diabetes education on individuals with T1D themselves, without considering the changes that may occur within the family unit. To our knowledge, no studies have analyzed dietary and lifestyle changes among family members of patients living in the same household as a child/adolescent with newly diagnosed T1D, either in Spain or in other countries. In this regard, there is a lack of studies describing changes in the family unit's diet within routine clinical practice.

4.2 Primary objective:

- To evaluate changes in dietary patterns and lifestyle among adults living in the family unit of a newly diagnosed patient with T1D one year after the diabetes diagnosis.

4.3 Secondary objectives:

*Due to the timeliness of the study, we also proposed:

- To characterize changes in the dietary patterns of parents or guardians of patients with T1D during follow-up (6 months after diagnosis).
- To determine, using a questionnaire, changes in the physical activity of the adult subjects in the study at 6 and 12 months.
- To determine, using a questionnaire, the emotional stress produced by the diagnosis and treatment of T1D in the adult parents or guardians belonging to the families of the incident case at 6 and 12 months.
- To determine, using a questionnaire, the level of anxiety and depression produced by the diagnosis and treatment of T1D in the adults in the families at 6 and 12 months.

5. METHODS

5.1 Study Design

This study will be a prospective, multicenter, observational study. The study will be conducted within the Pediatrics Department of the Hospital de la Santa Creu i de Sant Pau (HSCSP) (Barcelona) and the Hospital Universitari Arnau de Vilanova (HUAV) (Lleida). This study will be launched at the participating centers once a favorable opinion has been obtained from the Research Ethics Committee, and in accordance with the legislative requirements for this type of observational study.

The study design includes an initial visit that will coincide with the patient's inclusion in the study. Prior to the inclusion visit, a pre-screening period is planned. During this period, the potential candidate and their family will be invited, all study procedures will be explained and clarified, the selection criteria will be verified, and the inclusion visit will be scheduled. A follow-up visit will be conducted at 6 months throughout the study. A final visit will be conducted 12 months after enrollment (with a 1-month window).

Adult subjects from 26 households of patients recently diagnosed with T1D are planned to be included.

5.2 Study Period

The study period is three years, from April 2024 to April 2027.

5.2.1 Recruitment Period

Participants will be recruited for two years, from April 2024 to April 2026.

5.2.2 Observational Study Period

Participation is for one year from enrollment.

5.3 Participant Follow-up

Given this is an observational study, no interventions will be performed on the study participants. Only three visits are required—baseline, 6-month follow-up, and 12-month follow-up—to collect variables and complete the questionnaires. These visits will be conducted as closely as possible to the routine hospital check-ups of the patient with T1D.

5.4 Study Population

The study population is the immediate family (parents or guardians) who regularly live with the person newly diagnosed with T1D. The questionnaire will be prioritized for the family member responsible for most of the food in the home. In the case of minors living in two separate family units, the unit in which they spend more than 60% of their time will be included, or both if the estimated time spent living together is equal.

5.5 Selection Criteria

5.5.1 Inclusion Criteria:

- Adults.
- Subjects of both sexes.
- Relatives of the pediatric population with newly diagnosed T1D according to ADA criteria.
- Within a maximum of one week of diagnosis of the disease in the index case with T1D in the family.
- Living with the family member with T1D for more than 40% of their time.

- Being responsible for providing food for the household.

5.5.2 Exclusion Criteria:

- Relatives of patients diagnosed with other types of diabetes (type 2, MODY, gestational, or other causes).
- Participant's family environment with a chronic illness or physiological conditions (e.g., pregnancy) that may influence eating habits.
- Significant dietary changes (switching to vegan, ketogenic, macrobiotic, intermittent fasting diets, etc.) recent to the onset of T1D (within the last month or at the time of inclusion).

5.5.3 Withdrawal criteria:

All participants have the right to withdraw from the study at any time, withdrawing their consent, without having to justify this decision and without any detriment to their clinical follow-up. Participants may also revoke the use of their data in the analysis, without justifying their decision, and without incurring any liability or harm.

5.6 Study procedures

This study will be launched at the participating centers once a favorable opinion has been obtained from the Research Ethics Committee and in accordance with the legislative requirements for this type of observational studies.

5.6.1 Pre-screening

Each study subject will be identified by the local investigator at each center during the admission of the newly diagnosed patient. Family members (parents or guardians) of all newly diagnosed subjects with a clinical diagnosis of T1D will be invited to participate. Study procedures will be performed by the local investigators at each participating center, who in some cases will be the same pediatric physicians and nurses as the participants' family members with T1D. A dedicated visit will be scheduled with the local investigator at each center to perform all study procedures in a single visit.

5.6.2 Inclusion

Each participant invited to participate will be informed about the study both verbally and in writing, using language adapted to their understanding. Participants will be provided with a document called the "Patient Information Sheet" containing all the information of the study, adapted to a simple comprehensive level. No participant will be included until they have been duly informed by the researcher and have freely given their informed consent to participate in the study. Once compliance with all selection criteria has been confirmed and informed consent has been given, data collection will begin by completing an electronic data collection form (EDC), which will record the information available in the patient's medical history or obtained during the inclusion visit.

The inclusion visit will take place within the first week after a family member's T1D diagnosis. This will prevent any lifestyle and dietary changes from being made to the family environment.

The initial clinical evaluation of all included subjects will be performed during the study inclusion visit. Clinical and sociodemographic variables related to the participant (will be collected using an ad-hoc questionnaire and a physical examination. The variables to be collected are defined in **Table 1**. Diet and intake patterns will be collected using questionnaires related to lifestyle and dietary patterns.

These variables will be collected at the inclusion visit, the 6-month follow-up, and at the end of the study at 12 months.

Table 1. Study variables

Variable	Source	Value
Sociodemographic variables		
Date of birth	Questionnaire	dd/mm/yyyy
Age	Questionnaire	Years
Sex	Questionnaire	Male / Female / Other / N/A
Gender identity	Questionnaire	Male / Female / Other / N/A
Area	Questionnaire	—
Parents' education level	Questionnaire	No education / Secondary / Vocational training / University
Family variables		
Number of people in the household	Questionnaire	Number
Number of children and age	Questionnaire	Number
Age of child with T1D	Questionnaire	Number
Person responsible for feeding	Questionnaire	Mother / Father / Guardian
Number of meals per day	Questionnaire	Number
Number of meals at home per day	Questionnaire	Number
Type of diet	Questionnaire	Omnivorous / Vegetarian / Vegan / Ovo-lacto vegetarian / Other
Toxic habits (all)		
Tobacco use	Questionnaire	(Smoker, non-smoker, ex-smoker), cigarettes/day
Alcohol use	Questionnaire	(User, at-risk user, non-user), SDUs/day
Drug use	Questionnaire	Other, (User, non-user)
Other autoimmune diseases		
Celiac disease	Questionnaire	Yes / No
Intolerances / allergies	Questionnaire	Yes / No. Which
Autoimmune hypothyroidism	Questionnaire	Yes / No
Others	Questionnaire	Yes / No. Which
Other comorbidities		
Arterial hypertension	Questionnaire	Yes / No
Dyslipidemia	Questionnaire	Yes / No
Diabetes	Questionnaire	No / T1D / T2D / LADA / Other
Diabetes duration	Questionnaire	Years
Cardiovascular disease	Questionnaire	Yes / No
Liver disease (excluding steatosis)	Questionnaire	Yes / No
Liver steatosis	Questionnaire	Yes / No
Renal insufficiency	Questionnaire	Yes / No
Clinical variables		
BMI (Body Mass Index)	Visit	(kg/m^2)
Waist circumference	Visit	(cm)
Diastolic blood pressure	Visit	(mm Hg)
Systolic blood pressure	Visit	(mm Hg)
Weight	Visit	(kg)
Height	Visit	(cm)
Associated treatments		
Antidiabetic drugs	Questionnaire	Yes/No/if yes dosage
Lipid-lowering agents	Questionnaire	Yes/No/if yes dosage
Antiplatelet agents	Questionnaire	Yes/No/if yes dosage
Anticoagulants	Questionnaire	Yes/No/if yes dosage
Antihypertensives	Questionnaire	Yes/No/if yes dosage

5.7 Variables

This study aims to include as many dietary characteristics at baseline and follow-up as realistically possible. The variables considered essential are described below.

5.7.1 Main Variables

Eating patterns and dietary information collected using the following questionnaires:

- Semi-quantitative food frequency questionnaire (FFQ) validated in the Spanish population (20). This questionnaire consists of 137 items. They collect the average food intake over the past year. Food consumption frequencies are recorded in nine levels (never or mostly never, 1-3 times/month, 1 time/week, 2-4 times/week, 5-6 times/week, 1 time/day, 2-3 times/day, 4-6 times/day, and more than 6 times/day). Food consumption frequencies will be calculated as the number of meals per day and multiplied by the weight of the portion sizes indicated in the questionnaire. Nutrient intake will be adjusted for energy intake. In addition, participants who have not made any changes to their dietary habits during the past year prior to the study will be asked at the first visit. Nutritional data will be extracted using the Spanish Food Composition Database (BEDCA), developed by the RedBEDCA and the Spanish Agency for Food Safety and Nutrition (21).
  (An English version is attached at the end of this protocol).
- Mediterranean Diet Adherence Index (aMED) to assess the degree of adherence to the Mediterranean Diet. Based on the Mediterranean Diet Scale (22), which includes the intake of vegetables, legumes, fruits, nuts, grains, red and processed meats, fish, the ratio of monounsaturated/saturated fats, and alcohol; the scoring scale ranges from 0 to 9 points.
- Healthy Eating Index (aHEI), based on the American Dietary Guidelines and the Healthy Eating Pyramid (23), which contains 9 items related to healthy food intake, with a maximum score of 87.5.
- Mediterranean Diet Adherence Screener (MEDAS): The MEDAS (Mediterranean Diet Adherence Screener) is a tool used to assess the degree of adherence to the Mediterranean Diet. It consists of 14 questions that explore different aspects of the characteristic dietary pattern of this diet (24). Each question is assigned a value depending on the frequency or quantity of consumption reported. The total score of the MEDAS questionnaire can range from 0 to 14 points, where a higher score indicates greater adherence to the Mediterranean Diet. This questionnaire provides an overview of an individual's dietary pattern and its alignment with the principles of the Mediterranean diet.

Physical Activity Log:

- International Physical Activity Questionnaire (IPAQ) validated in Spanish (25). Physical activity will be classified as low, medium, and high, based on the estimated energy expenditure for each activity. Activities with a metabolic equivalent task (MET) of 8 METs will be classified as vigorous; moderate activities with an energy expenditure of 4 METs; and light activities with 3.3 METs, such as walking, will be classified as sedentary or active if study participants engage in moderate physical activity for at least 30 minutes per day.

Parental Stress:

- Pediatric Inventory for Parents (PIP) (26): This is a questionnaire comprising 42 items, grouped into four domains or subscales. The purpose of the questionnaire is to measure the stress levels experienced by parents or caregivers of children with chronic illnesses. This questionnaire is scored on a Likert scale ranging from 1 (never/not at all) to 5 (always/extremely). Higher scores indicate higher stress levels.

- The Hospital Anxiety and Depression Scale (HADS) (27) is a questionnaire that detects emotional stress in non-psychiatric patients in a hospital setting. The questionnaire has been previously used in several studies to measure the emotional stress levels of parents or caregivers of children with type 1 diabetes. This questionnaire consists of 14 items grouped into two subscales, one for anxiety and one for depression. Responses are scored on a Likert scale ranging from 0 to 4 points.

5.7.2 Other relevant variables

To conduct the study and properly assess the main variables, relevant sociodemographic and clinical variables will be collected to complement the information obtained through the questionnaires (**Table 1**). These secondary variables provide us with complementary information on their lifestyle, general health status, type of family unit, and the possible effects of changing.

6. DATA COLLECTION AND ANALYSIS

6.1 Data Collection Schedule

The study period is estimated to be 3 years (from April 2024 to February 2027). However, these times may be modified due to the administrative process for launching the study.

6.2 Source of Information

In all cases, the source of information will be that obtained through the diet and physical activity questionnaires and through the physical examination of parents/guardians during the visits according to the schedule on **Table 2**. All information will be recorded in the EDC.

Table 2. Data collection schedule during the study

	Inclusion	Basal (t= 0)	Follow-up (6 months)	Final (12 months)
Informed consent	X			
Physical exploration		X	X	X
FFQ		X	X	X
MEDAS		X	X	X
IPAQ		X	X	X
PIP		X	X	X
HADS		X	X	X

FFQ, Semi-quantitative food frequency questionnaire; MEDAS, Mediterranean Diet Adherence Screener; IPAQ, International Physical Activity Questionnaire; PIP, Pediatric Inventory for Parents; HADS, Hospital Anxiety and Depression Scale.

6.3 Data Analysis

Data validation and quality control will first be performed through a descriptive analysis, expressing frequencies and extreme values for all recorded variables. Any errors detected will be corrected through a search for and recovery of missing data and an analysis of inconsistencies. Subsequently, a description of the sample will be provided, expressing the frequency distribution of the qualitative variables, and the arithmetic mean, median, and standard deviation, as well as maximum and minimum values for the quantitative variables.

The main analysis will consist of estimating the frequency and/or mean of post-treatment changes (reduction/increase). A paired data analysis of the changes will also be performed. A mixed-effects analysis (linear link GLM) will be performed for continuous variables. This same analysis will be performed for other dichotomous efficacy variables (improvement or lack thereof in each parameter) using logistic link GLM models. In addition, for the comparative analysis from time 0 to 6 months, parametric and nonparametric comparison tests (Student's t-test, chi-square, Wilcoxon test) and linear regressions will be applied to observe the influence between variables, taking into account the follow-up time. Family units will be phenotyped based on their variables by creating clusters using the k-means algorithm.

In all analyses, a type I error or α of 5% will be established, with statistical significance when p values are less than 0.05, and a type β error of 20% (statistical power of 80%). Statistical analyses will be performed using the R Core Team statistical package (2023) v. 4.3.

6.4 Sample Size

The sample size was calculated based on the results of a previous study published by our group on the dietary pattern of adult patients with T1D compared to subjects without diabetes in Spain (6). This is the most informative method available, and we assume that the adults in our study will have a similar pattern. We considered the mean and standard deviation of a group of adult individuals with T1D for adherence to the Mediterranean Diet, calculated with aMED. With a statistical power of 80% and an alpha error of 5%, it was calculated that a total of 26 newly diagnosed patients (one family unit) would be necessary to detect a minimum difference of 1 point on the aMED, performing the mean comparison test for two paired samples (pre-post analysis). As a contingency, recruiting 16 family units would also guarantee a statistical power of 80% and an alpha error of 5% to detect a minimum difference of 5 points in the aHEI index. The latter is also based on our own study in the T1D population. The family unit can be composed of both or just one parent, as long as they are responsible for most of the family meals. In the case of patients with shared custody, if the patient spends 40% or more of their time with one family, that family will be counted as a family unit.

6.5 Limitations of the design, data source, and analysis methods

Several potential limitations have been identified in the study.

- Selection of a small number of participants. We prioritized a realistic approach for an initial project that is feasible but also sufficiently representative.
- Wide pediatric age range. The influence of the environment outside the family will have some impact on the older population.
- Family diversity. Our goal is to collect data on the real impact and avoid biases based on different family realities. Thus, it is anticipated that data will be collected from patients who live with one or more families.

7. DATA MANAGEMENT

7.1 Data Collection and Confidentiality

Data will be entered by the researchers themselves and/or authorized personnel directly into the EDC. To ensure the confidentiality of the data obtained from the study, only the local researcher and their team of collaborators, the sponsor or their designated person, the REC, the relevant health authorities, and those responsible for data analysis will have access to them.

Regarding the EDC, each researcher will be provided with a username and a password consisting of between 4 and 6 digits in a sealed document. These codes are considered confidential and non-transferable and are subject to the same confidentiality rules as all other documents, including the protocol. Researchers are responsible for keeping their passwords confidential and not disclosing them to third parties. To gain access to the EDC, researchers must sign the study investigator commitment and confidentiality agreement.

The content of the EDC, as well as the documents generated during the study and the database, will be protected from unauthorized use by persons outside the research project and, therefore, will be considered strictly confidential and will not be disclosed to third parties. Furthermore, the EDC will be automatically disconnected if there is no activity for more than 10 minutes. This will protect the EDC from unauthorized access, should the study investigator leave the EDC open for any reason.

Patients included at each center will have a consecutive number (code), automatically generated by the EDC once the informed consent form has been signed and the EDC inclusion criteria have been met. This patient code will be documented in the participant's medical record and in the confidential patient inclusion record in the investigator's folder at each participating center.

7.2 Mandatory requirements of the Data Protection Act, Regulation (EU) No. 2016/679, and Organic Law 3/2018 on the Protection of Personal Data and Guarantee of Digital Rights (GDPR)

7.2.1 Identification of the data and the subjects who process them

The variables required to carry out the study are those specified in the variable section (Table 1) and will be collected from the participants after obtaining informed consent and collecting data through the EDC during follow-up visits. The information will be coded. Coding will be done through the EDC as specified in section 7.1 Data collection and confidentiality.

7.2.2 Identification of the processing and legitimate basis for processing

The processing of the personal data required in this study is governed by Organic Law 3/2018, of December 5, on the protection of personal data. The principal investigator of the study and the sponsor, the Institut de Recerca Sant Pau (IR SANT PAU), C/ de Sant Quintí, 77, 08041 Barcelona, Tel: +34 93 556 56 17, act as data controllers within the framework of this study. The data ultimately recorded in the central database will remain the property of the sponsor. The identity of the participants will not be revealed to any other person except to the health authorities, when required or in cases of medical emergency. The Research Ethics Committees, representatives of the Health Authority for inspection purposes, and personnel authorized by the sponsor will only have access to the data to verify personal data, clinical study procedures, and compliance with good clinical practice standards (always maintaining the confidentiality of the information).

The researcher and the sponsor are required to retain the data collected for the study for at least 5 years after its completion. Subsequently, personal information will only be retained by the patient's healthcare center and the sponsor for other scientific research purposes if the patient has given their consent to do so, and if permitted by applicable law and ethical requirements.

Legal basis for processing: GDPR: 6.1 a) the data subject has given their consent to the processing of their personal data for one or more specific purposes.

7.2.3 Tools used to process data

The REDCAP platform will be used to carry out the project. It is hosted on the servers of the sponsor, the IR Sant Pau, and is implemented with the security measures established by the institution. The data is stored on the local web server where the organization has installed the software and is therefore only accessible on computers with a trusted connection via VPN and secure credentials (certificates, RSA keys, or complex passwords).

7.2.4 International data transfers

There will be no international data transfers.

7.2.5 Identification of processing operations that may pose a high risk to the rights and freedoms of participants in the research project

In accordance with Article 35 of the GDPR, the project does not meet the requirements that require the corresponding impact assessment.

7.2.6 Rights of data subjects

In accordance with Regulation (EU) No. 2016/679 and Organic Law 3/2018 on the Protection of Personal Data and the Guarantee of Digital Rights, patients may limit the processing of inaccurate data, request a copy, or request the transfer of the data they have provided for the study to a third party (portability). To exercise these rights, you must contact the principal investigator, the researchers at the study site, or the center's Data Protection Officer, where applicable, at the center or sponsor: IR SANT PAU, C/ de Sant Quintí, 77, 08041 Barcelona, Tel: +34 93 556 56 17, email: dpo_ir@santpau.cat, or the Spanish Data Protection Agency at Jorge Juan, 6, 28001 Madrid (https://www.aepd.es/es) or the Catalan Data Protection Authority (https://apdcat.gencat.cat).

If the participant wants to know more about it, he/she can contact the Data Protection Officer of the institution or the promoter IR SANT PAU, C/ de Sant Quintí, 77, 08041 Barcelona, Tel: 93 556 56 17, email: dpd@santpau.cat, or with the Spanish Data Protection Agency at Jorge Juan, 6, 28001 Madrid (https://www.aepd.es/es) or the Catalan Data Protection Authority (https://apdcat.gencat.cat).

7.2.7 Data Validation and Quality Control

All data received through the use of the EDC will be stored and subject to the appropriate working procedures to comply with FDA standard 21 CFRe Part 11, thereby guaranteeing their confidentiality, security, and authenticity. The adaptation of the 21 CFRe Part 11 standard ensures that data received via electronic transmission is as valid as original data received on paper. This standard establishes the rules for the use of electronic data and defines the requirements for all systems for their collection, storage, maintenance, and security.

All data entered by the researcher in the system will be reviewed by an automatic validation program, and discrepancy reports will be generated accordingly to facilitate correct and complete data entry (automatic queries). Furthermore, the entered data will be reviewed and verified by the study monitor. Corrections to the EDC will be made by the researchers themselves. The original data must be available and ready for review during scheduled monitoring visits.

Furthermore, all documents related to this study must be made available to the appropriately qualified personnel responsible for conducting any audits or inspections that may be carried out. Verification of the ECR data must be performed by direct inspection of the original documents.

8. WORK PLAN (tasks, milestones, and study timeline)

This project is divided into phases:

Phase 1 (April 2024 - April 2026): Recruitment.

Recruitment will begin in February, the expected date for obtaining the IRB documentation from each center. This period will last two years.

Phase 2 (April 2024 - April 2026): First visit.

Once the participants have been recruited and have signed the IRB, their first visit will include completing the questionnaires, interview, and physical examination. This first visit will take place no more than one week after the child's T1D diagnosis.

Phase 3 (September 2024 - September 2026): Follow-up.

The follow-up visit will take place 6 months after the first visit. The questionnaires, interview, and physical examination will be repeated.

Phase 4 (April 2025 - April 2027): Final visit.

The final visit will be conducted 12 months after the first visit. The questionnaires, interview, and physical examination will be repeated.

Phase 5 (September 2026 - April 2027): Data analysis.

In the final part of the study, the data of the patients who completed the final visit will be analyzed. This will begin with database cleaning and management, analysis, and subsequent interpretation and discussion of the results.

Phase 6 (April 2027): Study closure.

Once all final visits are completed, data analysis will be finalized, and communications and manuscripts will be prepared. A research meeting will be held to prepare the final report and close the study.

9. ETHICAL ASPECTS:

This study complies with all ethical aspects and the protection of participating subjects by complying with the ethical precepts formulated in Royal Decree 957/2020 and the Biomedical Research Law 14/2007, of July 3, and in the Declaration of Helsinki and all its revisions.

Given that this study is observational in nature, patient participation is considered to entail minimal risk, i.e., the risk is similar to that which the patient would have in clinical practice without participation in the study. It is an unconditional prerequisite for a patient's participation to obtain their consent after having been informed

by the researcher about the information, both verbally and in writing, in a language that allows its content to be fully legible and understandable to the patient.

The protocol will be submitted for evaluation by a Research Ethics Committee prior to the start of patient enrollment. Any data required by the protocol may be subject to audits by the sponsor, independent organizations, and/or competent authorities, but data confidentiality, in accordance with the aforementioned law, will always be an essential condition.

Participating subjects may revoke their consent for the use of their data in the analysis at any time, without giving reasons and without incurring any liability or harm.

Before accepting and signing the researcher's commitment, participating clinicians must ensure that their participation in the study does not interfere with their prescribing habits or their healthcare duties.

9.1 Benefit-Risk Assessment of the Research

This project addresses the priority of developing personalized medicine. This project adopts a research approach that is clearly aimed at improving clinical decision-making that affects the people we serve. The potential impact may be equivalent to that mentioned for diabetes itself. The patient will not be at risk in this study as it is entirely observational and therefore will not be subject to any intervention, whether dietary or pharmacological. This study is limited to recording anonymized data in a database that does not allow access to the patient's personal data.

9.2 Ethical Considerations, Regarding Subject Information and Informed Consent

The study will be conducted in strict accordance with international ethical recommendations for medical research involving humans. The researcher will be responsible for ensuring that the study is conducted in accordance with the standards set forth in the Declaration of Helsinki.

Before starting the study, the Research Ethics Committee of the HSCSP must approve the study protocol, the information that will be provided to the subject, and the informed consent form that will be used.

The Research Ethics Committee will be informed of any subsequent amendments to the protocol and should be requested if a further evaluation of the ethical aspects of the study is necessary.

It is the researcher's responsibility to obtain the patient's informed consent. The patient may not participate in any specific study procedure without obtaining their consent or that of their legal guardian/family member if the patient is unable to give consent due to their clinical condition.

Before including any subject in the study and before obtaining informed consent, the researcher or a person designated by the researcher will explain the objectives, methods, potential risks of the study, and any discomfort it may cause to the potential participant or their legal guardian/family member. The nature, scope, and potential consequences of the study will be explained in understandable language. Rights related to data protection law will be explained, as will the possibility of being contacted in the case of future studies related to diabetes. The potential participant or their legal guardian/family member must be given time to consider their decision to participate in the study and have the opportunity to ask questions. After this explanation, and before entering the study, consent must be properly recorded by the signature of the subject or their legal guardian/family member. The informed consent must be signed in three copies: one for the participant, one for the researcher, and the third copy for the biobank.

9.3 Data Confidentiality

Regarding the confidentiality of study data, the provisions of Organic Law 3/2018, of December 5, on the Protection of Personal Data and Guarantee of Digital Rights, and the General Data Protection Regulation (EU) 2016/679, will be followed.

9.4 Interference with the Physician's Prescribing Habits

The study will not interfere with the clinical management habits of patients.

10. PLANS FOR RESULT DISSEMINATION

It is anticipated that, starting in the second year of the project, the results generated will be presented at leading national and international conferences in diabetes research, such as the Spanish Diabetes Society Conference and the European Diabetes Society Conference.

In addition, a scientific article for each study objective will be published in high-impact journals in the field.

11. STUDY RESOURCES

This project uses the resources and infrastructure of the two participating centers.

At the HSCSP, the Pediatric Endocrinology Unit has three pediatric endocrinology specialists and a nurse specializing in nutrition who is responsible for the diabetes education of patients with T1D. The hospital serves five districts in the city of Barcelona, with a population of over 400,000. It is estimated that the number of new T1D diagnoses is 15 patients per year, to which will be added those diagnosed up to the age of 20. The estimated total is 24 patients. Patients are admitted through the emergency department or referred from other primary care centers and are admitted for one week, at which point the professionals begin nutritional education. The Endocrinology Department at Sant Pau Hospital has a research unit with statistical support available for data evaluation and management, as well as for processing results for analysis.

The Pediatric Endocrinology Unit of the Pediatric Department at HUAV in Lleida has two pediatric specialists with extensive experience in diabetes treatment and a dedicated diabetes educator nurse with specific training in diabetes and nutrition education and years of experience caring for patients. The unit serves a population corresponding to the province of Lleida, as well as patients referred from the Franja de Aragón region. Approximately 15 patients are admitted each year for onset diabetes. Admission care is provided for children up to the age of 15, and newly diagnosed children up to the age of 20 will be added; for an estimated total of 25 patients at this center. Patients receive education upon diagnosis, both from doctors and from nursing professionals, as well as from the diabetes educator. Patients are usually admitted for a week. Subsequently, they are followed up in outpatient clinics by various team professionals. Basic supervision is also provided by the mental health team at the CSMIJ in Lleida. Initial training includes nutritional education, which recommends the ideal number of servings for each patient and their distribution throughout the day, in addition to comprehensive education on healthy dietary habits. It is conducted annually.

Within the teaching function, a course is offered to teaching staff from schools and high schools in the area, in collaboration with the hospital's teaching classroom.

The Sant Joan de Déu Hospital, a leading pediatric hospital in the Barcelona area, is also participating in the study. Its endocrinology unit receives 13,000 visits per year, with consultations for DM1 being one of the most frequent. They have a team of pediatric endocrinologists and nurses who provide educational interventions to

patients and their families during the stay following a DM1 diagnosis. The hospital has a web portal with information, advice, and other resources for patients with DM1 and their families. The number of new DM1 diagnoses varies widely, but the expected recruitment rate is expected with the participation of both hospitals.

These hospitals have affiliated research institutes, the Lleida Biomedical Research Institute, the IR Sant Pau, and the Sant Joan de Déu Research Institute, which have the infrastructure and personnel necessary to carry out the project. The principal investigator of the project belongs to the Sant Pau Research Institute. The crucial leadership of women in this research not only promotes diversity and equity in scientific research but also represents an essential contribution to elevating excellence in biomedical research, opening new paths and approaches in the field of health. J. Rossell is a dietitian-nutritionist, with a PhD in Biomedicine, with extensive experience in the field of basic and translational research focused on nutrition, endocrinology, and complications associated with diabetes. She is an affiliated researcher with the CIBERDEM research group at the Sant Pau Biomedical Research Institute and is part of the Endocrinology, Diabetes, and Nutrition research group, both led by Dr. Mauricio. This group has extensive experience in the study of diabetes and complications associated with dietary and lifestyle habits, which has resulted in a large number of national and international projects and, consequently, scientific publications in high-impact international journals.

12.PROTOCOL MODIFICATIONS:

Any modification to the study protocol will always take the form of a written amendment or addendum. Formalization requires the approval of all persons responsible for the study. For significant modifications, express approval from the Clinical Research Ethics Committee will be requested.

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14. Supplementary material

Semi-quantitative food frequency questionnaire (Translated from the Spanish version)

	Never or almost never	Month	Times/week			Times/day			
		1-3 times	Once	2-4	5/6	Once	2/3	4/6	+6
Section I: Fruits & Fruit Juices (Items 1–12)									
1. Orange (1), grapefruit (1) or tangerines (2)									
2. Banana (1)									
3. Apple or pear (1)									
4. Fresh orange juice (1 glass, 200 mL)									
5. Bottled or canned fruit juice (200 mL)									
6. Cherries, sour cherries, plums (dessert plate)									
7. Grapes (1 bunch or 20 berries)									
8. Strawberries, raspberries, blackberries (dessert plate)									
9. Dried fruit (apricots, figs, raisins) (30 g)									
10. Other fresh fruit (1 piece or 150 g)									
11. Citrus fruits other than orange or tangerine									
12. Fruit salads or compotes (1 bowl)									
Section II: Vegetables & Legumes (Items 13–28)									
13. Raw leafy greens or salad vegetables (1 plate)									
14. Cooked leafy greens (spinach, chard) (1 plate)									
15. Raw cruciferous vegetables (broccoli, cauliflower, cabbage) (1 plate)									
16. Cooked cruciferous vegetables (1 plate)									
17. Tomatoes (raw or cooked) (1 medium fruit or 1 plate)									
18. Bell peppers, cucumber, celery (1 plate)									
19. Onion, garlic, leeks (added in cooking) (1 serving)									
20. Other cooked vegetables (eggplant, zucchini, carrots) (1 plate)									
21. Legumes (lentils, chickpeas, beans) (150 g)									
22. Peas (150 g)									
23. Broad beans (150 g)									
24. Soy products (tofu, edamame) (100 g)									
25. Potatoes (boiled, baked) (1 medium)									
26. French fries or potato chips (1 portion)									
27. Pickled vegetables (1 serving)									
28. Sofrito (tomato/garlic/onion sautéed in olive oil) (1 serving)									
Section III: Cereals & Bread (Items 29–36)									

29. Whole-grain bread (1 slice)									
30. Refined-grain bread (1 slice)									
31. Whole-grain rice, pasta, couscous (1 cup cooked)									
32. Refined-grain rice, pasta, couscous (1 cup cooked)									
33. Breakfast cereals (high-fiber) (30 g)									
34. Sweetened breakfast cereals (30 g)									
35. Oats or muesli (30 g)									
36. Other grains (quinoa, wheat berries) (1 cup cooked)									
Section IV: Dairy (Items 37–43)									
37. Whole-milk yogurt or rice pudding (125 g)									
38. Skim- or semi-skimmed-milk yogurt (125 g)									
39. Whole-milk (1 glass, 200 mL)									
40. Skim- or semi-skimmed-milk (1 glass, 200 mL)									
41. Cheese — hard/semi-hard (30 g)									
42. Fresh cheese (cottage, ricotta) (30 g)									
43. Fermented milk drinks (kefir, ayran) (200 mL)									
Section V: Meats & Eggs (Items 44–58)									
44. White meat (chicken, turkey, rabbit) — 1 portion (100–125 g)									
45. Red meat (beef, pork, lamb) — 1 portion (100–125 g)									
46. Liver or other organ meats — 1 portion (100–125 g)									
47. Hamburgers (beef, pork, chicken) — 1 unit									
48. Sausages (chorizo, salami, etc.) — 1 portion (50 g)									
49. Bacon, pancetta — 1 slice									
50. Cold cuts (ham, turkey breast, mortadella) — 1 slice									
51. Canned meat (corned beef, luncheon meat) — 1 portion (50–75 g)									
52. Meatballs — 1 unit									
53. Cooked meat (e.g., stews) — 1 portion									
54. Breaded or fried meat — 1 portion (100–125 g)									
55. Eggs — 1 unit									
56. Omelet — 1 portion									
57. Scrambled eggs or eggs with vegetables — 1 portion									
58. Boiled or fried egg — 1 unit									
Section VI: Fish & Seafood (Items 59–67)									
59. White fish (hake, cod, etc.) — 1 portion (100–150 g)									

60. Oily fish (salmon, sardines, mackerel) — 1 portion (100–150 g)									
61. Salted or smoked fish (cod, salmon, anchovies) — 1 portion (50 g)									
62. Shellfish (mussels, shrimp, clams) — 1 portion (4–5 units)									
63. Canned tuna — 1 small can (80–100 g)									
64. Canned sardines or mackerel — 1 small can (80–100 g)									
65. Fish sticks or breaded fish — 1 unit									
66. Fish soup or stew — 1 portion									
67. Surimi or imitation crab — 1 stick (25 g)									
Section VII: Oils, Fats & Sauces (Items 68–77)									
68. Extra virgin olive oil — 1 tablespoon (10 mL)									
69. Olive oil (not extra virgin) — 1 tablespoon									
70. Sunflower, corn or soybean oil — 1 tablespoon									
71. Butter — 1 portion (12 g)									
72. Margarine — 1 portion (12 g)									
73. Mayonnaise — 1 tablespoon									
74. Cream (liquid or whipped) — 1 tablespoon									
75. Other sauces (ketchup, mustard, barbecue) — 1 tablespoon									
76. Pesto, aioli or other oil-based sauces — 1 tablespoon									
77. Lard or animal fat — 1 tablespoon									
Section VIII: Beverages (Items 78–94)									
78. Coffee — 1 cup									
79. Decaffeinated coffee — 1 cup									
80. Tea (green, black, etc.) — 1 cup									
81. Herbal teas (chamomile, mint, etc.) — 1 cup									
82. Milkshakes or flavored milk drinks — 1 glass (200 mL)									
83. Soft drinks with sugar — 1 can (330 mL)									
84. Soft drinks without sugar (diet/light) — 1 can (330 mL)									
85. Bottled fruit juice (not freshly squeezed) — 1 glass (200 mL)									
86. Alcohol-free beer — 1 can/bottle (330 mL)									
87. Beer — 1 can/bottle (330 mL)									
88. Red wine (young) — 100 mL glass									
89. Red wine (aged/reserve) — 50 mL glass									
90. White or rosé wine — 100 mL glass									
91. Cava or sparkling wine — 100 mL glass									
92. Liquor (e.g., whiskey, gin, rum) — 30 mL shot									

93. Sweet liqueurs (Baileys, anise, vermouth) — 30 mL shot									
94. Mixed alcoholic drinks (cocktails, gin & tonic) — 1 glass									
Section IX: Sweets, Pastries & Snacks (Items 95–113)									
95. Pastries (croissants, doughnuts, etc.) — 1 unit									
96. Cookies or biscuits — 1 unit or portion (30 g)									
97. Cakes (sponge cake, pie, etc.) — 1 slice									
98. Chocolate (milk or dark) — 1 portion (30 g)									
99. Chocolates with filling or nuts — 1 portion (30 g)									
100. Candies, gummies or sweets — 1 portion (30 g)									
101. Honey or jam — 1 tablespoon									
102. Ice cream — 1 scoop or small cup									
103. Puddings or custards — 1 portion									
104. Snack bars or energy bars — 1 unit									
105. Potato chips — 1 small bag (30 g)									
106. Salted nuts — 1 handful (30 g)									
107. Popcorn (ready-to-eat) — 1 portion (30 g)									
108. Crackers or breadsticks — 1 portion (30 g)									
109. Savory snacks (nachos, cheese balls, etc.) — 1 portion (30 g)									
110. Sugar cubes or teaspoons added to drinks — 1 unit									
111. Artificial sweeteners — 1 packet or dose									
112. Desserts made at home (custards, rice pudding) — 1 portion									
113. Diet or sugar-free sweets — 1 portion									
Section X: Miscellaneous (Items 114–137)									
114. Pizza (homemade or commercial) — 1 slice or small unit									
115. Lasagna or cannelloni — 1 portion									
116. Stuffed pasta (ravioli, tortellini) — 1 portion									
117. Prepared foods (frozen meals, ready dishes) — 1 portion									
118. Fried rice or noodles — 1 portion									
119. Couscous or bulgur — 1 portion									
120. Vegetable soup — 1 bowl									
121. Meat or chicken broth — 1 bowl									
122. Fish soup — 1 bowl									
123. Mixed salads with dressing — 1 bowl									
124. Mixed dishes (paella, fideuá) — 1 portion									
125. Tapas or appetizers (small bites) — 1									

portion									
126. Food eaten outside home (per week)									
127. Takeaway or fast food (per week)									
128. Vitamin supplements — 1 tablet or dose									
129. Mineral supplements — 1 tablet or dose									
130. Fiber supplements — 1 dose									
131. Protein powder or shakes — 1 dose									
132. Herbal or natural remedies — 1 dose									
133. Meal replacement drinks — 1 bottle (200–250 mL)									
134. Sports drinks (isotonic) — 1 bottle (500 mL)									
135. Energy drinks (Red Bull, Monster, etc.) — 1 can									
136. Artificial supplements or ergogenic aids — 1 dose									
137. Other food supplements not listed — 1 dose									