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# Virtual diabetes care for young people with type 1 diabetes

**Submission date**
14/10/2019

**Recruitment status**
No longer recruiting

**Registration date**
23/10/2019

**Overall study status**
Completed

**Last Edited**
22/11/2023

**Condition category**
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Type 1 diabetes is where a person's immune system has attacked the cells in the body that produce insulin, which is the hormone that controls sugar levels in the blood. This means that they must take insulin in order to control their sugar levels. A person living with diabetes must take a large amount of responsibility for treating their illness. Living with diabetes is a balancing act between high and low blood sugar concentrations. A high blood sugar level can lead to serious complications that are only apparent later on when the damage has already been done. Low levels can lead to falling unconscious. Learning to control blood sugar levels can be overwhelming. Type 1 diabetes is usually diagnosed in children and young adults. A survey of the Diabetes Association's youth section show that 4 in 10 patients think of their diabetes 1-10 times each hour. This study aims to investigate whether a virtual (online) diabetes clinic, in addition to the normal hospital visits, can help support young adults with type 1 diabetes to manage their treatment and to have a better quality of life.

Who can participate?
Young adults aged 18-25 years with type 1 diabetes

What does the study involve?
The participants will be randomly allocated into one of two groups. One group will be given access to the virtual clinic straight away. The other group will wait 6 months before getting access. Both groups will be tested at 6-month intervals to understand their blood sugar levels, their use of insulin treatments and their feelings about their health, diabetes and treatment.

What are the possible benefits and risks of participating?
Young adults with type 1 diabetes often do not control their blood sugar levels well. Participants might benefit from the extra support and encouragement to manage their condition better. The virtual clinic will allow them to keep in touch with the same healthcare professional, even if they are studying or working away from their usual hospital. The virtual clinic might also benefit participants who cannot travel to the hospital diabetes clinic for health or other reasons.
The patients will be informed by several methods that participation in the study is voluntary and that they can end their participation at any time. The study is not associated with any known extra risk. Regular visits to the diabetes clinic are a part of the standard treatment of diabetes,

so there should not be any unknown risks. The questionnaires used in this study have been used in previous studies and have no questions that could be interpreted as offensive or a threat to their integrity.

Where is the study run from?
Uppsala University (Sweden)

When is the study starting and how long is it expected to run for?
January 2019 to June 2022

Who is funding the study?
Uppsala University Hospital (Sweden)

Who is the main contact?
Associate Professor Janeth Leksell, Janeth.Leksell@medsci.uu.se

# Contact information

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Scientific

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### Type(s)
Public

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
N/A

# Study information

### Scientific Title
Virtual diabetes care for young people with type-1 diabetes: A randomized controlled trial

### Study objectives
Our hypothesis is that a virtual diabetes clinic leads to improvements in glycemic control, treatment satisfaction, and quality of life.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 04/10/2019, Etikprövningsmyndigheten [Regional Ethics Approval Board] (Box 2110, 75002 Uppsala, Sweden; +46 010-4750800; registrator@etikprovning.se), ref: 2019-00133

### Study design
Randomized controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

## Health condition(s) or problem(s) studied
Type 1 diabetes

## Interventions
Current intervention as of 02/12/2019:
Randomisation:
After the participants are identified, patients are randomised to an intervention group or to a waiting list control group, using randomisation envelopes containing randomisation cards. Baseline data will be collected for both groups prior to randomisation. The intervention group will be offered access to the virtual clinic immediately, whilst the wait-list control group will be offered the intervention after 6 months. At the 6-month follow-up assessment the second data collection will be carried out for both groups. The intervention group will then continue with the intervention whilst the wait list control group starts the intervention. The third data collection point is after 12 months. The finally 18 months follow-up will be collected at the end of the study only for the wait-list control group.

Virtual clinic:
Participants who meet the inclusion criteria are offered the chance to take part in the virtual clinic. Vista Dialog (Diabetesdialog) offers a digital service specially designed to facilitate continuity of care between patients and diabetes nurse or doctor. The virtual package/care consists of a platform, partly a mobile application for patients, and partly a web interface/portal for staff with a secure log-in via a bank ID system (patient) and a secure login card (staff). The virtual package/care has been developed in close collaboration with young people with diabetes. Both parties can easily communicate in real time via text message and additionally, patients can themselves book an online appointment with the Diabetes Specialist Nurse in the times made available by the nurse in the application.

Data collected:
As well as the primary and secondary outcome measures, the following information will be collected:
1. Insulin requirements and type of insulin used assessed using patient medical records at baseline, 6 months, 12 months and (for the wait-list group only) 18 months
2. Diabetes duration and age at onset of diabetes collected using patient medical records at baseline
3. Demographic data, including gender, height, weight, age, lifestyle and education level, collected during an interview of the patient by a diabetes nurse at baseline, 6 months, 12 months and (for the wait-list group only) 18 months
4. Number of physical clinic visits assessed using patient medical records at 6 months, 12 months and (for the wait-list group only) 18 months
5. Number of virtual clinic visits assessed using patient medical records at 6 months, 12 months and (for the wait-list group only) 18 months

Qualitative interviews:
Qualitative interviews will be conducted on approximately 16 individuals. The researchers will perform a purposeful sampling with a maximum variation. The interviews will be conducted before and at the end of the intervention and follow a semi-structured interview guide. The interview guide will focus on the following three major topics:
- Perceptions about the virtual care (e.g. "Do you have any experiences of virtual care?" (before intervention), "Which changes do you see the virtual care has brought?"(after intervention).
- Hindering and facilitating factors in the context of virtual care (e.g. "Is it possible to describe some factors or events that may hamper virtual care?" (before intervention), "Which conditions

in your daily life have made it difficult or easy to achieve positive outcomes from the virtual care?" (after intervention).
- Problems with virtual care technology (e.g. "Do you have experience in digital or virtual technology?" (before intervention), "Did you have any problems with the internet or in reaching the diabetes team?" (after intervention).

The text from the interviews will be analysed using qualitative content analysis, a method that, according to Krippendorff, is appropriate for gaining inferences from verbal and communication data. The interviews will be listened to and the transcriptions from the interviews will be read several times as a whole to obtain a holistic view of the material, an overall impression of the content, and to obtain the content in relation to the aim of the study. Meaning units relevant to the aim of the study will be marked and transformed to condensed meaning units that will be labelled with codes, then grouped into subcategories that form the categories. The steps are described below.
The analysis of the interviews will be performed as follows:
Step 1: After the interviews are completed, they will be transcribed then will be read through several times.
Step 2: The transcribed text will be divided into units of meaning, which are condensed and labelled with codes. The codes will be discussed in the research group (all authors).
Step 3: The various codes will be compared. The research group looking for similarities and differences and then sort the codes into subcategories.
Step 4: The latent content of the categories will be formulated into an overarching theme.

Previous intervention:
Randomisation:
After the participants are identified, patients are randomised to an intervention group or to a waiting list control group, using randomisation envelopes containing randomisation cards. Baseline data will be collected for both groups prior to randomisation. The intervention group will be offered access to the virtual clinic immediately, whilst the wait-list control group will be offered the intervention after 6 months. At the 6-month follow-up assessment the second data collection will be carried out for both groups. The intervention group will then continue with the intervention whilst the wait list control group starts the intervention. The third data collection point is after 12 months. The finally 18 months follow-up will be collected at the end of the study only for the wait-list control group.

Virtual clinic:
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Data collected:
As well as the primary and secondary outcome measures, the following information will be collected:
1. Insulin requirements and type of insulin used assessed using patient medical records at baseline, 6 months, 12 months and (for the wait-list group only) 18 months
2. Diabetes duration and age at onset of diabetes collected using patient medical records at

baseline
3. Demographic data, including gender, height, weight, age, lifestyle and education level, collected during an interview of the patient by a diabetes nurse at baseline, 6 months, 12 months and (for the wait-list group only) 18 months
4. Number of physical clinic visits assessed using patient medical records at 6 months, 12 months and (for the wait-list group only) 18 months
5. Number of virtual clinic visits assessed using patient medical records at 6 months, 12 months and (for the wait-list group only) 18 months

### Intervention Type
Behavioural

### Primary outcome measure
HbA1c measured in blood taken at baseline, 6 months, 12 months and (for the wait-list group only) 18 months

### Secondary outcome measures
Current secondary outcome measures as of 02/12/2019:
1. Patient's satisfaction with their diabetes treatment assessed using the Diabetes Treatment Satisfaction Questionnaire (DTSQ) at baseline, 6 months, 12 months and (for the wait-list group only) 18 months
2. Patient's assessment of their physical health, mental and emotional wellbeing and quality of life assessed using the 'Ta tempen på din hälsa [Take the temp of your health]' questionnaire at baseline, 6 months, 12 months and (for the wait-list group only) 18 months
3. Change in patient's satisfaction with their diabetes treatment assessed using the Diabetes Treatment Satisfaction Questionnaire change version (DTSQc) at 12 months for the intervention group and 18 months for the wait-list group
4. Participant's views on the virtual care intervention assessed using qualitative analysis of interviews with a sample of participants before and at the end of the intervention

Previous secondary outcome measures:
1. Patient's satisfaction with their diabetes treatment assessed using the Diabetes Treatment Satisfaction Questionnaire (DTSQ) at baseline, 6 months, 12 months and (for the wait-list group only) 18 months
2. Patient's assessment of their physical health, mental and emotional wellbeing and quality of life assessed using the 'Ta tempen på din hälsa [Take the temp of your health]' questionnaire at baseline, 6 months, 12 months and (for the wait-list group only) 18 months
3. Change in patient's satisfaction with their diabetes treatment assessed using the Diabetes Treatment Satisfaction Questionnaire change version (DTSQc) at 12 months for the intervention group and 18 months for the wait-list group

### Overall study start date
01/01/2019

### Completion date
01/06/2022

## Eligibility

### Key inclusion criteria

1. Aged 18-25 years
2. Diagnosis of type 1 diabetes

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
25 Years

### Sex
Both

### Target number of participants
50 in each group

### Total final enrolment
79

### Key exclusion criteria
1. Severe depression, eating disorder or other serious mental illness
2. Alcohol/drug abuse
3. Severe diabetes late complications

### Date of first enrolment
01/11/2019

### Date of final enrolment
23/11/2020

## Locations

### Countries of recruitment
Sweden

### Study participating centre
**Uppsala University**
Department of Medical Sciences, UU
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# Sponsor information

### Organisation
Uppsala University Department of Medical Sciences

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### Sponsor type
University/education

### Website
www.medsci.uu.se/research/clinical-diabetes-and-metabolism

### ROR
https://ror.org/048a87296

# Funder(s)

### Funder type
University/education

### Funder Name
Akademiska Sjukhuset

### Alternative Name(s)
Uppsala University Hospital

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Universities (academic only)

### Location
Sweden

# Results and Publications

## Publication and dissemination plan
The study protocol is expected to be published in November 2019. The 6-month follow-up results will be published in May 2021 and 12-month follow-up results in January 2022.

## Intention to publish date
31/08/2023

## Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to lack of informed consent from the participants to share material outside the research group. In addition, we do not have ethical approval sharing data material outside the research group.

## IPD sharing plan summary
Not expected to be made available

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 05/09/2020 | 08/09/2020 | Yes | No |
| Results article | | 22/11/2023 | 22/11/2023 | Yes | No |