ISRCTN92107365 https://doi.org/10.1186/ISRCTN92107365

Use of a web 2.0 portal to improve education and communication in young diabetes patients with families

Submission date 25/11/2011	**Recruitment status** No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 10/02/2012	**Overall study status** Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 08/12/2015	**Condition category** Nutritional, Metabolic, Endocrine	☐ Individual participant data

Plain English summary of protocol

Background and study aims
Diabetes is a lifelong condition that causes a person's blood sugar level to become too high. A website was developed offering communication with local healthcare professionals, interaction with other patients, and access to relevant information and services. The aim of this study was to look at the use of the website and its effects on young patients with diabetes.

Who can participate?
Families with children and adolescents with diabetes, treated at two paediatric clinics in Sweden.

What does the study involve?
Participating families are randomly allocated to one of two groups. One group receive passwords for access to the website for one year, and the other group do not receive access for 1 year. All families are given access during the second study year. The website was used by patients without directions from healthcare professionals or researchers. We measured how patients used the website. Participants complete questionnaires before the study started and after 1 and 2 years.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Linköping University (Sweden).

When is the study starting and how long is it expected to run for?
April 2006 to September 2008.

Who is funding the study?
The Medical Research Council of Southeast Sweden (FORSS), ALF Grants, County Council of Östergötland, and the Swedish Child Diabetes Foundation.

Who is the main contact?
Dr Sam Nordfeldt
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Contact information

Type(s)
Scientific

Contact name
Dr Sam Nordfeldt

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Use of a web 2.0 portal to improve education and communication in young diabetes patients with families: a randomised controlled trial

Study objectives
A Web 2.0 portal, with diabetes-related information and the possibility to communicate with diabetes peers as well as with health care professionals, would
1. Be of complementary value in everyday life with diabetes, especially by newly diagnosed patients and patients in periods with instable metabolic control
2. Be perceived as helpful in self treatment; and
3. Contribute to improved metabolic control

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the Faculty of Health Science at Linköping University, Sweden, 04/11/2003

Study design
Randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
The patients and their families were randomised (stratified for clinic) to either the intervention group or the control group.

At baseline April 2006, all subjects in the intervention group were offered a personal password to the portal for the first year of the study. After study year one, all subjects in the previous control group were also offered passwords to the portal. For children 13 years of age and older, both parents and adolescents received passwords while for younger children only parents received passwords. Basic information about the concept was given by posted letters, and informed consent to study participation was required before the first visit.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. HbA1c
2. Number of severe hypoglycaemia incidents

Secondary outcome measures
1. Health-Related Quality Of Life (HRQOL)
2. Empowerment and perception of quality of care regarding information
3. Hypoglycaemia (self-reported) and

4. Numbers of self-controls of blood glucose (self-reported)
5. User activity by site visits and page visits logged per user

Overall study start date
11/04/2006

Completion date
25/09/2008

Eligibility

Key inclusion criteria
All the clinically diagnosed type 1 diabetes children registered in the Swedish paediatric diabetes quality registry, SWEDIABKIDS, belonging to the geographic population of the two paediatric clinics in Linköping and Jönköping, were eligible and invited to the study

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
474

Key exclusion criteria
1. No consent
2. Transferred to other clinic

Date of first enrolment
11/04/2006

Date of final enrolment
25/09/2008

Locations

Countries of recruitment
Sweden

Study participating centre
Linköping University
Linköping
Sweden
581 85

Sponsor information

Organisation
County Council of Östergötland (Landstinget i Ostergotland) (Sweden)

Sponsor details
Landstinget i Ostergotland
Linkoping
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Sponsor type
Government

ROR
https://ror.org/0326gsy75

Funder(s)

Funder type
Research council

Funder Name
The Medical Research Council of Southeast Sweden (FORSS) (Sweden)

Funder Name
ALF Grants, County Council of Östergötland (Sweden)

Funder Name
The Swedish Child Diabetes Foundation (Barndiabetesfonden) (Sweden)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/08/2013		Yes	No