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Theory based patient-education, acceptance and commitment Therapy (ACT), designed for people with type 1 diabetes

Submission date
12/12/2014

Recruitment status
No longer recruiting

Registration date
06/01/2015

Overall study status
Completed

Last Edited
26/11/2015

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Diabetes is a condition that causes a person's blood sugar (glucose) level to become too high. Insulin is a hormone (produced by an organ called the pancreas) that controls the amount of glucose in the blood. Type 1 diabetes occurs when the pancreas does not make any insulin. People with type 1 diabetes have to inject themselves with insulin every day and they have to balance the amount of insulin they inject with the amount of food they eat and the amount of exercise that they do. If the amount of glucose in the blood is higher than normal over a long period of time complications can be severe and include damage to blood vessels, nerve damage and internal organs. Even a mildly raised glucose level which does not cause any symptoms in the short term can affect the blood vessels in the long term. It can also affect a person's general mental well-being and how they interact with other people. For these reasons, educating people with diabetes has a very important part to play in helping them to manage their own condition. Such patient education could be provided on a one-to-one basis or in groups and is necessary to maintain good self-care. Currently, it is not known what educational programme might be the best in helping people with diabetes that are struggling with high levels of blood glucose. Acceptance and commitment therapy, ACT, is a scientifically based psychotherapeutic educational method which looks at how the person wants to live their life, how they live today as well as the relationship between the person and their inner experiences. The overall objective is to help the person live as full and meaningful life as possible. We will investigate if an educational model based upon ACT is suitable for people with high blood glucose. Can the education support people to acquire knowledge and tools necessary to manage diabetes in another way? We want to investigate whether the offered education based upon ACT leads to better blood glucose values and quality of life. The purpose of the education is teach patients how to best manage their diabetes.

Who can participate?
Adults aged between 18-55 with poorly controlled type 1 diabetes.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (treatment group)

are taught mindfulness and acceptance strategies to cope with the stress of living with their diabetes. Those in group 2 (control group) are placed on a wait list and are given the treatment after 12 months. The treatment focuses on living according to ones values and changing behaviours. The topics covered in the sessions include the acceptance of thoughts and feelings, and mindfulness and includes exercises, discussion and work to be done at home. As a homework assignment to one of the visits, each patient has to wear a hidden CGMS (continuous glucose monitor – which measures glucose levels in the blood every few minutes) for a week while accurately recording their activity, emotion and mood. During their next visit, the participants see their blood sugar curves and are able to link this with their self-registration. This is a way to get more knowledge about the many different ways that blood glucose levels can be affected. At the last session the focus is on maintaining and continuing practice of the course content. Each patient will choose what is important for them to focus on the next follow-up visit.

What are the possible benefits and risks of participating?
The main benefit that participants receive from taking part is the opportunity to learn more and get a deeper insight into how best to manage their life with diabetes. This can hopefully improve the quality of life, glycemic control, and in the longer term provide a reduced risk of late diabetic complications. The study is not associated with any known increased risk. It may be that the patient may feel that he will be reminded of his illness. This has been suggested in a study from the United States. As patient education is part of the standard treatment of diabetes (or usual diabetes care) and is a high priority in the Board's national diabetes guidelines should not be any unknown risks. The questionnaire used in the evaluation has been used in previous studies and contain no degrading questions.

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

When is the study starting and how long is it expected to run for?
January 2015 to February 2018

Who is funding the study?
Swedish Diabetes Federation (Sweden)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A Randomized Control study, of an intervention, based on Acceptence and Commitment Therapy for people with type 1 diabetes, evaluating glycemic control and self-perceived health, compared with usual care

Acronym
RCT-ACT-Diabetes

Study objectives
An intervention based upon ACT may improve glycemic control and perceived self-perceived health among people with type 1 diabetes with unsatisfactory glycemic control

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Revew Board, Uppsala, 27/08/2014, ref. 2014/301

Study design
Interventional single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
The PIS is not available in English

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

Interventions
The treatment is scheduled to run over a period of (twelve months). Participants in the treatment condition will learn mindfulness and acceptance strategies to cope with diabetes related distress. The treatment will focus on living according to one's values and on behavioural activation. As the treatment is targeted towards a population with poorly controlled diabetes, the intervention will also include one week of measurement with a hidden CGMS device facilitating for the patient to see how their behaviour influence their blood sugar levels. All sessions will be led by a psychologist with specialisation in cognitive behaviour therapy and training in ACT and a nurse specialized in diabetes. Each session will have an ACT specific theme about how to promote psychological flexibility. The topics include the acceptance of thoughts and feelings, and mindfulness. Exercise in mindfulness based in concrete practice, both during the course sessions and as homework. Acceptance practiced through experiential exercises, writing exercises and discussion. As a homework assignment to one of the visits, each patient will have to wear a hidden CGMS for a week while accurately record activity, emotion and mood. During the visit, the group participants see their blood sugar curves and linking this with their self-registration. This is a means to gain more knowledge about the many different aspects that affect blood glucose level. At the last conversation focus will be on maintaining and continuing practice of the course content. Each patient will choose a commitment to what is important for that person to continue to focus on the next follow-up visit

Participant and recruitment
Inclusion criteria for the study are that the participants are between 18 to 55 years old and have an HbA1c level >70 mmol/mol at the time of inclusion. Exclusions criteria to the study will be ongoing severe depression, eating disorder or other severe mental illness, alcohol or substance abuse or severe diabetes complication. Oral and written information about the present study will be given to patients who fulfil the inclusion criteria. Written informed consent or assent for participation in the study will be obtained from the participants. All patients who choose to participate, completed a baseline questionnaire, and had an HbA1c (pretest).

Randomization
Participant who fulfilled the inclusions criteria are willing to participate in the study and had completed the pre-test will be randomized to either intervention or wait-list control group.

Measures and data collection:
Before starting ACT: HbA1c, height, weight, insulin requirement, mean frequency of self-monitoring of blood glucose (SMBG), HADS, 'Check your health,and AAQ2; 6 and 12 months after starting ACT.

Intervention Type
Behavioural

Primary outcome measure
Glycemic control measured with HbA1c

Secondary outcome measures

1. Hospital Anxiety and Depression Scale questionnaire
2. Check your health questionnaire
3. Acceptence and Action questionnaire

Overall study start date
01/01/2015

Completion date
10/02/2018

Eligibility

Key inclusion criteria
1. Age between 18 to 55 years old
2. HbA1c level >70 mmol/mol at the time of inclusion

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80 patients

Key exclusion criteria
1. Ongoing severe depression
2. Eating disorder
3. Severe mental illness
4. Alcohol or substance abuse
5. Severe diabetes complication

Date of first enrolment
01/01/2015

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
Sweden

Study participating centre
Uppsala University Hospital
Medical Department
Uppsala
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Sponsor information

Organisation
Uppsala University Hospital

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01apvbh93

Funder(s)

Funder type
Charity

Funder Name
Swedish Diabetes Federation (Sweden)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

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	19/11/2015		Yes	No