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Feasibility study to evaluate a psychological treatment to reduce diabetic ketoacidosis episodes

Submission date
25/07/2016

Recruitment status
No longer recruiting

Registration date
02/08/2016

Overall study status
Completed

Last Edited
02/08/2016

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Type 1 diabetes mellitus (T1DM) is a lifelong condition where a person is unable to prevent their blood sugar (glucose) levels from becoming too high. When a person is suffering from TD1M, the body is unable to produce a hormone called insulin, which is responsible for breaking down glucose and turning it into energy. The only effective way of treating T1DM is by regularly injecting the insulin that the body is unable to produce. It is very important that sufferers take their insulin regularly, as otherwise it can lead to serious complications. Diabetic ketoacidosis (DKA) is a potentially life-threatening complication of T1DM. When glucose cannot be used for energy because there isn't enough insulin, the body starts to break down fats. This causes toxic chemicals called ketones to build up in the body which if left untreated, can lead to coma and death. It has been found that T1DM patients who suffer from other illnesses, are more likely to suffer repeated episodes of DKA (recurrent DKA, rDKA) because of not taking insulin or not managing to balance their medication with their lifestyle well enough (disease management). Mentalization-based therapy (MBT) is a type of talking therapy which aims to improve behavioural control, better regulation of emotions, improving personal relationships, and increasing the ability to achieve goals in life. The aim of this study is to assess the feasibility of using MTB as a treatment for diabetic patients with rDKA.

Who can participate?
Adults with T1DM and have had two or more admissions to hospital for diabetic ketoacidosis in the last 12 months.

What does the study involve?
In the first part of the study, four diabetes departments in south-east London are asked to count the numbers of potential participants (adults with T1DM who have rDKA) admitted, and the number of those who are transferred to intensive care units. In the second part of the study, participants are offered 40 weekly individual 50 minute mentalization based therapy (MBT) sessions, held at the King's College Hospital diabetes clinic. The participants are followed up at 3

months at which point the number of DKA episodes will be counted as well as having a blood test to test their blood sugar control. Participants also complete a number of questionnaires to assess their mental wellbeing.

What are the possible benefits and risks of participating?
Participants may benefit from a lower risk of suffering episodes of diabetic ketoacidosis in the future and improvements to their mental wellbeing which is likely to improve their blood sugar control. The main risk is that the program may not succeed and diabetic ketoacidosis admissions continue to occur.

Where is the study run from?
King's College Hospital (lead centre) and five other NHS hospital in London (UK)

When is the study starting and how long is it expected to run for?
June 2013 to September 2017

Who is funding the study?
Novo Nordisk UK Research Foundation (UK)

Who is the main contact?
Dr Christopher Garrett
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
004

Study information

Scientific Title
Pre and Post Feasibility study to evaluate an attachment focused psychological treatment to reduce DKA episodes

Study objectives
The aim of this study is to find out whether adequate numbers of participants can be recruited to a study using a psychological intervention for diabetic ketoacidosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Birmingham Research Ethics Committee, 07/07/2016

Primary study design
Interventional

Study design
Pre and post non-randomised feasibility study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetic ketoacidosis

Interventions
Part A:
The first part of the trial will assess whether a randomised controlled trial would get sufficient referrals from units in a 10 mile catchment area. This section of the study uses a survey design. NHS Diabetes services within approximately 10 mile catchment area of King's College Hospital will be contacted by email to request involvement. Survey data requested will include numbers of DKA admissions, numbers of rDKA admissions with number of admissions reaching intensive care units. The standardised questionnaire has also been designed to ascertain how rDKA is currently managed and willingness to refer to a study investigating a psychological intervention for rDKA.

Part B:
Patients will be offered 40 weekly individual 50 minute mentalization based therapy (MBT) sessions, by a clinician trained in MBT and experienced in managing complex physical and mental health problems. Supervision will be with a consultant psychiatrist experienced in supervising MBT. These sessions will be held at King's College Hospital in the diabetes clinic. The sessions involve involve Mentalization Based Therapy which is a NICE recommended psychoanalytically orientated psychotherapy used in personality disorder treatment focusing on interpersonal functioning and affect regulation, but in this setting will also be used to help participants to reflect on their relationship with type 1 diabetes.

The participants are followed up at 3 months at which point the number of DKA episodes will be counted as well as a biochemical assessment of insulin omission using HbA1c and behavioural assessment with a count of numbers of tests/day and numbers of boluses/day. The battery of psychological assessments will also be repeated and compared with initial assessment.

Intervention Type
Other

Primary outcome(s)
Feasibility outcomes:
1. Eligibility rate is measured by numbers of patients across 6 sites having 2 or more DKA episodes in last year
2. Recruitment rate is measured by number of patients recruited over number of patients assessed
3. Clinician willingness to recruit participants is measured by number of patients they would refer over TOTAL number eligible
4. Attrition rate is measured by the number of participants who consent to participate that remain in the study until follow-up at 3 months

Key secondary outcome(s)
1. Glycated hemoglobin (HbA1c) is measured using a HbA1c test at baseline and 3 months
2. Average blood glucose is measured using a blood glucose monitor at baseline and for the 2 weeks prior to 3 months follow-up
3. Tests/day is measured as number of tests done at baseline and for the 2 weeks prior to 3 months follow-up
3. Boluses/day is measured as recorded boluses on electronic meter at baseline and for the 2 weeks prior to 3 months follow-up
4. Depression symptoms are measured using the Becks depression inventory at baseline and 3 months
5. Anxiety symptoms is measured using the Becks anxiety inventory at baseline and 3 months
6. Interpersonal functioning is measured using IIP 32 at baseline and 3 months
7. Reflective functioning is measured using RFQ54 at baseline and 3 months

Completion date
30/09/2017

Eligibility

Key inclusion criteria
1. Two or more admissions for diabetic ketoacidosis in the last 12 months
2. Type 1 diabetes
3. Over 18 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Diagnosis of type 1 diabetes for less than 12 months
2. DKA admissions secondary to other types of diabetes (type 2 diabetes, gestational diabetes)
3. Established diagnosis of psychotic illness
4. Established diagnosis of alcohol dependence disorder or other substance misuse disorder
5. Established IQ < 70
6. Already receiving psychological intervention

Date of first enrolment
02/08/2016

Date of final enrolment
12/09/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RJ

Study participating centre
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Princess Royal University Hospital
Farnborough Common
Orpington
United Kingdom
BR6 8ND

Study participating centre
University Hospital Lewisham
Lewisham High Street
Lewisham
London
United Kingdom
SE13 6LH

Study participating centre
Croydon University Hospital
530 London Road
Croydon
London
CR7 7RE

Study participating centre
Royal London Hospital
Whitechapel Road
London
United Kingdom
E1 1BB

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Novo Nordisk UK Research Foundation

Alternative Name(s)
Novo Nordisk UK Research Foundation (NNUKRF), The Novo Nordisk UK Research Foundation, ovo Nordisk Research Foundation UK, NNUKRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available