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Treating Depression and Anxiety in People who have Type 2 Diabetes Mellitus

Submission date
13/08/2015

Recruitment status
No longer recruiting

Registration date
02/10/2015

Overall study status
Completed

Last Edited
08/03/2018

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
The most common form of diabetes in adults, type 2 diabetes mellitus (T2DM), occurs when the body does not produce enough insulin to function properly, or that the body's cells don't react to insulin as they should do. Many studies have shown that people suffering from long term conditions, such as T2DM, are more likely to suffer from depression and/or anxiety than the general population.
The Improving Access to Psychological Therapies (IAPT) service is a programme which offers treatments for people suffering from anxiety or depression. The aim of this study, is to find out how effective a modified programme providing interventions specifically for people suffering from type 2 diabetes and depression and/or anxiety

Who can participate?
Adults suffering from type 2 diabetes, experiencing mild to moderate depression and/or anxiety

What does the study involve?
Participants are randomly allocated into one of two groups, run by Psychological Wellbeing Practitioners (PWPs). Those running the experimental group receive additional training on working with people suffering from T2DM from healthcare professionals, so that both the diabetes and the psychological factors can be treated at the same time.

What are the possible benefits and risks of participating?
The benefit of taking part in the study is that people in the intervention group will receive a treatment for depression and anxiety that has been shown to be very effective. They also have that added benefit that they will receive help in the management of their diabetes. There are no significant risks of participating, however as therapy can raise distressing issues, people may find this distressing and would like further support within the service.

Where is the study run from?
Berkshire Healthcare NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
May 2011 to April 2013

Who is funding the study?
Department of Health Pathfinder Projects (UK)

Who is the main contact?
Dr Abigail Wroe

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
BHFT - diabetes

Study information

Scientific Title
IAPT and Long Term Medical Conditions: A Randomised Control Trial to evaluate the effectiveness of a modified IAPT intervention for People who have Type 2 Diabetes Mellitus

Study objectives
A modified group intervention as reported by Wroe et al (2014) , compared to the standard group intervention, will be more effective in terms of symptoms of anxiety and depression, self-management among adults with T2DM, glycaemic control (HbA1c), and subsequent healthcare utilisation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The National Research Ethics Service (NRES) Southampton A 12SC0103

Study design
Randomised Control Trial- parallel groups

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Diabetes Type 2

Interventions
Clients who experienced mild to moderate depression and/or anxiety and had a diagnosis of Type 2 Diabetes Mellitus (T2DM) are randomly allocated to either experimental group or the control group.
Control group: Received treatment as usual. This is a 6 session group course focusing on depression and anxiety, using a range of techniques: goal setting; problem solving; behavioural work; thought identification and thought challenging.
Experimental group: Received a 6 session group focusing on depression and anxiety, however participants were encouraged to think about how any low mood /anxiety was associated with management of diabetes. They were encouraged to identify and challenge thoughts related to their diabetes management, and to set goals in relation to diabetes.
Both groups are run by Psychological Wellbeing Practitioners (PWPs).

Intervention Type
Other

Primary outcome(s)
Depression, Anxiety, Management of Diabetes. This will be measured using self-report (VAS) at baseline (pre-group), post-group (6 weeks after baseline) and at a 3 month follow up.

Key secondary outcome(s))
Blood sugar markers, healthcare usage at baseline (pre-group), post-group (6 weeks after baseline) and at a 3 month follow up. The measure of IFCC was a blood result obtained from GP practice.

Completion date
30/04/2013

Eligibility

Key inclusion criteria
1. Suffering from Diabetes Mellitus Type 2
2. Experiencing low mood or anxiety

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex

All

Key exclusion criteria
1. Patients not suitable for IAPT Step 2 service.

Date of first enrolment
01/05/2011

Date of final enrolment
01/07/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Shinfield Health Centre
Berkshire Healthcare NHS Foundation Trust
South Reading Surgery
257 Whitley wood Road
Reading
United Kingdom
RG2 9EH

Sponsor information

Organisation
Department of Health

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
Department of Health Pathfinder Projects

Results and Publications

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	01/07/2015		Yes	No