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Overcoming psychological stress to injections for type 2 diabetes

Submission date
05/08/2015

Recruitment status
No longer recruiting

Registration date
21/08/2015

Overall study status
Completed

Last Edited
10/07/2018

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Many people suffering from type 2 diabetes mellitus (T2DM) will eventually need injection treatment to control their blood sugar levels. There is strong evidence to suggest that good control of blood sugar levels helps to lower the risk of complications from T2DM long term. For many patients, being told that they will have to start injection treatment can cause anxiety (psychological stress). This can lead to delays or even refusal of treatment, which is potentially harmful to their health. It has been suggested that educating patients on injection therapy and addressing patient concerns could help to prevent psychological stress. The aim of this study is to investigate whether attending an educational programme before starting the injection treatment can help to lower levels of anxiety in patients.

Who can participate?
Adults with T2DM at risk of hyperglycaemia (high blood sugar) who are suitable for injectable therapy

What does the study involve?
The study is made up of two phases. In phase one, four focus groups are created to help identify common concerns people have about injection therapy and how best to address these problems in an educational programme. Three of the focus groups are made up of people who have started injection therapy within the last year, and the other is made up of people who have refused injection therapy within the last year. From the information collected from these focus groups, an educational programme is designed for use in phase two of the study. In phase two of the study, participants are randomly divided into two groups. The first (control) group meets with a diabetes specialist nurse who will start the therapy and provide information about general healthy eating. The section group will be invited to go to the next education programme near them, before meeting with a diabetes specialist nurse who will start the therapy. All participants will complete questionnaires designed to measure their emotional wellbeing, diet and knowledge about diabetes and the injection treatment. These measurements will be taken at the start of the study, after 12 weeks and 24 weeks.

What are the possible benefits and risks of participating?
Those that take part will help shape and improve services for future patients with type 2

diabetes starting injection treatment and may also improve their own knowledge and how they manage their diabetes going forward. The study is unlikely to put those that take part at risk; however some may find certain question items to be personal as we are exploring stress and anxiety levels. To reduce any risk, a 'distress protocol' has been created.

Where is the study run from?
Altnagelvin Area Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2014 to September 2017

Who is funding the study?
The Health and Social Care Research and Development Division of the Public Health Agency (UK)

Who is the main contact?
Miss Deirdre McCay

Study website
N/A

Contact information

Type(s)
Scientific

Contact name
Miss Deirdre McCay

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
WT 13/48 156708

Study information

Scientific Title
Impact of structured education on psychological stress to overcome a barrier to injectable treatment for type 2 diabetes: a randomised controlled trial

Study objectives
Structured group education delivered before commencement of injectable therapy will alleviate psychological stress thus facilitating improved glycaemic control in adults with type 2 diabetes requiring injectable treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office of Research Ethics Committees Northern Ireland (ORECNI), 26/05/2015, ref: 15/NI/0091

Study design
Single-centre 2 phase study. Phase 1 involves qualitative data collection from focus group studies, phase 2 is a randomised 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 the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied

Type 2 Diabetes

Interventions

Phase 1
Four focus groups, assembled from each of the three study sites, will be explored to inform the development of the content of an education programme. Three of which will be comprised of people who have commenced injectable therapy in the previous 12 months. The other focus group will be comprised of those that have refused to make the transition to injectable therapy in the previous 12 months. A total of 12 diverse participants, selected from the diabetes register (DIAMOND) will be invited by letter to each of the focus groups lasting approximately 1-2 hours. Focus groups comprising of participants that have commenced injectable therapy will be scheduled on each site within a 3 week period. A 4th focus group, will be conducted on the Altnagelvin site within the same time period.
The schedules for the groups include questions about barriers experienced and possible strategies to overcome these, any reasons for delay/refusal of treatment, educational tools and resources, timing of sessions in relation to initiation of injectable therapy and post education support. The groups will help to establish beliefs regarding the perceived barriers causing stress, to identify possible strategies to address these issues and their views on how such an education programme should be organised and delivered. An education programme is then designed for phase two of the study, comprising of a evidence based education programme in line with guidelines for diabetes education (NICE, 2008) which will reverse negative attitudes, perceptions and barriers about injection initiation.

Phase 2
Potential participants will be identified by the diabetes team from the consultant-led diabetes clinics at Altnagelvin Hospital when a decision has been made that they are to commence injectable therapy. 150 eligible participants with type 2 diabetes from all 3 geographical sites will be randomly allocated to control (usual care) and intervention group (structured group education).
Demographic, anthropometric, dietary, clinical including time to commencement of injectable therapy or reasons for further delay or refusal of injections and psychological data will be collected at baseline (recruitment). Additional psychological data will be collected at weeks 12 & 24 post completion of intervention, using the Problem Areas in Diabetes Scale (PAID), the Hospital Anxiety and Depression Scale (HADS-A) and the Pearlin Mastery scale. The PAID Scale has been designed to measure diabetes specific emotional distress and a reduction in this score will form the primary outcome measure. The control group will not receive an education programme but will instead receive an appointment to attend the Diabetes Specialist Nurse to directly commence injectable therapy together with written information on general healthy eating. The intervention group will be informed of the time, date and venue of the next education programme in their locality. Following completion of the programme, each participant will receive an appointment to attend the Diabetes Specialist Nurse to commence injectable therapy.
The questionnaires to measure psychological outcomes will be repeated at weeks 12 and 24 for both groups. Data will also be collected at this time regarding dates of initial consultation regarding injectable therapy and subsequent commencement or reasons for delay or refusal.

Intervention Type

Behavioural

Primary outcome measure

Change from baseline between control and intervention group in the Problems Areas in Diabetes Scale (PAID). This will be measured at baseline (week 0 / first contact following consent to participate), week 12 and week 24.

Secondary outcome measures
Change from baseline in the Hospital Anxiety and Depression Scale (HADS), the Pearlin Mastery scale, the Diabetes Empowerment Scale - short form (DES-SF), nutritional intake, HbA1c, lipid profile, body weight, BMI. This will be measured at baseline (week 0 / first contact following consent to participate), week 12 and week 24.

Overall study start date
29/09/2014

Completion date
31/12/2018

Eligibility

Key inclusion criteria
Phase 1
1. Type 2 diabetes ≥1 year.
2. Aged between 25 and 75
3. Commencement of insulin or GLP-1 receptor agonist within the previous 12 months from the date of the audit
4. Refusal of insulin or GLP-1 receptor agonist within the previous 12 months from the date of the audit

Phase 2
1. Type 2 diabetes diagnosed ≥ 1 year
2. Aged between 25 and 75
3. HbA1c ≥ 58 mmol/mol and ≤90 mmol/mol.
4. Transfer from oral hypoglycaemic treatment to injectable therapy judged appropriate by the consulting physician

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150

Key exclusion criteria
Phase 2
1. Newly diagnosed type 2 diabetes < 1 year.

2. Patients who require immediate transfer to injectable therapy
3. HbA1c >90 mmol/mol
4. Patients undergoing retinal photocoagulation therapy or dialysis treatment
5. Those currently in receipt of psychiatry or clinical psychology input
6. Within 3 months of undergoing a major event including MI, stroke and major surgery
7. Within 3 months of diagnosis or treatment of a major coexisting medical condition

Date of first enrolment
03/08/2015

Date of final enrolment
01/02/2017

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Altnagelvin Area Hospital
Research and Development Office
Western Health and Social Care Trust
Clinical Translational Research and Innovation Centre
Altnagelvin Area Hospital
Londonderry
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BT47 6SB

Sponsor information

Organisation
Ulster University

Sponsor details
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Sponsor type

University/education

Organisation
Western Health and Social Care Trust

Sponsor details
Research and Development Office
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Sponsor type
Hospital/treatment centre

Organisation
University of Ulster

Sponsor details

Sponsor type
Not defined

Website
http://www.ulster.ac.uk/

ROR
https://ror.org/01yp9g959

Funder(s)

Funder type
Government

Funder Name
The Health and Social Care Research and Development Division of the Public Health Agency

Results and Publications

Publication and dissemination plan
The results of the study will be available on the Public Health Agency's Research and Development website. Results will also be reported in a PhD thesis from Ulster University

Intention to publish date
01/10/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No