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Insulin intervention development for people with type 2 diabetes

Submission date
16/07/2018

Recruitment status
No longer recruiting

Registration date
30/07/2018

Overall study status
Completed

Last Edited
12/06/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
In the UK the average duration of diabetes is 8.5 years with hyperglycaemia (high blood sugar) before insulin is first prescribed, suggesting a significant delay and a risk of diabetes complications. The role of specific psychological factors with regard to the delay in starting insulin is understudied. The aim of this study is to assess patient perspectives of starting insulin in type 2 diabetes mellitus (T2DM), and to use this knowledge to develop a motivational interviewing (MI) based intervention to address these issues.

Who can participate?
Patients with T2DM who receive treatment in the South London borough of Lambeth

What does the study involve?
Participants are interviewed to determine the barriers to insulin self-management, their views on current education courses and suggestions for additional support. Information gathered from the interviews and results from an 8-year follow-up of a study (identifying psychological factors associated with delay in starting insulin) are used in the development of a new psychological intervention. Initial testing of the intervention takes place in a sample of people who have started insulin (from Lambeth). Exit interviews are used to determine the acceptability of the intervention. Finally, patients are recruited to test the newly developed group MI intervention as an addition to starting insulin. Participants are randomly allocated to receive insulin plus the MI intervention, or to receive insulin only, to determine whether it is acceptable and appropriate for patients and whether the study can be run successfully within primary care.

What are the possible benefits and risks of participating?
Participants receive a newly developed, evidence-based group intervention for people with T2DM which is not currently available. This could result in improved health and wellbeing after starting insulin. Patients who agree to participate and attend the first treatment session receive a £10 high street voucher. Researchers explain the implications of participation to the patient and the details are included in the patient information sheet. It is possible that some participants may find answering questions about starting insulin distressing, or the prospect of starting insulin anxiety-provoking/depressing. Participants are reminded that they do not have to answer questions if they do not wish to. In addition, participants are able to withdraw from

the study at any time without giving a reason and this does not impact their usual diabetes treatment. Participants who decline to participate in the study once invited are not contacted by the research team again.

Where is the study run from?
University Hospital Lewisham (UK)

When is the study starting and how long is it expected to run for?
August 2018 to March 2021 (updated 03/10/2019, previously: January 2021)

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Kirsty Winkley
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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
34084

Study information

Scientific Title
A mixed methods study to support insulin self-management for people with type 2 diabetes

Acronym
DIME

Study objectives
In the UK the average duration of diabetes is 8.5 years with hyperglycaemia (HbA1c 84 mmols /mol) before insulin is first prescribed, suggesting a significant delay, which is bringing forward the risk of diabetes complications. The role of specific psychological factors with regard to the delay in insulin initiation is understudied. This research will aim to i) describe patient perspectives of insulin initiation in type 2 diabetes mellitus (T2DM), and ii) use this knowledge to develop a motivational interviewing (MI) based intervention to address these issues.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - South East Research Ethics Committee, 23/03/2018, ref: 17/LO/0363

Study design
Randomised; Both; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
See additional files

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

Interventions
Study 1:
Interviews of approximately 30 patients with type 2 diabetes mellitus (T2DM) who receive treatment in the South London borough of Lambeth who have either attended an insulin start group, been referred to one, or who are currently on insulin but have been referred/attended the insulin X-PERT group. Insulin X-PERT is a structured education course for people with type 1 and type 2 who need additional support with managing insulin. Interviews will be carried out by the chief investigator and PhD student. Participants will be sampled according to insulin

education course, gender, age, and ethnicity. Interviews will take place a community venue. The aim is to interview 20-40 people, a sample size of 30 is estimated to be the point of data saturation. Interviews are expected to last around 30 minutes. The interview topic guide will examine the following areas:
1. Patient perspectives of need for insulin, potential for psychological, social or other barriers to uptake and adherence
2. Views on the insulin group education they received or were referred to
3. Views on support with diabetes self-management needed to become confident with managing insulin
The interview topic guide will be discussed with primary care health professionals involved in the care of people with T2DM and it will be piloted with 2 participants so that changes can be made to improve its face validity. Semi-structured qualitative interviews will gain in-depth information which would be difficult to obtain in questionnaire format, interviewing can elicit further questions in addition to the interview schedule which can provide useful information for intervention design. Interviews will be transcribed and interview data will be entered and managed with Nvivo 10 (qualitative computer software programme) and a thematic framework method, will be used to analyse interview data.

Study 2:
A manual for a group psychological intervention as an adjunct to insulin start for people with T2DM will then be developed. The manual will be underpinned by the Theory of Planned Behaviour for initiation of behaviour change and Social Cognitive theory which emphasises the importance of significant others in shaping behaviour, supporting the group mode of delivery of the intervention. The psychological therapy underpinning the manual will stem from motivational interviewing (MI) therapy. MI is a directive focused non-judgemental person-centred counselling style that aims to work with resistance around behaviour change. Interview responses will be used to aid design of the manual. For example, determining which barriers of insulin initiation can be addressed in the intervention, advantages of group education course which can be drawn upon in intervention design as well as improving on disadvantages of current education programmes, and inputting ideas regarding additional support to aid positive insulin initiation outcomes. Two patients from the qualitative interviews will be invited to form the patient co-design team and will provide face validity for the manual.

Initial testing of the intervention will take place in a purposive sample of people who have initiated insulin (from Lambeth) with the aim of recruiting 6-10 people who will receive it. Testing will be delivered by a diabetes nurse (Chief Investigator). Exit interviews of these patients will be used to determine acceptability of the intervention. The testing of the intervention will take place at a community venue and will last between 1-2 hours.

Study 3:
The final element of the project will involve a multi-site 2-arm randomized controlled feasibility study to test the acceptability of the intervention. This RCT will test the specific hypothesis that adding MI to insulin start groups to address psychological barriers to insulin and lifestyle change is more effective in improving self-reported acceptance and adherence to insulin than insulin start groups alone. The sampling frame will be general practices with a list size >/= 5,000 and the clinical diabetes teams in Lambeth and Lewisham. Potential participants will be identified by practice staff by medical record searches using diagnosis and medication prescription codes. Formal invitation materials will include a letter, trial information sheet, consent form and a patient details form. These will be sent by practice staff. Those agreeing to further contact by study team will be invited by a research assistant student for baseline assessment prior to randomisation. Baseline measures will include; sociodemographic (age, gender, educational status, employment status), biomedical (weight, BMI, HBA1c), psychological (self-reported

acceptance of insulin, diabetes distress; and depressive symptoms), and economic measures (quality of life, self-reported service use). Selection bias will be minimised by randomly allocating participants to insulin start plus MI intervention, or to insulin start alone through online randomization site provided by King's College London clinical trials unit (CTU). Patients will be assigned to groups of up to 10 for both intervention and control conditions and 3-4 treatment groups will be run in each arm. A research assistant will recruit study participants and every effort will be made to keep them blind to allocation, although in studies of psychological therapy this can be difficult to maintain. Both groups will receive 3 weekly group sessions for 1-2 hours. The control group will receive standard group insulin start, following the current treatment model in Lambeth, clinical follow-up will take place at 3 months following randomisation. At 3 months post-randomisation, in the intervention group, there will be a booster session (for 1-2 hours). All sessions will be audiotaped. Both control and intervention will be delivered by a diabetes nurse (Chief Investigator). Outcome measures will be collected by a research assistant at 6 months post-randomisation. The study aims to recruit 60 patients (30 per treatment condition) then approaching 150 eligible patients, it is estimated a participation rate of 40% to within a 95% confidence interval of +/-10%. Changes over time, differences between treatment groups will also be assessed to ascertain the appropriateness of measures. The completeness of data will be documented. The difference in outcome data between those in the two treatment conditions and 6 month follow-up will be estimated using regression analysis (where a model will be selected dependent on the distribution of the outcome variable).

The evaluation of the patients' experience of the intervention will include interviews with participants who complete, drop out of the course, or decline to participate. Treatment fidelity in terms of adherence to the principles of MI will be measured using the motivational interviewing treatment integrity (MITI) tool by an external rater.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 12/06/2023:
Self-reported attitudes towards insulin treatment, measured using the insulin treatment appraisal scale (ITAS) at baseline and 6 months

Previous primary outcome measure:
Self-reported acceptance of insulin, measured using the beliefs in insulin treatment (BIT) scale at baseline and 6 months

Secondary outcome measures
1. Self-reported use of insulin and diabetes medication measured using the visual analogue scale (VAS) at baseline and 6 months
2. Diabetes distress measured using the Problems Areas in Diabetes scale (PAID score) at baseline and 6 months
3. Depressive symptoms measured using the Patient Health Questionnaire 9 (PHQ-9) at baseline and 6 months
4. Weight (kg) measured at baseline and 6 months
5. Blood glycated haemoglobin HbA1c (mmol/mol) measured using high performance liquid chromatography (HPLC) standard assay at baseline and 6 months

Overall study start date
27/08/2018

Completion date
31/03/2021

Eligibility

Key inclusion criteria
Initial interviews and testing:
1. Diagnosis of type 2 diabetes
2. 18 years or over

Randomized controlled feasibility study:
1. Diagnosis of type 2 diabetes
2. Aged 40-65 years
3. Identified by general practitioner as requiring insulin treatment, i.e. on maximum tolerated dose of 2 OADs and glycaemic control HbA1c >/=7.5% (58 mmols/mol) on two occasions

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 86; UK Sample Size: 86

Total final enrolment
17

Key exclusion criteria
Initial interviews and testing:
1. Non-fluency in English
2. Severe mental illness

Randomized controlled feasibility study:
1. Non-fluency in English
2. Morbid obesity (BMI >/=35)
3. In employment that contraindicates insulin treatment, e.g. HGV driver
4. Severe depression, anxiety disorders, psychotic disorders, or personality disorders, or cognitive impairment

Date of first enrolment
01/03/2019

Date of final enrolment

30/11/2020

Locations

Countries of recruitment
England

United Kingdom

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

Study participating centre
Lambeth Diabetes Intermediate Care Team
61 Crown Dale
London
United Kingdom
SE19 3NY

Sponsor information

Organisation
King's College Hospital NHS Foundation Trust

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR

https://ror.org/01n0k5m85

Funder(s)

Funder type
Government

Funder Name
NIHR Trainees Co-ordinating Centre (TCC); Grant Codes: ICA-SCL-2015-01-002

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/09/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Kirsty Winkley, kirsty.winkley@kcl.ac.uk, following publication of the trial paper.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v1	05/10/2016	30/07/2018	No	Yes
Results article	Feasibility and acceptability	26/05/2023	30/05/2023	Yes	No
HRA research summary			28/06/2023	No	No