ISRCTN10720065 https://doi.org/10.1186/ISRCTN10720065

Study to determine the feasibility and acceptability of an intensive weight management programme to achieve remission of diabetes in patients of South Asian ethnicity

Submission date
11/09/2017

Recruitment status
No longer recruiting

Registration date
27/09/2017

Overall study status
Completed

Last Edited
14/02/2023

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims

In Scotland, around 1% of the population are of South Asian ethnicity. People of South Asian origin are at higher risk of type 2 diabetes (T2DM), and develop the condition at a lower body weight than those of non-South Asian origin. T2DM is a condition that causes blood sugar to be too high. This, coupled with evidence that people of South Asian origin are less likely to access weight-management services, points to a need for a new weight management approach to manage the growing problem in this population. Published research in people of European origin demonstrates low/very low energy diets, achieving weight loss in the region of 15kg (2-3 stones), results in diabetes remission in a significant proportion of individuals with T2DM. The Diabetes Remission Clinical Trial (DiRECT) is currently underway in Tyneside and Scotland to assess long-term outcomes of this treatment approach in primary care. However, to date, research using this approach, has not been conducted with patients of South Asian origin. An existing evidence -based weight management programme, 'Counterweight-Plus', that initially focuses on a low energy liquid formula diet, is showing promising results in terms of acceptability, weight change and impact on diabetic status. However as the approach must be acceptable to the population being studied, the aim of this feasibility study is to examine if the initial phase of this programme using formula food products is acceptable to the South Asian population, and if it results in similar clinical outcomes in terms of weight loss and diabetic remission at 3-6 months. The study will provide data to support implementation of a larger study aimed at long-term weight change in this population.

Who can participate?

Patients aged 18 to 65 years old of South Asian origin in participating GP practices in Glasgow, diagnosed with type 2 diabetes within the previous 2 years, will be invited to participate.

What does the study involve?

Patients recruited from participating GP practices in Glasgow are randomly allocated to one of two groups. Those in the first group commence the Counterweight Plus weight management

programme immediately. This is delivered by research Dietitians experienced in programme delivery. Participants in the second group are advised to continue with usual care for three months before returning to receive the intervention.

What are the possible benefits and risks of participating?
There will be multiple clinical and personal benefits from any degree of weight loss achieved by participants. For those who are successful in achieving >15kg it is expected that that many will revert to a non-diabetic state.There are no major risks from taking part in this study. The only significant risk from more intensive weight loss is that gallstones may become symptomatic. This is still relatively uncommon and the risk will be minimised by the dietary provision which includes some fat consumption.

Where is the study run from?
Glasgow Royal Infirmary (UK)

When is the study starting and how long is it expected to run for?
October 2016 to February 2022 (updated 20/11/2021, previously: December 2021; updated 19 /04/2021, previously: December 2022; updated 30/03/2021, previously: September 2021))

Who is funding the study?
Investigator initiated and funded (UK)

Who is the main contact?
Professor Mike Lean
Dr Wilma Leslie

Contact information

Type(s)
Scientific

Contact name
Prof Mike Lean

Contact details
Department of Human Nutrition
University of Glasgow
Glasgow Royal Infirmary
Glasgow
United Kingdom
G31 2ER
+44 (0)141 201 8508
Mike.Lean@glasgow.ac.uk

Type(s)
Public

Contact name
Dr Wilma Leslie

Contact details

Dept of Human Nutrition
University of Glasgow
Glasgow Royal Infirmary
Glasgow
United Kingdom
G31 2ER
+44 (0)141 201 8609
Wilma.Leslie@glasgow.ac.uk

Additional identifiers

Protocol serial number
GN16DI505

Study information

Scientific Title
SouTh AsiAN Diabetes Remission Feasibility Trial

Acronym
STANDby

Study objectives
Losing weight using a structured weight management programme which includes an initial period of total diet replacement, followed by carefully managed food reintroduction and then weight loss maintenance, is a viable treatment for putting T2DM into remission, and can potentially be transferred to a larger scale as part of routine GP care, where large numbers of overweight people with T2DM are managed in the UK.

Ethics approval required
Old ethics approval format

Ethics approval(s)
WEST 3 Research Ethics Committee, 07/06/2017, ref: 17/WS/0104

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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

Interventions
The study follows a randomised controlled design. A blinded envelope system is used for treatment allocation. Participants randomised to control group continue with usual care for

three months before returning to receive the intervention. Participants randomised to intervention group commence the Counterweight Plus weight management programme immediately.

The weight management intervention programme is called Counterweight Plus, which includes an initial Total Diet Replacement (TDR) phase followed by structured food reintroduction. The intervention is delivered by research Dietitians experienced in programme delivery.

TDR phase (0 to 12-20 weeks): A commercial micronutrient-replete 825-853kcal/d LELD is provided (Counterweight Pro 800) to replace normal foods, with ample fluids, for 12-20 weeks. Participants return for review one week after commencing the TDR and at 2-weekly intervals thereafter until starting the food reintroduction stage.

Food Reintroduction (FR) phase (weeks 12-18):
A stepped transition to food based Weight Maintenance, replacing TDR with meals which contain 30% of energy from fat. Some further modest weight loss occurs. During this phase participants attend for review appointments every two weeks. On completion of the feasibility study, (at the end of FR), participants are offered the option to join the BEYOND Weight Loss Maintenance study currently running and recruiting patients from the Glasgow Clinical Research Facility.

Participants have magnetic resonance measurements of pancreas and liver fat taken at baseline and again at the point of maximal weight loss.

Intervention Type
Mixed

Primary outcome(s)
1. Number recruited to the study: analysis of trial data, at close of recruitment period, on number consented into study
2. Weight loss achieved, and changes in diabetes status: measurement of body weight and HbA1c at baseline, end of total diet replacement phase, and completion of intervention
3. Programme retention: analysis of trial data, at close of study, on number of participants completing the intervention
4. Acceptability of the intervention to people of South Asian origin measured using a process evaluation questionnaire on completion of intervention
5. Definition of the mechanisms behind type 2 diabetes remission in the South Asian population is measured using MRI scanning at baseline and point of maximal weight loss

Key secondary outcome(s)
Quality of life is measured using the EQ-5D-3L questionnaire at baseline and end of intervention

Completion date
28/02/2022

Eligibility

Key inclusion criteria
1. Inclusion criteria
2. Written informed consent
3. Men and women aged 18-65 years

4. South Asian ethnicities
5. Body mass index (BMI)>25 kg/m2 and <45 kg/m2
6. T2DM of duration 0-2years (diagnosis based on a recorded diagnostic-level test: HbA1c and/or blood glucose)
7. HbA1c > 48 mmol/mol and/or fasting plasma glucose > 7 mmol/l within last 12 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
25

Key exclusion criteria
1. Current insulin use
2. Recent routine HbA1c on record ≥12%
3. Weight loss of >5kg within the last 6 months
4. Recent eGFR on record <30 mls/min/1.732
5. Substance abuse
6. Known cancer
7. Myocardial infarction within previous 6 months
8. Severe or unstable Heart Failure defined as equivalent to the New York Heart Association (NYHA):
Grade 3 - marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation, or breathlessness, and
Grade 4 - unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.
or
Grade 2 if symptoms are not attributed to obesity - Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation, or breathlessness
9. Learning difficulties
10. Not fluent in English language
11. Current treatment with anti-obesity drugs
12. Diagnosed eating disorder or purging
13. Pregnant
14. Patients who have required hospitalisation for depression or are on antipsychotic drugs

15. People currently participating in another clinical research trial
16. People with metal implants or devices and those who have claustrophobia cannot take part as MR scans are required as part of the study

Date of first enrolment
12/02/2019

Date of final enrolment
30/04/2021

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
University of Glasgow
Glasgow Royal Infirmary
Glasgow
United Kingdom
G31 2ER

Sponsor information

Organisation
NHS Greater Glasgow and Clyde

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/02/2023	14/02/2023	Yes	No
HRA research summary			26/07/2023	No	No
Protocol file	version 12	28/01/2022	16/08/2022	No	No