ISRCTN73786674 https://doi.org/10.1186/ISRCTN73786674

Exploring the use of a digitally delivered low calorie diet and behaviour change programme on inducing diabetes remission in patients with type 2 diabetes.

Submission date
14/12/2022

Recruitment status
No longer recruiting

Registration date
04/01/2023

Overall study status
Completed

Last Edited
19/06/2024

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
Type 2 diabetes is a common condition that causes the level of sugar (glucose) in the blood to become too high.
Diabetes increases rates of mortality and morbidity as well as quality of life and presents a major and increasing economic burden, currently accounting for 10% of total healthcare expenditure in the UK and 12.5% in the USA. Research has shown that modest weight
loss of approximately 5-10% using diet and lifestyle approaches, can improve all areas of diabetes control including glycaemia, blood pressure, lipids, quality of life and fewer comorbidity complications.
The main aim of this study is to assess whether the Habitual Remission Programme is more likely to lead to weight loss and remission, compared to standard care, measured at 6 months. Remission is defined as HbA1c of less than 6.5% (<48 mmol/mol) at 3 months of not taking any glucose-lowering medication (for at least 2 months).

Who can participate?
Adults with type 2 diabetes diagnosed within the last 6 years and not on insulin.

What does the study involve?
Participants are randomly allocated to the Habitual Programme or standard care. They will take a home blood test for HbA1c at baseline, 3 months and 6 months, and complete online fortnightly surveys to record their weight, waist circumference, blood pressure, side effects and any changes in medication, for 6 months. These measurements will be taken at 6 months, 12 months after finishing the intervention, for those allocated to the intervention.

What are the possible benefits and risks of participating?
Taking part in the trial may help participants better manage their diabetes, and information gathered from this study can be used to improve the management and treatment of type 2 diabetes in the future.

There are a number of side effects associated with Habitual's Total Diet Replacement product, and stopping antidiabetic medications. Participants will report any potential side effects in fortnightly surveys or directly to the trial team.

Where is the study run from?
GP practices in England, managed by Lindus Health, will recruit for the trial. Research Nurses at Lindus Health will complete screening and informed consent procedures.

When is the study starting and how long is it expected to run for?
March 2022 to July 2024

Who is funding the study?
Habitual Health (UK)

Who is the main contact?
1. Professor Carel Le Roux (scientific contact), carel.leroux@ucd.ie
2. Miss Danni Maas (public contact), danni@lindushealth.com

Contact information

Type(s)
Principal investigator

Contact name
Prof Carol Le Roux

Contact details
University College Dublin
School of Medicine
Conway Institute
Belfield
Dublin
Ireland
D04 V1W8
+353 864117842
carel.leroux@ucd.ie

Type(s)
Public

Contact name
Miss Danni Maas

Contact details
Lindus Health
Studio A
The Leather Market
Weston Street
London
United Kingdom
SE1 3ER

+44 (0)7852716249
danni@lindushealth.com

Additional identifiers

ClinicalTrials.gov (NCT)
NCT05647226

Integrated Research Application System (IRAS)
312269

Central Portfolio Management System (CPMS)
53983

Study information

Scientific Title
Exploring the use of digital therapeutics alongside a remote intensive lifestyle programme on inducing weight loss and diabetes remission in patients with type 2 diabetes versus standard of care.

Acronym
DIGEST

Study objectives
The primary objective of the trial is to assess whether the Habitual Remission Programme (total diet replacement and digital therapeutic) delivered remotely, leads to remission and weight loss in patients with type 2 diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/11/2022, London Bridge Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)207 1048 387; londonbridge.rec@hra.nhs.uk), ref: 22/LO/0664

Primary study design
Interventional

Study design
Multicentre open-label prospective parallel design randomized study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Remission in patients with type 2 diabetes

Interventions

Participants will be randomised in a 2:1 ratio to the intervention arm vs control arm by sealed envelope. The intervention is the Habitual Remission Programme, which combines a digital therapeutic with Total Diet Replacement. Total Diet Replacement is required for the first 3 months, consisting of shakes and soups providing 800 kcal per day, and food is then gradually reintroduced for the final 3 months. The Habitual mobile App provides theory-informed behaviour change lessons, and emotional and social support for the entire 6 months.

Those in the control group will continue receiving standard care for patients with type 2 diabetes.

Intervention Type
Behavioural

Primary outcome(s)
1. Weight (kg) at baseline and 6 months
2. HbA1c after at least 2 months off all glucose-lowering medication, measured at 6 months

Key secondary outcome(s)
1. Glycaemic control measured using HbA1c at baseline, 3 and 6 months
2. Weight measured at baseline, 3 and 6 months
3. Waist circumference measured at baseline, 3 and 6 months
4. Systolic blood pressure measured at baseline, 3 and 6 months
5. Diastolic blood pressure measured at baseline, 3 and 6 months
6. Medication use reported by the participant at baseline, 3 and 6 months
7. Evaluation of overall safety of Habitual Remission Programme by the monitoring of the number of i) AEs, ii) SAEs, iii) (S)AEs that constitute Major Adverse Cardiovascular Events and iv) Major Adverse Diabetes Events, for 6 months
8. Intervention adherence measured by the number of participants starting the intervention at baseline compared to those completing the intervention at 3 and 6 months

Completion date
30/07/2024

Eligibility

Key inclusion criteria
1. Able and willing to give consent for the study prior to participation
2. Be aged 18 - 75 years, with type 2 diabetes mellitus of duration <6 years
3. Have access to a smartphone or a computer
4. Have a Body Mass Index (BMI) of at least 28 kg/m²
5. A HbA1c test >48 mmol/mol (6.5%) and ≤86 mmol/mol (10%), within the previous 12 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
100

Key exclusion criteria
1. Are currently using insulin
2. Weight change of >5% in the past 3 months
3. Have a history or are known to be suffering with alcohol/substance abuse
4. Have cancer or currently under investigation for cancer
5. Have had a myocardial infarction within the previous 6 months
6. Have severe or unstable heart failure e.g. NYHA grade IV
7. Have porphyria
8. Have learning difficulties
9. Are currently on treatment with anti-obesity drugs
10. Have had bariatric surgery
11. Have been diagnosed with eating disorder or purging
12. Are pregnant or less than 4 months postpartum or considering pregnancy in the next 2 years
13. Are currently breastfeeding
14. Have required hospitalisation for depression or taking antipsychotic drug
15. Have a history of illnesses that could interfere with the interpretation of the study results(e.g. HIV, Cushing syndrome, chronic kidney disease, chronic liver disease, hyperthyroidism, hereditary fructose intolerance, depression or antipsychotic drug use within the past 2 years)
16. Currently taking Glucagon-like peptide-1 receptor agonists (GLP-1 RAs)
17. Have pancreatitis
18. Currently taking part in a CTIMP trial for antidiabetic medication
19. Abnormal diabetic foot review (QOF codes for diabetic foot at moderate risk, at high risk, at increased risk, ulcerated).

Date of first enrolment
28/12/2022

Date of final enrolment
02/06/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Lindus Health Ltd
Lindus Health
Taper Studios
The Leather Market
London
United Kingdom
SE1 3ER

Sponsor information

Organisation
Habitual Health Ltd

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
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version 2.1	02/11/2022	16/12/2022	No	Yes