

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

<b>Submission date</b> 14/12/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 04/01/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/06/2024	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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](mailto:carel.leroux@ucd.ie)
2. Miss Danni Maas (public contact), [danni@lindushealth.com](mailto:danni@lindushealth.com)

## Contact information

### Type(s)

Principal investigator

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Integrated Research Application System (IRAS)**  
312269

**ClinicalTrials.gov (NCT)**  
NCT05647226

**Protocol serial number**  
IRAS 312269, 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

**Study design**  
Multicentre open-label prospective parallel design randomized study

**Primary study design**  
Interventional

**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/m<sup>2</sup>
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

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## 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	version 2.1	02/11/2022	16/12/2022	No	Yes