

Can unconscious persuasion in the form of a Slimpod programme help people with type 2 diabetes to lower blood sugar levels, cholesterol and blood pressure to recommended levels?

Submission date 18/08/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/09/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/10/2020	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The rising number of people suffering from type 2 diabetes, often linked to being overweight, poor diet and low exercise levels, is challenging. Type 2 diabetes is a global pandemic that threatens the health of the population and the sustainability of publicly-funded healthcare. In England in 2019, hospital admissions related to type 2 diabetes cost the NHS £986 million and 2,721,000 type 2 diabetes patients were on register. Finding alternative strategies to support weight loss and lower the level of glucose in the blood is essential. The aim of this study is to find out whether unconscious persuasion in the form of a Slimpod audio/visual programme can help people with type 2 diabetes to lower blood sugar levels, cholesterol and blood pressure to recommended levels.

Who can participate?

Patients with a BMI over 25 and a history of type 2 diabetes at Millgate Healthcare Partnership

What does the study involve?

Participants will be split randomly into the intervention and control groups to ensure that knowledge of the patients' medical history cannot influence which treatment they receive. The intervention group will receive the Slimpod audio/visual control and its associated programme. The control group participants will receive the standard NICE guideline treatment which focuses on patient education, dietary advice, managing heart disease risk, managing blood sugar levels, and identifying and managing long-term complications. The Slimpod audio recording will be listened to daily and videos watched as directed by the programme. There will be measurements of blood glucose, blood pressure and cholesterol levels at three times: at the start of the study and after 12 and 24 weeks.

What are the possible benefits and risks of participating?

In a previous study conducted at City University London, 95% of the participants lost weight over a 12-week period and participants in this study are expected to lose weight in a way which will nudge them towards healthier eating habits. Weight gain is a contributory factor in type 2 diabetes so it is anticipated that weight loss will help towards a better health outcome and a possible reduction in diabetes medication. There is no known risk to participants using the non-invasive Slimpod intervention or control intervention. An independent assessment by Mr Gideon Felton, MRCPsych, then a senior psychiatrist at the Central Middlesex Hospital, London, concluded: "I have found no evidence of any psychologically dangerous mechanisms and on this basis, I am willing to endorse Slimpod on safety grounds. I have found the benefits of it profound and positively life-changing." Data collection will be carried out by members of the clinical team at the Chief Investigator's surgery and at all times will protect and uphold the confidentiality and dignity of the participants.

Where is the study run from?

Millgate Healthcare Partnership (UK)

When is the start date for the study and how long is it expected to run for?

October 2019 to June 2021

Who is funding the study?

ThinkingSlimmer Ltd (UK)

Who is the main contact?

Sandra Roycroft-Davis

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Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

TSL110820

Study information

Scientific Title

To test the efficacy of a Slimpod audio/visual intervention for type 2 diabetics with particular reference to achieving NICE recommended targets for management of HbA1C, blood pressure and cholesterol

Study objectives

The rising number of people suffering from type 2 diabetes, often linked to being overweight, poor diet and low exercise levels, is challenging. Type 2 diabetes is a global pandemic that threatens the health of the population and the sustainability of publicly-funded healthcare. In England in 2019, hospital admissions related to type 2 diabetes cost the NHS £986 million and 2,721,000 type 2 diabetes patients were on register. Finding alternative strategies to support weight loss and lower the level of glucose in the blood is essential. This RCT addresses the gap in the literature surrounding unconscious persuasion and its use in weight loss, weight management and the reduction of blood sugar levels associated with type 2 diabetes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NHS/HSC ethics approval pending

Study design

Single-centre randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Type 2 diabetes mellitus

Interventions

Participants with a BMI over 25 and with a history of type 2 diabetes will be recruited by the GP practice staff for a 24-week trial. The planned size of the sample is circa 100.

Simple randomisation will occur to allocate participants to the intervention or control groups using a 1:1 allocation ratio. A computer-run programme will generate a random number which the surgery team will assign each participant to a trial arm. The trial statistician will be not involved in the process of recruitment, randomisation, or group assignment.

The intervention group will receive the Slimpod audio/visual control and its associated programme; control group participants will receive the standard NICE guideline treatment which focuses on patient education, dietary advice, managing cardiovascular risk, managing blood glucose levels, and identifying and managing long-term complications. The Slimpod audio recording will be listened to daily and videos watched as directed by the programme. There will be measurements of HbA1c, blood pressure and cholesterol levels at three timepoints, 0, 12 and 24 weeks.

Intervention Type

Behavioural

Primary outcome measure

Measured by clinical staff at the GP practice at weeks 0, 12 and 24:

1. Blood pressure (systolic pressure and diastolic pressure) measured using a sphygmomanometer
2. Blood glucose levels measured using a glycated haemoglobin (HbA1c) test
3. Cholesterol and triglyceride fats measured using a lipid profile test
4. Weight measured in kilograms on the surgery's scales

Secondary outcome measures

Prescribed doses of medication for controlling type 2 diabetes, reducing blood pressure and lowering cholesterol levels will be measured, recorded and then analysed using anonymised data from participants' medical notes at weeks 0, 12 and 24

Overall study start date

28/10/2019

Completion date

01/06/2021

Eligibility

Key inclusion criteria

1. Participants must have been registered as NHS patients at the Millgate Healthcare Partnership, 119 Manchester Road, Denton M34 3RA at least 4 weeks before the commencement of recruitment
2. Age between 30 and 65
3. BMI 25 or greater
4. Diagnosed as having type 2 diabetes

5. Any ethnicity
6. Any socio-economic grouping
7. Non gender-specific

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

100

Key exclusion criteria

1. Outside of location stated above
2. Outside of stated age range
3. Not suffering from type 2 diabetes
4. Having a BMI <25

Date of first enrolment

01/09/2020

Date of final enrolment

28/02/2021

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Millgate Healthcare Partnership

119 Manchester Road

Denton

Manchester

United Kingdom

M34 3RA

Sponsor information

Organisation

ThinkingSlimmer Ltd

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Sponsor type

Industry

Website

<https://www.ThinkingSlimmer.com>

Funder(s)**Funder type**

Industry

Funder Name

ThinkingSlimmer Ltd

Results and Publications**Publication and dissemination plan**

The data arising from the study in coded form shall be owned by the Sponsor. On completion of the study, the data will be analysed and tabulated and a final independent study report prepared. This full study report can be accessed via the Sponsor's website, <http://www.ThinkingSlimmer.com>. The Sponsor shall have the right to publish any of the anonymous study data within 24 months of completion of the full study report.

Participants in the study may be notified by email, letter or text of the outcome of the study at the sole discretion of the Chief Investigator. If a participant requests results from their individual outcome then that shall be a matter for the Chief Investigator and his clinical staff to decide.

Intention to publish date

01/06/2021

Individual participant data (IPD) sharing plan

The data-sharing plans for the 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?
Protocol file		24/08/2020	08/10/2020	No	No