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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

Registration date
08/09/2020

Overall study status
Completed

Last Edited
08/10/2020

Condition category
Nutritional, Metabolic, Endocrine

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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number

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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Millgate Healthcare Partnership
119 Manchester Road
Denton
Manchester
United Kingdom
M34 3RA

Sponsor information

Organisation
ThinkingSlimmer Ltd

Funder(s)

Funder type
Industry

Funder Name
ThinkingSlimmer Ltd

Results and Publications

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