ISRCTN75203062 https://doi.org/10.1186/ISRCTN75203062

Audio unconscious persuasion for weight loss in overweight adults

Submission date
13/02/2020

Recruitment status
No longer recruiting

Registration date
27/02/2020

Overall study status
Completed

Last Edited
23/09/2021

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Weight loss interventions using audio unconscious persuasion are increasingly popular. However, no robust trials have been conducted to assess their effectiveness.
The aim of this trial is to assess the effectiveness of an audio unconscious persuasion weight loss intervention incorporating techniques from NLP and hypnosis (Slimpod®) compared to audio relaxation (control) on weight loss and other measures.

Who can participate?
Healthy adult volunteers with BMI > 25 kg/m²

What does the study involve?
Participants will be randomly allocated to the intervention or control groups.
The intervention is Slimpod®, a nine-minute long digital audio recording focused on changing behaviours and attitudes related to diet and weight. Participants listen to the recording once a day for 24 weeks at a time and place of their choosing. Recordings are available in two formats: digital file (.MP3) and compact disc (CD); participants can select their preferred format.
The control group are asked to listen to nine-minute long recording informed by the principles of relaxation therapy once a day for 24 weeks. The control recording does not include a focus on behaviour change.

What are the possible benefits and risks of participating?
Benefits of participating: The potential to lose weight with the need for willpower or conscious effort such as conscious calorie restriction. There is no risk in participating.

Where is the study run from?
City University London (UK)

When is the study starting and how long is it expected to run for?
October 2013 to July 2014

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Christopher Roycroft-Davis
chris@thinkingslimmer.com

Contact information

Type(s)
Scientific

Contact name
Mr Christopher Roycroft-Davis

ORCID ID
http://orcid.org/0000-0003-3356-1544

Contact details
400 Harrow Road
London
United Kingdom
W9 2HU
+44 (0)207 760 7596
chris@thinkingslimmer.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PSYETH (UPTD) 12/13 71

Study information

Scientific Title
Revolutionising participants' health and wellbeing through Neuro-reprogramming via Slimpod® app: a RCT

Study objectives
The aim of this pilot randomised controlled trial is to assess the effectiveness of an audio unconscious persuasion weight loss intervention incorporating techniques from NLP and hypnosis (Slimpod®) compared to audio relaxation (control) on weight (primary outcome), eating self-efficacy, exercise confidence, and quality of life (secondary outcomes).

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 09/10/2013, Research and ethics committee of the department of psychology of City University London (Jay Leighton, Executive Assistant, School of Arts & Social Sciences, D217, Rhind Building, City, University of London, Northampton Square, London, EC1V 0HB, UK; +44 (0) 20 7040 3362; jay.leighton@city.ac.uk), ref: PSYETH (UPTD) 12/13 71

Study design
Pilot randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Obesity

Interventions
The intervention is Slimpod®, a nine-minute long digital audio recording focused on changing behaviours and attitudes related to diet and weight. Participants listen to the recording once a day for 24 weeks at a time and place of their choosing. Recordings are available in two formats: digital file (.MP3) and compact disc (CD); participants can select their preferred format.
The control group are asked to listen to nine-minute long recording informed by the principles of relaxation therapy once a day for 24 weeks. The control recording does not include a focus on behaviour change.

To assess the effectiveness of an audio unconscious persuasion weight loss intervention called Slimpod® compared to audio relaxation (control), overweight adults (i.e., age < 18 years, self-reported Body Mass Index < 25.0 kg/m²) will be randomized to intervention and control groups. Weight (primary outcome) will be assessed at trial commencement, mid-trial (12 weeks) and trial end (24 weeks). Secondary outcomes are assessed using the Eating Self-Efficacy Scale (ESES), Exercise Confidence Scale (ECS) and Quality of Life Index Generic Version III (QLI-G3) at the start and end of the trial. The nine-minute Slimpod audio recording and the nine-minute control audio are provided to participants as MP3 files to be listened to daily every day for 24 weeks.

Simple randomization is used to allocate participants to the intervention or control groups using a 1:1 allocation ratio. A computer programme operated by the study researcher is used to generate a random number to assign each participant to a trial arm. The trial statistician is not

involved in the process of recruitment, randomization, or group assignment. Blinding It is not possible to blind participants to their group allocation. Participants became aware of their allocation on first listening to the audio recording they had received as the recording for those in the intervention group included weight loss messages, whereas the control group recording did not.

Statistical methods
Data analysis is conducted using R version 3.4.3. Baseline characteristics are reported as mean and standard deviation (SD) for continuous data and n (%) for categorical data. For each measure, baseline is defined as the value collected prior to the commencement of randomised therapy. The two therapy arms are compared using analysis of covariance (ANCOVA) using the change from baseline at each post-baseline assessment separately, with the baseline fitted as a covariate; interaction between baseline and treatment are assessed but removed from the model as not statistically significant.

Intervention Type
Behavioural

Primary outcome measure
Weight (kg) at baseline, 12, and 24-weeks

Secondary outcome measures
At baseline and 24-weeks:
1. Eating Self-Efficacy Scale (ESES)
2. Exercise Confidence Scale (ECS)
3. Quality of Life Index Generic Version III (QLI-G3)

Overall study start date
14/01/2014

Completion date
01/07/2014

Eligibility

Key inclusion criteria
1. BMI above 25 kg/m²
2. Aged 18 years or above

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
82

Total final enrolment
82

Key exclusion criteria
1. Pregnant
2. Diagnosed with mental health condition
3. Seeking medical support for a medical diagnosis unless prior consent was obtained from their medical practitioner

Date of first enrolment
05/10/2013

Date of final enrolment
01/01/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
City University London
Northampton Square
Clerkenwell
London
United Kingdom
EC1V 0HB

Sponsor information

Organisation
ThinkingSlimmer Ltd

Sponsor details
400 Harrow Road
London
United Kingdom
W9 2HU
+44 (0)7770381733
chris@thinkingslimmer.com

Sponsor type
Industry

Website
https://www.ThinkingSlimmer.com

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Poster presentation at the British Journal of General Practitioners' research conference on March 12, 2020.

Intention to publish date
12/03/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request, data will be available from April 2, 2020 indefinitely.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		18/06/2020	23/09/2021	No	No