

Working memory training in type 2 diabetes

Submission date 08/01/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/01/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/08/2020	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Diabetes is a lifelong condition that causes a person's blood sugar level to become too high. Many people with diabetes report difficulty controlling their diet. The aim of this study is to investigate whether working memory training can help people with diabetes to better resist temptation and control their eating habits without adversely affecting quality of life. Known regions of the brain (subcortical regions) respond to tempting food cues. Frontal regions of the brain have control over these subcortical regions. Our working memory is located within the frontal brain regions, so training in working memory could improve control over subcortical responses to foods. A recent study supported this, finding reduced alcohol intake after working memory training in people with alcohol consumption problems. Working memory training could similarly enhance people's ability to resist tempting foods. Ultimately, this could improve people's health and quality of life.

Who can participate?

Patients aged between 18 and 70 with type 2 diabetes who are overweight, have poor control of their diabetes and report difficulty following their diet, but are otherwise in good health.

What does the study involve?

Participants are randomly allocated to receive either 25 sessions of web-based working memory training (where the complexity of the memory learning task is adjusted to reflect their level of competence) or placebo training (where only the lowest level of complexity is used). Before, after and at 3 months follow-up, participants' height and weight are measured and blood tests are conducted. Participants also fill out questionnaires, complete a food diary, do a reaction time computer task involving images of food, and take part in a buffet lunch. Participants are interviewed to gain an understanding of their experience with the training. The working memory training can be completed at home, with participants attending the university for all test.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Middlesex University (UK)

When is the study starting and how long is it expected to run for?
November 2014 to December 2016

Who is funding the study?
Diabetes UK

Who is the main contact?
Dr Arie Nouwen

Contact information

Type(s)
Scientific

Contact name
Dr Arie Nouwen

Contact details
Middlesex University
Department of Psychology
The Burroughs
Hendon
United Kingdom
NW4 4BT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16328

Study information

Scientific Title
Does neurocognitive training have the potential to improve dietary self-care in type 2 diabetes?

Study objectives
Many people with diabetes report difficulty controlling their dietary intake, reducing their quality of life. The aim of this study is to investigate whether working memory training can help people with diabetes to better resist temptation and control their eating habits without adversely affecting quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)

14/WM/0056; First MREC approval date 11/07/2014

Study design

Randomised; Interventional

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

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

Topic: Diabetes, Cardiovascular disease; Subtopic: Type 2, Cardiovascular (all Subtopics); Disease: Diabetic Control, Other

Interventions

Working memory training.

1. Intervention group: The training consists of 25 sessions of working memory training comprising three tasks: letter span task, backwards digit task, visuo-spatial task. In the letter span task, a sequence of letters is presented one at a time in a circle. Once the sequence has finished, one of the positions in the circle is cued and participants have to enter the letter that appeared in this location using the keyboard. In the backwards digit task, several numbers are presented on the screen one at a time, which par

2. Control group: Placebo training (lowest level of competence only)

Intervention Type

Other

Primary outcome measure

Working memory capacity (trained tasks)

Secondary outcome measures

N/A

Overall study start date

01/11/2014

Completion date

01/12/2016

Eligibility

Key inclusion criteria

1. Aged between 18 and 70 years
2. Having type 2 diabetes for at least 2 years
3. Poor diabetes control (HbA1c >8.0mmol/l)
4. BMI= 25
5. Self-reported difficulty to follow a healthy diet;
6. Being in general good health
7. Treatment of diabetes by diet only or tablets

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 48; UK Sample Size: 48

Total final enrolment

81

Key exclusion criteria

1. Neurological and psychiatric disorders including eating disorders and clinical depression
2. Alcohol and/or substance abuse
3. Treatment by insulin, GLP-1 or DPP-4 inhibitors

Date of first enrolment

01/11/2014

Date of final enrolment

01/12/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Middlesex University
Department of Psychology
The Burroughs
Hendon
United Kingdom
NW4 4BT

Sponsor information

Organisation

Middlesex University (UK)

Sponsor details

Department of Psychology
The Burroughs
Hendon
England
United Kingdom
NW4 4BT

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/01rv4p989>

Funder(s)

Funder type

Charity

Funder Name

Diabetes UK

Alternative Name(s)

DIABETES UK LIMITED, British Diabetic Association

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/12/2015	17/08/2020	Yes	No
Results article	results	01/09/2018	17/08/2020	Yes	No
HRA research summary			28/06/2023	No	No