

Light therapy for depression and diabetes

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25152

Source

Nationaal Trial Register

Health condition

major depression; type 2 diabetes mellitus

Sponsors and support

Primary sponsor: VU University Medical Center, Department of Psychiatry/ GGZ inGeest

Source(s) of monetary or material Support: European Foundation for the Study of Diabetes (EFSD) Mental Health Grant

Intervention

Outcome measures

Primary outcome

Depression symptoms (Inventory of Depressive Symptoms (IDS)); insulin sensitivity (hyperinsulinaemic euglycaemic clamp).

Secondary outcome

Psychometrical secondary outcome measures will include depression remission (IDS score of 13 or less); anxiety symptoms (Beck Anxiety Inventory); diabetes distress (Problem Areas In

Diabetes questionnaire); and quality of life (EQ-5D) and disability (Sheehan Disability Scale). Endocrine secondary outcome measures will include HbA1c, fasting plasma glucose, insulin dosage (in insulin dependant participants) as reported in the trial diary, and number of hypoglycaemic events as reported in the trial diary. Mediating factors that reflect circadian rhythmicity will include diurnal HPA-axis activity, objective accelerometer measures of sleep duration, and subjective measures of sleep duration and quality (questionnaires). Other potential mediating factors include autonomic nervous system function; body weight, body mass index, and body composition (percentage of fat and lean muscle, waist-hip ratio) as measured by bioelectrical impedance analysis; and physical activity as measured using a wrist worn accelerometer.

Study description

Study design

Measures will be normally performed at three time points: just before the start of light therapy, after completion of four weeks of light therapy, and after four weeks follow-up. Several measures will be evaluated continuously during the intervention period.

Intervention

The intervention will consist of light therapy for four weeks 30 minutes every morning at home with bright white-yellowish light or dim green light.

Contacts

Public

Postal Box 7057 (ZH-3A87)

M.A. Bremmer,
Amsterdam 1007 MB
The Netherlands
+31 (0)20 4440196

Scientific

Postal Box 7057 (ZH-3A87)

M.A. Bremmer,
Amsterdam 1007 MB
The Netherlands
+31 (0)20 4440196

Eligibility criteria

Inclusion criteria

(1) male and female subjects 18 years or older; (2) having type 2 diabetes mellitus as judged by an expert panel based on HbA1c, diabetes medical history, use of glucose-lowering medication, and when deemed necessary additional tests (e.g. antibodies); and (3) having a major depressive episode according to DSM-IV criteria

Exclusion criteria

1) a recent history of, or current, light therapy; (2) shift worker; (3) a recent change in antidepressant or blood-glucose lowering medication or therapy (e.g. psychotherapy); (4) use of oral glucocorticoids, melatonin, or cytostatics; (5) pregnancy; (6) psychosis, mania, (probable) dementia, severe drug or alcohol abuse, delirium, and severe acute suicidality; (7) a history of light-induced migraine or epilepsy, or severe side effects to light therapy in the past; (8) visual acuity <60%, diabetic retinopathy EURODIAB grades 3, 4 or 5 (severe non-proliferative or preproliferative retinopathy, photocoagulated retinopathy, proliferative retinopathy), senile macula degeneration; (9) a(nother) medical condition or recent medical event that potentially compromises the effects or safety of light therapy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-06-2014
Enrollment:	74
Type:	Anticipated

Ethics review

Positive opinion

Date: 13-01-2015

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44883

Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4802
NTR-old	NTR4942
CCMO	NL45295.029.13
OMON	NL-OMON44883

Study results