Light therapy for depression and diabetes

Gepubliceerd: 13-01-2015 Laatst bijgewerkt: 15-05-2024

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25152

Bron
Nationaal Trial Register

Aandoening

major depression; type 2 diabetes mellitus

Ondersteuning

Primaire sponsor: VU University Medical Center, Department of Psychiatry/ GGZ inGeest
Overige ondersteuning: European Foundation for the Study of Diabetes (EFSD) Mental Health Grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

(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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2014
Aantal proefpersonen:	74
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-01-2015

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44883
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten