Light Therapy for better Mood and Metabolic control: a randomised double-blind placebo-controlled clinical trial in patients with Type 2 Diabetes Mellitus and Depression

Published: 31-03-2014
Last updated: 15-05-2024

(1) To investigate the efficacy of LT in patients with T2DM and comorbid depression, and (2) whether LT leads to improved insulin sensitivity, and (3) whether effects on mood and metabolic control are mediated by restoration of the circadian...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON44883

Source
ToetsingOnline

Brief title
Light therapy for Depression and Diabetes (LiDDia)

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Mood disorders and disturbances NEC

Synonym
adult onset diabetes, Depression; Type 2 Diabetes Mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: European Foundation for the Study of Diabetes

Intervention

Keyword: Depression, Diabetes, Light Therapy, Sleep

Outcome measures

Primary outcome

o Mean change in IDS-SR scores in the active versus placebo condition (T0-T4).

Secondary outcome

Depression

o Mean change in depressive symptoms (IDS-SR) in the active versus placebo

condition (T0-T8).

o Depression (sustained) remission rates in the active versus placebo condition

(remission is a priori defined as a score of 13 or less (IDS-SR) at T4;

sustained remission is a priori defined as a score of 13 or less (IDS-SR) at T4

and T8).

o Temporal changes in depressive symptoms (IDS-SR) in the active versus placebo

condition (T0,T1, T2, T3, T4, T8).

Diabetes

o Mean change HEC-derived M-value, as measure of whole-body insulin sensitivity

in the active versus placebo condition (T0-T4).

o Mean change in HbA1c in the active versus placebo condition (T0-T4, T0-T8).

o Mean change in fasting plasma glucose in the active versus placebo condition

(T0-T4, T0-T8).

o Mean change in self-reported glucose measures and insulin dosages (if applicable) in the active versus placebo condition (T0-T4, T0-T8).

Anxiety, emotional functioning in diabetes, quality of life, and disability

o Mean change in anxiety symptoms in the active versus placebo condition (T0-T4, T0-T8).

o Temporal changes in anxiety symptoms in the active versus placebo condition (T0-T4, T0-T8).

o Mean change in emotional functioning in diabetes in the active versus placebo condition (T0-T4, T0-T8).

o Mean change in quality of life in the active versus placebo condition (T0-T4, T0-T8).

o Mean change in disability in the active versus placebo condition (T0-T4, T0-T8)

Primary mediators

o Mean change in diurnal cortisol variability in the active versus placebo condition (T0-T4, T0-T8).

o Mean change in objective actigraphic measures of sleep duration and circadian rhythmicity in the active versus placebo condition (T0-T4, T0-T8).

o Mean change in subjective measures of sleep duration and quality and circadian rhythmicity in the active versus placebo condition (T0-T4, T0-T8).

Secondary mediators

o Mean change in the ANS-balance in the active versus placebo condition (subgroup) (T0-T4, T0-T8).

o Mean change in body mass and composition measures in the active versus placebo condition (T0-T4, T0-T8).

o Mean change in blood pressure in active versus placebo condition (T0-T4, T0-T8).

o Mean change in objective actigraphic measures of physical activity and energy expenditure in the active versus placebo condition (T0-T4, T0-T8).

Safety and tolerability

o Mean change in side-effects in the active versus placebo condition (T0-T4, T0-T8).

o Temporal changes in side-effects in the active versus placebo condition (T0, T1, T2, T3, T4, T8).

o Mean changes in ophthalmological measures (fundoscopy, visual acuity, and contrast sensitivity (subgroup)) (T-3-T8).

Study description

Background summary

Depression is common in patients with type 2 diabetes mellitus (T2DM), leading to increased morbidity and mortality risks. Both depression and T2DM are associated with a dysfunction of the biological clock, which is implicated in both diurnal glucose homeostasis and the regulation of the stress-response. Light Therapy (LT) is an effective, patient friendly, non-pharmacological antidepressant that stimulates the biological clock. We hypothesize that LT

will improve depressive symptoms and insulin sensitivity, possibly by resetting the biological clock.

Study objective

(1) To investigate the efficacy of LT in patients with T2DM and comorbid depression, and
(2) whether LT leads to improved insulin sensitivity, and
(3) whether effects on mood and metabolic control are mediated by restoration of the circadian rhythmicity.

Study design

A randomized double-blind placebo-controlled clinical trial, consisting of a 2-week run-in period to allow for study effects (T-2-T0), a 4-week intervention period (T0-T4), and a 4-week follow-up (T4-T8), to assess direct and more chronic effects of LT.

Intervention

Partcipants will be randomly assigned to the experimental or control condition: 4 week exposure to bright white-yellowish light, 10.000Lux, 0.5 hour every morning, or 4 week exposure to dim green light, 500 Lux, 0.5 hour every morning at their homes. Participants choose a 4-week-lasting fixed starting time anchored within 1 hour from their habitual wake-up time. During therapy, they sit in front of the boxes on a distance of 50 cm, and can have breakfast or do some reading (Protocol as recommended by Wirz-Justice, 2009). All lamps will be equipped with UV-A and UV-B filters, and will contain relatively less blue-light. We chose to use dim green light as a placebo, reasoning that because the geen part of the spectrum is biologically relatively inactive, there would be no substantial effect, although green light may induce positive expectations, as was proven for dim red light (Loving, 2005). Particicpants will be informed that the primary goal of the study is to investigate spectrum-dependent efficacy differences.

Study burden and risks

LT is generally well tolerated, and has proven to be safe and efficacious in previous studies. However, the efficacy of LT in depressed patients with comorbid T2DM has never been proven. In our opinion, taking together the burden associated with participation (LT, actometery, study-diary, questionnaires, fundus photography, venapunction, and optionally a euglycemic hyperinsulinemic clamp procedure), and the low risks associated with the protocol, we believe the potential group benefit outweighs the burden and risks associated with participation. If proven efficacious, LT could be a valuable and affordable non-pharmacological treatment option for patients with depression and comorbid

T2DM, improving both psychiatric and metabolic outcomes.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1118
Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1118
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy subjects (pilot studie):
(1) Age 18-75 years
(2) Physically and psychiatrically healthy, as judged by an expert panel;Patients:
(1) Age 18 years or older
(2) Type 2 Diabetes Mellitus, as judged by an expert panel
(3) Depression (DSM-IV)

Exclusion criteria

Healthy subjects (pilot studie):
(1) A recent history of a serious medical event, as judged by an expert panel
(2) Hypersensitivity to drugs used
(3) Pregnancy
(4) Poor commandment of the Dutch language or any (mental) disorder that precludes full understanding the purpose, instruction and hence participation in the study
(5) Individuals who are investigator site personnel directly affiliated with the study, or are immediate family;Patients:
(1) Recent history (<2 months ago) of, or current light therapy
(2) Type 1 Diabetes Mellitus
(3) Recent history of a serious medical event or a serious medical condition, as judged by an expert panel
(4) Current use of oral glucocorticoids, melatonin, or cytostatics
(5) Recent change in antidepressant (<1 months ago) or blood-glucose lowering (<1 months ago) medication
(6) Psychosis, mania, (probable) dementia, severe drug or alcohol abuse, delirium, and severe acute suicidality, as judged by an expert panel
(7) Visual Acuity <60%, severe non-proliferative or preproliferative retinopathy, photocoagulated retinopathy, proliferative retinopathy (EURODIAB grades 3,4, and 5), recent history (<6 months ago) of relevant eye surgery, relevant eye surgery scheduled in the near future, senile macula degeneration
(8) A history of light-induced migraine or epilepsy, or severe side effects to light therapy in the past
(9) Hypersensitivity to drugs used
(10) Pregnancy
(11) Shift workers
(12) Poor commandment of the Dutch language or any (mental) disorder that precludes full understanding the purpose, instruction and hence participation in the study
(13) Individuals who have previously completed or withdrawn from the experimental phase of this study
(14) Individuals who are investigator site personnel directly affiliated with the study, or are immediate family

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-04-2014
Enrollment:	98
Type:	Actual

Medical products/devices used

Generic name:	Diamond-5 Bright Light Therapy Lamp (adapted)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	31-03-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-09-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-12-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-10-2017

Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25152
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL45295.029.13
OMON	NL-OMON25152