Bright up! A randomized, double-blind, placebo-controlled study of light therapy for depression during pregnancy.

No registrations found.

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

Summary

ID

NL-OMON20500

Source
Nationaal Trial Register

Brief title
Bright up!

Health condition

Depression during pregnancy.
Depressie tijdens de zwangerschap.

Sponsors and support

Primary sponsor: Erasmus University Medical Centre
Source(s) of monetary or material Support: Philips

Intervention

Outcome measures

Primary outcome

The average change in depressive symptoms between the two groups, as measured by HAM-D and EPDS, after 6 weeks of treatment compared to baseline.

Secondary outcome

- Changes in depressive symptoms between the two groups, as measured by HAM-D and EPDS, measured at different time points (T2, T3, T5, T6 and T7);

- Changes in cortisol and melatonin levels between the two groups, measured at different time points (T0, T1, T2, T3 and T5);

- Changes in circadian rhythms between the two groups, such as total sleep time and sleep efficiency, measured at different time points (T0, T1, T2, T3, T5);

- Changes in birth outcome in the newborns between the two groups, such as birth weight and Apgar score;

- Changes in child behavior, as assessed by Mother and Baby Scales (MBAS), between the two groups, at the age of 2 months;

- Changes in cortisol stress response in infants between the two groups, at the age of 2 month;

- Changes in long-term cortisol exposure (hair sample) in infants between the two groups, at the age of 2 months

Study description

Background summary

About 5-10% of the pregnant women in the Netherlands suffer from depression. Children who are exposed to maternal depression during pregnancy have a higher risk of adverse birth outcomes and more often show cognitive, emotional and behavioural problems. Therefore, early detection and treatment of depression during pregnancy is essential.

Psychotherapy, a first choice treatment for depression in non-pregnant women, shows limited relevance during pregnancy, for the direct availability of psychotherapists is poor. Since the window of opportunity is small during pregnancy and treatment bridges a long time span, the unborn child would not benefit from this treatment. A second treatment, the use of antidepressants, is controversial, for the effects to the (unborn) child are not entirely clear.

Therefore, it is relevant to investigate non-pharmalogical approaches to treat depression during pregnancy. Bright light therapy is a promising treatment for depression during pregnancy, for it has shown positive effects in other populations and for the little adverse reactions. Moreover, it is relatively cheap and easy to administer.

It has been shown that the effects of bright light therapy are associated with an improved

circadian rhythm. This is expressed in improved sleep quality and the normalisation of stress hormones. This is relevant during pregnancy, for increased stress hormones, as a consequence of depression, might (partly) explain the unfavorable development of the unborn child.

This study investigates whether bright light therapy is an effective treatment for depression during pregnancy compared with low-intensity placebo light therapy (proof-of-principle). Secondly, it investigates the late effects of bright light therapy versus placebo on quality of sleep, endocrine function during pregnancy and birth outcome. Furthermore, it studies the effects on emotional and behavourial development of the child.

Study objective

This study investigates whether light therapy is an effective treatment for depression during pregnancy. Secondly, it investigates the late effects of bright light therapy on quality of sleep, endocrine function during pregnancy and birth outcome. Furthermore, it studies the effects on emotional and behavorial development of the child.

Study design

T0: baseline

T1: after 6 weeks of treatment

T2: 3 weeks after end treatment

T3: 10 weeks after end treatment

T4: birth

T5: 2 months postpartum
T6: 6 months postpartum
T7: 18 months postpartum

Intervention

Two groups will be treated daily for 6 weeks with 30 minutes light therapy within 30 minutes of habitual wake-up time. In both groups, two different colours of light will be studied.

Contacts

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Eligibility criteria

Inclusion criteria

Women

18-45 years of age

Normal ocular function

12-32 weeks pregnant, as assessed by the gynaecologist or midwife

DSM diagnosis depressive disorder, as assessed by the researchers

Exclusion criteria

Insufficient proficiency in Dutch or English

Multiple pregnancies (because of increased risk for adverse birth outcomes that might act as confounder and bias the results)

The use of selective serotonin reuptake inhibitors (SSRI’s) shorter than 2 months before starting therapy

DSM diagnoses of bipolar I or II disorder

Seasonal affective disorder

Any psychotic episode

Substance abuse

Primary anxiety disorder

Recent history of suicide attempt

Habitual sleep disorders

Jetlag

Shift-work

Somatic and/or obstetric conditions that override study participation

Previous treatment with bright light therapy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2015
Enrollment:	150
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 02-11-2015
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43734
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5375
NTR-old	NTR5476
CCMO	NL55208.078.15
OMON	NL-OMON43734

Study results