Optimization, Working Mechanisms and Response Predictors of Bright Light Therapy for Depressive Disorders- a multicenter randomized controlled trial

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON53312

Source
ToetsingOnline

Brief title
BioClock: Bright light therapy for depressive disorders

Condition

- Mood disorders and disturbances NEC

Synonym
Depression, Depressive Disorders

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden

Source(s) of monetary or material Support: NWA-ORC BioClock Consortium

Intervention

Keyword: Bipolar Disorder, Bright Light Therapy, Chronobiology, Depressive Disorders

Outcome measures

Primary outcome

The primary outcome is clinical improvement, as indexed by a difference in MADRS scores between the baseline and 4 weeks after the start of treatment.

Secondary outcome

Secondary clinical outcome measures are: time to recovery (the number of treatment weeks needed to achieve remission), remission rate (percentage of patients that score lower than 6 on the MADRS 4 weeks after the start of the treatment); and response rate (percentage of patients with at least 50% reduction in MADRS -score).

Study description

Background summary

Bright Light Therapy (BLT) is an effective treatment for seasonal and non-seasonal depressive disorders, as well as for bipolar depression. Recent meta-analyses show that BLT effectively reduces depressive symptoms within 5-7 days in approximately 60% of patients with seasonal depression, and in 40% of other depressive disorders. This effectiveness is comparable to that of commonly used pharmacological agents, but light therapy seems to work significantly faster and lead to fewer side effects. Optimization of the treatment strategy, a better understanding of the working mechanisms, and the patient characteristics and behaviours that predict treatment response is needed to increase the effectiveness and useability of BLT in clinical practice and enable personalized intervention.

Study objective

This study has the following study aims:
1) Investigate whether treatment context and the addition of chronotherapeutic and social rhythm interventions improve the efficacy of BLT,
2) examine the role of circadian phase resetting and changes in sleep quality in the working mechanisms of BLT
3) identify which patient characteristics and behaviours predict treatment outcomes
4) establish a brain model for the effects of BLT in depression.

Study design

A randomized, multicentre, single-blind clinical trial. We will compare three treatment arms with different BLT administration strategies. Depressive symptom severity will be assessed by a blind rater at baseline and after BLT. Circadian rhythm will be assessed using actigraphy data and salivary melatonin assessment. Ecological momentary assessment will be used to gain insight into the dynamics of changes in vitality, sleep and affect across treatment. Predictors of treatment response will be assessed at baseline and include clinical characteristics, subjective and objective measures of sleep, circadian parameters (dim light melatonin onset and light-induced melatonin suppression) and light-related behaviours. MRI will give insight into functional and structural brain changes after light therapy treatment.

Intervention

In all arms, patients will receive 10,000 lux BLT in the morning for 30 min/day on 5 consecutive days. Treatment duration will be one, two or three weeks, depending on the remittance of depressive symptoms. Participants will be randomized to receive:

1) BLT in their home environment,
2) BLT in a café setting, supervised by clinical staff and promoting lifestyle changes and social interaction,
3) Same as arm 2, complemented by BLT timing strategies to optimize and stabilize sleep-wake patterns and by the use of blue-light blocking glasses in the evening.

Study burden and risks

At least 40% of participants are expected to recover from their depressive episodes. In rare cases, the light therapy might result in mild and short-lasting side effects, including eyestrain, headache, nausea, irritability or agitation. A recent meta-analysis reported that the risk of triggering a manic episode in patients with bipolar disorder after treatment with BLT is not different from placebo treatment (estimated rate of manic switches: 4.7%). We expect the benefits to be greater in arm 2 than arm 1 and greatest in arm 3,

with equal amounts of side effects in each arm.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Age between 18 and 65.
- Diagnosis of unipolar or bipolar depression (seasonal or non-seasonal)
- A current depressive episode
- Sufficient knowledge of Dutch or English language to fill in questionnaires

Exclusion criteria

- A current (hypo)manic or mixed episode

- Current psychotic episode
- Prominent active suicidality
- Antidepressant therapy that started less than 2 months prior to study entry
- Participants with bipolar disorder that are not on mood stabilizing medication in a recommended dose for the last month prior to study entry
- Use of melatonin or agomelatine in the last month
- Current use of antibiotics
- Current use of light sensitivity-increasing medication
- Travelled more than 1 time zone or to a sunny holiday destination/wintersports during the past month
- Pre-existing eye and skin disorders (retinitis pigmentosa, porphyria, chronic actinic dermatitis and sun-induced urticaria)
- Systemic disorders with potential retinal involvement (rheumatoid arthritis and systemic lupus erythematosus)
- Suffering from (retinal) blindness, severe cataract, glaucoma or colour blindness
- Participated in night shift work in the last three months
- Light-induced migraine and epilepsy
- Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-02-2024

Enrollment:	231
Type:	Actual

Ethics review

Approved WMO Date:	17-10-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL83497.058.23