Bright light therapy in rheumatoid arthritis to improve symptoms of fatigue and other disease outcomes.

No registrations found.

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

Summary

ID

NL-OMON22327

Source
Nationaal Trial Register

Brief title
Bright light therapy in rheumatoid arthritis.

Health condition

Rheumatoid arthritis

Sponsors and support

Primary sponsor: Leiden University
Source(s) of monetary or material Support: Dutch Arthritis Association / Lucimed

Intervention

Outcome measures

Primary outcome

The main endpoint is the difference between the intervention and control group in change from T0 to T1 in the primary study outcome fatigue (CIS-8 score). This difference will be reported as descriptive and will be preliminary statistically tested.

Secondary outcome

The secondary outcomes (e.g. disease activity (Disease Activity Scale (DAS)) and circadian entrainment (assessed by the melatonin onset in saliva and a sleep diary)) will be explored in the same way as the primary outcome. We also report the relevant parameter estimates and variances needed to design a possible future full-scale RCT.

Study description

Background summary

Rheumatoid arthritis (RA) is often associated with symptoms, including fatigue, which reduce quality of life negatively. Unfortunately, treatments for these symptoms are not adequate for all patients. A disturbed circadian rhythm has been found in patients with RA and may be an important underlying mechanism for those symptoms. In the current study, the efficacy of a 4-week Bright Light Therapy (BLT) program is examined for the first time in patients with RA. This study is a randomized, double blind, parallel-arm, placebo controlled pilot study that could serve as preparation for a future larger full-scale randomized controlled trial (RCT). The primary study objective is to explore the difference between an intervention group that receives active BLT and a control group that receives sham BLT in fatigue while taking into account baseline fatigue levels. As secondary objectives, we explore a) secondary efficacy outcomes, b) the potential of the therapy in delaying the circadian entrainment, c) the 4-week follow-up effects, and 4) (barriers to) therapy adherence, therapy acceptability as well as study feasibility and acceptability.

We need to have in both study arms 19 adult patients with RA that completed the study. Taking into account the possibility for drop-outs (expected 20%), we expect to include (19 divided by 0.8 =) 24 participants in each arm which means a total of (2 x 24 =) 48 participants for the entire study.

Patient are being recruited from the Department of Rheumatology of the LUMC.

Eligible patients have elevated feelings of fatigue (CIS-8 ¡Ý27) and low disease activity or are in remission. In both therapy arms, light therapy glasses are worn in the home of the participant every day for 30 minutes in the evening (between 20:00-21:00 h) during four consecutive weeks. The arms differ in the wavelength of light that is emitted by the glasses. The primary outcome is assessed by Checklist Individual Strength - Subscale Fatigue (CIS-8).

Study objective

The primary objective of this pilot trial is to explore in patients with rheumatoid arthritis (RA) the difference between an intervention and a control group in change from baseline (T0) to at the end of a 4-week bright light therapy (T1) in the primary therapy efficacy study outcome fatigue as assessed by Checklist Individual Strength - Subscale Fatigue (CIS-8). We hypothesize that the intervention group show a larger decrease in fatigue level from T0 to T1 compared to the control group.

We will also explore some secondary outcomes (e.g. disease activity and circadian entrainment). Moreover, 4-week follow-up effects for primary and secondary outcomes will be explored as well as (barriers to) therapy adherence, therapy acceptability, study feasibility, and study acceptability.. The last objective of this pilot trial is to acquire relevant parameter estimates which are needed to design a possible future full-scale randomized controlled trial (RCT).

Study design

Outcomes will be assessed at baseline (T0), at the end of the 4-week BLT (T1), and at follow-up (4 weeks after BLT; T2).

Intervention

In both arms, light therapy glasses will be worn in the home of the participant every day for 30 minutes in the evening (between 20:00-21:00 h) during four consecutive weeks. The two arms differ in the wavelength of light that is emitted by the glasses.

Contacts

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Eligibility criteria

Inclusion criteria

Eligible patients are Dutch-speaking patients from the Department of Rheumatology of the Leiden University Medical Center with a physician-based diagnosis of RA and an age ≥ 18y.

A subject must meet all of the following criteria:

I. Patient is on stable disease-modifying anti-rheumatic drug (DMARD) therapy for at least 3 months before the start of the study.

II. Disease Activity Scale (DAS) ≤ 3.2

III. Patient has abnormal feelings of fatigue as assessed by the CIS-8 ≥ 27.

Exclusion criteria

I. Treatment with glucocorticoids, melatonin, or photosensitizing medication and/or changed in type or dose within the last 3 months before start of the study.

II. Patient's medical conditions or recent medical events potentially compromises the effects of safety of light therapy (e.g. psychosis, mania, (probable) dementia, severe drug or alcohol abuse, delirium, severe acute suicidality, history of light-induced migraine or epilepsy or severe side effects to light therapy in the past, and/or pre-existing ocular abnormalities (e.g. glaucoma, retinitis, retinopathy, and/or macular degeneration)).

III. Midsleep on free days corrected for sleep deficit build up during working days (as measured with the Munich Chronotype Questionnaire) > 4:00h which reflected patients with a late chronotype.

IV. Patient has been involved in light therapy within 1 year before the start of the study.

V. Patient has been unable to maintain a regular sleep schedule (e.g. due to shift work) within 1 year before start of the study and/or expected during the study.

VI. Patient has travelled within three months before study start and/or has the plan to travel during the study to a time zone that deviates two or more hours from the Netherlands; and,

VII. Patient or partner is pregnant, has a wish for pregnancy, or gives breastfeeding during the study period.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2018
Enrollment:	48
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-05-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44172
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7011
NTR-old	NTR7209
CCMO	NL62780.058.17
OMON	NL-OMON44172

Study results

Summary results
NA