Bright light therapy in rheumatoid arthritis to improve symptoms of fatigue and other disease outcomes: a randomized controlled pilot trial.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON44172

Source
ToetsingOnline

Brief title
Bright light therapy in reumatoid arthritis.

Condition

- Autoimmune disorders

Synonym
rheumatoid arthritis / inflammatory arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden

Source(s) of monetary or material Support: Lucimed (voor het uitlenen van 12 Placebo lichtbrillen voor de duur van de studie en het schenken van 12 Bright Light therapiebrillen,Reumafonds

Intervention

Keyword: o Bright Light Therapy, o Fatigue, o Pilot Study, o Rheumatoid Arthritis

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

In the same way will be explored: secondary therapy efficacy outcomes and

circadian entrainment outcomes as well as follow-up effects (changes from T0 to

T2). Also, the mediating role of circadian entrainment and depression on

therapy efficacy will be explored. We also report the relevant parameter

estimates and variances needed to design a possible future full-scale RCT

(Feeley et al., 2009).

Study description

Background summary

Although large progress has been made in the diagnosis and treatment possibilities for patients with rheumatoid arthritis (RA), RA is often associated with symptoms which reduce quality of life negatively, including fatigue. Unfortunately, treatments for these symptoms are currently not for all patients adequate and many symptoms are left untreated. A disturbed circadian rhythm (i.e. 24-hour rhythm) has been found in patients with RA and may be an

important underlying mechanism for those symptoms. Bright light can possibly restore circadian rhythmicity in RA as it is the most important synchronizer of this rhythm. In the current study, the efficacy of a 4-week Bright Light Therapy (BLT) program will be examined for the first time in patients with RA. The current study is a pilot study that could serve as preparation for a future larger full-scale randomized controlled trial (RCT).

Study objective

The primary objective of this pilot trial is to explore the difference between the intervention and control group in change from baseline (T0) to the end of therapy (T1) in therapy efficacy of the primary study outcome fatigue assessed by Checklist Individual Strength (CIS-8).

As a secondary objective, we will also explore the following therapy efficacy outcomes: pain and morning joint stiffness (Impact of Rheumatic diseases on General health and Lifestyle; subscale Pain), sleep (diary and Insomnia Severity Index), and emotional well-being and general health status (RAND-36), depression (Hospital Anxiety and Depression Scale), and disease activity (Disease Activity Scale). Furthermore, we will explore the potential of the therapy in delaying the circadian entrainment (assessed by the melatonin onset in saliva and sleep diary) and the mediating role of circadian entrainment changes for therapy efficacy as well as the mediating role of depression in reducing fatigue. Moreover, follow-up effects for primary and secondary therapy efficacy outcomes and circadian entrainment outcomes will be explored. Additionally, this pilot trial will assess therapy adherence, barriers to adherence, therapy acceptability as well as study feasibility and study acceptability. This will give insight into potential modifications that are needed to the therapy and study. The last objective of this pilot trial is to acquire relevant parameter estimates which are needed to design a possible future full-scale RCT.

Study design

This is a randomized, double-blind, parallel-arm, placebo controlled (ratio 1:1), single center pilot trial consisting of an intervention group (active BLT) and a control group (sham BLT). Outcomes will be assessed at baseline (T0), at the end of the 4-week BLT (T1), and at follow-up (four weeks after BLT; T2). The study will be reported according to the *Consolidated Standards of Reporting Trials (CONSORT) 2010 statement: extension to randomised pilot and feasibility trials* (Eldridge et al., 2016).

Intervention

In both arms, light therapy glasses (Luminette® (CE certified); Lucimed) 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 (i.e. active bright light vs. sham bright light).

Study burden and risks

At each measurement, participants fill in a questionnaire at home (± 25 minutes), they have to take ten saliva samples on a predefined evening and night at home and they fill in a sleep diary at home for one (T0 and T2) or two (T1) weeks (5 minutes / day). Participants will also visit the hospital at T0, T1, and T2 for a physical examination and blood draw (i.e. DAS examination; ± 15 minutes); this is part of the standard treatment of patients with RA and will therefore not impose any additional risks (only the frequency of measurement is higher). All other measurements are considered minimally invasive and pose little risk.

Patients are able to continue other light activities during the 30 minutes of BLT. The therapy is expected to have no (long-lasting) negative effects. To distinguish actual therapy effects from placebo effects, it is necessary to include a control group receiving sham BLT.

This study may have a large impact for patients (as most important patients centered outcomes could be improved by this therapy), health professionals, researchers (e.g. rheumatologists and chronobiologists), and the society (e.g. by reducing costs associated with fatigue and other outcome measures).

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Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

I. Patient is on stable disease-modifying antirheumatic drug (DMARD) therapy for at least 3 months before the start of the study.
II. Disease Activity Scale (DAS) 28 <= 3.2.
III. Patient has abnormal feelings of fatigue as assessed by Checklist Individual Strength (CIS)-8 >= 27 (indicates abnormal levels of fatigue) (Bultmann et al., 2000).

Exclusion criteria

I. Patient*s treatment consists of glucocorticoids, melatonin, or photosensitizing medication (e.g. amiodarone, benoxaprofen, chlorpromazine, demeclocycline, fleroxacin, nalidixic acid, ofloxacin, piroxicam, porfimer, psoralens, quinidine, and/or temoporfin (Anderson et al., 2016)) 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 or has a wish for pregnancy during the therapy period or gives breastfeeding.

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):	13-12-2017
Enrollment:	48
Type:	Actual

Medical products/devices used

Generic name:	Luminette glasses (Lucimed®;CE Medical Devices)
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	16-11-2017
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

ID: 22327
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL62780.058.17
OMON	NL-OMON22327

Study results

Date completed:	27-05-2019
Actual enrolment:	48