Improving sleep quality, psychosocial functioning, and cancer related fatigue with light therapy (SPARKLE-study).

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(1) To examine whether the exposure to BWL yields clinically significant reductions in CRF compared to exposure to dim white light in (non-)Hodgkin survivors. (2) To examine the effect of exposure to BWL compared to DWL on sleep quality and...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47562

Source
ToetsingOnline

Brief title
To decrease fatigue with light therapy (SPARKLE-study).

Condition

- Other condition
- Lymphomas Hodgkin's disease
- Sleep disorders and disturbances

Synonym
tiredness, weariness

Health condition

vermoeidheid

Research involving

Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: cancer related fatigue, circadian rhythm, light therapy

Outcome measures

Primary outcome

The main study parameter in this study is the change in cancer related fatigue from baseline to post-intervention and at 3 and 9 months follow-up. This will be assessed with the Multidimensional Fatigue Inventory.

Secondary outcome

Secundary study parameters include the following psychological variables: sleep quality, depression, anxiety, quality of life, cognitive complaints, cancer worries, fatigue catastrophizing, and self-efficacy to manage with fatigue complaints. Moreover, biological levels of cortisol and melatonin will be measured in saliva. Blood samples will be used to assess vitamin D, hsIL-6, sTNF-RII, IL-1RA, hsCRP, and genotype.

Study description

Background summary

Cancer related fatigue (CRF) is one of the most prevalent and distressing long-term complaints reported by (non-)Hodgkin survivors. So far, there is no standard treatment. Some non-pharmacological interventions have shown large effects but show limitations as well, e.g. they are labour intensive. A novel and promising treatment for CRF is exposure to bright white light (BWL)

therapy. This low-cost intervention is easy to deliver and has a low burden for professionals as well as for patients.

Study objective

(1) To examine whether the exposure to BWL yields clinically significant reductions in CRF compared to exposure to dim white light in (non-)Hodgkin survivors.
(2) To examine the effect of exposure to BWL compared to DWL on sleep quality and psychological variables (depression, anxiety, cognitive complaints, and quality of life).
(3) To investigate whether exposure to BWL, compared to DWL, affects biological circadian rhythms (reflected in variability in cortisol and melatonin levels), circadian physical activity rhythms (actigraph), and concentrations of vitamin D and inflammation markers (hsIL-6, hsCRP, sTNF-RII, and IL-1RA).
(4) To explore whether the effects of exposure to BWL, compared to DWL, on CRF are predicted by the effect of BWL on sleep quality, psychological variables, biological and physical activity circadian rhythms, and biological factors associated with fatigue.
(5) To explore the association between changes in the production of cortisol and melatonin with cancer related fatigue.
(6) To investigate whether the efficacy of light therapy is associated with specific genotypes.

Study design

This explanatory clinical trial will use a double blind randomized controlled trial design with one intervention group exposed to BWL and a control group exposed to DWL. Upon completion of the study, the patients assigned to the control group will be given the opportunity to receive the intervention.

All participants will be asked to complete a battery of questionnaires prior to light therapy (T0), immediately post-intervention (T1), at 3 months (T2) and at 9 months (T3) follow-up. Furthermore, participants will be asked to wear an actigraph to determine sleep-wake cycles for 10 days at all measurement points. This will be combined with the completion of a sleep diary. Moreover, blood and saliva samples will be collected at T0 and T1 for those participants that consent to provide these materials.

Intervention

The light intervention includes exposure to bright white light (10.000 lux at a distance of 45 cm) for 30 minutes within the first half hour after awakening during 3 weeks and 4 days. This can be done while engaged in other activities, for example reading the newspaper or eating breakfast). Participants in the control condition receive the same instructions but are exposed to dim white

light (10-20 lux at a distance of 45 cm).

Study burden and risks

Participation in this study includes completion of a light intervention for three weeks and four days (30 min each day) and 2 visits (1h) to the treating hospital pre- and post-intervention. The visits aim to complete three cognitive tasks (15 min), provide instructions and equipment and to collect blood samples (two tubes per visit). Additionally, 5 (or 10) saliva samples will be collected by the participant at home pre- and post-intervention. Moreover, participants complete questionnaires (30 min, 4 times) and wear an accelerometer (10d, 4 times) to objectively measure sleep quality and activity. Risks of the light intervention are limited, although there are few known reports of agitation, headache and nausea during the first days of light exposure. Benefits are the use of an easy to administer treatment for one of the most distressing symptoms frequently reported by (non-) Hodgkin survivors.

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

(Non-)Hodgkin lymphoma survivors (survivorship of min. 2 years) with moderate to severe fatigue symptoms; or survivors with moderate to severe restrictions on work and social activities to avoid clinical levels of fatigue.

Exclusion criteria

Fatigue is explained by a somatic factor as defined in the guidelines of chronic fatigue syndrome of the Dutch internists association; or fatigue is explained by the treatment of (treatment for) secondary cancer in the past 12 months.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-07-2017
Enrollment:	160
Type:	Actual

Medical products/devices used

Generic name:	Luminette
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	09-05-2017
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	25-05-2017
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	13-07-2017
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	14-09-2017
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	25-01-2018
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	26-04-2018
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO	

Date:	12-07-2018
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	26-09-2018
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	27-09-2018
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	21-11-2018
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL61017.031.17