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Combined wake and light therapy in children and adolescents with depression and affective dysregulation

Submission date
13/08/2013

Recruitment status
No longer recruiting

Registration date
30/09/2013

Overall study status
Completed

Last Edited
10/07/2015

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronotherapeutic treatments such as bright light therapy (BLT), wake therapy (WT) and sleep phase advance (SPA) have been successful for the treatment of adults with seasonal and major depression. WT is the fastest acting antidepressant we know. The combination with BLT leads to a stabilization of the anti-depressive effect. To our knowledge, the effect of a combined WT and BLT has never been studied in adolescents suffering from juvenile depression. Juvenile depression is becoming more common and established treatments like medication and psychotherapy are insufficient. Furthermore, the vast majority of patients suffer from sleeping disorders. Wake and light therapy could be powerful instruments for patients with juvenile depression because of their large positive impact on sleep patterns and their anti-depressive effect. Our study aims to find out whether a combined wake and light therapy has an additional benefit compared to light therapy alone.

Who can participate?
We recruit 60 boys and girls, aged 13 to 18 years, who are admitted to the hospital suffering from moderate to severe depressive symptoms.

What does the study involve?
Participants are randomly allocated to one of two groups: the control group or the experimental group. The control group receives active morning BLT lasting for two weeks and the experimental group receives one night of WT followed by two weeks of active morning BLT. The experimental group patients stay awake for one whole night and they are not allowed to sleep until 5 pm the next day. All patients take part in ten sessions of morning BLT which last 45 minutes each. We use UV-filtered white light. At the end of the study we compare the depressive symptoms, sleep, attention, day and night time activity level, and various other parameters. The patients are followed up immediately after treatment, and two weeks, four weeks and six months after the treatment.

What are the possible benefits and risks of participating?
Our study is an add-on therapy and all patients receive treatment as usual (TAU) in the hospital.

The chronotherapeutic treatment could lead to a faster improvement of depressive symptoms. It is non-invasive and has almost no side-effects. Rarely patients suffer from headache or stinging eyes caused by the bright light.

Where is the study run from?
The study is run from LWL-University Hospital for Child and Adolescents Psychiatry, Hamm, Germany.

When is the study starting and how long is it expected to run for?
The study started in December 2012 and the recruitment is expected to end in December 2013. The data collection will end in July 2014.

Who is funding the study?
LWL-University Hospital of Child & Adolescent Psychiatry, Hamm, Germany.

Who is the main contact?
Prof.Martin Holtmann
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Combined wake and light therapy in children and adolescents with depression and affective dysregulation: a randomized controlled trial

Study objectives

In adults, chronotherapy has been established as an adjunctive treatment for major depression, not only for seasonal affective disorder. Preliminary results indicate that chronotherapy (light therapy, sleep deprivation, sleep phase advance) might also be helpful more generally for disorders with a disturbed circadian rhythm, such as for attention defecit hyperactivity disorder (ADHD) and affective dysregulation. Up to date, the efficacy of chronotherapy for children and adolescents has not been investigated before. We want to accomplish a combined total sleep deprivation/ wake therapy and light therapy study (CoWaLi-study) and compare the effects on depressive symptoms, sleeping behaviour, affective dysregulation and ADHD-Symptoms of the combined design with light therapy alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the Department of Medicine, Ruhr University Bochum, 26/09/2012, ref: 4418-12

Study design
Randomized controlled parallel-group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Juvenile depression and affective dysregulation

Interventions
Patients will be randomly assigned to the following two groups (2:2).
1. Control group:
45 min morning light therapy (10.000 Lux, DAVITA LD 110) approx. 8.5 h after estimated melatonin-onset [DLMO, assessed by the morningness-eveningness-questionnaire (MEQ)] for 10 consecutive days, excluding the weekend.
2. Experimental group:
One night of total sleep deprivation in an attended group setting of 2 to 4 patients followed by two weeks morning light therapy as in the control group.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Change in depression rating scale at pre-test, post tests: directly after intervention (post-test 1), two weeks after intervention (post-test 2), four weeks after intervention (post-test 3) and 6 months after intervention (follow up) (assessed by BDI-II)

Key secondary outcome(s))
The following will be assessed at pre-test, all post-tests and at the follow up:
1. Clinical Global Impressions - Severity (CGI-S) Scale (at pre-test) and Clinical Global Impressions - Improvement (CGI-I) Scale (at all post-test)
2. Sleep parameters (Schlaffragebogen B; Görtelmeyer, 2011)
3. Number of responders (Clinical Global Impression- Improvement (CGI-I) from 1 to 2 / 25% improvement on BDI-II)
4. Strengths and Difficulties Questionnaire parent- and self-rating (SDQ; Goodman et al., 1997) (not at post-test 3)
5. Parameters of attention: alertness, flexibility, divided attention, go/nogo (not at post-test 3)
6. Dim Light Melantonin Onset (DLMO) (not at follow up)
7. Assessment of adverse events

The following parameters are only accessed once:
1. Therapy expectancy (pre-test)
2. Assessment of the individual chronotype (Horne-Ostberg-Morningness-Eveningness-Questionnaire, MEQ german version; D-MEQ; Griefahn et al., 2001) (pre-test)
3. Child Behaviour Checklist (CBCL) / 4-18 (pre-test)
4. Activation level at day and night while intervention determined by actimeters

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Moderate to severe depression assessed by the Beck Depression Inventory (BDI-II)
2. Boys and girls aged 13-18 years
3. Ability of a patient to understand character and individual consequences of such a clinical trial
4. Written informed consent of the person with primary custody must be available before enrolment in the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
13 years

Upper age limit
18 years

Sex
All

Key exclusion criteria
1. Acute suicidality
2. Pregnancy or lactation
3. Treatment with beta-blocker
4. Bipolar 1 Disorder, schizophrenia
5. Diseases of the eye with involvement of the retina
6. Highly potent neuroleptics
7. Narcolepsy

Date of first enrolment
01/12/2012

Date of final enrolment
01/12/2013

Locations

Countries of recruitment
Germany

Study participating centre
LWL University Hospital Hamm of the Ruhr- Universität Bochum
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Sponsor information

Organisation
Ruhr University Bochum (Germany)

ROR
https://ror.org/04tsk2644

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes