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Chronotherapy in children and adolescents with depression and affective dysregulation

Submission date
01/08/2011

Recruitment status
No longer recruiting

Registration date
11/08/2011

Overall study status
Completed

Last Edited
16/01/2014

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Chronotherapy (including light therapy) helps adults suffering from depression to get better. This initial study investigates the possible effects of chronotherapy on mood, attention and sleep in children and adolescents.

Who can participate?
You can be included when you are an inpatient between the age of 12 and 18 with a moderate to severe depression and you do not get any medication (antidepressants, neuroleptics or beta-blocker).

What does the study involve?
You will receive morning light therapy for 14 consecutive days, each day for 45 minutes at an individually determined time point that fits your biological sleep rhythm (whether you are a morning, evening or in-between type)
Two groups are compared: you either receive active light therapy with 10.000 Lux or inactive light therapy with 100 Lux
Psychological and physiological tests are made before and after the intervention and again after a few weeks to investigate changes of your depression, sleep rhythm and other parameters

What are the possible benefits and risks of participating?
Benefits of chronotherapy include symptom amelioration, additional therapeutic offer for inpatients, possibility of a treatment without medication, high predictability of the mechanisms of action.
Possible risks of chronotherapy include headache, nausea, irritability, burning eyes, unexpected awakening during the night.

Where is the study run from?
The study takes place in the LWL-University Hospital Hamm in Germany

When is the study starting and how long is it expected to run for?
The study started in August 2011 and will last until August 2014.

Who is funding the study?
Funded by the study investigator.

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Chronotherapy in children and adolescents with depression and affective dysregulation: a double-blind 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. The primary objective in a first pilot trial is to investigate the effects of light therapy on depression and affective dysregulation in children and adolescents.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Department of Medicine, Ruhr University Bochum approved on 27th June 2011 (ref: 3996-11)

Study design
Double-blind randomized controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
Patients will be randomly assigned to the following two groups (1:1).

Experimental 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 14 consecutive days. When theres no improvement of depressive symptoms within the first 3 days of the intervention (assessed by the BDI II), the duration can be prolonged to 60 min to reach maximal effects.

Control group
45 min "inactive morning light therapy (approx. 100 Lux, DAVITA Luxor LED), approx. 8.5 h after estimated melatonin-onset (DLMO, assessed by the morningness-eveningness-questionnaire (MEQ)) for 14 consecutive days. A luxmeter (PCE-172) will ensure that the number of lux will be held constantly low.

After a "light therapy" pilot trial has been conducted, a combination trial with sleep deprivation (wake therapy), sleep phase advance and early morning light therapy will be realised.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Change in depression rating scale at pre-test, post-test 1, post-test 2, post-test 3, post-test 4 and follow up (assessed by BDI II)

Secondary outcome measures
The following will be assessed at pre-test, post-test 1, and follow-up:
1. Clinical Global Impressions - Severity (CGI-S) Scale (at pre-test) and Clinical Global Impressions - Improvement (CGI-I) Scale (at post-test 1 and follow-up)
2. Sleep parameters (Schlaffragebogen B; Görtelmeyer, 2011)
3. Number of responder [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)
5. Parameters of attention: alertness, flexibility, Go-No / Go, divided attention (Zimmermann & Fimm, 2009)
6. Dim Light Melantonin Onset (DLMO) and cortisol saliva-melatonin and saliva-cortisol
7. Therapy expectancy
8. Assessment of the individual chronotype (Horne-Ostberg-Morningness-Eveningness-Questionnaire, MEQ german version; D-MEQ; Griefahn et al., 2001)
9. Child Behaviour Checklist (CBCL) / 4-18
10. Assessment of adverse events

Overall study start date
01/08/2011

Completion date
01/08/2014

Eligibility

Key inclusion criteria
1. Moderate to severe depression [assessed by the Beck Depression Inventory (BDI) II]
2. 12-18 years of age
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

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
30. 16/01/2014: number is 60.

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

Date of first enrolment
01/08/2011

Date of final enrolment
01/08/2014

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)

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Sponsor type
University/education

Website
http://www.ruhr-uni-bochum.de

ROR
https://ror.org/04tsk2644

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	17/06/2013		Yes	No