

# Chronotherapy in children and adolescents with depression and affective dysregulation

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		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 11/08/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 16/01/2014	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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**  
Prof Martin Holtmann

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## Additional identifiers

**Protocol serial number**  
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 deficit 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

## **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 (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 there is 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(s)**

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)

## **Key secondary outcome(s)**

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 Melatonin 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

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

12 years

**Upper age limit**

18 years

**Sex**

All

**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

Hamm

Germany

59071

## 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

[Protocol article](#)

Details  
protocol

Date created

17/06/2013

Date added

Peer reviewed?

Yes

Patient-facing?

No