

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

<b>Submission date</b> 13/08/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/09/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/07/2015	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

[martin.holtmann@wkp-lwl.org](mailto:martin.holtmann@wkp-lwl.org)

### **Study website**

<http://www.lwl-jugendpsychiatrie-hamm.de/herzl-willkommen2/>

## **Contact information**

### **Type(s)**

Scientific

### **Contact name**

Prof Martin Holtmann

### **Contact details**

LWL University Hospital Hamm of the Ruhr- Universität Bochum

Clinic of Child and Adolescent Psychiatry, Psychotherapy and Psychosomatic Medicine

Heithofer Allee 64

Hamm

Germany

59071

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[martin.holtmann@wkp-lwl.org](mailto:martin.holtmann@wkp-lwl.org)

## **Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 deficit 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

## Secondary study design

Randomised parallel 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 (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 measure**

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)

**Secondary outcome measures**

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 Melatonin 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

**Overall study start date**

01/12/2012

**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

**Age group**

Child

**Lower age limit**

13 Years

**Upper age limit**

18 Years

**Sex**

Both

**Target number of participants**

30 / 30

**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

Hamm

Germany

59071

**Sponsor information**

**Organisation**

Ruhr University Bochum (Germany)

**Sponsor details**

Department of Child and Adolescent  
Psychiatry and Psychotherapy  
Postbox 102148  
Bochum  
Germany  
44721

**Sponsor type**

University/education

**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