

# Effectiveness of Sleep Promotion Program on Sleep behavioral Practices among Adolescents in Selected Schools

<b>Submission date</b> 04/09/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
<b>Registration date</b> 10/09/2015	<b>Overall study status</b> Completed	
<b>Last Edited</b> 29/01/2019	<b>Condition category</b> Mental and Behavioural Disorders	

## Plain English summary of protocol

### Background and study aims

Sleep plays an important role in both physical and emotional wellbeing. Studies have shown that many adolescents do not get enough sleep at night, and as many as 25% report less than six hours of sleep each night. There is a lot of evidence to suggest that not getting enough sleep can have a negative influence on academic performance, as when we are asleep, information that is learned throughout the day is converted into long term memories (memory consolidation). Sleep has also been found to play a key role in lowering stress levels, and so not getting enough sleep can lead to mood disturbances such as anxiety or depression. It is recommended that adolescents need between eight and nine hours of sleep every night, in order to ensure that they are alert during the day. Treatment encouraging good sleep practices to counteract the adverse effects of lack of sleep is a relatively unexplored area of research. The aim of this study is to find out whether providing adolescents with an educational programme promoting good sleep hygiene would have a positive impact on their sleeping habits and alertness throughout the day.

### Who can participate?

Adolescents studying in schools in Mangalore who can understand the English language.

### What does the study involve?

Participants are randomly allocated into two groups. Those in the first group (intervention group) are provided with a sleep promotion programme. This involves educating participants about good sleep practices, teaching relaxation techniques and improving time management (planning and consciously controlling the time spent on different activities). Participants in the control group receive normal, routine education, with no additional training. Quality and length of sleep are assessed using questionnaires at the start of the study (baseline), after 10 days, and after 6 weeks.

### What are the possible benefits and risks of participating?

Possible benefits of participating include improving sleeping habits and quality of sleep. There are no known risks of participating in the study.

Where is the study run from?  
Nine schools in the Mangalore region of India.

When is the study starting and how long is it expected to run for?  
July 2011 to August 2014

Who is funding the study?  
Nitte University (India)

Who is the main contact?  
Ms Bindu John

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Ms Bindu John

**ORCID ID**  
<http://orcid.org/0000-0001-9749-0592>

**Contact details**  
College of Health Sciences  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
NU/CEC/Ph.D-44/2011

## Study information

**Scientific Title**  
Efficacy of Sleep Promotion Program on Sleep Hygiene Practices, Sleep Quality and Daytime Functioning among Adolescents in Selected Schools: A Randomized Controlled Trial

**Study objectives**

The study aims to look at the effect of sleep promotion program on adolescents' sleep hygiene practices, sleep quality, daytime sleepiness and at the moment functioning, compared with those adolescents' who are on a regular educational program in the schools.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Central Ethical Committee (Nitte University), 16/04/2012, ref: NU/CEC/Ph.D-44/2011

**Study design**

Multi-centre randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

School

**Study type(s)**

Quality of life

**Participant information sheet****Health condition(s) or problem(s) studied**

Sleep disturbances

**Interventions**

Participants are randomly allocated into the control group or the intervention group:

Intervention group: The treatment consisted of an educational intervention, which was provided in two sessions over a 30 minute and 20 min sessions; a visualization or imagery training which was provided over two sessions each with a duration of 25-30 minutes; and time management skills - which is combined along with second day of visualization training for 15 minutes. The whole intervention for the experimental group is completed over a 3 week period.

Control group: Provided with routine education with no additional training throughout the intervention period. Participants in the control group are offered the intervention after the end of the study (for ethical fairness).

**Intervention Type**

Mixed

**Primary outcome measure**

All outcomes are measured at baseline, after 10 days, and after 6 weeks:

1. Improvement in Sleep Hygiene Practices, measured using the sleep Hygiene Index questionnaire
2. Sleep Quality measured using the Pittsburgh Sleep Quality Index questionnaire

3. Daytime Sleepiness measured using the Cleveland Adolescent Sleepiness Questionnaire
4. Emotional functioning measured using the PedsQL TM- Present Functioning Scales (Visual Analog Scale)

### **Secondary outcome measures**

All outcomes are measured at baseline, after 10 days, and after 6 weeks:

1. Improvement in sleep duration measured using the questionnaire for collecting demographic data, with some additional questions regarding sleep (in hours and minutes). For example "How much sleep you get on a average during a school day?" and "How much sleep do you get on an average during a weekend?"
2. Improvement in self-reported sleep problems measured using the PSQI scale

### **Overall study start date**

01/07/2011

### **Completion date**

31/08/2014

## **Eligibility**

### **Key inclusion criteria**

1. Adolescents studying in various schools in Mangalore, India,
2. Aged from 11 to 17 years (grade VI to grade XII)
3. Who can comprehend English Language.

### **Participant type(s)**

Healthy volunteer

### **Age group**

Other

### **Sex**

Both

### **Target number of participants**

660

### **Key exclusion criteria**

1. Those who are diagnosed as having a sleep disorder or a psychiatric problem and who are on treatment
2. Those who are on medication for known allergies

### **Date of first enrolment**

11/07/2013

### **Date of final enrolment**

24/06/2014

## **Locations**

### **Countries of recruitment**

India

**Study participating centre**

**Kanachur Public School**

Mangalore University Road

Deralakatte

Mangalore

India

575 018

**Study participating centre**

**Narayana Guru College**

Barke Road

Kudroli

Mangalore

India

575 003

**Study participating centre**

**Lourdes Central School**

Bejai Church Road

Mangalore

India

575 004

**Study participating centre**

**Canara High School**

Kodailbail

Mangalore

India

575 003

**Study participating centre**

**St. Rita's English Higher Primary School**

Ccb Point

Attend

Kankanady

Mangalore

India

575 002

**Study participating centre****Canara High School**

Urwa

Nehru Avenue

Mangalore

India

575 006

**Study participating centre****Canara Higher Primary School**

Urwa

Mangalore

India

575 003

**Study participating centre****Cascia High School**

Jeppu

Mangalore

India

575 001

**Study participating centre****Sarojini Madhusudhan Kushe College**

P.V.S. Bhag,

Attavar

Mangalore

India

575 001

**Sponsor information****Organisation**

Nitte University

**Sponsor details**

Medical Sciences Complex

Deralakatte

Mangalore  
India  
575018

**Sponsor type**  
University/education

**Website**  
www.nitte.edu.in

**ROR**  
<https://ror.org/029nydt37>

## Funder(s)

**Funder type**  
University/education

**Funder Name**  
Nitte University

## Results and Publications

**Publication and dissemination plan**  
Part of the study to be published in 6 months, with the full study being published in 6-9 months.

**Intention to publish date**  
30/04/2016

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/01/2016	29/01/2019	Yes	No
<a href="#">Results article</a>	results	15/03/2017	29/01/2019	Yes	No