

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

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

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

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Protocol serial number
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

Study type(s)

Quality of life

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(s)

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)

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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

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

Funder(s)

Funder type

University/education

Funder Name

Nitte University

Results and Publications

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?
Results article	results	01/01/2016	29/01/2019	Yes	No
Results article	results	15/03/2017	29/01/2019	Yes	No