ISRCTN13083118 https://doi.org/10.1186/ISRCTN13083118

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

Submission date
04/09/2015

Recruitment status
No longer recruiting

Registration date
10/09/2015

Overall study status
Completed

Last Edited
29/01/2019

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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

Contact details
College of Health Sciences
Nursing Department
University of Bahrain
Sakeer
Bahrain
32038

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