The MTSM study: Evaluating the effectiveness of the Motivating Teens to Sleep More program in helping adolescents go to bed earlier

Submission date 02/07/2013	Recruitment status No longer recruiting	 Prospectively registered [X] Protocol
Registration date 17/07/2013	Overall study status Completed	 Statistical analysis plan Results
Last Edited 29/05/2020	Condition category Nervous System Diseases	 Individual participant data Record updated in last year

Plain English summary of protocol

Background and study aims

Evidence indicates that 61% of teenagers do not get enough sleep. Late bedtime is the main cause of lack of sleep. Therefore, we are carrying out this study to find out how teenagers can be motivated to go to bed earlier.

Who can participate? We aim to enrol 30 teenagers (age 12-18 years old) from a high school in Montreal, Canada.

What does the study involve?

The study involves four 1-hour sessions and the completion of several online questionnaires. The sessions will be one-on-one and will happen during four consecutive weeks. Participants will also complete online questionnaires, which assess sleep-related variables like bedtime.

What are the possible benefits and risks of participating?

Participation in this study can help the teenager go to bed earlier, which can have a positive impact on many aspects of his/her daily life (e.g. attention, mood). Also, they may better understand the importance of a good nights sleep, as well as ways to improve their sleep habits. It is expected that the findings of the study will help in understanding effective ways to encourage teenagers to go to bed earlier. It can potentially improve the overall health and wellbeing of teenagers. There are no anticipated risks of participation in this study.

Where is the study run from? This study is run from McGill University, Canada.

When is the study starting and how long is it expected to run for? Recruitment of participants started in November 2012. Participants will be enrolled in the study for four consecutive weeks. The study will end after collecting information from following the participants for 6 months. Who is funding the study?

This study is funded by the Doctoral Research Allowance and Doctoral Research Award of the Canadian Institute for Health Research (CIHR), Canada.

Who is the main contact? Ms Jamie Cassoff jamie.cassoff@mail.mcgill.ca

Contact information

Type(s) Scientific

Contact name Dr Reut Gruber

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Evaluating the effectiveness of the Motivating Teens to Sleep More program in advancing bedtime in adolescents: a randomized controlled trial

Acronym MTSM

Study objectives

It is hypothesized that adolescents participating in the Motivating Teens to Sleep More program will go into bed earlier, fall asleep earlier and obtain longer sleep duration than the participants in the control group (sleep education only).

The null hypothesis is that there will be no differences in bedtime, sleep onset and sleep duration between the experimental and the control group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study has obtained approval by the McGill Research Ethics Board in November 2012 (REB# 115-0912)

Study design One-month single-blinded randomized parallel group controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Other

Study type(s) Quality of life

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

Sleep restriction in adolescents

Interventions

Participants in the study will be randomly assigned to either the experimental arm (Motivating Teens to Sleep More program), or the active control group (sleep education only). Participants in both groups will undergo four one-on-one (the interventionist and the participant) 1-hour sessions during four consecutive weeks. Both arms of this sleep promotion program aim at improving adolescents sleep habits and will be delivered by doctoral students in Psychology trained in the necessary clinical techniques.

Participants in the active control group will receive sleep education only (i.e. presentations about why we need sleep, sleep in adolescence, sleep disorders etc.).

Adolescents in the experimental group will not only receive information about sleep but will also be encouraged to change their bedtime. The goal of the experimental session is to increase participants intrinsic motivation to go to bed earlier by using the principles of Motivational Interviewing, tailoring the session activities to personal characteristics and conducting session activities that are congruent with the participants current levels of readiness to go to bed earlier. Before the first session in both the experimental and control condition, each participant will fill out a computerized questionnaire to assess background characteristics and information related to their sleep behaviours and personal attitudes. In both conditions, participants will be asked to wear an actiwatch for a period of one week before and after completing the program in order to assess their sleep. An actiwatch is a small sleep-watch that records body movement during the night. Three months and six months after completing the sessions, all participants will be asked to complete a few questionnaires about their sleep habits.

Joint/Scientific contact details Drs. Bärbel Knäuper and Reut Gruber are Co-PIs on this study.

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Intervention Type Other

Phase Not Applicable

Primary outcome measure

 Bedtime, self-reported and assessed with an actiwatch (a small sleep-watch that records body movement during night) at baseline, mid-study, end of the study, three months and six months.
 Sleep onset, assessed with an actiwatch at baseline and at the end of the study.
 Sleep duration, assessed with an actiwatch at baseline, mid-study, end of the study, three months and six months.

Secondary outcome measures

1. Sleep-related self-efficacy, assessed with the Sleep Specific Self-Efficacy questionnaire (Watts, East & Coyle, 1995; Schwarzer & Renner, 2009) at baseline, after each session, at three months and six months.

2. Attitudes toward sleep, assessed with a Decisional Balance questionnaire (developed by the authors for this study) at baseline, after the study, at three months and six months.

Overall study start date

01/11/2012

Completion date 01/01/2015

Eligibility

Key inclusion criteria

1. The participants in this trial can be male or female between the ages of 12-18 years old

2. The participants in this trial obtain 8 or less hours of sleep during a weeknight

2. The participants in this trial are open to changing their sleep habits within the next year

Participant type(s)

Patient

Age group

Child

Lower age limit

12 Years

Upper age limit 18 Years

Sex

Both

Target number of participants 30

Key exclusion criteria The participants in this trial cannot not suffer from a medical, mental or sleep disorder.

Date of first enrolment 01/11/2012

Date of final enrolment 01/01/2015

Locations

Countries of recruitment Canada

Study participating centre Attention, Behaviour and Sleep Lab Verdun Canada H4H 1R3

Sponsor information

Organisation McGill University (Canada)

Sponsor details

c/o Lynda McNeil Research Ethics Officer, REB-I,II,III Office of the Vice-Principal (Research&International Relations) Research Ethics & Compliance James Administration Building, Room 429 845 Sherbrooke Street West Montreal Canada H3A 0G4 514-398-6831 lynda.mcneil@mcgill.ca

Sponsor type University/education

Website http://www.mcgill.ca/research/researchers/compliance/human/

ROR https://ror.org/01pxwe438

Funder(s)

Funder type Government

Funder Name

This study is funded by the Doctoral Research Allowance and Doctoral research award (Priority Announcement: Patient-Oriented Research) of the Canadian Institute for Health Research (CIHR) to Jamie Cassoff, PhD Candidate at McGill University (application number 291062).

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/12/2014	29/05/2020	Yes	No