Clinical Trial Registration

Study Protocol and Data Analysis Plan

Official Title: A School-based Sleep Education Program

Date: 24 July 2018

NCT ID: not yet assigned

Study Protocol

The present study aims to examine the effectiveness of a class-based interactive Sleep Education Program in improving sleep behavior of secondary school students. Participants will be randomly assigned to a Sleep Education Program or a Control Program. Participants in the Sleep Education Program will learn about the importance of sleep, what factors may prevent them from getting enough sleep, how they can manage their time to create more opportunity for sleep, and how they can overcome obstacles to time management. Participants in the Control Program will learn about various health-related topics, but will not learn about sleep. All participants will undergo four weekly class-based lessons, which use video presentations, in-class activities, discussions and take-home assignments to deliver the materials. Data will be collected on students' sleep habits, daytime functioning, mood, and time use at three time points: pre-program, immediately post-program and during a later follow-up. Sleep knowledge, habits, and attitudes towards sleep will be measured once during each time point using a sleep questionnaire. Sleep-wake patterns will be measured in two ways: objectively using actigraphy, and subjectively using sleep diaries. At each time point, participants will wear the actiwatch for one week, and during this week they will also fill in a daily sleep diary. Additionally, during the same period of one week they will rate their subjective mood and subjective sleepiness daily, and time use will be measured using a time use diary app. For this, participants are asked to chronologically log their daily activities in the diary over the one-week period. Activities recorded will be analyzed in order to find out which activities take up most of the students' time, and time spent on each activity will be correlated with data from various sleep variables, as collected by actigraphy and sleep diaries. Furthermore, time use data will be analyzed in order to asses if there are changes in the way students spend their time following the Sleep Education Program.

Statistical Analysis Plan

Primary outcome measures acquired in the current study are planned to be analyzed using SPSS Statistics (IBM) and MATLAB (MathWorks). Statistical analyzes that will be conducted include Analyses of Variance (ANOVAs), *t*-tests and correlations.

Primary Outcome Measure

1. Change in actigraphically measured sleep behavior between time 1 (pre-program), time 2 (post-program) and time 3 (follow-up), measured for one week in each of the three phases.

Actigraphy will be used to objectively measure the following sleep behavior variables: bedtime, wake up time, time in bed, total sleep time, sleep efficiency, and number and duration of daytime naps. Data will be collected daily over the period of one week, at three time points (pre-program, post-program and follow-up). ANOVAs will be used to analyze changes in each variable between and within the two groups throughout the program. The independent variables are group, time point, and their interaction. Analyses will be performed on the average within each week of data collection, as well as between each individual time point (pre-program, post-program and follow-up). Post-hoc tests will be used to compare groups.

2. Change in sleep dairy reported sleep behavior between time 1 (pre-program), time 2 (post-program) and time 3 (follow-up), recorded for one week in each of the three phases.

Sleep diaries will be used to subjectively measure the following sleep behavior variables: bedtime, wake up time, total sleep time, sleep efficiency, and number and duration of nighttime awakenings and daytime naps. Data will be collected daily over the period of one week, at three time points (pre-program, post-program and follow-up). ANOVAs will be used to analyze changes in each variable between and within the two groups throughout the program. The independent variables are group, time point, and their interaction. Analyses will be performed on the average within each week of data collection, as well as between each individual time point (pre-program, post-program and follow-up). Post-hoc tests will be used to compare groups.

3. Change in the level of subjective mood between time 1 (pre-program), time 2 (post-program) and time 3 (follow-up), measured once daily with a Mood Rating Scale over the period of one week.

Score on the mood rating scale (1-9 points) will be measured. Data will be collected once daily over the period of one week, at three time points (pre-program, post-program and follow-up). ANOVAs will be used to analyze changes in subjective mood between and within the two groups throughout the program. The independent variables are group, time point, and their interaction. Analyses will be performed on the average within each week of data collection, as well as between each individual time point (pre-program, post-program and follow-up). Post-hoc tests will be used to compare groups.

4. Change in the level of subjective sleepiness between time 1 (pre-program), time 2 (post-program) and time 3 (follow-up), measured once daily with the Karolinska Sleepiness Scale over the period of one week.

Score on the Karolinska Sleepiness Scale (1-9 points) will be measured. Data will be collected once daily over the period of one week, at three time points (pre-program, post-program and follow-up). ANOVAs will be used to analyze changes in subjective sleepiness between and within the two groups throughout the program. The independent variables are group, time point, and their interaction. Analyses will be performed on data within each week of data collection, as well as between each individual time point (pre-program, post-program and follow-up). Post-hoc tests will be used to compare groups.

5. Change in sleep knowledge, habits and attitudes between time 1 (pre-program), time 2 (post-program) and time 3 (follow-up), measured with a sleep questionnaire.

Score on the sleep knowledge questionnaire will be measured (12 questions, true or false). Data will be collected once at three time points (pre-program, post-program and follow-up). ANOVAs will be used to analyze changes in score on the sleep questionnaire between and within the two groups throughout the program. The independent variables are group, time point, and their interaction. Analyses will be performed on the average within each week of data collection, as well as between

each individual time point (pre-program, post-program and follow-up). Post-hoc tests will be used to compare groups.

6. Change in time use between time 1 (pre-program), time 2 (post-program) and time 3 (follow-up), measured daily with a time use diary over the period of one week.

Time use will be measured using a time use diary, in which activities are logged chronologically throughout the day. Data will be collected daily over the period of one week, at three time points (pre-program, post-program and follow-up). ANOVAs will be used to analyze changes in amount of time spent on different activities between and within the two groups throughout the program. The independent variables are group, time point, and their interaction. Analyses will be performed on the average within each week of data collection as well as separately for school days and free days, and also between each individual time point (pre-program, post-program and follow-up). Post-hoc tests will be used to compare changes between the two groups.

7. Relationship between sleep and time use.

Amount of time spent on each activity, measured by a time use diary, will be correlated with sleep variables, measured by actigraphy and a sleep diary, to identify types of activities that relate to short sleep. Data will be collected daily over the period of one week, at three time points (pre-program, post-program and follow-up). Pearson’s or Spearman’s correlations will be used to correlate scores on the different variables.