

Effects of music listening and music video interventions on sleep quality in adults with sleep disturbances

Submission date 06/08/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/08/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 22/07/2019	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Many healthy adults suffer from sleep disturbances. Some sleep disturbances may be serious enough to interfere with normal physical, mental, social and emotional functioning. Doctors may prescribe drugs for the treatment of some sleep disturbances, but sleeping pills increase drowsiness, are potentially addictive and can cause problems with memory and attention. Therefore, sleeping pills are usually not recommended for long-term treatment of sleeping problems. Music has long been considered a complimentary therapy for sleep problems. The right kind of music may soothe people into a perfect state of relaxation. However, the effectiveness of music is not completely clear yet. Besides music, some researchers found that music videos are another kind of complementary treatment for sleep, but to date, the effectiveness of using music and music videos is not widely confirmed yet. Therefore, the aim of this study is compare the effects of music and music videos on sleep quality in adults with sleep disturbances.

Who can participate?

People aged over 20 with sleep disturbances

What does the study involve?

Participants are randomly allocated to the control, music, and music video groups. Participants in the music group listen to Buddhist music during the 4 test days (Days 2–5) for 30 minutes before sleep. Participants in the music video group watch Buddhist music videos during the 4 test days (Days 2–5) for 30 minutes before sleep. Participants in the music and the music videos groups are instructed to not listen/watch to the music/music videos on the first night (Day 1) and the final night (Day 6). The control group receive no music and no music videos. Sleep is assessed using electroencephalography (a recording of brain activity) in the participants' homes and questionnaires.

What are the possible benefits and risks of participating?

Participants may benefit from the chance to help society by contributing to research, and the opportunity to be the first to benefit from Buddhist music/music videos, which may be more

effective than sleeping pills. Listening to music or watching music videos requires more time than just taking sleep pills, and may feel unpleasant if the music is not liked by the listeners.

Where is the study run from?
Tzu Chi University (Taiwan)

When is the study starting and how long is it expected to run for?
September 2014 to June 2016

Who is funding the study?
National Science Council (Taiwan)

Who is the main contact?
Prof. Hui-Ling Lai

Contact information

Type(s)
Scientific

Contact name
Prof Hui-Ling Lai

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NSC102-2628-B-320-001-MY3

Study information

Scientific Title
Effects of music and music video interventions on sleep quality: a randomized controlled trial in adults with sleep disturbances

Study objectives
Listening to music and watching music videos would improve sleep quality in adults with sleep disturbances.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethics Committee of Tzu Chi Hospital, 27/09/2013, ref: IRB102-91

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Sleep disturbances

Interventions

A randomized controlled trial was performed on 71 adults who were recruited from the outpatient department of a hospital with 1100 beds. After collecting baseline data, participants were randomly assigned to the control, music, and music video groups. The random allocation sequence was consecutively numbered for the participants and sealed, opaque envelopes determining groups were generated using a random number generator (Microsoft Excel) by a statistician. The statistician was not involved in the rest of the study.

The interventions consisted of listening to Buddhist music or watching Buddhist-related music videos (MVs). Both music and MV interventions have positive effects on sleep quality in elderly adults with insomnia. The music had tempos ranging from 60 to 80 beats/min, while the musical tempos of MV ranged from 60 to 85 beats/min. Both of the music and MV used in this study had minor tonalities, and smooth melodies to achieve a deep relaxing effect. The research team members included a physician, registered nurses, and a musician. After collecting pretest sleep parameters on the first night (Day 1), the two music interventions were implemented on 4 consecutive nights (Days 2–5). On Day 6, no music or MV intervention was administered to evaluate the persistent effects on sleep parameters.

Participants in the music group listened to Buddhist music during the 4 test days (Days 2–5) for 30 min before nocturnal sleep. Participants in the MV group watched Buddhist music videos during the 4 test days (Days 2–5), for 30 min before nocturnal sleep. The participants in the music and the MV groups were instructed to not listen/watch to the music/MV on the first night (pretest, Day 1) and the final night (Day 6). The control group received no music and no MV

intervention. Sleep was assessed using a one-channel electroencephalography machine in the participants' homes and self-reported questionnaires.

Intervention Type

Other

Primary outcome measure

Objective sleep quality, measured by electroencephalography at baseline (Day 1), Day 2, Day 3, Day 4, Day 5, and Day 6

Secondary outcome measures

Subjective sleep quality, measured by self-reported questionnaire at baseline (Day 1), Day 2, Day 3, Day 4, Day 5 and Day 6

Overall study start date

01/09/2014

Completion date

30/06/2016

Eligibility**Key inclusion criteria**

1. Have experienced sleep disturbances, defined as Pittsburgh Sleep Quality Index (PSQI) > 5, sleep onset latency (SOL) > 30 min, wake time after sleep onset (WASO) > 30 min, or total sleep time (TST) \leq 6.5 h
2. Aged \geq 20 years

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

71

Total final enrolment

71

Key exclusion criteria

1. Neurological or psychiatric problems
2. Pregnant or nursing women
3. A history of alcohol or drug abuse

Date of first enrolment

03/09/2014

Date of final enrolment

30/04/2016

Locations

Countries of recruitment

Taiwan

Study participating centre

Tzu Chi University

Taiwan

970

Sponsor information

Organisation

Tzu Chi University

Sponsor details

No. 701, Section 3, Zhongyang RD

Hualien

Taiwan

970

Sponsor type

University/education

Website

<http://www.tcu.edu.tw/>

ROR

<https://ror.org/04ss1bw11>

Funder(s)

Funder type

Research council

Funder Name

National Science Council

Alternative Name(s)

National Science Council, Taiwan, National Science Council of Taiwan, NSC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Taiwan

Results and Publications

Publication and dissemination plan

The trialists plan to publish the study results in a high-impact peer reviewed journal. The study protocol and statistical analysis will be available in the journal that they intend to submit to.

Intention to publish date

09/09/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available because the participants' permission was not obtained.

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	01/10/2017	22/07/2019	Yes	No