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App-based cognitive behavioral therapy for sleep problems in cancer patients

Submission date
30/01/2020

Recruitment status
No longer recruiting

Registration date
13/02/2020

Overall study status
Completed

Last Edited
28/03/2023

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
Cancer not only creates physical problems but can also cause psychological problems, including sleep-related problems. Sleep-related problems, including insomnia, are known to be effectively treated using cognitive-behavioral therapy (CBT). However, CBT is expensive in terms of space, time, and monetarily. Therefore, in this study, a CBT mobile application was developed, and the aim of this study is to find out whether the developed mobile application is effective in reducing sleep-related problems in cancer patients.

Who can participate?
Those aged 16-65 years with a past diagnosis of any type of cancer may participate.

What does the study involve?
The study involves filling out a few questionnaires, and doing a simple 10-minute computer task. After this step, the participant will be randomly placed in a group which either uses or does not use a mobile application. In the group that uses a mobile application, CBT methods will be taught everyday for 10-15 minutes on weekdays for 66 days. After 66 days for all groups, the questionnaires and computer task that was previously done will be completed again, after which participation is ended.

What are the possible benefits and risks of participating?
Benefits of the study are that participants, regardless of which group they are placed in, will have access (at the end of the study for some groups) to the CBT application which may help them reduce their sleep-problems. Risks include fatigue from using mobile phones, or having to access the application everyday.

Where is the study run from?
Yonsei University (South Korea)

When is the study starting and how long is it expected to run for?
April 2016 to April 2019

Who is funding the study?
National R&D Program for Cancer Control, Ministry of Health and Welfare, Republic of Korea (HA16C0021)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRB No. 7001988-315 201901-SB-153-17

Study information

Scientific Title
A pilot randomized controlled trial on an app-based cognitive behavioral therapy program for sleep problems in cancer patients

Study objectives
The intervention group that used an app-based CBT program will have less sleep-related symptoms compared to a control group that did not use an app-based CBT program.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/12/2019, Yonsei University Institutional Review Board (), ref: IRB NO. IRB No. 7001988-315 201901-SB-153-17

Study design
Multi-centered interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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-problems in cancer patients

Interventions
All participants went through the following steps: screening, pre-intervention assessment, intervention in the intervention or attention control group or waiting in the waitlist control group, and post-intervention assessment.

The participants who met the inclusion criteria were randomly assigned to the three groups (HARUToday Sleep, HARUCard Sleep, and waitlist control group). Each participant drew a card from a shuffled deck of three cards, one for each group, and was assigned into the drawn group. Participants were blinded about which treatment they were receiving and what type of groups were being compared in the study.

HARUToday Sleep:
The participants installed the HARUToday Sleep program on their personal smartphones after the pre-intervention assessment and were instructed to complete one session per day for a total of 10 weeks (66 days) at home, excluding weekends.
The HARUToday Sleep program is composed of five cognitive behavioral therapy zones and 48 sessions, each of which takes approximately 10 to 15 minutes to complete. All sessions are composed of four phases: 1) Sleep quality rating, 2) Lesson, 3) Summary, and 4) Quizzes. In the

“Sleep quality rating” phase, participants rate their sleep quality from 0 points to 10 points, after which there was a “Lesson” phase, “Summary” phase, and “Quiz” phase. Other features included reward and prompting systems.

HARUCard Sleep:
The HARUCard Sleep program was developed for the attention control group. This group was added in order to control, at least partially, the confounding factor of viewing and paying attention to a mobile application during the training period. Participants in this group received cancer-related information or information on how to manage sleep problems for 66 days, for one session a day, excluding weekends. The sleep quality ratings, as well as the reward and prompting system, were the same as in the HARUToday program.

Participants in all groups completed the same pre-intervention assessment package, which included two questionnaires and a dot-probe computer task.

Trained research assistants administered both the questionnaires and the computer task. All assessments were carried out in laboratory spaces within the present institution or in empty spaces within hospitals.

All participants from the three groups returned to the research lab or the hospital within two weeks of completing the program for the post-intervention and completed the satisfaction survey and post-intervention assessment.

All participants who completed the post-intervention assessment received a monetary reward, and those who were in the attention control or waitlist control group were provided with the HARUToday Sleep app upon request.

Intervention Type
Behavioural

Primary outcome measure
Sleep quality measured using the Pittsburgh Sleep Quality Index score at baseline, and after the intervention was completed (66 days excluding weekends)

Secondary outcome measures
Measured at baseline, and after the intervention was completed (66 days excluding weekends):
1. Attention bias measured using the attentional bias score
2. General health measured using the Short-Form 36 score
3. Program satisfaction using the program satsfaction questionnaire

Overall study start date
30/04/2016

Completion date
30/04/2019

Eligibility

Key inclusion criteria
1. All genders
2. Age range of 16-65 years

3. Has a past diagnosis of any type of cancer
4. 8.5 points or more on the Pittsburgh Sleep Quality Index (PSQI)
4. Taking no medications (such as antidepressants)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
66

Total final enrolment
57

Key exclusion criteria
Taking sleep-related medication

Date of first enrolment
01/06/2018

Date of final enrolment
28/02/2019

Locations

Countries of recruitment
Korea, South

Study participating centre
Yonsei University
50 Yonsei-ro
Seodaemun-gu
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Sponsor information

Organisation
Yonsei University

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Sponsor type
University/education

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Funder(s)

Funder type
Government

Funder Name
Ministry of Health and Welfare

Alternative Name(s)
Ministry of Health, Welfare and Family Affairs, MOHW

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Korea, South

Results and Publications

Publication and dissemination plan
A paper describing the results of the study will be published in 2020, and the application is currently being freely disseminated on mobile application stores.

Intention to publish date

01/03/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/06/2022	28/03/2023	Yes	No