Testing the effectiveness of online cognitive behavioral therapy for insomnia compared to waiting list on sleep-efficiency in adolescent and young adults after childhood cancer.

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Objectives: 1) to evaluate the effectiveness of the e-CBT-i *i-Sleep* compared to a waiting list condition on sleep efficiency at 3, 6 and 12 months in ACC. 2) to assess the effects of eCBT-I on secondary outcomes: fatigue, quality of life, chronic…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sleep disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON50766

Source
ToetsingOnline

Brief title
Managing Insomnia after cancer in adolescents (MICADO-2 project)

Condition

- Sleep disorders and disturbances

Synonym
Insomnia, sleeplessness

Research involving
Human

Sponsors and support

Primary sponsor: Prinses Máxima Centrum voor Kinderoncologie
Source(s) of monetary or material Support: KWF

Intervention

Keyword: childhood cancer, cognitive behavioral therapy, insomnia, online

Outcome measures

Primary outcome

The main outcome sleep efficiency will be evaluated at baseline (T0), 3 (T3), 6 (T6) and 12 (T12) months after randomization. Sleep efficiency will be measured with a 7-day watch Actigraph (GTX3+) and sleep log. SE contains information on difficulties falling asleep as well as difficulties staying asleep and is therefore often considered the best primary outcome measure as it represents different types of sleep problems.

Secondary outcome

Insomnia: Insomnia Severity Index (ISI)

Quality of life: Pediatric Quality of Life Inventory (PedsQL)

Fatigue: Checklist Individual Strenght (CIS)

Depressive and Anxiety symptoms: Hospital Anxiety and Depression Scale (HADS)

Chronic stress: Chronic Stress Questionnaire for Children and Adolescents (CSQ-CA)

General questionnaire will also be assessed with suicidality and current psychological treatment for psychopathology on T0 and subjective pain, sleep medication use on T3, T6 and T12.

Post-treatment intervention feedback and satisfaction of i-Sleep will be

evaluated at T3 with a a 20-item satisfaction questionnaire, adherence and

intervention feedback per session.

Study description

Background summary

Insomnia after childhood cancer is prevalent (26-28%) and a disabling sleep disorder impacting quality of life, fatigue, pain and general functioning. Adolescents after childhood cancer (ACC) may be also at increased risk for insomnia, being critically ill during a phase of life that is important in the development of good sleep habits. Currently, screening for insomnia is not routinely done and guidelines for treatment are lacking within pediatric oncology. The first-line treatment of insomnia is the cognitive behavioral therapy for Insomnia (CBT-I)- protocol. However, access this care is often limited. Therefore, the online CBT-I treatment *i-Sleep* has been developed to facilitate access via online care. i-Sleep has been shown feasible and effective in adult (cancer) patients, but it is unknown if online CBT-I is feasible and effective in adolescents after cancer treatment.

Study objective

Objectives:
1) to evaluate the effectiveness of the e-CBT-i *i-Sleep* compared to a waiting list condition on sleep efficiency at 3, 6 and 12 months in ACC.
2) to assess the effects of eCBT-I on secondary outcomes: fatigue, quality of life, chronic stress and psychosocial functioning.
3) To psychometrically assess the responsiveness of the PROMIS sleep item banks over time.
4) Feasibility and acceptability of i-Sleep in the target population

Study design

Randomized-controlled clinical trial with two conditions: 1) e-CBT-I and 2) a waiting-list condition, stratified on sleep medication use in the past month. There are 3 (control group) to 4 (intervention group) measurement at T0, T3, T6 and T12. After T6 participants in the waiting-list condition are offered to also follow the e-CBT-I.

Intervention

Participants that are randomized to the intervention group will receive 5 online sessions within the eCBT-I program i-Sleep over 5-8 weeks supported by

an online coach. The coach will be a trained and supervised by a clinical psychologist. Participants in the waiting-list (WL) group will be asked not to seek any new sleep interventions for the duration of the study. After 6 months they will be offered the eCBT-I program.

Study burden and risks

The risks for taking part in this study are minimal. Participants will invest time to complete the e-CBT-I program. The time-burden of the accompanying measurements per time-point are: wearing an Actigraph for 7 days, sleep log (+/- 1 minute/day) and filling out questionnaires (25-30 min.). We expect that participation will improve insomnia complaints and increase the quality of life of the participants. Patients that are allocated to the WL-group, are therefore offered the program after 6 months.

Contacts

Public
Prinses Máxima Centrum voor Kinderoncologie

Heidelberglaan 25
Utrecht 3584 CS
NL
Scientific
Prinses Máxima Centrum voor Kinderoncologie

Heidelberglaan 25
Utrecht 3584 CS
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)

Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- insomnia symptoms according to the ISI >= 8
- diagnosed with cancer
- diagnosed with cancer within the last 10 years
- 12-30 years old at time of study participation

Exclusion criteria

- anti-cancer treatment within the last 6 months
- patients receiving palliative therapy
- patients that are not able to properly fill out the study questionnaires or participate in the online CBT-I because they are insufficiently fluent in Dutch or have significant cognitive impairment
- patients with comorbidities that can affect sleep: retinoblastoma with severely diminished eye-sight, schizophrenia, substance abuse or history of seizure disorder or seizure in the past 12 months
- pregnancy or had a baby <6 months
- shift work employment
- current psychological treatment for a sleeping disorder or psychopathology
- comorbid sleep disorders explain the sleep problems instead of insomnia as assessed in telephonic screening.
- suicidality
- lack of informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-01-2019
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	01-08-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	14-11-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-04-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-10-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-12-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	02-12-2021
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27901
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	inschrijving NTR/NCT na goedkeuring METC
CCMO	NL65009.041.18
OMON	NL-OMON27901