The effectiveness of an online intervention for insomnia 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	Leukaemias
Study type	Interventional

Summary

ID

NL-OMON27901

Source
Nationaal Trial Register

Brief title
MICADO-2

Condition

- Leukaemias

Health condition

childhood cancer insomnia

Research involving
Human

Sponsors and support

Primary sponsor: Prinses Máxima Centrum voor kinderoncologie

Source(s) of monetary or material Support: KWF

Intervention

- Psychosocial intervention

Explanation

Outcome measures

Primary outcome

The primary outcomes include sleep efficiency (actigraphic) and insomnia severity (self-report) and 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. Insomnia severity is measured with the Insomnia Severity Index (ISI)-questionnaire.

Secondary outcome

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. Therefore, we will evaluate the effectivity of the online CBT-i: i-Sleep youth for adolescents after cancer within a

randomized controlled trial compared to a waiting-list control. Managing Insomnia after Childhood cancer in Adolescents (MICADO-2).

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

Four time points: at baseline (T0), posttreatment after 3 months (T3), follow-up after 6 months (T6) and after 12 months (T12).

Intervention
Online cognitive behavioral therapy (iSleep youth)

Contacts

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Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (12-15 years)
Adolescents (16-17 years)
Adolescents (16-17 years)
Adults (18-64 years)
Adults (18-64 years)

Inclusion criteria

- diagnosed with insomnia according to the DSM-5 criteria (ISI>8)

- diagnosed with cancer before the age of 19 years

- diagnosed with cancer within the last 7 years

- 12 years or older at the time of the study

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 parent of a newborn <6 months

- shift work employment

- current psychological treatment for a sleeping disorder or psychopathology

- suicidality

- lack of informed consent

Study design

Design

Study phase:	4
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Supportive care

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2018
Enrollment:	70
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO

Date:	31-07-2018
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

ID: 50766
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7220
NTR-old	NTR7419
CCMO	NL65009.041.18
OMON	NL-OMON50766

Study results