Effectiviteit van een online cursus voor slapeloosheid na kinderkanker

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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…

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Leukemieën
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27901

Bron
Nationaal Trial Register

Verkorte titel
MICADO-2

Aandoening

- Leukemieën

Aandoening

childhood cancer insomnia

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Prinses Máxima Centrum voor kinderoncologie
Overige ondersteuning: KWF

Onderzoeksproduct en/of interventie

- Psychosociale interventie

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Online cognitive behavioral therapy (iSleep youth)

Contactpersonen

Publiek

Princess Maxima Center for childhood oncology
Shosha Peersmann
Utrecht
The Netherlands
+31650006730

Wetenschappelijk

Princess Maxima Center for childhood oncology
Shosha Peersmann
Utrecht
The Netherlands
+31650006730

Deelname eisen

Leeftijd
Adolescenten (12-15 jaar)
Adolescenten (12-15 jaar)
Adolescenten (16-17 jaar)
Adolescenten (16-17 jaar)
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Fase onderzoek:	4
Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geen controle groep

Doel:	Verzorging

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2018
Aantal proefpersonen:	70
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Goedgekeurd WMO

Datum:	31-07-2018
Soort:	Eerste indiening
Toetsingscommissie:	METC NedMec

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50766
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Register	ID
OMON	NL-OMON50766

Resultaten