Modifying psychologicAl Treatment to the CHaracteristics and needs of cancer survivors.

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- Personalized psychological care is more efficacious than standard, non-personalized psychological treatment in improving functioning of cancer survivors. - Personalized psychological treatment is more efficacious than standard, non-personalized...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22291

Bron
NTR

Verkorte titel
MATCH

Aandoening

Psychological symptoms, cancer-related fatigue, personalized treatment, ecological momentary assessment (EMA), cancer survivors.

Psychische klachten, vermoeidheid bij patiënten met kanker, gepersonaliseerde behandeling, EMA-metingen, overlevenden na kanker.

Ondersteuning

Primaire sponsor: Amsterdam UMC, location AMC
Overige ondersteuning: KWF Kankerbestrijding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Patient functioning

Toelichting onderzoek

Achtergrond van het onderzoek

The aim of this study is to establish whether personalized psychological treatment has added value to standard, non-personalized psychological treatment. We therefore aim to evaluate the efficacy of personalized psychological treatment on patient functioning in cancer survivors with severe, persistent depressive symptoms, fear of cancer recurrence and/or cancer-related fatigue, compared with standard, non-personalized psychological treatment. In addition, efficiency of personalized psychological care will be evaluated.

Psychological treatment will be personalized on four levels (a) treatment indication; (b) treatment form; (c) focus and content of treatment; (d) treatment duration. Efficacy of personalized psychological treatment will be evaluated in a randomized controlled trial. Primary outcome is patient functioning, secondary outcomes are level of symptom(s), quality of life, and goal attainment

The study will be carried out in the Netherlands.

Doel van het onderzoek

- Personalized psychological care is more efficacious than standard, non-personalized psychological treatment in improving functioning of cancer survivors.

- Personalized psychological treatment is more efficacious than standard, non-personalized psychological treatment in decreasing symptoms, improving quality of life and goal attainment (secondary outcomes).

- Personalized psychological treatment is more efficient and dropout is lower compared with standard non-personalized psychological treatment.

Onderzoeksopzet

Self-report assessments consist of questionnaires (in the intervention group and the control group) and electronic diary measurements (EMA) (only in the intervention group).

Patients will fill out questionnaires at three time points:

- At baseline (before start of the psychological intervention, T0)

- At six months follow-up (T1).

- At twelve moth follow-up (T2).

The following questionnaires will be used at the timepoints described above:

- Patient functioning: Sickness Impact Profile-8 (SIP-8)

- Symptom level:

o Fatigue; Checklist Individual Strength (CIS-fatigue), subscale fatigue severity.

o Depressive symptoms; Beck Depression Inventory Primary Care

o Fear of cancer recurrence; Cancer Worry Scale (6-item)

- Quality of life: EORTC QLQ-C30 version 3.0.

- Goal attainment: following the Goal Attainment Scaling (GAS) procedure.

- Resilience: Resilience Scale-14

Patients in the intervention group will complete the EMA measurements at two time points:

- At baseline (after intake but before start of the psychological intervention, E0)

- After completing four to six modules (E1)

Onderzoeksproduct en/of interventie

The control group will receive standard, non-personalized psychological treatment for either fatigue, depressive symptoms or anxiety symptoms. This treatment will consist of existing evidence-based treatment protocols for depression, fear of cancer recurrence or fatigue in patients with cancer. The intervention group will receive personalized psychological treatment, in which the existing evidence-based treatment protocols for depression, fear of cancer recurrence or fatigue in patients with cancer will be tailored on four levels: (a) treatment indication; (b) treatment form; (c) focus and content of treatment; (d) treatment duration. In both groups, treatment will be provided by well-trained psychologists.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Be ≥ 18 years old

- Be able to speak and read Dutch

- Previously diagnosed with cancer
- Be at least six months and maximum 5 years after end of primary treatment with curative intent.

- Have no disease activity at time of inclusion in the study.

- Report either severe fatigue (Checklist Individual Strength - Fatigue, cutoff ≥ 35 subscale fatigue severity) , severe fear of cancer recurrence (6-item Cancer Worry Scale, cutoff ≥ 10) of severe depressive symptoms (Beck Depression Inventory Primary Care, cutoff ≥ 4), from which they experience functional impairments (Work and Social Adjustment Scale (W&SAS), cutoff ≥ 10).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Insufficient command of the Dutch language

- Currently receiving psychological or psychiatric treatment

- No informed consent

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2018
Aantal proefpersonen:	190
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	24-01-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7481
NTR-old	NTR7723
Ander register	METC AMC : KWF Kankerbestrijding, project number: 11351

Resultaten