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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22291

Source
NTR

Brief title
MATCH

Health condition

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.

Sponsors and support

Primary sponsor: Amsterdam UMC, location AMC
Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Outcome measures

Primary outcome

Patient functioning

Secondary outcome

- Symptom level

o Fatigue

o Depressive symptoms

o Fear of cancer recurrence

- Quality of life

- Goal attainment

- Number of therapy sessions

- Therapist time per patient

- Dropout rate

Study description

Background summary

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.

Study objective

- 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.

Study design

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)

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

- 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).

Exclusion criteria

- Insufficient command of the Dutch language

- Currently receiving psychological or psychiatric treatment

- No informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2018
Enrollment:	190
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	24-01-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results