Putting the patient at the center of care: personalized treatment for psychological symptoms and fatigue in cancer survivors

Published: 15-01-2019
Last updated: 12-04-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON55738

Source
ToetsingOnline

Brief title
MATCH

Condition

- Other condition
- Adjustment disorders (incl subtypes)

Synonym
depressive symptoms and fatigue after cancer, fear of cancer recurrence

Health condition

angst, depressieve symptomen en vermoeidheid na kanker

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: cancer, personalized, psychological

Outcome measures

Primary outcome

Primary outcome is patient functioning (questionnaire: Sickness Impact

Profile-8 (SIP-8)).

Secondary outcome

Secondary outcomes are symptom level (fear or cancer recurrence (Cancer Worry

Scale, CWS), depression (Beck Depression Inventory for Primary Care, BDI-PC),

and fatigue (Checklist Individual Strength, CIS), quality of life (EORTC

QLQ-C30 questionnaire), and goal attainment (Goal Attainment Scaling (GAS).

Study description

Background summary

Approximately a third of patients with cancer experience clinically relevant levels of psychological symptoms for which referral to a specialized health care provider is indicated. Severe fatigue is also highly prevalent during and after cancer treatment, in at least a quarter of patients. Both adversely impact patients* functioning and quality of life, often co-occur, and can strengthen each other.

Previous studies evaluated interventions for psychological symptoms and fatigue in patients with cancer. The vast majority of these interventions are based on a cognitive behavioral model which assumes that although cancer and cancer

treatment may trigger the symptoms, cognitive and behavioral factors subsequently perpetuate and maintain these symptoms. Treatment targeting these perpetuating and maintaining factors has been shown to decrease psychological symptoms and fatigue and improve functioning in patients with cancer. However, effect sizes of these psychological interventions are only small to medium, uptake of interventions in clinical practice is rather low, and attrition rates are relatively high.

Following the personalized medicine development, there has been a repeated call for personalized psychological treatment. Tailoring treatment to specific patient characteristics and needs is assumed to improve effectiveness of interventions and increase engagement and adherence. There is, however, no evidence that the tailoring of psychological interventions has added value to standardized psychological care. Only one study made a direct comparison: tailored internet-based cognitive behavior therapy (ICBT) versus non-tailored ICBT in patients with major depression and comorbid psychological symptoms. Although there was a trend in favor of tailored ICBT, effectiveness did not significantly differ from non-tailored ICBT. No further evidence in favor of either tailored therapy or non-tailored treatment exists.

Psychological treatment can be tailored in several ways and on various levels. One level on which tailoring can take place, is treatment indication. Currently, referral from patients with cancer to psychological care mainly occurs based on availability of interventions or symptom level, rather than need for care. This follows partly from national guidelines which recommend screening for high symptom levels. Distress, even high distress, can be a sign of normal adjustment, however, and patients may not be in need for professional care. Fatigue can be severe, but not causing hindrance or disability. We and others previously established this gap between distress and care needs. Symptom level in itself does not provide information on whether the symptom is burdensome or disabling, and whether patients have a need for care. It has been repeatedly suggested that care needs should be evaluated and maybe even leading the decision whether treatment is indicated.

Another level of tailoring concerns the focus and content of treatment. Currently, psychological treatment is aimed at factors that are generally known to maintain symptoms, such as inactivity or illness beliefs. There have been attempts to tailor psychological interventions, mainly by providing basic treatment modules and some optional modules. Which modules to follow was, however, determined unsystematically (e.g. by patients* choice, regardless of presence of maintaining factors) or by presence of factors potentially maintaining the symptom. Presence of a potential maintaining factor does not imply, however, that this factor and the main symptom are associated. Smart technologies such as electronic diaries (ecological momentary assessments, EMA) can establish temporal associations between (maintaining) factors and symptoms of interest. EMA delivers personalized and contextualized information. Therefore, EMA is primarily suited for personalizing interventions, adjusting

treatment on an individual level, as the specific maintaining factors in a specific individual can be identified and targeted.

The aim of this proposal is to systematically personalize psychological treatment, aimed at individual patient preferences and characteristics. Tailoring therefore takes place on four levels:
1. Treatment indication: most studies select patients based on their symptom level. A patient*s need for psychological care should also be considered, however, and treatment indication should be determined by patients* experienced burden from the symptom.
2. Treatment form: patients now receive either face-to-face, blended, or online treatment according to availability. Research studies mostly include only one treatment form. Tailoring comprises patients being able to choose for either one of these three forms.
3. Focus and content of treatment: in current evidence-based treatments, every patient receives the same treatment, aimed at decreasing symptom levels. Pilot studies we undertook showed that ecological momentary assessments are capable of registering individual symptom patterns over time and identifying factors that maintain these symptoms in the individual patient. Thus, treatment will be aimed at the specific factors that maintain symptoms in this specific individual.
4. Treatment duration: the use of ecological momentary assessments during treatment will enable the evaluation of treatment response and accordingly the individual adjustment of treatment duration.
We expect this package of measures will make treatment more personalized and thereby more effective, less burdensome and more efficient, with lower dropout rates.

Study objective

The primary objective of the proposed study is to test the efficacy of personalized psychological care for improving functioning in cancer survivors with severe and persistent depressive and/or fear of cancer recurrence and/or cancer-related fatigue, and compare it to standard, non-personalized psychological treatment. Hypothesized is that personalized psychological treatment is more efficacious in improving functioning compared with standard, non-personalized psychological treatment.

Secondary objective(s):
a. To determine the efficacy of personalized psychological treatment for symptom level (fear of cancer recurrence, depression, fatigue), quality of life, and goal attainment. Hypothesized is that personalized psychological treatment will be more efficacious in reducing symptom levels, and improving quality of life, compared with standard, non-personalized psychological treatment. Goal attainment is an individualized outcome measure that is suitable for problems that warrant an individual approach. Expected is that personalized psychological treatment will be more efficacious in improving goal

attainment compared with standard, non-personalized psychological treatment;
b. To determine whether the expected positive effects of personalized psychological treatment on patients* functioning are sustained at 12 months after start of treatment;
c. To determine efficiency of treatment by evaluating treatment duration and therapist time in personalized psychological treatment compared with standard, non-personalized psychological treatment;
d. To evaluate dropout rates in the group receiving personalized psychological treatment, compared with the group receiving standard, non-personalized psychological treatment.

Study design

The study is designed as a multicenter randomized controlled trial with two treatment arms: (a) personalized psychological treatment, versus (b) standard, non-personalized psychological treatment. Participating therapists, each as a separate unit, and participating patients will be randomly assigned to either personalized psychological treatment or standard, non-personalized psychological treatment. Patient functioning (primary outcome) and secondary outcomes are evaluated at baseline (T0), 6 months (T1) and 12 months (T2) after start of psychological treatment.

Intervention

Personalized treatment group:

Psychological treatment will be systematically tailored on four levels:
1. Treatment indication: most studies select patients based on their symptom level. A patient*s need for psychological care should also be considered, however, and treatment indication should be determined by patients* experienced burden from the symptom.
2. Treatment form: patients now receive either face-to-face, blended, or online treatment according to availability. Research studies mostly include only one treatment form. Tailoring comprises patients being able to choose for either one of these three forms.
3. Focus and content of treatment: in current evidence-based treatments, every patient receives the same treatment, aimed at decreasing symptom levels. Pilot studies we undertook showed that ecological momentary assessments are capable of registering individual symptom patterns over time and identifying factors that maintain these symptoms in the individual patient. Thus, treatment will be aimed at the specific factors that maintain symptoms in this specific individual.
4. Treatment duration: the use of ecological momentary assessments during treatment will enable the evaluation of treatment response and accordingly the individual adjustment of treatment duration.

Personalized psychological treatment consists of the following steps:
1. Patient is referred for participation in this study via their treating doctor or via self-referral
2. Screening and baseline questionnaires
3. Intake interview (verification of patients* need for psychological care; identification of patients* most burdensome symptom). Following the standard protocols of the treatment for fear of cancer recurrence, fatigue or depression, additional questionnaires need to be filled out.
4. EMA assessment during 14 consecutive days. Auto-VAR analyses to identify patients* individual maintaining factors on which to intervene.
5. Results of assessments will be discussed and verification of patients* preference for face to face, blended, or internet therapy will take place.
6. Start treatment aimed at maintaining factors.
7. Evaluation of treatment response through EMA measurement, focused on maintaining factors, measurement of symptoms, and individual treatment goals. Based on the results (treatment had effect on maintaining factors; symptom level is below predefined cutoff; patient reached his/her personal treatment goals): discuss with patient whether treatment continuation or treatment end is preferable.
8. In case of multiple symptoms: after ending treatment for the first symptom, evaluation whether patient needs further treatment for the other symptoms (questionnaire, need for care).
9. Duration of treatment will be variable (see (e)), but has a maximum of eight months.

A concept personalized treatment protocol will be developed using evidence based diagnosis-specific treatment protocols aimed at treating fear of cancer recurrence, depression, and/or fatigue in patients with somatic conditions, preferably patients with cancer. These are the standard protocols for treating fear of cancer recurrence [21,31], the standard protocol for treating depressive disorder with cognitive behavior therapy [31] and a treatment protocol for treating fatigue in patients following cancer treatment [4,19]. These treatment protocols have been proven effective in nomothetic (group-based) research. For personalizing the protocols, the following steps will be taken:
1. The protocols will be divided into modules, based on the maintaining factors these modules aim at. The result will be two general modules, essential for every patient, and several optional modules, which will be only provided to patients with these maintaining symptoms.
2. Each of the modules and corresponding maintaining factors will be linked to one or more questions in the electronic diary. This will be piloted in regular care, in 10 patients referred to the department of Medical Psychology of the Academic Medical Center, who are regularly asked to fill out questionnaires as part of their diagnostic phase.

Standard treatment group:
1. Patient is referred for participation in this trial via their treating

doctor or via self-referral
2. Screening and baseline questionnaires
3. Intake interview. Following the standard protocols of the treatment for fear of cancer recurrence, fatigue or depression, additional questionnaires need to be filled out
4. Results of assessments will be discussed
5. Start blended therapy for the symptom for which the score on the accompanying questionnaire is above the cutoff
6. Patient receives the whole treatment protocol
7. At the end of treatment, questionnaire to assess symptom level.

Treatment protocols used for the standard, non-personalized treatment arm are the same as those used for developing the personalized treatment protocol: (a) ConquerFear protocol for treating fear of cancer recurrence [21]; (b) protocol for treating depressive disorder [31]; and (c) treatment protocol for treating fatigue in patients with cancer [4,19]. These treatment protocols have been proven effective in nomothetic (group-based) research.

Study burden and risks

The risk of adverse events in the MATCH trial is negligible. The therapy will be delivered by trained clinical psychologists who are highly skilled in helping patients to manage distress and who have considerable expertise in working with patients with cancer. Hence, only time investment is asked regarding the completion of the questionnaires and psychological treatment, and for the intervention group the completion of short diary measurements during 14 consecutive days. It is anticipated that patients in both treatment arms will receive direct therapeutic benefits in the domains of anxiety, depressive or fatigue symptoms.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a patient must meet all of the following criteria: 1) be >=18 years old; 2) be able to speak and read Dutch; 3) be diagnosed with a cancer diagnosis; 4) be at least six months and maximum 5 years after end of primary treatment with curative intent; 5) have no disease activity at time of inclusion in the study; 6) report either clinical relevant levels of fatigue (Checklist Individual Strength (CIS), cutoff >= 35 on the fatigue severity subscale), and/or fear of cancer recurrence (Cancer Worry Scale (CWS, 6-item), cutoff >= 10) and/or depressive symptoms (Beck Depression Inventory Primary Care (BDI-PC), cutoff >= 4), and must experience functional impairments (Work and Social Adjustment Scale (W&SAS), cutoff >=10 [22,23]); 7) in case of fatigue: be determined by their physician to have no clinical condition or disease that could account for their fatigue presentation.

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:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-02-2019
Enrollment:	190
Type:	Actual

Ethics review

Approved WMO Date:	15-01-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-08-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-11-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	16-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL66845.018.18