REFINE: Personalizing psychological care for chronic cancer-related fatigue

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By providing patients and therapists with feedback on these networks we can explore whether and to what extent networks can contribute to personalizing psychological treatment for CCRF.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Somatic symptom and related disorders
Study type	Interventional

Summary

ID

NL-OMON48211

Source
ToetsingOnline

Brief title
REFINE

Condition

- Somatic symptom and related disorders

Synonym
chronic cancer-related fatigue, longlasting exhaustion after cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: chronic cancer-related fatigue, experience sampling method, network approach, personalized care

Outcome measures

Primary outcome

We will combine qualitative data from an observation and interview. At the patient*s first meeting with the therapist at the HDI, therapist will discuss the network report with the patient. Patients will be asked to discuss how they experience this feedback. A researcher will be present to observe the meeting. Moreover, after two therapy sessions, the therapists will be interviewed about how they experience the (added) value of a network report in personalising treatment.

Secondary outcome

We will also interview patients about and whether they experience (1) filling out the Energie inZicht app and (2) the descriptive feedback report as helpful in gaining more insight in their fatigue. THese interviews will also be used to explore how patients experience the content and design of the app and feedback reports. This will hopefully help us to further optimize the app and feedback reports. Based on the individual networks, we also hope to gain more insight into which factors are helpful and less helpful in coping with CCRF at an individual level.

Study description

Background summary

Chronic Cancer-Related Fatigue (CCRF), is a complex, multifactorial condition that is often accompanied by significant distress and reduces patients* quality of life. While existing treatment options can be effective in reducing fatigue, we do not know which (combination of) treatment is most effective for the individual patient. Individual dynamic networks of symptoms of fatigue and related risk and protective factors can inform us what kind of behaviour, cognitions or emotions are helpful or less helpful in coping with CCRF.

Study objective

By providing patients and therapists with feedback on these networks we can explore whether and to what extent networks can contribute to personalizing psychological treatment for CCRF.

Study design

We will use the experience sampling method (ESM) and qualitative research (interviews and observation) as an explorative mulitple case intervention study design (n=5). The case studies will be implement in the routine clinical care of the Helen Dowling Institute.

Intervention

We have developed an ESM questionnaire, called *Energie inZicht*, which will be distributed via a smartphone application. The *Energie inZicht* assessment will be filled out 5 times a day on random moments within a set time frame for 21 days. It will contain questions regarding energy level (physical and mental fatigue), activity level (physical and mental activity), mood (positive and negative), fatigue reactivity (worrying, taking some quiet time, accepting, catastrophizing, having a sense of control) and context (location, company).

Study burden and risks

Risk of participation is negligible. Participating in the study (i.e. descriptive feedback and feedback on individual networks) could facilitate the therapist to personalize treatment, leading to more efficient and effective psychological care for the patient. Participation in the study will also help to provide useful information about how to personalize treatment. As such, the care for future patients with CCRF can be improved (i.e. more efficient and more effective care). Participation will cost much time: the briefing at baseline, the daily ESM questionnaires, personal feedback on low hanging fruit and personal feedback on individual networks with accompanying interviews will take approximately 7.5 hours in total.
We do not expect a mental burden from the content of the questions within the ESM or screening questionnaires, especially because many questions are

positively framed.

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

- Cancer (all types) patients who have finished curative-intent cancer treatment at least three months previously;
- suffer from severe fatigue since end of treatment (35 or higher on Checklist Individual Strength - Fatigue Severity subscale);
- have visited their general practitioner, who ruled out a somaic explanation for their fatigue;
- are referred to the Helen Dowling Institute for psychological care for their fatigue;
- are 18 years of age or older;

- and have a sufficient understanding of the Dutch language.

Exclusion criteria

N/A.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-10-2019
Enrollment:	5
Type:	Actual

Ethics review

Approved WMO

Date:	17-09-2019
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL70459.028.19