The effectiveness and working mechanisms of two different e-health interventions for people suffering from chronic fatigue after cancer.

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This study aims at investigating the efficacy of two home-based interventions, an ambulant personalized acitivity feedback intervention (AAF) and an online mindfulness-based cognitive therapy (MBCT) in reducing chronic cancer-related fatigue...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44111

Source
ToetsingOnline

Brief title
E-health interventions for CCRF

Condition

- Other condition

Synonym
chronic cancer related fatigue, fatigue after cancer

Health condition

chronische vermoeidheid na kanker

Research involving

Human

Sponsors and support

Primary sponsor: Roessingh Research and Development i.s.m. Helen Dowling Instituut
Source(s) of monetary or material Support: Stichting Alpe d□Huzes/KWF kankerbestrijding

Intervention

Keyword: cancer, effectiveness, e-health, fatigue

Outcome measures

Primary outcome

Primary outcome measure

- Fatigue will be assessed with the fatigue severity subscale of the Checklist

Individual Strength (CIS).

T2 (and not combined with T2') will be the main endpoint of this study.

Mediating factors

- Physical activity: accelerometer

- Level of Mindfulness: Freiburg Mindfulness Inventory, short form (FMI-S)

- Sense of control over symptoms (SES)

- Subjective sleep quality: Subjective Sleep Quality Scale (SSQS)

- Credibility and expectancy: Credibility/Expectancy Questionnaire (CEQ)

- Working alliance: working alliance inventory, short form (WAI-S)

Secondary outcome

Secondary outcome measures

- Mental health will be measured by two instruments, namely 1) Positive and

negative affect (PANAS), and 2) Psychological distress (HADS).

- Work ability (return to work, hours work per week), Trimbos/iMTA

questionnaire for Costs associated with psychiatric Illness (TIC-P))

- Self perceived ability to work: Work Ability Index (WI)

Other study parameters

(Attachment 4 "Study schedule supplement" and paragraph 6.1.3 of the protocol

offer more detailed information on this topic.)

- sex

- age

- work status

- subjective physical activity

- causal attributions

- duration of fatigue

- social support

- experience with mindfulness-exercise

- perceived probability of and anxiety over cancer recurrence

- perceived life threat of cancer

- desirable responding

- Degree of limitation in physical activity by pain

- perceived effect of intervention

- Self-efficacy over physical activity

- Important life events during study period

- psychological help during study period.

Study description

Background summary

About a quarter of cancer survivors suffer from severe chronic fatigue. Chronic fatigue may persist for many years after treatment and has a considerable impact on a patient's life because of its interference with daily activities and because it hinders patients to participate optimally into the society and work. Physical activity interventions and psychosocial interventions, specifically designed to reduce fatigue, seem to be effective. Though, research is needed to However, there is a considerable number of severely fatigued cancer survivors who do not have access to these specific interventions. Delivering interventions through the internet enables treatment at home and as such makes interventions available for patients who do not have the time or energy to travel.

Study objective

This study aims at investigating the efficacy of two home-based interventions, an ambulant personalized acitivity feedback intervention (AAF) and an online mindfulness-based cognitive therapy (MBCT) in reducing chronic cancer-related fatigue compared to a control group (primary objective). In addition, we will study how these interventions work and what type of intervention is best for whom (secondary objective). More specifically we will test if these interventions reduce fatigue by treatment specific mechanisms as increasing activity and balancing activities during the day and increasing mindfulness and sleep quality or by more generic mechanisms as working alliance and client's expectation about the effect of the intervention.

Study design

A randomized controlled trial will be performed, including three conditions: two intervention conditions and a minimal intervention control condition. Patients in the control condition will receive supportive e-mails during their waiting period. The study sample will consist of 330 cancer survivors who have finished their last cancer treatment at least three months before and suffer from severe fatigue; which means a score >/= on the severity of fatigue subscale of the self-report Checklist Individual Strength (CIS). Patients apply via internet and will be randomly allocated to one of the three conditions. Primary objective will be the effectiveness of the interventions. Primary outcome will be fatigue severity, secondary outcomes will be mental health and work ability.

Patients in all three conditions will fill out questionnaires at the start of the (minimal) intervention (T0), the second week after finishing the (minimal) intervention (T1), and six months after baseline (T2) (see attachment *Study schedule* of the research protocol for clarification). The intervention groups will fill out the last questionnaire 12 months after T0 (T3).

After T2, patients in the control condition will be offered online MBCT or AAF at random. In this group, T2 will therefore be combined with T0c*. They will fill out questionnaires the second week after the intervention (T1') and 6 months after starting the intervention (T2').

To be able to test mediation, physical activity will be assessed with tri-axial accelerometers and mindfulness, sleep quality and fatigue with questionnaires three times during the intervention. Expectations and working alliance between client and therapist will be assessed three times during the first four weeks. To learn more about mechanisms of change, 15 patients per intervention group will be interviewed from each intervention condition after at T0 and 10 of these 15 patients per intervention group will be interviewed again after T1.

Intervention

AAF:
Patients will first receive an e-mail from their personal physiotherapist containing information about physical activity and CCRF and the intervention. They will be asked about the kind of activity they prefer and will be able to download suggestions about activity from the website. They will receive a tri-axial accelerometer and a Personal Digital Assistant (PDA). Patients will wear these devices during their everyday live. The intervention consists of a monitoring and a feedback period. During the monitoring part, patients will be monitored for seven days in their own environment to establish a baseline daily activity pattern (week 0). No feedback will be given to the patient during this period. During the feedback period, patients are instructed to use the PDA for regulation of their daily physical activities. The PDA displays the patient's activity and the goal activity.

Online MBCT:
Clients start the intervention by studying the reader for that first week and downloading a MP3-file with the body scan exercise, which they are asked to practice every day. They register their experience with the exercise in their homework logs during the week and upload this information at the end of this week. The therapist delivers a reaction to the logs on a predetermined day of the week. Patients continue with the next week by downloading the reader and new mindfulness exercises for that week, and so on for all nine weeks. Clients cannot continue with a next session before they have registered their experience with homework assignment of the previous week.

Minimal intervention control condition:

Patients that are assigned to the minimal intervention condition will receive weekly supportive e-mail containing standard texts with psycho-education and information about CCRF. Participants cannot reply to these e-mails.

Study burden and risks

This study involves capacitated adults and therapeutic research. Participation is free of charge. Both interventions have been studied in patients suffering from chronic fatigue before, indicating that no concrete risks are related to the interventions. Both pilot interventions showed beneficial effects, mainly diminishment of fatigue and a rise in wellbeing.

Participating in this study can be time consuming, as participants will fill out several questionnaires at different time points. These questionnaires contain questions that might be confronting for the participant, as they confront the participant with his/her current situation. Though, we do not expect this to be harmful. Also, they will wear the tri-axial accelerometer for several days during the intervention. Also, personal feedback of the therapists can be confronting, but hypothetically helpful in the end.

Participants are requested not to take part in any other therapy directed at fatigue simultaneously with the intervention, thus during a period of one year. Still, if the participant is in need for help, he/she can contact his/her general practitioner. Fifteen participants from each intervention (AAF and online MBCT) will be interviewed before the start of the intervention and 10 of these 15 participants will again be interviewed directly after the intervention about their experiences to study how the interventions cause change.

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

- CIS-fatigue score of 35 or higher on the fatigue severity subscale of the Checklist Individual Strength (CIS) (administered via website)
- Patient has been suffering from severe fatigue for at least three months (self-report)
- Completion of treatment for cancer at least three months ago (checked during referral). Treatment is defined as surgery, chemotherapy, radiation / radiotherapy, immunotherapy, and/or bone marrow transplant. Hormonal therapy, the use of anti-inflammatories and monitoring visits are not considered as treatment
- Disease-free, as defined by the absence of cancer activity parameters (checked during referral)
- Age older than 19 years (self-report)
- Age at disease onset minimal 18 years (self-report)
- Capable of reading and writing Dutch language (self-report)
These criteria are based on self-report unless stated otherwise.

Exclusion criteria

- Current or former severe psychiatric morbidity as major depression, psychoses or schizophrenia, or current addiction (checked during referral). Exception: Mild depression is no exclusion criterion. Any addiction in the past that has long been under control is no exclusion criterion. If a patient scores above cutoff score on the HADS (see paragraph 6.1.2) at the intake questionnaire, which is an indication for depression, the patient will be contacted by a psychologist of the Helen Dowling Institute to exclude whether the participant suffers from major depression.
- Pregnancy (self-report).
- Being dependent on a wheelchair for daily activity (self-report).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-05-2013
Enrollment:	330
Type:	Actual

Ethics review

Approved WMO Date:	19-11-2012
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	29-03-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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
Other	12860
CCMO	NL41109.044.12