Reducing Cancer-Related Fatigue: Untire App as an Evidence-Based mHealth Solution

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20482

Source
Nationaal Trial Register

Brief title
Untire

Health condition

Cancer related fatigue (Kankergerelateerde vermoeidheid)

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Afd. Gezondheidspsychologie (FA12)
Hanzeplein 1
POB 30.001
09700 RB Groningen
Source(s) of monetary or material Support: Tired of Cancer BV
Lucasbolwerk 6
3512EG Utrecht

Tired of Cancer BV is using a Grant of the European Union:Phase II – SMEInst-06-2016-2017: Accelerating market introduction of ICT solutions for Health, Well-Being and Ageing Well

Intervention

Outcome measures

Primary outcome

Change in cancer related fatigue (CRF) from baseline to 12 weeks, assessed with the self-report questionnaire Fatigue Symptom Inventory (FSI).

Secondary outcome

- Change in overall quality of life (QoL) from baseline to 12 weeks, assessed with the 1-item on quality of life in the EORTC QLQ-C30 questionnaire.

- Insight in usage of the application using log data (automatically stored data about the assessments and activities that users complete). Patterns of usage and most often performed activities will be explored and related to CRF and QoL.

- Explore whether domains targeted within the app mediate the relation with users' outcomes of CRF or QoL.

- Moderating factors on CRF and QoL will be explored.

Study description

Background summary

Rationale: Many cancer patients worldwide experience disabling fatigue as a side effect of their illness and the onerous treatments involved, in Europe this was estimated to be over 50% of the 14 million cancer patients. The severe fatigue lasts for up to 10 years in at least 30% of cancer survivors, who experience fatigue daily, affecting their activities and quality of life.

Objective: The aim of this project is to assess the effectiveness of the Untire app in reducing Cancer Related Fatigue (CRF) and improving Quality of Life (QoL) in (former) cancer patients. It further aims to identify the parts of the app that are the strongest predictors for a decrease in CRF and which factors moderate or mediate this decrease.

Study design: The application is available in the English-speaking countries from start of the

trial (phase 1) and will be translated and launched during the trial in non-English speaking countries (phase 2). Phase 1 is a randomized controlled trial design with intervention and control arm. In phase 2, the period in which the app is not available is the control period, the period in which the app is launched is the intervention period.

Study population: The study population consists of individuals <18 years and older>, who have/had a diagnosis of cancer, experience moderate or severe CRF and have a smartphone, and do not have treatment, medication or a diagnosis of a mental disorder and do not have a diagnosis of chronic fatigue syndrome (CFS)/myalgic encephalomyelitis (ME) or fibromyalgia (FM).

Intervention: The Untire application is developed based on several decades of academic research in psycho-oncology, using beneficial therapeutic key elements. The intervention group receives free access to the Untire app for six months. The control group has no access to the Untire app in the first 12 weeks of the study. After their 12-weeks measure, control participants are offered to use the app freely for six months. The app will be brought to the market on payment, but study participants will benefit from six months of free access to the app. Participants use the app as they wish to use it.

Outcomes: Outcomes are assessed using questionnaires and log data. Participants receive a questionnaire at baseline (76 items) and 12 weeks (65 items), and short questionnaires after 4, 8 and 24 weeks. The main outcome is the decrease in CRF after twelve weeks of having access to the Untire app compared to controls. The secondary outcome is improvement in QoL after twelve weeks of having access to the Untire app compared to controls. Information about the usage (% active users versus % non-active users), patterns in use and the parts of the app that are most strongly related to improvements in CRF will be explored using automatically stored user data (log data) in the application. Moderating and mediating factors on CRF and QoL will be assessed using questionnaire and log data.

Study objective

The Untire app will create awareness by proving psycho-education and will give insight in ones' energy levels, ones' thoughts and behaviors in relation to energy levels and provides exercises that help users to challenge ineffective thoughts and behaviors. It is hypothesized that creating awareness and adjusting ineffective thoughts and behaviors will lead to improvements in cancer related fatigue and quality of life.

Study design

Assessments are planned at baseline, and after 4, 8, 12 and 24 weeks.

Intervention

The Tired of Cancer app is developed by the Tired of Cancer BV, based on years of academic experiences in the field of psycho-oncology within the Helen Dowling Institute (The Netherlands). The app is based on successful ingredients of face-to-face therapy for cancer-related fatigue (CRF) and the translation of this therapy into a therapist-supported web-based therapy. Both therapies are successful in the reduction of CRF, but are considered resource-intensive. The aim to reach a larger public has resulted in a mHealth version which is the Tired of Cancer application.

Participants in the intervention condition receive free access to the Tired of Cancer App for six months. They are advised to use the app on a regular base. The App starts with an introduction on how to use the app and a basic explanation of cancer-related fatigue. Hereafter participants will receive (bi)weekly an assessment of fatigue and fatigue related factors, and daily a new program containing four parts (the daily program). Participants can choose which parts of the daily program they would like to do or they can choose a part that they have done previously.

This daily program consists of:

• themes to learn about factors related to fatigue

• physical activity: exercises and guidance to increase daily physical activity

• stress-reduction exercises

• tips

Participants in the control condition do not get access to the app.

Contacts

Public
POB 30.001
Anne Looijmans
Universitair Medisch Centrum Groningen
Afd. Gezondheidspsychologie (FA12)
Hanzeplein 1

Groningen 9700 RB
The Netherlands

050-3616613
Scientific
POB 30.001
Anne Looijmans
Universitair Medisch Centrum Groningen
Afd. Gezondheidspsychologie (FA12)
Hanzeplein 1

Groningen 9700 RB
The Netherlands
050-3616613

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

• 18 years and older;

• was/is diagnosed with cancer;

• has a smartphone.

• experiences persistent fatigue at moderate or severe level; an average composite score (items 1, 2 and 3) of ≥3 on the Fatigue Symptom Inventory.

Exclusion criteria

If participants will answer the following statement and question with “yes”, they are not perceived eligible to participate:

• I receive treatment for, take medication for or have a diagnosis of a mental disorder (major depression, anxiety disorder, psychotic disorder or addiction).

• Do you have a diagnosis of chronic fatigue syndrome (CF)/myalgic encephalomyelitis (ME) or fibromyalgia (FM)?

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-01-2018
Enrollment:	6000
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	29-11-2017
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	NL6642
NTR-old	NTR6828
Other	Project ID Horizon 2020 : 756641

Study results