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

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

Summary

ID

NL-OMON44512

Source
ToetsingOnline

Brief title
Untire

Condition

- Other condition

Synonym
cancer, cancer-related fatigue

Health condition

kanker, kanker-gerelateerde vermoeidheid

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Europese Unie; verstrekt aan Tired of Cancer BV. Het UMCG is door Tired of Cancer BV. aangesteld om het onderzoek uit te voeren.

Intervention

Keyword: (former) cancer patients, Cancer-related fatigue, eHealth application, Quality of life

Outcome measures

Primary outcome

The main outcome is the decrease in CRF after twelve weeks of having access to

the Untire app compared to controls.

Secondary outcome

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 description

Background summary

A large part of the cancer patients experience disabling fatigue as a side effect of their illness and the onerous treatments involved. The severe fatigue lasts for up to 10 years in 30% of cancer survivors, who experience fatigue daily, affecting their activities and quality of life.

Study 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 the potential 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.

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 during the study. After their 12-weeks measure, control participants are offered to use the app freely for six months.

Study burden and risks

Outcomes are assessed using questionnaires and log data. Participants receive a questionnaire at baseline (74 items) and 12 weeks (65 items), and short questionnaires after 4, 8 and 24 weeks after start. 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. Therefore, no adverse side effects of the measurements or app use are foreseen.

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

- 18 years or older
- has cancer of has had cancer
- has a smartphone
- experiences moderate or severe cancer-related fatigue, as measured with the Fatigue Symptom Inventory with a fatigue composite score of on average 3 or higher

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)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-03-2018
Enrollment:	750
Type:	Actual

Ethics review

Approved WMO Date:	20-02-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL63425.042.17