CARE-FIT: Comprehensive AppRoach for Embedding lifestyle support in oncology care - Focusing on Increasing physical activity, better sleep and reducing stress Through eHealth

Published: 08-04-2025
Last updated: 19-04-2025

The primary aim of this study is to investigate the effects on PA, sleep, stress, health and QoL of a tailored eHealth intervention for cancer patients when embedded in oncological care. Additional aims are to gain insight into the cost-...

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON57405

Source
ToetsingOnline

Brief title
CARE-FIT

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
Malignant neoplasm; Cancer

Research involving
Human

Sponsors and support

Primary sponsor: Open Universiteit
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Lifestyle, Oncological care, Tailored eHealth intervention

Outcome measures

Primary outcome

Changes in PA, sleep, stress-levels, health and QoL are the main study outcomes during this study and are measured via online questionnaires at 0, 3 and 6 months. In addition, accelerometer measurements are performed at 0 and 6 months to assess PA and sleep.

Secondary outcome

Cost-effectiveness, cost-utility and use and appreciation of the eHealth intervention are secondary outcomes of the study and are assessed through online questionnaires and intervention log data. Additionally, use and feasbility of implementation protocols for embedding the intervention in practice by HCOs and HCPs is a secondary outcome of this study, which is assessed through online questionnaires and semistructured interviews among HCPs in the intervention group.

Study description

Background summary

Sufficient physical activity (PA), good sleep quality and paying attention to stress-management is extremely important for cancer patients during and after treatment, since these behaviors have a positive impact on physical and mental

functioning, health, quality of life (QoL), treatment outcomes and reduce side effects. However, insufficient attention is currently paid to lifestyle support within oncological care which is often due to lack of time, knowledge and skills among health care professionals (HCPs). Therefore, there is an urgent need for accessible lifestyle interventions where HCPs can refer cancer patients to in a time-efficient way. Tailored electronic health (eHealth) interventions are considered a viable solution for this purpose.

Study objective

The primary aim of this study is to investigate the effects on PA, sleep, stress, health and QoL of a tailored eHealth intervention for cancer patients when embedded in oncological care. Additional aims are to gain insight into the cost-effectiveness, use and appreciation of the intervention and the use and feasibility of implementation protocols for embedding the intervention in practice by health care organizations (HCOs) and HCPs.

Study design

Randomized controlled trial applying a parallel two group (intervention vs usual care) design with repeated measures across 3 occasions (0, 3, 6 months) with HCOs as unit of randomization.

Intervention

The intervention group receives access to a tailored online eHealth intervention targeting the behaviors PA, sleep and stress-management. Participants are referred to the intervention by their HCP in the hospital, rehabilitation centre or physiotherapy practice. The control group receives care as usual and receives access to an online lifestyle intervention after completion of the study.

Study burden and risks

No risks are associated with participation since it concerns a behavioral eHealth intervention study targeting PA, sleep and stress-management and not a medical or pharmacological intervention study. The burden associated with study participation is considered small since participants are asked to fill in three online questionnaires and wear two times an accelerometer for four days over a period of six months. The potential benefits of the intervention outweigh the burden associated with participation in this study since it is expected that the intervention will improve PA, sleep, stress-management, health and QoL.

Contacts

Public
Open Universiteit

Valkenburgerweg 177
Heerlen 6419 AT
NL
Scientific
Open Universiteit

Valkenburgerweg 177
Heerlen 6419 AT
NL

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 subject must meet all of the following criteria:
a. Patients who are diagnosed with cancer from the moment of diagnosis up until one year after completing the primary treatment for cancer (e.g. radiotherapy, chemotherapy, surgery)
b. Patients undergoing primary treatment for cancer are treated with a curative intent
c. Aged 18 years or older
d. Able to read and speak Dutch
e. Having a PC/tablet and internet

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
a. Having a serious medical, psychiatric or cognitive disease that would interfere with participation (e.g. Alzheimer*s disease, blindness, sever obesity (BMI>=35))
b. Being in the palliative phase

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2025
Enrollment:	356
Type:	Anticipated

Medical products/devices used

Generic name:	OncoActive+
Registration:	No

Ethics review

Approved WMO

Date:	08-04-2025
Application type:	First submission

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

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
ISRCTN	ISRCTN61846887
CCMO	NL88212.096.25