

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

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Miscellaneous and site unspecified neoplasms benign
<b>Study type</b>	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 feasibility 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

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## 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

## 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