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Increasing physical activity, better sleep and reducing stress through ehealth for embedding lifestyle support in oncology care

Submission date
13/01/2025

Recruitment status
Recruiting

Registration date
14/01/2025

Overall study status
Ongoing

Last Edited
18/03/2026

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Sufficient physical activity (PA), good sleep quality and paying attention to stress management are extremely important for cancer patients during and after treatment, since these lifestyle 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 a lack of time, knowledge and skills among healthcare professionals (HCPs). Therefore, there is an urgent need for accessible lifestyle interventions where HCPs can refer cancer patients in a time-efficient way. Tailored electronic health (eHealth) interventions are considered a viable solution for this purpose. Therefore, this study aims to investigate the effects on PA, sleep, stress, health and QoL of a tailored eHealth intervention for cancer patients when embedded in oncological care.

Who can participate?
Patients aged 18 years old and over who are diagnosed with cancer from the moment of diagnosis up until one year after completing the primary treatment with a curative intent (e.g. radiotherapy, chemotherapy, surgery).

What does the study involve?
Participants will be allocated to the intervention group or the control group. All participants fill in online questionnaires at the start, after 3 months and after 6 months and wear an accelerometer at the start and after 6 months. Participants in the intervention group will receive access to the eHealth intervention targeting PA, sleep and stress management at the start of the study. Participants in the control group receive access to an online lifestyle intervention after study completion at 6 months.

What are the possible benefits and risks of participating?
Possible benefits of participating in this study are potential improvements in PA, sleep, stress management, health and QoL. No risks are involved for study participation.

Where is the study run from?
The Open University of the Netherlands

When is the study starting and how long is it expected to run for?
November 2024 to October 2026

Who is funding the study?
The Netherlands Organisation for Health Research and Development (ZonMw)

Who is the main contact?
Prof. dr. Lilian Lechner, Lilian.Lechner@ou.nl

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ZonMw grant decision on file number
10930012310013

Study information

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

Acronym
CARE-FIT

Study objectives
A tailored in oncological care embedded eHealth intervention focusing on physical activity, sleep and stress-management for cancer patients improves physical activity levels, sleep quality, health and quality of life and reduces stress.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 08/04/2025, METC Z (Zuyderland Sittard-Geleen | Dr. H. van der Hoffplein 1, Sittard-Geleen, 6162 BG, Netherlands; +31 088-4590129; metc@zuyderland.nl), ref: NL88212.096.25 | METCZ20250006

Study design
Multicenter interventional unblinded parallel randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Prevention, Quality of life

Health condition(s) or problem(s) studied
Improving physical activity, sleep and stress-management in cancer patients during and after treatment

Interventions
This study uses clustered randomisation at the health care organisation (HCO) level. A total of 10 hospital departments, 6 rehabilitation centers and 16 physiotherapy practices will be included in the study (recruitment ongoing). The three different types of HCOs will be equally allocated to either the intervention group or the control group by an independent researcher. As a result, respectively 5 hospital departments, 3 rehabilitation centers and 8 physiotherapy practices will participate in the intervention group and 5 hospital departments, 3 rehabilitation centers and 8 physiotherapy practices will participate in the control group.

Participants in the intervention group receive access to a tailored online eHealth intervention targeting the behaviors of physical activity, sleep and stress management. The intervention consists of several online modules to support patients in being physically active, having good sleep and coping with stress on different occasions over twelve weeks. The intervention content is tailored to users' personal situation based on their answers to preceding online questionnaires. Examples of variables that are taken into account during tailoring procedures are cancer type, treatment phase, other comorbidities and current physical activity, sleep and stress behavior. Participants are referred to the intervention by their HCP in the hospital, rehabilitation center or physiotherapy practice. The control group receives care as usual and receives access to an online tailored lifestyle intervention after completion of the study at 6 months. Measurements through online questionnaires in both the intervention group and control group take place at baseline, 3 months and 6 months and accelerometer measurements take place at baseline and 6 months.

Intervention Type
Behavioural

Primary outcome(s)
1. Physical activity is measured via the short questionnaire to assess health-enhancing physical activity (SQUASH) at baseline, 3 months and 6 months and via ActiGraph accelerometers at baseline and 6 months.
2. Sleep is measured via the Pittsburgh Sleep Quality Index (PSQI) at baseline, 3 months and 6 months and via ActiGraph accelerometers at baseline and 6 months.
3. Stress is measured via the Perceived Stress Scale (PSS) at baseline, 3 months and 6 months
4. Health-related quality of life is measured via the European Organization for Research and Treatment of Cancer, Quality of Life Questionnaire (EORTC QLQ-C30) at baseline, 3 months and 6 months
5. Fatigue is measured via the Checklist Individual Strength 20 items (CIS20-R) at baseline, 3 months and 6 months

Key secondary outcome(s))
1. Cost-effectiveness and cost-utility is measured via the IMTA Medical Consumption Questionnaire (iMCQ), the IMTA Productivity Cost Questionnaire (iPCQ) and the EQ-5D-5L questionnaire at 6 months.
2. Amount of accessed intervention modules, duration of use and use of exercises is measured via intervention software log data
3. Intervention rating and appreciation is measured via an online questionnaire at 6 months
4. Use and feasibility of the implementation protocols for embedding the intervention in oncological care by health care professionals is measured via an online questionnaire and semistructured interviews

Completion date
01/10/2026

Eligibility

Key inclusion criteria
In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. 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)

2. Patients undergoing primary treatment for cancer are treated with a curative intent
3. Aged 18 years or older
4. Able to read and speak Dutch
5. Having a PC/tablet and internet

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
A potential subject who meets any of the following criteria will be excluded from participation in the study:
1. Having a serious medical, psychiatric or cognitive disease that would interfere with participation (e.g. Alzheimer’s disease, blindness, severe obesity (BMI≥35))
2. Being in the palliative phase

Date of first enrolment
01/09/2025

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
Netherlands

Study participating centre
Zuyderland Medical Centre
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Sponsor information

Organisation
Netherlands Organisation for Health Research and Development

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
Pseudonomized and processed datasets without personal characteristics will be made available under restriction for reuse in the DANS repository after completion of the project according to the FAIR principles. Metadata will be made available at the end of the project after an embargo period (after finishing up publications). Raw data is not made public, nor databases where personal characteristics are described according to GDPR guidelines. More detailed information regarding data storage in a repository will be added to the study record at a later stage.

IPD sharing plan summary
Stored in publicly available repository