

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

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|--------------------------|-----------------------------|---|
| <b>Submission date</b>   | <b>Recruitment status</b>   | <input checked="" type="checkbox"/> Prospectively registered    |
| 13/01/2025               | Recruiting                  | <input type="checkbox"/> Protocol                               |
| <b>Registration date</b> | <b>Overall study status</b> | <input type="checkbox"/> Statistical analysis plan              |
| 14/01/2025               | Ongoing                     | <input type="checkbox"/> Results                                |
| <b>Last Edited</b>       | <b>Condition category</b>   | <input type="checkbox"/> Individual participant data            |
| 06/01/2026               | Other                       | <input checked="" type="checkbox"/> 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 September 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](mailto:Lilian.Lechner@ou.nl)

## Contact information

### Type(s)

Principal investigator

### Contact name

Prof Lilian Lechner

### ORCID ID

<https://orcid.org/0000-0002-5160-7086>

### Contact details

Valkenburgerweg 177  
Heerlen  
Netherlands  
6419 AT  
+31 045-5762888  
[Lilian.Lechner@ou.nl](mailto:Lilian.Lechner@ou.nl)

### Type(s)

Public, Scientific

### Contact name

Dr Eline Collombon

### ORCID ID

<https://orcid.org/0000-0003-1729-8766>

### Contact details

Valkenburgerweg 177  
Heerlen  
Netherlands  
6419 AT  
+31 045-5762888  
[Eline.Collombon@ou.nl](mailto:Eline.Collombon@ou.nl)

## Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

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**

01/09/2026

## **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 ( $BMI \geq 35$ ))
2. Being in the palliative phase

**Date of first enrolment**

01/09/2025

**Date of final enrolment**

28/02/2026

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**  
**Zuyderland Medical Centre**  
Dr. H. van der Hoffplein 1  
Geleen  
Netherlands  
6162 BG

**Study participating centre**  
**Laurentius Ziekenhuis**  
Monseigneur Driessenstraat 6  
Roermond  
Netherlands  
6043 CV

**Study participating centre**  
**Fysiotherapie Bruinsma**  
Schoolstraat 96  
Landgraaf  
Netherlands  
6374 GZ

**Study participating centre**  
**Oncologisch Expertise Centrum Weert**  
Biest 37  
Weert  
Netherlands  
6001 AP

**Study participating centre**  
**Fysiotherapie Helma Weekers**  
Maaseikerweg 45  
Weert  
Netherlands  
6005 AA

**Study participating centre**  
**Fysiotherapie Molenberg MSP**  
Voskuilenweg 129  
Heerlen  
Netherlands  
6416 AJ

**Study participating centre**

**Fysiotherapie Mulders**

Pastoor Vullinghsstraat 10

Sevenum

Netherlands

5975 AP

**Study participating centre**

**fysioHelden Fysiotherapie**

J. F. Kennedylaan 210

Panningen

Netherlands

5981 WX

**Study participating centre**

**FysioRosmalen**

Dorpsstraat 56A

Rosmalen

Netherlands

5241 ED

**Study participating centre**

**Fysiotherapie Den Bosch Oost**

Van Broeckhovenlaan 6

's Hertogenbosch

Netherlands

5213 HX

**Study participating centre**

**Fysiotherapie Tilburg Reeshof**

Ketelhavenplein 243

Tilburg

Netherlands

5045 NE

**Study participating centre**

**VieCuri Medisch Centrum**

Tegelseweg 210

Venlo  
Netherlands  
5912 BL

**Study participating centre**

**Vietaal Kerkrade**  
Heiveldstraat 107  
Kerkrade  
Netherlands  
6466 AJ

**Study participating centre**

**Fysio Centrum Tegelen**  
Industriestraat 94a  
Tegelen  
Netherlands  
5931 PK

**Study participating centre**

**Wolbert Fysio**  
Hertog Janplein 28  
Erp  
Netherlands  
5469 BJ

**Study participating centre**

**Fysiotherapie de Maat**  
Stationsstraat 17  
Heythuysen  
Netherlands  
6093 BJ

**Study participating centre**

**MTC Bernheze**  
Raadhuisplaza 2  
Heeswijk Dinther  
Netherlands  
5473 CX

**Study participating centre**

**Adelante Zorggroep**

Zandbergseweg 111

Hoensbroek

Netherlands

6432 CC

**Study participating centre**

**FysioSport/Therapie Midden-Brabant**

Benatzkystraat 38

Tilburg

Netherlands

5011 ED

**Study participating centre**

**Fysio Loon op Zand**

Kloosterstraat 37

Loon op Zand

Netherlands

5175 BH

**Study participating centre**

**Admiraal de Ruyter Ziekenhuis**

's-Gravenpolderseweg 114

Goes

Netherlands

4462 RA

**Study participating centre**

**Radboudumc**

Geert Grootplein Zuid 10

Nijmegen

Netherlands

6525 GA

**Study participating centre**

**Bernhoven**

Nistelrodeseweg 10

Uden

Netherlands

5406 PT

**Study participating centre**  
**Wilhelmina Ziekenhuis Assen**  
Europaweg-Zuid 1  
Assen  
Netherlands  
9401 RK

**Study participating centre**  
**Libra Revalidatie & Audiologie**  
Toledolaan 2  
Eindhoven  
Netherlands  
5629 CC

**Study participating centre**  
**Fysiotherapeutisch Centrum Beusen-Foudraine**  
Goorstraat 15  
Soerendonk  
Netherlands  
6027 NB

**Study participating centre**  
**St. Jans Gasthuis Weert**  
Vogelsbleek 5  
Weert  
Netherlands  
6001 BE

**Study participating centre**  
**Kr8 Horst**  
Westsingel 104  
Horst  
Netherlands  
5961 DH

**Study participating centre**  
**Knooppunt Baarlo + Venray**  
Kruisstraat 3

Baarlo  
Netherlands  
5991 EM

**Study participating centre**  
**Revant Medisch Specialistische Revalidatie**  
Brabantlaan 1  
Breda  
Netherlands  
4817 JW

**Study participating centre**  
**Fysiotherapie de Meierij**  
Borchmolendijk 1  
Sint-Oedenrode  
Netherlands  
5492 AJ

**Study participating centre**  
**Spaarne Gasthuis**  
Spaarnepoort 1  
Hoofddorp  
Netherlands  
2134 TM

**Study participating centre**  
**SaxenBurgh Medisch Centrum**  
Jan Weitkamplaan 4a  
Hardenberg  
Netherlands  
7772 SG

**Study participating centre**  
**Elkerliek Ziekenhuis**  
Wesselmanlaan 25  
Helmond  
Netherlands  
5707 HA

**Study participating centre****Zaans Medisch Centrum**

Kon. Julianaplein 58

Zaandam

Netherlands

1502 DV

**Study participating centre****HagaZiekenhuis**

Els Borst-Eilersplein 275

's-Gravenhage

Netherlands

2545 AA

**Study participating centre****Maastricht UMC+**

P. Debyelaan 25

Maastricht

Netherlands

6229 HX

**Study participating centre****Frisius MC**

Thialfweg 44

Heerenveen

Netherlands

8441 PW

**Study participating centre****FunQtio Venlo**

Veestraat 5B

Venlo

Netherlands

5914 RJ

**Study participating centre****De Berekuyl**

Reigershofweg 5

Hierden

Netherlands

3849 RT

# 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

## Study outputs

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |