Combined Lifestyle Intervention for cancer patients

Published: 04-02-2025
Last updated: 22-05-2025

The objective of the proposed study is to assess the effect of a combined lifestyle intervention for patients with cancer, who suffer from the consequences of cancer and its treatment, on Health-Related Quality of Life (HRQoL)

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON57521

Source
Onderzoeksportaal

Brief title
GLINK

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Cancer, Carcinoma, malignancies

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMw

Intervention

- Life style intervention

Explanation

N.a.

Outcome measures

Primary outcome

The primary endpoint is HRQoL measured with the EORTC QLQ-C30 summary score at 6 months after baseline.

Secondary outcome

Secondary outcomes: Function and symptom scales of Health-related Quality of Life (EORTC-QLQ-C30)
Cancer-related fatigue
Positive Health (Positive Health measurement model) Sleep hygiene (SHI)
Physical Activity (SQUASH & ActivPAL)
Diet components: fruit and vegetables, red and processed meat, alcohol, and nutritional supplements
Smoking status (yes/no) and packyears
Anthropometrics (height, weight, waist, body composition)
Cost-effectiveness (EQ-5D-5L, societal and healthcare costs)
Safety: (serious) adverse events

Study description

Background summary

A growing number of people is living with the (long-term) consequences of cancer and its treatment. These consequences may substantially affect their overall health-related quality of life (HRQOL).

Study objective

The objective of the proposed study is to assess the effect of a combined lifestyle intervention for patients with cancer, who suffer from the consequences of cancer and its treatment, on Health-Related Quality of Life (HRQoL)

Study design

The GLINK study is a pragmatic randomized controlled trial with two study arms: an intervention (n=122)- and a control arm (n=122).

In this study, we will recruit 244 cancer patients with a reduced HRQoL, as indicated by a clinically relevant impairment in at least one of the five functioning scales of the EORTC-QLQ-C30 questionnaire. Participants will be either within five years post-primary treatment **OR** have advanced cancer (stage IV) with a prolonged life expectancy.

Intervention

Patients in the intervention arm will be offered a combined lifestyle intervention guided by a lifestyle coach and oncology nurse. The intervention consists of an intensive intervention phase of 6 months and a maintenance phase of another 6 months. The intensive phase consists of six group sessions and three to five individual sessions. The program starts shortly after the baseline measurements. In the maintenance phase, there will be fewer sessions: three group sessions and one individual session. Group sessions take place near the home of the patients.

The control patients will receive four online group sessions with a lifestyle coach and all educational materials after the intervention period of 6 months.

Study burden and risks

Burden

The burden of the study comprises time investment, i.e., two visits of the study team at home, completion of questionnaires at home, and participation in combined lifestyle intervention (9 group- and 5-7 individual sessions). Additionally, participants will be asked to wear an activity tracker one week after the baseline visit and before the 6-month visit.

Risks

Participation in this study does not involve direct health risks. However, there are some indirect risks associated with lifestyle changes:

Starting or increasing physical activity: As with any physical activity, there is a risk of injury. To ensure safety, the lifestyle coach will advise patients with stage IV disease and/or potential medical conditions that may increase exercise-related risks (e.g., high blood pressure, heart problems) to obtain medical clearance before. For these patients, the lifestyle coach may also advise exercise under the supervision of a(n) (oncology) physiotherapist.

Behavioural changes: Adjusting to new lifestyle habits can be challenging and may lead to feelings of frustration.

Benefit

We expect that the intervention will have a beneficial effect on the participant’s health status by improving their lifestyle. Potential health improvements include:

- Enhanced physical fitness
- Increased self-efficacy
- Reduced stress
- Higher energy levels, etc.

Contacts

Scientific
Universitair Medisch Centrum Utrecht
EM Monninkhof
Heidelberglaan 100
Utrecht 3584CX
Netherlands
088-7568181
Public
Universitair Medisch Centrum Utrecht
EM Monninkhof
Heidelberglaan 100
Utrecht 3584CX
Netherlands
088-7568181

Trial sites

Trial sites in the Netherlands

Universitair Medisch Centrum Utrecht
Target size: 244

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

To be eligible to participate in this study, a participant must:

- Be diagnosed with an invasive or haematological cancer type
- Be within five years post-primary treatment with curative intent **OR** having advanced cancer (stage IV) with a prolonged life expectancy (chronic cancer patients). Primary treatment in this context, includes among others surgery (> 3 months ago), radiotherapy, and/or chemotherapy or stem cell transplant in case of haematological cancers.
- Report a reduced HRQoL, i.e., a low score on at least 2 of the functioning scales and/or the symptom scale fatigue of the EORTC-QLQ-30 based on the thresholds of clinical importance of Giesinger et al.
- Be 40 years of age or older.
- Be able to speak and understand Dutch

Exclusion criteria

A participant who meets any of the following criteria will be excluded from participation in this study:

- o Following, or planning to follow a combined lifestyle intervention (i.e., one of the existing interventions for overweight) during the intervention period
- o Patients in the terminal phase (life expectancy < 3 months)
- o Mental or behavioural problems that hinder participating in group lifestyle coaching indicated by the health care professional who is referring to GLINK or by the study team
- o Any circumstances that would impede the ability to give informed consent or adherence to study requirements as determined by the study team or treating physician

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	No intervention
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2025
Enrollment:	244
Duration:	24 months (per patient)
Type:	Anticipated

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Approved WMO

Date:	01-05-2025
Application type:	First submission
Review commission:	METC NedMec

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
Research portal	NL-009215