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Cancer aftercare in general practice

Submission date
14/12/2021

Recruitment status
No longer recruiting

Registration date
15/12/2021

Overall study status
Completed

Last Edited
13/02/2025

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
In our ageing society, diagnoses of cancer will be more common each year. With an expected 116,500 diagnoses in 2030, in the next decade more than 1 million people will be living with cancer or its consequences in the Netherlands. Even though early detection and new treatment methods are leading to improved chances of survival, cancer survivors have a high risk for recurrence and other illnesses. This puts them at a priority for prevention. Moreover, treatment often has physical and or psychological consequences that interfere with their return to normal life. This stresses the relevance of structural integration of cancer aftercare in the healthcare system.
After treatment, however, patients are often dismissed from healthcare. Even though bi-yearly check-ups are protocol, there is no support to deal with the side effects of cancer and its treatment. To accommodate the growing number of cancer survivors eHealth solutions have been presented that focus on prevention by means of lifestyle promotion or reduction of common problems after cancer, such as fatigue and depression. One such solution is the Cancer Aftercare Guide, which has been proven effective to promote vegetable intake and physical activity and reduce fatigue and depression. A large group of survivors, however, is unaware of the Cancer Aftercare Guide's existence and as a result does not access this tool.
In order to improve the reach of the Cancer Aftercare Guide, this project delivers the eHealth intervention by means of blended care. This research will investigate the use of blended care to integrate the Cancer Aftercare Guide in the primary care setting, with a focus on lifestyle support after cancer treatment. This study aims to evaluate the effectiveness, cost-effectiveness, feasibility, use and appreciation of the blended care approach.

Who can participate?
Patients aged 18 years or older who have successfully completed the primary treatment for any type of cancer (e.g. radiotherapy, chemotherapy, surgery) with the last treatment to have been between 6 weeks ago and 3 years ago, or belong to a watchful waiting condition (e.g. option for prostate cancer patients) recruited from around 40 different general practices in the Netherlands.

What does the study involve?
Participants will receive a letter or a phone call from their general practitioner in which they are asked to participate in the study. Participants who agree to participate are requested to send a signed consent form to the researcher. Upon receiving the consent form, the researcher will

invite the patient to fill out the first questionnaire and will notify their general practitioner. General practitioners are randomly assigned to either an intervention group or control group. Dependent on randomization either of the following procedures will be conducted by a general practitioner or practice nurse (hereinafter referred to as "health care provider"):
In the intervention group, patients will be invited for an intake consultation with their health care provider as a part of the blended care counseling. Participants are instructed to bring the results of the baseline questionnaire to the intake consultation either as a digital PDF or a printed out version. During the intake, the health care provider will discuss participant's results on the baseline questionnaire in order to identify their care needs. The health care provider will then further introducethe Cancer Aftercare Guide and motivate participants to work on their recovery with the online program. Participants will be granted access to the Cancer Aftercare Guide for 6 months. At the end of the intake a second appointment will be made for a follow-up consultation after 4 to 6 weeks. During the second consultation, or follow up, the participant's progress in the Cancer Aftercare Guide modules and their intentions and goals to continue lifestyle behavior(s) are discussed. The health care provider recommends the participant to further use the Cancer Aftercare Guide as a self-management tool (see explanation on online component below). The protocol ends after the follow-up consultation. In case participants are in need of or prefer more support in lifestyle change or psycho-social issues, the healthcare provider is instructed to refer them to specialized care, which is in line with the usual care for cancer survivors.
In the waiting list control group, patients will be actively encouraged to access the eHealth intervention after the last measurement at 12 months, in the meantime they will receive care as usual. This implies that patients receive regular care from their general practitioner, which is initiated per patient request, and is usually complaint-driven. The use of the co-intervention will be measured.
In the online Cancer Aftercare Guide participants receive tailored advice regarding lifestyle and psychosocial subthemes, based on a baseline self-report questionnaire. A total of nine subthemes are assessed, including: physical activity, diet, alcohol, smoking, fatigue, mood, relationships, work and residual problems. The results are presented in a module referral advice in which scores are depicted by a traffic light image. This module referral advice aims to guide participants through the wide-ranging Cancer Aftercare Guide portal, based on experienced complaints and identified needs, as assessed by the screening questionnaire. However, participants are free to visit any module that is of interest to them. Within these modules participants receive tailored interventions that have been proven to be effective and are theoretically based. For modules that cover lifestyle subthemes (physical activity, diet, alcohol and smoking) advice is tailored to fit participants' current health behavior, intention to change, perceived advantages of the behavior and perceived barriers as indicated by their results on the baseline questionnaire.
All participants are requested to fill out a self-report questionnaire to assess lifestyle, experienced distress, fatigue and health-related quality of life (at baseline, 6 months and 12 months) and health-related costs (included in the 6-month measurement). Moreover, cholesterol, blood glucose, and blood pressure are measured at 6 months at the general practice center. Additionally, participants in the intervention group will be requested to fill out a process evaluation questionnaire, evaluating the blended care protocol, at 6 months.

What are the possible benefits and risks of participating?
When involved in the study participants may receive benefits of a healthy lifestyle (smoking abstinence, healthy diet, physical activity, abstinence from or limiting alcohol use), and may reduce their psychosocial problems such as experienced distress and fatigue. As a result their health-related quality of life may improve.
There are no risks or negative side effects related to participation in this study. Participants in the intervention group are free to decide how much time and effort they put into the online

program. Moreover, all participants are allowed to cease their participation at any time. This will be made clear to participants at the start of the study.

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

When is the study starting and how long is it expected to run for?
April 2022 to December 2024

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

Who is the main contact?
Michelle Smits, michelle.smits@ou.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
555003204

Study information

Scientific Title
Cancer aftercare in the general practice: (cost) effectiveness of a blended care approach on the lifestyle behaviors of cancer survivors

Study objectives
The blended care intervention for cancer aftercare in general practice will result in higher adherence to lifestyle recommendations for diet, physical activity (PA), smoking and alcohol use in cancer survivors than usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/04/2022, Name of the Ethics Board: METC Z (Secretariaat, T3 Heerlen, PO Box 5500, 6130 MB Sittard, The Netherlands; +31 (0)88 459 0129; metc@zuyderland.nl), ref: METCZ20210192

Study design
Two-armed interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Adherence to lifestyle recommendations in cancer survivors

Interventions

Current interventions as of 24/01/2023:

Cancer survivors will receive a blended care intervention, administered by their general practitioner or a practice nurse (PN). The blended care intervention consists of two face-to-face consultations at the general practice and use of the online Cancer Aftercare Guide eHealth program. In the online Cancer Aftercare Guide the patient will receive tailored advice based on a self-report questionnaire on lifestyle and psychosocial problems that are common in cancer survivors. During the face-to-face consultations, the GP or PN will instruct the patient how to use the online program, support them in interpreting the advice and motivate them to act on this advice accordingly. The intervention takes 6 months, patients visit their GP or PN at baseline for the first consultation and 4 to 6weeks later for the second consultation. Use of the online program will take place in the private setting.

Participants will receive a letter or a phone call from their general practitioner in which they are asked to participate in the study. Participants who agree to participate are requested to send a signed consent form to the researcher. Upon receiving the consent form, the researcher will invite the patient to fill out the first questionnaire and will notify their general practitioner. General practitioners are randomly assigned to either an intervention group or control group. Dependent on randomization either of the following procedures will be conducted by a general practitioner or practice nurse (hereinafter referred to as "health care provider"):

The unit of randomization is the General Practice; around 40 GPs will be computer randomized using the OpenEpi open source program (OpenEpi, 2013) to either intervention of control group by an independent researcher.

When assigned to the intervention condition, participants will be invited for an intake consultation with their health care provider, as a part of the blended care counseling. Participants are instructed to bring the results on the baseline questionnaire to the intake consultation, either as a digital PDF or a printed-out version. During the intake, the health care provider will discuss participant's results on the baseline questionnaire in order to identify their care needs. The health care provider will then present the Cancer Aftercare Guide and motivate participants to work on recovery with the online program. Participants will be granted access to the Cancer Aftercare Guide for 6 months. At the end of the intake, a second appointment will be made for a follow-up consultation after 4weeks.

During the second consultation, the participant’s progress in the Cancer Aftercare Guide modules and their intentions and goals to continue lifestyle behavior(s) are discussed. The health care provider recommends the participant to further use the Cancer Aftercare Guide as a self-management tool (see explanation on the online component below). The protocol ends after the follow-up consultation. In case participants are in need of or prefer more support in lifestyle change or psycho-social issues, the healthcare provider is instructed to refer them to specialized care, which is in line with the usual care for cancer survivors (Comprehensive Cancer Centre the Netherlands, 2011).

Participants in the waiting list control condition will be actively encouraged to use the online intervention after the last measurement at 12 months. In the meantime, they will receive care as usual, which implies that patients receive regular care from their general practitioner, which is initiated per patient request, and is usually complaint-driven. The use of co-intervention will be measured.

In the online Cancer Aftercare Guide participants receive tailored advice regarding lifestyle and psychosocial subthemes, based on a baseline self-report questionnaire. A total of nine subthemes are assessed, including: physical activity, diet, alcohol, smoking, fatigue, mood, relationships, work, and residual problems. The results are presented in a module referral advice in which scores are depicted by a traffic light image. This module referral advice aims to guide participants through the wide-ranging Cancer Aftercare Guide portal, based on experienced complaints and identified needs, as assessed by the screening questionnaire. However, participants are free to visit any module that is of interest to them. Within these modules participants receive tailored interventions that have been proven to be effective and are theoretically based (Willems et al., 2015). For modules that cover lifestyle subthemes (physical activity, diet, alcohol, and smoking) advice is tailored to fit participants' current health behavior, intention to change, perceived advantages of the behavior, and perceived barriers as indicated by their results on the baseline questionnaire.

All participants are requested to fill out a self-report questionnaire to assess lifestyle, experienced distress, fatigue, and health-related quality of life (at baseline, 6 months, and 12 months) and health-related costs (included in the 6-month measurement). Moreover, cholesterol, blood glucose, and blood pressure are measured at 6 months at the general practice center. Additionally, participants in the intervention condition will be requested to fill out a process evaluation questionnaire, evaluating the blended care protocol, at 6 months.

Previous interventions:

Cancer survivors will receive a blended care intervention, administered by their general practitioner or a practice nurse (PN). The blended care intervention consists of two face-to-face consultations at the general practice and use of the digital Cancer Aftercare Guide eHealth program. In the online Cancer Aftercare Guide the patient will receive tailored advice based on a self-report questionnaire on lifestyle and psychosocial problems that are common in cancer survivors. During the face-to-face consultations, the GP or PN will instruct the patient how to use the online program, support them in interpreting the advice and motivate them to act on this advice accordingly. The intervention takes 6 months, patients visit their GP or PN at baseline and 4-6 weeks later, and use of the online program will take place in the private setting.

Participants will receive a letter or a phone call from their general practitioner in which they are asked to participate in the study. Participants who agree to participate are requested to fill out the baseline questionnaire and visit the general practice for biomedical measurements.

The unit of randomization is the General Practice; around 40 GPs will be computer randomized using the OpenEpi open source program (OpenEpi, 2013) to either intervention of control group by an independent researcher.

When assigned to the intervention condition, participants will be invited for an intake consultation with their general practitioner, as a part of the blended care counseling. During the intake, the general practitioner will briefly discuss the patient's recovery from treatment and the current status of the patient's quality of life. The general practitioner will then present the Cancer Aftercare Guide and motivate participants to work on recovery with the online program. Participants will be granted access to the Cancer Aftercare Guide for 6 months. At the end of the intake, a second appointment will be made for a follow-up consultation after 4-6 weeks.

The follow-up consultation will be held by either the general practitioner or the practice nurse (hereinafter referred to as “health care provider”). Participants are requested to bring their personal Cancer Aftercare Guide results to the consultation either as a digital PDF or a printed-out version. During the consultation, the health care provider will discuss participants’ results on the baseline questionnaire as presented in the overview, their progress in the Cancer Aftercare Guide modules and their intentions and goals to continue lifestyle behavior(s). The health care provider recommends the participant to further use the Cancer Aftercare Guide as a self-management tool (see explanation on the online component below). The protocol ends after the follow-up consultation. In case participants are in need of or prefer more support in lifestyle change or psycho-social issues, the healthcare provider is instructed to refer them to specialized care, which is in line with the usual care for cancer survivors (Comprehensive Cancer Centre the Netherlands, 2011).

Participants in the waiting list control condition will get access to the intervention after the last measurement at 12 months, in the meantime, they will receive care as usual, which implies that patients receive regular care from their general practitioner, which is initiated per patient request, and is usually complaint-driven. The use of co-intervention will be measured.

In the online Cancer Aftercare Guide participants receive tailored advice regarding lifestyle and psychosocial subthemes, based on a baseline self-report questionnaire. A total of nine subthemes are assessed, including: physical activity, diet, alcohol, smoking, fatigue, mood, relationships, work, and residual problems. The results are presented in a module referral advice in which scores are depicted by a traffic light image. This module referral advice aims to guide participants through the wide-ranging Cancer Aftercare Guide portal, based on experienced complaints and identified needs, as assessed by the screening questionnaire. However, participants are free to visit any module that is of interest to them. Within these modules participants receive tailored interventions that have been proven to be effective and are theoretically based (Willems et al., 2015). For modules that cover lifestyle subthemes (physical activity, diet, alcohol, and smoking) advice is tailored to fit participants’ current health behavior, intention to change, perceived advantages of the behavior, and perceived barriers as indicated by their results on the baseline questionnaire.

All participants are requested to fill out a self-report questionnaire to assess lifestyle, experienced distress, fatigue, and health-related quality of life (at baseline, 6 months, and 12 months) and health-related costs (included in the 6-month measurement). Moreover, cholesterol, blood glucose, and blood pressure are measured at baseline and 6 months at the general practice. Additionally, participants in the intervention condition will be requested to fill out a process evaluation questionnaire, evaluating the blended care protocol, at 6 months.

Intervention Type
Behavioural

Primary outcome measure
At baseline, 6 months and 12 months:
1. Physical activity (PA) will be assessed with the SQUASH questionnaire (Wendel-Vos et al., 2003)
2. Smoking behavior will be assessed by a validated 7-days point prevalence abstinence questionnaire (Mudde et al., 2000)
3. Alcohol consumption will be assessed using a standardized scale (GGD, 2003)
4. Dietary behaviors will be assessed using a validated food frequency questionnaire (VanAssema et al., 2002)

Secondary outcome measures
Current secondary outcome measures as of 24/01/2023:

1. Effects on self-reported health-related Quality of Life will be assessed with the EORTC QLQ-C30 at baseline, 6 months and 12 months; self-reported distress will be assessed with the Hospital Anxiety and Depression Scale (HADS) at baseline, 6 months and 12 months; and self-reported fatigue will be assessed with the Checklist Individual Strength (CIS) at baseline, 6 months and 12 months
2. Biomarkers, including TC/HDL cholesterol, blood glucose and blood pressure are assessed by means of clinical measurement at 6 months
3. Evaluation of health-related costs based on self-reported Medical consumption (assessed with the iMTA-MCQ at 6 months); self-reported Productivity costs (assessed with the iMTA-PCQ at 6 months); and QALY (assessed with the EQ-5D-5L at 6 months)
4. Process evaluation based on self-report data assessed by means of a process evaluation questionnaire at 6 months

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Previous secondary outcome measures:

1. Effects on self-reported health-related Quality of Life will be assessed with the EORTC QLQ-C30 at baseline, 6 months and 12 months; self-reported distress will be assessed with the Hospital Anxiety and Depression Scale (HADS) at baseline, 6 months and 12 months; and self-reported fatigue will be assessed with the Checklist Individual Strength (CIS) at baseline, 6 months and 12 months
2. Biomarkers, including TC/HDL cholesterol, blood glucose and blood pressure are assessed by means of clinical measurement at baseline and 6 months
3. Evaluation of health-related costs based on self-reported Medical consumption (assessed with the iMTA-MCQ at 6 months); self-reported Productivity costs (assessed with the iMTA-PCQ at 6 months); and QALY (assessed with the EQ-5D-5L at 6 months)
4. Process evaluation based on self-report data assessed by means of a process evaluation questionnaire at 6 months

Overall study start date
01/03/2020

Completion date
21/03/2025

Eligibility

Key inclusion criteria
1. Patients who have successfully completed the primary treatment for cancer (e.g. radiotherapy, chemotherapy, surgery), with the last treatment to have been between 6 weeks ago and 3 years ago, or belong to a watchful waiting condition (e.g. option for prostate cancer patients)
2. 18 years of age and older
3. Able to read and speak Dutch
4. Internet access and at least minimal internet experience
5. Access to a computer or tablet

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
376

Total final enrolment
127

Key exclusion criteria
1. Patients with a serious medical, psychiatric, or cognitive disease that would interfere with participation (e.g. Alzheimer’s disease, blindness)
2. Patients who did not complete primary treatment or who were not treated with curative intent

Date of first enrolment
22/06/2022

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
Netherlands

Study participating centre
Open Universiteit
Valkenburgerweg 177
Heerlen
Netherlands
6401 DL

Sponsor information

Organisation

Netherlands Organisation for Health Research and Development

Sponsor details
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info@zonmw.nl

Sponsor type
Research organisation

Website
http://www.zonmw.nl/en/

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

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal

Intention to publish date

01/04/2025

Individual participant data (IPD) sharing plan

Data will be collected and handled according to the Data Management Plan that was drafted for this project. Data is stored on hard disks on systems equipped with power failure back-up devices and automatic back-up systems. Data will be handled confidentially and anonymously. Each participant will receive a unique respondent number, not connected to name or personal details, under which the data is filed. Only researchers on this project will have access to the data.

Data will be stored in a publicly available repository as far as this concerns metadata (documentation about the data, documentation about the research process, syntaxes, and (information about) the software that was used). Raw data, as well as data that pertains to the personal data of participants, will not be made publicly available (in accordance with GDPR). Data documentation that has been cleared from personal data (processed data) will be made available upon request. Personal data are only available upon further discussion and application procedure. This will require a processing contract. A contact at the Open University will be available for such requests.

For access to the datasets please contact: Mellanie Geijen MSc., Datasteward@ou.nl
Type of data: processed data, raw data, syntaxes
Data will become available after all analyses are completed and will be available up to ten years after data collection.
Access criteria will be defined with the help of a legal advisor at the moment the data will become available (after all analyses are completed).
Data that do not contain personal information will be made publicly available (protocol, method, etc).
Data that contains personal information will only be made available via restricted access. Access will be granted only after approval by the data steward that is assigned to this project.
Participants will give their permission for reuse of the data and data will be anonymized.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (preprint)		28/11/2023	17/01/2025	No	No
Protocol article		12/02/2025	13/02/2025	Yes	No