Cancer aftercare in general practice - A blended lifestyle medicine approach

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The primary objective of this research is to gain insight into the short term (6 months) and long term (12 months) effects of the blended care protocol on cancer survivors* lifestyle behaviours. The secondary goal of this research is to gain insight...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON51779

Source
ToetsingOnline

Brief title
Cancer aftercare in general practice

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
□malignant neoplasm□ and □cancer□

Research involving
Human

Sponsors and support

Primary sponsor: Open Universiteit
Source(s) of monetary or material Support: Subsidie ZonMw

Intervention

Keyword: Blended care, Cancer survivors, EHealth, General practice

Outcome measures

Primary outcome

Primary outcomes at baseline, 6 months and 12 months are effects on lifestyle behaviors:

1) Physical activity: the amount of minutes per week of moderate physical activity, number of muscle strengthening exercises

2) Smoking

3) Alcohol use

4) Diet: weekly intake of vegetables, fruit, fiber and fish

Secondary outcome

Secondary outcomes at 6 months are biomarkers:

- Blood pressure

Secondary outcomes at baseline, 6 months and 12 months are:

- Experienced distress (depression and anxiety)

- Experience fatigue

- Health related quality of life

Secondary outcomes at 6 months are:

- Disease burden

- Medical consumption

- Productivity costs

- QALY*s

- Appreciation and use of the intervention

Study description

Background summary

In our ageing society, diagnoses of cancer will be more common each year. With an expected 116.500 diagnoses in 2030 (GLOBOCAN, 2020), the next decade will have more than 1 million people will be living with cancer or its consequences in the Netherlands (KPMG, 2018). Even though early detection and new treatment methods are leading to improved chances of survival, cancer survivors have a high risk for recurrence and comorbidity. This puts them at a priority for prevention (Overholser & Callaway, 2018). Moreover, treatment often has physical and or psychological consequences that interfere with their return to normal life.

In order to support these survivors the Cancer After Care Guide has been developed. The Cancer Aftercare Guide is an eHealth intervention that promotes a healthy lifestyle and teaches self-management skills to deal with the consequences of cancer. Earlier research has proven the Cancer After Care Guide to be effective in improving diet and physical activity (Kanera et al., 2016) and reducing fatigue and depression (Willems et al., 2017). Since 2018 the Cancer After Care Guide has been available via kanker.nl (Dutch national website about cancer), however only a small number of patients has used the program.

In their 2015 Oncology Standpoint, the Dutch College of General Practitioners (NHG, 2015) stated that GP involvement is crucial to meet patients* demand for cancer aftercare. They further stress the importance of self-management and patient engagement in cancer aftercare. In order to increase reach of the Cancer Aftercare Guide and support structural integration of cancer aftercare in the general practice, a blended care protocol has been developed. This study will investigate the effects of the blended care protocol on survivors* lifestyle behaviors primarily. Secondary outcomes are the effects of the blended care protocol on survivors* quality of life and health related costs to evaluate cost-effectiveness of the program. In a previous research on the Cancer Aftercare Guide cost-effectiveness was not evaluated.

Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries

Kanera, I. M., Bolman, C. A., Willems, R. A., Mesters, I., & Lechner, L.

(2016a). Lifestyle-related effects of the web-based Kanker Nazorg Wijzer (Cancer Aftercare Guide) intervention for cancer survivors: a randomized controlled trial. Journal of cancer survivorship : research and practice, 10(5), 883-897. https://doi.org/10.1007/s11764-016-0535-6

KPMG in opdracht van KWF Kankerbestrijding. Toekomstverkenning betere kwaliteit van leven, 2018

Overholser, L. S., & Callaway, C. (2018). Preventive Health in Cancer Survivors: What Should We Be Recommending?. Journal of the National Comprehensive Cancer Network : JNCCN, 16(10), 1251-1258. https://doi.org/10.6004/jnccn.2018.7083

Willems, R. A., Bolman, C. A., Mesters, I., Kanera, I. M., Beaulen, A. A., & Lechner, L. (2017a). Short-term effectiveness of a web-based tailored intervention for cancer survivors on quality of life, anxiety, depression, and fatigue: randomized controlled trial. Psycho-oncology, 26(2), 222-230. https://doi.org/10.1002/pon.4113

Study objective

The primary objective of this research is to gain insight into the short term (6 months) and long term (12 months) effects of the blended care protocol on cancer survivors* lifestyle behaviours.

The secondary goal of this research is to gain insight into the effects of the blended care protocol on blood pressure, as well as psychosocial distress, fatigue and health-related quality of life. Additionally, the cost-effectiveness of the intervention will be evaluated based on burden of disease, medical consumption, sick days, the presence of co-morbidity and QALY*s.

Furthermore, the blended care protocol, the usage of the website and the different modules of the Cancer Aftercare Guide will be evaluated by means of a process evaluation.

Study design

This research will be carried out by means of a randomised clinical trial (RCT). A clinical trial will be executed to compare the experiment group and waiting list control group. General practices that participate in the study will be randomly assigned to either intervention of control group. General practices will invite their patients to participate in the study by means of an information letter and informed consent. In case patients want to partake in the study they are requested to send a signed copy of the informed consent to the reseachers. Once the informed consent is processed by the research team,

the participant will receive a link and login code to the online baseline questionnaire. Meanwhile GPCs will be informed about which patients agreed to participate in the experiment. After completing the baseline questionnaire, participants in the intervention group will be invited for a first consultation with the GP or PN. This is the start of the blended care intervention. The blended care intervention consists of an intake consultation and a follow up consultation 6 weeks later. The consultations will be held either by a general practitioner or a practice nurse. After the intake consultation participants in the intervention group will be encouraged to use the online Cancer Aftercare Guide. During the follow up consultation participants will discuss their progress with the online Cancer After Care Guide receive personal counselling regarding the interpretation of the lifestyle advice given by the program. Participants in the control group will only partake in the online questionnaires and the blood pressure measurement during the course of the study. GPCs in the control group will offer their patients care as usual. Care as usual means that participants in the control group have access to all normal health care, including eHealth interventions such as the existing Cancer Aftercare Guide program. They are free to use this program, albeit at their own initiative. Participants from the control group will be informed about and encouraged to use the Cancer After Care Guide after the last measurements at 12 months. Blood pressure will be measured with all participants at 6 months. Every participant will receive an online questionnaire at baseline, 6 months and 12 months.

The design of the study is as displayed below:

E: T0 x T1 x T2 -
C: T0 - T1 - T2 x

E: experimental group
C: control group

Measurements:
T0: baseline: lifestyle physical activity, diet, smoking behaviour and alcohol consumption), level of distress, fatigue and health-related quality of life (health related QoL)

T1: 6 months after first measurement: lifestyle physical activity, diet, smoking behaviour and alcohol consumption), blood pressure, level of distress, fatigue and health-related quality of life (health related QoL), health-related costs, process evaluation.

T2: 12 months after first measurement: lifestyle physical activity, diet, smoking behaviour and alcohol consumption), level of distress, fatigue and health-related quality of life (health related QoL)

X: use of the online Cancer Aftercare Guide program

-: no use of the online Cancer Aftercare Guide program

Intervention

The experimental group receives the blended care intervention. The blended care intervention consists of:
One consultation with the general practitioner or practice nurse in which participants will be motivated to start using Cancer Aftercare Guide;
One consultation with the general practitioner or practice nurse, which will take place 6 weeks after the first consultation and in which the participant will receive personal counseling with interpreting the lifestyle advice received in the Cancer Aftercare Guide;
Use of the Cancer Aftercare Guide up until 6 months after the first consultation. The Cancer Aftercare Guide will provide personally tailored information within different modules:
• Physical Activity
• Diet
• Smoking
• Alcohol use
• Psychological complaints as a consequence of cancer such as distress or fatigue
•(Disease) Self-Management.
•Problem solving skills (coping mechanisms)
•Return to work and social relationships

The modules consist of textual information and advice, video clips (in which former cancer patients tell their story) and assignments/exercises. The assignments have been based on evidence-based methods, such as CBT, mindfulness, modelling, action planning and coping planning. Participants in the experimental group are free to decide to what extent they use the online Cancer Aftercare Guide. Participants will be referred to modules that cover subjects that are most useful to them, based on the baseline questionnaire. They are free to follow modules of their own choice and decide whether or not they complete the assignments. Participants will use the program independently. In case of questions they will be referred to the research team. Under no conditions medical advice is given in the online program. For medical questions we will always refer to the specialist providing treatment. Participants in the control group are informed about and encouraged to use the online Cancer Aftercare Guide program after the last measurement at 12 months.

Study burden and risks

There are no risks of negative consequences related to this research. Participants in the intervention group are free to decide to what extent they partake in the online Cancer Aftercare Guide. Moreover, all participants (both the intervention as well as the control group) are allowed to stop

participation at any time.

The participant load of two visits to the general practitioner and practice nurse in the timeframe of 2 months is minimal. The participant load of undergoing blood pressure measurement within a timeframe of 6 months is minimal. Participant load for filling out questionnaires at 3 time points within 12 months is minimal.

Furthermore, we expect that the use of the intervention will contribute to a healthy lifestyle, will have positive effects on participants* quality of life and will reduce the experienced distress and fatigue in participants. The personal contact with the general practitioner or practice nurse that results from this protocol is a desirable side effect..

Participants of the control group will only fill out questionnaires and undergo blood presurre measurements. Besides that they will receive care as usual. They will not be withheld from care (neither from seeking additional professional support if they wish to do so). After the final measurements at 12 months are completed, participants in the control group will be informed about and encouraged to use the online Cancer Aftercare Guide program.

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

a) Patients who have successfully completed the primary treatment for cancer (e.g. radiotherapy, chemotherapy, surgery) and were treated with curative intent, 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)
b) 18 years of age and older
c) Able to read and speak Dutch
d) Without a serious medical, psychiatric or cognitive disease that would interfere with participation
e) Internet access and at least minimal internet experience
f) Access to a computer or tablet

Exclusion criteria

a) Patients with a serious medical, psychiatric, or cognitive disease that would interfere with participation (e.g. Alzheimer*s disease, blindness);
b) Patients who did not complete primary treatment or who were not treated with curative intent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-08-2022
Enrollment:	376
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	13-04-2022
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	22-05-2023
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	18-06-2024
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	ISRCTN12451453
CCMO	NL80166.096.21