The effectiveness and evaluation of the online 'Kanker Herstel Hulp' intervention in cancer survivors.

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

Summary

ID

NL-OMON37256

Source
ToetsingOnline

Brief title
Online 'Kanker Herstel Hulp' intervention

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 door KWF Kankerbestrijding

Intervention

Keyword: Cancer survivors, E-health, Psychosocial distress, Quality of Life

Outcome measures

Primary outcome

Primary effect outcomes at baseline and 3, 6 and 12 months after the start of

the intervention are:

1) Quality of life

2) The extent of psychological distress

Secondary outcome

Secondary outcomes at baseline and 3, 6 and 12 months after the start of the

intervention are:

1) Lifestyle behaviors

2) Self-management skills and problem solving skills (coping)

3) Information needs

4) Perceived social support

Study description

Background summary

In the Netherlands 83.000 new cancer cases occur each year. It is estimated that the number of patients who survive their cancer and have to live with the aftermath will rise to almost 700.000 patients in 2015. This means that each year large numbers of cancer patients end their treatment en try to move on with their lives. These survivors however often experience a number of social, psychological and physical problems, for which they receive insufficient after

care treatment. The Health Council of the Netherlands recently concluded that current after care for cancer survivors is insufficient and doesn't meet their needs. To provide in this need for information, help and advice, an inegrated and tailored website will be developed, the 'Kanker Nazorg Wijzer'. The effectiveness of this webite in improving quality of Life, reducing distress and physical en psychosocial problems, fulfillment of informational needs and promoting a healthy lifestyle, self-management and problem solving skills will be studied.

Study objective

The project primarily aims to study short (3 and 6 months) and long term (12 months) health related effects of the 'Kanker Nazorg Wijzer' on survivors' psychosocial distress and quality of life (QoL). Furthermore, process aspects of usage and evaluation of different modules of the 'Kanker Nazorg Wijzer' will be studied.

Secondary aims are to study the effect of the use of the intervention on disease self-management and problem solving skills, the amount of experienced social support from important others, the extent to which a healthier lifestyle is achieved and the extent to which the information need is fulfilled.

It is expected that the use of the 'Kanker Nazorg Wijzer' will lead to better disease self-management and problem solving skills, a healthier lifestyle, better fulfilled informational needs and more satisfactory support, which in turn is expected to decrease the level of distress and improve quality of life in cancer survivors.

Study design

The study is a randomised clinical trial (RCT). A clinical trial will be carried out to compare the experimental group with the waiting list control group. The cancer survivors will be randomised to one of the two conditions.

Randomisation takes place after the participants have returned the signed informed consent form to the researchers. After returning their informed consent, they can log in on the online research site. They then receive some short questions to check again whether the participants meet the inclusion criteria. Participants who do not meet the criteria will be excluded. Participants who meet the criteria will be online randomly assigned to the intervention condition or the control condition. To secure a balanced allocation to the two groups with respect to some core variables like age and gender, these variables will be taken into account. During the randomisation process, a correction in allocation will be made when gender and age are unevenly divided between the two groups.

After randomisation, the experimental group first fills out a baseline questionnaire and then gets access to the online intervention, the 'Kanker Nazorg Wijzer' for a period of 6 months. Moreover, this group has access to the general information about the study. The control group will have access tot the intervention after the last measurement at 12 months. During the study period, they only have access to the part of the intervention with general information about the study. There they are also presented the questionnaires they have to fill in. All participants will receive (online) questionnaires: at baseline (see the explanation above) and then at 3, 6 and 12 months after the first measurement.

Outline of the study design:

E: O1 x O2 x O3 - O4 -
C: O1 - O2 - O3 - O4 x

Measurements:
E: Experimental group
C: Control group
O1: baseline: Quality of life (Qol), level of distress and physical and psychosocial problems, lifestyles, self-management and problem solving skills, information needs, before access to intervention
O2: 3 months after first measurement: Quality of life, level of distress and physical and psychosocial problems, lifestyles, self-management and problem solving skills, information needs. In addition, in the experimental group a process evaluation of the intervention (usage and evaluation of modules, process data),
O3: 6 months after first measurement: Quality of life, level of distress and physical and psychosocial problems, lifestyles, self-management and problem solving skills, information needs. Process evaluation of the intervention (in the experimental group)
O4: 1 year after first measurement: Quality of life, level of distress and physical and psychosocial problems, lifestyles, self-management and problem solving skills, information needs.
x: access to the intervention
-: no access to the intervention

Intervention

The participants in the experimental group receive access to the online intervention for 6 months. The intervention will provide information and tailored advice through different modules on the following subjects:

- (disease) self-management
- problem solving skills (coping)
- lifestyle behaviors
- psychological distress due to the disease

- physical complaints due to the disease (e.g. fatigue)
- handling the social environment / return to work

The modules consist among other things of written text, short videos (in which former cancer patients tell their story) and assignements/exercises. These are based on proven effective methodes, like cognitive behavioral therapy, mindfulness, modelling, action planning and coping planning.

Participants in the experimental group can log in as often and as long as they want to. Participants receive an advice to follow one or two modules, based on the baseline questionnaire. However, participants can choose for themselves which modules they want to follow or which information they want to read. Also, participants can decide for themselves whether they want to follow the advice given in the module or whether they want to do the assignments/exercises. Participants use the programma independently, but they can always contact the research team when needed. Medical advice will never be given. When participants have questions regarding medical issues, they will be referred to their own physician.

A discussion forum will probably be a part of the online programma. This discussion forum is secured, as is the programma itself, which is not publicly accesible. A moderator with a medical or health-psychological background will monitor the discussion forum for the safety of the participants. However, this person will never give personal advice and will refer participants to their own physician when they have questions regarding their medical condition.

Participants in the waiting list control group get access to the intervention after the last measurement at 12 months.

Study burden and risks

There are no risks and detrimental consequenses related to the study. Participants in the experimental group can decide for themselves when and how often they make us of the intervention. Moreover, all the participants (in the experimental group and in the control group) can stop their participation in the study at any time. The burden of filling out four questionnaires in a period of 12 months is low. Moreover, expectation is that the use of the intervention will have positive effects on the quality of life of the participants, that it will decrease levels of distress and physical and psychosocial problems and will contribute to a healthier lifestyle and better self-management and problem solving skills. The participants in the control group only complete the questionnaires during the study period. They receive their usual health care. They won't be refrained from care (including extra professional care they would like to seek). The participants in the control group will receive access to the intervention (the online programme) after the end of the study period.

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) diagnosis of cancer;
b)18 years of age or older;
(c) no cancer activity diagnosed at the last hospital control visit;
(d) successful completion of the main treatment period, up to one year ago;
(e) able to read and to speak Dutch;
(f) internet access and minimal internet experience (weekly access; so that access and skill in using the internet do not confound study results); and
(g) no serious medical, psychiatric or cognitive disease that would interfere with participation (e.g. Alzheimer*s disease).

Exclusion criteria

Patients with a serious medical, psychiatric, or cognitive disease that would interfere with participation.

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:	Recruitment stopped
Start date (anticipated):	12-11-2013
Enrollment:	376
Type:	Actual

Ethics review

Approved WMO

Date:	23-11-2012
Application type:	First submission
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
CCMO	NL41445.096.12