CoCo in cancer rehabilitation: evaluation of use, satisfaction and clinical effects

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35213

Source
ToetsingOnline

Brief title
CoCo in oncology

Condition

- Other condition

Synonym
cancer, malignant neoplasm

Health condition

Lichameljike en psychosociale gevolgen na (behandeling van) kanker

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh
Source(s) of monetary or material Support: Senter Novem (uitvoeringsorgaan agentschap NL)

Intervention

Keyword: cancer rehabilitation, clinical change, computer technology, user experience

Outcome measures

Primary outcome

The implementation of the CoCo oncology application will be evaluated in terms of use (login, number and type of exercises, fims and questionnaires that have been filled in and/or seen, amount of time that have been spent on the program), satisfaction with the technology (UTAUT questionnaire), satisfaction with the treatment (CSQ) and quality of the provision of the services (SERVQUAL questionnaire).

Secondary outcome

The clinical effectiveness will be evaluated in terms of burden of the disease (10-point NRS), quality of life (EORTC-QLQ-C30), phyical functioning (SF-36), fatigue (CIS-20), anxiety (HADS-A) and depression (HADS-D).

Study description

Background summary

Cancer is a common disease with serious consequences for patient*s physical and psychosocial functioning. These consequences may last for a long time, even after completion of the curative treatment. To overcome cancer-related problems and to improve quality of life, many cancer survivors participate in a multidimensional rehabilitation program. One drawback of these programs is that they require a lot of contact time between the therapist and the patient. To

improve the efficiency of the treatment, the CoCo (ConditionCoach) oncology application will be implemented in the traditional cancer treatment of Het Roessingh, center for rehabilitation. This application can by used by patients at home and will partially replace traditional (face-to-face) treatment. To justify the use of the CoCo oncology application in the traditional treatment and to enable further implementation, it is important to evaluate the use of the application among patients.

Study objective

Primary goal of this study is to evaluate the use of and satisfaction with the CoCo oncology application among cancer survivors in het Roessingh, center for rehabilitation. Secondary goal is to evaluate the clinical effectiveness of the implementation of the CoCo oncology application in the traditional treatment.

Study design

The implementation of the CoCo oncology application will be evaluated in a cross-sectional study. The clinical effectiveness will be investigated in a exploratively controlled study. Three conditions will be compared: (1) traditional treatment (based on historical data), (2) traditional treatment + CoCo oncology application, (3) shortened traditional treatment + CoCo oncology application.

Intervention

The CoCo oncology application is a technology assisted service to improve physial and mental fitness. The application consists of two modules for the patient: (1) activity registration with feedback and (2) online exercise program values-based choices. The application further contains a module telemonitoring (for the therapist), which summarizes several patient results.

Study burden and risks

The risks associated with participation in this study are minimal. Participants receive traditional (face-to-face) treatment and have the ability to use the CoCo oncology application at home (as supplement to their traditional treatment). This application consists of an activity registration (twice one week), online information (texts and films), and exercises. Daily, the patient is asked to fill a few online questions (2-5 minutes each day). At three times the patient is asked to complete an extensive questionnaire (30-45 minutes each time). Drugs and physical procedures are no part of the protocol. Main study parameters only consist of patient-reported questionnaires and information registered by the system. Most of these questionnaires are already included in the traditional treatment and do not add extra burden to the patient.

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

- age > 18 years;
- finished primary curative treatment for > 3 months (except herceptin, Tamoxifen, etc.);
- cancer related symptoms;
- sufficient physical capacities to participate in sport activities twice a week;
- mild to moderate psychosocial symptoms and fatigue (Symptom Checklist-90 < 165; Checklist Individual Strength < 46).

Exclusion criteria

- palliative demand for care;
- serious psychopathology;

- insufficient understanding of the Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-09-2011
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	06-09-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)

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	NL37542.044.11