Case Management in Oncology Rehabilitation

Submission date [] Prospectively registered Recruitment status 11/10/2010 No longer recruiting [X] Protocol [] Statistical analysis plan Registration date Overall study status 24/11/2010 Completed [X] Results [] Individual participant data Last Edited Condition category 30/03/2017 Cancer

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.hausarztmedizin.uzh.ch

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Effect of case management on the quality of life in patients with cancer after one year of ambulant rehabilitation - a randomised, controlled, parallel-group clinical trial

Acronym

CAMON

Study objectives

The implementation of several elements of the Chronic Care Model (CCM) via a case manager in the rehabilitation (trained registered oncology nurse) has a positive effect of the quality of life of cancer patients one year after an adjuvant therapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Board of the Kanton Zurich (Switzerland), 20/05/2010, ref: KEK-ZH-NR-2009 - 0145/1

Study design

Multicentre parallel-group randomised two-arm intervention trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Cancer - neoplasm

Interventions

Apart from the usual medical provision, i.e., consultations with the general practitioner and oncologist, and the therapies and measures prescribed as part of rehabilitation - randomised patients in the intervention group will be allocated an additional contact person (case manager) for the duration of one year after completion of adjuvant therapy. The contact person will be concerned with non-medical issues, information brokerage, encouragement of self-management and self-efficacy, as well as individually planning the rehabilitation program, and giving support

with coordination management. The task is carried out by an experienced oncology nurse with additional training.

Patients who have been randomised in the control group will receive the usual medical provision.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Quality of life: Fact G, (FACIT), measured at month 0, 3, 6 and 12

Secondary outcome measures

- 1. Ability to work: recorded by means of sick leave questionnaire
- 2. Self-efficacy: Questionnaire self-efficacy expectation
- 3. Health care utilisation (general practitioner/oncologist, specialists and hospitalisation), illustrated as number of contacts: Questionnaire
- 4. Unplanned consultations (general practitioner/oncologist, specialists and hospitalisation), illustrated as number of contacts that were unplanned: Questionnaire
- 5. Satisfaction with medical care: PACIC Questionnaire

Overall study start date

01/06/2010

Completion date

31/12/2011

Eligibility

Key inclusion criteria

- 1. Aged 18 years or greater, either sex
- 2. Completion of a therapy with chemo- and/or radiotherapy/surgery (longer term hormone and antibody therapy are excluded)
- 3. Therapy with curative intention or longer term estimated survival time
- 4. Increased distress score (score 2 7)
- 5. Intention to undertake ambulant rehabilitation
- 6. Rehabilitation need/prevailing strain

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Target number of participants

132

Key exclusion criteria

- 1. Patients with metastasis and/or cancer at an advanced stage with palliative therapy
- 2. Patients with an estimated survival time of less than one year
- 3. Patients with insufficient knowledge of the German language to take part in counselling and evaluations
- 4. Patients with severe psychiatric diagnoses or apparent great distress requiring medical psychiatric treatment
- 5. Completion of therapy longer than one month ago

Date of first enrolment

01/06/2010

Date of final enrolment

31/12/2011

Locations

Countries of recruitment

Switzerland

Study participating centre Institut für Hausarztmedizin

Zurich Switzerland 8091

Sponsor information

Organisation

Swiss Cancer League (Krebsliga Schweiz) (Switzerland)

Sponsor details

Effingerstrasse 40 Bern Switzerland 3001

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Sponsor type

Charity

Website

http://www.krebsliga.ch/de/index.cfm

ROR

https://ror.org/01pd7my79

Funder(s)

Funder type

Charity

Funder Name

Krebsliga Schweiz

Alternative Name(s)

Lega Svizzera Contro il Cancro, Swiss Cancer League, Ligue Suisse Contre le Cancer

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Switzerland

Funder Name

Universität Zürich

Alternative Name(s)

University of Zurich, Switzerland, University of Zurich, UZH

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Switzerland

Funder Name

University Hospital Zurich (Universitätsspital Zürich) (Switzerland)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	28/04/2011		Yes	No
Results article	results	28/03/2017		Yes	No