Couple therapy for cancer survivors : A prospective, randomized controlled study.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON43754

Source
ToetsingOnline

Brief title
CODA-study: couple therapy for cancer survivors.

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Miscellaneous and site unspecified neoplasms benign
- Breast disorders

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: (Colorectal/prostate/breast) cancer, Emotion-Focused Therapy, Partner relationship, Web-based Online Digital Assistance

Outcome measures

Primary outcome

The primary study outcomes on baseline (T0), after completement of the

intervention (T1) and after 6-months follow-up (T2) are:

1) Level of dyadic coping

2) Level of relational satisfaction

Secondary outcome

The secondary study outcomes on baseline (T0), after completement of the

intervention (T1) and after 6-months follow-up (T2) are:

1)The level of sexual functioning

2) The level of sexual distress

3) The level of sexual satisfaction

4) The level of perceived intimacy

5) The level of supportive communication (about sexual issues)

6)The body image

7) The amount of psychological distress

8) The generic Health Related Quality of Life

Study description

Background summary

Annualy, more than 40.000 men and women in the Netherlands are diagnosed with colorectal, prostate and breast cancer. There is compelling evidence that specific relational problems are a prevalent complication of these types of cancer and its treatment. Impaired relational functioning can also have a negative effect on intimacy (including mutual emotional support), on sexual functioning and satisfaction, and on health-related quality of life (HRQoL).

In the general population, Emotion-Focused Couple Therapy (EFCT) for relational problems has been demonstrated to be very effective. Steps in EFCT are: (1) stabilization and de-escalation; (2) change; and (3) integration, consolidation, and relapse prevention. To our knowledge, the efficacy of EFCT has not be investigated among cancer survivors. Adjuvant Online Digital Assistance (ODA) can enhance the effects of psychotherapy for various psychosocial problems. It may be particularly attractive for relational problems as it can be delivered within the privacy of one*s home where the intended behavioral changes in relational communication need to be implemented. ODA offers tailored suggestions, based on data collected with the Experience Sampling Methodology (ESM). ESM is an ecologically valid method of assessment in the natural environment. Both partners receive ODA advice through a web-based assessment tool.

In this study, a group of cancer survivors and their partners will be offered EFCT-ODA and will be compared with a waiting-list control group. It is hypothesized that the EFCT-ODA group will show more dyadic coping and is more satisfied with the relationship than the control group, as well on short term as on long term (6 months follow-up). Moreover, it is hypothesized that sexual functioning, perceived intimacy, body image, psychological wellbeing and general health related quality of life will improve compared with the control group.

Study objective

The primary objective of the study is to gain insight in the short term and long term effects of the EFCT-ODA therapy on 1) dyadic coping abilities in the relationship and 2) relational satisfaction. Moreover, the process aspects of the ODA will be evaluated.

The secondary objective of the study is to gain insight in the short term and long term effects of the EFCT-ODA therapy on the level of experienced intimacy, sexual functioning, sexual distress, sexual satisfaction, supportive sexual communication, body image, psychological distress and generic health related

quality of life. Moreover, the secondary objective of the study is to demonstrate whether the EFCT-ODA intervention is a cost-effective intervention.

Study design

In a randomised controlled trial (RCT), 160 cancer survivors and their partners will be recruited in several hospitals in the Netherlands. Participants: 1) have completed their primary treatment between 12 months and 5 years ago and are disease free at study; 2) meet clinical criteria for relational functioning problems, and be motivated to undergo therapy together with their partner.

Patients and their partners who show their interest in participating in the study, will be screened by means of several questions to assess couple problems regarding relational satisfaction, unsupportive communication, and low perceived intimacy.
When at least the cancer survivor scores positive on any of these (relational satisfaction, perceived intimacy, or supportive communication: low or very low) questions, and when both patient and partner are motivated for participation, the couple will be included in the study.

Included couples will be randomized by means of the minimization technique, with cancer form, gender, time since diagnosis and treatment form as stratification variables. The couples will be allocated to the EFCT-ODA group or a waiting list control group (n = 80 pairs per group). EFCT will be executed in 12 face-to-face sessions of 60-70 minutes. ODA will be provided on three days per week.
The intervention group and the control group complete a questionnaire before the start of the intervention (T0) as well as after the finish of the intervention (T1). Only de intervention group will also complete a questionnaire at 6-months follow-up (T2).

The control group will be offered the intervention after T1. The couples who accept this offer, will be asked to complete a questionnaire directly after finishing the intervention, as well as at 6-months follow-up.

Examine the study design in the overview below:

E: S * T0 * randomization * EFCT-ODA * T1 * T2
C: S * T0 * randomization * waiting list * T1 * EFCT-ODA * T1 * T2

E = experimental group
C = control group
S = screening
T0 = baseline questionnaire
Randomization = allocation to experimental or control group by means of minimization technique
EFCT-ODA = Emotion Focused Couple Therapy with Online Digital Assistance

Waiting list = no intervention
T1 = first follow-up questionnaire after completing therapy
T2 = second follow-up questionnaire after 6 months

Intervention

Couples in the intervention group will receive 12 sessions of Emotion Focused Couple Therapy (EFCT), offered by a registered EFT therapist. This is the same treatment for relation problems as is offered in regular health care. Emotion Focused Couple Therapy has been demonstrated to be very effective in the general population. Steps in EFCT are: 1) Stabilization and de-escalation; 2) change; and 3) integration, consolidation and relapse prevention.
Couples will also be asked to fill in a short questionnaire through the internet using Experience Sampling Methodology (ESM) during 3 days a week. During the second half of the therapy, couples might receive tailored advice or assignments that match the EFCT therapy. It is assumed that this will increase the treatment effect.

Couples in the control group will not be offered the EFCT-ODA intervention during the study, but afterwards (waiting list control group).

Study burden and risks

There are no risks and detrimental consequences associated with participating in the study. Participant will receive the same therapy which is offered to couples with relational problems in the regular health care. 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 completing a questionnaire twice or three times in a year is low. The burden of following the EFCT therapy is higher, but it is expected that this form of relational therapy will have beneficial consequences, among other things satisfaction with the (sexual) relationship. Participants will be offered this intervention free of charge.
The questionnaires that have to be completed by the intervention group through the internet are very short and take only a small amount of time to complete. Moreover, it is expected that it will enhance the positive therapeutic effect.
Participants won't be refrained from care. The only exception is that they will be asked to refrain from therapeutic relationship counseling during 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

- diagnosis of colorectal, prostate or breast cancer
- primary cancer treatment was completed between 12 months and 5 years earlier, no recurrence of cancer has been diagnosed
- aged between 18 and 75 years
- has a partner relationship of at least three months duration
- screened positive for distressing relational dissatisfaction or low dyadic coping
- both patient and partner are interested in undergoing counseling

Exclusion criteria

- Major psychopathology of patient or partner
- Lack of basic proficiency in the Dutch language
- No access to Internet
- Participation in concurrent treatment to alleviate relational problems

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-12-2015
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	24-04-2015
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	18-07-2016
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
CCMO	NL51907.096.15

Study results

Date completed:	01-05-2017
Actual enrolment:	29