

Couple therapy for cancer survivors.

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Colorectal, prostate and breast cancer are among the most prevalent forms of cancer in the Netherlands. There is evidence that specific relational problems and impairment in sexual functioning are a prevalent complication of these cancer forms and...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20233

Bron

NTR

Verkorte titel

CODA

Aandoening

Colorectal Cancer; Emotion-Focused Therapy; Experience Sampling Method; Online Treatment Support; Web-based Online Digital Assistance; Partner Relationship.

In Dutch: Colorectaal kanker; Emotion-Focused Therapie; Experience Sampling Methode; Online Behandeling Ondersteuning; Web-based Online Digitale Assistentie; Partnerrelatie

Ondersteuning

Primaire sponsor: Open University, Tilburg University, The Netherlands Cancer Institute

Overige ondersteuning: KWF Kankerbestrijding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Dyadic coping

 2. Marital Satisfaction
-

Dyadic coping will be measured with the Revised Dyadic Adjustment Scale (RDAS). The RDAS is a 14-item self-report measure of dyadic coping and relational adjustment in steady couples. Marital satisfaction will be measured with the Maudsley Marital Questionnaire (MMQ). The MMQ is a 20-item self-report questionnaire. Both primary outcomes will be assessed at all time points.

Toelichting onderzoek

Achtergrond van het onderzoek

Approximately 40.000 men and women are diagnosed with either colorectal cancer, breast cancer or prostate cancer annually. Impaired relational and sexual functioning can be a consequence of these cancer forms and its treatment. Although cancer survivors with relational problems express interest in receiving professional help, relatively few receive face-to-face therapy. Therefore, in this study, colorectal, breast and prostate cancer survivors and their partners will be offered Emotionally-Focused Couple Therapy (EFCT), which is an effective form of therapy for relational problems. This face-to-face therapy will be complemented with adjuvant Online Digital assistance (ODA), which offers tailored suggestions based on the EFCT therapy. The Online Digital Assistance can enhance the effect of the face-to-face EFCT since it promotes behavioral changes in relational communication, not only during the therapy sessions, but also in the home setting. This study will evaluate the efficacy and cost-effectiveness of face-to-face EFCT complemented with Online Digital Assistance in a group of cancer survivors and their partners. We hypothesize that, compared to a waiting list control group:

1. Cancer survivors who receive the EFCT-ODA will report significantly greater improvement from baseline to post-treatment and 6 months follow-up in dyadic coping, and relational satisfaction
2. Cancer survivors exposed to the intervention will report significantly more improvement in sexual functioning, sexual distress and sexual satisfaction, perceived intimacy, supportive sexual communication, body image, psychological distress, and generic health-related quality of life
3. EFCT-ODA will prove to be a cost-effective intervention

Changes after amendement 23-aug-2016.

Doel van het onderzoek

Colorectal, prostate and breast cancer are among the most prevalent forms of cancer in the

Netherlands. There is evidence that specific relational problems and impairment in sexual functioning are a prevalent complication of these cancer forms and its treatment. In the general population, Emotionally-Focused Couple Therapy (EFCT) for relational problems has been demonstrated to be very effective. Also, adjuvant Online Digital Assistance (ODA) can enhance the effects of psychotherapy for diverse psychosocial problems, including relational problems. ODA can be delivered in the privacy of one's home where the intended behavioral changes in relational communication need to be implemented. ODA offers tailored suggestions, dependent on the answers given on a short questionnaire, collected using Experience Sampling Methodology (ESM). This study will evaluate the efficacy and cost-effectiveness of EFCT, in a blended form of face-to-face therapeutic sessions combined with ODA (EFCT-ODA) in a group of colorectal, prostate and breast cancer patients who successfully completed cancer treatment. It is hypothesized that the EFCT-ODA group, compared to a waiting-list control group, will significantly increase dyadic coping and relational satisfaction, improve perceived intimacy, sexual functioning, sexual distress and sexual satisfaction, supportive sexual communication, body image, psychological distress, and generic health-related quality of life and will prove to be a cost-effective intervention.

Onderzoeksopzet

In the experimental group, both primary and secondary outcomes will be measured at baseline (T0), post-treatment (T1) and at 6 months follow-up (T2). In the control group, both primary and secondary outcomes will be measured at baseline and post-treatment. After completing post-treatment assessment, participants allocated to the control group will be offered the full intervention, if desired. Control group patients who choose to undergo therapy will be asked to complete post-treatment assessment, and follow-up assessment after 6 months.

Onderzoeksproduct en/of interventie

Cancer survivors in the experimental group will receive the intervention, which will consist of 12 face-to-face therapeutic EFT sessions, complemented with ODA. During treatment, the couple learns to recognize the cycle of defensive strategies that each partner uses to cope with threats. These strategies are validated and normalized, and not the person but the cycle is framed as the cause of the emotional problems and the issue that needs to be resolved. The therapist helps both partners to uncover the primary emotions that underlie their defensive strategies and to express these and their personal emotional needs in a more constructive way. Moreover, the adjuvant ODA offers tailored suggestions for behavioral actions to implement the EFCT elements into their daily lives. The ODA starts in the second half of the EFT therapy.

Participants in the waiting list control group will receive an empathetic telephone session with one of the researchers in order to provide some control for a possible attention-placebo effect. For this same purpose, they will also receive a digital or printed booklet with relevant questions about dyadic coping, relational functioning, intimacy and cancer. They are offered EFCT-ODA upon completion of post-treatment assessment.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Diagnosis of colon or rectal cancer, prostate cancer or breast cancer
- Primary cancer treatment was completed between 12 months and 5 years earlier; no recurrence of cancer was diagnosed
- Aged between 18 and 75 years
- Has a partner relationship of at least three months duration
- Screened positively for distressing relational dissatisfaction or low dyadic coping
- Both patient and partner are interested in undergoing counseling

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-12-2015
Aantal proefpersonen:	320
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	09-12-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4830
NTR-old	NTR4953
Ander register	NA : NOU 2013-6204

Resultaten

Samenvatting resultaten

N/A