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No effect of CBT-based online self-help training to reduce fear of cancer recurrence: First results of the CAREST multicenter randomized controlled trial

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Abstract

Objective: Fear of cancer recurrence (FCR) is a common consequence of surviving cancer; therefore, easily accessible self-help training could help many cancer survivors deal with FCR at low costs. The CAncer REcurrence Self-help Training (CAREST) trial evaluates the effectiveness of an online-tailored self-help training on the basis of evidence-based cognitive behavioral therapy principles in breast cancer survivors. Also, possible predictors for benefitting from the online self-help training were examined.

Methods: This multicenter randomized controlled trial included 262 female breast cancer survivors, randomly assigned to either online self-help training (n = 130) or care as usual (CAU; n = 132). Participants completed questionnaires at baseline (T0), 3 months (T1; after intervention), and 9 months (T2). The primary outcome was FCR (Fear of Cancer Recurrence Inventory Severity subscale). Both effectiveness and predictors were analyzed with latent growth curve modeling (LGCM) according to the intention-to-treat principle.

Results: LGCM showed no differences between the average latent slope in both groups (χ^2_1 = .23, P = .63), suggesting that the treatments did not differ in their change in FCR over time. Moreover, no differences were found in the effects of the predictors on the latent slope in both groups (χ^2_1 = .12, P = .73), suggesting that no significant predictors were found for the effect of the intervention on FCR.

Conclusion: There was no effect of the CBT-based online self-help training "Less fear after cancer" in the current study. Therefore, we recommend adding professional support to online interventions for FCR.

KEYWORDS

breast cancer, cancer, cancer survivors, cognitive behavioral therapy, eHealth, fear of recurrence, oncology, online, self-help, treatment

Clinical Trial Registration: The CAREST-trial has been registered in the Netherlands Trial Register (NTR4119).

1 | BACKGROUND

Fear of cancer recurrence (FCR) is defined as "fear, worry, or concern about cancer returning or progressing" and considered one of the most prevalent and stable long-term psychological consequences of surviving (breast) cancer.[1,2] FCR ranges from low or healthy levels in the majority of breast cancer survivors to clinical levels (moderate-high FCR) in 17% of breast cancer survivors.[2,3] In younger (age 18-45) early-stage breast cancer survivors, 70% experiences clinical levels of FCR.[4] High levels of FCR may negatively affect self-examining–, cancer-screening–, and follow-up behaviors, mood, quality of life, health outcomes, and may increase healthcare costs.[1,3-6]

There is a growing body of research on evidence-based interventions for FCR.[1,7,8] However, easily accessible and cost-effective interventions are still scarce. Online self-help interventions, although probably not suitable for every patient, have several advantages, including convenience, low costs, greater privacy, greater accessibility, and patients can work at their own pace.[9,10] Therefore, we started the CAncer REcurrence Self-help Training (CAREST) randomized controlled trial (RCT) to test an online self-help training on the basis of evidence-based cognitive behavioral therapy (CBT) to reduce FCR.[11]

In the trial, we evaluated the effectiveness of this online self-help training in reducing FCR compared with a care as usual (CAU) control group in women with curatively treated breast cancer (breast cancer survivors).[11] We hypothesized greater FCR reduction in the intervention group compared with CAU alone at 3 and 9 months after ending the intervention. Moreover, since we expected that online self-help is not suitable for all patients, we were interested in predictors to identify the group for whom it may work.[11] Therefore, the following predictors were investigated: sociodemographic variables, medical variables, self-efficacy for online self-help, coping strategies, functioning impairments, psychological distress, and psychosocial problems and risk factors. Hypotheses concerning the predictors are described in detail in Data S1.

2 | METHODS

2.1 | Setting and ethical issues

The study protocol of this RCT is published elsewhere.[11] Recruitment was carried out in eight hospitals in the Netherlands. Ethical approval was granted by the Medical Ethical Committee of the Maasstad hospital (TWOR) in Rotterdam (reference number 2013/41) and the local ethics committees of all participating hospitals. All participants signed an informed consent form before study participation. The CAREST trial has been registered in the Netherlands Trial Register (NTR4119). The study was conducted according to the principles of the Declaration of Helsinki.[12]

2.2 | Recruitment procedures

Between April 2014 and May 2016, patients were recruited during their regular check-up at the outpatient clinic or by sending them a comprehensive information letter by mail (recruitment strategies differed because of pragmatic reasons). After 2 weeks, patients were reminded of the study by phone or they were sent a letter by the researcher. Patients who decided to participate, returned the informed consent form within 1 week. On this form, they indicated whether they agreed to participate in the RCT or to complete the Dutch version of the Fear of Cancer Recurrence Inventory (FCRI-NL) once.

2.3 | Participants

For growth models, a sample size of at least 100 is preferred.[13] Between April 2014 and July 2016, eligible patients were recruited consecutively from the eight participating hospitals. Women were eligible to participate if they had a diagnosis of breast cancer 1 to 5 years ago, had no signs of local or regional recurrence or metastatic disease (according to their oncologist or oncology nurse), were capable of completing questionnaires in Dutch, were 18 years or older at disease onset, and had access to a computer with an internet connection. There were no exclusion criteria.

2.4 | Randomization

Block randomization (block size 10) was carried out through a sealed envelope system by an independent research assistant of the Helen Dowling Institute (HDI). The researchers did not have any influence on (and were blinded for) the randomization process. Participants were randomly assigned to either the online self-help training (intervention) or CAU, with an allocation ratio of 1:1 stratified by hospital. Data was made anonymous by coding and separating personal data from the research data.

2.5 | Intervention

A detailed description of the intervention is published elsewhere.[11] In short, the intervention "Less fear after cancer" is a tailored and CBT-based online self-help to reduce FCR, developed by researchers of the HDI. The program includes two basic modules containing psycho-education about FCR and the basic principles of CBT and four additional modules: (a) how to stop rumination, (b) making an action plan for when FCR arises, (c) audio files with relaxation practices, and (d) how and when to seek reassurance. More details of the intervention are provided in Data S2. Participants in both the control and intervention groups received CAU: standard care (which may also include psychological or other support) in their own hospital.

2.6 | Measures

Outcomes were collected through online self-report questionnaires at baseline (T0), 3 months (T1; after intervention), and 9 months (T2). Participants received an invitational email with a link to complete the questionnaires online. Sociodemographic variables were assessed at baseline, medical variables at all time points, and both were self-reported.

The primary outcome was FCR, assessed with the severity subscale of the Dutch translation of the Fear of Cancer Recurrence Inventory (FCRI-SF-NL), which can be used to screen for clinical levels of FCR.[14-16] The FCRI-NL consists of 42 items on a 5-point Likert scale and comprises seven subscales: triggers, severity (FCRI-SF-NL; range 0-36), psychological distress, coping strategies, functioning impairments, insight, and reassurance.[15] A cutoff score of 13 or higher (FCRI-SF-NL) is considered optimal for detecting the presence of clinically significant FCR.[14] The FCRI-SF-NL demonstrated good reliability and validity.[16]

Coping strategies, functioning impairments, and psychological distress were assessed with the FCRI-NL (described above). Since there was no measure for self-efficacy for online self-help available, self-efficacy was assessed with a 15-item questionnaire developed for this RCT and described in the study protocol, which measured: (1) general internet use (three items); (2) health-related behavior (seven items); and (3) patients' expectations of online self-help training for fear of cancer recurrence (five items).[11] In this study, the estimated reliability of this questionnaire was good (Cronbach α = .82 for the total scale and Cronbach α = .72-.93 for the subscales). Psychosocial problems and risk factors were assessed with the Psychosocial Distress Questionnaire-Breast Cancer (PDQ-BC).[17] The PDQ-BC is a 35-item multidimensional screening instrument specific for breast cancer patients. Its subscales measuring trait anxiety (10 items), (lack of) social support (one item), depressive symptoms (seven items), and physical problems (four items) were included in this study. Higher scores indicate more psychosocial problems, except for social support for which higher scores indicate fewer problems.[17,18] The PDQ-BC showed good estimated reliability (Cronbach α = .70-.87) for the subscales used in this study, and satisfactory construct validity for the physical problems subscale (other subscales were not reported).[17-19]

2.7 | Statistical analyses

Type of recruitment and reminder were compared with chi square tests and independent samples *t* tests. Prior to data analysis, we assessed the multivariate normality assumption for the primary outcome variable FCRI-SF-NL, both with numerical tests (Shapiro, Mardia, Henze-Zirkler, and Royston test for multivariate normality) and graphical tests (Q-Q plot).[20] Because this assumption was violated (see Data S3), robust maximum likelihood (MLR) estimation was used to estimate the model parameters. Significance level was set at 5%. Little's MCAR test suggested that the data were likely missing completely at random, therefore we can use multiple imputation to handle missing data.[21-23] Data were analyzed according to the intention-to-treat (ITT) principle.[11]

In contrast with our study protocol, analyses were conducted with latent growth curve modeling (LGCM); a newer, more advanced and flexible technique than originally planned.[11,24] LGCM is similar to linear mixed models (and repeated measures ANOVAs as a special case).[25] However, by using the repeated measurements to estimate a latent intercept and slope for each patient, LGCM allows for assessing change at the intra-individual level, as well as predicting what influences change at the inter-individual level. Moreover, the LGCM fit indices can be used to evaluate whether the hypothesized growth model adequately fits the observed data.[26] The new analysis was preregistered at the Open Science Framework.[27]

A multigroup LGCM technique was used to examine effects on both group level (eg, intervention versus CAU) and individual level (ie, individual differences).[28] Within each group, individual changes in the FCR scores over time were used to estimate two latent growth factors (intercept and slope). These factors not only indicate whether the intervention and CAU on average resulted in a higher or lower FCR over time, but also how much the change in FCR varied across patients. Constraining the latent slope factors to be equal across the groups directly tests whether the intervention and the CAU differ in their FCR change over time. However, to adjust this effect for the confounding influence of the predictors (presented in Appendix A), we first investigated whether these predictors showed an equal effect on the latent slope factor in both groups, similar to the homogeneity of regression slopes assumption in the analysis of covariance (ANCOVA) models.[29] In LGCM, this assumption is met when the chi-square difference test indicates that the model, including equal predictors effects across groups (homogeneous model), does not show significantly worse model fit than the model without those restrictions (unconditional model).

In general, model fit was assessed with the maximum-likelihood chi-square statistic (χ^2), the comparative fit index (CFI), the Akaike information criterion (AIC), the Bayesian information criterion (BIC), and the root mean squared error of approximation (RMSEA).[13,30,31] The goodness of fit criteria for the fit indices are: CFI $\geq$ .95 and RMSEA $\leq$ .06.[30,31] The χ^2, AIC, and BIC criteria were used to compare models with higher χ^2 and lower values of AIC and BIC, indicating a better fit to the data.[30,31]

Analyses were performed with IBM SPSS 23 for Windows and R statistical software (version 3.4.1), with software packages lavaan (for the LCGM, version 0.5-23.1097) and BaylorEdPsych (for checking missing data for random occurrences, version 0.5).

3 | RESULTS

3.1 | Response rate and patient characteristics

Recruitment of patients by oncology nurses resulted in a higher response than recruitment by mail (χ^2 = 7.15, *P* = .03), and reminders by phone resulted in a higher response than reminders by mail (χ^2 = 16.37, *P* < .001). However, recruitment and reminder methods did not significantly differ in baseline FCR level (t_{467} = −.82, *P* = .42 and t_{50} = .17, *P* = .87), age (t_{1133} = −1.87, *P* = .06 and $t_{88.55}$ = 1.01, *P* = .32), and time since diagnosis (t_{1130} = −1.75, *P* = .08 and t_{232} = 1.57, *P* = .12). A total of 516 (44%) of the eligible patients gave their consent to participate (see Appendix B: flowchart). The patients who chose to complete the FCRI only once (n = 254; nonparticipants) were older (M = 61.05, SD = 10.55 vs M = 55.55, SD = 9.89; *P* < .001) and had lower FCRI-SF-NL scores (M = 12.19, SD = 6.63 vs

M = 15.22, SD = 6.88; $P < .001$) than patients who signed up for the RCT (n = 262, hereafter referred to as participants). Of the nonparticipants, patients who completed the questionnaire on paper were older (M = 64.81, SD = 10.60 vs M = 60.24, SD = 10.33; $P < .001$) and had higher FCRI-SF-NL scores (M = 13.55, SD = 6.23 vs M = 11.23, SD = 6.69; $P = .01$) than patients who completed the questionnaire online. In the RCT, all measures were completed online. Participants in the two RCT conditions did not differ from one another in terms of drop-out rate ($\chi^2 = 7.23$, $P = .06$). Reasons for drop-out were personal circumstances (13), not experiencing FCR (six), questionnaires (six), technical difficulties (three), intervention (two), randomization outcome (two), cancer recurrence (two), or unknown (30). More details can be found in the flowchart (Appendix B). Appendix C shows the demographic and medical characteristics of the participants. Some participants reported recurrence or metastasis of cancer, while they were referred to this study as having "no signs of local or regional recurrence or metastatic disease" by their nurse practitioners. We decided to include all participants because recurrences were reported more than 1 year ago or were another primary cancer, most metastases reported were in the sentinel nodes (and probably curatively treated), and some cases were in fact no recurrence or metastasis.

3.2 | Latent growth curve models

In the LGCM, model 1 indicated no differences between the average latent slope in the intervention versus CAU group based on the chi-square difference test comparing submodels 1A and 1B (Appendix D). Thus, constraining the latent slopes to be equal in both groups did not result in significantly worse model fit ($\chi^2_1 = .23$, $P = .63$). Furthermore, in both groups, the mean latent slope did not significantly differ from zero. Thus, on average, participants in the intervention as well as the CAU group did not show lower FCR scores over time. This result can also be seen in Appendix E, which shows the individual growth curves of participants in each group. In both groups, the latent intercepts varied significantly across participants, indicating differences in FCR levels at baseline. However, though patients also showed considerable variation in their change in FCRI, the average latent slopes did not significantly differ between both groups, suggesting that the absence of change in FCR over time was similar across participants.

Model 2 indicated no significant differences in the effects of the predictors on the latent slope between groups based on the chi-square difference test comparing submodels 2A and 2B (Appendix D). Thus, constraining the effects of the predictors on the latent intercept and slope to be equal across groups did not result in significantly worse model fit ($\chi^2_{17} = 14.10$, $P = .66$), suggesting that the predictors have similar effects in both groups on the latent FCR intercept and slope. The final chi-square difference test comparing submodels 2B and 2C indicates that after satisfying the assumption of equal predictor effects in the two groups, the average latent FCR slopes remain equal across groups ($\chi^2_1 = .12$, $P = .73$).

For all model comparisons, the results of the chi-square difference test are corroborated by the results of the model fit indices. Both AIC and BIC suggest better fit for the models including equal latent slopes across groups. Although the CFI indicated good fit for all models, the RMSEA only showed acceptable fit in model 2 after constraining the predictor effects on the latent intercept and slope to be equal across groups (Appendix D).

Appendix F shows the parameter estimates of the full linear growth curve model for predictors of the change in FCR following the intervention. In both the intervention and CAU, depressive symptoms are a significant predictor (intervention group: $\beta = -.37$, B = −.21, SE(B) = .07, $P < .01$; CAU: $\beta = -.30$, B = −.21 SE(B) = .07, $P < .01$). In other words, participants (in both groups) who score high on depressive symptoms, show more decrease in FCR than participants with lower depressive symptoms scores. Because this effect occurred in both groups, depressive symptoms cannot be seen as a predictor of the intervention effect. In the intervention group, strong positive relations were found at baseline between FCR and education ($\beta = .16$, B = .61, SE(B) = .26, $P = .02$), between FCR and psychological distress ($\beta = .44$, B = .72, SE(B) = .15, $P < .01$), and between FCR and depressive symptoms ($\beta = .20$, B = .35, SE(B) = .15, $P = .02$). In CAU, strong positive relations were found at baseline between FCR and psychological distress ($\beta = .35$, B = .59, SE(B) = .23, $P < .01$) and between FCR and depressive symptoms ($\beta = .28$, B = .54, SE(B) = .24, $P = .02$). Data S4 illustrates the LGCM including all parameter results.

4 | CONCLUSIONS

This RCT demonstrates that there is no effect of CBT-based online self-help training to reduce FCR in breast cancer survivors compared with CAU (after 3 and 9 mo). Moreover, no significant predictors were found for the effect of the intervention on FCR. Interestingly, depressive symptoms were found to be a predictor for decrease in FCR in both groups.

In line with the findings from Willems et al, we did not find an effect of our online self-help intervention for FCR.[32] Their web-based computer-tailored intervention to support cancer survivors with managing psychosocial issues was effective in reducing depression and other outcome measures, but no effects were found for anxiety.[32] Although this intervention was not specifically aimed to reduce FCR and included a mixed sample, this is an online self-help intervention for cancer patients and therefore more or less comparable to our online self-help training. Other studies showed that online interventions with (face-to-face or online) therapist support, standard email reminders, or studies that selected only patients with high FCR were effective.[33-35] The modest mean level of FCR and the high drop-out rate in our study could explain the absence of an effect of the intervention. Furthermore, the limited usage of the intervention may be an explanation for the lack of effect. Yet, the current study probably shows a realistic picture.

4.1 | Study limitations

This study had several limitations. First, CAU slightly differed for participants since they were recruited from different hospitals. This is a

realistic picture, since participants of online self-help interventions will not receive the same CAU in each hospital. Moreover, to prevent a distorted picture, randomization was done "stratified by hospital" to create equally distributed groups. Second, despite randomization, significant baseline differences were found, which could have influenced the results. However, CONSORT guidelines recommend against significance tests of baseline differences in RCTs, because differences in baseline characteristics after proper random assignment are the result of chance rather than bias.[36] Third, some participants reported recurrence or metastasis of cancer, while the inclusion criterion was "no signs of local or regional recurrence or metastatic disease." Nevertheless, out of participants explanations, we could extract that all participants could be included. Also, self-reported outcomes may be less reliable than the nurse practitioner's assessment.

4.2 | Study strengths

Study strengths are the study design, which included a large consecutive sample, sufficient power, and state-of-the-art analysis. Second, the ecological validity of the current study is high, because not screening on level of FCR, the use of CAU and self-help without extra help or emails reflects a realistic picture of online self-help interventions. Third, the study population of this RCT consisted of relatively young women both compared with the other women in our patient cohort (56 years vs 61 years) and to Dutch breast cancer survivors (80% of 50 years and older).[37] Given the high prevalence of FCR in young breast cancer survivors, and the fact that young women use the internet more often than older women for both searching for information and for personal development, we did reach the right target group with this RCT.[4,38] Last, this RCT showed a large variation in the change in FCR scores within participants over time, which supports the importance of our choice to model individual differences in growth curves using a latent growth curve models. Many studies merely compare treatments on the average change in FCR over time, thereby obscuring the large variation between patients within a particular treatment group.

4.3 | Clinical implications

This RCT showed a large variation in FCR scores within participants, which is important information when considering who needs treatment for FCR. Also, the mean level of FCR was lower than expected based on the literature, and the usage of the intervention was limited, which might indicate that we should offer treatment for FCR only to those patients who consistently score high on FCR. Since results from other RCTs showed that interventions with email reminders or some form of support were effective, we suggest implementing programs with professional support, for example, from nurses or primary care workers. Future research should focus on the best form of support, while maintaining the advantages of online help.

4.4 | Final summary

In conclusion, overall there was no effect of the CBT-based online self-help training "Less fear after cancer" in the current study. Therefore, we recommend adding professional support, like email contact or face-to-face assistance, to future online interventions for FCR.

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CONFLICT OF INTEREST

None.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

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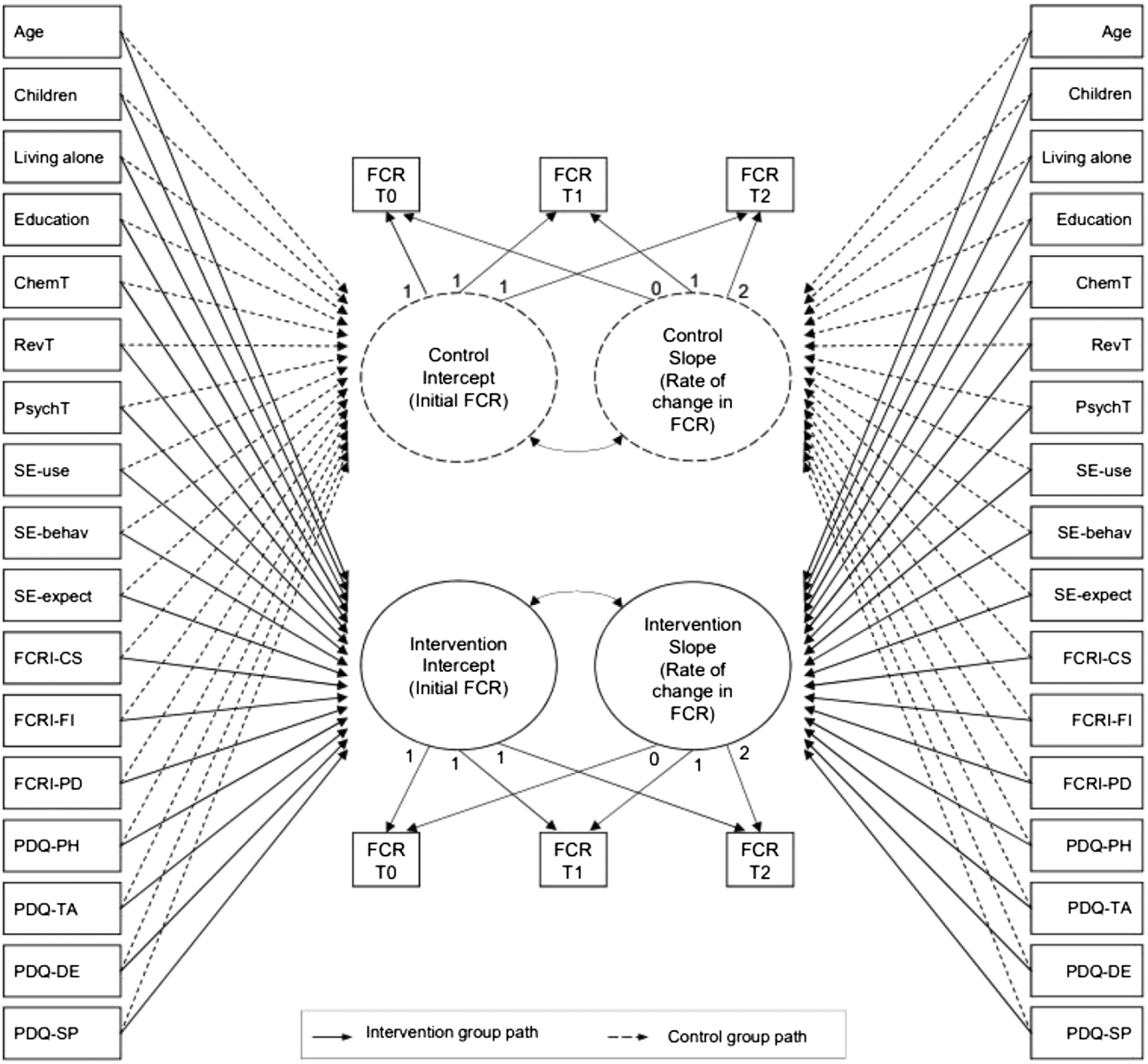
APPENDIX A

MULTI-GROUP LATENT GROWTH CURVE MODEL ON THE CHANGE IN FCRI OVER TIME FOR BOTH THE INTERVENTION GROUP AND CAU CONTROL GROUP

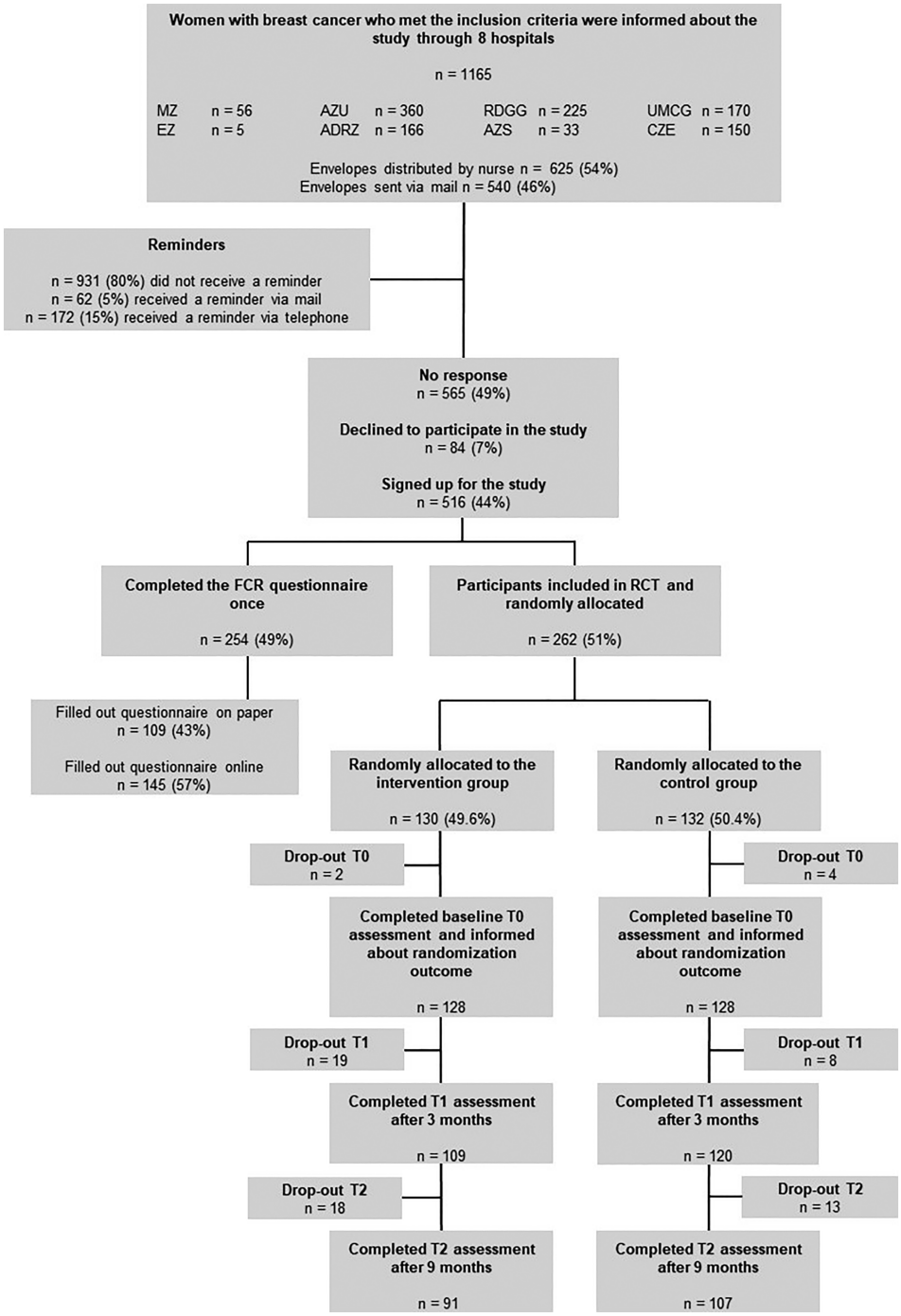


The rectangles represent measured variables and the circles designate latent growth factors. The loadings on the latent intercept factors are fixed at 1, and the latent slope factor are fixed at 0, 1, and 2, respectively, for the three repeated FCR measurements. One-headed arrows represent regression paths; two-headed arrows represent correlations.

Abbreviations: FCR = fear of cancer recurrence; control = care as usual (CAU); intervention = online self-help for fear of cancer recurrence; T0 = time-0 (baseline); T1 = time-1 (3 mo); T2 = time-2 (9 mo); ChemT = treatment chemotherapy; RevT = treatment revalidation; PsychT = treatment psychologist/psychiatrist; SE-use = self-efficacy for online self-help questionnaire, general internet use subscale; SE-behav = self-efficacy for online self-help questionnaire, health-related behavior subscale; SE-expect = self-efficacy for online self-help questionnaire, expectations of online self-help subscale; FCRI-CS = fear of cancer recurrence inventory, coping strategies subscale; FCRI-FI = fear of cancer recurrence inventory, functioning impairments subscale; FCRI-PD = fear of cancer recurrence inventory, psychological distress subscale; PDQ-PH = psychosocial distress questionnaire, physical problems subscale; PDQ-TA = psychosocial distress questionnaire, trait anxiety subscale; PDQ-DE = psychosocial distress questionnaire, depressive symptoms subscale; PDQ-SP = psychosocial distress questionnaire, social support subscale.

APPENDIX B

FLOWCHART FOR PARTICIPANT INCLUSION AND RETENTION IN THE RANDOMIZED CONTROLLED TRIAL



Abbreviations: MZ = Maasstad Hospital Rotterdam; EZ = Elisabeth Hospital Tilburg; AZU = St Antonius Hospital Utrecht; ADRZ = Admiraal de Ruyter Hospital Vlissingen; RDGG = Reinier de Graaf Hospital Delft; AZS = Antonius Hospital Sneek; UMCG = The University Medical Center Groningen; CZ = Catharina Hospital Eindhoven; control group = care as usual (CAU); intervention group = online self-help for fear of cancer recurrence; RCT = randomized controlled trial; T0 = baseline measure, before intervention; T1 = 3 months after inclusion, directly after intervention; T2 = 9 months after inclusion, 6 months after intervention.

APPENDIX C

DEMOGRAPHIC AND MEDICAL CHARACTERISTICS OF THE SAMPLE

	Intervention (n = 130)		Care as Usual (n = 132)		Total (n = 262)	
	n	%	n	%	n	%
Demographic characteristics						
Age	n = 126		n = 128		n = 254	
M (SD)	55.3	(10.1)	56.2	(9.8)	55.8	(9.9)
	n = 128		n = 128		n = 256	
Having a partner	109	85.2	110	85.9	219	85.5
Having children under 12 years	18	14.1	13	10.2	31	12.1
Living situation	n = 128		n = 128		n = 256	
Alone	14	10.9	15	11.7	29	11.3
With partner	41	32.0	52	40.6	93	36.3
With children	4	3.1	4	3.1	8	3.1
With partner and children	33	25.8	31	24.2	64	25.0
Alone, with (adult) children living on their own	0	0.0	1	0.8	1	0.4
With partner and (adult) children living on their own	19	14.8	16	12.5	35	13.4
With both children and (adult) children living on their own	2	1.6	1	0.8	3	1.1
With partner and both children and (adult) children living on their own	12	9.4	5	3.9	17	6.5
Other	3	2.3	3	2.3	6	2.3
Education[a]	n = 128		n = 128		n = 256	
Low (ISCED 0-1-2)	17	13.3	15	11.7	32	12.5
Medium (ISCED 3-4-5)	60	46.9	62	48.4	122	47.7
High (ISCED 6-7-8)	50	39.1	51	39.8	101	39.5
Other	1	0.8	0	0	1	0.004
Employment	n = 128		n = 128		n = 256	
Fulltime paid work	13	10.2	12	9.4	25	9.8
Less than fulltime paid work	50	39.0	45	35.1	95	37.1
Self-employed entrepreneur	6	4.7	9	7.0	15	5.9
Housewife	19	14.8	16	12.5	35	13.7
Unemployed	3	2.3	4	3.1	7	2.7
Sick leave	3	2.3	5	3.9	8	3.1
Disability insurance act	8	6.3	6	4.7	14	5.5
Retired	17	13.3	21	16.4	38	14.8
Other	9	6.9	10	7.8	19	7.4
Medical characteristics						
Time since diagnosis	n = 125		n = 128		n = 253	
M (SD)	2.5	(1.1)	2.6	(1.2)	2.6	(1.1)
Affected lymph nodes	n = 128		n = 128		n = 256	
	48	39.3	50	40.3	98	39.8
	n = 128		n = 128		n = 256	
Hereditary cancer	4	3.8	4	3.8	8	3.8
Treatment	n = 128		n = 128		n = 256	
Mastectomy	54	42.2	65	50.8	119	46.5
Lumpectomy	77	60.2	70	54.7	147	57.4

(Continued)

	Intervention (n = 130)		Care as Usual (n = 132)		Total (n = 262)	
	n	%	n	%	n	%
Lymph node removal	49	38.3	46	35.9	95	37.1
Radiotherapy	94	73.4	79	61.7	173	67.6
Chemotherapy	83	64.8	78	60.9	161	62.9
Hormone therapy	76	59.4	69	53.9	145	56.6
Immunotherapy	20	15.6	22	17.2	42	16.4
Other	13	10.2	7	5.5	20	7.8
Disease status (self-reported)	n = 128		n = 128		n = 256	
(No activity)	107	83.6	107	83.6	214	83.6
Recurrence	5	3.9	5	3.9	10	3.9
Metastasis	8	6.3	6	4.7	14	5.5
Previous serious illnesses	n = 128		n = 128		n = 256	
	16	12.5	15	11.7	31	12.1
Previous rehabilitation program	n = 126		n = 127		n = 253	
	39	31.0	53	41.7	92	36.4
Previous psychological care	n = 128		n = 128		n = 256	
	39	30.5	44	34.4	83	32.4
FCR Severity (Baseline)	n = 128		n = 128		n = 256	
M (SD)	15.9	(7.2)	14.5	(6.6)	15.2	(6.9)

Abbreviations: M = mean, SD = standard deviation, ISCED = International Standard Classification of Education, FCR = fear of cancer recurrence.

[a]UNESCO Institute for Statistics (UIS). International Standard Classification of Education: ISCED 2011. Montreal, Quebec: UIS; 2012.

APPENDIX D

LATENT GROWTH MODELS INCREASING IN COMPLEXITY FOR ESTIMATING CHANGE IN FEAR OF CANCER RECURRENCE SEVERITY

Model		Parameters (df)	χ^2 (robust)[a]	χ^2 difference (robust)*	AIC[b]	BIC[b]	RMSEA[c] (95% CI)	CFI[d]
1A	Random intercept and random slope (unconditional)	16 (2)	5.56	-	4062.70	4119.42	.118(.000-.239)	.99
1B	- with restricted equal latent slope mean across groups	15 (3)	5.81	.23	4060.93	4114.11	.085(.000-.189)	.99
2A	Model 1 with time-invariant predictors (unconditional)	84 (36)	56.91	-	20 281.90	20 580.02	.065(.029-.096)	.97
2B	- with constrained equal group effects of the predictors on the latent slope (homogenous)	67 (53)	70.61	14.10	20 261.58	20 499.37	.049(.000-.078)	.97
2C	- additional constrained mean of the latent slope to be equal in both groups	66 (54)	70.73	.12	20 259.68	20 493.92	.048(.000-.076)	.98

Abbreviations: df = degrees of freedom; χ^2 = Chi square; AIC = Akaike information criterion; BIC = Bayesian information criterion; RMSEA = root mean squared error of approximation; CI = confidence interval; CFI = comparative fit index.

*None of the χ^2 differences were significant;

[a]higher χ^2 values indicate a better model;

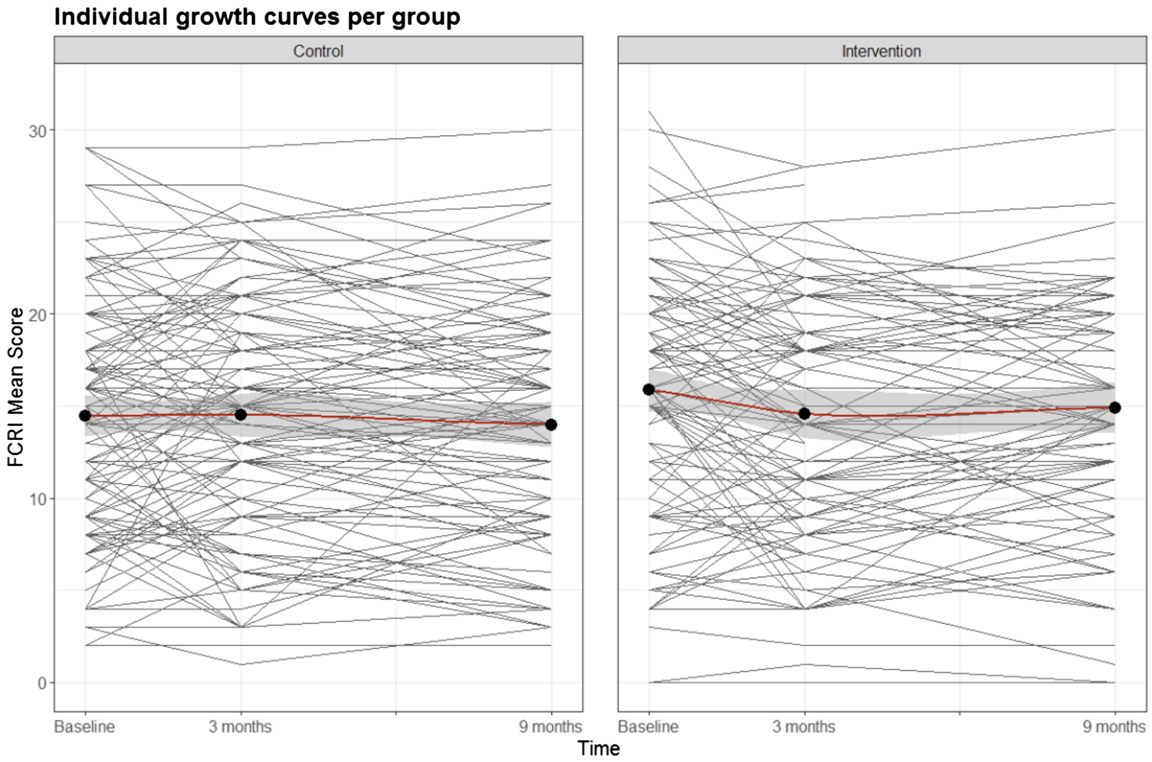
[b]lower AIC and BIC values indicate a better model;

[c]RMSEA less than or equal to .06 indicates good model fit;

[d]CFI greater than or equal to .95 indicates good model fit.

APPENDIX E

GROWTH CURVES FOR PARTICIPANTS WITHIN EACH CONDITION



Control = care as usual (CAU); intervention = online self-help for fear of cancer recurrence. For each condition, the line between the dots represents the average FCRI score

APPENDIX F

PARAMETER ESTIMATES AND STANDARD ERRORS FROM THE MAIN EFFECTS OF PREDICTORS ON THE FEAR OF CANCER RECURRENCE LATENT INTERCEPT AND SLOPE FACTORS

	Intervention						Care as Usual					
	Latent intercept			Latent slope			Latent intercept			Latent slope		
	B	SE (B)	β	B	SE (B)	β	B	SE (B)	β	B	SE (B)	β
Age	0.098	0.060	0.144	−0.018	0.022	−0.082	0.044	0.054	0.067	−0.018	0.022	−0.075
Children (<12 years old)	−0.445	0.994	−0.032	−0.422	0.382	−0.097	0.883	0.918	0.064	−0.422	0.382	−0.086
Living alone	−0.190	1.202	−0.009	0.077	0.444	0.012	−0.255	1.141	−0.013	0.077	0.444	0.011
Education	0.614*	0.262	0.160*	−0.015	0.100	−0.013	0.387	0.262	0.104	−0.015	0.100	−0.012
Chemotherapy (ChemT)	1.493	1.133	0.105	−0.541	0.535	−0.121	0.210	0.888	0.016	−0.541	0.353	−0.115
Revalidation (RevT)	0.861	0.885	0.059	0.453	0.323	0.098	−0.114	0.746	−0.009	0.453	0.323	0.097
Psychological care (PsychT)	1.372	1.009	0.093	−0.402	0.355	−0.086	−1.325	0.901	−0.098	−0.402	0.355	−0.083
General internet use (SE-use)	0.182	0.132	0.084	−0.088	0.053	−0.129	0.126	0.125	0.069	−0.088	0.053	−0.136

(Continued)

	Intervention						Care as Usual					
	Latent intercept			Latent slope			Latent intercept			Latent slope		
	B	SE (B)	β	B	SE (B)	β	B	SE (B)	β	B	SE (B)	β
Health-related behavior (SE-behav)	−0.067	0.086	−0.046	−0.025	0.039	−0.054	−0.098	0.090	−0.068	−0.025	0.039	−0.048
Expectations self-help (SE-expect)	0.166	0.101	0.106	−0.038	0.046	−0.078	0.084	0.119	0.054	−0.038	0.046	−0.068
Coping strategies (FCRI-CS)	0.059	0.070	0.059	0.016	0.021	0.050	0.084	0.059	0.103	0.016	0.021	0.054
Functioning impairments (FCRI-FI)	0.252	0.178	0.172	−0.006	0.051	−0.013	0.279	0.149	0.218	−0.006	0.051	−0.013
Psychological distress (FCRI-PD)	0.721***	0.146	0.439***	−0.025	0.054	−0.048	0.593**	0.225	0.351**	−0.025	0.054	−0.041
Physical problems (PDQ-PH)	−0.160	0.212	−0.040	0.170	0.099	0.136	−0.233	0.239	−0.066	0.170	0.099	0.135
Trait anxiety (PDQ-TA)	−0.250	0.149	−0.098	0.053	0.055	0.066	−0.052	0.121	−0.023	0.053	0.055	0.066
Depressive symptoms (PDQ-DE)	0.352*	0.148	0.195*	−0.211**	0.065	−0.371**	0.544*	0.235	0.278*	−0.211**	0.065	−0.302**
Social support (PDQ-SP)	−0.407	0.537	−0.050	−0.009	0.221	−0.003	0.471	0.557	0.052	−0.009	0.221	−0.003

Note: results of the latent growth curve model. All estimated parameters are standardized. B = unstandardized parameter, covariance of intercept and slope; SE = standard error; β = standardized parameter, correlation.

Abbreviations: SE-use = self-efficacy for online self-help questionnaire, general internet use subscale; SE-behav = self-efficacy for online self-help questionnaire, health-related behavior subscale; SE = -expect = self-efficacy for online self-help questionnaire, expectations of online self-help subscale; FCRI-CS = fear of cancer recurrence inventory, coping strategies subscale; FCRI-FI = fear of cancer recurrence inventory, functioning impairments subscale; FCRI-PD = fear of cancer recurrence inventory, psychological distress subscale; PDQ-PH = psychosocial distress questionnaire, physical problems subscale; PDQ-TA = psychosocial distress questionnaire, trait anxiety subscale; PDQ-DE = psychosocial distress questionnaire, depressive symptoms subscale; PDQ-SP = psychosocial distress questionnaire, social support subscale.

Significance levels:

*$P < .05$, **$P < .01$, ***$P < .001$