Short Report

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Need for a primary care–based intervention for fear of cancer recurrence: conclusions from the BLANKET trial

Yvonne L. Luigjes-Huizer[a,b,*], Charles W. Helsper[b], Marloes M. J. G. Gerrits[c], Niek de Wit[b], Marije L. van der Lee[a,d]

Abstract

Background: More than half of cancer survivors experience fear of cancer recurrence (FCR). There has been a call for easily accessible, inexpensive interventions for moderate FCR to complement existing specialized care. In the randomized BLANKET trial, we investigated the effectiveness of a short, primary care intervention for FCR. We report on the potential of the intervention and the suitability of primary care to offer this intervention.

Methods: The BLANKET trial is a cluster randomized controlled trial with change in FCR severity (severity subscale of the Fear of Cancer Recurrence Inventory) as its main outcome. Participating general practitioners invited all patients who completed successful curative cancer treatment between 3 months and 10 years ago. We report effect measures, outcome of our recruitment strategy, intervention uptake, reasons not to participate, and experiences with the intervention.

Results: Sixty-two of 1368 (4.5%) invited cancer survivors participated. Main reported reasons not to participate were not experiencing FCR and not wanting help. Owing to the low participation, we could not robustly evaluate the intervention's effectiveness. Indicatively, in the intention-to-treat analysis, FCR severity decreased from T0 to T1 by 2.7 points (standard deviation [SD] = 4.7) in the intervention group (n = 27) and 1.8 points (SD = 3.6) in the control group (n = 18). In the per-protocol analysis, the decreases were 3.5 points (SD = 4.5) and 0.7 points (SD = 2.7), respectively.

Conclusion: Although the prevalence of FCR and the need for help for FCR are high according to the literature, the uptake of our primary care–based intervention was low. Although the intervention shows potential, alternative delivery routes need to be explored because of the low number of patients who need help for FCR per primary care practice. We recommend additional research on the impact of FCR, on which patients require and desire help, and on what kind of intervention and setting are fitting for what patients.

Keywords: blended health care, cancer, ehealth, fear of cancer recurrence, mental health worker, oncology, primary care, RCT

1. Introduction

With improved cancer treatments, the number of cancer survivors and the number of people facing challenges during cancer survivorship are increasing.[1] Over half of cancer survivors experience fear of cancer recurrence (FCR),[2] which has been labeled their most important unmet need.[3,4] FCR can lead to decreased quality of life[5] and increased health care costs,[6] and for most people, FCR does not dissolve over time without intervention.[7] Several effective interventions to treat FCR have been developed. Most include aspects of cognitive behavioral therapy[8] and are provided by specialized psychologists.[9] However, for patients with low levels of FCR, low intensity interventions may be sufficient and preferred.[9]

Primary care may be well-positioned to provide this type of care. It offers accessible care[10] that includes both physical and psychosocial aspects.[11] Primary care is also increasingly involved in cancer survivorship, and cancer survivors frequently favor their general practitioner (GP) for psychosocial care.[12] In the Netherlands, most primary care practices use mental health workers (MHWs), who provide low threshold psychological care.[13]

Therefore, we designed a blended, low-intensity, primary care intervention for cancer survivors with FCR. In the BLANKET trial, we aimed to evaluate the effectiveness of this intervention in reducing patients' FCR in a real-world setting. We present the results of the trial and lessons we learned because of challenges with recruitment and uptake.

2. Materials and methods

2.1. Design

The BLANKET trial is a 2-armed cluster randomized controlled trial, comparing our intervention with usual care. The intervention consists of an intake with the GP, 5 sessions with an MHW, and an online cognitive behavioral therapy–based program. The GP practice is the unit of randomization. Outcomes are measured at the patient level. For full details, see the protocol article.[14]

[a] Helen Dowling Institute, Bilthoven, the Netherlands, [b] Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht, Utrecht University, Utrecht, the Netherlands, [c] Leidsche Rijn Julius Gezondheidscentra, Utrecht, the Netherlands, [d] Department of Medical and Clinical Psychology, Center of Research on Psychology in Somatic diseases, Tilburg University, Tilburg, the Netherlands.

*Corresponding author. Address: Yvonne L. Luigjes-Huizer, Helen Dowling Institute, Bronkhorstlaan 20, 3723 MB, Bilthoven, the Netherlands. E-mail address: y.l.huizer@umcutrecht.nl, +31 30 252 4020 (Y.L. Luigjes-Huizer).

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2.2. Participants

Eligible patients had finished successful curative cancer treatment between 3 months and 10 years ago, were registered at a participating GP practice, were 18 years or older, desired support for FCR, and had sufficient Dutch reading and writing abilities. The required sample size was 244 patients.

2.3. Recruitment

Sixty-two GPs and 21 MHWs from 20 GP practices participated in this study. They identified all registered patients who met the eligibility criteria and invited them by letter, except patients with severe comorbidity (eg, severe psychiatric morbidity). Patients who wished to participate provided informed consent through mail. After completing the first questionnaire, patients in both groups were asked to go to their GP for a consult on FCR. Because this study took place in a real-world setting, we chose not to screen on FCR severity to reflect daily primary care practice. Besides, the intervention also targets patients with moderate FCR, so screening for clinical-level FCR would not identify our target group.

2.4. Outcomes and data collection

Data were collected at baseline, after 4 months (T1), and after 12 months (T2). The primary outcome was the difference between the groups in FCR severity at T1, measured by the validated Dutch version of the Fear of Cancer Recurrence Inventory-Short Form (FCRI-SF).[15] Both intention-to-treat analyses and per-protocol analyses were conducted. In the per-protocol analysis, only those who went to their GP (control group) and those who received the intervention from the MHW (intervention group) were included.

Owing to the initial low response, we inquired reasons for nonparticipation in the second phase of inclusion. A form to indicate reasons for nonparticipation was included with the 256 remaining invitation letters. GPs who had already sent their invitations were asked to call 3–5 invited patients and ask them for their reasons not to participate.

3. Results

3.1. Participation

In total, 1368 invitation letters were sent between April 1, 2019, and September 1, 2020. Sixty-two patients (4.5%) joined this study: 36 in the intervention group and 26 in the control group. On average, 1 patient per GP participated. Trial participation is depicted as a flowchart in Figure 1. Thirty GPs recorded the reasons for not inviting patients who fit the criteria. They omitted 110 (21%) of 521 patients. Of them, 77% was considered too vulnerable (eg, because of Alzheimer) and 14% did not speak sufficient Dutch. We received 88 nonparticipation surveys (34% of those invited), and 26 patients were approached over phone. Their main reasons not to participate were not experiencing FCR (76% and 69%) and feeling no need for support (38% and 12%). We suspect no impact of COVID-19 on participation because most letters were sent before the pandemic.

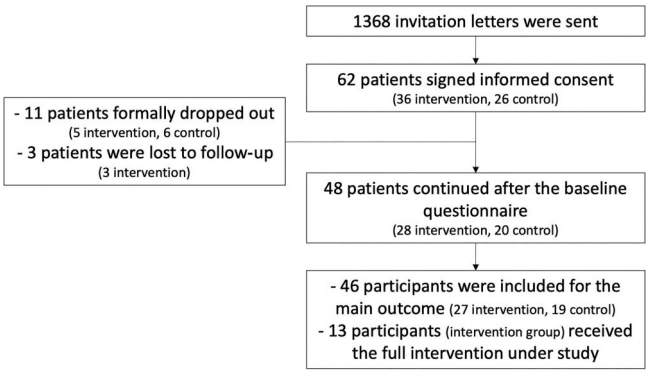

Figure 1. Flowchart on trial participation and data collection.

3.2. Demographic characteristics

The mean age of the participants was 62.9 years, and 56% were women. Most had breast cancer (36%) or colorectal cancer (29%). More demographic characteristics are presented in Supplemental Digital Content 1 (http://links.lww.com/OR9/A37).

3.3. Intervention uptake

Nineteen (83% [because of the COVID-19 pandemic, data could only be collected from the GP practices of 43 participants]) participants in the intervention group and 14 (70%) in the control group went to the GP. In the intervention group, 14 (74%) went to the MHW with an average of 4 sessions, compared with 3 (21%) in the control group with an average of 5 sessions.

3.4. Main outcomes

In the intention-to-treat analysis, FCR severity decreased from T0 to T1 by 2.7 points (standard deviation [SD] = 4.7) in the intervention group and 1.8 points (SD = 3.6) in the control group (Table 1). In the per-protocol analysis, the decreases were 3.5 points (SD = 4.5) and 0.7 points (SD = 2.7), respectively.

3.5. Experiences with the intervention

Mean patient satisfaction was higher in the intervention group (n = 10) than in the control group (n = 7) (3.5 vs 3 on a scale of 5). Both groups considered the care practical (3.6 and 3.5/5), and neither considered it burdensome (1.6 and 1.8/5). The intervention group was more likely to recommend the care (3.9 vs 3.2/5). MHWs (n = 12) in both groups rate the expected reduction in fear 3 on a scale of 5. Seventy-eight percent of MHWs in the intervention group plan to continue providing this intervention.

4. Discussion

Although reviews show that more than half of patients with cancer experience FCR[2] and that care for FCR is the largest

Table 1

Mean FCR severity scores and FCR severity reduction in the intervention and control groups (intention-to-treat analysis).

	Intervention group		Control group	
Outcome	**n**	**Mean (SD)**	**n**	**Mean (SD)**
FCR severity T0	33	17.7 (7.5)	24	17.1 (7.1)
FCR severity T1	27	15.1 (7.2)	19	16.2 (6.4)
FCR severity T2	25	13.1 (6.5)	18	14.3 (7.0)
FCR severity reduction T0-T1	27	2.7 (4.7)	19	1.8 (3.6)
FCR severity reduction T0-T2	25	3.6 (5.8)	17	3.2 (3.8)

unmet need for survivors,[3] only 4.5% of invited patients participated in our study. The main reported reasons not to participate were not experiencing FCR and not needing support for FCR. Although the number of participants was too low for a valid effect estimate, the results of the trial suggest that the intervention has potential. FCR decreased more in the intervention group than in the control group, and practitioners and patients were positive about the intervention.

We consider 4 reasons for patients' low interest in this primary care FCR intervention. First, it could indicate a low prevalence of FCR, but a recent review (n = 7,190) shows that over half of survivors experience at least moderate FCR.[2] Second, it may indicate less need for help than earlier research suggests. Patients who experience FCR do not always desire or require help,[16] and some patients only experience FCR when triggered, for example, around medical check-ups.[17] Thus, for some, the impact on daily life may not be enough to seek help. Third, it is possible that this type of intervention was not appealing to some patients, who may prefer self-help,[18] support from friends and family,[19] or treatment from a different health care provider (eg, at the hospital). Some patients may have also wished to avoid the confrontation with cancer. Finally, we may have used a suboptimal way of inviting patients. If the intervention would have been offered in person by the GP, the response may have been greater.

4.1. Future research

Despite the low response, we still believe there is a need for easily accessible, inexpensive interventions for FCR. More research is needed on the impact of FCR, on which patients require and desire help, and on what kind of intervention and setting are fitting for what patients.

For future FCR research and interventions, we also recommend addressing the barriers for participation that arose in our study, for example, by not using invitation letters. Invitation letters may easily be forgotten and may come at a time when patients are not interested, especially because FCR may fluctuate over time.[20] In addition, some may not participate because of avoidance. Finally, some patients may feel more addressed by the words "worry" and "concern" than "fear." Based on the above findings and patient feedback, we have adapted our recruitment strategy and intervention and we are currently assessing the effectiveness of an online FCR intervention, with video calls replacing face-to-face visits.

4.2. Clinical implications

In all, our results suggest that there are a group of people who can benefit from this primary care–based intervention, but that this group is much smaller than previously expected. Therefore, offering it in all general practices is probably not (cost)effective. Alternative delivery routes, that is, joint provision within groups of practices or online in video calls, need to be explored.

Ethics approval

The Medical Research Ethics Committee (METC) Utrecht has reviewed the study in accordance with the Dutch Medical Research Involving Human Subjects Act (WMO) and other applicable Dutch and European regulations. Based on the requirements of the WMO, the METC Utrecht has issued an approval of the abovementioned study with number 18/879.

Trial Registration Number: NL7573 in the Netherlands Trial Register on 25-02-2019.

Data sharing statement

The data sets generated during this study are available from the corresponding author on reasonable request.

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Conflicts of interest statement

The authors report no conflicts of interest.

Authors' contributions

Y.L. Luigjes-Huizer, C.W. Helsper, N. de Wit, and M.L. van der Lee contributed to the study conception and design. Y.L. Luigjes-Huizer performed data collection and analysis. M.M.J.G. Gerrits was involved in patient recruitment. The first draft of the manuscript was written by Y.L. Luigjes-Huizer, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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