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Assessing the impact of a self-guided digital intervention for fear of cancer recurrence (iConquerFear) in ovarian cancer survivors: a pilot randomised waitlist-controlled trial

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Abstract

Background Approximately 50% of ovarian cancer (OC) survivors report fear of cancer recurrence/progression (FCR/P) as the most challenging aspect of living with cancer. This pilot, randomised waitlist-controlled trial aimed to evaluate the feasibility, acceptability, and safety of iConquerFear, a self-guided online FCR intervention for OC survivors.

Methods Stage I-III OC survivors were recruited via Ovarian Cancer Australia (OCA) between October-December 2022. Participants were randomised to access iConquerFear immediately (intervention) or after 8 weeks (waitlist-control). Primary outcomes were feasibility, acceptability, and safety. Secondary outcomes included: engagement barriers/enablers, perceived impact of iConquerFear, and suggested improvements via semi-structured interviews. Exploratory outcomes included group differences in FCR and FoP after iConquerFear use.

Results Of 62 eligible survivors, 55 (61%) were randomised (intervention $n = 29$; control $n = 26$). At baseline 55% (30/55) reported severe FCR (FCRI-SF ≥ 22). Of those randomised, 51% ($n = 28$) accessed iConquerFear; 16/28 (57%) users completed $\geq 3/5$ modules. Mean post-intervention acceptability score (IEUQ) was 3/4 (SD = 0.8). Three (11%) users withdrew due to distress from iConquerFear. Qualitative interviews ($n = 13$) identified 6 key themes (e.g., participant factors influencing engagement). Differences between intervention and control group changes in FCR/P were non-significant.

Conclusions iConquerFear does not appear appropriate for OC survivors in its current format due to limited engagement, varied acceptability, safety concerns and minimal group differences in FCR/P after iConquerFear use. More work is needed regarding how to augment online interventions addressing sensitive issues such as FCR/P in OC survivors (e.g., offering complementary in-person support) to ensure feasibility, acceptability and safety.

Trial registration This trial is registered with ANZCTR.org (ACTRN12622000592741p) on 21 April 2022.

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Keywords Ovarian cancer, eHealth, Fear of cancer recurrence, Fear of progression, Self management, Web-based, Online

Introduction

Ovarian cancers are diagnosed in more than 300,000 women globally each year [1], with more than 1,800 occurring in Australia [2]. Recurrence is likely to occur in almost 20% of cases with early-stage disease (i.e., stage 1 and 2), and in more than 80% of cases with advanced stages (i.e., stage 3 and 4) [3]. The most common concern expressed by people living with or beyond cancer (i.e., cancer survivors) is fear of cancer recurrence (FCR) [4, 5], defined as the ‘fear, worry, or concern relating to the possibility that cancer will come back or progress’ [6, 7]. While few studies focus on ovarian cancer survivors, evidence suggests up to 56% report clinical levels of fear of progression (FoP) [8], and 51% identify FCR as the most challenging aspects of living with and beyond ovarian cancer [9]. FCR has also been strongly associated with increased emotional distress in ovarian cancer survivors [10]. The high prevalence and burden of FCR among ovarian cancer survivors highlights the critical need for FCR interventions.

Existing intensive interventions have demonstrated efficacy in reducing FCR among cancer survivors [11, 12]. Contemporary cognitive behavioural therapy (CBT) approaches focused on changing thought processes and how people relate to their inner experiences have demonstrated greater efficacy in reducing FCR than traditional CBT approaches focused on modifying thought contents [12]. Considering that FCR is a rational concern for many people affected by cancer, particularly those with a high risk of relapse (e.g., stage 3 ovarian cancer survivors), contemporary CBT interventions focused on helping people change the way they engage with thoughts/worries about recurrence, to make them more manageable and less distressing, may be particularly helpful. ConquerFear [13] is an example of one such intervention found to be efficacious in reducing FCR, underpinned by a theoretical model positing the centrality of unhelpful metacognitive processes and individual risk factors in the development and maintenance of FCR [14]. ConquerFear provides strategies for managing worry, unhelpful beliefs, and excessive threat monitoring, and education about appropriate behaviours for risk reduction of recurrence, addressing existential issues, and goal setting. However, like many FCR interventions, ConquerFear is time intensive and requires face-to-face sessions with a psychologist/psychiatrist [12], which can be challenging due to factors like distance from a provider, work or other commitments, and health issues [15, 16]. In a systematic review of FCR interventions, only four of thirty-two studies included self-directed interventions [12],

indicating a critical need for more accessible and scalable FCR interventions.

Online psychosocial interventions can overcome barriers related to face-to-face interventions [15, 16]. Advantages of online interventions include allowing users greater flexibility in how, when, and where they engage with content, and minimising time burden on patients and healthcare professionals [17]. Online FCR interventions may help people affected by cancer self-manage FCR in instance where this is preferred or where FCR is not addressed by health professionals [18, 19]. Evidence suggests that online interventions are moderately effective in reducing FCR, with improvements comparable to face-to-face interventions [20]. However, most online interventions have focused on people affected by breast cancer [17, 20]. There is a need for accessible FCR interventions for ovarian cancer survivors. A brief online information booklet incorporating elements of the therapist-delivered ConquerFear intervention [13] was developed in partnership with Ovarian Cancer Australia (OCA), a not-for-profit community-based organisation providing support services to women living with ovarian cancer, to address this need. While ratings of satisfaction and helpfulness were relatively high, there was no change in FCR after one week of use [8], suggesting a static booklet may not have been sufficient to address the high levels of FCR (FoP-Q-SF $M = 35.58$) reported by the survivors in this study. These findings highlight the challenge of balancing accessibility with sufficient intensity to treat and reduce FCR.

Our team developed a self-guided digital adaptation (iConquerFear [21]) of the ConquerFear intervention [13] to address this need for scalable intensive FCR interventions. iConquerFear retains the same theoretical components as ConquerFear, and includes exercises based on metacognitive therapy (e.g., attention training and detached mindfulness), and Acceptance and Commitment Therapy (ACT) principles (e.g., values clarification) [22]. A single-arm pilot study in curatively treated breast cancer survivors demonstrated acceptability, feasibility and preliminary efficacy, with reductions in FCR from pre- to post-intervention [23]. However, the utility of the intervention among patients with ovarian cancer warrants further exploration considering many women with ovarian cancer are diagnosed with later stage disease, have a higher likelihood of recurrence/progression, poorer prognosis [24–26], and different monitoring and follow-up schedules to women with breast cancer [27]. iConquerFear was subsequently adapted to the ovarian cancer context (further details in Methods), including

changing the terminology to focus more on FoP. The core therapeutic content did not change from the breast cancer version of iConquerFear, considering key intervention targets (i.e., metacognitions and intrusions) appear to underpin both FCR and FoP [28]; it was therefore expected iConquerFear may reduce both FCR and FoP.

In response to the need for an accessible intervention to address FCR among ovarian cancer survivors, this study primarily aimed to evaluate the feasibility, acceptability, and safety, of iConquerFear (in addition to the information booklet) in ovarian cancer survivors in a pilot randomised waitlist-controlled trial. A secondary aim was to qualitatively explore barriers and facilitators to iConquerFear engagement, perceived impact on FCR, and potential improvements to the intervention. Group differences in FCR and FoP changes among ovarian cancer survivors were examined as exploratory outcomes.

Based on iConquerFear development [22] and piloting [23], hypotheses regarding our primary outcomes were as follows:

Feasibility

1. $\geq 50\%$ of study participants (in both groups) would access iConquerFear, and of those who accessed iConquerFear (iConquerFear users);
 - a. $\geq 50\%$ would complete $\geq 3/5$ modules;
 - b. $\geq 50\%$ would log in > 8 times (i.e., 1/week on average);
 - c. $\geq 50\%$ would spend 120+ minutes on iConquerFear.

Acceptability

1. iConquerFear users would report an overall mean acceptability score of $\geq 3/4$;
2. $\geq 75\%$ of iConquerFear users would respond mostly/very to individual acceptability items on the Internet Evaluation and Utility Questionnaire [29].
3. iConquerFear users would report mean module satisfaction ratings of $\geq 3/5$;
4. $\geq 75\%$ of iConquerFear users would be moderately/very likely to recommend iConquerFear.

Safety

1. $\leq 5\%$ of iConquerFear users would:
 - a. Report clinical levels of FCR ($\text{FCR-1r} \geq 5$) and distress ($\text{DT} \geq 5$) attributed to website usage;
 - b. Withdraw from the study due to heightened FCR and/or distress.

Methods

Design

A two-arm pilot randomised waitlist-controlled trial was conducted incorporating a qualitative sub-study, according to Consolidated Standards of Reporting Trials (CONSORT) guidelines [30]. Pilot studies are vital for determining the suitability of an intervention for further efficacy testing when it is adapted for a new population. They help determine whether the intervention is feasible for individuals from the new population to engage with, acceptable in content and format, and safe to use [31]. These findings can determine whether a definitive trial evaluating efficacy is warranted and inform any further modifications that may be needed. The present study was prospectively registered in the Australian New Zealand Clinical Trials Registry (ACTRN12622000592741p). The study was approved by the University of New South Wales Ethics Committee (reference: HC220186) and conducted in collaboration with OCA.

Participants and setting

Participants were recruited from October to December 2022 through nurse referrals from the OCA Teal Support Program (a free telehealth program for women diagnosed with ovarian cancer) [32], and social media. Prospective participants from each recruitment pathway were provided a link to the iConquerFear website (<https://iConquerFear.org.au>), which directed them to a brief online screening questionnaire, participant information sheet and consent form.

Survivors aged ≥ 18 years were eligible to participate if they were: (i) diagnosed with ovarian cancer (stages I-III), (ii) finished hospital-based treatment (surgery, radiation therapy, or chemotherapy); (iii) able to provide informed consent; (iv) proficient in English; (v) able to use an electronic device with internet access and an email address; (vi) living in Australia. Prospective participants were assessed for severe depression ($\text{PHQ-9} \leq 19$), and/or suicidal ideation using the 9-item Patient Health Questionnaire (PHQ-9) [33]. If present, survivors were excluded from the study and offered immediate support. Participants diagnosed with a recurrence during the study retained iConquerFear access, but were excluded from analysis.

Sample size

The target sample size was 60 participants based on feasibility study guidelines [34, 35].

Procedure

From the iConquerFear website, prospective participants completed an online screening survey which included questions about their demographics and diagnosis, and the Patient Health Questionnaire (PHQ-9) [36]. Eligible

participants were then directed to the online participant information sheet and consent form and followed-up by a research assistant to answer outstanding questions and confirm participation, including interest in completing an optional telephone interview. Following consent, participants were given a unique iConquerFear login and access instructions and asked to complete the baseline questionnaire (T0). Participants were then randomly assigned to either intervention or waitlist control group in a 1:1 ratio, using a block randomisation sequence automatically generated by an algorithm embedded in the iConquerFear website, and informed of their group allocation by email.

Intervention participants were given immediate access to iConquerFear and an OCA FCR information booklet [37], while waitlist-control participants initially received an OCA FCR information booklet and were able to access iConquerFear after completing the 8-weeks post-baseline (T0.5) questionnaire. Both groups were offered the information booklet to enable assessment of the added benefit of iConquerFear relative to existing resources. Both groups were asked to complete questionnaires after 8 weeks (T1) and 20-weeks (T2) of iConquerFear access. All participants who consented to the optional telephone interview were contacted after their 8-week access period. Interviews were conducted by author (AnPa), audio-recorded, uploaded, and transcribed using Microsoft Stream. Transcripts were checked for accuracy by AnPa and participants who requested an opportunity to review their data.

Intervention

FCR Booklet

The information booklet was developed by OCA, and provides psycho-educational material on FCR, including management strategies derived from the ConquerFear intervention [13]. The FCR booklet served as ‘treatment-as-usual’ for the intervention and wait-list control groups in this study, as OCA routinely provides ovarian cancer survivors with ongoing support from nurses and access to written resources (such as the information booklet). The booklet can be accessed online at: www.ovariancancer.net.au/booklet/fear-of-cancer-recurrence.

iConquerFear intervention

iConquerFear is a web-based intervention, based on the ConquerFear intervention, using contemporary cognitive-behavioural therapy (CBT) techniques from acceptance and commitment therapy (ACT) and meta-cognitive therapy to reduce unhelpful beliefs about worry and attention to intrusive thoughts about recurrence [13] and increased focus on living according to values. A detailed description of iConquerFear and its development is published elsewhere [22]. The iConquerFear intervention comprised an optional welcome module

and five therapeutic modules: (1) goal setting; (2) attention training; (3) detached mindfulness; (4) learning to live well and manage worry; and (5) maintaining changes. In the absence of targeted interventions addressing FCR in women living with ovarian cancer, iConquerFear was adapted to the ovarian cancer context. Key changes included: (1) provision of images and videos of ovarian cancer survivors demonstrating their lived experience of FCR; (2) tailored advice around symptom monitoring and removal of self-examination suggestions, and (3) changes to the language such that it acknowledged FoP and tailoring of health behaviour advice to focus on living well with cancer, rather than minimising risk of recurrence.

The adapted iConquerFear intervention comprised written information, interactive activities (e.g., attention training and mindfulness exercises), and videos of ovarian cancer survivors reflecting on their experiences of FCR and their strategies for management. Regular feedback and email reminders were sent to participants to encourage engagement. While modules could be completed in any order, sequential completion was recommended.

Outcomes

Primary outcomes

Feasibility was determined by iConquerFear uptake (i.e., proportion of women who accessed iConquerFear) and engagement (i.e., proportion of women completing the modules, number of logins, time spent) according to referral and website logs.

Acceptability was evaluated using the Internet Evaluation and Utility Questionnaire (IEUQ) [38], post-module satisfaction ratings, and purpose-designed questions regarding the likelihood of recommending iConquerFear and best time to offer iConquerFear. The IEUQ comprises: (1) 13 items ($\alpha = 0.69$) [38] assessing participant’s experiences (e.g., ease of use and acceptability) and perceptions (e.g., usefulness and credibility) of a digital health intervention (i.e., iConquerFear) on a 5-point Likert scale from 0 (“not at all”) to 4 (“very”), with 5 being “Not Applicable”. Item 6 which pertains to concerns about privacy was reverse scored; (2) two open-ended items asked about the “most helpful” and “least helpful” parts of iConquerFear.

Safety was determined by the proportion of iConquerFear users (i.e., participants who accessed iConquerFear): (1) reporting clinical levels of FCR and/or distress attributed to website usage on single-item validated measures of FCR (FCR-1r) [39] and distress (Distress Thermometer) [40] administered at the end of each module; (2) withdrawing due to heightened FCR and/or distress.

Secondary outcomes

Semi-structured interviews were conducted to explore participants' experiences using iConquerFear including barriers and facilitators influencing engagement, perceived impact of iConquerFear, and suggested improvements (see Additional File 1 for interview schedule).

Exploratory outcomes

While a larger trial would be needed to provide a definitive evaluation of efficacy, we explored group differences that could indicate iConquerFear's potential for reducing FCR and FoP assessed using the following measures (see further details in Additional File 2):

- *Fear of cancer recurrence* was assessed by the 9-item Fear of Cancer Recurrence Inventory-Short Form (FCRI-SF) [41, 42].
- *Fear of progression* was assessed by the 12-item Fear of Progression Questionnaire- Short Form (FoP-Q-SF) [43].

The key comparison of interest regarding group differences was change in FCR and FoP in the intervention versus waitlist control-group from baseline (T0) to 8 weeks post-baseline (T1/T0.5 respectively). We also explored changes in FCR and FoP from baseline to 3 months post-intervention in both the intervention and control group and proportion of iConquerFear users experiencing reliable and clinically significant change.

Sample characteristics

Participant demographic and clinical characteristics including age, relationship status, education, employment, cancer stage, time since diagnosis, and treatment received were assessed at baseline.

Statistical methods

Quantitative analysis was conducted via IBM SPSS Statistics version 27. Descriptive statistics were used to summarise sample characteristics, and acceptability outcomes. Between-group differences in changes in FCR and FoP from baseline (T0) to 8 weeks post-baseline (T1), and 3 months post-baseline (T2) were evaluated using independent samples t-tests. Cohen's *d* was used to indicate effect size (small $d=0.2$, medium $d=0.5$, large $d=0.8$) [44]. Within-group changes in FCR and FoP from baseline to 3 months post-intervention were evaluated in the intervention and control group separately using repeated measures t-tests. Reliable change in FCR and FoP was calculated to determine whether individual changes in outcomes exceeded what could be expected due to measurement error. Jacobson and Truax's recommendations for calculating the reliable change index (i.e., $\text{baseline standard deviation} \times \sqrt{2 \times (1 - \text{reliability})} \times 1.96$

) [45] were followed. The standard deviation of baseline FCRI-SF and FoP-Q-SF scores were inputted along with the published Cronbach's alpha of the English versions of the FCRI-SF (Cronbach alpha = 0.89 [46]) and FoP-Q-SF (Cronbach alpha = 0.87 [43]) to estimate reliability. Clinically significant change was determined as a change in clinical category post-intervention according to FCRI-SF and FoP-Q-SF cut-offs [47, 48].

Qualitative feedback from semi-structured interviews was thematically analysed using Braun & Clarke's six-step process [49, 50]. AnPa reviewed the data, generated preliminary codes, and grouped codes into overarching themes using NVivo 12 software. VW and BS then worked with AnPa to review, finalise and write-up themes.

Results

Participants

Ninety ovarian cancer survivors expressed interest in participating in the trial, 25 did not complete the online consent form and screening questionnaire, and three declined participation (see Fig. 1). Sixty-two survivors were screened for eligibility: three were deemed ineligible due to reporting stage IV cancer; two reported suicidal ideation (and were provided mental health support); and two did not complete the baseline questionnaire. Consequently, 55 survivors were randomised to either the immediate intervention access group ($N=26$) or waitlist control group ($N=29$). Nineteen participants subsequently withdrew (9 due to disease recurrence) and 7 were lost to follow-up (i.e., did not complete both follow-up questionnaires after three reminders). Twenty-three out of 29 remaining participants completed both post-intervention questionnaires.

Sample characteristics

Participants ($N=55$) had a mean age of 56 years ($SD=12.7$) and were 2 years ($SD=1.8$) post-diagnosis (see Table 1). Most participants were: partnered/married (69%), tertiary educated (64%), employed (53%), primarily English-speaking (96%). At baseline, 30/55 (55%) of participants reported severe FCR (FCRI-SF ≥ 22), 17 (31%) moderate FCR (FCRI-SF 13–21), and 8 (15%) mild FCR (FCRI-SF < 13). Fourteen women (25%) were receiving psychological treatment at enrolment.

Feasibility

Twenty-eight (51%) of 55 survivors randomised (intervention $n=14$; control $n=14$) accessed (i.e., started) at least one iConquerFear module. Sixteen (intervention $n=8$; control $n=8$) of the 28 (57%) commencing iConquerFear (i.e., users) completed at least 3/5 therapeutic modules. Modules were generally completed sequentially,

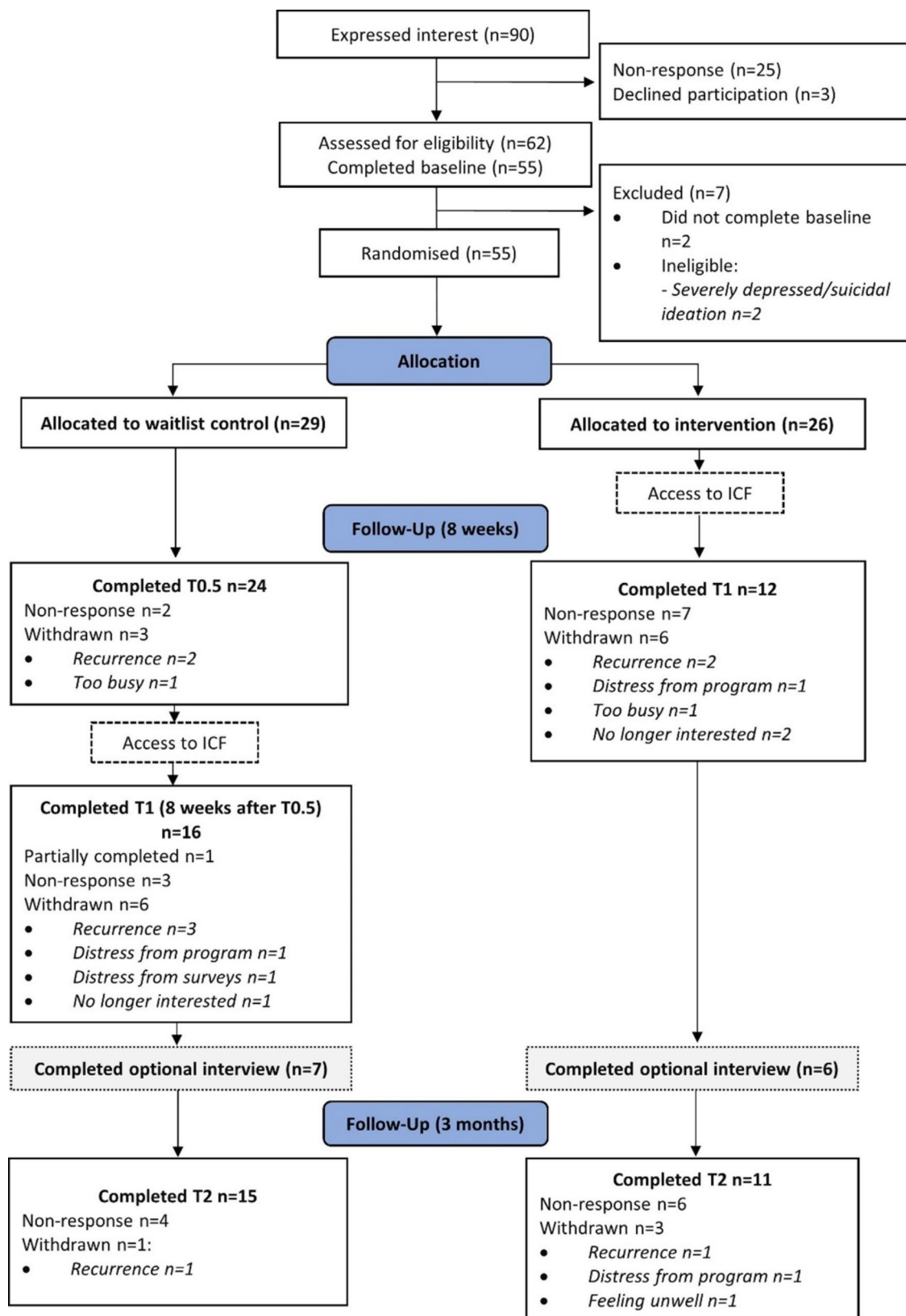
**Fig. 1** CONSORT participant recruitment flow diagram

Table 1 Baseline demographics of study participants

Characteristic	Total sample N=55	Inter- vention n=26	Control n=29
Age (mean, SD)	56 (12.7)	55.8 (11.9)	56.2 (13.6)
Years since diagnosis (mean, SD)	2 (1.8)	1.5 (0.8)	2.5 (2.3)
Years since treatment completion (mean, SD)	1.2 (1.3)	1 (0.8)	1.3 (1.6)
Relationship	N(%)	n(%)	n(%)
Single	6 (11)	2 (8)	4 (14)
Partnered	38 (69)	19 (73)	19 (66)
Divorced/separated/widowed	11 (20)	5 (19)	6 (20)
Education			
High school education	7 (13)	6 (23)	1 (3)
TAFE certificate/diploma	13 (24)	5 (19)	8 (28)
Tertiary education	35 (64)	15 (58)	20 (69)
Employment			
Full-time/part-time/self-employed	29 (52)	14 (54)	15 (52)
Unemployed	5 (9)	4 (15)	1 (3)
Retired/pensioner	13 (24)	6 (23)	7 (24)
Home duties	2 (4)	1 (4)	1 (3)
Student/other	6 (11)	1 (4)	5 (17)
Country of birth			
Australia	39 (71)	17 (65)	22 (76)
Other	16 (29)	9 (35)	7 (24)
Language spoken at home			
English only	53 (96)	25 (96)	28 (97)
Aboriginal or Torres Strait Islander			
No	53 (96)	25 (96)	28 (97)
Yes, Aboriginal	2 (4)	1 (4)	1 (3)
Have children			
Yes	38 (69)	19 (73)	19 (65)
Cancer stage			
Stage I	12 (22)	7 (27)	5 (17)
Stage II	9 (16)	5 (19)	4 (14)
Stage III	34 (62)	14 (54)	20 (69)
Treatment received*			
Surgery	55 (100)	26 (100)	29 (100)
Chemotherapy	53 (96)	25 (96)	28 (96)
Radiotherapy	4 (7)	1 (4)	3 (10)
Hormonal therapy	3 (5)	0 (0)	3 (10)
Other	6 (11)	2 (8)	4 (14)
Other psychological treatment			
No psychological treatment	41 (74)	17 (65)	24 (83)
Psychologist	12 (22)	9 (35)	3 (10)
Counsellor	1 (2)	0 (0)	1 (3)
Other	1 (2)	0 (0)	1 (3)

*Participants could select more than one option

with Module 1 completed by 24/28 (86%) of users, and Module 5 11/28 users (39%).

Nineteen (68%) of 28 users logged on to the website at least 8 times, 36% ($n=10/28$) spent ≥ 120 min on iConquerFear. The average amount of time spent accessing iConquerFear modules was 44.1 min (range = 0–226 min,

SD = 63 min), spread across 7 logins (range = 1–37 logins, SD = 6).

Acceptability

Internet evaluation and utility questionnaire (IEUQ)

After excluding responses where participants selected ‘not applicable’ (e.g., because they did not access iConquerFear), the mean overall IEUQ score was 3/4. However, only 7/13 (54%) IEUQ items achieved the target of $\geq 75\%$ of users responding ‘mostly/very.’ More than 90% of respondents indicated iConquerFear was ‘mostly/very’ easy to understand ($n=25/27$, 93%), and to use ($n=23/26$, 92%). Approximately 90% ($n=26/29$) responded they were ‘not at all’ worried about their privacy, and that the information was trustworthy ($n=24/27$, $n=98\%$) (see Fig. 2). Items with the lowest ratings included that iConquerFear was acceptable (i.e., a good fit for them, 52% ($n=14/27$) ‘mostly/very’ ratings), and useful (62% ($n=16/26$) ‘mostly/very’ ratings).

Module satisfaction

The overall mean satisfaction rating ($n=23$) for all five modules was 4/5 stars which met our target of $\geq 3/5$. Module 4: Living well and managing worry received the highest post-module satisfaction score (mean = 4.27/5, SD = 1.0), followed by Module 1: A new way to manage FCR (mean = 4.21, SD = 0.8), and Module 3: Detached mindfulness (mean = 4.15, SD = 1.0). Thirty-two participants (58%) completed the post-intervention questionnaire. Of these, 19 (59%) indicated they would be moderately/very likely to recommend the program to others. Views on optimal time to use iConquerFear were divided, with 56% ($n=18$) selecting at diagnosis but 38% ($n=12$) indicating at treatment completion.

Safety

Of the 28 users who accessed iConquerFear, one (4%) reported distress (DT score $\geq 5/10$) attributed to iConquerFear content in a post-module survey. Open-ended responses from the post-module surveys indicated other reasons for distress such as concern about recurrence rate ($n=4$, 14%), and worries pertaining to upcoming follow-up appointments/test ($n=4$, 14%). Three of 28 users (11%) withdrew from the study due to distress attributed to iConquerFear. All three participants who withdrew reported severe FCR (FCRI-SF SF ≥ 22 , range 23–26) at baseline, with two never accessing any iConquerFear modules. One additional participant (2%) withdrew citing distress from the survey questions.

Exploratory aims (group differences)

The mean difference in intervention and control group FCRI-SF score changes from baseline to 8-week assessment were small ($d=0.16$) and non-significant ($p=0.65$).

Internet Utility and Evaluation Questionnaire responses (N=32)

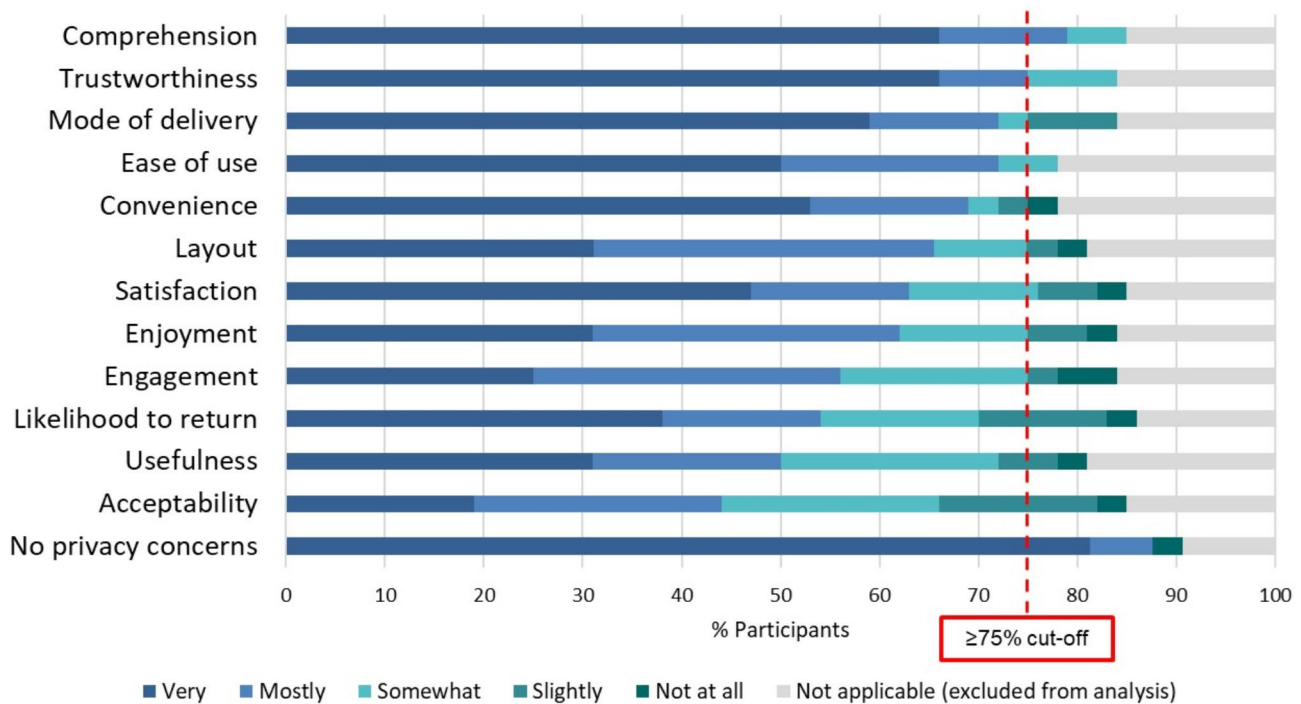


Fig. 2 User ratings of acceptability (IEUQ). Note: Responses depicted in blue (i.e., Very and Mostly) are indicative of higher levels of acceptability for most domains, excluding privacy concerns

Table 2 Group differences from baseline to post-intervention

		Baseline (T0)	Pre-intervention (T0.5 ^a)	Follow-up 8 weeks (T1)	Follow-up 20 weeks (T2)	T0-T1 (Pre- to post-intervention)			T0-T2 (Pre- to post-intervention)		
N (Int/Cont)		26/29	24	12/17	11/15	Difference within- and between-groups			Difference within- and between-groups		
FCRI-SF	Arm	M (SD)	M (SD)	M (SD)	M (SD)	MDiff (SD/SE)	d	p	MDiff (SD/SE)	d	p
	Int	20.03 (5.62)	NA	19.00 (4.49)	18.82 (4.53)	0.08 (4.38)	0.02	0.94	-0.36 (6.30)	-0.06	0.85
	Cont	19.59 (7.31)	17.91(7.97)	17.88 (8.44)	14.80 (8.55)	0.88 (5.57)	0.16	0.52	1.6 (5.57)	-0.29	0.29
						0.80 (1.85)	0.16	0.65	1.96 (2.38)	0.33	0.23
FoP	Int	32.96 (9.21)	NA	33.75 (8.73)	30.73 (8.65)	-0.83 (3.64)	-0.23	0.44	0.63 (6.82)	0.09	0.76
	Cont	34.59 (10.15)	30.95 (10.55)	27.75 (8.50)	26.93 (9.66)	5.75 (7.63)	0.75	0.008	5.87 (9.04)	0.65	0.025
						6.58 (2.18)	1.05	0.003	5.238 (3.11)	0.64	0.12

Abbreviations: Int-Intervention; Cont-Control. Bold font indicates significant results.

^aControl group only

Control participants experienced large ($d = 1.05$) statistically significant ($p = 0.003$) reductions in FoP-Q-SF scores relative to intervention participants (see Table 2).

Reliable and clinically significant change in FCR and FoP

The reliable change criterion for the FCRI-SF was calculated to be 5.98 (Cronbach's $\alpha = 0.89$ from literature [46], and baseline survey standard deviation = 6.51). From immediately pre-intervention to immediately post-intervention 2/29 (7%) participants experienced reliable and

clinically significant improvement, and one (3%) participant experienced reliable and clinically significant deterioration. At three months post-intervention 4/26 (15%) participants experienced reliable and clinically significant improvement, and two (8%) participants reported reliable and clinically significant deterioration.

The reliable change criterion for the FoP-Q-SF was calculated to be 9.66 (Cronbach $\alpha = 0.87$ from literature [43], and baseline survey standard deviation = 9.66). No participants experienced reliable and clinically significant

improvement or deterioration from immediately pre-intervention to immediately post-intervention. Three months post-intervention, 3/26 (12%) participants experienced reliable and clinically significant improvement, while one (4%) participant experienced reliable and clinically significant deterioration.

Qualitative evaluation

Of the 24 participants who initially consented to an interview 13 participated (54%, intervention $n=6$; control $n=7$). Mean length was 47 min (range = 32–71 min). Most interviewees ($n=11$) completed at least 3/5 iConquerFear modules, two ($n=1$ intervention, $n=1$ control) had not completed any modules. Thematic analysis produced six themes relating to barriers and facilitators to engagement, perceived impact of iConquerFear, and suggested improvements (see Table 3 for themes and illustrative quotes).

Interviewees generally perceived iConquerFear to be a useful tool with relevant and helpful techniques for managing FCR, although two interviewees who did not engage with iConquerFear expressed a preference for in-person support. Engagement was hindered by participant factors (e.g., lack of time and energy) and website and content factors (e.g., perception that repeated reminders about anxiety was unhelpful). Perceived effects of iConquerFear on participants' level of FCR were variable, with some interviewees reporting it improved their coping strategies, while one felt their FCR did not change. Suggested improvements included more detail in audio-visual content of cancer survivors discussing their lived experiences and how to incorporate FCR management techniques in their daily lives, and complementing the flexibility of the online format with in-person support.

Abbreviations: Int-Intervention; Cont-Control. Bold font indicates significant results.

^aControl group only.

Discussion

This study evaluated the feasibility, acceptability, and safety of iConquerFear, an online intervention aiming to address the critical need for accessible and scalable FCR interventions in ovarian cancer survivors. Regarding our hypotheses, 3/4 *feasibility* targets were met: 1) $\geq 50\%$ of participants accessed iConquerFear; 2) $\geq 50\%$ of users completed at least 3 therapeutic modules; 3) $\geq 50\%$ of users logged in at least 8 times. For *acceptability*, 2/4 criteria were met: (1) overall acceptability mean score was 3/4 which met our overall target of $\geq 3/4$; (2) overall mean 5-star rating was 4/5, which met our target of $\geq 3/5$ stars. Only 1/2 of our *safety* criteria was met, with $\leq 5\%$ of users reporting clinical FCR/distress attributed to website usage. The findings are discussed in further detail below.

Primary outcome: feasibility

Managing FCR has been identified as a top priority for ovarian cancer survivors [9]. Despite this, we did not meet our recruitment target of $n=60$ (actual recruitment $n=55$). We observed limited uptake of iConquerFear, with just over half of participants accessing the program, indicating it may not have been perceived as appropriate for meeting ovarian cancer survivors' FCR support needs. Offering a self-management program to ovarian cancer survivors who were more than one year post-treatment on average, and may have already established ways of attempting to cope with FCR, may have limited uptake. More than half of qualitative interview participants believed iConquerFear would be best offered at diagnosis, whereas a third believed it should be offered at treatment completion. Anxiety tends to increase following treatment completion [51], and the reduced frequency of medical appointments and challenges monitoring for recurrence may also increase FCR. The mixed perceptions about the best timing to offer iConquerFear may result from differing individual needs. Consideration of where survivors are situated in their illness trajectory, and their previous experiences with self-management and professional support (e.g., coping strategies tried) may be warranted when determining appropriate timing for intervention delivery [52].

Although more than half of users who accessed iConquerFear completed at least 3/5 modules, only 36% spent ≥ 120 min (i.e., moderate usage) using the program, which did not satisfy our hypothesis of $\geq 50\%$. In contrast, 51% of breast cancer survivors ($n=47$) who took part in a previous feasibility study of iConquerFear engaged in at least 120 min of use [23]. This categorisation of moderate usage was based on the estimated amount of time to complete at least 2 therapeutic modules (i.e., one hour each module). However, it is possible that this does not reflect moderate levels of usage in the real world, where survivors may expect online interventions to be brief in the present digital age. Interview participants shared that lack of time and/or energy prevented them from engaging regularly with iConquerFear, with one participant describing that completing iConquerFear was akin to completing a lengthy 'course'. These barriers to engagement have previously been reported as contributing to participants' difficulties integrating digital mental health interventions in their lives [53]. The self-directed, but still somewhat time intensive nature of iConquerFear, may not have been a good fit for ovarian cancer survivors struggling with other concerns related to their illness.

Survivors with ovarian cancer have previously reported feeling isolated due to lack of shared experiences and understanding from others, particularly those living in rural areas and diagnosed with early-stage disease [54].

Table 3 Themes, sub-themes, and supporting quotes

Theme/Description	Sub-theme	Example Quotes
Theme 1: Individual factors influencing engagement	Commitment to research and curiosity to learn	<i>"I just wanted to finish it and find out how I felt at the end of it [...] was I still going to feel the same or was I going to feel different?"– P011</i>
	Participants may lack time and/or energy	<i>"I remember there was a video or two in there. I haven't got time for that. On so many levels. Psychologically. Physically. [...] With ovarian cancer, fatigue is a huge thing. Do you want to spend your good hours thinking about bad things?"– P044</i>
Theme 2: Website and content factors influencing engagement	Suitability of tone and language for ovarian cancer survivors	<i>"The word conquer, it's a very masculine word. Problem number one: ovarian cancer only affects women. And it's also a very militaristic word. And it implies a kind of warfare, and when you think about warfare, there's an enemy, you know, outside you. But fear is not that"– P016</i> <i>"I liked the short videos from cancer survivors because it's nice to hear how someone actually puts it into practice, but also you get a sense of connection to the module, the information, the people. It's more than just some kind of sterile learning experience."– P047</i>
	Reminders and progress markers motivated engagement	<i>The percentage counter for completion in the top corner kind of felt like you're actually getting somewhere [...] It's good to have like an achievement bar"– P047</i> <i>"I really like the reminder emails because sometimes you can get caught up with work and things like that."– P006</i>
	Contrasting opinions on appropriate amount of content	<i>"I think there was enough content in the modules because then it offered you the option to, you know, to follow up further, it recommended resources and the other things to go to."– P006</i> <i>"It was too, too long. It was too– as if I was doing a course. No one wants to do a course when you got cancer."– P014</i>
Theme 3: Varying ideas on ways to recommend iConquerFear to maximise engagement	Differing recommendations on appropriate timing	<i>"Because you're in such a whirl initially, that probably this wouldn't make much sense to you until you probably got to about four to six months into your treatment. [...] You need to be in a more regular place where you recognize how the treatment may be impacting you physically, emotionally."– P051</i> <i>"I think probably at the end of your treatment. I found that's when reality kicked in. Because when you're going through the treatment, you're so in it and you're so sick, that's your whole focus [...] But afterward, when you're in that recovery stage and people start to drift off and you, then you realize that, okay, I've had this terrible experience and there is a chance I could have to go through this all again."– P002</i>
	Different avenues of sharing iConquerFear	<i>"To me you would advertise it far and wide through the Ovarian Cancer Council people and all those other areas that people are going into for help. The oncologists, you'd sponsor it far and wide. [...] Because there are people out there that are scared stiff and they need to know that there's available– there's societies available for them."– P045</i> <i>"And I already have [recommended iConquerFear through word-of-mouth] actually. So Ovarian Cancer Australia has a Facebook page and there was somebody who was quite distressed not long ago and people were making suggestions on it. [...] I wrote something about it and to tell them to contact the Ovarian Cancer Association or their teal support nurse and ask for information on iConquerFear."– P049</i>
Theme 4: Personal impact of iConquerFear	Reinforced familiar coping strategies	<i>"It's probably for me just reinforced the things that I was sort of using but perhaps didn't have a name for, you know, I had been trying to do the worry postponement, but I wouldn't have termed it that. And I certainly– I would have talked about mindfulness, but I wouldn't have talked about it being detached. So, I've sort of put some labels to some of those things."– P051</i>
	No impact due to little pre-existing fear of recurrence	<i>"I don't have a fear... because for me, I have taken it out, it's 100% out. You know, that's not gonna come back"– P024</i>
Theme 5: Desire for deeper, more diverse discussions of lived experiences	In-depth exploration of lived experiences	<i>"More examples of how they had used some of the techniques, or how it had directly benefited them."– P006</i>
	Representation of diverse experiences in survivor videos	<i>"The only thing that wasn't there was for someone specifically like me who has had it return multiple times. [...] I think very differently now than what I did after I had it once."– P047</i>
	Significant details about fear may be distressing	<i>"Putting things on, like, you know, how it really makes you feel, being fearful of cancer coming back, may upset some people [...] and that's why I thought they've done this on purpose because they wanted to be generic and quite vanilla, I suppose, because, you know, it's not going to upset anybody"– P049</i>
Theme 6: Balancing the flexibility of online programs with opportunities for social connection	Online format provides convenience and autonomy	<i>"The best program as such has been set up so you have like a toolbox, you have resources at your fingertips that you can use whenever you get into this mental minefield"– P021</i>
	Social and personalised element encourages engagement	<i>"Well, face-to-face support would be very important for those women who really do have fear. They would need to have literally the eye contact. I would definitely advocate that. And those who go and quietly see somebody and shed their tears and their fears etcetera on a face-to-face basis. So for them, online is too cold and typically not appropriate."– P045</i>
	Complementary online and in-person tools offers dual benefits	<i>"If you can do a bit of 50–50 and have an online program and have at some stage an in-person forum, meeting, webinar, a seminar [...] I don't think you can replace one with the other. [...] You need to have someone to talk to, about what you've read, listened to, whatever, you know, it's nice to have that as well as another method. They are complementary."– P006</i>

The self-guided nature of iConquerFear may have provided inadequate support to enable engagement with the therapeutic intervention content. Several interviewees suggested complementing iConquerFear with human support (e.g., psychologist, online and in-person peer support groups). The presence of human support facilitating engagement is supported by recent systematic review findings demonstrating that guided digital interventions (i.e., with a facilitator present) report consistently higher levels of engagement by cancer survivors, compared to self-directed (i.e., completed independently by the patient) digital interventions [55]. It seems that without human guidance to encourage motivation and accountability to adhere [56], participants are likely to disengage from online self-directed interventions.

Primary outcome: acceptability

Only 7/13 of the IEUQ items received $\geq 75\%$ user ratings of 'very/mostly' which did not satisfy our hypothesis, and only 14/21 (67%) of users indicated they were moderately/very likely to recommend iConquerFear to others. Key aspects of iConquerFear acceptability, such as fit for user needs, usefulness, and likelihood of returning were less favourably rated. In contrast, a web-delivered cognitive behavioural therapy for cancer patients with distress (CancerCope) which used the same measure for acceptability found that patients rated the acceptability and usefulness of the program more favourably [57]. Qualitative feedback from interviews revealed that some survivors desired an intervention more broadly focused on aspects of living with ovarian cancer other than FCR (e.g., fatigue) needing to be resolved before they could benefit from iConquerFear. This is congruent with previous research showing ovarian cancer survivors report various unmet supportive care needs across the physical and daily living, health system/information, patient care, and sexuality domains [58, 59]. It may be iConquerFear alone did not address survivors' diverse needs, hence was perceived less favourably. More broadly focused online psychosocial programs such as Finding My Way [60] have demonstrated favourable engagement and efficacy in people newly diagnosed with early-stage cancer and further research is underway to see if this extends to women living with metastatic breast cancer [61]. This may help further elucidate whether the variable acceptability of iConquerFear was due more to the narrowly focused intervention content or the online self-directed intervention mode more broadly.

Primary outcome: safety

While $\leq 5\%$ of iConquerFear users reported elevated distress attributed to iConquerFear content, which satisfied one of our a-priori safety hypotheses, 11% of users who withdrew from the study reported distress attributed to

iConquerFear, which did not satisfy our criteria of $\leq 5\%$. Additionally, two of the participants who withdrew citing distress attributed to iConquerFear had not accessed any of modules, which suggests the thought of completing a FCR-focused intervention may be distressing to those with severe FCR, particularly those who use more avoidant coping strategies [62]. These findings highlight the need for self-guided digital tools addressing sensitive topics, such as FCR, to be embedded in psychosocial support services that provide a safety net for people who may require support beyond online interventions. The high proportion of study participants diagnosed with stage III cancer, and the number of participants who withdrew due to recurrence should also be taken into consideration. The late stage at which ovarian cancer is typically diagnosed and the high risk of recurrence [24–26] suggests these survivors face may require more tailored and intensive FCR care compared to other cancer populations.

Exploratory outcomes: Group differences in FCR and FoP

Although not powered to definitively evaluate whether iConquerFear was efficacious for reducing FCR and FoP in ovarian cancer survivors in this pilot study, preliminary data based on group differences did not suggest the intervention is likely to be effective in reducing FCR and FoP. Taken together with the limited engagement, varied acceptability, and qualitative suggestions for improvement, it seems that adaptations to the therapeutic content of iConquerFear that consider the greater uncertainty and poorer prognosis faced by women affected by ovarian cancer may be needed. A nurse-led telehealth FCR intervention adapted from ConquerFear has shown promising results in a pilot with people living with advanced cancer (one quarter ovarian cancer survivors) [63].

Adding human support to online interventions to reduce FCR has been consistently recommended in recent literature, including a systematic review of psychological interventions for ovarian cancer survivors [64], the feasibility study of iConquerFear among patients with breast cancer [23], and a study involving a blended online/telehealth intervention for gynaecological cancer survivors [65]. Further research is needed to explore whether complementing iConquerFear with human support is an effective strategy for reducing FCR. An asynchronous, therapist guided version of iConquerFear is currently being trialled in Denmark among colorectal cancer survivors [66].

Strengths and limitations

iConquerFear content is derived from ConquerFear, which demonstrated efficacy in reducing FCR [13], and was adapted for the ovarian cancer context, but our

findings suggest it was not tailored enough to maximise engagement and benefit in our sample. It was not possible to examine quantitative moderators of engagement (such as age) due to low sample size. While we sought to interview ovarian cancer survivors with varying degrees of iConquerFear use, qualitative perspectives were largely from survivors who engaged more with the intervention, constraining our understanding of the barriers to uptake and engagement. Time spent on iConquerFear could only be captured for users who had completed a module, limiting our understanding of the experiences of those who only briefly engaged with iConquerFear. The high post-module satisfaction ratings should be interpreted with caution, as ratings may not be representative of those who did not complete modules, possibly because they found them less acceptable. Group differences in outcomes after iConquerFear use should also be interpreted with caution given the high degree of variability in our small sample.

Finally, ovarian cancer survivors who took part in this trial were predominantly English-speaking, tertiary-level educated, and diagnosed with stage III ovarian cancer. Further exploration of the feasibility and impact of online self-guided FCR interventions in survivors from culturally and linguistically diverse backgrounds, with varied levels of technological literacy, and diagnosed with other types of advanced cancer is needed.

Conclusions

In its current form iConquerFear does not appear suitable for addressing FCR/FoP in ovarian cancer survivors. Findings indicated limited engagement, varied acceptability ratings, safety concerns, and inconclusive evidence regarding group differences in FCR and FoP after use. More tailored intervention, offered from diagnosis, supplemented by personal support may be needed for online interventions like iConquerFear to address the greater uncertainty and supportive care needs beyond FCR experienced by many ovarian cancer survivors.

Co-design with end-users is warranted to address the outstanding challenges and issues emerging from this study and inform further adaptation. Further research is also needed to better understand the specific nature of FCR experienced by ovarian cancer survivors to ensure therapeutic content of online interventions, like iConquerFear, are meeting their needs.

Abbreviations

DT	Distress Thermometer
FCR	fear of cancer recurrence
FCRI-SF	Fear of Cancer Recurrence Inventory– Short Form
FOP	fear of progression
FoP-Q-SF	Fear of Progression Questionnaire– Short Form
IEUQ	Internet Evaluation and Utility Questionnaire
OCA	Ovarian Cancer Australia
PHQ-9	Patient Health Questionnaire

Supplementary Information

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Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

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Author contributions

All authors (except for VSW, AnPa, OR, LL) contributed to study conception. All authors contributed to study design and material preparation. Data collection and analysis were performed by VSW, ABS, AnPa, and DC. All authors contributed to interpretation of the study results. The first draft of the manuscript was written by VSW, ABS and AnPa, and all authors reviewed and commented on manuscript drafts. All authors read and approved the final manuscript.

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Data availability

The datasets generated and analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Ethical approval was obtained from the University of New South Wales Ethics Committee (approval number: HC220186). Informed consent was obtained from all participants.

Consent for publication

Not applicable.

Competing interests

Allan 'Ben' Smith, Adeola Bamgboje-Ayodele, Lisa Beatty, Alison Pearce, Joanna Fardell, and Afaf Girgis hold a copyright licensed to Blue Note Therapeutics, Inc., for the ConquerFear and iConquerFear interventions. All other authors have no competing interests to declare.

Additional files

Additional file 1: Semi-structured interview schedule (Additional File 1.docx).
Additional file 2: Measures for exploratory outcomes (Additional File 2.docx).

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