

# **A guided internet-delivered psychosocial intervention for women treated for gynecological cancer: a randomized crossover waiting list controlled trial.**

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# A guided internet-delivered psychosocial intervention for women treated for gynecological cancer: a randomized crossover waiting list controlled trial.

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## Abstract

**Background:** The number of gynecological cancer survivors is increasing. Cancer survivors also live longer, often with long-term somatic and psychosocial late effects and challenges. Interventions to support adapting to life after illness, is thus paramount. One scalable method for including psychosocial interventions in the follow up for cancer survivors are guided internet-delivered interventions

**Objective:** The aim of this study was to evaluate the feasibility of a guided psychosocial internet-delivered intervention for women treated for gynecological cancer. This included the participants' evaluations of the program and the preliminary effects on quality of life and depression.

**Methods:** Method: The intervention was evaluated in a randomized crossover waiting list controlled trial. Results: Results: A total of 70 women was included in the trial. The findings show that the program was highly used, accepted and perceived as helpful on important psychosocial areas such as coping, emotional support, understanding and communication with others. Positive effects on quality of life were identified and significant, however, limited effects were noted on measures related to distress, quality of life and impact of cancer. Conclusions: Conclusion: This guided internet-delivered intervention was well-received and feasible for women following primary treatment for gynecological cancer. Positive, but limited effects on quality of life were identified. The intervention should be tested in a larger group of women and other questionnaires focusing on health literacy, self-efficacy and/or empowerment are suggested. Clinical Trial: ClinicalTrials.gov (9612)

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## Original Manuscript

A guided internet-delivered psychosocial intervention for women treated for gynecological cancer: a randomized crossover waiting list controlled trial.

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## Abstract

**Background:** The number of gynecological cancer survivors is increasing. Cancer survivors also live longer, often with long-term somatic and psychosocial late effects and challenges. Interventions to support adapting to life after illness, is thus paramount. One scalable method for including psychosocial interventions in the follow up for cancer survivors are guided internet-delivered interventions.

**Aim:** The aim of this study was to evaluate the feasibility of a guided psychosocial internet-delivered intervention for women treated for gynecological cancer. This included the participants' evaluations of the program and the preliminary effects on quality of life and depression.

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**Results:** A total of 70 women was included in the trial. The findings show that the program was highly used, accepted and perceived as helpful on important psychosocial areas such as coping, emotional support, understanding and communication with others. Positive effects on quality of life were identified and significant, however, limited effects were noted on measures related to distress, quality of life and impact of cancer.

**Conclusion:** This guided internet-delivered intervention was well-received and feasible for women following primary treatment for gynecological cancer. Positive, but limited effects on quality of life were identified. The intervention should be tested in a larger group of women and other questionnaires focusing on health literacy, self-efficacy and/or empowerment are suggested.

## Introduction

Cancer survivors report a multitude of late and long-term effects of the disease itself and of the associated treatment (Galica et al., 2022; Jeppesen et al., 2019; Sekse et al., 2019). In fact, most cancer survivors do not regain their former level of health, quality of life and functioning (Hewitt &

Ganz, 2006; Wu & Harden, 2015). As the survival rate and life expectancy of cancer patients is steadily increasing, late and long-term effects represents a major challenge in the lives of an ever-increasing number of people (Bray et al., 2018; Jemal et al., 2017). This holds also true for survivors of gynecological cancer, where commonly reported late and/or long-term effects include menopausal symptoms, intestinal and urinary tract problems, lymphedema, pain, altered appearance of the external genitalia, as well as challenges related to sexual health, womanhood, and fertility (Faller et al., 2017; Sekse et al., 2019; Seland et al., 2022; Thisted, Zoffmann, & Olesen, 2020).

For women suffering these late and long-term effects, surviving through treatment and going into remission is only the first step in a long and challenging road to recovery (Campbell et al., 2019; Kristoffersen et al., 2022). However, a recent review of the needs of gynecological cancer survivors reported that late and long-term effects are inadequately addressed through the existing care and treatment programs (Galica et al., 2022). More specifically, the patients reported unmet needs related to information about commonly cited long-term effects, psychosocial support, opportunities to talk about their worries and concerns, as well as help in planning and organizing their own recovery.

Addressing late and long-term effects, health related quality of life, patient satisfaction, and rehabilitation at an early stage after treatment has been suggested to improve long-term patient care (Beesley, Alemayehu, & Webb, 2019; Galica et al., 2022). Unfortunately, available rehabilitation options are often fragmented and unevenly available throughout the healthcare system, leaving patients themselves to research and ask for such rehabilitative care (de Rooij et al., 2018; Seland et al., 2022). This may be particularly difficult for survivors of gynecological cancer as these cancer types affect body parts related to sexuality and childbearing, which are often the subject of taboo and stigma.

There are promising findings for psychosocial intervention programs addressing the issues of late and long-term effects among gynecological cancer survivors. In a review focusing on the most promising intervention strategy to address quality of life (QoL), Hersch et al. (2009) concluded that

information alone seemed largely unable to provide meaningful benefits, while psychosocial interventions had some positive effects. Another systematic review by Chow et al. (2012) confirmed that interventions may improve patients' sexual functioning, reducing distress, anxiety and depression among the patient group. Furthermore, this review suggested an effective design to be theory-based, incorporating information provision, behavior therapy, and psychological support. In a randomized trial examining the effects of a psychosocial intervention, Olesen et al. (2016) found significantly higher physical well-being in the intervention group compared to controls. Taken together, psychosocial interventions targeting late and long-term effects among gynecological cancer survivors holds promising results.

Due to the needs described above and the scarce resources in the health care services combined with a widespread access to technology, there has been an increasing interest on the possibility of giving information and psychosocial follow up via internet-delivered interventions (see for instance Li et al., 2022; Slev et al., 2016; Triberti et al., 2019). Internet-delivered interventions focusing on psychoeducational, informational and psychosocial support for cancer survivors have yielded promising results so far (Buneviciene et al., 2021; Corbett et al., 2018; Escriva Bouley et al., 2018; Kim, Kim, & Mayer, 2017; Li et al., 2022; Marthick et al., 2021). In a review and meta-analysis of internet interventions for patients with cancer, Slev et al. (2016) showed positive effects on perceived support, knowledge, and information competence. However, this review showed an inconsistent effect on QoL and psychological well-being. Another review by Lin et al. (2020), on internet-delivered interventions designed especially for gynecological cancer survivors found effects on QoL measures, however, with inconclusive results related to effects on symptom distress, social support, psychological distress and sexual well-being. Given inconclusive findings regarding the effect of previously developed internet-delivered interventions for survivors of gynecological cancer, further developments are needed to arrive at a suitable intervention targeting these women's needs.

The main aim of the current study was to evaluate the feasibility, acceptability and

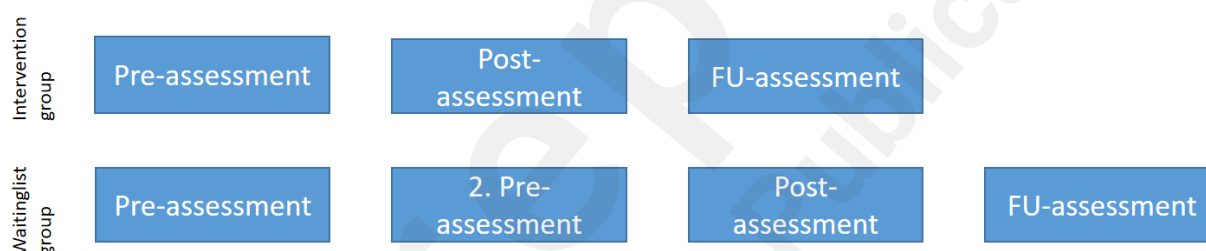
preliminary effect of a guided internet-delivered psychosocial intervention for women treated with curative intent for a gynecological cancer compared to a waiting-list control group.

## Methods

### *Study design*

The study was designed as a pilot two-arm RCT study comparing a treatment group to a waiting list control group followed by a cross-over design wherein waiting list controls were given the same treatment as the treatment group after a waiting list observation period equal to the duration of the treatment intervention. Group allocation was determined using an online randomization tool with no restrictions and by using numbered closed envelopes conducted by a person outside the studyteam. Figure 1 outlines the measurement timepoints of the two study groups:

Figure 1



### *Participants and procedure*

Participants were recruited to the study through advertisement on social media, dedicated websites, as well as print- and digital media. Additionally, posters and information pamphlets were distributed to cancer coordinators in local municipalities as well as local hospitals. Interested candidate participants were asked to fill out a brief contact-information form and were invited to complete a short telephone interview to assess their eligibility for participation. Participants were invited to participate in the study if they qualified for the following inclusion criteria: a) had completed primary treatment for gynaecological cancer between 6 weeks and fifteen months; ago b) were above 18 years of age; c) could read and speak Norwegian; d) had access to the internet. Potential participants were excluded if they qualified for any of the following exclusion criteria: a)

had a known cancer recurrence; b) had a present or previous history of severe mental health disorder (assessed with MINI); c) insufficient cognitive or Norwegian language skills; d) no curative intent of treatment.

The study was initially planned as an open feasibility study as a first step followed by a RCT. Due to delays and slow recruitment the study was re-defined as a pilot RCT three months into the inclusion period. From then all eligible participants were randomly assigned to either the treatment group or the waiting list control group by the last author using random.org. Participants with cancer recurrence throughout the intervention, were offered to complete the intervention, but were excluded from the analysis. A written consent to participate was obtained before the start of the study.

### *Intervention*

The intervention offered to participants in the current study was developed by a nurse together with a gynecologist, clinical psychologist, gestalt supervisors, Human Computer Interaction researchers, as well as five user representatives with former gynecological cancer (see Sekse et al., 2021 for a more detailed description of the intervention development).

The intervention consisted of six modules presented to participants over the course of six weeks with one module opening at each week of the treatment program. The six modules covered psycho-educational material concerning physical, psychological, social and existential changes and challenges after treatment, mindfulness exercises, focusing on being present and self-compassion. The content was among others presented through fictional character stories, and the full program was administered through an online portal. Patients also had weekly telephone consultations with an experienced nurse throughout the program.

### *Ethics*

The project was approved by The Regional Ethical Committee for Medical and Health Research Ethics (2019/491) and registered in ClinicalTrials.gov (9612). The study was conducted in line with all prevailing ethical and research regulations, providing the participants with oral and

written information, and obtain written consent before any study related activities started.

### *Security*

In order to ensure adequate data security, participants used 2-factor authentication to log in to the online portal where the intervention was administered, and data collection was conducted. The web-solution used for this study was developed by Youwell AS and had already been assessed and approved through a Risk and Vulnerability procedure at the University of Bergen.

### *Outcome measures*

For the purposes of the current study, three sets of measures were collected. Firstly, with respect to the first research question concerning the feasibility of the intervention, the number of participants who completed each module was collected from user-data in the online intervention platform. Secondly, with respect to the second research question concerning evaluation, patients were asked to rate the individual modules, as well as the intervention program as a whole, on items regarding their usefulness. For individual modules, evaluation scores were collected through a 2-item questionnaire at the end of each module. For the intervention program as a whole, a 13-item questionnaire was administered at the end of the full treatment program, 6 items concerning the satisfaction with the program and 7 items concerning the specific elements in the intervention (e.g., the use of case examples and exercises). Lastly, with respect to evaluating preliminary between- and within-group effects, a set of outcome measures were collected concerning quality of life, impact of cancer and depressive symptoms:

Quality of Life Scale - Cancer Survivor (QOL-CS). The QOL-CS is a 41-item self-report form assessing Quality of Life. Scores are grouped into four subscales: 1) Physical Wellbeing (8 items); 2) Psychological Wellbeing (18 items); 3) Social Wellbeing (8 items); and 4) Spiritual Wellbeing (7 items). A total score can also be calculated by averaging scores across all items. The QOL-CS has been found to have acceptable psychometric properties with adequate interrater reliability and internal consistency scores for both total and subscale scores (Ferrell, Hassey Dow, &

Grant, 1995). Cronbach's alpha estimated at baseline for the current sample was .93.

Impact of Cancer Version 2 (IOCv2). The IOCv2 is a 41 to 45-item self-report form assessing positive and negative consequences of cancer (the number of items varies based on individual answer profiles with certain items only being administered when applicable based on previous items). Scores are grouped into four positive (Awareness concerning own health; Positive self-evaluation; Altruism and empathy; Experienced meaning of cancer) and four negative (Worry; Concern over bodily changes; Concern over appearance changes; Impact on daily life) impact scales. The IOCv2 has been found to have acceptable psychometric properties with acceptable reliability and consistency scores for the four subscales (Crespi et al., 2008). Cronbach's alpha estimated at baseline for the current sample was .89.

Patient Health Questionnaire (PHQ-9). The PHQ-9 is a 9-item self-report form assessing symptoms of depression. Scores are added to generate a total score representing level of depression. In clinical practice scores are often grouped into four levels of severity ranging from mild (scores 5-9) to severe (scores 20-27). The PHQ-9 has been found to have acceptable psychometric properties with adequate internal consistency scores and predictive validity (Kroenke, Spitzer, & Williams, 2001). Cronbach's alpha estimated at baseline for the current sample was .76.

### *Analysis*

All analyses were conducted using STATA version 16. In order to evaluate feasibility and patient evaluation of the intervention, descriptive statistics of the compliance and evaluation data were examined at the level of the combined sample of participants who had completed the intervention. To evaluate preliminary efficacy and effect of the intervention, two separate arms of analysis were carried out:

Firstly, the relative effect of the intervention as compared to waiting list controls, the pre-crossover between-groups samples were analyzed. Linear mixed models were estimated to examine and compare fixed effects of treatment between groups. Separate random intercept fixed slope

models were estimated for each outcome measure. Differences in treatment effects over time between the intervention group and waiting list controls were represented by a Group (0 = waiting list controls, 1 = intervention group) x Time (0 = pretreatment, 1 = posttreatment) interaction effect. Data for all participants were included in the analysis regardless of adherence in accordance with an intention to treat approach, assuming missing at random. Effect sizes were calculated based on estimated values following the recommended calculation (dppc2) for randomized controlled trials

with repeated measures by Morris (2008):

$$d_{ppc2} = C_p \left[ \frac{(M_{post_t} - M_{pre_t}) - (M_{post_c} - M_{pre_c})}{\sqrt{\frac{(nt-1)SD_{pre_t}^2 + (nc-1)SD_{pre_c}^2}{nt+nc-2}}} \right]$$

Secondly, the treatment effect of the intervention for all participants was analyzed. Here, we examined within-subjects change across repeated measures across pre-treatment, post-treatment and three months follow-up. Separate random intercept fixed slope mixed linear models were estimated for each outcome measure. Treatment effect was represented by two dummy variables capturing pre-treatment to post-treatment change (0 = pretreatment, 2 = posttreatment) and post-treatment to follow-up change (0 = post-treatment, 1 = follow-up). Data for all participants were included in the analysis regardless of treatment adherence in accordance with an intention to treat approach, assuming missing at random. Effect sizes were calculated based on estimated values for both

baseline-to-post treatment change: ( $d = \frac{M_{baseline} - M_{follow\ up}}{SD_{baseline}}$ ) and post-treatment-to-follow up change: ( $d = \frac{M_{post} - M_{follow\ up}}{SD_{post}}$ )

$$d = \frac{M_{post} - M_{follow\ up}}{SD_{post}}$$

## Results

A total of 70 patients were recruited between May 2020 until September 2022. The first 10

participants were included as part of an open design, and consequently not randomized and started the intervention group. The following 60 included participants were randomly assigned to either the treatment group ( $n = 30$ ) or waiting list control group ( $n = 30$ ).

#### *Adherence, missing data and dropout*

Missing data was found to generally represent dropout from the study with 85% of instances of missing data representing a participant dropping out of the study. Across timepoints, the rate of missing for the combined sample was seen to increase from 0% at pre-screening, 20% at post treatment and 37% at follow up. In general, the rate of dropout was largest in the waiting list control group with a total of 14 participants (47%) dropping out before completing follow-up assessment. Comparatively, for the treatment group, 8 participants (20%) dropped out before completing follow-up assessment with three of these participants dropping out of the study before enrolling in the treatment program. Retention was good for the control group during the waiting list period with only one control group participant dropping out of the study during the 6-week waiting list period. Similarly, retention was fairly good from post to follow-up, with the majority of participants who dropped out of the study (63% for the intervention group and 57% for the waiting list control group) dropping out sometime between the first screening and the post intervention screening. A significant difference was seen in the number of dropouts between the intervention group and waiting list controls ( $p = .02$ ,  $\chi^2 = 5.66$ ). The difference in the number of dropouts between the two groups were greater at follow-up (6 versus 3) than at posttreatment (7 versus 5). Some systematic tendencies could be observed for missing data/dropout (e.g., between groups differences in missing/dropout, differences in missing/dropout between timepoints in the study and tendencies for missing data to indicate dropout. Comparing baseline measures between participants who had/did not have instances of missing data across measurements did not reveal significant differences on baseline measures of included outcomes, however. Planned linear mixed model analyses were therefore carried out in accordance with an assumption of missing at random.

### Descriptive statistics

In the combined sample ( $N = 70$ ) the mean age was 48.55 ( $SD = 11.39$ ). The vast majority of participants had a partner (62/70, 88.6%), had completed some kind of higher education (50/70, 71.4%), and had children (63/70, 90.0%). The intervention group and waiting list controls did not differ significantly in age ( $t = 0.73$ ,  $p = .47$ ), the number of participants who had a higher education ( $\chi^2 = 0.58$ ,  $p = .45$ ), or the number of participants who had a partner ( $\chi^2 = 0.19$ ,  $p = .66$ ). A larger number of participants in the intervention group had children compared to the control group ( $\chi^2 = 4.38$ ,  $p = .04$ ). Table 1 summarizes descriptive statistics across groups.

Table 1

#### Demographic variables by group

|                      | Intervention Group | Waiting list Control Group | Baseline comparison<br>t / $\chi^2$ p |     |
|----------------------|--------------------|----------------------------|---------------------------------------|-----|
| Age (mean, SD)       | 49.43 (11.38)      | 46.4 (11.49)               | 0.73                                  | .47 |
| Higher Education (%) | 75%                | 67%                        | 0.58                                  | .45 |
| Having a Partner (%) | 90%                | 87%                        | 0.19                                  | .66 |
| Having Children (%)  | 85%                | 63%                        | 4.38                                  | .04 |

*Note.* An independent samples t-test was done for Age. For the remaining three variables, a  $\chi^2$  test of independence was conducted.

### Feasibility

Participant retention across treatment modules was high with most participants (93.85%) completing all five treatment modules once enrolled in the treatment program.

Table 2

#### Number of participants who completed each treatment module, $N = 70$

|                       | Module 1 | Module 2 | Module 3 | Module 4 | Module 5 |
|-----------------------|----------|----------|----------|----------|----------|
| Treatment Group       | 37       | 36       | 37       | 37       | 36       |
| Waiting list controls | 28       | 27       | 26       | 25       | 25       |
| Total                 | 65       | 63       | 63       | 62       | 61       |

*Note.* Module 1 = Everyday life after illness, Module 2 = A changed female body, Module 3 = Sexual health,

Module 4 = Fatigue, Module 5 = Fear of recurrence.

### *Acceptability*

In general, participants reported a high level of acceptability with the treatment modules and with the treatment program as a whole. Table 3 outlines evaluation scores for each treatment module. As can be seen from this table, participants consistently reported each module to be highly useful (Mean rating across modules = 7.4 out of 10.0). Module 5 received the highest mean score for this item at 8.2 out of 10.0, while Module 3 received the lowest mean score at 6.5 out of 10.0. High evaluation scores were also seen for the question of whether participants would recommend the module to a friend. Here, the average rating across modules was 8.1 out of 10.0. Module 4 was rated the highest, with a mean score of 8.6 out of 10.0, while Module 3 was again rated the lowest, with a mean score of 7.5.

Table 3  
*Evaluation per module, N = 70*

| Question – M (SD)                                           | Module 1  | Module 2  | Module 3  | Module 4   | Module 5   |
|-------------------------------------------------------------|-----------|-----------|-----------|------------|------------|
| How useful was this module for you?                         | 7.6 (1.7) | 7.1 (2.2) | 6.5 (2.2) | 7.7 (2.0)  | 8.2 (1.8)  |
| To what degree would you recommend this module to a friend? | 8.2 (2.0) | 7.6 (2.4) | 7.5 (2.2) | 8.55 (1.8) | 8.51 (2.0) |

*Note.* The questions were rated on a scale of 1 to 10, with higher scores indicating a greater level of satisfaction. Scores are displayed as Mean (Standard Deviation). Module 1 = Everyday life after illness, Module 2 = A changed female body, Module 3 = Sexual health, Module 4 = Fatigue, Module 5 = Fear of recurrence.

As for the evaluation of the program as a whole, participants consistently rated the program highly on 5-point scale for questions concerning satisfaction, with an average rating across items of 4.3 out of 5. The highest mean rating was observed for understandability, where the mean rating was 4.9, while the item concerning whether the program had helped participants find solutions to their problems received the lowest mean rating of 4 out of 5. Table 4 summarizes mean scores across all six items.

Table 4

*Evaluation of the program as a whole*

| Question                                                                                                                  | Rating M (SD) |
|---------------------------------------------------------------------------------------------------------------------------|---------------|
| The content in the modules was easy to understand                                                                         | 4.88 (0.44)   |
| The program has given me what I needed to handle changes to my everyday life                                              | 4.16 (0.82)   |
| The program has supported me in coping with the emotional reaction to what I've been through                              | 4.28 (0.83)   |
| The program has contributed to an increased understanding of the bodily changes brought about by my disease and treatment | 4.56 (0.73)   |
| The intervention content may be usefull to access for a partner, family member or friend.                                 | 4.18 (0.96)   |
| The program has helped me find solutions to my problems                                                                   | 4.00 (0.83)   |

*Note.* All questions were rated on a scale of 1 (worst) to 5 (best). Scores are displayed as Mean (Standard Deviation).

Lastly, ratings of specific intervention elements were also consistently high with an average rating across elements of 4.31 out of 5. The highest mean rating was observed for the weekly telephone guidance with an experienced nurse (4.68) while the lowest mean rating was observed for the use of pictures as a form of expression (3.88). Table 5 summarizes mean scores across all 7 items.

Table 5

*Evaluation of intervention elements*

| Question                                                      | Rating M (SD) |
|---------------------------------------------------------------|---------------|
| Accessing the intervention digitally                          | 4.26 (1.05)   |
| Reading text about different topics                           | 4.56 (0.71)   |
| Completing tasks                                              | 4.14 (0.9)    |
| Completing exercises                                          | 4.10 (0.97)   |
| Reading about the experiences of the three fictive characters | 4.54 (0.89)   |
| The use of pictures as a form of expression                   | 3.88 (1.04)   |
| Weekly telephone guidance by an oncology nurse                | 4.68 (0.71)   |

*Note.* All questions were answered on a scale of 1 - 5 with greater scores indicating greater satisfaction. Scores are displayed as Mean (Standard Deviation)

*Between-groups treatment effects*

Linear mixed models comparing between group effects of treatment between the treatment group (n = 40) and waiting list controls (n = 30) found significant between group differences in intervention effect for only the Physical Quality of Life subscale of the QoL (Table 6). For the remaining outcome measures there were no significant between group differences in treatment effect.

Table 6

*Fixed effect estimates from intention-to-treat linear mixed model analyses*

| Measure                  |              | T1<br>M (SD) | T2<br>M (SD) | Time<br>b p |      | Group * Time<br>b p |       | Effect<br>Size<br>d <sub>b</sub> |
|--------------------------|--------------|--------------|--------------|-------------|------|---------------------|-------|----------------------------------|
| PHQ-9                    | Control      | 9.80 (4.99)  | 9.9 (4.56)   | -.085       | .893 | -.735               | .377  | -0.15                            |
|                          | Intervention | 10.25 (4.49) | 9.3 (5.1)    |             |      |                     |       |                                  |
| QOL Total                | Control      | 5.34 (1.33)  | 5.4 (1.33)   | .102        | .324 | .073                | .600  | 0.06                             |
|                          | Intervention | 5.72 (1.10)  | 5.9 (1.32)   |             |      |                     |       |                                  |
| QOL Physical             | Control      | 6.25 (1.78)  | 6.0 (1.81)   | -.166       | .325 | .543                | .018* | 0.32                             |
|                          | Intervention | 6.5 (1.61)   | 7.0 (1.62)   |             |      |                     |       |                                  |
| QOL Psychological        | Control      | 5.01 (1.44)  | 5.1 (1.47)   | .118        | .360 | .044                | .796  | 0.03                             |
|                          | Intervention | 5.39 (1.22)  | 5.5 (1.51)   |             |      |                     |       |                                  |
| QOL Social               | Control      | 5.17 (1.82)  | 5.4 (1.61)   | .313        | .062 | -.018               | .934  | -0.01                            |
|                          | Intervention | 5.67 (1.46)  | 5.9 (1.61)   |             |      |                     |       |                                  |
| QOL Spiritual            | Control      | 5.55 (0.98)  | 5.5 (1.03)   | -.006       | .959 | -.079               | .621  | -0.08                            |
|                          | Intervention | 5.96 (0.94)  | 5.8 (0.97)   |             |      |                     |       |                                  |
| IOC Positive Total       | Control      | 3.33 (0.59)  | 3.3 (0.65)   | -.007       | .906 | .092                | .278  | 0.17                             |
|                          | Intervention | 3.31 (0.51)  | 3.4 (0.52)   |             |      |                     |       |                                  |
| IOC Health Awareness     | Control      | 4.19 (0.7)   | 4.1 (0.74)   | -.096       | .205 | .084                | .404  | 0.13                             |
|                          | Intervention | 4.13 (0.63)  | 4.1 (0.63)   |             |      |                     |       |                                  |
| IOC Self Evaluation      | Control      | 3.48 (0.73)  | 3.4 (0.87)   | -.014       | .906 | .074                | .626  | 0.1                              |
|                          | Intervention | 3.34 (0.74)  | 3.4 (0.75)   |             |      |                     |       |                                  |
| IOC Altruism and Empathy | Control      | 3.34 (0.82)  | 3.4 (0.83)   | .045        | .587 | -.055               | .613  | -0.08                            |
|                          | Intervention | 3.53 (0.64)  | 3.4 (0.64)   |             |      |                     |       |                                  |
| IOC Cancer Meaning       | Control      | 2.49 (0.68)  | 2.5 (0.8)    | .041        | .695 | .212                | .128  | 0.29                             |
|                          | Intervention |              |              |             |      |                     |       |                                  |

|                                |              |                 |            |            |      |      |       |      |       |
|--------------------------------|--------------|-----------------|------------|------------|------|------|-------|------|-------|
| IOC Negative Total             | Intervention | (0.75<br>2.44 ) | 2.7<br>3 ) | (0.89<br>) |      |      |       |      |       |
|                                | Control      | (0.51<br>3.57 ) | 3.6<br>5 ) | (0.54<br>) | .082 | .185 | -.129 | .122 | -0.2  |
| IOC Worry                      | Intervention | (0.69<br>3.4 )  | 3.3<br>5 ) | (0.78<br>) |      |      |       |      |       |
|                                | Control      | (0.65<br>3.81 ) | 3.8<br>6 ) | (0.75<br>) | .074 | .433 | -.077 | .534 | -0.11 |
| IOC Body Change Concerns       | Intervention | (0.70<br>3.62 ) | 3.6<br>4 ) | (0.83<br>) |      |      |       |      |       |
|                                | Control      | (0.87<br>3.77 ) | 3.8<br>3 ) | (0.83<br>) | .05  | .681 | -.305 | .061 | -0.34 |
| IOC Appearance Change Concerns | Intervention | (0.88<br>3.77 ) | 3.4<br>9 ) | (1.03<br>) |      |      |       |      |       |
|                                | Control      | (1.03<br>3.12 ) | 3.3<br>2 ) | (1.11<br>) | .188 | .118 | -.221 | .168 | -0.21 |
| IOC Life Interference          | Intervention | (1.08<br>3.03 ) | 2.9<br>8 ) | (1.04<br>) |      |      |       |      |       |
|                                | Control      | (0.73<br>3.44 ) | 3.5<br>1 ) | (0.72<br>) | .079 | .364 | -.102 | .380 | -0.12 |
|                                | Intervention | (0.93<br>3.17 ) | 3.1<br>6 ) | (1.10<br>) |      |      |       |      |       |

Note.

\* = significant within-group change compared with baseline ( $p < 0.05$ ).  $b$  = regression coefficient,  $d_b$  = Between group Cohen's  $d$ .

### Within-subjects treatment effect

Table 7 summarizes the findings of the combined cross-over within-subjects analyses. As can be seen from this table, significant change was observed for only three of the 15 included outcome measures. Participants showed small (Cohen's  $d < 0.5$ ) but significant ( $p < .05$ ) change from pre to post in their QOL total scores ( $p = .046$ ,  $d = 0.14$ ), QOL Physical Quality of Life subscale scores ( $p = .002$ ,  $d = 0.22$ ) and the IOC Cancer Meaning subscale scores ( $p = .041$ ,  $d = 0.21$ ). There were no significant changes on any outcome variables from post to follow up.

Table 7

Combined sample pre - post and post - follow up change

|                               | T1<br>M (SD) | T2<br>M (SD) | T3<br>M (SD) | Pre - Post |       |       | Post - FU |       |       |
|-------------------------------|--------------|--------------|--------------|------------|-------|-------|-----------|-------|-------|
|                               |              |              |              | p          | b     | d     | p         | b     | d     |
| PHQ-9                         | 10.12 (4.49) | 9.38 (4.79)  | 9.76 (5.47)  | .163       | -.685 | -0.15 | .27       | .591  | 0.11  |
| QOL Total                     | 5.6 (1.20)   | 5.79 (1.28)  | 5.83 (1.19)  | .046*      | .168  | 0.14  | .33       | -.086 | -0.07 |
| QOL Physical                  | 6.33 (1.69)  | 6.77 (1.75)  | 6.82 (1.49)  | .002*      | .38   | 0.22  | .34       | -.122 | -0.07 |
| QOL Psychological             | 5.28 (1.33)  | 5.40 (1.43)  | 5.57 (1.34)  | .212       | .131  | 0.10  | .73       | .038  | 0.03  |
| QOL Social                    | 5.59 (1.51)  | 5.84 (1.49)  | 5.68 (1.59)  | .073       | .257  | 0.17  | .08       | -.269 | -0.16 |
| QOL Spiritual                 | 5.81 (0.99)  | 5.8 (1.08)   | 5.69 (1.11)  | .450       | -.074 | -0.08 | .10       | -.172 | -0.15 |
| IOC Positive Total            | 3.32 (0.56)  | 3.39 (0.55)  | 3.32 (0.57)  | .127       | .07   | 0.12  | .50       | -.034 | -0.06 |
| IOC Health Awareness          | 4.13 (0.67)  | 4.12 (0.59)  | 4.04 (0.73)  | .749       | .021  | 0.03  | .56       | -.042 | -0.06 |
| IOC Self Evaluation           | 3.38 (0.79)  | 3.53 (0.81)  | 3.41 (0.85)  | .257       | .096  | 0.12  | .38       | -.08  | -0.09 |
| IOC Altruism and Empathy      | 3.49 (0.72)  | 3.41 (0.73)  | 3.50 (0.81)  | .717       | -.025 | -0.03 | .22       | .09   | 0.12  |
| IOC Cancer Meaning            | 2.48 (0.77)  | 2.66 (0.86)  | 2.52 (0.78)  | .041*      | .164  | 0.21  | .26       | -.097 | -0.11 |
| IOC Negative Total            | 3.5 (0.64)   | 3.41 (0.71)  | 3.44 (0.77)  | .070       | -.09  | -0.14 | .19       | .07   | 0.10  |
| IOC Worry                     | 3.72 (0.73)  | 3.7 (0.78)   | 3.7 (0.74)   | .601       | .038  | -0.05 | .71       | .029  | 0.04  |
| IOC Body Change Concerns      | 3.79 (0.85)  | 3.64 (0.96)  | 3.72 (1.01)  | .088       | -.129 | -0.15 | .46       | .060  | 0.06  |
| IOC Apparance Change Concerns | 3.15 (1.09)  | 3.02 (1.14)  | 3.16 (1.24)  | .234       | -.109 | -0.10 | .11       | .158  | 0.13  |
| IOC Life Interference         | 3.32 (0.86)  | 3.18 (0.93)  | 3.2 (0.94)   | .114       | -.115 | -0.13 | .35       | .073  | 0.08  |

Note. N = 70. M = Mean. SD = Standard Deviation

\* = significant within-group change compared with baseline ( $p \leq .05$ ). b = regression coefficient (beta).

$d_w$  = Within group Cohen's d. FU = Follow Up.

## Discussion

The aim of this study was to evaluate the feasibility, acceptability, and effect of a novel internet-delivered guided psychosocial intervention for women treated for gynecological cancer. Overall, the adherence rate was high as 94% of the sample completed all modules. Moreover, the intervention was rated by participants as being highly acceptable and useful across a range of psychosocial factors (e.g., helping them understand and handle challenges in everyday life, supporting them in coping with emotional reactions and for aiding in communicating with others). Also, participants reported a high level of satisfaction with the intervention (a mean of 4.34 on a 5 point Likert scale). These findings are in line with a qualitative study from the same trial, elaborated in another publication (Breistig et al., 2023), where in-depth interviews were carried out with 20 of the women in this sample. These findings are also in line with previous research showing that the perceived support and increased knowledge are positively rated after receiving psychosocial programs for cancer survivors (Slev et al., 2016).

This study found limited between group effects on measures of quality of life, impact on cancer and depression. One exception was a small but positive between -group effect on physical quality of life in favor of the intervention group. Moreover, for the total sample, the within-group effects also showed small but positive outcomes on overall quality of life, physical quality of life, and the impact of cancer on meaning. This is in line with the recent review by Lin et al., (2020) examining psychosocial support after gynecological cancer where it was reported that psychosocial support after gynecological cancer has positive effects on quality of life. However, there were small and limited effects in the current study, a finding in line with the review from Slev et al., (2016) who reported inconsistent effect on quality of life after receiving psychosocial support after cancer.

In the current study no effects on depressive symptoms were identified. This is in line with the reviews by Slev et al., (2016) and Lin., (2020) who reported inconsistent findings on the effects on psychological well-being and psychological distress after receiving psychosocial treatment after

gynecological cancer.

In sum, our findings suggest that the program was highly used, accepted, and perceived as helpful on important psychosocial areas such as coping, emotional support, understanding, and communication with others, but the effects of the standardized measures of distress, quality of life and impact of cancer were limited.

The results from this study may be seen as a contradictory and may be discussed from at least three different perspectives. First, the findings may be understood as a result of the program being primarily educational with less emphasis on evidence-based therapeutic techniques such as behavioral activation, exposure to intrusive thoughts or addressing avoidant behavior. This is also confirmed in the qualitative study by Breistig et al (2023), where the findings show that it is health literacy as well as support for the changed situation after cancer that are decisive for the benefits of the program. Second, the results may be explained by the fact that the inclusion criteria were limited to being diagnosed and treated for gynecological cancer, and not reported distress, psychological complaints or reduced quality of life. Finally, this contradiction in our results may be explained by the selection of outcome measures being little sensitive to change or less relevant to this user-group. Similarly, it may be that participants experienced changes across areas not sufficiently captured by the measures included in the current study. This assumption is at least partially supported by the high levels of satisfaction reported for the intervention, as well as by the qualitative interview study by Breistig et al. (2023).

In sum, the findings suggest that the program was highly used, accepted and perceived as helpful on important psychosocial areas such as coping, emotional support, understanding and communication with others. Although positive effects on quality of life were identified, the effect of the intervention across standardized assessment instruments was very limited.

Future research should examine other outcome measures relevant to late-effects in this patients group and examine which areas of outcome patients themselves consider most relevant to

their own well-being. As it is possible that the measures used in the current study did not tap into the main areas of improvement experienced by participants, exploring questionnaires that focus on health literacy, self-efficacy and/or empowerment would be beneficial in future studies. It would also be useful to compare the feasibility, satisfaction and effect between those who has elevated levels of distress or psychological complaints and those who not, and thereby understand what works for whom in this large group of cancer survivors.

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