Published in final edited form as:

Gynecol Oncol. 2017 February ; 144(2): 354–362. doi:10.1016/j.ygyno.2016.11.025.

A Comparison of Two Psychological Interventions for Newly-diagnosed Gynecological Cancer Patients

Sharon L. Manne^a, Shannon Myers Virtue^a, Melissa Ozga^b, Deborah Kashy^c, Carolyn Heckman^d, David Kissane^e, Norman Rosenblum^f, Mark Morgan^g, and Lorna Rodriguez^a

^aRutgers Cancer Institute of New Jersey, 195 Little Albany Street, New Brunswick, NJ, 08903, USA

^bMemorial Sloan Kettering Cancer Center, 1275 York Avenue, New York, NY, 10065, USA

^cMichigan State University, Department of Psychology, 316 Physics Rm 262, East Lansing, MI, 48824, USA

^dFox Chase Cancer Center, 333 Cottman Avenue, Philadelphia, PA, 19111, USA

^eMonash University, Department of Psychiatry, Wellington Rd & Blackburn Rd, Clayton VIC 380, AU

^fThomas Jefferson University, 925 Chestnut Street, Philadelphia, PA, 19107, USA

^gUniversity of Pennsylvania, 800 Walnut Street, Philadelphia, PA, 19107, USA

Cancers of the female reproductive organs (cervical, endometrial, ovarian, or uterine) are the fourth most common in American women [1]. Due to vague symptoms and a lack of routine screening for gynecological cancers other than cervical, up to 80% are diagnosed late and thus have a poor prognosis. Treatment typically involves surgery followed by chemotherapy, which can have debilitating side effects, and the risk for recurrent disease is high. Given the difficult treatment course and poor prognosis for many women with a gynecological cancer diagnosis, it is not surprising that rates of psychological distress are high. Between 30% and 42% of women with gynecological cancer report moderate to severe anxiety [2,3] and up to one third report moderate to severe levels of depressive symptoms [2, 4-6]. Post-treatment studies indicate that between 22% and 27% report elevated anxiety and between 6% and 13% report elevated depression [3,7].

Despite this significant psychosocial morbidity, studies of psychological interventions have shown inconsistent results. Some trials have illustrated significant short-term reductions in distress [8-12] or improvements in physical well-being [13], while others have not [14,15].

Corresponding Author: Sharon Manne, 195 Little Albany Street, New Brunswick, New Jersey, 08903, USA. Phone: (732) 235-6759, Fax: (732) 235-6805; Sharon.Manne@rutgers.edu, myerssb@cinj.rutgers.edu, ozgam@mskcc.org, kashyd@msu.edu, carolyn.heckman@fccc.edu, david.kissane@monash.edu

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

Conflict of Interest

The authors declare no conflicts of interest.

In our prior work [16], we developed and evaluated the efficacy of two interventions: a coping and communication-enhancing intervention (CCI) and a supportive counseling intervention (SC) and tested them against Usual Care (UC) in a large randomized clinical trial of 353 women. The goal of CCI, which was based on cognitive-affective-social processing theory [17], was to facilitate coping with the distressing thoughts and feelings associated with cancer, as well as to help patients vent their emotions and obtain support from family and friends. The goal of SC was to enhance adaptation by encouraging emotional expression, supporting existing coping behaviors, and enhancing self-esteem and autonomy. There is evidence that supportive counseling is an effective intervention for some psychological issues [18] and that SC is an effective intervention to reduce distress among individuals dealing with chronic illness [19]. In our prior work, both CCI and SC. Both CCI and SC reduced patient depressive symptoms when compared with UC [16]. SC had a stronger effect on depressive symptoms among patients who pre-intervention reported higher positive emotional expressivity and whose physicians reported greater patient physical disability over the next 9-months. Neither intervention impacted cancer-specific distress. In the current study, we extended our work in four ways. First, to better impact distress, we bolstered CCI by adding an additional session focused on improved coping with fears of recurrence and disease progression. We bolstered SC by training therapists to facilitate expression of emotional reactions and understanding them. Second, we examined more comprehensively the impact of the interventions by including a mid-treatment assessment and two longer-term follow ups at 12 and 18 months post-baseline. Few studies have followed participants for more than three months. Third, we evaluated whether CCI and SC had an effect on two additional outcomes: emotional quality of life and concerns about disease recurrence. Finally, we examined one novel moderator of the intervention's effects: baseline levels of depression.

The present study compared CCI and SCI with a usual care control (UC). We predicted that both CCI and SC would have greater impact than UC, but that CCI would have greater short- and long-term positive effects than SC, because of its focus on teaching skills to manage disease-specific stressors. Based on other work suggesting that distressed patients benefit more from psychological interventions [20, 21], we proposed that women with higher depression before intervention would benefit more from both CCI and SC. We also included moderators evaluated in our prior work: age, baseline metastatic status, baseline self-reported physical symptoms, and baseline dispositional emotional expressivity [16].

Method

Participants

The inclusion criteria were: 1) > 18 years; 2) recruitment within six months of diagnosis with gynecological cancer; 3) a Karnofsky Performance Status of > 80 or an Eastern Cooperative Oncology Group (ECOG) score of 0 or 1; 4) lived within a two-hour commuting distance from recruitment center; 5) English speaking; and 6) no hearing impairment.

Procedures

Research assistants identified and mailed an introductory letter to eligible women before contacting them in-person or by phone to explain the study. Interested women signed an informed consent approved by the Institutional Review Board at each site. Participants completed a baseline survey and were randomly assigned to CCI, SC or UC. To insure that the distribution of depressed participants was balanced across study groups, randomization was stratified by baseline Beck Depression Inventory score (BDI) [22]. The cutoff was selected based on Beck and Beamsderfer [23]: moderate to severe depressive symptoms were defined as > 19 versus a score < 19 . Blinding to study condition was not possible. Participants completed surveys at six time points (T1-T6) over the course of 18 months: T1= baseline, T2 = 5 weeks after baseline, T3 = 9 weeks, T4 = 6 months, T5 = 12 months, and T6 = 18 months. All participants were paid an incremental amount for completing each survey (\$15 for T1, \$20 for T2, \$25 for T3, \$30 for T4, \$35 for T5, \$40 for T6). Participants randomized to CCI or SC were paid incrementally for session attendance (Session 1 -\$15, Session 2-\$20, Session 3-\$25, Session 4-\$30, Session 5-\$35, Session 6/7/8-\$45). This study took place at five comprehensive cancer centers located in the Northeastern US and two community hospitals in New Jersey.

As shown in Figure 1, 1147 women were approached. Of these, 352 consented and completed a baseline survey (30.7%). Of these, 118 were assigned to CCI, 118 to SC, and 116 to UC. The most common for refusal were: too ill to participate (8.1%), insufficient time (9.4%), or not needing help (9.5%). Comparisons were made between participants and refusers on available data (i.e., age, ethnicity, type of cancer, stage, ECOG performance status, time since diagnosis). Study participants were significantly younger ($M_{\text{participants}} = 55.2$, $SD = 10.3$, $M_{\text{refusers}} = 60.1$, $SD = 12.1$, $t(1140) = 7.1$, $p < .001$), diagnosed a shorter period of time ($M_{\text{participants}} = 4.9$ months, $SD = 2.6$, $M_{\text{refusers}} = 6.2$ months, $SD = 2.6$), $t(1140) = 7.4$, $p < .001$), and more likely to be diagnosed with non-ovarian gynecological cancer ($M_{\text{participants}} = 31.6\%$, $M_{\text{non-participants}} = 24\%$, Chi-square = 8.8, $p < .01$). There were no differences in ethnicity (Caucasian vs. non-Caucasian), disease stage, or ECOG status.

Of the 352 participants, 324 completed T2 follow-up (92%), 312 completed T3 (88.6%), 307 completed T4 (87%), 284 completed T5 (80.7%), and 266 completed T6 (75.6%). By 18 months, 26 participants had died (7.3%). There were significant differences in survey completion rates at T3, with a lower return rate among participants in CCI (83.1%) compared with the other two conditions (90% SC, 93.1% UC) (Chi-square (2) = 6.1, $p < .05$). Figure 1 shows the study CONSORT.

Analyses comparing participants who completed all surveys with participants who dropped after completing T1-T6 surveys on baseline demographic, medical, and psychological variables did not indicate significant differences.

Intervention Conditions

CCI consisted of seven hour-long individual weekly sessions and one telephone booster session two to three weeks after session seven. Sessions were held in the oncology offices at the study site. Session content focused on enhancing coping and support-solicitation skills,

self-care, evaluating and altering life priorities, managing fear of recurrence, and identifying and dealing with emotional reactions to cancer. Sessions contained didactic content, in-session skill practice, and home practice assignments. For a detailed description of session content, please see Table 3. SC also involved seven hourly individual weekly sessions and a phone booster session two to three weeks after session seven. Sessions were also held at each sites' oncology offices. Treatment components were drawn from published manuals [24, 25]. The goal of SC was to enhance adaptation by encouraging emotional expression, facilitating an understanding of emotional reactions, supporting strengths, and enhancing self-esteem. SC used restatement, reflection, emotional exploration, empathy, reassurance, and validation. The therapist was active, but non-directive, non-interpretive, and skills were not taught. Themes and goals of treatment were formulated and reviewed each session. The SC manual is available from the study's first author (SLM).

UC participants received standard psychosocial care, which was equivalent at all sites. Social Work consultations were routinely provided for all women. If indicated, a referral to a psychiatrist or psychologist was provided by physicians.

Interventionists

Fifty-nine therapists contributed, but CCI and SC were delivered by different teams of clinicians. Therapists comprised social workers, master-level or doctoral-level psychologists, or psychiatrists who were practicing in the community or employees of each cancer center. They had between one and 34 years of therapy experience. Each therapist underwent six hours of training in the manual-based CCI or SC interventions. To facilitate treatment fidelity, all sessions were audiotaped and treatment fidelity was rated by the supervisor on all sessions. The CCI manual was structured with in-session exercises and participant handouts. The SC manual included readings on supportive counseling (e.g., [24]) and a set of rules regarding what was permitted (e.g., reflection, validation) and what was prohibited (e.g., coping skills, didactic presentations). Telephone-delivered individual supervision was provided for each session and consisted of review of treatment integrity scores, fidelity issues, and a discussion of the upcoming session.

Outcome Measures

Beck Depression Inventory [22]—The BDI is a 21-item measure of depressive symptoms which has been widely used in oncology (scale range, 0 -63). Cronbach's alphas ranged from .82 to .89, from Time 1-6.

Cancer-related distress – The Impact of Events Scale—(IES) [26]. The IES is a 15-item measure focusing on intrusive and avoidant ideation associated with a stressor, namely gynecological cancer and its treatment (scale range = 0-75). Cronbach's alphas were .89 to .91 from Time 1 -6.

Quality of Life- Emotional Functioning [27]—This is a 6-item subscale of the Functional Assessment of Cancer Therapy – Emotional Functioning (FACT-G). The FACT-G is widely used in oncology [27]. Cronbach's alphas were .81 to .87 from Time 1 -6.

Fear of Recurrence/Progression [28]—This 4-item subscale of the Concerns about Recurrence Scale measures the extent and nature of fear of recurrence, adapted here for gynecological cancer. Cronbach's alphas ranged from .91 to .94 from Time 1 to 6.

Moderators

Positive Emotional Expressivity [29]—At T1, expression of positive emotions was measured by this 7-item subscale of the Emotional Expressiveness Questionnaire. Cronbach's alpha was .72.

Self-reported Physical Symptoms [30]—At T1, the 26-item functional status subscale of the Cancer Rehabilitation Evaluation System (CARES) was used to assess physical symptoms (scale range, 0-104). Cronbach's alpha was .93.

Treatment evaluation and fidelity [31]—The treatment evaluation was a 20-item scale was administered after the last session (scale range = 20-99) and assessed perceptions of intervention success, helpfulness, convenience, educational relevance, interest, and appropriateness. Treatment fidelity was assessed by research assistants who were trained in monitoring fidelity for either the CCI or SC intervention. Details about fidelity monitoring are in the supplemental materials.

Data Analytic Approach

Multilevel modeling (MLM) using SPSS version 22 was used to examine whether there were significant differences between the CCI, SC, and UC groups over time. This approach yields main effects for intervention and time, and an interaction between time and intervention. In our primary analysis, both time and intervention were treated as categorical and covariates included were five effect-coded variables representing ethnicity (White-not Hispanic/others), marital status (married/not married), education (College degree or more/less than a college degree), whether the patient had metastatic cancer (yes/no), and whether the patient died sometime during the study (yes/no). Grand mean centered age, cancer stage at baseline, and time since diagnosis at baseline were also included as covariates in the models. The random components of the models included a random intercept which measured variation in average outcomes across participants, a random linear slope for change over time which measured the extent to which participants varied in their linear change across the study, and a residual. There was significant evidence of intercept and slope variance for each of the four outcomes.

Two sets of analyses were conducted. We tested short-term intervention effects by examining the data up to T4, the 6 month assessment (4 observations over time) and then long-term intervention effects by examining the full set of observations including T5 and T6. The advantage of MLM is that it does not delete participants with missing data at some time points, as would be the case if a traditional ANOVA were used.

For moderation analyses with continuous or dichotomous moderators, we used MLM with a mixed model approach, wherein condition was treated as a categorical predictor but time was treated as a quantitative variable that was coded in months (e.g., 0 for baseline, 1.15 for

5 weeks, 2.07 for nine weeks, and 6 for 6 months), and then grand-mean centered. Thus, we included time as a linear predictor in the model rather than treating it as categorical. We limited our moderation analyses. We limited our moderation analyses to the first six months of observations where condition effects were evident.

Moderator variables were also grand-mean centered (baseline depression, baseline dispositional emotional expressivity, age, self-reported physical symptoms) or effects coded (and metastatic status at baseline; both coded Yes = 1, No = -1.). This approach allowed us to test whether the effect of the moderator on change over time differed for the three conditions.

Results

Pre-intervention Differences and Distress Characteristics

Table 1 contains summary data for the participants by study condition regarding demographic, medical, and baseline distress characteristics. Multivariate analysis of covariance and chi-square tests, in which hospital site served as a covariate, revealed no differences between the three conditions regarding demographic, medical, or baseline depression and positive emotional expressivity scores. Because examination of hospital site as a covariate did not reveal any significant differences, data from hospital sites were combined in all analyses.

Treatment Attendance and Therapist Fidelity

Eighty-two percent of SC and 81.4% of CCI participants attended all eight sessions. Five percent of SC and 9.3% of CCI participants attended no sessions after being assigned. Participants who did not attend sessions were still asked to complete follow-up surveys. For CCI, average therapist fidelity across all 7 sessions was 89.8%. Individual session fidelity ranged from 81.2% (Session 7) to 93.2% (Session 2). Because there were no fidelity criteria for SC, we will present the key indicators of supportive counseling practices, in terms of overall occurrence in each sessions: restatement (range = 79-85% across sessions), reflection (25-38%), empathy (22-32%), validation (17-20%), exploring experiences (69-75%), encouraging emotional expression (28-39%), developing themes (10-22%), advice giving (1-11%), restatement (79-85%), explanation (6-11%), and reflection (25-37%). Rates for behaviors that were not consistent with SC were low: Average rates of interruption, deep interpretation, and education were very low (0-1.9%).

Treatment Evaluation

Treatment evaluation scores by participants across all interventions were also high ($M = 51.2$, $SD = 4.9$, maximum = 69). Comparisons indicated that CCI evaluation ratings were significantly higher than SC ratings ($M_{CCI} = 52.3$, $SD = 4.4$; $M_{SC} = 50$, $SD = 5.2$, $t = 3.2$, $p < .01$).

Effects of the covariates

Multilevel models that included eight covariates as predictors were conducted for each of the four outcomes. On average, women who were older were significantly less depressed, $b = -$.

097, $\beta = -.136$, $t(323) = 2.97$, $p = .003$, experienced less cancer-specific distress, $b = -.158$, $\beta = -.100$, $t(325) = 2.04$, $p = .042$, reported higher emotional well-being, $b = .062$, $\beta = .126$, $t(327) = 2.74$, $p = .006$, and reported less fear of recurrence, $b = -.025$, $\beta = -.179$, $t(332) = 3.80$, $p < .001$. Women with metastatic cancer were significantly less depressed, $b = -.796$, $\beta = -.108$, $t(323) = 2.06$, $p = .040$. Women who died over the 18 month course of the study reported higher levels of cancer-specific distress at baseline, $b = 3.24$, $\beta = .200$, $t(353) = 2.09$, $p = .037$ and reported lower emotional well-being, $b = -.908$, $\beta = -.178$, $t(362) = 1.98$, $p = .049$. Women with more advanced cancer also reported significantly lower emotional well-being, $b = -.523$, $\beta = -.107$, $t(325) = 2.01$, $p = .045$. Finally, Caucasian women reported significantly higher fear of recurrence, $b = .425$, $\beta = .294$, $t(338) = 5.21$, $p < .001$, and lower emotional well-being, $b = -1.283$, $\beta = -.251$, $t(334) = 4.57$, $p < .001$. There were no significant associations between marital status, education, or time since diagnosis on the four outcomes.

Intervention Effects

The means and standard errors across the six assessments, three conditions, and four outcome variables are presented in Table 2, and graphs of these means over time are presented in Figure 2. In terms of treatment effects from baseline to 6 months, the time by condition interaction emerged as statistically significant for depression, cancer-specific distress, and emotional well-being. CCI participants evidenced the greatest declines in depression ($M = 5.86$ points) and cancer-specific distress ($M = 7.87$ points) and the greatest increases in emotional well-being ($M = 2.28$ points) over the six month time period. However, CCI did not have an effect on fear of recurrence.

In terms of long-term treatment effects (at 12 and 18 months), when the full study including all six assessments was considered, only the effect of time emerged as statistically significant. There was no evidence of either a condition main effect or the anticipated condition by time interaction.

Follow-up ANCOVAs including the same set of covariates were conducted separately for each time-point to test for differences as a function of condition. For depression, the only significant comparison occurred at 9 weeks (T3), $F(2,294) = 6.43$, $p = .002$. Follow-up Tukey tests indicated that depression in CCI was significantly lower than in the UC group. SC did not differ significantly from either CCI or UC. At 6 months (T4), the mean difference was diminished and the ANOVA was not significant, $F(2,292) = 2.52$, $p = .082$. Tests for T1, T2, and T5-6 all had $ps > .30$. For cancer-specific distress, no follow-up tests attained statistical significance. In contrast, emotional well-being showed significant differences between the three conditions at 9 weeks (T3), $F(2,295) = 4.28$, $p = .015$. Participants in the CCI condition had significantly higher emotional well-being than participants in the UC group. The tests for differences in emotional well-being at T1, T2, T4-6 all had $ps > .19$.

Moderation Effects

We examined whether baseline status on five variables - depression, functional impairment, positive emotional expressivity, metastatic status, and age - moderated the effects of

intervention on outcomes. There was no evidence of moderation by depression, functional impairment, metastatic status, and age. However, positive emotional expressivity did moderate on three of the four outcomes: cancer-specific distress, $F(2,319) = 6.47, p = .002$, fear of recurrence, $F(2,323) = 11.39, p < .001$, and emotional well-being, $F(2, 321) = 6.78, p = .001$. In each case, the interaction was driven by the fact that positive emotional expressivity was significantly related to the average outcomes in the SC condition, but not in the other two groups. Specifically, the regression coefficients relating emotional expressivity to average cancer-specific distress were $b = -1.297, \beta = -.353, t(316) = 4.07, p < .001$ for SC, $b = -.060, \beta = -.016, t(321) = 0.20, p = .839$ for CCI, and $b = .184, \beta = .049, t(321) = 0.61, p = .545$ for UC. The interaction is shown in Figure 3. The findings indicate that, for women in the SC condition, a one-point increase in emotional expressivity was associated with a 1.3 point drop in average cancer-specific distress.

For fear of recurrence, the same pattern was evident: $b = -.150, \beta = -.463, t(320) = 5.63, p < .001$ in SC, $b = -.015, \beta = -.047, t(325) = 0.63, p = .530$ in CCI, and $b = .016, \beta = .049, t(326) = 0.61, p = .540$. Finally, emotional expressivity was significantly positively related to average emotional well-being in SC, $b = .485, \beta = .427, t(317) = 5.39, p < .001$, but not in CCI, $b = .074, \beta = .065, t(324) = 0.89, p = .373$, or in UC, $b = .109, \beta = .096, t(324) = 1.26, p = .207$.

Discussion

In this second evaluation of two psychological interventions for women with gynecological cancer [16], we bolstered treatments and evaluated effects on a broader range of outcomes such as fear of recurrence and emotional well-being. Treatment fidelity was given careful attention, and session attendance was high, with more than 80% of patients attending all therapy sessions. With these improvements, our results differed in several ways from the prior study [16]. First, CCI had a beneficial impact on depressive symptoms over the first six months as compared with UC and SC. These effects were more dramatic with a 6-point compared to our prior 4-point reduction on the BDI at six months [16]. Second, CCI now impacted cancer-specific distress, not found in the prior study, as well as having a beneficial impact on emotional well-being. The greater coping skill development in CCI has made it a more effective intervention than traditional supportive counseling across a broader range of key psychological outcomes. Third, whereas SC participants had previously achieved significant reductions in depressive symptoms, in our current study declines were not significantly different from UC. Treatment evaluations for the SC condition were also significantly lower than CCI. Although emotional support is appreciated, without the direct teaching of coping skills, beneficial gains did not materialize as needed in a brief and focused supportive counseling intervention. Our findings suggest a new minimum standard for intervention content to optimally help patients' distress and coping.

When long-term intervention effects at 12 and 18 months were evaluated, CCI did not have enduring effects on depression, cancer-specific distress, or emotional well-being. One possible reason is the effect of time as levels of emotional well-being improved in the UC group. Other confounders, such as disease recurrence, treatment burden and new life events may explain the lack of an enduring effect. This pattern of change among UC participants

was different than the prior study, where depression declined in the first six months post-baseline and then increased over the last three months participants were followed. A second reason is related to the longer follow-up period in the current study. Over the 18 months patients were followed, depression declined in CCI over the first six months, but did not remain flat in the CCI condition. For depression, cancer-specific distress, and emotional well-being, distress increased after six months and then decreased slightly after twelve months in the CCI group. There was a similar pattern for UC participants.

For health care providers, the identification of what patients might benefit from what type of psychological intervention can assist in knowing which patient characteristics to screen for so that treatments that are most likely to provide the greatest benefit are offered. This approach is particularly important when there are limited psychological resources in the clinical setting (e.g., social workers). When we evaluated moderators, neither baseline depression, baseline functional impairment, metastatic status, nor age proved significant. Thus, at least when considering these initial patient characteristics, all patients may benefit from CCI. Although SC did not show an overall treatment effect, consistent with our prior study [16], SC was more effective for women who were more expressive of positive emotions than for women who were less expressive of positive emotions. Because SC is more client-centered and awareness and expression of affect was promoted, it is possible that women who were more able to verbalize their feelings may be able to engage and take more advantage of SC than women who were less able to express their feelings.

Among study limitations, we had a relatively low rate of study acceptance, particularly among older patients and patients diagnosed with ovarian cancers. Our findings may not generalize to older patients who have other forms of gynecological cancer. A second limitation regards sample composition, which was primarily Caucasian (89%) and those diagnosed with ovarian cancer. Both interventions may have had a different effect among minority women and those with other forms of gynecological cancer. Third, participants were aware of their experimental assignment, which may have biased their reports of psychological outcomes. Fourth, cancer-specific distress declined, but levels remained relatively high at 12 and 18 months across all groups, suggesting that participants in this study continued to have persistent intrusive worries and avoidance of thinking about cancer. Cancers with high rates of recurrence (ovarian) are especially challenging in this regard. Videotaping of sessions and monitoring of treatment fidelity may have impacted patient and/or therapist.

Overall, this study extends the literature on psychological interventions for women diagnosed with gynecological cancer in several ways. First, we illustrated that the CCI intervention had significant effect on patients' depression, cancer-specific distress, and emotional well-being during a time when the majority of newly diagnosed patients experience elevated levels of distress. Ameliorating such distress post-diagnosis merits its incorporation into clinical care. A brief 8-session structured intervention can be readily applied to this distressed population in need. Perhaps more importantly, our results suggest that brief supportive counseling, which is the prevailing treatment model in oncology settings, did not impact psychological distress. This finding has important clinical implications for oncology mental health care delivery. To truly deliver benefits to newly-

diagnosed gynecological cancer patients, training mental health professionals in structured, cognitive-behavioral approaches may be appropriate.

Our findings illustrate the importance of replicating intervention studies and including long-term follow ups. As mentioned previously, the vast majority of randomized trials do not assess treatment effects for more than six months post-treatment. These findings also suggest that the inclusion of usual care comparison group is extremely important because patterns of change over time may vary across studies.

There are several implications for psychological care provided to newly-diagnosed gynecological cancer patients. First, CCI is a brief and effective treatment to reduce depression, cancer-specific distress, and to improve well-being. Second, SC is not an effective treatment for this patient population. Third, CCI did not impact fear of recurrence, and an examination of the cancer-specific distress scores suggested that, while levels declined, the levels were elevated. To have an impact on these two psychological outcomes, specialized treatments [32], intensive intervention sessions focused on cancer worries and fears that are delivered after the initial treatment is complete, and/or adding these intensive sessions to CCI may be needed. Fourth, the increase in depression and cancer-related distress noted between six months and one year suggests that future studies of CCI may need to bolster treatment gains at this point in time. Providing in-person booster sessions to reinforce coping skills, helping patients cope with fears about cancer progression, and manage cancer-specific intrusive thoughts may prove helpful. Identifying coping and social processing patterns that predict participants who have persistent distress over the course of the first year may prove beneficial in terms of identifying who may be at most risk and benefit from more targeted and longer-term psychological treatment.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

This work was supported by grant #CA85066 from the National Cancer Institute.

References

- [1]. Cancer Facts and Figures. American Cancer Society. 2015
- [2]. Bodurka-Bervers D, Basen-Engquist K, Carmack CL, Fitzgerald MA, Wolf JK, deMoor C, Gershenson DM. Depression, anxiety, and quality of life in patients with epithelial ovarian cancer. *Gynecologic Oncology*. 2000; 78:302–308. doi: 10.1006/gyno.2000.5908. [PubMed: 10985884]
- [3]. Goncalves V, Jayson G, Tarrier N. A longitudinal investigation of psychological disorders in patients prior and subsequent to a diagnosis of ovarian cancer. *Journal of Clinical Psychology in Medical Settings*. 2010; 17:167–173. doi: 10.1007/s10880-010-9196-1. [PubMed: 20490630]
- [4]. Clevenger L, Schrepf A, DeGeest K, Bender D, Goodheart M, Ahmed A, Lutgendorf SK. Sleep disturbance, distress and quality of life in ovarian cancer patients during the first year post-diagnosis. *Cancer*. 2013; 119:3234–3241. doi: 10.1002/cncr.28188. [PubMed: 23797955]

- [5]. Norton TR, Manne SL, Rubin S, Carlson J, Hernandez E, Edelson MI, Bergman C. Prevalence and predictors of psychological distress among women with ovarian cancer. *Journal of Clinical Oncology*. 2004; 22:919–926. doi: 10.1200/JCO.2004.07.028. [PubMed: 14990648]
- [6]. Hipkins J, Whtworth M, Tarrier N, Jayson G. Social support, anxiety and depression after chemotherapy for ovarian cancer: a prospective study. *British Journal of Health Psychology*. 2004; 9:569–581. do: 10.1348/1359107042304542. [PubMed: 15509362]
- [7]. Watts S, Prescott P, Mason J, McLeod N, Lewith G. Depression and anxiety in ovarian cancer: a systematic review and meta-analysis of prevalence rates. *BMJ Open*. 2015; 5:e007618. doi: 10.1136/bmjopen-2015-007618.
- [8]. Cain EN, Kohorn EI, Quinlan DM, Latimer K, Schwartz PE. Psychosocial benefits of a cancer support group. *Cancer*. 1986; 57:183–189. [PubMed: 3079660]
- [9]. Nelson EL, Wenzel LB, Osann K, Dogan-Ates A, Chantana N, Reina-Patton A, Monk B. Stress, immunity, and cervical cancer: biobehavioral outcomes of a randomized clinical trial. *Clinical Cancer Research*. 2008; 14:2111–2118. doi: 10.1158/10780432.CCR-07-1632. [PubMed: 18381952]
- [10]. Otis-Green S, Ferrell B, Sun V, Spolum M, Morgan R, Macdonald D. Feasibility of an ovarian cancer quality-of-life psychoeducational intervention. *Journal of Cancer Education*. 2008; 23:214–221. doi: 10.1080/08858190802188784. [PubMed: 19058068]
- [11]. Peterson RW, Quinlivan JA. Preventing anxiety and depression in gynaecological cancer: A randomized clinical trial. *British Journal of Oncology and Gynecology*. 2002; 109:386–394.
- [12]. Rost AD, Wilson K, Buchanan E, Hidlebrandt MJ, Mutch D. Improving psychological adjustment among late stage ovarian cancer patients. *Cognitive and Behavioral Practice*. 2012; 19:508–517. doi: 10.1016/j.cbpra.2012.01.003.
- [13]. Olesen M, Duun-Henriksen A, Hansson H, Ottesen B, Andersen K, Zoffman V. A person centered intervention targeting the psychological needs of gynecological cancer survivors: A randomized clinical trial. *Journal of Cancer Survivorship*. 2016; 10:832–841. doi: 10.1007/s11764-016-0528-5. [PubMed: 26902366]
- [14]. Chow KM, Chan JC, Choi KK, Chan CW. A review of psychoeducational interventions to improve sexual functioning, quality of life, and psychological outcomes in gynecological cancer patients. *Cancer Nursing*. 2016; 39:20–31. doi: 10.1097/NCC.0000000000000234. [PubMed: 25730595]
- [15]. Wenzel L, Robinson S, Blake D. The effects of problem-focused group counseling for early-stage gynecologic cancer patients. *Journal of Mental Health Counseling*. 1995; 17:81–93.
- [16]. Manne SL, Rubin S, Edelson M, Rosenblum N, Bergman C, Hernandez E, Winkel G. Coping and communication-enhancing intervention versus supportive counseling for women diagnosed with gynecological cancers. *Journal of Consulting and Clinical Psychology*. 2007; 75:615–628. doi: 10.1037/0022-006.75.4.615. [PubMed: 17663615]
- [17]. Lepore, S. A social cognitive-processing model of emotional adjustment to cancer. In: Baum, A.; Andersen, B., editors. *Psychological interventions for cancer*. American Psychological Association; Washington DC: 2001. p. 99-116.
- [18]. Maina G, Forner F, Bogetto F. Randomized Controlled Trial Comparing Brief Dynamic and Supportive Therapy with Waiting List Condition in Minor Depressive Disorders. *Psychother Psychosom*. 2005; 74:43–50. [PubMed: 15627856]
- [19]. Hener T, Weisenberg M, Har-Even D. Supportive versus cognitive-behavioral intervention programs in achieving adjustment to home peritoneal kidney dialysis. *J Consult Clin Psychol*. 1996; 64(4):731–741. [PubMed: 8803363]
- [20]. Helgeson VS, Lepore SJ, Eton DT. Moderators of the benefits of psychoeducational interventions for men with prostate cancer. *Health Psychology*. 2006; 25:348–354. do: 10.1037/0278-6133.25.3.348. [PubMed: 16719606]
- [21]. Scheier MF, Helgeson VS, Schulz R, Colvin S, Berga SL, Knapp J, Gerszten K. Moderators of interventions designed to enhance physical and psychological functioning among younger women with early-stage breast cancer. *Journal of Clinical Oncology*. 2007; 25:5710–5714. doi: 10.1200/JCO.2007.11.7093. [PubMed: 17998547]

- [22]. Beck A, Ward C, Mendelson N, Mock J, Erbaugh J. An inventory for measuring depression. *Archives of General Psychology*. 1961; 4:53–63.
- [23]. Beck, A.; Beamesderfer, A. Assessment of depression. In: Pichot, P., editor. *Modern problems in pharmacopsychiatry*. Karger; Basel, Switzerland: 1974. p. 151-169.
- [24]. Novalis, P.; Rojcewicz, S.; Peele, R. *Clinical manual of supportive therapy*. American Psychiatric Association Press; Washington, DC: 1993.
- [25]. Pinkser, H.; Rosenthal, R. *Social and Behavioral Sciences Documents*. Vol. 18. Beth Israel Medical Center; New York: 1988. Beth Israel Medical Center supportive psychotherapy manual.
- [26]. Horowitz M, Wilner N, Alvarez W. Impact of event scale: A measure of subjective stress. *Psychosomatic Medicine*. 1979; 41:209–218. [PubMed: 472086]
- [27]. Cella DF, Tulsky DS, Gray G, Sarafian B, Linn E, Bonomi A, Harris J. The functional assessment of cancer therapy scale: development and validation of the general measure. *Journal of Clinical Oncology*. 1993; 11:570–579. [PubMed: 8445433]
- [28]. Vickberg SM. The Concerns About Recurrence Scale (CARS): a systematic measure of women's fears about the possibility of breast cancer recurrence. *Annals of Behavioral Medicine*. 2003; 25:16–24. [PubMed: 12581932]
- [29]. King LA, Emmons RA. Conflict over emotional expression: Psychological and physical correlates. *Journal of Personality and Social Psychology*. 1990; 58:864–877. [PubMed: 2348373]
- [30]. Schag CA, Ganz PA, Heinrich RL. Cancer rehabilitation evaluation system-short form (CARES-SF): A cancer specific rehabilitation and quality of life instrument. *Cancer*. 1991; 68:1406–1413. [PubMed: 1873793]
- [31]. Borkovec TD, Nau SD. Credibility of analogue therapy rationales. *Journal of Behavior Therapy and Experimental Psychiatry*. 1972; 3:117–126.
- [32]. Thewes B, Brebach R, Dzidowska M, Rhodes P, Sharpe L, Butow P. Current approaches to managing fear of cancer recurrence; a descriptive survey of psychosocial and clinical health professionals. *Psycho-Oncology*. 2014; 23:390–396. doi: 10.1002/pon.3423. [PubMed: 24307136]

Highlights

- A brief 8-session cognitive-behavioral intervention reduced distress.
- This brief intervention also improved well-being.
- Supportive counseling did not reduce distress as compared to usual care.
- The cognitive behavioral intervention can be readily used for these patients.

Fig. 1.
Study Schema

Fig. 2. Change in depression, distress, fear of recurrence and emotional well-being over time for CCI, SC, and UC. CCI = Coping and Communication-enhancing Intervention, SC = Supportive Counseling, UC= Usual Care. Time is shown in number of months post-baseline.

Fig. 3. Plot of the interaction of positive emotional expressiveness and average cancer-specific distress. SC = Supportive Counseling; CCI = Coping and Communication-Enhancing Intervention; UC = Usual Care.

Table 1

Pre-Intervention Characteristics of the Full Sample and Each Intervention Condition

Characteristic	Full Sample			CCI n=118			SC n=118			UC n=116		
	M	(SD)	N	%	M	(SD)	N	%	M	(SD)	N	%
Age, years	55.3	10.3			53.8	11.1		55.7	10.0	56.4	9.6	
Race												
White			278	79.0			90	76.3			92	79.3
Non-white			73	20.8			28	23.6			24	20.6
Missing			1	0.3			0	0.0			1	0.8
Marital status												
Single, divorced, widowed			115	32.7			41	34.7			31	26.7
Married			237	67.3			77	65.3			85	73.3
Employment												
Unemployed/on leave			209	59.4			67	56.8			68	58.6
Part-time			51	14.5			16	13.6			19	16.4
Full-time			91	25.9			34	28.8			29	25.0
Missing			1	0.3			1	0.8			0	0.0
Education level												
Less than college degree			130	36.9			44	37.3			44	37.9
Completed college degree			105	29.9			30	25.4			39	33.6
Post-college education			116	33.0			44	37.3			33	28.4
Missing			1	0.3			0	0.0			0	0.0
Site of Disease												
Ovary			216	61.4			75	63.6			70	60.3
Endometrium			46	13.1			18	15.3			13	11.2
Primary Peritoneal			8	2.3			2	1.7			2	1.7
Cervical			14	4.0			5	4.2			6	5.2
Uterine			30	8.5			11	9.3			7	6.0
Fallopian tube			31	8.8			6	5.1			17	14.7
More than 1			7	2.0			1	0.8			1	0.9

Characteristic	Full Sample			CCI n=118			SC n=118			UC n=116		
	M	(SD)	N	%	M	(SD)	N	%	M	(SD)	N	%
FIGO stage at time of diagnosis												
I			55	15.6			24	20.3			18	15.3
II			43	12.2			17	14.4			12	10.2
III			174	49.4			52	44.1			61	51.7
IV			74	21.0			23	19.5			23	19.5
More than 1			2	0.6			0	0.0			2	1.7
Missing			4	1.2			2	1.7			2	1.6
Metastatic disease (yes)			31	8.8			9	7.6			11	9.3
ECOG rating												
0			248	70.5			88	74.6			83	70.3
1			94	26.7			28	23.9			31	26.3
2			2	0.6			1	0.8			1	0.8
3			1	0.3			0	0.0			1	0.8
Missing			7	2.0			1	0.8			2	1.7
Baseline self-reported physical symptoms	34.1	19.8			33.6	20.8			34.9	19.3		
Baseline positive emotional expressiveness	17.1	4.4			16.8	4.5			17.3	4.3		
Baseline Beck Depression Inventory	13.7	7.4			13.5	6.9			14.2	8.2		
									13.5	7.1		

Note. CCI = Coping and Communication-enhancing Intervention; SC = Supportive Counseling; UC = Usual Care; ECOG= Eastern Cooperative Oncology Group

Table 2

Means, standard errors, and F-tests comparing SC, CCI, and UC on depression, distress, fear of recurrence, and emotional well-being

	Means and Standard Errors Over Time							Full Study:				Short Term:			
	Baseline to 18 Months							Baseline to 18 Months				Baseline to 6 Months			
	Baseline M (se)	5 Week M (se)	9 Week M (se)	6 Month M (se)	12 Month M (se)	18 Month M (se)		Time F (df)	Cond F (df)	Time by Cond F (df)		Time F (df)	Cond F (df)	Time by Cond F (df)	
Depression															
SC	13.97 (.67)	11.22 (.67)	9.60 (.67)	8.69 (.66)	9.05 (.70)	9.66 (.80)		64.54** (5,853)	1.31 (2,328)	1.64 (10,854)		96.08** (3,672)	1.79 (2,327)	2.53* (6,672)	
CCI	13.15 (.66)	11.20 (.68)	7.94 (.68)	7.29 (.66)	8.36 (.70)	8.38 (.79)									
UC	13.58 (.66)	11.81 (.67)	10.81 (.66)	8.65 (.66)	9.35 (.70)	9.29 (.81)									
Cancer-Specific Distress															
SC	27.74 (1.54)	24.78 (1.55)	24.90 (1.56)	24.34 (1.54)	23.76 (1.59)	24.11 (1.70)		14.69** (5,916)	0.33 (2,326)	1.52 (10,918)		22.18** (3,630)	0.40 (2,330)	2.31* (6,631)	
CCI	29.57 (1.53)	26.79 (1.55)	23.08 (1.57)	21.70 (1.54)	24.37 (1.60)	23.56 (1.70)									
UC	29.31 (1.52)	27.72 (1.54)	26.51 (1.53)	23.41 (1.55)	25.66 (1.60)	24.68 (1.74)									
Fear of Recurrence															
SC	3.73 (.13)	3.67 (.13)	3.63 (.13)	3.63 (.13)	3.58 (.14)	3.57 (.15)		3.51** (5,864)	0.36 (2,332)	1.07 (10,866)		3.84* (3,617)	0.85 (2,326)	0.80 (6,618)	
CCI	3.75 (.13)	3.56 (.13)	3.51 (.13)	3.45 (.13)	3.63 (.14)	3.76 (.15)									
UC	3.87 (.13)	3.73 (.13)	3.79 (.13)	3.66 (.13)	3.57 (.14)	3.82 (.15)									
Emotional Well-Being															
SC	15.62 (.47)	16.77 (.47)	17.22 (.48)	17.34 (.47)	16.53 (.49)	16.50 (.53)		12.69** (5,900)	1.53 (2,328)	1.62 (10,902)		19.13** (3,690)	1.68 (2,328)	2.36* (6,691)	
CCI	15.78 (.47)	16.74 (.48)	18.25 (.48)	18.06 (.47)	17.36 (.49)	16.98 (.54)									
UC	15.82 (.46)	16.26 (.47)	16.34 (.47)	16.66 (.47)	16.05 (.50)	16.26 (.54)									

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

Note.

CCI = Coping and Communication-enhancing Intervention; SC = Supportive Counseling; UC = Usual Care; Multilevel analyses included the following covariates: Whether the person died during the study (1 = yes, -1 = no), Metastatic status (1 = metastasized, -1 = not metastasized), Ethnicity (1 = White-not Hispanic, -1 = other), Marital Status (1 = married, -1 = not married), Education (1 = College Graduate or more, -1 = less than a college degree), and Age, Cancer Stage, and Time since Diagnosis all grand mean centered. Means are estimated marginal means at the sample average of all the covariates.

* $p < .05$,
** $p < .01$.

Table 3

Description of interventions

	Coping and Communication Intervention (CCI)	Supportive Counseling Intervention (SC)
Overview of Intervention	A structured coping and communication intervention with techniques drawn from cognitive-behavioral interventions.	A non-directive, supportive interventions with techniques drawn from supportive counseling and emotion-focused therapy.
Format	Individual	Individual
Number of Sessions	Seven in-person sessions plus an 8 th phone session scheduled 2-3 weeks after the 7 th session	Seven in-person sessions plus an 8 th phone session scheduled 2-3 weeks after the 7 th session
Session Length	One hour	One hour
Overview of Session Content		
Session 1	<i>Session Goals:</i> 1)Orient patient to the intervention 2)Develop understanding of patient's cancer experience 3)Teach and practice deep breathing	<i>Session Goals:</i> 1)Orient patient to the intervention 2)Patient shares her cancer experience 3)Begin to develop goals and themes for therapeutic work
Session 2	<i>Session Goals:</i> 1)Introduce concept of stress 2)Teach and practice relaxation skills (e.g., deep breathing, progressive muscle relaxation, guided imagery) 3)Introduce the concept of problem-focused and emotion-focused coping 4)Apply problem-focused coping to a cancer-related concern	<i>Goals of Sessions 2 through 6: Enhance the patient's adaptation to cancer by:</i> 1)Encouraging emotional expression 2)Facilitating an understanding of emotional reactions 3)Supporting existing coping behaviors 4)Enhancing self-esteem
Session 3	<i>Session Goals:</i> 1)Introduce emotion-focused coping skills (e.g., distraction, cognitive restructuring) 2)Practice cognitive-restructuring techniques with a cancer-related issue 3)Engage in exercise on redefining values and priorities in the face of cancer 4)Identification of losses and acceptance of losses	<i>Techniques consistent with the model that were utilized in the sessions:</i> 1)Restatement 2)Reflection 3)Emotional exploration 4)Empathy 5)Validation 6)Reassurance
Session 4	<i>Session Goals:</i> 1)Discuss the benefits and barriers to communicating feelings 2)Explore strategies to overcome communication barriers 3)Assist patient identifying emotional needs and support needs 4)Develop plan to overcome barriers and communicate emotional and support needs in dealing with the cancer experience	<i>Techniques not consistent with the model and were discouraged from being utilized in the sessions:</i> 1)Direct didactic teaching 2)Coping skills training 3)Deep Interpretation 4)Interruption
Session 5	<i>Session Goals:</i> 1)Identify patient fears about disease progression/recurrence 2)Review skills to cope with fears 3)Develop plan to utilize coping skills	<i>Development of Goals and Themes</i> The therapist worked with the patient to develop cancer-related themes that were relevant to the therapeutic work
Session 6	<i>Session Goals:</i> 1)Provide information on the impact of gynecologic cancer on sexuality 2)Discuss skills for coping with effects on sexuality and body image	Themes were discussed each session The therapist made connections between session content and overall themes

	Coping and Communication Intervention (CCI)	Supportive Counseling Intervention (SC)
	3)Discuss importance of self-care and a plan to care for oneself 4)Provide resource information	
Session 7	<i>Session Goals:</i> 1)Review skills learned 2)Apply problem-focused and emotion-focused coping skills to cancer-related concerns 3)Identify barriers to using skills and plans to overcome barriers 4)Wrap-up, review community resources, and schedule booster session	<i>Session Goals:</i> 1)Patient discusses issues she would like to explore related to cancer 2)Review of themes discussed throughout the sessions 3)Discussion of progress across the sessions 4)Wrap-up, review community resources, and schedule booster session
Phone Booster	<i>Goals:</i> 1)Check-in with patient 2)Review effective use of coping and communication skills 3)Discuss situations for skills with which patient was having difficulty = and ways to overcome	<i>Goals:</i> 1)Check-in with patient 2)Discuss any relevant issues patient would like to address 3)Provide support and encouragement