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A comparison of two psychological interventions for newly-diagnosed gynecological cancer patients☆

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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.

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ABSTRACT

Objective. This study compared the efficacy of two psychological interventions, a coping and communication-enhancing intervention (CCI) and supportive counseling (SC), in reducing depressive symptoms, cancer-specific distress, fear of recurrence, and emotional well-being of women diagnosed with gynecological cancer. Demographic, medical, and psychological moderators of intervention effects were evaluated.

Methods. Three hundred fifty-two women with gynecological cancer were randomly assigned to eight sessions of CCI, eight sessions of SC, or usual care (UC). Participants completed measures of distress and wellbeing at six time points over an 18 month period of time.

Results. CCI had a beneficial impact on depressive symptoms and cancer specific distress over the first six months as compared with UC and SC and had a beneficial impact on emotional well-being. The greater coping skill development in CCI has made it a more effective intervention than traditional SC across a broader range of key psychological outcomes. Declines among women in the SC condition were not significantly different from UC.

Conclusions. 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. Brief supportive counseling did not evidence treatment effects, suggesting that more structured approaches are crucial to truly deliver benefits.

1. Introduction

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

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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]. 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 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].

2. Method

2.1. 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.

2.2. 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 Figs. 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

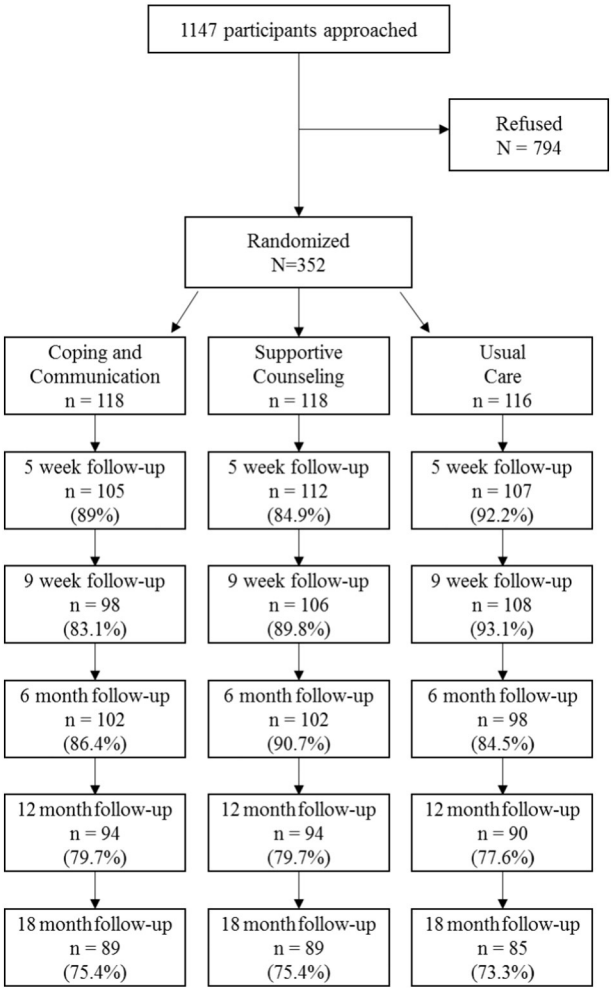

Fig. 1. Study schema.

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