A pilot, multisite, randomized controlled trial of a self-directed coping skills training intervention for couples facing prostate cancer: Accrual, retention, and data collection issues

Running title: Pilot of a couple-based self-directed coping skills intervention

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Abstract

Purpose: Examine the acceptability of the methods used to evaluate *Coping-Together* – one of the first self-directed coping skills intervention for couples facing cancer and collect preliminary efficacy data.

Methods: 42 couples, randomized to a minimal ethical care (MEC) condition or to *Coping-Together*, completed a survey at baseline and two months after, a cost diary, and a process evaluation phone interview.

Results: 170 patients were referred to the study. However, 57 couples did not meet all eligibility criteria, and 51 refused study participation. On average, two to three couples were randomized per month, and each couple enrollment took 26 days. Two couples withdrew from MEC, none from *Coping-Together*. Only 44% of the cost diaries were completed, and 55% of patients and 60% of partners found the surveys too long, and this despite the follow-up survey being five pages shorter than the baseline one. Trends in favour of *Coping-Together* were noted for both patients and their partners.

Conclusions: This study identified the challenges of conducting dyadic research and a number of suggestions were put forward for future studies, including to question whether distress screening was necessary and what kind of control group might be more appropriate in future studies.

Keywords: Coping, Pilot study, Self-care, Self-directed intervention, Caregivers, Partners

Although research has traditionally focused on the negative impact of cancer on patients, it is now well-recognized that cancer also evokes numerous issues to be confronted, questions to be answered, and emotions to be faced for their partners [1]. Recent analyses conducted by Lambert et al. [2, 3] among a mixed group of cancer caregivers found that 35.8% of caregivers reported clinically significant levels of anxiety six months post survivor diagnosis. This prevalence exceeded the anxiety rate reported by the survivors themselves [4] and population norm [2]. Additional analyses [3] revealed that caregivers reporting anxiety or depression at six months, continued to be anxious and depressed up to two years post-diagnosis.

To help partners and caregivers tackle cancer challenges in a way that optimizes their and patients' health and functioning, much attention has been given to developing coping skills and self-management interventions to: a) address caregivers' information needs; b) equip them with the adaptive strategies and behaviors they need to curtail the impact of cancer on their daily lives (e.g., problem-solving); c) strengthen the patient-caregiver relationship (e.g., communication skills training); and/or d) connect them to other resources/services [5, 6]. A number of trials have substantiated the efficacy of these interventions in reducing caregivers' burden and improving their ability to cope, relationship functioning, and aspects of quality of life (QOL) [5, 6]. Furthermore, studies have found that when interventions engage patients and caregivers (as a dyad), important synergies are achieved that contribute significantly to each person's well-being outcomes [7].

Although the sizeable benefits of coping skills and self-management interventions are well-documented, these are typically not part of routine cancer care. Most often, these interventions are delivered by highly trained health professionals through one-on-one sessions or workshops, which raises two major barriers. First, costs tend to be high and demand can easily exceed the availability of qualified professionals. Second, these interventions are often not accessed due to the additional demands they impose (e.g., travel) and personal preferences [8]. The challenge then is to use alternate delivery formats that provide ongoing support in a way that is cost-effective and, at the same time, offer caregivers the flexibility to choose when and where to engage in the intervention.

The recent urgency to find sustainable modes to deliver coping skills and self-management interventions has contributed to an exponential increase in the evidence supporting the efficacy and cost-effectiveness of a self-directed (or self-administered) format [9, 10]. Although self-directed interventions are promising [9, 10], most of these still do not include patients' partners. To address this gap in the literature, our team has recently developed *Coping-Together*, a self-directed coping skills intervention for patients diagnosed with cancer and their partners [11]. A qualitative evaluation of *Coping-Together* supported its practical approach and potential to facilitate independent coping [11]. The present pilot study builds on this study to further a) examine the feasibility of a trial to evaluate *Coping-Together* among couples facing prostate cancer and b) collect preliminary efficacy data.

Methods

Design

This pilot is a multicenter, stratified, double-blind, two-group, parallel, randomized controlled trial to compare *Coping-Together* to a minimal ethical care (control) group [12]. The design of this study was guided by the CONSORT statement [13]. The development of *Coping-Together* has been described elsewhere [11, 12].

Sample

A convenience sample of men diagnosed with early-stage, prostate cancer and their partners were invited to participate in the study by their clinicians across six recruiting sites. Patient inclusion criteria were: diagnosed in the past 4 months, receiving or planning to receive treatment (including active surveillance), having no previous cancer diagnosis, and having a partner (spouse, boy/girlfriend, or de facto) willing to participate in the study. In addition, to be eligible for this study, the patient or their partner had to score four or more on the Distress Thermometer (DT) at the time of recruitment and both needed to be sufficiently fluent in English and cognitively able to participate in the study.

Procedures

Most participants were recruited through urologists' private practices in Australia. Eligible patients were invited to meet with the on-site research assistant (RA) to further discuss study participation and obtain their DT score. If the patient scored less than four on the DT, and their partner was present, the DT was then administered to them. If the partner was not present, consent was obtained from the patient to contact them and screen for distress by phone. The RA then gave or mailed a study pack to eligible couples. If the RA was not present at the time of recruitment, the urologists gave interested patients a study pamphlet and obtained verbal consent for the RA to contact them within the following week. For these patients, all additional eligibility assessment was conducted over the phone. The study was also advertised through a range of media outlets (e.g., newspaper). Once patients' and partners' consent forms and baseline surveys were returned, the couple was randomized. This study was approved by the relevant ethics committees.

Randomization and Group Assignment

A computer-generated randomization schedule with block lengths of variable size (4 and 6) and stratified by recruitment source was accessible to the study co-ordinator. Couples were randomized to *Coping-Together* or the minimal ethical care (MEC) control condition. Intervention couples received the four *Coping-Together* booklets that propose specific coping strategies to address the following challenges: a) symptom management (coping with common treatment side effects), b) communicating effectively with health care professionals (tips to enhancing communication with the health care team), c) supporting your partner (focused on enhancing the patients' and their partners' communication skills and tips to adjusting to changes in the relationship), and d) managing worries and emotions (suggestions to address the emotional reactions to the diagnosis and treatment) [18]. Couples were not expected to read each booklet cover-to-cover. Rather, the couples were encouraged to review the content of the booklets and the suggested strategies together to select those that were most appropriate to address current challenges. Across the booklets, the proposed strategies were aimed at either the individuals' coping ability (e.g., tips to deal with a symptom, relaxation strategies) or the couple's dyadic coping skills (e.g., strategies to talk about difficult topics, conflict resolution skills, active listening strategies). The booklets were complemented by a relaxation CD and a DVD, which featured clinicians who delivered key content of the second booklet and included scenarios with couples (actors) to demonstrate specific coping skills (e.g., use of a question prompt list). One to two weeks after receiving *Coping-Together*, all couples participated in an orientation phone call conducted by the RA to review the material received. Couples were able to use *Coping-Together* at their own discretion and pace for 2 months. Couples also received, fortnightly, a 'Top Tips' newsletter highlighting timely content of *Coping-Together*, and a follow-up telephone call from a RA to monitor the use of *Coping-Together* (Mean duration of Call 1 = 27 minutes, *SD* = 15.35; Call 2 duration = 21 minutes, *SD* = 12.95; Call 3 = 16 minutes, *SD* = 12.72).

MEC couples were mailed the Cancer Council New South Wales *Understanding Prostate Cancer* and *Caring for Someone with Cancer* and the Helpline brochure. They also received initial and follow-up phone calls comparable in intent and content to the *Coping-Together* couples. All phone calls were audio-recorded and reviewed to ensure that counselling was not inadvertently provided.

Data Collection

Data collection included distress screening at recruitment, a baseline and follow-up survey, a health service-use diary, and a process evaluation interview. A health service-use diary was included to reflect all methods that would be part of a larger trial to evaluate the efficacy and cost-effectiveness of *Coping-Together*. However, as the present study is a pilot, the feasibility of using a cost diary is presented and discussed, but not the actual cost data.

Distress screening at the time of recruitment.

The DT asked individuals to select a number, from 0 = ‘no distress’ to 10 = ‘extreme distress’, that best described their overall distress [14]. A DT cut-off point of four has typically been found to result in optimal sensitivity and specificity [15].

Primary and secondary outcomes.

The measures used are summarized below, and further details are provided in the protocol [12].

- *Anxiety and depression* were measured using the corresponding subscales on the Hospital Anxiety and Depression Scale (HADS) [16]. The Cronbach’s alpha for the HADS subscales ranges from 0.68 to 0.93 [17].
- *Cancer-specific distress* was measured by the Revised Impact of Event Scale (IES-R [18], α = 0.78-0.96 [19]).
- *QOL* was measured with the physical and mental subscales of the Assessment of Quality of Life – 8 dimensions (AQoL-8D) [20]. Caregivers also completed the four subscales (burden, disruptiveness, positive adaptation, financial concerns) of the QOL Index-Cancer (CQOLC, α = 0.91) [21].
- *Relationship satisfaction* was measured using the Revised-Dyadic Adjustment Scale (R-DAS [22], α = 0.89-0.95 [23]), which is comprised of three subscales: consensus, satisfaction, and cohesion.
- *Illness appraisal* was measured by Kessler’s Cognitive Appraisal of Health Scale (α > 0.70) [24], Mishel’s Uncertainty in Illness Scale (MUIS) (α =.64-.92) [25], and the Appraisal of Caregiving Scale (ACS, α > 0.85) [26]. The ACS measures two types of stressful appraisals, threat and general stressfulness, and one type of positive appraisal (benefit) [26].
- *Self-efficacy* was measured by the Lewis Cancer Self-Efficacy Scale (LCSES [27], α = 0.97 [28]) and the three subscales (understand and participate in care, maintain a positive attitude,

and seek and obtain information) of the Communication and Attitudinal Self-Efficacy for cancer (CASE-Cancer, α = 0.76-0.77 [29]).

- *Individual coping strategies* were assessed by the Brief COPE (α = 0.60-0.90) [30]. Items were combined according to the structure proposed by Cooper et al. [31]: emotion-focused, problem-focused, and dysfunctional coping. The nine subscales of the Dyadic Coping Inventory (DCI), α = 0.63-0.93 [32, 33]) were used to measure *dyadic coping*: stress communication by oneself, supportive dyadic coping by oneself, delegated dyadic coping by oneself, negative dyadic coping by oneself, stress communication of the partner, supportive dyadic coping of partner, delegated dyadic coping of partner, negative dyadic coping by the partner, and common dyadic coping.

Health service-use diary.

A "My Cancer Care Diary" [34] was also completed by patients and their partners, separately, to record their own costs related to: a) care from health care professionals, b) hospital or respite care, c) medication use, d) community services or pastoral care, e) additional costs, and f) time off from usual activities.

Feasibility and acceptability of study methods.

Feasibility and acceptability data included response and accrual rates as well as attrition. At the end of the surveys, participants were also asked to indicate how much time it took to complete the survey, whether the survey was too long (yes/no), and preferences for completing the survey in the future (online, pen and paper, or over the phone). Last, the process evaluation interview served as an exit interview for those couples who consented (21 patients and 17 partners), and focused on summarizing use of *Coping-Together* as well as the acceptability of the methods.

Demographic information.

In addition, demographic information was collected at the time of the orientation phone call.

Data analysis

Data were analyzed using Stata v13 and SAS v9.3. Means, standard deviations, and proportions were calculated to describe the sample and flow of participants. For the primary and secondary outcomes, intention-to-treat analysis was conducted separately for patients and partners. The primary outcome, anxiety at two months post-baseline, was analyzed using ANalysis of COVAriance (ANCOVA). The main predictor variable in the ANCOVA model was treatment group, and the participants' baseline score was included as a covariate. ANCOVA was also used to explore the secondary outcomes. As this is a pilot study, $p \leq 0.30$ was taken to be indicative of an efficacy trend in the data.

Results

Sample

Table 1 details participants' demographic and treatment variables by group.

Referral

During the recruitment period, 170 patients were referred to the study (see Figure 1). Of these, 57 couples did not meet all eligibility criteria, and 51 couples declined study participation. Ineligible dyads mainly had no willing partner (n = 16), the patient was more than four months post-diagnosis (n = 11), or the patient and partner scored less than four on the DT (n = 11). The top reason for refusal was being not interested (n=31). As a result, 42 couples were randomized.

Retention

Of the 42 couples enrolled, 32 patients and 32 partners returned a follow-up survey. Two couples withdrew from MEC (see Figure 1) and four patients and five partners were considered lost to follow-up. No couples withdrew from *Coping-Together*; however, four patients and three partners were lost to follow-up.

Feasibility and Acceptability of Data Collection Methods

Distress screening.

None of the participants refused to provide a DT score. However, only one clinic had in place distress screening procedures, and having to screen for distress was a deterrent for clinicians to recruit. This led to a change in the procedures whereby the RA would screen once patients were referred to the study. The average score on the HADS at baseline for patients was 4.9 (SD=3.6) and for partners was 6.7 (SD=4.4) (p = 0.045).

Surveys.

At baseline, patients took 98.7 minutes (SD = 47.6 min) to complete the survey, and 55% felt the survey was too long. Similarly, partners took an average 99.2 min to complete the survey (SD = 52.8 min), with 60% feeling the survey was too long. At follow-up, the survey was five pages shorter (from 30 to 25 pages); however, 60% of patients and 65% of partners still felt the survey was too long. Almost a third of participants in the process evaluation said the survey was the aspect of the study they liked least (29.7%). In general, both patients and partners preferred to complete the survey using pen and paper (87.8% patients, and 84.2% partners) compared to other means (by phone and online).

Cost diary.

Of the 84 cost diaries sent, 23 patient and 24 partner diaries were returned. However, 10 of these were blank (i.e., 44% returned a completed diary). This, despite 83% of participants in the process evaluation reporting that the diaries were not burdensome to complete.

Orientation and follow-up phone calls.

Across the 164 follow-up calls, only 46 (28%) were conducted with patients and partners together. Main reasons for not conducting these as a couple were: available at different times due to work and other commitments, not having a speaker phone, participants preferring to be interviewed separately, and patient and partner living separately. In the process evaluation interviews, the orientation call was felt necessary by 65% of participants. Similarly, the frequency (86%), length (79%), and topics (61%) discussed were found to be acceptable.

Primary and Secondary Outcome Data

As indicated in Table 2, a number of differences at baseline between patients and partners on primary and secondary outcomes are noteworthy. For patients (see Table 3), results suggest that *Coping-Together* might improve distress (intrusion and avoidance) and contribute to potentially appraising cancer as less challenging. Although both groups reported a decrease in consensus, *Coping-Together* couples' decline was smaller than MEC participants'. Some improvements in the MEC group were also noted in terms of mental quality of life, uncertainty, harm/loss appraisal, and supportive dyadic coping by oneself.

For partners (see Table 4), results suggest that *Coping-Together* might lower caregiver burden, general stress, and financial strain. Changes in illness and caregiving appraisal potentially in favour of *Coping-Together* were also noted for the benign/irrelevant and benefit-finding subscales. The *Coping-Together* partners also appeared to maintain their perceived level of cohesion with their partners, whereas this decreased for MEC partners. A similar pattern of findings is noted for emotion-focused coping strategies. In contrast, trends favoring the MEC partners were noted for appraising the cancer as less challenging and using fewer dysfunctional coping strategies.

Discussion

In the past five years, there has been considerable interest in couple-based interventions, including using a self-directed format to increase reach and accessibility [6]. However, the resources required to conduct dyadic research are often underestimated [35]. The current pilot identified some challenges in evaluating *Coping-Together*, and each is discussed in turn.

Patient refusal and ineligibility.

The refusal rate was slightly higher than expected (expected = 30% [12], actual = 39.9%), but still lower than other trials with men with prostate cancer [36, 37]. However, the uptake rate of 37.2% in this study is lower than what has been reported in a review of couple-based interventions [8]. Although the self-directed format was acceptable, the dyadic focus might have adversely impacted the level of interest. A review by Regan et al. [8] found that among couple-based interventions, uptake rates did vary according to the intervention's focus, whereby coaching and individual-based interventions (patient and partner receive the same intervention separately) had higher uptake rates than dyadic interventions.

The ineligibility rate was estimated at 60%, which was mainly based on the expected prevalence of distress [38]. Although the actual ineligibility rate was lower, one of the main reasons for ineligibility was a patient or partner scoring less than 4 on the DT. The DT inclusion criterion was set, because it is well-recognized that ignoring patients' baseline distress and the potential for floor effects can undermine the efficacy of psychosocial interventions [39]. Despite screening, in our study, patients' baseline HADS-Anxiety score might still be too low to overcome floor effect. A recent meta-analysis found that the efficacy of an intervention was zero for a baseline HADS-Anxiety score of 4.20; however, significantly positive outcomes were predicted for baseline scores of 5.85 or more [40]. Hence, consideration might be given to increasing the DT cut-off score used [38]. Another suggestion is to consider level of distress in the context of additional services [41]. However, in a study by van Scheppingen et al. [42] including only distressed patients who also indicated a need for additional help resulted in halving the pool of eligible patients.

Survey burden.

Although the evidence remains equivocal on whether survey length has an impact on response rate [43], the survey was nevertheless the most burdensome aspect of this study. Culling five pages from the follow-up survey did not increase acceptability. No study has documented the impact of survey length on response rate among individuals with cancer or their caregivers. However, in other contexts, studies have suggested that a 13-15 page survey was significantly more acceptable than a 23-24 page survey [44, 45]. Mond et al. [46] found no difference between an 8 and 14 page survey in terms of response. It has also been suggested that survey length is a factor when it takes more than 20 minutes to complete [47].

Cost diary.

Increasingly, including cost-effectiveness analyses in psychosocial research is advocated. Common self-report methods for health care data include questionnaires or cost diaries [48]. In this pilot, a health service-use diary was used, as this method is generally reported to reduce recall bias [48], but a high proportion of missing data was noted. Among patients with rectal cancer, van den Brink et al. [48] found that for the assessment of health-care utilization, a cost questionnaire with structured closed questions might replace a diary for recall periods up to six months.

Conceptual and methodological questions about *Coping-Together*.

This pilot study was not powered to examine the efficacy of *Coping-Together*. Nevertheless, some trends in favor of the intervention were noted, particularly for partners. This is similar to a study by Northouse et al. [27] that found partners and caregivers benefited more from a dyadic intervention than patients in the outcomes of quality of life, appraisal, self-efficacy, and symptoms. The two months post-baseline data collection time point might have been too soon to detect the potential efficacy of an intervention that requires patients and partners to identify, learn, and apply skills on their own. One outcome that might reflect this limitation is supportive dyadic coping by oneself. Although relationship satisfaction trends were in favor of *Coping-Together*, MEC patients reported a slight increase in supportive dyadic coping by oneself. It can be posited that *Coping-Together* exposed patients to gaps in their supportive behaviors, which in turn might have negatively impacted on their frame of reference. However, with time, if dyadic coping skills are learned and applied, the intended positive impact of *Coping-Together* on this outcome might be noted.

Another question raised by this pilot is whether choosing an attention control group was appropriate. Providing the Cancer Council booklets was in the end an intervention in and of itself, as few MEC participants received these booklets as part of 'usual care'. The Cancer Council booklets focus on factual information about diagnosis and treatment, and might have met participants' most proximal information needs [49], which is particularly reflected in the impact of the booklets on patients' uncertainty. Hence, future studies might examine the impact of providing the Cancer Council booklets initially and then tailoring the content of *Coping-Together* to match patients' and partners' specific needs related to coping.

Strengths and limitations.

Notwithstanding the exploratory nature of this pilot study, results lay some groundwork to further develop and test interventions for couples facing prostate cancer. A potential bias relating to participants who declined because their partner was not interested in the study is acknowledged. It may be the case that these couples simply did not feel they needed an intervention, or conversely that these couples might have been too distressed. In addition, the sample was largely homogenous; limiting generalizability of the findings. Some scales (e.g., CAHS) were adapted for partners, and due to the small sample size, their psychometric properties cannot be tested.

Conclusion

This study reported on the feasibility of evaluating one of the first self-directed coping skills intervention for couples facing cancer. This study highlighted a number of challenges, including patient refusal and ineligibility, and survey burden. Findings contribute to the growing evidence for couple-focus psychosocial interventions and a number of suggestions have been put forward for future studies.

Conflict of Interest: The authors declare that they have no conflict of interest.

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References

[1] Resendes LA, McCorkle R. Spousal responses to prostate cancer: an intergrative review. Cancer Invest. 2006;24:192-8.
[2] Lambert S, Girgis A, Lecathelinais C, Stacey F. Walking a mile in their shoes: anxiety and depression among caregivers of cancer survivors at six and 12 months post-diagnosis. Support Care Cancer. 2013;21:75–85.
[3] Lambert SD, Jones B, Girgis A, Lecathelinais C. Distressed partners and caregivers do not recover easily: adjustment trajectories among partners and caregivers of cancer survivors. Ann Behav Med. 2012;44:225-35.
[4] Boyes A, Girgis A, D'Este C, Zucca A. Flourishing or floundering? Prevalence and correlates of anxiety and depression among a population-based sample of adult cancer survivors 6 months after diagnosis. J Affect Disord. 2011;135:184-92.
[5] Northouse LL, Katapodi MC, Song L, Zhang L, Mood DW. Interventions with family caregivers of cancer patients: meta-analysis of randomized trials. CA: a Cancer Journal for Clinicians. 2010;60:317-39.
[6] Regan T, Lambert SD, Girgis A, Kelly B, Turner J, Kayser K. Do couple-based interventions make a difference for couples affected by cancer? BMC Cancer. 2012;12:279.
[7] Scott JL, Halford KW, Ward BG. United we stand? The Effects of a couple-coping intervention on adjustment to early stage breast or gynecological cancer J Consult Clin Psychol. 2004;72:1122-35.
[8] Regan T, Lambert S, Kelly B. Uptake and attrition in couple-based interventions for cancer: perspectives from the literature. Psychooncology 2013;22:2639-47. [6] Regan T, Lambert SD, Girgis A, Kelly B, Turner J, Kayser K. Do couple-based interventions make a difference for couples affected by cancer? BMC Cancer. 2012;12:279.
[9] Jacobsen PB, Meade CD, Stein KD, Chirikos TN, Small BJ, Ruckdeschel JC. Efficacy and costs of two forms of stress management training for cancer patients undergoing chemotherapy. J Clin Oncol. 2002;20:2851-62.
[10] Beatty L, Koczwara B, Rice J, Wade T. A randomised controlled trial to evaluate the effects of a self-help workbook intervention on distress, coping and QOL after breast cancer diagnosis. Med J Aust. 2010;193(5 Suppl):S68-73.
[11] Lambert SD, Girgis A, Turner J, Regan T, Candler H, Britton B, et al. "*You need something like this to give you guidelines on what to do*": Patients' and partners' use and perceptions of a self-directed, coping skills training resource. Support Care Cancer. 2013;21:3451-60.
[12] Lambert SD, Girgis A, Turner J, McElduff P, Kayser K, Vallentine P. A pilot randomized controlled trial of the feasibility of a self-directed coping skills intervention for couples facing prostate cancer: rationale and design. Health Qual Life Outcomes. 2012;10:119.
[13] Altman D, Schulz K, Moher D, Egger M, Davidoff F, Elbourne D, et al. The revised CONSORT statement for reporting randomized trials: explanation and elaboration. Ann Intern Med. 2001;134:663-94.
[14] National Comprehensive Cancer Network. Distress management clinical practice guidelines. National Comprehensive Cancer Network; 2012.
[15] Jacobsen PB, Donovan KA, Trask PC, Fleishman SB, Zabora J, Baker F, et al. Screening for psychologic distress in ambulatory cancer patients: a multicenter evaluation of the distress thermometer. Cancer. 2005;103:1494-502.
[16] Zigmond AS, Snaith RP. The Hospital Anxiety and Depression Scale. Acta Psychiat Scand. 1983;67:361-70.
[17] Bjelland I, Dahl A, Haug T, Neckelmann D. The validity of the Hospital Anxiety and Depression Scale: an updated literature review. J Psychosom Res. 2002;52:69-77.
[18] Weiss. D. S., Marmar CR. The impact of event scale – revised. In: Wilson JP, Keane TM, editors. Assessing psychological trauma and PTSD. New York: Guilford Press; 1997. p. 399–411.

[19] Manne S, Ostroff J, Fox K, Grana G, Winkel G. Cognitive and social processes predicting partner psychological adaptation to early stage breast cancer. Br J Health Psychol. 2009;14:49-68.
[20] Richardson J, Khan M, Iezzi A, Sinha K, Mihalopoulos C, Herrman H, et al. The AQoL-8D (PsyQoL) MAU Instrument: overview September 2009 Research paper39, Centre for Health Economics2009.
[21] Weitzner MA, Jacobsen PB, Wagner H, Friedland J, Cox C. The Caregiver Quality of Life Index–Cancer (CQOLC) scale: development and validation of an instrument to measure quality of life of the family caregiver of patients with cancer. Qual Life Res. 1999;8:55-63.
[22] Busby DM, Christensen C, Crane DR, Larson JH. A revision of the dyadic adjustment scale for use with distressed and nondistressed couples: contruct hierarchy and multidimensional scales. J Marital Fam Ther. 1995;21:289-308.
[23] Manne SL, Norton TR, Ostroff JS, Winkel G, Fox K, Grana G. Protective buffering and psychological distress among couples coping with breast cancer: the moderating role of relationship satisfaction. J Fam Psychol. 2007;21:380-8.
[24] Kessler TA. The Cognitive Appraisal of Health Scale: development of psychometric evaluation. Res Nurs Health. 1998;21:73-82.
[25] Mishel MH. The measurement of uncertainty in illness. Nurs Res. 1981;30:258-63.
[26] Lambert SD, Yoon H, Ellis K, Northouse L. Measuring appraisal during advanced cancer: psychometric testing of the appraisal of caregiving scale. Patient Educ Couns. 2015 [Epub ahead of print].
[27] Northouse LL, Mood DW, Schafenacker A, Montie JE, Sandler HM, Forman JD, et al. Randomized clinical trial of a family intervention for prostate cancer patients and their spouses. Cancer. 2007;110:2809-18.
[28] Lewis FM. Family Home Visitation Study Final Report. Bethesda, MD: National Cancer Institute, National Institutes of Health.; 1996.
[29] Wolf MS, Chang CH, Davis T, Makoul G. Development and validation of the Communication and Attitudinal Self-Efficacy scale for cancer (CASE-cancer). Patient Educ Couns. 2005;57:333-41.
[30] Carver CS. You want to measure coping but your protocol's too long: consider the Brief COPE. Int J Behav Med. 1997;4:92-100.
[31] Cooper C, Katona C, Orrell M, Livingston G. Coping strategies, anxiety and depression in caregivers of people with Alzheimer's disease. Int J Geriatr Psychiatry. 2008;23:929-36.
[32] Feldman BN, Broussard CA. The influence of relational factors on men's adjustment to their partners' newly-diagnosed breast cancer. J Psychosoc Oncol. 2005;23:23-43.
[33] Bodenmann G. Dyadisches Coping Inventar: Testmanual [Dyadic Coping Inventory: Test Manual]. Bern, Switzerland: Huber; 2008.
[34] Girgis A, Shih STF, Lambert SD, Mihalopoulos C. My Cancer Care Cost Diary University of New South Wales & Deakin University 2011.
[35] Northouse L, Rosset T, Phillips L, Mood D, Schafenacker A, Kershaw T. Research with families facing cancer: the challenges of accrual and retention. Res Nurs Health. 2006;29:199-211.
[36] Hacking B, Wallace L, Scott S, Kosmala-Anderson J, Belkora J, McNeill A. Testing the feasibility, acceptability and effectiveness of a 'decision navigation' intervention for early stage prostate cancer patients in Scotland--a randomised controlled trial. Psychooncology. 2013;22:1017-24.
[37] Berglund G, Petersson LM, Eriksson KC, Wallenius I, Roshanai A, Nordin KM, et al. "Between Men": a psychosocial rehabilitation programme for men with prostate cancer. Acta Oncol. 2007;46:83-9.
[38] Lambert SD, Pallant J, Clover K, Britton B, King M, Carter G. Using Rasch analysis to examine the Distress Thermometer's cut-off scores among a mixed group of patients with cancer. Quality of Life Research. 2014;23(8), 23, 2257-2265.
[39] Linden W, Satin JR. Avoidable pitfalls in behavioral medicine outcome research. Ann Behav Med. 2007;33:143-7.

[40] Schneider S, Moyer A, Knapp-Oliver S, Sohl S, Cannella D, Targhetta V. Pre-intervention distress moderates the efficacy of psychosocial treatment for cancer patients: a meta-analysis. J Behav Med. 2010;33:1-14.
[41] Lambert SD, Kelly B, Boyes A, Cameron A, Adams C, Proietto A, et al. Insights into preferences for psycho-oncology services among women with gynaecologic cancer following distress screening. J Natl Compr Canc Netw. 2014;12:899-906.
[42] van Scheppingen C, Schroevers MJ, Pool G, Smink A, Mul VE, Coyne JC, et al. Is implementing screening for distress an efficient means to recruit patients to a psychological intervention trial? Psychooncology. 2013;23:516–23.
[43] Porter SR. Raising response rates: What works? New Directions for Institutional Research. 2004;2004:5-21.
[44] Sahlqvist S, Song Y, Bull F, Adams E, Preston J, Ogilvie D, et al. Effect of questionnaire length, personalisation and reminder type on response rate to a complex postal survey: randomised controlled trial. BMC Med Res Methodol. 2011;11:62.
[45] Kalantar JS, Talley NJ. The effects of lottery incentive and length of questionnaire on health survey response rates: a randomized study. J Clin Epidemiol. 1999;52:1117-22.
[46] Mond JM, Rodgers B, Hay PJ, Owen C, Beumont PJ. Mode of delivery, but not questionnaire length, affected response in an epidemiological study of eating-disordered behavior. J Clin Epidemiol. 2004;57:1167-71.
[47] Lavrakas PJ. Encyclopedia of survey research methods. Thousand Oaks, Calif.: SAGE Publications; 2011.
[48] van den Brink M, van den Hout WB, Stiggelbout AM, Putter H, van de Velde CJH, Kievit J. Self-reports of health-care utilization: Diary or questionnaire? Int J Technol Assess Health Care. 2005;21:298-304.
[49] Rutten LJ, Arora NK, Bakos AD, Aziz N, Rowland J. Information needs and sources of information among cancer patients: a systematic review of research (1980-2003). Patient Educ Couns. 2005;57:250-61.