

A parallel-group, randomised controlled trial of a multimedia, self-directed, coping skills training intervention for patients with cancer and their partners: design and rationale

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ABSTRACT

Introduction: Coping skills training interventions have been found to be efficacious in helping both patients and their partners manage the physical and emotional challenges they face following a cancer diagnosis. However, many of these interventions are costly and not sustainable. To overcome these issues, a self-directed format is increasingly used. The efficacy of self-directed interventions for patients has been supported; however, no study has reported on the outcomes for their partners. This study will test the efficacy of *Coping-Together*—a multimedia, self-directed, coping skills training intervention for patients with cancer and their partners.

Methods and analysis: The proposed three-group, parallel, randomised controlled trial will recruit patients diagnosed in the past 4 months with breast, prostate, colorectal cancer or melanoma through their treating clinician. Patients and their partners will be randomised to (1) a minimal ethical care (MEC) condition—selected Cancer Council New South Wales booklets and a brochure for the Cancer Council Helpline, (2) *Coping-Together* generic—MEC materials, the six *Coping-Together* booklets and DVD, the Cancer Council Queensland relaxation audio CD and login to the *Coping-Together* website or (3) *Coping-Together* tailored—MEC materials, the *Coping-Together* DVD, the login to the website and only those *Coping-Together* booklet sections that pertain to their direct concerns. Anxiety (primary outcome), distress, depression, dyadic adjustment, quality of life, illness or caregiving appraisal, self-efficacy and dyadic and individual coping will be assessed before receiving the study material (ie, baseline) and again at 3, 6 and 12 months postbaseline. Intention-to-treat and per protocol analysis will be conducted.

Ethics and dissemination: This study has been approved by the relevant local area health and University ethics committees. Study findings will be disseminated not only through peer-reviewed publications and conference presentations but also

ARTICLE SUMMARY

Article focus

- Coping skills training interventions to promote patients' illness adjustment following a cancer diagnosis have been trialled, but equivalent research efforts to identify effective support for their partners are scarce, despite partners reporting as much if not more distress than patients.
- This study will examine the efficacy and cost-efficacy of a novel, evidence-based, multimedia, self-directed coping skills training intervention to empower patients and partners to manage the physical and psychosocial challenges posed by a cancer diagnosis.
- To the best of our knowledge, *Coping-Together* is the first intervention of its kind for couples adjusting to a recent cancer diagnosis.

Key messages

- *Coping-Together* is an innovative coping skills training intervention that targets patients as well as their partners, and translates current, evidence-based strategies for effective illness self-management and coping into a readily accessible format that couples can use where and when they need to.
- Over a 12-month period, this trial will directly examine the efficacy of *Coping-Together* in not only reducing negative psychological outcomes but also on a range of outcomes known to impact patients' and partners' cancer experience (eg, self-efficacy and dyadic coping).
- The self-directed format of this intervention has the potential to address issues of access to psychosocial support, especially for couples in non-metropolitan areas. In addition, the self-directed nature of *Coping-Together* means that it has the potential to be cost-effective and be integrated into practice without increasing pressures on the oncology workforce.

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ARTICLE SUMMARY

Strengths and limitations of this study

- Strengths include the projected sample size, recruitment from multiple sites across states and the use of a longitudinal design. Also, *Coping-Together* covers a broad range of cancer-related challenges identified to be common unmet needs of couples facing cancer. The cost-efficacy of the intervention will be directly assessed in this trial, an important consideration as economic evaluation is an often overlooked element of intervention research.
- Challenges include recruitment and retention of the target population (which is vulnerable and facing the acute stress of a cancer diagnosis), and the longitudinal nature of the design potentially increases the likelihood of attrition.

through educational outreach visits, publication of lay research summaries in consumer newsletters and publications targeting clinicians.

Trial registration: Australian New Zealand Clinical Trials Registry ACTRN12613000491763 (03/05/2013)

Although substantial progress in the early detection and treatment of cancer means that the 5-year relative survival is now 66% for all cancers combined,¹ a cancer diagnosis is still appraised as a life-threatening illness and elicits greater distress than any other medical diagnosis.² From the time of diagnosis and throughout treatment, patients and their partners contend with a wide range of complex physical (eg, treatment side effects), psychosocial (eg, fear, uncertainty, anxiety) and health-care challenges.^{3–9} The complexity of the situation is further heightened, as patients and partners contend with any number of these challenges at the same time that they are also trying to remain afloat with other life priorities.⁶

The difficulties experienced in managing cancer challenges are such that approximately one third of the patients experience high levels of physical or psychological distress,^{2 6 10 11} with some studies reporting comparable, if not higher, burden and distress among their partners.^{12–14} This might, in part, be attributed to partners' tendency to subjugate their own needs for those of the patient and to protect patients from additional distress, often at the expense of their own emotional well-being. Although it is generally assumed that elevated anxiety and depression are confined to the acute post-diagnosis phase, a few studies have found that patients and partners experience chronic distress well into survivorship.^{15 16} This is concerning as high distress has been associated with lower treatment adherence,^{17 18} lower quality of life,^{11 19 20} higher incidence of cancer-related symptoms and side effects,²¹ higher health-risk behaviours¹⁷ and reduced-workplace productivity.²²

Given the substantial burden of cancer, considerable research has focused on the impact of patients' and partners' coping with cancer challenges on their health

and well-being.^{14 23} In their seminal book on stress and coping, Lazarus and Folkman²⁴ defined coping as "cognitive and behavioural efforts to manage the demands of a situation or condition that is appraised as taxing or exceeding the resources of the person." Coping is typically characterised either as problem-focused coping (alter the stressful situation using strategies such as information-seeking, planning and problem solving) or emotion-focused coping (regulate situation-related emotions using strategies such as positive reappraisal and behavioural disengagement) and further considered for their adaptive versus maladaptive nature. The assumption is that if individuals use adaptive coping and are able to regain a sense of control over cancer challenges and negative emotions, they are then less likely to experience distress.²⁵ In this sense, coping is not only a valuable explanatory concept regarding variability in response to stress, it can also serve as a portal for intervention, that is, if adaptive coping skills are not known, they can then be learnt.^{23 26} Despite conflicting results, most studies support the notion that increasing patient engagement with the stressor, through both problem-focused and emotion-focused coping, is generally associated with more positive adjustment than when less functional coping responses are used (eg, avoidance and denial).^{13 25 26} A number of studies have also corroborated these findings among partners of individuals with cancer.^{14 27}

Beyond individual approaches to coping, recent studies have further considered how patients and partners interact as they attempt to cope together with cancer-related stressors and challenges (termed dyadic coping).^{13 28 29} The evidence on the impact of different dyadic coping strategies mirrors to a certain extent that of individual coping, whereby adjustment is greater when patients and partners respond to each other's stress, view cancer challenges as a shared problem and engage in joint problem solving that involves the pooling of resources.^{28 29} Berg *et al*²⁸ found that the relationship between collaborative coping and illness adjustment for men diagnosed with prostate cancer and their wives was partially moderated by heightened perceptions of coping effectiveness. Conversely, when patients and/or partners use avoidant coping,^{13 30} control³⁰ or protective buffering³¹ illness adjustment was compromised.

On the basis of the aforementioned evidence on individual and dyadic coping, considerable research efforts have focused on the development of coping skills training interventions to maximise the use of adaptive coping by patients and partners and so decrease physical and psychological distress in response to cancer challenges.^{2 32} Coping skills fostered by these interventions typically include problem solving, symptom management, communication (with family/friends or health-care professionals) and stress management. A number of reviews and meta-analyses have supported the efficacy of such multicomponent coping skills training interventions in decreasing patient and partner anxiety and

increasing quality of life, particularly if these are based on principles of cognitive behaviour therapy.^{26–33} Traditionally, these interventions have mainly focused on how patients cope with cancer-related challenges; however, with the increased recognition of the substantial burden of cancer on partners and the reciprocal relationship between partner's reactions to the cancer diagnosis,¹² coping skills training interventions are increasingly targeting both patients and partners as a unit.³⁴ Recent reviews have suggested that, in some contexts, couple-based interventions might be more efficacious in achieving optimal patient and partner adjustment than individual-based interventions.^{34–36} This might in part be attributed to the shared learning that occurs in couple-based coping skills training interventions.³⁴

Although couple-based coping skills interventions seem promising for patients and/or their partners, issues pertaining to their accessibility and delivery linger.³² Most coping interventions are labour intensive, requiring access to highly trained healthcare professionals, limiting their long-term sustainability due to high costs and problems with accessibility in rural and regional areas. Furthermore, there is evidence to suggest that conventional interventions may not be accessed by patients, due to personal preference, geographical barriers and mobility issues.^{32–38} One study found the uptake rate of referrals to psychosocial services by distressed patients to be as low as 14%.³⁹ This suggests that service providers need to consider alternate approaches to ensure that the coping interventions for couples are not only efficacious and cost-effective but also accessible and sustainable. Using a group format instead of an individual format has been proposed to address cost issues.⁴⁰ However, research has been equivocal regarding the suitability of these interventions in comparison to individual ones.^{40–41} In addition, failure to create and sustain a functioning group is a challenge with some patient populations, which in turn might compromise the efficacy of the intervention.⁴⁰ To overcome some of the challenges, while maintaining cost-effectiveness, the use of a self-directed approach has been proposed.⁴²

Self-directed (also termed self-help or self-administered) interventions address some of the issues surrounding access to face-to-face interventions and provide couples with greater flexibility regarding when and how they engage with the intervention content. There is a growing body of evidence to suggest that self-directed coping skills training interventions are cost-effective and acceptable to patients.^{42–45} Furthermore, research supports the efficacy of self-directed interventions for enhancing patient well-being,^{42–45} especially for patients reporting elevated levels of distress⁴⁴ or high uncertainty.⁴³ Regrettably, all self-directed interventions reviewed to date are mainly developed to directly address patients' concern, neglecting those of the partners. To address this gap in the literature our team has recently developed *Coping-Together*,^{46–48} a self-directed

coping skills training intervention for couples affected by cancer. This study will examine both the efficacy and cost-efficacy of this intervention.

COPING-TOGETHER INTERVENTION

Coping-Together is an evidence-based, multimedia, self-directed coping skills training intervention to provide couples with the resources they need to confront the challenges posed by the cancer diagnosis and enhance their ability to cope with these.^{46–48} *Coping-Together* takes a holistic approach to coping with cancer by addressing a range of common physical, social and psychological challenges. The Medical Research Council framework for developing and evaluating complex interventions⁴⁹ was used to guide the development and evaluation of *Coping-Together*.

Theoretical underpinnings

Coping-Together builds on three main theoretical frameworks:

1. Lazarus and Folkman's Stress and Coping framework,⁵⁰ which assumes that if individuals are able to cope and regain a sense of control over cancer challenges, they are then less likely to experience distress.
2. Bodenmann's⁵¹ framework of dyadic coping extends Lazarus and Folkman's framework by acknowledging the reciprocal nature of stress and coping within couples and has become increasingly popular in the cancer literature.⁵²
3. Bandura's⁵³ self-efficacy theory, which posits that people are likely to engage in activities to the extent that they perceive themselves to be competent at those activities. Individuals are postulated to achieve self-efficacy through various means, including performing a task successfully, witnessing other people successfully completing a task, being persuaded that one has the skills to succeed and managing psychological responses that can adversely impact on how a person feels about their abilities in a particular situation.⁵⁴

A detailed description of how each of these frameworks has guided the development of *Coping-Together* has been published elsewhere.⁴⁸

Content

Coping-Together encourages patients and their partners to try new skills and strategies demonstrated to be effective in helping couples: (1) manage symptoms and side effects, (2) forge a strong relationship with the healthcare team, (3) cope with treatment decision-making, (4) locate additional support, (5) communicate about cancer and (6) manage worries and emotions. These challenges were selected based on an initial perusal of the literature and content of existing couple-based interventions. *Coping-Together* collates the evidence on coping with these challenges and presents these as 'suggestions'

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to patients and partners across six booklets, a DVD, a relaxation CD, and a website.

For each key cancer challenge addressed by this intervention, the booklets focus on providing the following type of information: (1) social comparison information (testimonial and quotes from other patients and partners), (2) evidence-based, concrete 'suggestions' to manage the challenges, (3) comments about the effectiveness of these strategies from others diagnosed with cancer and (4) empirical evidence supporting the coping 'suggestion'. In addition, the booklets include several cognitive-behavioural therapy-based exercises, adapted from other self-directed coping skills interventions with patients^{37 55} or developed by experienced clinicians and designed to encourage active learning. [Table 1](#) summarises the content of each booklet. To ensure the accuracy of the information, the booklets were reviewed by experts in the field, including clinicians and researchers and the experts' endorsement is included throughout each booklet.

The *Coping-Together* DVD features a clinician who delivers key content of the booklets and includes scenarios with couples (actors) to demonstrate specific coping

skills. The Cancer Council Queensland relaxation CD is included to supplement the *Dealing with Stress and Worry* booklet. Lastly, the *Coping-Together* website contains the booklets and DVD content, complemented with interactive features such as a question checklist generator, and tips for addressing common negative thoughts. The website also contains an announcements page for communication postings by the research team, contacts page for participants to communicate with the research team and links to a variety of credible information and support websites.

Feasibility testing of the Coping-Together booklets

A recent acceptability study of the *Coping-Together* booklets supported its self-directed format and its practical approach. Patients and partners identified a number of benefits to using these booklets, including increased awareness of challenges to prepare for, facilitated independent coping, increased hope that something can help you 'pull through', provided a sense of normality, connected patients and partners to people and services and complemented support received from healthcare professionals.^{46 47 56} Many couples rated the booklets

Table 1 *Coping-Together* booklet content

Booklet title	Description	Example Challenges	Example coping strategies
Getting What You Need From Your Health Care Team	Working with your medical team, knowing how to ask the right questions, getting and understanding the information you need	We don't know what questions to ask We leave our appointments feeling we didn't get what we wanted	Use question checklists Prepare for appointments, communicate assertively and use other methods of communication
Making Your Treatment Decision	Considering your options, treatment planning and adjusting to treatment-related delays	We feel overwhelmed by options We want more of a say in the decision	Identify what is most important to you, talk to your healthcare team and use decision aids Use assertive communication and consider a second opinion
Getting on Top of Symptoms	Coping with common treatment side effects	Fatigue Pain	Use a symptom diary, talk to your healthcare team and use self-care strategies
Dealing with Stress and Worry	Addressing the emotional reactions to diagnosis and treatment	I feel sad, down and/or isolated I'm having difficulties sleeping	Do pleasant activities and connect with others Practice good sleep hygiene throughout the day
Supporting Each Other	Enhancing your communication and connection to your partner, and adjusting to changes that may arise in your relationship	I just don't know how to make my partner feel better I'm stressed by changes in my roles and responsibilities	Use listening skills, body language and empathy, avoid roadblocks to listening well Negotiate changes in roles and responsibilities and accept offers of help from others
Getting the Support You Need	Finding appropriate support to address practical, emotional, financial, legal and informational needs	We need more information We need legal help	Identify your information needs, identify the right source of information, check the information credibility and manage information overload Identify the legal issues you need addressed and find a service that is right for you

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highly and the concrete coping strategies described was a feature that set *Coping-Together* apart from other resources. Participants also made particular comments on the appropriateness of the resource focusing on the couple, rather than on the individual.

STUDY AIMS AND HYPOTHESES

The *primary aim* of this study will be to assess the efficacy of *Coping-Together*, in comparison to a minimal ethical care (MEC) condition, in decreasing anxiety in patients diagnosed with breast, prostate or colorectal (bowel) cancer or melanoma and their partners at 3, 6 and 12 months postbaseline.

The *secondary aims* will be to assess (1) the efficacy of *Coping-Together* in comparison to the MEC condition in decreasing distress and depression, and increasing positive-illness appraisal or caregiving appraisal, self-efficacy, quality of life, relationship satisfaction and positive individual and dyadic coping at 3, 6 and 12 months postbaseline; (2) the efficacy of generic *Coping-Together* in comparison to a tailored version of *Coping-Together* in enhancing primary and secondary outcomes over time and (3) cost-efficacy of *Coping-Together* in comparison to the MEC condition.

The *tertiary aim* will be to explore moderators of outcomes, including distress, social support, self-efficacy, information needs and preferences and relevance and use of the material sent to address challenges experienced.

Hypotheses

- Primary hypothesis: Significantly fewer *Coping-Together* participants will experience anxiety at 3, 6 and 12 months postbaseline than MEC participants.
- Secondary hypotheses: (1) From the health and broader societal perspective, *Coping-Together* (generic or tailored) will be more cost-efficacious than the MEC condition and (2) *Coping-Together* participants will experience significantly less distress and depression and more positive illness or caregiving appraisal, self-efficacy, quality of life, relationship satisfaction and positive individual and dyadic coping at 3,6 and 12 months postbaseline than MEC participants.

- Tertiary hypotheses: (1) Couples in the tailored *Coping-Together* condition will report greater use of the resource and higher illness adjustment across primary and secondary outcomes than couples in the generic *Coping-Together* condition and (2) the significant changes over time in anxiety among groups will be moderated by distress, social support, self-efficacy, information needs and preferences, resource use and perceived relevance of the material sent to address the challenges experienced.

METHODS/DESIGN

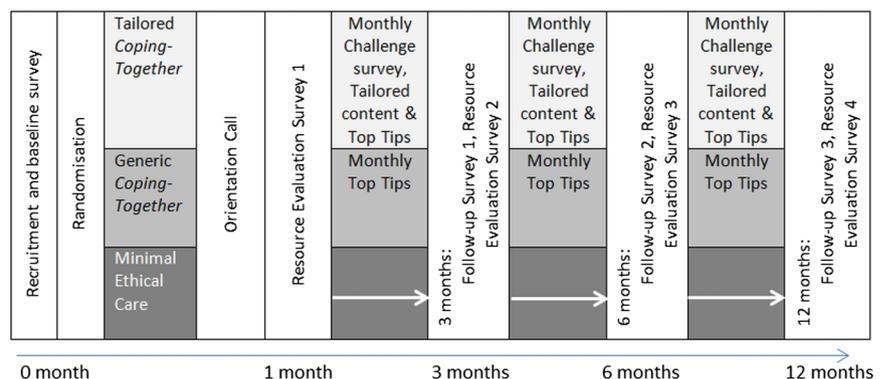
Design

The proposed study is a multicentre, stratified, double-blind, three-group, parallel, randomised controlled trial to compare generic *Coping-Together*, tailored *Coping-Together* and the MEC condition (see figure 1). The CONSORT statement⁵⁷ guided the design of this study.

Sample and setting

Patients will be recruited from participating private and public outpatient, multidisciplinary oncology clinics in Australia (Australian Capital Territory, New South Wales, South Australia, Western Australia and Queensland). These clinics typically exist within large, general metropolitan or rural hospitals. Inclusion criteria are (1) a patient recently diagnosed (within 4 months) with a primary, early-stage breast, prostate or colorectal (bowel) cancer or melanoma and receiving or planning to receive cancer treatment with curative intent, (2) has a partner (spouse, boy/girlfriend or de facto) who is also willing to participate in the study, (3) the patient or their partner scores ≥ 4 on the Distress Thermometer (DT) and (4) the patient and partner are sufficiently fluent in English and cognitively able to read study materials and complete surveys. The patient's and the partner's consents are required for the couple to participate in this trial. These inclusion criteria were selected to reflect current recommendations for intervention studies in psycho-oncology, including targeting couples with elevated levels of distress to avoid the potential for floor effect.⁵⁸

Figure 1 Study design and groups.



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Sample size

Assuming that the SD of patients' and partners' scores on the Hospital Anxiety and Depression Scale-Anxiety subscale (HADS-A) is 4^{14 39} and the correlation of baseline and follow-up measurement is approximately 0.5, 133 couples per group will be sufficient to have 90% power to detect the minimal clinically significant difference of 1.5 on the HADS-A,⁵⁹ at the 2.5% significance level. This corresponds to over 80% power to detect a difference in the level of anxiety between treatment groups at follow-up of 17% (eg, 37% MEC vs 20% *Coping-Together*). The 2.5% significance value is chosen to adjust for the multiple comparisons, because the primary endpoint will be tested on the patient and partner separately. Assuming that the correlation between baseline and follow-up measurements of each of the secondary outcomes is similar to that of anxiety, the study will have 90% power to detect a difference between treatment groups of 0.375 SDs in each secondary outcome at the 2.5% significance level. In the unusual situation where there is no correlation between baseline and follow-up values, the study will have 90% power to detect a difference of 0.438 SDs between groups at the 2.5% significance level. To account for a 10% loss to follow-up at each time point,⁶⁰ 187 couples per group will be recruited at baseline. Based on our most recent pilot,⁴⁸ it is estimated that recruitment will take 18 months.

Procedures

Most participants will be referred to the study by their main treating clinicians, who will identify patients meeting the medical and English fluency inclusion criteria, and briefly introduce the study to patients, provide them with the study brochure and obtain verbal or written consent to pass on their contact information to the research team. The research team will then follow-up with potential participants in approximately 1 week to confirm interest, further screen for their eligibility, and mail a study pack to eligible participants. The study pack will include an information statement, a consent form and baseline survey and a study pack to pass on to their partner. Couples will then be asked to return their consent forms and surveys, using the reply paid envelopes provided, with non-responders followed-up, initially by mail and then by phone. Potential participants can refuse to supply their contact details to their clinician and only take the brochure. Study participation will not be further discussed with their healthcare team.

Alternative recruitment strategies to cater to site-specific requirements include having an on-site research assistant (RA) to explain the study and provide the study pack or the referring clinician may choose to mail invitation letters and study brochures to patients who meet the eligibility criteria. The study will also be promoted by cancer care support organisations and through various media facilities, including print (eg, cancer care

organisations consumer newsletters), radio, television and online (eg, Facebook). Interested individuals will also be able to contact the research team directly for more information. Study posters and brochures will also be available at all recruitment sites. This protocol has been approved by relevant local area health and University ethics committees.

Randomisation of group assignment

A computer-generated randomisation schedule with block lengths of variable size (6 or 9 couples) and stratified by cancer type will be programmed into a secure web-based randomisation service, only accessible to the main project manager. Allocation concealment will be ensured, as the website will not release the randomisation code until participants have returned their consent forms/baseline surveys and their consent and information is entered into the secure website.

Coping-Together and MEC conditions

At recruitment, participants will be informed that they will be mailed one of the three packs: the generic *Coping-Together* pack, the tailored *Coping-Together* pack or the MEC condition pack. All couples will receive their respective resource pack within 2 weeks of returning their baseline survey, and they will be informed that they can use any or all of these resources sent to them, at their own discretion and pace throughout the duration of the study.

Blinding

Participants are blinded to study hypotheses and group allocation, as they do not know which pack is the 'study' intervention, and the survey and contact with the research team are comparable across groups. Selected RA(s) will not be blinded to group allocation, and as part of their role will facilitate the randomisation of participants, assign participants identification numbers and follow-up with participants in accordance with the protocol. The chief investigators and statisticians will remain blinded to group allocation until the database is locked.

MEC condition

A 'no treatment' control group will not be employed to ensure that participants are blinded to group allocation and because participants have reported elevated distress. Couples randomised to this condition will receive two booklets (cancer-specific and the 'Caring for Someone with Cancer' booklets) from the 'Understanding Cancer Series' available at the Cancer Council New South Wales along with a Cancer Council Helpline brochure. One to 2 weeks thereafter, a member of the research team will phone the participants to orient them to the materials received (anticipated duration=20–35 min).

Generic Coping-Together

Generic *Coping-Together* couples will receive the six *Coping-Together* booklets previously described, the

Coping-Together DVD, a relaxation audio CD and the login to the *Coping-Together* website. To ensure methodological equivalence of all groups, the generic *Coping-Together* group will also receive the relevant Cancer Council NSW booklets and Helpline brochure (as per the MEC condition). One to 2 weeks thereafter, a member of the research team will phone participants to orient them to *Coping-Together*. Then, monthly, the couples will be mailed a 'Top Tips' newsletter, featuring the timely aspects of the booklets.

Tailored Coping-Together

Patients and partners randomised to the tailored *Coping-Together* group will receive the log-in to the *Coping-Together* website and the DVD as well as an overview of the topics addressed by the *Coping-Together* booklets; however, throughout the study, they will only receive the *Coping-Together* booklet sections that pertain to their immediate concerns (main difference between this condition and generic *Coping-Together*). The first pack will be created on the basis of the challenges identified by the baseline survey, and will also contain the relevant Cancer Council NSW booklets and Helpline brochure (as per the MEC condition). Subsequent packs will be tailored based on the participant's responses to the Cancer-Related Challenge Scale, sent monthly throughout the study. Patients and partners might receive different tailored *Coping-Together* materials. Couples in this group will receive the orientation call previously described in the MEC condition.

Data collection

Initial distress screening with the DT

The DT will ask participants to rate their overall distress in the past week using a visual analogue scale ranging from 0='no distress' to 10='extreme distress'.¹⁷ Since its publication, the DT has quickly become the measure of choice for screening for distress, as it is short, simple to use and quick to interpret. To be eligible, either the patient or their partner must score 4 or above, which is the recommended cut-off score on this measure.^{61 62}

Survey

A survey will be completed at baseline (pen and paper) and at 3, 6 and 12 months postbaseline (pen and paper or online, according to participants' preferences) to measure the outcome variables, potential moderators, and sociodemographic and disease variables. [Table 2](#) summarises all measures that will be used. The primary outcome (anxiety) will be measured using the seven-item anxiety subscale of the Hospital Anxiety and Depression Scale,⁶³ the measure of choice to detect anxiety among patients with cancer^{64 65} and their partners.⁶⁶

Secondary outcomes (distress, depression, illness or caregiving appraisal, self-efficacy, quality of life, relationship satisfaction, individual and dyadic coping) will be measured by the DT,¹⁷ the Hospital Anxiety and Depression Scale depression subscale,⁶³ Kessler's

Cognitive Appraisal of Health Scale,⁶⁷ Mishel's Uncertainty in Illness Scale,⁶⁸ Caregiving Illness Appraisal Scale,^{69 70} the Communication and Attitudinal Self-Efficacy scale for cancer Scale,⁷¹ Strategies Used by People to Promote Health,⁷² Health Education Impact Questionnaire,⁷³ Caregiver Empowerment Scale,⁷⁴ Assessment of Quality of Life (AQoL-8D),⁷⁵ Caregiver's QOL Index-Cancer,⁷⁶ Spanier Dyadic Adjustment Scale,⁷⁷ the Brief COPE⁷⁸ and the Dyadic Coping Inventory.⁷⁹

Moderators will be measured at baseline and at 3, 6 and 12 months postbaseline, including unmet information needs (The Cancer Information Needs Survey—designed for the current study) and social support (MOS-Social Support Survey⁸⁰). Data pertaining the use/relevance of the resource, including coping skills learned will be collected shortly after receipt of the resource materials (first month) then again at 3, 6 and 12 months by the Resource Evaluation Survey. The Profile of Preferences for Cancer Information will also be completed within 1 month of receipt of the intervention materials. The main survey will also measure key sociodemographic, disease and medical variables.

Cost data

For the purpose of the economic analysis, couples will be asked to provide consent for the research team to access their Medicare data (Australia's universal health insurance scheme). Additional questions regarding disruption to usual activities, hospital admissions, use of private allied healthcare services, use of community support services and the use of complementary/alternative therapies will be assessed in the baseline and follow-up surveys.

Orientation phone calls

In addition, all couples (regardless of group allocation) will be contacted by a member of the study team for an initial orientation phone call, approximately 1–2 weeks after they receive their respective resource package. The intent of the orientation call is to ensure that participants received the material, to provide an overview of the content and to explore intended use of the resource. With the participant's consent, all phone calls will be audio recorded and coded to ascertain and monitor the topics that are discussed and as a quality check to ensure that counselling was not provided.

Strategies to enhance recruitment and minimise attrition

Based on other couple-based intervention studies⁸³ and our pilot study,⁴⁷ the following strategies will be used to maximise recruitment and minimise attrition: (1) the study will be presented to the staff at each participating clinic to elicit support; (2) bright posters will be displayed in the clinics; (3) couples will be approached at a time when the psychological aspects of their illness are more salient, thereby reinforcing psychosocial support as an important aspect of overall health⁸⁴;

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Table 2 *Coping-Together* study outcomes and measures

Outcomes	Measures and psychometrics	
	Patients	Partners
Primary outcome		
Anxiety	Main survey: 7-item HADS-Anxiety Subscale ⁶³ ($\alpha=0.68-0.93$) ⁹¹	
Secondary outcome		
Depression	Main survey: 7-item HADS Depression subscale ⁶³ ($\alpha=0.68-0.93$) ⁹¹	
Distress	Main survey: Single-item Distress Thermometer ¹⁷	
Quality of life (QOL)	Main survey: 35-item Assessment of Quality of Life—8 Dimensions Scale ⁷⁵ (overall $\alpha=0.91$, subscale $\alpha=0.64-0.87$) ⁹²	Main survey. 35-item Assessment of Quality of Life—8 Dimensions Scale ⁷⁵ (overall $\alpha=0.91$, subscale $\alpha=0.64-0.87$) ⁹² Main survey. 35-item Caregiver's QOL Index-Cancer ($\alpha=0.91$) ⁷⁶
Relationship satisfaction	Main survey: 32-item Dyadic Adjustment scale ⁷⁷ ($\alpha=0.89-0.95$) ³¹	
Appraisal	Main survey: 28-item Kessler Cognitive Appraisal of Health Scale ($\alpha>0.70$) ⁶⁷ Main survey: 33-item Mishel's Uncertainty scale ($\alpha=.64-0.91$) ⁶⁸	Main survey. 28-item Kessler Cognitive Appraisal of Health Scale (adapted) ($\alpha>0.70$) ⁶⁷ Main survey. 33-item Mishel's Uncertainty scale ($\alpha=0.64-0.91$) ⁶⁸ Main survey. 27-item Appraisal of Caregiving Scale ($\alpha>0.85$) ^{69 70}
Self-efficacy	Main survey: 12-item Communication and Attitudinal Self-Efficacy Scale for cancer (CASE-Cancer; $\alpha=0.76-0.77$) ⁷¹ Main survey: 29-item Strategies Used by People to Promote Health (SUPPH, $\alpha=0.76-0.92$) ⁷² Main survey: 40-item Health Education Impact Questionnaire (heiQ, $\alpha=0.70-0.89$) ⁷³	Main survey. 12-item Communication and Attitudinal Self-Efficacy Scale for cancer (CASE-Cancer (adapted); $\alpha=0.76-0.77$) ⁷¹ Main survey. 29-item Strategies Used by People to Promote Health (SUPPH, $\alpha=0.76-0.92$) ⁷² Main survey. 48-item Caregiver Empowerment Scale ($\alpha=0.76-0.92$) ⁷⁴ Main survey. 40-item Health Education Impact Questionnaire (adaptation, heiQ) ⁷³
Dyadic and individual coping	Main survey: 37-item Dyadic Coping Inventory ($\alpha=0.73-0.96$) ⁷⁹ Main survey: 28-item Brief COPE measures 14 individual-level coping strategies ($\alpha=0.60-0.90$) ⁷⁸	
Moderators		
Information-seeking preferences	Resource evaluation survey: 45-item Profile of Preferences for Cancer Information (PPCI) (adapted for partners) ^{81 82}	
Information needs	Main survey: 37-item Cancer Information Needs Survey designed for use in the current study to assess the importance of receiving information on a variety of cancer-related topics, and the participant's degree of satisfaction with the information received to date.	
Social support	Main survey: 19-item MOS Social Support Survey ($\alpha=0.91-0.97$) ⁸⁰	
Cancer-related challenges	Main survey (all groups) and monthly for the tailored group: 28-item Cancer-Related Challenge Scale, developed for use in the current study, aligns with the challenges presented in the <i>Coping-Together</i> intervention materials and will assist in assessing resource relevance	
Use and relevance of Material sent	Resource evaluation survey: Developed for use in the current study, and ascertains the extent to which participants used the material sent to them, including proportion of the material used and amount of time spent reading the material. Also examines the coping strategies learnt and the usefulness of the resource	
Economic evaluation	Main survey: 26-items developed for the current study assessing health service usage, hospital admissions, out-of-pocket expenses, medication usage, community and pastoral care services, disruption to work and usual activities	

(4) a self-directed intervention reduces participation burden, as participants can work through the materials at home and at their own pace and (5) communication with the *Coping-Together* participants will be maintained for the duration of the study period to encourage attachment and completion (ie, monthly 'Top Tips' newsletter).

DATA MANAGEMENT

All participant consent forms and surveys will be stored in a locked cabinet, as soon as logged by the project manager in the log and monitoring database. The data will be entered in a database specifically designed for this trial by trained personnel. A random 10% of all data entry will be double-checked.

DATA ANALYSIS

Analysis of primary and secondary outcomes

Intention-to-treat and per protocol (ie, patients and carers who used the intervention for most of the duration of the study) analyses will be conducted. The primary outcome, anxiety, will be measured repeatedly across time, and therefore analysed using generalised-linear mixed models (GLMMs). In this context, GLMMs are similar to linear regression models, but take account of the correlation between repeated measurements on individuals. Sensitivity analysis will explore the robustness of the results against a range of missing data assumptions.⁸⁵ Separate analyses for patients and partners will examine differences between conditions in anxiety at 3 and 6 months. The outcome in the model will be the participants' scores at 3 and 6 months, the main predictor variable will be treatment group and the participants' baseline score will be included as a covariate. Similar models will be used to determine if differences between groups are sustained to 12 months. GLMM will also be used to explore the secondary outcome measures. Multiple testings will be handled using the Benjamini and Hochberg method⁸⁶ with a nominal α set at 0.05.

Economic analysis

This study will include a formal economic evaluation to assess the cost-efficacy of the intervention. The economic evaluation will comprise a cost-consequences analysis whereby the incremental costs of the intervention will be compared with the full spectrum of outcomes included in the study. This means that a series of cost-efficacy ratios will be determined rather than just one—such an approach has been shown to be useful to decision-makers. The inclusion of the AQoL-8D⁷⁵ will also enable a cost-utility analysis to be undertaken whereby outcomes are expressed as generic quality adjusted life years (QALYs). Outcomes expressed as QALYs have the advantage of allowing practical judgements regarding the value for money credentials of the intervention to be made. The economic analysis will be largely from a societal perspective, although secondary analysis from narrower perspectives, such as health or government, will also be undertaken, as appropriate, to the different stakeholders of such a project. The actual costs of the interventions will be determined using information from the research team and provider records including interviews with key budgetary personnel to ensure all costs associated with the interventions have been captured. The Medicare data and information obtained during periodic follow-up surveys will be used to determine other resource use and costs incurred by patients and their partners.

The evaluation will first measure and value any change to the use of healthcare resources over the period of the study among the three arms of the trial and then compare any additional costs to the additional outcomes achieved. Standardised economic evaluation

techniques including incremental analysis of mean differences, dominance analysis (where more than two interventions are compared) and bootstrapping to determine CIs will be used in the evaluation.

Analysis of orientation calls

All audiorecordings will be analysed by the interviewer using a summary data collection form to monitor the content of the orientation calls.

ETHICS AND DISSEMINATION

Minor adverse events (eg, a participant being tearful and distressed during a session) will be logged and fed back to the study team. Serious adverse events (eg, expressing suicidal thoughts) will be reported immediately to the chief investigator and to the ethics committees. Any protocol amendments will be submitted to the ethics committees before these are implemented, and changes will also be communicated to other relevant organisations (eg, trial registry). Study findings will be disseminated not only through peer-reviewed publications and conference presentations but also through educational outreach visits and interactive educational meetings, publication of lay research summaries and recommendations for further actions in consumer newsletters and websites and publications targeting clinicians.

DISCUSSION

Coping-Together is an innovative coping skills training intervention that translates evidence-based strategies for effective illness self-management and coping into a readily accessible format that couples can use where and when they need to. To the best of our knowledge, *Coping-Together* is the first intervention of its kind for couples adjusting to a recent cancer diagnosis. Over a 12-month period, we will investigate how *Coping-Together* is used by both patients and their partners to address their main cancer-related challenges and examine how it impacts on the psychosocial outcomes of patients and partners, with a focus on anxiety, depression, distress, coping, self-efficacy, dyadic adjustment and quality of life. The findings of this trial will add to the literature arguing for greater psychosocial care in the acute post-diagnostic phase and early survivorship, while simultaneously identifying both individual-level and couple-level factors that contribute to patient and partner outcomes.

There are several strengths to this study and numerous potential benefits of the *Coping-Together* resource that make it potentially an invaluable addition to the psychosocial care of couples dealing with cancer. First, the projected sample size, recruitment from multiple sites across states and the use of a longitudinal design will address some of the methodological limitations of previous couple-based interventions in cancer care (eg, being under powered).⁸⁷ Second, *Coping-Together* covers a broad range of cancer-related challenges recently identified across three reviews as common unmet needs of

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couples facing cancer. Specifically, the areas identified as requiring greater inclusion in interventions that are covered by *Coping-Together* are strategies for communicating with healthcare professionals,^{7 87} addressing communication difficulties between partners,^{7 88} dealing with emotional reactions such as fear, uncertainty, anxiety and depression in both partners^{7 87 88} and learning new skills to overcome a lack of effective coping skills.^{87 88} Third, this trial will directly examine the efficacy of *Coping-Together* in not only reducing negative psychological outcomes but also on a range of outcomes known to impact patients' and partners' cancer experience (eg, self-efficacy, dyadic coping). Fourth, the self-directed format addresses issues of access to psychosocial support, especially for couples in non-metropolitan areas. The use of multiple formats also potentially increases the appeal of the resource, and therefore may increase utility to a broader population of cancer patients and their partners. Finally, the self-directed nature of *Coping-Together* means that it has the potential to be cost-effective and be integrated into practice without increasing pressures on the oncology workforce. The cost-efficacy of the intervention will be directly assessed in this trial, an important consideration as economic evaluation is an often overlooked element of intervention research.⁸⁹

Despite these strengths, there are also several challenges for the trial. The target population is vulnerable and experiencing an acute stressor, which in turn may impact on both recruitment and retention, a challenge identified by other trials with couples facing cancer.⁹⁰ Furthermore, the longitudinal nature of the design increases the likelihood of attrition. An additional challenge is whether the measures employed to assess change over time will be sensitive enough to detect clinically significant improvements experienced by the couples.⁸⁷ This challenge is partly mitigated by the integration of the Resource Evaluation Survey, which may help to clarify trends detected in the outcome data.

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Contributors SDL conceived the study, participated in its design, led the development of the *Coping-Together* resource and drafted the manuscript. AG, JT, JL and KK participated in the design of this study, provided critical

feedback on *Coping-Together* and provided feedback on the draft of this manuscript. CM and PME developed the economic and statistical analysis plan for the study and provided feedback on the draft of this manuscript. STFS and DB have critically reviewed all aspects of this study and the manuscript. All authors have read and approved the final manuscript.

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