The development of an online intervention (Care Assist) to support male caregivers of women with breast cancer: a protocol for a mixed methods study

Janelle V Levesque,1,2,3 Martha Gerges,1,2 Afaf Girgis1,2

ABSTRACT

Introduction It is projected that 17 730 women will be diagnosed with breast cancer in Australia in 2017, with 3114 of these predicted to be fatal. Caregiving for a person with cancer can significantly impact caregivers' physical and mental health. Many caregivers feel ill-prepared for this role, especially when care involves complex medical needs accompanied by the psychological challenges experienced following a cancer diagnosis.

Methods and analysis This study employs a convergent, parallel, mixed methods design combining an online survey with an optional interview. Eligible, consenting participants will be invited to participate in a survey to examine (1) participants' unmet needs, (2) challenges experienced throughout the cancer journey, (3) perceived self-efficacy to determine participants' level of confidence in undertaking caregiver tasks, (4) views regarding suitable content to include in a caregiver training intervention, (5) preferred method of intervention delivery (ie, website, smartphone application and/or interactive video), and (6) preferences for the timing of delivery of the intervention content (ie, ability to choose a module, access to the entire content or have a set order in which they receive the information). Caregivers will be eligible to participate if they (1) are male, (2) have previously cared for or are currently caring for a woman with breast cancer, (3) are aged over 18 years, and (4) do not currently suffer from a cognitive impairment or mental health condition (ie, depression, anxiety). Data analysis will include examination of differences in psychological outcomes and needs based on demographic variables, and mediation analysis to explore whether self-efficacy mediates the relationship of differences in psychological outcomes and needs based on demographic variables. The study uses a mixed methods design. Through the combination of quantitative and qualitative approaches, complex research questions can be explored.

Ethics and dissemination The study was reviewed and approved by two human research ethics committees. Content developed for the Care Assist intervention will need a phase II study exploring the views of caregivers on the developed intervention. The Cancer Related Challenges Scale is a relatively new measure with limited information currently available regarding psychometric properties.

INTRODUCTION

In the past 20 years, there has been a significant shift towards the provision of cancer care through ambulatory treatment centres. For example, in Australia, cancer care is primarily delivered through outpatient clinics, and in 2015–2016, 78% of cancer care in Australian hospitals was conducted in same-day clinics.1 This change in care delivery results in the transfer of care to informal caregivers, accompanied by increasing complexity of the tasks such caregivers are required to perform.2 3 An informal caregiver is any person who provides assistance to another person without training and economic reimbursement for the care they provide.4 In Australia, it is estimated that informal caregivers save the federal budget $40.9 billion, highlighting the economic value of the role that they provide.5

Caregiving has a significant impact on caregivers. However, caregiving comes at a cost for many,6 with some caregivers reporting high levels of anxiety and depression.7–9 burden
and unmet needs, declines physical well-being, and significant financial burden. Furthermore, there is evidence to suggest that some caregivers do not recover after a period of initial adjustment, creating an ‘at-risk’ group of caregivers. In light of this evidence, some argue that family caregivers should be considered a ‘co-user’ or ‘co-client’ of cancer services. However, in reality, most caregivers are not the recipient of care in relation to their caregiving role, and are often considered by healthcare providers as being outside their scope of responsibility, despite growing recognition of their unmet needs.

There is also evidence to suggest that caregivers’ physical and mental well-being may influence patient status. For example, a meta-analysis conducted by Hodges et al found that there is a positive correlation between patient and caregiver psychological distress. Self-efficacy, an individual’s belief in the ability to succeed in situations and accomplish tasks, has the potential to affect caregiver outcomes and positively impact on patients. Keefe et al. found that high self-efficacy for pain management tasks in caregivers was linked to increased patient energy and time spent out of bed, and reduced patients’ sense of feeling ill. Other studies have also shown beneficial outcomes for patients when their caregivers have received support, with improvements in patient depression and hopelessness, enhanced symptom management, and reduced symptom severity/intensity. Therefore, by supporting caregivers and improving their well-being and self-efficacy, there is the potential to enhance quality of life for patients with cancer.

Male caregivers of women with breast cancer continue to experience heightened levels of psychological stress even after treatment, (ie, surgery) has been undertaken by their loved one, lasting anywhere between 3 and 12 months, and this is directly related to their feelings and role as a caregiver. Similarly, a study conducted by Duggleby et al. found that male spousal caregivers have altered quality of life, which is positively influenced by hope and negatively influenced by guilt and method of coping with transition periods. Coping strategies used by male caregivers include gender-specific attitudes, which were in line with feelings of masculinity, such as focusing on the task at hand or keeping stress to themselves.

Given the high burden associated with being a caregiver, as well as the potential benefits to both caregivers and patients if caregivers are appropriately supported in their role, there is an imperative to consider whether available supports are sufficient and, if not, to develop additional support for caregivers. Support groups can be of assistance to some caregivers. However, there is a paucity of such groups specifically for male partners of women diagnosed with breast cancer, and many caregivers do not have the time to attend such groups. Caregivers may also require support to undertake the more practical tasks of caregiving. For example, research has consistently found that cancer caregivers have insufficient knowledge and skills relating to caregiving tasks (eg, symptom management), and experience communication barriers and lack of emotional support. Most caregivers indicate that they need some level of support, and identify education, such as caregiver training, as an avenue to address their needs. Two recent reviews undertaken in caregiver training interventions in the cancer context suggest that caregiver training significantly improves caregiver burden, quality of life and self-efficacy, including improved emotional support gained from interventions.

Notably, Ferrell and Wittenberg concluded that since 2010 there had been an increase in the number of caregiver interventions using technology and a self-directed format. A recent review of online interventions for family caregivers examined 17 studies, finding positive changes in levels of depression, anxiety and stress/distress, knowledge, bonding, and reduced anger-hostility were achieved through such programmes. However, the results were not unequivocal, with numerous null findings reported and variable quality of the research being reported. For cancer caregivers, Kaltenbaugh et al. reviewed web-based intervention and concluded that such interventions may reduce caregiver burden, negative mood and cancer-specific distress, while increasing quality of life, emotional functioning, bonding and social support. Notably, the six studies in this review were rated as weak in terms of reporting quality and were primarily based on majority of female samples. It may therefore be tentatively concluded that online caregiver interventions have potential to improve outcomes for caregivers; however, to date little is known about how such interventions may aid men who care for women with breast cancer.

Self-efficacy is a potential avenue that may enhance caregiver outcomes. Bandura conceptualised self-efficacy as the person’s view of their ability to perform confidently and capably in a particular situation. In the context of caregiving, a person with high self-efficacy will believe themselves to be able to perform the required tasks, and therefore is more likely to be successful in such tasks and less likely to experience distress or burnout. Higher levels of caregiver self-efficacy are associated with higher quality of life, and lower anxiety, caregiver strain and psychological distress. Importantly, self-efficacy is a variable trait that is influenced by the context, task and individual’s mood, and therefore may be modifiable through intervention. While few studies have examined self-efficacy as the focus of caregiver intervention, available evidence suggests that caregiver training interventions can successfully improve self-efficacy in informal caregivers. Importantly, recent work by Havyer et al. has demonstrated that the odds of caregivers having low self-efficacy are significantly higher among caregivers who feel inadequately trained to take on care-related duties. From a broader societal view, evidence suggests that caregivers with high levels of self-efficacy and lower levels of stress are able to more independently support the patients they care for, and achieve better patient outcomes in terms of symptom management and...
psychological well-being, which may in turn contribute to reduced demand on healthcare and supportive care services. From our research with couples affected by cancer, the Coping-Together trial. 50% of partners of patients with breast cancer indicated a preference to receive psychosocial information in an online format such as a website or an app rather than through booklets, DVDs or CDs. Their reasons for preferring websites and apps were that they are easier to access (via computer, tablet or smartphone), they are quicker to access, do not require as much time to use (as opposed to a DVD that required dedicating a set amount of time) and are easily re-accessible. Partners indicated they would be able to refer back to a website or app at any time, and hence they are preferable over having a booklet that you need to have with you. Furthermore, Maxwell found that self-efficacy mediated the relationship between men using technology-related tools and engagement in health-related activities, suggesting that an online caregiver training may be highly suitable for the target population of male caregivers.

The project aims to address a significant void in support for male caregivers of women with breast cancer, by gathering data to inform the development of a caregiver training intervention for this subgroup of cancer caregivers. The information gathered will include (1) an understanding of the challenges and unmet needs experienced by men caring for a patient with breast cancer; and (2) indepth input from male caregivers of women with breast cancer regarding suitable content and timing of delivery for an online caregiver intervention. We will also examine the role of self-efficacy as a potential mechanism to target in the intervention. The following are the specific hypotheses:

1. that unmet need and number of challenges experienced will predict psychological well-being in men who care for women with breast cancer
2. that self-efficacy will mediate the relationship between number of challenges and psychological well-being
3. that self-efficacy will mediate the relationship between unmet needs and psychological well-being.

METHODS AND ANALYSIS

The study will employ a mixed methodology design, collecting data relating to caregiver concerns and outcomes, while also gaining insight from participants regarding essential inclusions for a caregiver intervention. While a convergent, parallel, mixed methods design will be used as it allows the researchers to obtain concurrently different forms of data to address a research question, an explanatory approach is being undertaken, where the qualitative data will be used to add depth and greater insight into the quantitative results. The study uses online surveys and individual phone interviews with male caregivers of women diagnosed with breast cancer.

Participants
Caregivers will be eligible to participate if they are (1) male, (2) have previously cared or are currently caring for a woman with breast cancer (in the capacity of being a relative—such as brother, father, son, uncle, cousin, nephew—spouse or friend of that patient), (3) aged 18 years or older, and (4) are mentally and cognitively able to participate. A minimum sample size of 89 participants is suggested using G*Power: Statistical Power Analyses. This will allow us to test the hypotheses through multiple regression with two predictor variables, medium effect size ($f^2=0.15$), 0.05 level of statistical significance and 95% power. The proposed sample size is the minimum we anticipate achieving and will give us a broad cross section of male caregivers’ experiences and needs while also ensuring we can perform the proposed data analysis. All potential participants will be responsible for self-screening and will determine their own eligibility based on questions set up in SurveyMonkey. The survey is designed to automatically exclude respondents who select ‘yes’ to the question ‘Do you currently suffer from a mental health condition (ie, depression, anxiety)?’ As the study is designed to explore the challenges experienced throughout the cancer journey, and that such challenges may be present years after diagnosis, no limit has been placed on time since diagnosis as an exclusion criterion.

Recruitment
The study will employ a convenience sampling strategy with recruitment through two organisations with databases containing members who have previously indicated their willingness to be informed about research opportunities relating to cancer. Specifically, Breast Cancer Network Australia will contact their members on the Review and Survey Group database and promote the study through social media, and Register will contact members whom they deem to be eligible for this study and promote the study through their email newsletter. Data collection is anticipated to take 12 months to ensure the sample size is met, with data collection commencing in January 2017.

Procedure
Men who respond to the recruitment efforts will follow a link provided in the recruitment message to the online survey. At this point, they will again be presented with the study participant information statement to ensure they are aware of the study details and the contact details of support organisations. Men who consent to take part in the study will then progress to the online survey, which is hosted on SurveyMonkey. The survey is estimated to take 10–20 min for participants to complete.

SurveyMonkey has comprehensive privacy measures set up in order to ensure participant data are protected. Under their privacy policy, we are the sole owners of the data collected using our survey link, and the data are held on secure servers located in the USA. Data can only be accessed by members of the research team who have been
given the username and password to the SurveyMonkey account.\(^{64}\)

At the completion of the online survey, participants will be asked if they wished to participate in an optional phone interview to further explore their answers to the survey items. Participants who elect to take part in the interview will be directed to a second survey site, where they will provide their name, contact details, and preferred day and time for interview. Date of birth will be collected in both the online survey and interview consent to allow researchers to match data based on date of birth and date of survey submission, and to examine survey data prior to conducting phone interviews.

Participants who consent to take part in the interview will be contacted by a member of the research team to set a time and date for the interview. Interviews will take approximately 20–30 min and will explore in greater depth participants’ challenges, caregiving needs and preferences for supportive intervention materials. All interviews will be recorded and transcribed verbatim.

Measures

Online survey

As detailed in this section, the online survey will include measures to assess participant demographics, care recipient’s breast cancer history, participants’ emotional well-being, their cancer-related challenges, self-efficacy and unmet needs, and their perceptions about aspects of the proposed online caregiver training programme, including the content and modes of delivery of such a training programme.

Demographics and breast cancer history

Demographic data include date of birth, country of birth, language spoken at home, relationship status, level of education, employment status and residential postcode, and relationship to the woman with breast cancer (e.g., spouse, sibling, father). Participants will also be asked to report on the stage of cancer, time since diagnosis and type of treatment undertaken by the woman with breast cancer for whom they care(d).

Financial strain

This will be assessed using the Emotion Thermometers (ET),\(^{65}\) which are a simple, rapid measure of emotional disorders, including distress, anxiety, depression and anger. Validity of the distress, anxiety and depression components of this tool was achieved using the subscales of the Hospital and Anxiety Depression Scale that correspond to that area, and the depression component of the tool was validated using the Diagnostic and Statistical Manual for Mental Disorders-IV symptom criteria for depression.\(^{65}\) Using a 0–10 rating scale, participants indicate the severity of each emotion over the past week. Individual thermometer scores can be used, or an overall score created by summing all thermometers, with scores above 9 indicating mild problems, above 14 as moderate problems and above 20 as severe emotional problems.\(^{66}\)

The ET also asks participants to rate their need for help on a scale on 0 (can manage myself) to 10 (desperately). The ET has demonstrated strong sensitivity and validity when assessing distress, anxiety and depression in patients with cancer.\(^{65}\) Two additional questions were added to the current study, asking participants to rate the impact of their loved one’s breast cancer and whether the caregiver had needed help dealing with the impact of breast cancer.

Cancer-related challenges

These will be assessed using the Cancer Related Challenge Scale (CRCS), which measures the number of challenges participants faced throughout the cancer experience.\(^{67}\) The 39-item CRCS was originally designed for use among patients with cancer and their partners but was adapted for use in the current study to explore cancer-related challenges more fully. The adaption included the addition of two subscales addressing (1) whether the challenge was currently being experienced and (2) whether participants had sought help for such challenges. Participants will respond to each subscale by indicating yes or no, and the number of ‘yes’ responses within each subscale will be counted to create a subscale score. The current scale is yet to be validated, although psychometric properties are currently being established through its use in this project and through another project which is nearing completion.\(^{67}\)

Caregiver self-efficacy

The Communication and Attitudinal Self-Efficacy Scale for Cancer (CASE-Cancer)\(^{68}\) was adapted for use with a caregiver population in the current study. The scale consists of 12 items comprising three subscales: (1) understanding and participating in care; (2) maintaining a positive attitude; and (3) seeking and obtaining information.\(^{68}\) Items were measured using a 4-point response scale (1=strongly disagree, 2=slightly disagree, 3=slightly agree, 4=strongly agree). Individual items in each of the three 4-item subscales are summed to achieve subscale scores. Higher scores indicate higher self-efficacy for that specific cancer outcome. The CASE-Cancer scale has demonstrated high internal consistency using Cronbach’s coefficient alphas (α=0.76–0.77 for subscales) and construct validity when used among patient populations.\(^{68}\)

Caregiver unmet needs

The Supportive Care Needs Survey-Partners and Caregivers (SCNS-P&C)\(^{69}\) is a 45-item tool used to measure caregivers’ unmet needs across multiple systems, including (1) psychological, (2) health system and information, (3) physical and daily living, (4) patient care and support, and (5) sexuality.\(^{69}\) Participants rate items using a 5-point scale (1=not applicable, 2=satisfied, 3=low need, 4=moderate need, 5=high need), with scores of 3–5 indicating varying levels of unmet need. The SCNS-P&C has been shown to hold psychometrically sound features, including internal consistency (minimum α=0.70) and construct validity.\(^{69}\) Construct validity of the tool was
achieved using the known-groups approach and internal consistency achieved using the ‘eigenvalue <1 rule, scree plot and parallel analysis.... where items were primarily included in the factor where their loading was the highest (minimum 0.30). 89

**Content and delivery of caregiver training intervention**

Participants will be asked to rate their level of interest in participating in a breast cancer supporters training programme (0=not at all interested, to 10=extremely interested). Questions also asked about preferred format (eg, static or dynamic website, apps, DVDs), optimal time to receive the intervention (eg, at diagnosis, any time, at commencement of treatment), and whether content should be always available or released in module (eg, one section per week over 4 weeks).

**Telephone interviews**

After the online survey, participants will be asked whether they would like to take part in an optional telephone interview. If they indicated yes, participants will be redirected to an additional survey site where they will be presented with an online consent form, confirming their willingness to participate in the interview. After indicating their consent, participants provide their name and preferred contact details so the interview could be arranged. The phone interview is designed to further explore the challenges participants have experienced and discuss their ideas for a male caregiver intervention. An interview guide has been developed to explore two main areas: (1) the experience of caregiving and (2) intervention content. To explore the experience of caring for a woman with breast cancer, participants will be asked about the main challenges faced, how communication and daily routine were impacted, the extent to which caregivers felt informed about their loved one’s condition, and whether they had struggled with uncertainty. An example question is: What would you say were the main challenges faced as a result of caring for your wife/sister/mother? To explore potential intervention content and mode of delivery, participants will be asked about their potential interest in a caregiver training/support intervention, what information they believe should be included, the preferred method of intervention delivery and the timing of participating in a supportive care intervention. An example question is: What do you think would be the essential elements for a caregiver training or support package?

Interviews will be conducted by several members of the research team, led by an experienced qualitative researcher (JVL). The interviewers have undergone training in general interviewing techniques and/or have been involved in previous studies involving the interviewing of patients with cancer and their caregivers. Prior to study commencement, a training meeting and mock interviews were conducted to ensure familiarity with the interview schedule. Additionally, the lead researcher (JVL) will review the initial interviews conducted by other team members to provide any required feedback.

**Data analysis**

Demographic variables will be examined to determine whether they are indicative of higher challenges, unmet needs or poorer psychological outcomes for male caregivers of women with breast cancer. This will be determined through a number on multivariate analysis of variances (MANOVAs), allowing simultaneous examination of the three dependent variables (distress, challenges and needs) to reduce the risk of type 1 error. To address the first hypothesis, hierarchical multiple regression analyses will be conducted with any demographic items identified as risk factors for distress entered in step 1, with challenges and unmet needs entered at step 2. We anticipate the self-efficacy may mediate the relationship between challenges and unmet needs to emotional distress. If this is found to be the case, our goal is to develop a caregiver support programme specifically designed to enhance self-efficacy in male caregivers. Therefore, two mediation analyses will be performed, using the methodology and PROCESS tool developed by Hayes. 90 Due to multiple analyses being conducted on the data, a Bonferroni correction will be applied to reduce the risk of familywise error. 71

Qualitative data will be transcribed verbatim in preparation for data analysis. Participants who indicate as part of their consent process that they would like to receive a copy of their transcript will have the opportunity to review the data for accuracy prior to analysis. The qualitative data collected via the interviews will be analysed using thematic analysis (TA). This approach to qualitative data reflects a creative process in which the data and the researcher’s interpretative and analytical skills interact in the creation of patterned meanings, of themes, which are drawn from the data. 72 Using the procedure suggested by Braun et al, 73 the analysis will begin with a reading and rereading of the data set to ensure the researcher is familiar with the data, with points of potential interest noted. After familiarity is established, coding will begin, with codes or labels assigned to elements of the data. Once coding is complete, the creation of themes will be undertaken, by clustering related codes that speak to similar meanings. At this point, potential themes will be checked back to the original data, to ensure that they represent the data in its entirety. The final stage involves defining and naming the themes, culminating in a thematic definition. TA will be conducted by one researcher (JVL) with a proportion of cases reviewed and the coding and theme review processes discussed with a second researcher (MG) as a credibility check. 74 Direct member checking (ie, participants’ review of the data analysis) will not be undertaken as it is anticipated that there will be great diversity on the accounts that will be gathered, and this may create issues regarding members’ ability to synthesise data, members’ inability to recognise that there is no single objective truth and conflict regarding whose interpretation should be presented if there are disagreements in interpretation. 75

Levesque Jv, et al. BMJ Open 2018;8:e019530. doi:10.1136/bmjopen-2017-019530
An integration approach \(^7^6\) will be undertaken for the combination of the two forms of data. This approach requires the two sets of data to be collected concurrently and then analysed independently.\(^7^6\) Once quantitative and qualitative data have been analysed, they will be combined in an attempt to address the central mixed methods research goal of gaining insight into the challenges experienced by male caregivers, and their views on what content is suitable for an intervention to support male caregivers. In this process, the qualitative themes and quantitative results will be compared and complemented with each other, resulting in a summary of the findings.\(^7^6\) The integration of the two forms of data will enable the researchers to draw meta-inferences that relate to how the qualitative data provide greater insight to the quantitative conclusions.\(^7^7\)

**Ethical considerations and dissemination**

The study involves a potentially vulnerable group within our community and requires participants to reflect on a distressing time in their life. As such, it is imperative that the study is conducted in a sensitive manner and that participants are provided with access to suitable support services (eg, Lifeline, Cancer Council). Participants were also informed of their right to withdraw from the project or decline to answer questions that elicited distress. The study design also excludes people who have been diagnosed with a mental health condition or other condition that impacts on their cognition (eg, dementia, intellectual disability). This is due to the nature of the study, requiring discussion of potentially upsetting topics, but also that participants will be asked to voice their views on how to develop an online intervention, hence they must have the cognitive capacity to reflect on their experience and express their opinions coherently.

The study findings will greatly enhance our understanding of the experience of breast cancer caregivers including the challenges they face and their unmet needs. As such, we anticipate that at least two to three publications may be developed from the study, including a publication of the qualitative results.

**DISCUSSION**

Male caregivers are an under-recognised and under-researched group,\(^3^3\) and it is therefore important that studies are conducted to explicitly examine the unmet needs, challenges and psychological outcomes for this group. This study will shed some insight into the experiences of men caring for women with breast cancer, and guide the development of a suitable caregiver training intervention, Care Assist, developed specifically to address the most common challenges of male caregivers. Additionally, by exploring the potential for self-efficacy to explain the association between challenges, unmet needs and emotional problems, this study will clearly examine a potentially modifiable pathway on which to target interventions for male caregivers.

The use of a mixed methods design is a strength of the study. Through the combination of quantitative and qualitative approaches, complex research questions can be explored.\(^7^8\) For example, the study will cover a broad snapshot of the types of challenges experienced through the online survey. However, the lived experience of such challenges, the impact they have on participants and the suitability of including such challenges in an intervention can be explored in the qualitative interviews, hence adding a depth of understanding and guiding intervention development in a nuanced manner. Furthermore, should the findings of the qualitative and quantitative elements of the project converge, the validity of the findings, the conclusions drawn and the intervention developed is enhanced.\(^7^8\)

The results of this project will inform the development of an online self-management intervention to assist male supporters of women with breast cancer, following the four key steps proposed by McKleroy et al.\(^7^9\) In brief, the current project will provide the information usually gathered through a needs assessment (step 1); we will develop the intervention content, incorporating ongoing feedback from male supporters to allow iterative modifications as necessary (step 2); we will undertake preliminary adaptation testing to determine the feasibility of the intervention material, including the suitability of content, format and scope of the intervention materials (step 3); and then undertake final intervention refinement through testing of intervention content (step 4).

**Limitations**

While the proposed study have several strengths, there are also notable limitations. The CRCS is a relatively new measure with limited information currently available regarding its psychometric properties. We have used this scale in research being undertaken by our group,\(^6^7\) and hope that the current study will further contribute to the measure’s development. Additionally, the eligibility criteria are relatively broad, with no time frame imposed between time of diagnosis and participation. While this decision was made to ensure that we captured challenges throughout the experience of caring for a woman with breast cancer, we do acknowledge that recall bias may be present. Finally, the content developed for the Care Assist intervention will need a phase II study exploring the views of caregivers on the developed intervention content.

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**Contributors** JVL contributed to the study conception and design, attaining the funding to support the project, and preparing documents for ethical approval. She contributed content to the original manuscript and has assisted with revisions. MG contributed to the preparation of documents for ethics approval, including study materials (survey, patient information and so on) to support data collection, managed the liaison with recruitment partners, managed the data collection, and contributed to the preparation and review of the manuscript. AG contributed to the study conception and design, attaining the funding to support the project, and preparation and review of the manuscript.

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