A pilot, quasi-experimental, mixed methods investigation into the efficacy of a group psychotherapy intervention for caregivers of outpatients with cancer: the COPE study protocol

Rathi Mahendran,1,2,3 Joyce Yi Siang Tan,2 Konstadina Griva,4 Haikel Asyraf Lim,2,3 Hui Ying Ng,1 Joanne Chua,1 Siew Eng Lim,5 Ee Heok Kua1,2

ABSTRACT
Introduction: Despite the rising trend of cancer prevalence and increase in family caregiving, little attention has been paid to the efficacy of psychosocial interventions among Asian caregiver samples, particularly support groups, given the benefits that have been shown in studies on Western populations. This trial aims to evaluate the effectiveness of a pilot 4-week group psychotherapy for Singaporean family caregivers of patients receiving outpatient care.

Methods and analysis: Facilitated by a clinical psychologist, this intervention is primarily based on the brief integrative psychological therapy with a supportive-expressive intent. Participants will be recruited while they are accompanying their care recipients for outpatient consultations. Since this is a pilot study, a sample size of 120 participants is targeted on the basis of sample sizes of previous studies. The study adopts a quasi-experimental design, as participants are assigned the intervention or control arms based on their availability to attend the intervention. A mixed methods approach is used to evaluate the outcomes of the intervention. A self-administered battery of tests is completed at four time points: baseline, postintervention and follow-up at 1-month and 2-month postinterventions; semi-structured interviews are conducted at baseline and post-intervention. Primary outcomes are quality of life and anxious and depressive symptoms; secondary outcomes are stress and basic psychological needs. Analysis using analysis of covariance would be on the various measures, in addition to the influence the psychological outcomes reported stage of participants.

Ethics and dissemination: This study protocol has ethics approval from the National Healthcare Group Domain Specific Review Board (NHG DSRB Ref: 2013/00662). Written informed consent is obtained from every participant. Results will be disseminated through journals and conferences, and will be particularly relevant for clinicians intending to implement similar support groups to address the psychosocial concerns of caregivers, as well as for researchers seeking to refine the structure and evaluate the effectiveness of such programmes.

Strengths and limitations of this study
- The intervention here catering to caregivers of ambulatory patients with cancer expands the limited work done among Asian caregivers on support group interventions.
- A 4-week psychosocial intervention builds on previous programmes and approaches developed for local caregivers, and hence directly addresses their concerns.
- The complementary strengths of the quantitative and qualitative data collection methods employed here provide a comprehensive understanding of the daily caregiving experience and effectiveness of the support group.
- Self-selection bias into study conditions may influence the evaluative outcomes, understanding the actual effectiveness of the intervention.
- There is no restriction on the cancer type or stage of participants’ care recipients, which may influence the psychological outcomes reported on the various measures, in addition to the intervention.
- Restriction to English speaking participants for the intervention may limit the generalisability of the findings.

Trial registration number: Current Controlled Trials NCT02120183 (https://clinicaltrials.gov/show/NCT02120183)

INTRODUCTION
Background and rationale
Cancer is a major cause of morbidity and mortality with worldwide prevalence estimated at 14.1 million new cases and 8 million cancer-related deaths in 2012. Each patient’s cancer journey is shared by their caregivers who may be as profoundly affected...
by the diagnosis and outcomes. The American Cancer Society defines a caregiver as a family member, friend, loved one or other support person who lends physical, emotional or other support to someone at any time during the cancer journey. Importantly, they are part of a triadic model of involvement together with the patient and healthcare professional and take on multiple roles, from involvement in treatment decision-making in cancer, to acting as conduits of information between the patient and the specialist and vice versa and supporting the patient’s decisions.

Functional expectations of caregivers are often huge with multiple responsibilities such as household chores, emotional support, providing transportation and symptom management. As cancer survivorship grows, from 50% in the 70s, to 54% between 1983 and 1985, to 65% in 2009, the illness may become a chronic disease, further stressing caregivers with a cumulative and unrelenting burden of care and responsibility. Psychological morbidity or psychiatric symptomatology among cancer caregivers is high. Levels of distress have also been shown to be higher than those reported by patients themselves.

As identified in stress process models (see example of Pearlin et al), personal resources moderate the psychosocial impact or strain related to caregiving. Key among those are the more malleable psychological resources such as coping strategies and social support, which have consistently been shown to be associated with better caregiving outcomes and thereby form core parts in interventions for cancer caregivers (see review by Waldron et al). This line of work indicates that the most efficacious interventions comprised skills training and supportive educational components such as psychosocial coping skills, family involvement and symptom management. While there is a good evidence base for caregiving interventions, most of the work has been conducted in Western settings.

Group therapy for caregivers of patients in Western studies has been shown to be beneficial due to group processes of social comparison, information sharing and peer support. In Asia, the effectiveness of group therapy for caregivers of patients with cancer is unclear as research work in this area has largely been absent. Cultural features specific to Asian cultures may influence caregiver outcomes differently, in comparison to Western populations. For example, Chinese caregivers displayed a tendency for collective decision-making regarding important decisions, adopted a fatalistic explanation for the care recipients’ illness, experienced a sense of guilt and shame, and had reservations in expressing their feelings to avoid placing unnecessary burden on other family members. Familial obligation to care for the family member with cancer was also emphasised. Distress was often experienced in terms of physical symptoms, and emotional coping involved the strategy of endurance.

Since these culturally derived attitudes and perceptions frame the caregiving experience, interventions that are culturally sensitive, patient-centred and theoretically motivated have been advocated.

Existing interventions among Asian populations focus mainly on imparting practical skills to caregivers of patients with cancer requiring palliative care, through home-based care or home visits from nurses, with an emphasis on coping with end-of-life issues and bereavement. However, interventions for caregivers of non-palliative care recipients tend to be delivered via the phone or over the internet, while others work with couple dyads, where one spouse provides care for the other who has cancer.

Among Asian caregivers of other patient populations, studies have provided evidence of its effectiveness and suitability. For example, by comparing different types of psychosocial interventions for caregivers of patients with schizophrenia in Hong Kong, results from a randomised controlled trial (RCT) showed that caregivers in the mutual support group had greater improvements in family and patient functioning than caregivers in the psychoeducation and standard care groups, with benefits being sustained over the long term. While Asian families are known to be reluctant to seek external help, including professional help beyond the family unit, they appear willing to share their experiences with peers who are facing similar difficulties, making support groups a more attractive option of seeking help.

To the best of our knowledge, the only one cancer caregiving intervention in Singapore has recruited exclusively caregivers of patients with advanced cancer, with a majority of the care recipients being on home hospice care; hence, generalisability to caregivers of ambulatory patients is not clear. Outcomes such as quality of life (QOL) and burden have been shown to be better for caregiving in the context of home palliative care relative to those in ambulatory outpatient care. Hence, the present study seeks to expand on this work by developing and evaluating the effect of an intervention programme for Asian cancer caregivers in ambulatory settings. The key consideration was to adopt a culturally sensitive and pragmatic intervention approach that would facilitate participation and retention among this group. As such, recommendations for interventions that integrate various therapies and are time efficient were deemed paramount. Developed in response to these considerations, the protocol of this current intervention—Caregiver Outpatients PsychoEducation support group therapy, or known as COPE—is described here.

Covered in four 1 h long weekly sessions, the intervention encompasses topics on the psychosocial and emotional aspects of the caregiving role. Through facilitation by the clinical psychologist and group interactions, it sought to increase self-knowledge, emotional regulation and coping strategies.

Aims of study

Using both quantitative and qualitative data collection methods, this study aims to evaluate the efficacy of the...
intervention. Clinical indicators of QOL and depressive and anxious symptoms form the primary outcomes, while secondary outcomes comprise stress and basic psychological needs. Interviews are also conducted to qualitatively elicit responses surrounding the challenges and needs caregivers face, as well as their caregiving motivations, and feedback on the intervention.

We hypothesise that there would be improvements in QOL and decreases in depressive and anxious symptoms after the intervention. Stress levels will be lower, with gains in caregivers’ sense of autonomy, competence and relatedness.

METHOD
Trial design
Evaluation of the intervention will be done by comparing two groups of participants:
Group 1: Family caregivers attending the support group;
Group 2: Family caregivers interested in, but are unavailable to attend the support group at the moment, and will be waitlisted to attend subsequent support groups.

Two arms of the study will be formed—the intervention arm and the control arm.

Eligibility criteria
The inclusion criteria are:
1. 21–74 Years of age;
2. Willingness to attend a 1 h programme every week for 4 weeks;
3. Ability to understand and speak basic English, and ability to understand and complete self-report questionnaires with minimal assistance;
4. Status as a primary adult family member who provides care and support for the patient and lives together with the patient.

The exclusion criteria are:
1. Age younger than 21 years of age, or older than 75 years;
2. Inability to understand and speak basic English, and inability to understand and complete self-report questionnaires with minimal assistance.

Since this is a pilot study, and we hope to include as many caregivers as possible, no exclusion was made on the basis of care recipients’ cancer type, cancer stage, time since first diagnosis or current treatment of patients. Participants can request to withdraw from the study at any time without having to give any reason.

Delivery of intervention
The intervention will be run by a clinical psychologist who will provide psychoeducation and facilitate the discussion among caregivers. The programme will be formalised in a series of materials handed out to participants in each session of the intervention, summarising each specific session’s topic.

Participants who become intensely distressed will have a personal consultation with the clinical psychologist.

COPE intervention
This intervention is part of the ongoing quality improvement efforts to implement Psycho-oncology services at the National University Cancer Institute, Singapore (NCIS), which includes a needs assessment survey using the Caregiver Quality of Life—Cancer instrument, and modified 5-week mindfulness-based cognitive therapy (MBCT) groups conducted previously.

Results from the survey and feedback from MBCT group participants indicated a unique set of needs of Singaporean caregivers. While endorsing the needs of emotional and social support, and physical/practical concerns, constraints in time commitment resulted in preferences for shorter interventions, as well as interventions that encompass additional therapeutic components beyond mindfulness, such as supportive talk therapy and psychoeducation. These needs and preferences of local caregivers were taken into consideration when the expert team—made up of psychiatrists and a psychologist—collaborated to develop this intervention.

Accommodating local preferences for a multifaceted therapeutic programme, the brief integrative psychological therapy (BIPT)—developed at the National University of Singapore—was the primary therapeutic approach guiding the intervention. Originally developed in response to local needs for time-efficient therapy that combines various psychotherapy techniques, the BIPT’s eclectic approach integrates cognitive–behavioural, psychodynamic and supportive approaches, as well as meditation and relaxation therapy. In addition, the patient-centric focus emphasises customised therapeutic approaches to target patients’ specific needs. In designing this current intervention, we infused elements of cognitive–behavioural therapy and supportive therapy.

Recognising the psychological changes accompanying the caregiving role, the self-determination theory (SDT) motivated the secondary focus of the intervention. The theory proposes that when social environments are supportive of individuals’ basic psychological needs for autonomy, competence and relatedness, greater psychological well-being is attained. This gives an intrinsic motivation for behaviours driven by these psychological needs. Hence, support group sessions are designed towards creating a platform that promotes participants’ sense of autonomy, competence and relatedness, while measures focusing on autonomy, competence and relatedness are utilised as secondary outcomes.

The group psychotherapy format—pioneered by Yalom and colleagues—was adopted instead of a one-to-one psychotherapy session. Through providing a platform for interpersonal interaction between peers with similar life experiences, group psychotherapy enables social learning, a normalisation of experiences and mutual validation among the group. This fulfils the supportive-expressive intent of the intervention. A practical advantage of the group format is its capacity to
reach out to a larger number of caregivers, in comparison with individual psychotherapy.

Content of intervention
Topics were tailored in response to the specific concerns of burden, physical/practical concerns, emotional reactivity, self-needs and social support endorsed by Singaporean caregivers on the Caregiver Quality of Life Index-Cancer (CQOLC) in the study mentioned earlier. The content of each session is described here:
- Week 1: Coping with the diagnosis, through general coping skills, normalisation of personal reactions and dealing with uncertainty;
- Week 2: Behavioural change, through self-care, stress management and mindfulness concepts;
- Week 3: Cognitive change, through challenging negative thoughts and the reinterpretation of events;
- Week 4: Managing emotions, through handling emotional reactivity using self-soothing, safe-place imagery and distraction.

The more intense, sensitive topics are kept till later, so that caregivers can become more familiar with the structure of the sessions and with one another.

Study setting for recruitment and data collection
Participants recruited are caregivers who are accompanying their care recipients for outpatient consultations at NCIS, where the intervention is also held.

Recruitment
Research assistants (RAs) will approach family members accompanying patients at the waiting areas of the clinic and provide them with a flyer and introduce the study in brief. If interested, family members are provided with a participant information sheet that provides more details of the study. Those who are keen to participate will be asked to leave their contact details (phone number) with the RA who will first verify the eligibility against a checklist, before subsequently confirming the availability and register the caregiver in the next available support group session.

Outcomes
Measurements will be taken at baseline (time 1), immediately after the 4-week intervention (time 2), and at 4 weeks (time 3) and 8 weeks (time 4) postintervention. Assessment will comprise self-report questionnaires (as listed below) and a qualitative component (interviews) undertaken only with intervention participants at time 1 and at time 2. Administered at all four time points, self-report questionnaires will consist of: QOL, stress level, basic psychological needs, depressive and anxiety symptoms.

QOL and depressive and anxiety symptoms are primary outcomes; stress level, basic psychological needs and caregiving motivations are secondary outcomes.

Quality of life
This is measured using the CQOLC scale, designed to measure the QOL of family caregivers of patients with cancer. It comprises 35 items and yields a single QOL score. The items are scored on a five-point Likert scale ranging from 0 (not at all) to 4 (very much). Scores range from 0 to a maximum of 140. Higher scores indicate better QOL and the scale has good psychometric properties.

Anxiety and depressive symptoms
The Hospital Anxiety and Depression Scale (HADS) is a widely used self-rated 14-item questionnaire. Participants indicate which of four options from 0 to 3— with 3 indicating higher symptom frequency— best describes their feelings over the past week. Anxiety and depressive symptoms are scored on separate subscales of 7 items each. Scores range to a maximum of 21 for each subscale and good psychometric properties are frequently reported.

Basic psychological needs
The Basic Psychological Needs in General Scale (BPNS) contains 21 items that measure the degree to which people experience the basic psychological needs in their lives. It is divided into subscales measuring a need for autonomy (7 items), competence (6 items) and relatedness (8 items) with each item measured on a seven-point scale from 1 (not at all) to 7 (very true). A previous study using the original scale found acceptable to excellent psychometric properties for the full scale (α=0.89), and its subscales of autonomy (α=0.69), competence (α=0.71) and relatedness (α=0.86).

A shortened version is used in this study to reduce the burden of completion and fatigue among participants completing the study questionnaire. Previous studies have employed various brief versions containing either 9 or 15 items with good psychometric properties. Fifteen-item versions of the scale demonstrate acceptable reliability (α=0.79 to 0.87) and studies have worked with only 9 items, namely 3 items per subscale. This study uses a modified version of the 9-item short scale. One item (‘I get along with people I come into contact with’) was replaced with another item from the original scale (‘I really like the people I interact with’) based on recommendations that wording in scale items be as specific, concrete and non-ambiguous as possible. The 9-item questionnaire has three subscales with three items each: autonomy, competency and relatedness. Participants were asked, on the basis of their role as a caregiver in the past month, about the degree to which they agreed with the statements on a seven-point Likert-type scale from 1 (not at all) to 7 (very true).

Stress
The Perceived Stress Scale (PSS) is originally a 14-item scale, developed as a global measure of stress. To
reduce participants’ response burden, we used the PSS-10, a 10-item short version with high reliability and validity.\textsuperscript{53} It requires participants to indicate how often they have experienced each of the statements in the past month on a five-point scale from 0 (never) to 4 (very often). Scores are obtained by reversing responses to the positively worded items and then summing across all scale items. It has been used to assess stress among Singaporean adults and has good reliability coefficients.\textsuperscript{54}

**Qualitative interviews**

Semistructured interviews will be conducted to allow deeper insights into the lived caregiving experience, beyond the information gathered using questionnaires. An interview guide will be used to explore issues on caregiving duties; needs and challenges of caregiving; the reasons and motivation pertaining to taking up caregiving. At time 2, questions will be added to explore participants’ experience and feedback with the intervention. Interview topics (questions and probes) will be used flexibly to allow participants to share issues of importance to their experience.

At time 1, interview questions will focus on the goals and motivations of caregiving (example: ‘Why do you give care to your loved one?’), the nature of the caregiving relationship (example: ‘How would you describe your relationship with your loved one?’), and challenges faced in caregiving (example: ‘What challenges do you face in caring or your loved one? How have you coped with these challenges?’).

At time 2 (postintervention), a similar interview guide will be used to explore how the caregiving experience or motivations may have changed (example: ‘Since the last time we spoke, how have your ideas about your goals and motivations changed?’) in addition to questions to get feedback on the intervention programme (example: ‘What have you learnt from the intervention and from interacting with the group?’).

**Sample size calculation**

Prior information on support group interventions for caregivers is largely lacking in Singapore and as a pilot study, hence, we are unable to compute a sample size. Nonetheless, on the basis of the sample sizes of similar studies conducted locally and overseas,\textsuperscript{31, 33, 55, 56} as well as what is deemed feasible within the available time frame and resources, we aim to recruit 120 participants in total, with 60 participants for each arm.

**Allocation of participants to study arms**

This study follows a quasi-experimental design to accommodate participants’ schedules and preferences, as such consenting participants are assigned to either study condition based on their availability and preference instead of using randomisation. On consent, caregivers can enter either of two conditions: the intervention group or the control group, which is waitlisted. Available caregivers are placed in the first group (group 1a) until a group size of 10 is reached. The next 10 will be put on a waitlist and form the control group (group 1b), which will still be able to benefit from the programme at a later time. In this manner, subsequent treatment and control groups will be recruited.

Participants’ written informed consent is taken and the baseline questionnaire administered before the start of the first support group session (time 1). At the final session, after 4 weeks, participants complete a second questionnaire (time 2) and are handed a packet of two follow-up questionnaires (time 3 and time 4) with stamped envelopes addressed to the principal investigator. These are to be returned after completion at the 1-month and 2-month follow-up assessment points.

The RA meets participants on the waitlist control group separately to get the informed consent and complete the first questionnaire.

An inconvenience fee of $15 is paid to each participant after completion of each support group session. Participants in the waitlist control arm are paid $15 on receipt of their completed questionnaire.

**Missed sessions**

To accommodate caregivers’ schedules, participants who are unable to make it for one or more sessions are permitted to complete the session they had missed in a following month; that is, if a participant missed session 2 of the intervention, they could complete the other sessions first before completing session 2 in the following month.

**Qualitative interviews**

A subset of 20 participants from the intervention arm will be interviewed twice—one at time 1 before the intervention starts, and the second time at time 2.

**Data management**

Each participant will be assigned a unique subject identification number so that they can be tracked anonymously throughout. The trial data will be entered into an SPSS database by the RAs.

**Statistical considerations**

Outcomes will be analysed at times 2, 3 and 4. Participants will be assessed on an intention-to-treat basis. To examine changes between groups (intervention vs control) on baseline and follow-up assessments, analysis of covariance will be performed for each outcome measure. Demographic and casemix differences between the groups that are significant confounds will be entered as covariates. Alternatively, latent growth modelling might be considered, depending on the quality of the data obtained.

In addition, a ‘per protocol’ analysis will be conducted to examine caregivers who were able to complete all four sessions of the intervention arm.

No formal subgroup analyses are planned but exploratory analyses of the caregiver demographics (eg, age

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range, ethnicity, income level) and the disease characteristics of the care recipient (eg, cancer type, cancer stage) on the effect of the intervention will be carried out.

**DISCUSSION**

Although support group interventions have had a significant positive impact on multiple outcomes, there is a paucity of research on caregiver populations in Asia. The majority of studies have been mainly conducted on female Caucasian caregiver populations. Studies of the Asian caregiving experience are few and far between. Moreover, research on caregivers in Singapore is concentrated on dementia and elderly care recipients. However, with the rising prevalence of non-communicable chronic diseases such as cancer and depression, there is a greater need for research on how caregivers in Asia are impacted and cope. The common finding that depression prevalence is higher among Asian caregiver populations than Western caregiver populations suggests the possibility that Asian populations may experience a greater burden of caregiving.

Group-based approaches may provide cost-effective means of providing mental healthcare. However, few studies have examined the impact of support groups on family caregivers. Only two of 29 RCTs reviewed in a meta-analysis conducted caregiver-only groups. Group-based interventions are of interest because they are more cost-effective than one-on-one counselling in providing structured support. Moreover, feedback has been generally positive. Caregiver-focused groups were rated as providing skills such as information and support that reduced the negative appraisal of caregiving, decreased uncertainty and lessened hopelessness, while also teaching skills to cope with the stresses of caregiving. This supports suggestions that such groups might give caregivers the chance to openly interact with other caregivers in the absence of their care recipients. Moreover, in a systematic review of psychosocial interventions, group based or otherwise, caregivers listed the most useful aspect of interventions as regular interactions with a professional, providing the chance to openly communicate issues with them, and as a time to talk about feelings and questions related to cancer.

There is also a need to expand qualitative understanding of how a support group is received in cultural contexts which are not attuned to support groups, much less one for cancer. In Singapore, cancer is still seen as a terminal disease with little hope of recovery, and there is also a stigma against psychological counselling and psychiatric support, facilitated by the general stigma against mental illness amongst both patients and, paradoxically, healthcare professionals. Furthermore, a family-centred model of decision-making tends to be predominant in Asian populations, and in Singapore this is further encouraged by public policy such as healthcare subsidies that are based on a calculation of the immediate family’s total income, rather than individual income. Beliefs or expectations of the role that the family caregiver ought to play may thus exist and may influence the way individuals respond to the intervention.

With the rising trend of cancer and other non-communicable diseases, the global disease burden will be increasingly shouldered by chronic outpatient care. Much of this will involve the immediate family and bring with it costs to caregiver well-being. Effective short-term interventions are needed to provide support to caregivers managing busy schedules.

However, the current trial does pose methodological challenges in recruiting and ensuring attendance for all consecutive sessions of the support group. To accommodate caregivers’ needs, caregivers will make up for sessions they miss in follow-up sessions. These will be taken into account in data analysis.

**Limitations**

Since the study design accommodates participants’ preferences and availability, a self-selection process into either the intervention or control arm may occur. Those who decline to attend may be more stressed due to multiple commitments, but yet are in greater need of the support. Since those who attend are possibly better adjusted caregivers, a ceiling effect may result when evaluating the effectiveness of the programme, hence understating its actual effectiveness. This can be corrected for by comparing the baseline characteristics of both study arms during data analysis.

The heterogeneity of the care recipients—in terms of cancer types and stages of cancer—might influence the outcomes reported by caregivers on the various measures. The prognosis of the cancer and progress of cancer treatment would inevitably contribute to the psychological state of participants. Hence, fluctuations in the outcomes measured might not be solely attributable to the intervention. If confounding differences arise, cancer type and stage, together with other relevant case mix variables, will be controlled for during data analysis later.

Another limitation is the restriction of the intervention to only English-speaking participants. This excludes the segment of non-English-speaking caregivers, who may have different supportive needs. Generalisability of the findings is thus limited to only English-speaking caregivers.

**Ethics and dissemination**

Informed consent will be obtained from all participants and confidentiality of the issues raised during the support group will be maintained strictly. All data will be anonymised and maintained in accordance with the guidelines stated by the National Healthcare Group (NHG) Domain Specific Review Board (DSRB).

Dissemination of findings will include presentations at conferences and publications in peer-review journals.
Author affiliations
1Department of Psychological Medicine, National University Hospital, Singapore
2Department of Psychological Medicine, National University of Singapore, Singapore
3Duke-NUS Graduate Medical School, Singapore, Singapore
4Department of Psychology, National University of Singapore, Singapore
5National University Cancer Institute, Singapore, National University Health System, Singapore

Twitter Follow Haikel Lim at @haikelim

Contributors HYN and JT coordinated the support groups and administered the questionnaires. HYN conducted the interviews. JT also helped to draft the manuscript. KG advised on study methodology, statistical analysis and helped to draft the manuscript. HL participated in the design of the study and will be conducting statistical analysis. JC conducted the support groups. RM and EHK conceptualised the study, and participated in its design and coordination and helped draft the manuscript. SEL was involved in the study design and in facilitating the conduct of the study at the National University Cancer Institute, Singapore. All the authors read and approved the final manuscript.

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