

## A STUDY PROTOCOL OF A PILOT RCT OF AN ACCEPTANCE AND COMMITMENT THERAPY FOR FAMILY CAREGIVERS OF PALLIATIVE CARE PATIENTS

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**Abstract—** *Caregivers of palliative care patients often experience high burden levels. Caregiving burden may impair quality of life and induce psychological distress. These caregivers often experience emotional feeling and thoughts that are hard to change, and trying to alter, or control may increase caregiver distress. Acceptance and Commitment Therapy (ACT) offers a potential solution as it helps individuals creating a life worth living by boosting psychological flexibility. The study aims to assess the preliminary efficacy of an ACT-based caregiver supporting programme (ACT-CSP) for caregivers of palliative care patients. This is a pilot 2-arm parallel group randomized controlled trial with follow-ups at Week 6 and Week 8 after recruitment. Thirty caregivers of palliative care patients at palliative care outpatient ward of two hospitals will be recruited, and randomized to either the ACT-CSP with two 45- to 60-min sessions in an individual online format or usual care arm. The primary outcome is caregiver burden. Secondary outcomes are depression/anxiety, caregiving self-efficacy, resilience, quality of life and psychological flexibility. Outcomes of the two groups will be compared generalized estimating equations. This study will provide information for designing a full-scale trial to shed light in developing clinical guideline in supporting caregivers of palliative care patients*

**Index Terms—** *Acceptance and commitment therapy; Burden; Caregivers; Palliative care.*

### Introduction

Palliative care patients are discharged from hospital quickly because of shortage of hospital beds and they are often re-admitted due to breakdown in caregiver support at home, even if the patients are supported by palliative home-care [1]. Family caregivers deliver intimate patient care and interventions at home, which can improve patient access to supportive modalities and potentially reduce the cost [2]. However, caregivers themselves are in need of support when facing the additional concurrent stress of significant role transitions and the responsibilities of managing patients' need, and that commonly results in caregiver burden [3]. The caregiving burden may impair caregivers' quality of life (QoL), and often comes along with a range of health complications, including anxiety, fatigue, and depression [4],[5].

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Footnote: This work is supported by Departmental General Research Fund, The Hong Kong Polytechnic University (Project No. P0033677)

There have been recent interventions focused on improving the caregiving experience by supporting caregivers with additional programmes. Recent systematic reviews (SRs) had produced some promising findings supporting cognitive behavioural therapy (CBT) on reducing psychological distress and caregiver burden and improving for caregivers in palliative care but mixed effect on coping skills, no effect on generic QoL, and non-significant effect on common psychological complaints [6],[7]. These findings arouse a need for further exploration of the applicability of CBT in caregivers taking care of palliative care patients as CBT primarily aims to reduce psychological distress and enhance the use of adaptive coping strategies by altering negative thoughts and beliefs.

The extant literature has documented a high level of psychological distress in caregivers of palliative care patients [8]. Providing care to palliative care patients can be very stressful due to the specific situations in palliative care, including the chronic nature of the disease, the lack of foresight about the time of its finalization, and the fear of the expected loss of the patient [5]. Caring for a relative receiving palliative care is linked to stressors (e.g. physical deterioration of the patient, uncertainty about future, and fear of the loss of the patient), emotions (e.g. worry, depressive rumination, and self-criticism), or thoughts (e.g. why is that happening to me, and guilty) that are often impossible or very difficult to change. This issue is commonly addressed in traditional CBT by training caregivers in strategies for changing cognitions or behaviours that may increase their chances of coping better with caregiving [9], but trying to change, avoid, or control these events may increase caregiver distress [9]. Qualitative data from a large RCT provides preliminary support to this assertion among hospice caregivers as some of the participants felt guilty when failed to execute their planned actions after receiving a CBT treatment on promoting problem-solving skills [10].

Acceptance and commitment therapy is a third-wave of CBT [11], which aims to fostering psychological flexibility by (i) promoting ‘distress’ is understood as a normal reaction to a difficult situation; and (ii) supporting people to become more resilient, self-efficacious, and self-compassionate when in distress [12],[13]. It expands traditional CBT, and focuses on helping the client relate to their thoughts differently with de-emphasizing the need to change or ‘restructure’ specific cognitions [14]. According to the Hexaflex model in ACT, psychological flexibility is increased through two sets of procedures: (1) acceptance and mindfulness skills and (2) behaviour change procedures with the use of the therapeutic techniques [11]. Acceptance and mindfulness skills aim at helping the individual to cope with negative thoughts, emotions and body sensations with mindfulness and relaxation exercises by accepting these feelings and thoughts non-judgementally, thereby letting them go without fighting against these discomforts by deliberating efforts in avoiding, or controlling these feelings and thoughts or try to restructure meanings of these feelings. Behaviour-change procedures, such as helping the individual identify core values, develop action plans against limited resources and working towards committed actions skills to help achieving the goals. Engaging in these two procedures are expected resulting in favourable outcomes including reducing burden, anxiety and depressive symptoms, and improving caregiving self-efficacy, resilience and QoL. When applying ACT to caregiving

in palliative care setting, the framework suggests that feeling distress experienced in caregiving such as fear of losing of the loved one and failed to execute some of the caregiving tasks, which are hard or impossible to change, is a normal reaction and hence no need to suppress these distressing thoughts or try to restructure meanings of these feelings. At the same time, ACT also supports caregivers to identify what is important to them in the caregiving process, and help them live a life of meaning, quality and value, even when faced with challenging situations.

There is empirical support to theoretical application of ACT for caregivers in palliative care. First, there is already a good evidence base for the type of psychological problems reported by people affected by difficult situations, such as anxiety and depression [15],[16]. Furthermore, data from mediation analyses suggest that psychological flexibility is the central therapeutic mechanism behind the improvement [17]. Second, early evidence was observed for the effectiveness of a self-help ACT booklet supplemented with telephone support among hospice caregivers, with a moderate effect size in psychological distress. But this pilot study did not examine positive caregiver outcomes such as resilience, caregiving self-efficacy or QoL or patient outcomes [18]. Third, the concept of ‘acceptance’ is well received in the local community. ACT also produced positive results in managing parental distress in childhood asthma in Hong Kong [19]. A local RCT comparing culturally attuned CBT and integrative body-mind-spirit interventions (i.e. emphasis on ‘acceptance then transformation, and psychosocial resilience regarding an uncertain future’) on caregivers of lung cancer patients resulted in improvement in QoL, anxiety, and stress although no effect on caregiver burden and depression [20].

Therefore, we plan to conduct this study which aims to examine the potential efficacy of an acceptance and commitment therapy intervention (ACT-CSP) for caregivers of palliative care patients in reducing caregiver burden and anxiety and depressive symptoms and improving caregiving self-efficacy, resilience, and QoL. We hypothesize that caregivers receiving the ACT-CSP will have greater reductions in caregiver burden and anxiety and depressive symptoms, and greater improvement in caregiving self-efficacy, resilience, and quality of life than caregivers receiving usual care.

## Methods

### Study Design

This is a 2-arm parallel group randomized controlled trial (RCT) with two follow-ups at Week 6 and Week 8 after enrolment. The methodology of the study was developed according to the CONSORT checklist to ensure the quality of the study [21].

### Participants

Caregivers will be eligible if they are (1) aged  $\geq 18$ ; (2) self- or patient-identified as a family caregiver of an adult patient receiving palliative care at the study site (3) have been taking care of the patient in the past 3 months; (4) able to communicate in Cantonese at the time of recruitment; and (5) have caregiver burden as measured by Caregiver Strain Index (CSI)  $\geq 7$  [22]. Caregivers will be excluded if they are (1) mentally incompetent (Mini-Mental State

Examination (MMSE) < 23) [23], or (2) participating in regular psychosocial interventions.

### Treatment Conditions

*Intervention group:* Caregivers in the intervention group will receive the ACT-based Caregiver Support Programme (ACT-CSP), which consists of two online sessions to be delivered within four weeks after enrolment. Each session will last 45-60 minutes and to be delivered by a trained ACT facilitator, who has a master degree in health-related discipline and more than three-year experience in conducting ACT sessions. In the two sessions, the core components of ACT process will be emphasized, including perspective taking, self-as-context and defusion, identifying values and acceptance of present-moment experience with respect to the values, and committed action [11]. If participants experience negative emotions caused by the sensitive issues during the intervention, the sessions will be stopped and they will be comforted by the facilitator and be referred to professional counseling if needed.

*Control group:* Caregivers in the control group will receive usual treatment provided in the participating hospital, such as psychosocial support or counselling provided by staff nurse or social worker. This service is ad hoc and provided as needed, rather than on a regular basis.

### Procedure

*Randomization and masking:* Caregivers will be randomized into the two arms using a 1:1 allocation. Before subject recruitment, a separate sequence of group identifies based on computer-generated random codes will be prepared and placed in serially numbered opaque sealed envelopes by an independent person who is blinded to the conditions and will not have contact with potential participants.

*Recruitment, baseline assessment, and allocation:* Research assistant of the project (RA1) approach caregivers individually and screen for eligibility at palliative care ward in the participating site, and provide project details to eligible caregivers. After obtaining informed written consent, the caregivers will self-complete the baseline questionnaire (T0) independently. RA1 then will randomly assign the caregiver to either the intervention or control group using the pre-prepared envelopes. For those caregivers assigned to the intervention group, RA1 will collect information on the time slots that the caregiver is available for the intervention, and information of the caregiver will be sent to the trained ACT facilitator of the study to receive the ACT-CSP. For those assigned to the control group, they will receive usual care of the respective hospital. If more than one caregiver of the patient indicates their willingness to join the study, only one of them will be recruited to the study to complete the study assessments while other caregivers can attend the ACT-CSP but do not need to complete the study assessments.

*Follow-ups:* Another RA (RA2), blinded to the allocation, will conduct the two follow-ups at Week 6 (T1) and Week 8 (T2) (i.e. about 2-week and 4-week after intervention) with the caregivers by telephone or WhatsApp.

*Ethical consideration:* The study will comply with the Declaration of Helsinki to ensure confidentially, anonymity in result dissemination and there will be no interference with the patient's treatment in the study. Caregivers have every right to stop the conversation or withdraw

from the study at any time without reprisal.

## Measures

### Primary outcome

1) *Caregiver burden*: The validated Chinese version of the 13-item Caregiver Strain Index (CSI) [22] will be used to assess the global burden of family caregivers. It has been widely used in studies on burden of caregivers of patients with chronic illness. Items are rated on a yes (1) or no (0) response, with the total score ranges from 0-13.

### Secondary outcomes

2) *Anxiety and depressive symptoms*: The Patient Health Questionnaire-4 (PHQ-4) [24] is an ultra-brief tool to measure symptoms of anxiety and depression. This questionnaire has four items with a Likert rating scale of 0 to 3. The Chinese version of the PHQ-4 was found to be reliable [25],[26].

3) *Caregiving self-efficacy* will be measured by the validated Chinese version of the 18-item modified Caregiver Inventory (C-CGI-18) [27],[28]. The C-CGI-18 covers 3 domains: Care of the Care Recipient, Managing information and Self-Care, and Managing Emotional Interaction with Care Recipient. Items are rated on a 9-point Likert scale with higher scores indicating more confidence.

4) *Resilience*: will be measured by the validated 10-item Chinese version of the Connor–Davidson Resilience Scale (CD-RISC) using a 5-point Likert-type response scale from ‘not true at all’ (0) to ‘true nearly all of the time’ (4) in the past month [29]. An overall resilience score will be calculated, and higher scores indicate higher levels of resilience.

5) *Caregiver quality of life* will be measured by Caregiver Quality of Life Index-Revised (CQOLI-R) which consists of four items covering four dimensions: emotional, social, financial, and physical [30]. Items are rated on a 11-point Likert scale, with higher scores indicating better QoL. The instrument has been shown to have good psychometric properties among three samples of hospice caregivers [30].

### Process measure

6) *Psychological flexibility*: The Acceptance and Action Questionnaire II (AAQII) measures patient’s psychological flexibility to accept undesirable thoughts and feelings, whilst acting in congruence with personal values and goals. The AAQII has been adopted and used in our local studies [31].

## Plan of Analyses

1) *Sample size determination*: As recommended by Whitehead and colleagues, a sample size of 15 subjects per treatment arm will be sufficient for a planned main trial with 90% power and two-sided 5% significance to detect a medium standardized effect size (0.5) [32]. Thus, this pilot study will recruit a total of 30 caregivers of palliative care patients.

2) *Preliminary efficacy*: Intention-to-treat will be applied in all the analyses whenever applicable. Descriptive statistics summarize demographic characteristics. Independent t-tests for continuous variables and chi-square test for categorical variables examine comparability of groups produced

by randomization. Variables that are statistically different between the two groups will be accounted for in subsequent analyses. The preliminary efficacy of the ACT-CSP on caregivers of palliative care patients will be evaluated by comparing the study outcomes from baseline, Week 6 to Week 8 follow-ups between the two groups using generalized estimating equation (GEE) methods with appropriate link functions, with the control of the frequency of usual care treatments caregiver received. Significant “time x group” interaction term in GEE will support the hypotheses on the effects of the ACT-CSP.

3) *Effect size estimation*: Between-group Cohen’s d will be calculated to estimate the effect sizes of the ACT-CSP on all the outcome measures separately. All statistical analyses will be performed using SPSS with a significant level at 5%.

## Discussions

Caregivers in palliative care usually have high level in burden and may have low level in caregiving self-efficacy based on our previous local finding, both influencing the quality of care they provide and their own psychological well-being. Yet, existing interventions either via palliative care or supportive programmes to caregivers produce only small to very small effect sizes in caregiver outcomes, highlighting the need to support these caregivers with new and effective interventions. The application of ACT seems feasible and acceptable among caregivers of palliative care patients, and is believed to better handle psychological distress specific to caregiving in palliative care so as to reduce their negative impacts. Thus, it would be valuable to determine the acceptability and preliminary efficacy of an ACT intervention for caregivers of palliative care patients.

We proposed a pilot randomized controlled trial to investigate the preliminary efficacy of an acceptance and commitment therapy-based caregiver support programme on psychological well-being among caregivers of palliative care patients. If this pilot RCT demonstrates potential efficacy of ACT-CSP as an intervention to reduce burden, anxiety, and depressive symptoms and to improve resilience, caregiving self-efficacy, and quality of life of the caregivers, such findings will support for a proposal on a main RCT. The study will, hopefully, provide directions for extending service in palliative care by supporting caregivers in maintaining their own health.

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