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Development of a novel COMPAssion focused online psyChoTherapy for bereaved informal caregivers: the COMPACT feasibility trial protocol

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ABSTRACT

Introduction An easy-to-access and effective psychotherapy for bereaved informal caregivers has not been established. People with higher self-compassion status tend to have lower bereavement related grief, psychotherapy focused on self-compassion can be promising for this population. This study aimed to examine the feasibility of online self-compassion focused psychotherapy for bereaved informal caregivers.

Method and analysis A total of 60 study participants will undergo an intervention programme comprising online sessions of 2 hours per week for five consecutive weeks and undertake postsession work. The intervention personnel will comprise psychologists who have received more than 10 hours of structured training. The primary endpoint will be assessed on the intervention completion rate, with secondary endpoints consisting of the Complicated Grief Questionnaire, Patient Health Questionnaire-9, Generalised Anxiety Disorder-7, Brief Resilience Scale and Self-Compassion Scale. Evaluations will be conducted preintervention, immediately after intervention, and 4 and 12 weeks after intervention.

Ethics and dissemination This study has been reviewed and approved by the Ethics Committee of the Kyoto University Graduate School and Faculty of Medicine, Kyoto University Hospital, Japan (Approved ID: C1565). The results of this study will be disseminated through publication in a peer-reviewed journal and conference presentations.

Trial registration number UMIN000048554.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study will outline the structured online interventions for bereaved informal caregivers, who comprise the population most difficult to reach.
⇒ The study participants will be extensively recruited via both online (including social networking services) and on-site nationwide announcements.
⇒ Study participants will be limited to those who access the internet, either by themselves or with support.

INTRODUCTION

Life-threatening illnesses impose a serious burden not only on the patients but also on their informal caregivers, who are involved in the patients' support and the medical treatment for the patients.[1–4] Moreover, caregivers experience psychological distress associated with bereavement, and 20%–60% of them are known to experience long-term psychological distress such as complicated grief, anxiety and insomnia.[5–10] Caregivers' depression is also known to be particularly prevalent, with 54% experiencing bereavement-related depression, and it is known to be associated with complicated grief.[11 12] However, only 3.5% of caregivers are shown to consult with specialists about their psychological problems.[13–15] In general, the delayed initiation of psychological support tends to result in poor clinical outcomes.[16 17] Therefore, providing psychological support to caregivers immediately after bereavement is important.

In common clinical settings, healthcare professionals face many barriers in providing continuous care to informal caregivers after bereavement.[15] However, support for caregivers does not necessarily involve clinical care at hospitals or clinics; therefore, alternative solutions, such as delivering online support, can overcome the access barrier to reach the relevant caregivers.[18 19] Further, online bereavement care has displayed merit in alleviating mental health stigma, cost and geographical limitations.[18 19] Accordingly, developing a feasible intervention that considers the real-world resources and the individual condition of the bereaved informal caregiver is important. However, the number of intervention studies on psychological support for bereaved caregivers is limited,

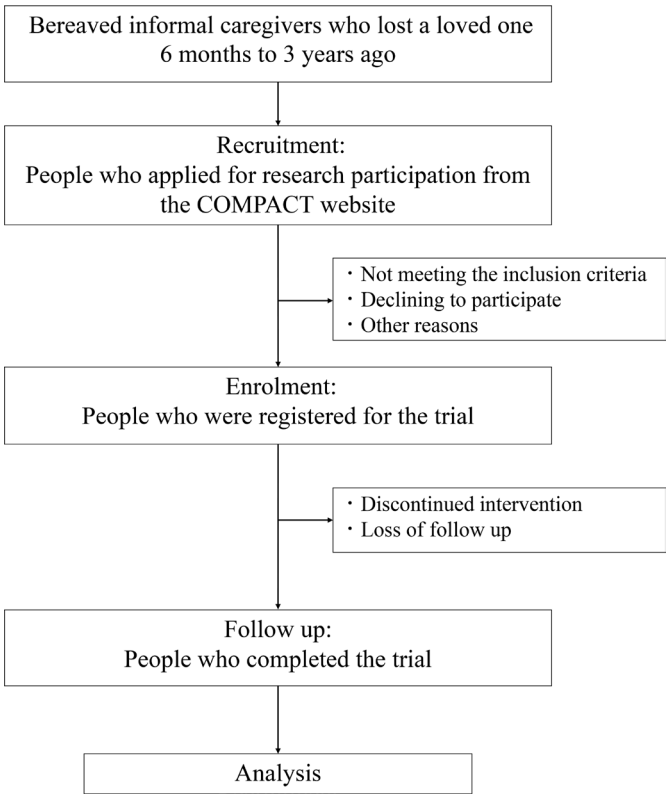

Figure 1 The CONSORT flow diagram of this study. CONSORT, Consolidated Standards of Reporting Trials.

and a standard approach for this population has not yet been established.[20]

Psychotherapy focused on self-compassion for bereaved caregivers can be one of the promising approaches.[21] Self-compassion refers to compassion for oneself and aligns with positive psychology 2.0 approaches.[22 23] Self-compassion focused psychotherapy has been established as an effective intervention for people with psychological distress in various settings.[24–26] Moreover, many people tend to associate shameful feelings with their mental health problems; hence, care that focuses on negative factors, such as depression and stress, can amplify the shameful feelings, which can exacerbate poor mental health.[27–29] However, an approach that strengthened people's psychological assets has been revealed to be promising.[27–29] Additionally, a high level of self-compassion has been revealed to be associated with a low level of grief.[30 31] Therefore, self-compassion focused psychotherapy can be an effective approach to strengthen the psychological assets of bereaved informal caregivers.

Thus, this study's primary aim is to investigate the feasibility of a novel self-compassion focused online psychotherapy for bereaved informal caregivers, and the secondary aim is to explore its effectiveness.

METHODS

This study's design will be a single-arm feasibility trial (figure 1). We considered that a randomised feasibility trial would not be appropriate for the population with challenges, because this study includes two new components, online sessions and self-compassion. The study period will be from September 2022 to August 2024.

Eligibility criteria of the study participants are as follows: (1) informal caregivers, over 18 years of age, who lost a loved one 6 months to 3 years ago; (2) people who can continue to participate in the online sessions and perform postsession work by themselves; and (3) people who can use smartphones or PCs with a stable internet connection, with or without support from others. Exclusion criteria are as follows: (1) people currently receiving psychiatric treatment (excluding cases the psychiatrist deems fit for participation) and (2) people judged to be unsuitable for participation in this research by one of the researchers due to physical, mental or cognitive problems (eg, respiratory disease, dementia, serious traumatic experience of bereavement). Informal caregiver is defined as 'family members, relatives or close friends who delivered daily support and care (eg, nursing, housework, shopping, emotional, financial aspects) for the deceased'.[1]

Recruitment

For this study, we will design a website to make an announcement regarding the current research, nationwide. People will receive the URL (https://compact-trial.com/, website in Japanese) or QR code through social networking services (Twitter, Instagram, Facebook and/or YouTube), relevant mailing lists and posters will be distributed to nationwide clinical institutes and patient support groups. People who are interested in the research can send the filled application forms to research staff through the website, and an individual online conference (Cisco Webex, California, USA) will be held on a convenient date to obtain electronic informed consent. To mitigate the disadvantage associated with a possible gap of digital literacy among participants, participants who are not familiar with using online materials (eg, application form, online interviews) will be allowed to receive support from their family members or friends. Once consent is confirmed, the participants will be registered for the trial.

Sample size

The number of required study participants was ascertained to be 60. The previous feasibility study in this area was conducted in about 25–50 cases.[19 32–36] Adding the 10 cases for drop-out, we determined 60 as the appropriate target sample size. When 42 cases participate in 4 or more sessions, the intervention completion rate of 70% can be estimated with the accuracy of the Wilson CI (57.5% to 80.1%). The researchers agreed that the lower limit of the CI of 57.5% was acceptable.

Intervention

Intervention personnel will perform an intervention involving (1) psychology education, (2) improvement of self-compassion and (3) strengthening of resilience; this was developed by YK, who is an accredited psychotherapist and researcher focused on self-compassion. The

online sessions (via Cisco Webex), which include both individualised and group work, will be held for 2 hours per week, for five consecutive weeks, and postsession assignments will be set after each session. Intervention personnel can be a certified public psychologist/clinical psychologist or a person who has obtained their master's degree or higher in clinical psychology or relevant subjects. Intervention personnel will receive 10 hours of structured training on the study intervention organised by YK.

Each session has a specific focus of the contents:

Week 1: Psychoeducation on grief and practising a specific kind of breathing technique.

Week 2: Psychoeducation on grief, anxiety, self-care and mindfulness and practising mindfulness.

Week 3: Psychoeducation and work on self-compassion, three emotion regulatory systems and imageries and self-compassion.

Week 4: Psychoeducation and work on cognitive distortion, ABC model, compassionate messages and cognitive reframing.

Week 5: Work on loss and gain, reflections and conclusion.

The therapy sessions will be recorded and structurally evaluated by the investigators for their intervention fidelity.

Measurements

Primary outcome

Intervention completion

The proportion of the intervention completion will be calculated by dividing 'the number of study participants who participated in four or more sessions out of the five online sessions' by 'the number of people registered in this study'.

Secondary outcomes

Satisfaction

Study participants will be asked the following questions: 'Did self-compassion focused psychotherapy help you?' and 'Would you like to recommend self-compassion-focused psychotherapy to others?' Participants' answers will be recorded on a five-point Likert scale: (1) disagree; (2) somewhat disagree; (3) I can't say either; (4) somewhat agree and (5) agree'.

Consent of enrolment

The consent proportion will be obtained by dividing 'the number of people who have consented to participate and registered in the study registration centre' by 'the number of people who have applied for study participation'.

Attrition

The attrition proportion will be calculated by dividing 'the number of people who have discontinued due to withdrawal of consent or adverse events' by 'the number of people registered in this study'.

Survey response

The survey response proportion will be calculated by dividing 'the number of people who have completed the survey responses immediately after the intervention and 4 weeks and 12 weeks later' by 'the number of people registered in this study'.

Postsession work submission

The postsession work submission proportion will be obtained by dividing 'the number of people who have submitted postsession work for each session' by 'the number of people registered in this study'.

Generalised Anxiety Disorder-7 Japanese version

According to the guidelines of the National Institute for Health and Care Excellence, Generalised Anxiety Disorder-7 (GAD-7) is the recommended measurement tool for the easy assessment of general anxiety disorder.[37] Verification of the reliability and validity of the Japanese version has already been reported.[38] For the symptoms of the past 2 weeks, the items on GAD-7 are rated on a 4-point Likert scale where 0=never anxious, 1=experience anxiety for several days, 2=experience anxiety for more than half the days and 3=experience anxiety almost every day. Obtaining 0–4 points implies that one does not exhibit symptoms of anxiety, 5–9 indicates mild symptoms of anxiety, 10–14 signify moderate symptoms of anxiety and 15–21 points indicate that one suffers from severe symptoms/level of anxiety.

Patient Health Questionnaire-9 Japanese version

The Patient Health Questionnaire-9 (PHQ-9) is a nine-item questionnaire for measuring the severity of depressive disorder symptoms, and verification of the reliability and validity of the Japanese version has already been reported.[39–41] For the symptoms of the past 2 weeks, the items on PHQ-9 are rated on a 4-point Likert scale where 0=never, 1=several days, 2=more than half the days and 3=almost every day. Obtaining 0–4 points implies that one does not exhibit symptoms of depression, 5–9 indicates mild symptoms of depression, 10–14 signify moderate symptoms of depression, 15–19 points indicate that one exhibits moderate to severe symptoms/level of depression and 20–27 points indicate severe symptom levels.

Self-Compassion Scale-Japanese version (26 questions)

Neff proposed that self-compassion consists of three constructs: self-kindness, common humanity and mindfulness, which are positioned against self-judgement, isolation and overidentification.[22] The Self-Compassion Scale consists of 26 items under 6 domains.[42] Verification of the reliability and validity of the Japanese version has already been reported.[43] The 26 items were rated on a five-point Likert scale ranging from 1 = 'almost completely (do not)' to 5 = 'almost always (do)', and the total score ranges from 26 to 130 points. The mean score will be used, which is calculated by dividing the total score by six.

Brief Resilience Scale-Japanese version (six questions)

Smith developed the Brief Resilience Scale based on the original concept of resilience: an ability to bounce back from difficulties.[44] The Brief Resilience Scale consists of six items. The reliability and validity of the Japanese version has already been verified and reported.[45] Responses will be rated on a five-point Likert scale ranging from 1 = 'almost completely (do not)' to 5 = 'almost always (do)'; the total score range is 6–30 points.

Complicated Grief Questionnaire Japanese version (19 questions)

A scale for assessing the severity of complicated grief was developed by Prigerson *et al*, comprising 19 items under 5 domains.[46] It is the most frequently used measure in Complicated Grief studies, and its reliability and validity have been verified in the original version. Prigerson *et al* reported that more than 26 points can be regarded as complicated grief.[46] The Japanese version was developed by Nakajima *et al*, and its reliability and validity have been verified.[47] Answers for the 19 items were rated on a five-point Likert scale ranging from 1 = 'none' to 5 = 'always' and the total score range was 19–95 points.

Baseline characteristics

Study participants' background information regarding age, gender, marital status, cohabitation, employment status, relationship with the bereaved, date of bereavement, disease name at the time of bereavement and religion will be obtained at the time of their enrolment in the study.

Schedule of outcome measurements

The schedule of these outcome measurements is shown in table 1. The research team will send study participants an email guiding them how to respond to the web questionnaire system (created with Google Forms, California, USA) and requesting them to respond. The web questionnaire system was piloted in respect to usability, in conjunction with appropriate guidance.[48] It will be acceptable for responses to be supported by the study participants' family members or friends, but the responses will be requested from the study participants themselves. The evaluation will be required within ±7 days, but the maximum evaluation period will be +14 days. If the response is not received within the +day 7; the study participants will be reminded of the same via phone or email. If no response is obtained by day 14, it will be treated as missing data.

Qualitative evaluation of the intervention

Online semistructured interviews (via Cisco Webex) of the study participants will be conducted with study participants and the intervention personnel. The interview will be designed to obtain general feedback about the intervention, the components that the participants perceived as helpful and unhelpful, and the subjective changes that they perceived after the intervention. Interviews will be conducted by research staff who specialise in psychology. However, they will not be in charge of the intervention. Additional consent will be obtained for conducting the interviews, and those individuals who

Table 1 Study schedule for outcome measurements

	Measurement	Baseline	After the first to the fourth sessions (within 7 days after each session)	Immediately after the intervention (within 14 days after the end of all five sessions)	4 weeks after the end of the intervention (–7 to 14 days)	12 weeks after the end of the intervention (–7 to 14 days)
Participants' Characteristics	N/A	•				
Depression	PHQ-9	•	•	•	•	•
Anxiety	GAD-7	•	•	•	•	•
Resilience	Brief Resilience Scale	•		•	•	•
Self-compassion	Self-Compassion Scale	•		•	•	•
Grief	Inventory of Complicated Grief	•		•	•	•
Satisfactory survey of the intervention	N/A			•		
Feedback on the online session	Semi-structured interviews			• (within 56 days after the end of all five sessions)		

GAD-7, General Anxiety Disorder-7; NA, not available; PHQ-9, Patient Health Questionnaire.

consent to participate will be interviewed until theoretical saturation is reached. Interviews will be conducted by two independent researchers using an interview guide based on the Helpful Aspects of Therapy, and the interview results will be qualitatively analysed by performing content analysis.[49–51]

Statistical analyses

All study participants who have registered will be included in the statistical analysis. For the primary endpoint, point estimates and CI in intervention completion rate will be calculated. More than 70% of the intervention completion rate will imply that the intervention is feasible. Other variables will be calculated in an appropriate manner including frequency, mean, median or longitudinal analysis. Exploratory effectiveness will be evaluated based on the longitudinal change of the psychological indicators.

Data collection and monitoring

Investigators will collect data electronically using Google Forms, while maintaining confidentiality. Study participants' recruitment process, data entry, data management, intervention personal's training record, curriculum vitae of intervention personnel and intervention fidelity records will be independently monitored by the Institute for Advancement of Clinical and Translational Science, Kyoto University Hospital. Auditing will not be performed for this study.

ETHICS AND DISSEMINATION

This study has been reviewed and approved by the Ethics Committee of the Kyoto University Graduate School and Faculty of Medicine, Kyoto University Hospital in conjunction with the current Ethical Guidelines for Medical and Health Research Involving Human Subjects of Japan (Approved ID: C1565) and was conducted according to the Standard Protocol Items: Recommendations for Interventional Trials guidelines (online supplemental table 1).[52] Electronical informed consent will be obtained from all study participants. The study participants will be allowed to withdraw their consent at any time. If an adverse event is confirmed, the situation will be promptly assessed and recorded, and the researchers will take appropriate measures. The study information was registered at the Japanese clinical trial registry (UMIN CTR: UMIN000048554). The results will be submitted for presentation at academic meetings and for publication in a peer-reviewed journal.

Patient and Public Involvement

During the protocol development phase, we asked several members of the patient advocacy group for their opinions regarding the research contents, and the protocol reflected these opinions. We also plan to seek assistance from several bereaved family support groups in recruiting the study participants and interpreting the study results.

DISCUSSION

This paper provided an overview of the feasibility of online self-compassion focused bereavement care. It outlines the structured online interventions conducted for bereaved informal caregivers, who comprise the population most difficult to reach and have left hospital premises and clinical settings. Further, to the best of our knowledge, this will be the first clinical trial of a self-compassion focused intervention for the population. This study will demonstrate its feasibility and data that will contribute to the planning of the upcoming randomised controlled trial (RCT).

This study has some limitations. The first is selection bias. Study participants will be limited to those who access the internet, either by themselves or with support. That is, those who are isolated after bereavement or do not have access to the internet cannot be included in this study. Second, the effects of the intervention will be an exploratory result. This will be tested in future RCTs. Finally, there is the possibility of diminished effectiveness due to the online nature of these interventions. Online interventions have been demonstrated to possess an impact equivalent to that of in-person interventions; however, these are still unknown among the bereaved population.[53] Moreover, we allow family and friends to assist in the process so that people with limited digital literacy can participate, but they must give consent, participate in the online session, and answer the questionnaire. Therefore, even if help from family and friends affects feasibility, it is unlikely to affect efficacy.

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YKo and NM developed the materials for the recruitment of study participants. MM supervised the project. YU and YKo will perform the data analysis and all co-authors will be involved in the interpretation of data. YU wrote the first draft of the manuscript, and all coauthors reviewed the manuscript and recommended critical revisions. All authors have approved the final version of the manuscript.

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