






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

Yu Uneno ¹, Yasuhiro Kotera ², Daisuke Fujisawa,³ Yuki Kataoka ^{4,5,6,7}, Kazuhiro Kosugi,⁸ Nanami Murata ⁹, Takaomi Kessoku,^{10,11} Akihiko Ozaki ¹², Hirotomo Miyatake,¹³ Manabu Muto¹

To cite: Uneno Y, Kotera Y, Fujisawa D, *et al.* Development of a novel COMPAssion focused online psyChoTherapy for bereaved informal caregivers: the COMPACT feasibility trial protocol. *BMJ Open* 2022;**12**:e067187. doi:10.1136/bmjopen-2022-067187

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2022-067187>).

Received 05 August 2022
Accepted 09 December 2022



© Author(s) (or their employer(s)) 2022. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

Correspondence to

Dr Yasuhiro Kotera;
yasuhiro.kotera@nottingham.ac.uk

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.

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,

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.

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,

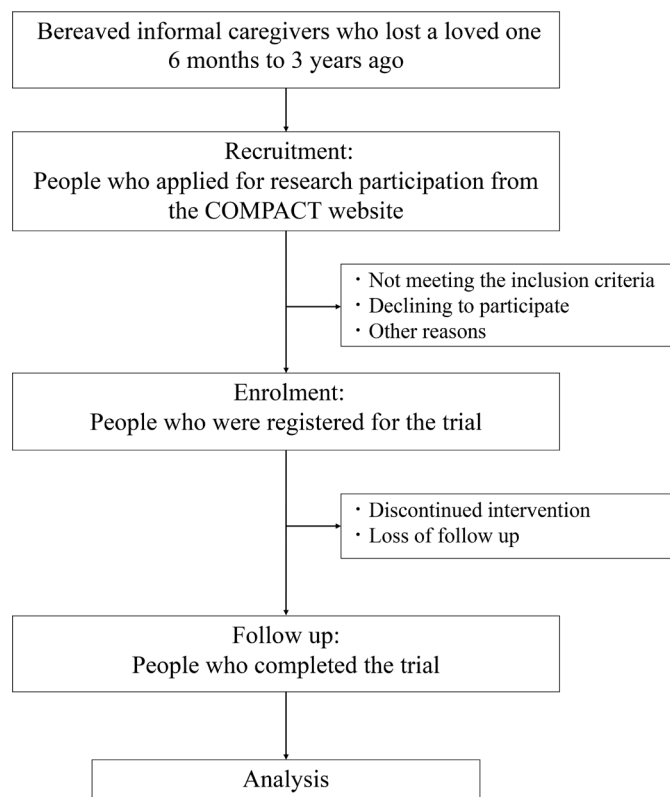


Figure 1 The CONSORT flow diagram of this study. CONSORT, Consolidated Standards of Reporting Trials.

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.

Author affiliations

¹Department of Therapeutic Oncology, Kyoto University, Graduate School of Medicine, Kyoto, Japan

²Faculty of Medicine and Health Sciences, University of Nottingham, Nottingham, UK

³Department of Neuropsychiatry and Palliative Care Center, Keio University School of Medicine, Tokyo, Japan

⁴Department of Internal Medicine, Kyoto Min-Iren Asukai Hospital, Kyoto, Japan

⁵Scientific Research Works Peer Support Group (SRWS-PSG), Osaka, Japan

⁶Section of Clinical Epidemiology, Department of Community Medicine, Kyoto University Graduate School of Medicine, Kyoto, Japan

⁷Department of Healthcare Epidemiology, Kyoto University Graduate School of Medicine / School of Public Health, Kyoto, Japan

⁸Department of Palliative Medicine, National Cancer Center Hospital East, Kashiwa, Japan

⁹Medical School, Wakayama Medical University, Wakayama, Japan

¹⁰Department of Gastroenterology and Hepatology, Yokohama City University School of Medicine Graduate School of Medicine, Yokohama, Japan

¹¹Department of Palliative Medicine, Yokohama City University Hospital, Yokohama, Japan

¹²Department of Breast Surgery, Jyoban Hospital of Tokiwa Foundation, Fukushima, Japan

¹³Orange Home-Care Clinic, Fukui, Japan

Twitter Yasuhiro Kotera @YasuKotera

Acknowledgements We sincerely appreciate Drs. Harue Tada, Yu Hidaka, Keiichi Narita and Ms Chie Tsunetoshi for their invaluable support in the development of the study monitoring protocol, providing statistical advice, and helping with the recruitment of intervention personnel, respectively.

Contributors YU, YKo, DF, YKa, KK, NM, TK, AO and HM contributed to the study conception and design protocol development. YU and YKo contributed to the intervention design and recruitment and training of intervention personnel. YU,

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.

Funding This work was supported by the research grant delivered by the Japanese Society for Palliative Medicine (Grant Number n/a.).

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

ORCID iDs

Yu Uneno <http://orcid.org/0000-0002-0322-8815>

Yasuhiro Kotera <http://orcid.org/0000-0002-0251-0085>

Yuki Kataoka <http://orcid.org/0000-0001-7982-5213>

Nanami Murata <http://orcid.org/0000-0001-5625-418X>

Akihiko Ozaki <http://orcid.org/0000-0003-4415-9657>

REFERENCES

- Hoang VL, Green T, Bonner A. Informal caregivers of people undergoing haemodialysis: associations between activities and burden. *J Ren Care* 2019;45:151–8.
- Mamom J, Daovisan H. Listening to caregivers' voices: the informal family caregiver burden of caring for chronically ill Bedridden elderly patients. *Int J Environ Res Public Health* 2022;19:567.
- Thana K, Lehto R, Sikorskii A, et al. Informal caregiver burden for solid tumour cancer patients: a review and future directions. *Psychol Health* 2021;36:1514–35.
- Koopman E, Heemskerk M, van der Beek AJ, et al. Factors associated with caregiver burden among adult (19–64 years) informal caregivers - An analysis from Dutch Municipal Health Service data. *Health Soc Care Community* 2020;28:1578–89.
- Stroebe M, Schut H. The dual process model of coping with bereavement: rationale and description. *Death Stud* 1999;23:197–224.
- Zarit SH, Todd PA, Zarit JM. Subjective burden of husbands and wives as caregivers: a longitudinal study. *Gerontologist* 1986;26:260–6.
- Costa-Requena G, Espinosa Val MC, Cristòfol R. Caregiver burden in end-of-life care: advanced cancer and final stage of dementia. *Palliat Support Care* 2015;13:583–9.
- Große J, Tremel J, Kersting A. Impact of caregiver burden on mental health in bereaved caregivers of cancer patients: a systematic review. *Psychooncology* 2018;27:757–67.
- Jho HJ, Choi JY, Kwak KS, et al. Prevalence and associated factors of anxiety and depressive symptoms among bereaved family members of cancer patients in Korea: a nation-wide cross-sectional study. *Medicine* 2016;95:e3716.
- Ishida M, Onishi H, Matsubara M, et al. Psychological distress of the bereaved seeking medical counseling at a cancer center. *Jpn J Clin Oncol* 2012;42:506–12.
- Clesse F, Leray E, Bodeau-Livinec F, et al. Bereavement-related depression: did the changes induced by DSM-V make a difference? results from a large population-based survey of French residents. *J Affect Disord* 2015;182:82–90.
- Sung SC, Dryman MT, Marks E, et al. Complicated grief among individuals with major depression: prevalence, comorbidity, and associated features. *J Affect Disord* 2011;134:453–8.
- Seeman N, Tang S, Brown AD, et al. World survey of mental illness stigma. *J Affect Disord* 2016;190:115–21.
- Currow DC, Allen K, Plummer J, et al. Bereavement help-seeking following an 'expected' death: a cross-sectional randomised face-to-face population survey. *BMC Palliat Care* 2008;7:19.
- Lichtenthal WG, Nilsson M, Kissane DW, et al. Underutilization of mental health services among bereaved caregivers with prolonged grief disorder. *Psychiatr Serv* 2011;62:1225–9.
- Lieberman JA, Fenton WS. Delayed detection of psychosis: causes, consequences, and effect on public health. *Am J Psychiatry* 2000;157:1727–30.
- Bertolote JM, Fleischmann A, De Leo D, et al. Psychiatric diagnoses and suicide: revisiting the evidence. *Crisis* 2004;25:147–55.
- Mifsud A, Pehlivan MJ, Fam P, et al. Feasibility and pilot study of a brief self-compassion intervention addressing body image distress in breast cancer survivors. *Health Psychol Behav Med* 2021;9:498–526.
- Krieger T, Martig DS, van den Brink E, et al. Working on self-compassion online: a proof of concept and feasibility study. *Internet Interv* 2016;6:64–70.
- Akechi T, Kubota Y, Ohtake Y, et al. Clinical practice guidelines for the care of psychologically distressed bereaved families who have lost members to physical illness including cancer. *Jpn J Clin Oncol* 2022;52:650–3.
- Grimby A, Johansson AK. Does early bereavement counseling prevent ill health and untimely death? *Am J Hosp Palliat Care* 2007;24:475–8.
- Neff K. Self-compassion: an alternative conceptualization of a healthy attitude toward oneself. *Self and Identity* 2003;2:85–101.
- Kotera Y, Van Gordon W. Effects of self-compassion training on work-related well-being: a systematic review. *Front Psychol* 2021;12:630798.
- Krieger T, Reber F, von Glutz B, et al. An Internet-based compassion-focused intervention for increased self-criticism: a randomized controlled trial. *Behav Ther* 2019;50:430–45.
- Kirby JN. Compassion interventions: the programmes, the evidence, and implications for research and practice. *Psychol Psychother* 2017;90:432–55.
- Leaviss J, Uttley L. Psychotherapeutic benefits of compassion-focused therapy: an early systematic review. *Psychol Med* 2015;45:927–45.
- Kotera Y, Green P, Sheffield D. Roles of positive psychology for mental health in UK social work students: Self-compassion as a predictor of better mental health. *Br J Soc Work* 2020;50:2002–21.
- Kotera Y, Ting S-H. Positive psychology of Malaysian university students: impacts of engagement, motivation, self-compassion, and well-being on mental health. *Int J Ment Health Addict* 2021;19:227–39.
- Kotera Y, Van Laethem M, Ohshima R. Cross-Cultural comparison of mental health between Japanese and Dutch workers: relationships with mental health shame, self-compassion, work engagement and motivation. *CCSM* 2020;27:511–30.
- Vara H, Thimm JC. Associations between self-compassion and complicated grief symptoms in bereaved individuals: an exploratory study. *Nordic Psychology* 2020;72:235–47.
- Lenferink LIM, Eisma MC, de Keijser J, et al. Grief rumination mediates the association between self-compassion and psychopathology in relatives of missing persons. *Eur J Psychotraumatol* 2017;8:1378052.
- Jerome H, Smith KV, Shaw EJ, et al. Effectiveness of a cancer bereavement therapeutic group. *J Loss Trauma* 2019;23:574–87.
- Forkert A, Brown P, Freeman D, et al. A compassionate imagery intervention for patients with persecutory delusions. *Behav Cogn Psychother* 2022;50:15–27.
- Ellis DA, Carcone A, Slatcher R, et al. Feasibility of mindfulness-based stress reduction for older adolescents and young adults with poorly controlled type 1 diabetes. *Health Psychol Behav Med* 2018;6:1–14.
- Park S, Sado M, Fujisawa D, et al. Mindfulness-based cognitive therapy for Japanese breast cancer patients—a feasibility study. *Jpn J Clin Oncol* 2018;48:68–74.
- Knowles LM, Stelzer E-M, Jovel KS, et al. A pilot study of virtual support for grief: feasibility, acceptability, and preliminary outcomes. *Comput Human Behav* 2017;73:650–8.
- Spitzer RL, Kroenke K, Williams JBW, et al. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med* 2006;166:1092–7.

- 38 Muramatsu K, Miyaoka H, Kamijima K. Validity and usefulness of the Japanese version of the GAD-7. *Jpn J Psychosom Med* 2010;50:592.
- 39 Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med* 2001;16:606–13.
- 40 Muramatsu K, Miyaoka H, Kamijima K, *et al*. Performance of the Japanese version of the patient health Questionnaire-9 (J-PHQ-9) for depression in primary care. *Gen Hosp Psychiatry* 2018;52:64–9.
- 41 Muramatsu K, Miyaoka H, Kamijima K, *et al*. The patient health questionnaire, Japanese version: validity according to the mini-international neuropsychiatric interview-plus. *Psychol Rep* 2007;101:952–60.
- 42 Neff KD. The development and validation of a scale to measure self-compassion. *Self Identity* 2003;2:223–50.
- 43 Arimitsu K. Development and validation of the Japanese version of the Self-Compassion scale. *JJ pshicho* 2014;85:50–9.
- 44 Smith BW, Dalen J, Wiggins K, *et al*. The brief resilience scale: assessing the ability to bounce back. *Int J Behav Med* 2008;15:194–200.
- 45 Tokuyoshi Y, Moriya M. Development and validation of the brief resilience scale Japanese version (BRS-J). *The Proceedings of the Annual Convention of the JPA* 2015;79:1EV-055.
- 46 Prigerson HG, Maciejewski PK, Reynolds CF, *et al*. Inventory of complicated grief: a scale to measure maladaptive symptoms of loss. *Psychiatry Res* 1995;59:65–79.
- 47 Nakajima S, Ito M, Ishimaru K. Prevalence and risk factors for prolonged grief disorder in adults who lost significant others. *Meiji Yasuda Kokoro Health Foundation Research Grant Thesis* 2010;45:119–26. (in Japanese).
- 48 The European Organisation for Research and Treatment of Cancer (EORTC). *Guidance in the implementation and management of EORTC quality of life instruments in electronic applications*. Brussels: EORTC, 2018. ISBN: 978-2-930064-46-8.
- 49 Elliott R. Qualitative methods for studying psychotherapy change processes. In: *Qualitative research methods in mental health & psychotherapy*. Chichester, UK: Wiley-Blackwell, John Wiley & Sons, Ltd, 2011: 69–81. ISBN: 9780470663707.
- 50 Elo S, Kyngäs H. The qualitative content analysis process. *J Adv Nurs* 2008;62:107–15.
- 51 Elo S, Kääriäinen M, Kanste O, *et al*. Qualitative content analysis: a focus on trustworthiness. *SAGE Open* 2014;4.
- 52 Chan A-W, Tetzlaff JM, Altman DG, *et al*. Spirit 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013;158:200–7.
- 53 Wagner B, Rosenberg N, Hofmann L, *et al*. Web-Based bereavement care: a systematic review and meta-analysis. *Front Psychiatry* 2020;11:525.



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	5, 18
	2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	3	Date and version identifier	n/a
Funding	4	Sources and types of financial, material, and other support	29
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	28, 29
	5b	Name and contact information for the trial sponsor	29
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	29
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	28, 29
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	6-8
	6b	Explanation for choice of comparators	n/a
Objectives	7	Specific objectives or hypotheses	8

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	8
--------------	---	---	---

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8, 9
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8,9
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10, 11
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	18
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	n/a
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	11- 15
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Table 1
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	9, 10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	n/a
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	n/a
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n/a
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	16, 17
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	16, 17
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	17, 18
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	17
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	17, 18
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17, 18

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	17, 18
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	17, 18
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	18
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	18
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	n/a
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	18
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	29
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	n/a
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	18

Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	18
	31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Available upon request to the authors
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.