

Online-Group Intervention after Suicide Bereavement through the Use of Webinars: Study Protocol for a randomized controlled Trial

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Study protocol

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Abstract

Introduction The death of a significant person through suicide is a very difficult experience and can have long-term impact on an individual's psychosocial and physical functioning. However, there are only few studies which have examined the effects of interventions in suicide survivors. In the present study, we examined an online-group intervention for people bereaved by suicide using a group-webinar. **Methods** The intervention was developed based on focus groups with the target group. The cognitive-behavioral 12-module webinar-based group intervention focuses on suicide bereavement related themes such as feelings of guilt, stigmatization, meaning reconstruction and the relationship to the deceased. Further, the webinar includes testimonial videos and psychoeducation. The suicide survivors are randomized to the intervention or the waiting-list in a group cluster randomized controlled trial. Primary outcome were suicidality (BSSI) and depression (BDI-II), secondary outcomes are symptoms of prolonged grief disorder (ICG-D), PTSD (IES-R), stigmatization (STOSASS) and posttraumatic cognitions (PTCI). **Discussion** Previous studies of internet-based interventions for the bereaved were writing interventions showing large treatment effects. Little is known about the use of webinars as group interventions. Advantages and challenges of this novel approach of psychological interventions will be discussed.

Background

Background and rationale

Global data showed that age-standardized mortality rates for suicide decreased between 1990 and 2016 by 32% worldwide [1]. However, suicide is still the leading cause of age standardized years of lost life in the Global Burden of Disease, specifically in high income countries. The suicide of a significant person can leave a long-term impact on the surviving parent, child, partner, sibling or friend. While older research estimated about six individuals affected by a suicide [2], more recent studies found much higher estimates, including not only the nuclear family, but also considering the social network of the deceased person. Berman [3] estimated that 45 to 60 people are intimately affected by the death of suicide, depending on the close daily or weekly contact the deceased person had to their social network.

Since 1989, the WHO describes people bereaved through suicide as a high-risk group for suicides and describes the aftercare of this group of victims as an essential part of national and international suicide prevention [4]. Suicide bereavement differs significantly from other circumstances of death in the grieving process. Typical reactions after a suicide are, in addition to normal grief reactions, the feeling of guilt and responsibility for the suicide, feeling of shame and rejection, low-self-esteem, one's own suicidal tendencies, the experience of stigmatization, and exposure to traumatic images [5]. Those affected often suffer lifelong functional impairment (e.g. inability to work, early retirement) as a result of suicide [6]. Kersting and colleagues [7] associated a higher risk of prolonged grief disorder in people bereaved by suicide (18.1%) or violent death (20%) compared with people to sudden but natural deaths. Furthermore, people bereaved by suicide report sleep disorders, somatic diseases (e.g. stomach ache, headache), and a significantly increased risk of being hospitalized [5, 8]. They are also more susceptible to crises [9]. In fact, more than half of the survivors suffer depression and about 20% alcoholism, with the combination of the different disorders in particular having the highest suicide risk [10-14]. Pitman and colleagues [5] found in their systematic review

on mental health outcomes after suicide bereavement an increased admission to psychiatric care specifically for bereaved parents after a child's death through suicide and an increased risk of depression in bereaved children after parental suicide.

Further, numerous population-based representative studies have demonstrated a higher mortality after suicide compared to control groups. A Swedish epidemiological study with surviving siblings (N = 160.588) showed that the brother or sister's suicide in all age groups (18-69 years) had an up to 3.1 times higher mortality rate among the siblings than in non-sibling mourning control groups [15, 16]. Guldin and colleagues [17] investigated the consequences of the death of a parent in the first 18 years of life related to the suicidality of adult children (N = 7.302.033). The adult children had an 82% higher risk of suicidal death if a parent also committed suicide. Children who had a parent who died before they reached 6 years of age were specifically at high risk to commit suicide themselves, and this risk remained high for at least 25 years [17]. Further, Pitman and colleagues [5] found an increased risk of suicide of a partner who died of suicide. Therefore, the suicide of a significant person does not only increase the risk for mental health disorders but shows an increased mortality rate, specifically of dying of suicide themselves. For this reason, bereavement interventions aimed specifically at people who are bereaved by suicide play an important role in the aftercare.

Interventions for suicide survivors

Interventions targeted at people bereaved by suicide are an important preventive measure for psychiatric illnesses and suicidal behavior. While self-help groups or counseling services of suicide survivors in the voluntary sector steadily increase, only few psychotherapeutic interventions for survivors following suicide have been developed and have been scientifically evaluated. A recent systematic review included a total of 11 studies aimed at suicide bereavement; however, only a few of the included studies showed evidence of effectiveness for people suffering uncomplicated grief, and empirical evidence for interventions aimed at prolonged grief disorder after suicide are still lacking [18]. McDaid and colleagues [19] point in their systematic review to the lack of methodological quality of these studies, and thus, a lack of evidence-based interventions. The thin empirical evidence that exists, however, suggests that (cognitive-behavioral) interventions might be effective for the reduction of maladaptive grief reactions and the perceived responsibility for suicide [20], the reduction of anxiety and depression in suicidal children [21], and the reduction of suicide-associated grief and depression [22]. In summary, while there is a high need for care for the prevention of suicide survivors, there is little empirical evidence of their effectiveness.

Internet-based bereavement intervention

In recent years internet-based psychological support has been established in social media for bereaved populations, including online support groups (e.g Facebook), memorial websites and discussion forums. Parallel to the use of social media, web-based interventions for different types of losses have been developed and evaluated in recent years. Those internet-based bereavement interventions were aimed at bereaved people in general [23-26] or for specific bereavement populations such as parents after pregnancy loss [27, 28]. The

treatment effects found for internet-based interventions on grief symptoms were moderate to large, which could be maintained over time [29]. The largest and most robust effects, however, were found for grief-related PTSD symptoms. Most internet-based bereavement interventions included writing assignments, ranging from extensive structured writing assignments to online diaries and homework assignments and were based in an individual setting.

Unfortunately, even though they are a high-risk group, suicide survivors are precisely the group that is the least likely to seek professional help. A study from Great Britain showed that suicide survivors in particular were less likely to receive formal (e.g. psychotherapists, doctors) or informal support (e.g. friends, religious counselling), and only every fourth interviewed person made use of any form of support at all. Reasons for the low use of professional psychological support include, for example, a lack of psychosocial care or fear of stigmatization (Pitman et al., 2016b; Pitman et al., 2017). Therefore, the anonymity of the internet might support bereaved patients in overcoming their initial shame or perceived feelings of stigma which might prevent them from looking for support. Another advantage of internet-based intervention is that these interventions offer geographic independence and a widespread dissemination of the treatment offer. This is of particular interest for people living in remote areas without any access to local bereavement groups or specialized grief counsellors. Further, internet-based interventions provide a more user-friendly and flexible approach that is more responsive to the mobile and digitalized society.

The aim of this study is to develop and evaluate a manualised CBT-based online-group intervention after suicide bereavement using webinars. Previous internet-based bereavement interventions were almost always writing interventions based in an individual setting. Contrarily, we chose the novel format of a webinar to provide real-time simultaneous interaction between the therapists and the group participants. Grief group interventions can provide unique therapeutic elements such as universality of the suffering, group cohesiveness, role model learning, and interpersonal learning [30, 31]. So far, studies of online-group interventions have taken place mainly via videoconferencing. Backhaus and colleagues [32] included in their systematic review of videoconferences in psychotherapy 7 studies altogether which used the group format. The results indicated similar clinical outcomes such as face-to-face interventions. Webinars are, next to videoconferencing, most similar to traditional group interventions for bereaved people after the loss of suicide. Webinars provide the possibility to participate in the group sessions from a remote location in real-time but have the additional advantage of providing the possibility of showing videos and psycho-educative PowerPoint presentations, as is customary in e-learning environments.

Objectives

The main objective of this trial and the proposed online-group intervention is to reduce depression and suicidality of people bereaved by suicide. Secondary outcomes of the trial are prolonged grief disorder, posttraumatic stress disorder, anxiety, stigmatization, posttraumatic grief cognitions and social support. More precisely, our treatment-specific objectives are:

1. The online-group intervention significantly reduces symptoms of depression, suicidality, prolonged grief disorder posttraumatic stress disorder, , anxiety after the loss through suicide.

2. The treatment effects (symptom reduction of primary and secondary outcomes) of the online-group intervention are significantly greater than those of the control group after the end of treatment.

In addition, the study addresses the following process-specific research questions:

1. Which factors (such as age, sex, depression, severity of symptoms) are most likely to predict the effect of the treatment?
2. To which extent does the relationship with the deceased (e.g. spouse, sibling, child, parent, friend) influence treatment outcomes in terms of grief and trauma symptoms?
3. Which cognitive processes (such as stigma experience, guilt) influence the general psychopathology of study participants (e.g. depression, prolonged grief, trauma symptoms)?

Trial design

This study is a randomized control group design with two groups of equal sample size: The treatment group and the waitlist control group. The treatment group will receive treatment through the online-group intervention immediately after registration. This intervention is based on cognitive-behavioral principles (psychoeducation, cognitive restructuring, dealing with difficult emotions such as guilt, shame, suicidality) and will take place once a week over a course of 12 weeks in total. The waitlist control group will receive the same intervention 12 weeks after registration. Participants will be randomly assigned to either group using a computer-generated block-randomization. The study protocol was written in accordance with the SPIRIT 2013 Statement [Standard Protocol Items: Recommendations for Interventional Trials; see 33] for the SPIRIT Checklist see Appendix A).

Methods

Study setting and recruitment

The main recruitment centers are located in Berlin, Leipzig, and Bayreuth and are directed in accordance with the Medical School Berlin, the Federal Association of Bereaved Parents and Grieving Siblings in Germany (VEID e.V.), and the Association for Relatives to Suicide (AGUS e.V.). In addition, we will recruit participants through the study website (www.hilfe-nach-suizid.de) and advertisements in social media (e.g. social media platforms, self-help forums, specific websites for bereaved people), newspaper articles, flyers for self-help groups, or churches.

Participants and eligibility criteria

All participants who meet the following criteria will be included in the study: a) aged between 18 and 75 years, b) experienced a loss of the suicide of a close person, c) have access to the Internet, d) have sufficient German language skills, and e) provide a signed consent form (Appendix B). Participants who show one of the following criteria will be excluded from the study: a) acute suicidality, b) elevated depression (the score in the Beck Depression Inventory-II > 35), 3) bipolar disorder, c) current psychotic experience, d) elevated alcohol,

drug, or substance use, e) suspect of Borderline Personality Disorder, and f) self-injurious behavior. The group intervention will be conducted by two group leaders a) an approved psychotherapist or a trainee in psychotherapy in the last phase of the training and b) a group leader of a face-to-face self-help group for suicide bereavement.

Sample size

We based the power and sample size estimations in the current study on results from previous studies examining the effectiveness of online bereavement interventions [34]. Assuming a between-subject effect size of $d = 0.80$, a power of 0.80, an alpha of 0.05 (two-sided) and a dropout rate of 30%, the within group sample size should consist of at least $n = 52$ participants. Hence, we aim to include $N = 104$ participants in total.

Procedure

The flow of all participants is depicted in Figure 1. Participants who are interested in the treatment can obtain general information about the program on the study website (www.hilfe-nach-suizid.de). This website provides widespread information on relevant topics for bereaved people after suicide. In addition, visitors of the website receive further information on helpful services (e.g. psychotherapy, counselling) as well as recommendations of useful literature.

To take part in the online intervention, participants have to register on the website first. Afterwards they receive comprehensive information about the process of the study as well as a consent form for participation. As soon as participants have signed the consent form and have sent it back (e.g. email, fax, or by post), they are invited to an online survey which contains several questionnaires for diagnostic purposes (Table 1). To further examine the inclusion and exclusion criteria, participants will take part in a clinical telephone interview. This interview tests for acute suicidality, severe depression, acute psychotic experiences, bipolar disorder, posttraumatic stress disorder (PTSD), as well as Borderline Personality Disorder (BPD). Participants who do not meet the inclusion criteria receive further information on psychotherapy, counselling or self-help groups. In case of clearly elevated scores on the measurements, participants are debriefed and are advised to see a doctor or psychotherapist. If the interviewer finds evidence for acute suicidality, he or she engages in crisis management strategies [35] or will arrange another telephone meeting to monitor the process.

Randomization

We will use block randomization without extra stratification: As soon as ten participants are included, they are considered to form a group. Then, the whole group is randomly assigned to either the treatment or the waitlist control group. One of the authors (BW) who is not involved in participant recruitment (UM, LH), clinical assessments (UM, LH), or treatment (external group leaders) executes the randomization using a generated list of www.random.org.

Blinding

Because of the high level of organizational effort involved in randomizing groups, it is not possible to blind the participants, group leaders, or study employees.

Symptom assessment

During the intervention, participants are requested to complete online surveys to assess potential changes in the therapeutic process. More precisely, there are 15 measurement points (Table 1): at the initial stage (pre-assessment, T0), after each group session (T1 to T12 including a treatment mid-point assessment after six weeks, T6, and a post-assessment at the end of the intervention, T12), after a three-months follow up (T13), and finally, after a six-months follow-up (T14).

The online-group intervention

The online group intervention is manualized and consists of 12 weekly sessions with a length of 90 minutes. Each group has a maximum of ten participants and is guided by a psychologist (i.e. a psychotherapy trainee) and a self-help counsellor, who is herself or himself bereaved by suicide. The participation is voluntary and free. Participants are allowed to skip sessions or to drop out of the program at any time.

Development of the intervention

Focus groups. In order to develop the intervention, a total of three focus groups were conducted. The composition of the groups was based on gender, age and kinship to the deceased. Also, they had to be at least 18 years old, and the time since the suicide should be at least one year. The 23 recruited participants were on average 53 years old (SD = 13, Range: 20-72) and 86% were women. Most participants had lost a child (52%), followed by a spouse or partner (24%), a parent or sibling (each 10%), or others (5%). Almost all participants received support at the time of measurement, namely from psychotherapy (86%), self-help group (48%), a doctor (29%), pastoral care (19%), or grief counselling (14%).

The focus group participants were asked what they believed were difficulties during their grief process and effective strategies to find meaning with the suicide. Further, they were interviewed which themes are relevant to be included in an internet-based intervention. The group conversations took place for four hours with a one-hour break and were recorded in audio format, transcribed, and evaluated with respect to the important themes for a group intervention.

Testimonial Videos. Most of the sessions start with a testimonial video in which a person bereaved by suicide talks about her or his own experiences of the session's topic (e.g. guilt, own suicidality). The screen-plays of

the protagonist's monologue (played by an actor/actress) were developed with the excerpts of the transcribed focus-groups. In order to ensure a balanced gender ratio, both men and women were presented equally in the testimonial videos. All testimonial videos follow the same structure: 1) How did the bereaved person experience e.g. feelings of guilt in the first days and weeks after the loss? 2) How did the bereaved person experience feelings of guilt over the course of time? 3) How did the bereaved person experience feelings of guilt today? The protagonists in the testimonial videos aim to function as a role model in dealing with difficult emotions which occur after a suicide over the course of time.

Treatment modules. The selection of the relevant themes for the intervention were based on the literature on grief or treatment of traumatized people [34] as well as the results from the focus groups. Focus group interviews were analyzed and relevant themes were included in the treatment manual. Table 2 describes the complete content by session. The manual is based on cognitive-behavioral principles and consists of a) testimonial videos, b) psychoeducation (e.g. grief, guilt, suicidality), c) a guided group discussion about the topic of the session, and d) individual tasks between the sessions (e.g. writing a farewell letter to the deceased).

The internet tool. The Webinar will be held using the internet tool Adobe Connect[®]. Participants receive a link to log into an online-seminar room and log in with a self-chosen user name. They are connected with each other via micro- and headphones but without video-transmission. The visual transmission is disconnected to keep increased anonymity for the participants. The participants are able to see PowerPoint slides or videos, which are part of the treatment program on their computer-screen. The two group leaders can additionally access a name-list of all group members. There is also a chat option which could be used by group participants or group leaders.

Measures

Screening for eligibility criteria. The study coordinators will screen the participants for eligibility criteria using a semi-standardized clinical telephone interview. To exclude the presence of a current major depressive or manic episode, bipolar disorder, BPD, PTSD, or alcohol and substance misuse, the corresponding sections from the German version of the Structured Clinical Interview for DSM-IV [37] will be applied. The inter-rater reliabilities of the diagnoses vary between fair (e.g. Agoraphobia) and excellent (e.g. PTSD, BPD) scores [38]. In addition, the German translations [39] of the Dutch Screening Device for Psychotic Disorder [40] and the Suicide Risk Assessment Interview [41] will be used to screen for acute schizophrenia and suicidality, respectively.

Primary outcomes. The primary outcomes will be the level of suicidality and depression at post treatment, three- and six-months follow-up. Suicidality and depression will be assessed with the following instruments:

Revised Acquired Capability of Suicide Scale [ACSS-FAD; 42]. This instrument assesses fearlessness from death with seven items using a five-point rating scale (1 = "fits not at all to me", 5 = "fits completely to me"). It showed a good internal consistency ($\alpha = .79$) in a German student sample.

Beck-Depression-Inventory [BDI-II; 43]. The BDI-II is one of the most used inventories to examine the severity of depression within the last two weeks. There are 21 symptom groups and participants chose one statement out of four to seven response categories (coded 0, 1, 2, and 3) per symptom. Sum scores of 29 indicate severe depressions. Internal consistencies were $\alpha = .90$ in a healthy sample and $\alpha = .93$ in a client sample, respectively.

Beck Scale for Suicide Ideation [BSSI; 44, 45]. Suicidal thinking is assessed with the BSS that has 21 symptom groups, each with three different response categories, representing a three-point rating scale. The first five groups are for screening purposes and the last two groups not included into the total BSS sum score. Higher sum scores (Range 0 to 38) indicate a higher risk of suicide. The internal consistency in a non-clinical German sample was very good ($\alpha = .94$).

Secondary outcomes. As secondary outcomes, prolonged grief disorder, PTSD hopelessness, anxiety, perceived stigmatization, and perceived social support will be assessed at post-treatment, 3-months follow-up, and 6-months follow-up. These variables will be assessed with the following instruments:

Short Version of the Patient Health Questionnaire [PHQ-D; 46]. The short version of the PHQ-D is a 15-item screening test for depressive disorders (nine items, four-point rating scale: 1 = “not at all”, 4 = “almost every day”), panic disorders, (i.e. panic attacks, five items, dichotomous rating scale: 1 = “no”, 2 = “yes”) and psychosocial impairment (one item, four-point rating scale: 1 = “not at all impaired”, 4 = “very impaired”). Graefe, Zipfel, Herzog, and Loewe [47] report a satisfactory Cronbach’s alpha of $\alpha = .88$ for the depression scale of the PHQ-D in a German clinical sample.

Screening for Complex PTSD [SkPTBS; 48]. The SkPTBS is a screening instrument for complex PTSD with 34 items including traumatic events (self of witness) and reactions to the most burdening event on a seven-point rating scale (1 = “not at all”, 7 = “completely”). The internal consistency was $\alpha = .91$ in a German clinical sample.

Revised Impact of Event Scale [IES-R; 49]. We will assess posttraumatic stress reactions within the last seven days with the IES-R, which consists of the three subscales *intrusion* (seven items), *avoidance* (eight items), and *hyperarousal* (seven items) and uses a four-point rating scale (1 = “not at all”, 4 = “often”). Internal consistencies for each subscale were reported for patient groups and vary between $\alpha = .71$ and $\alpha = .90$.

Posttraumatic Cognitions Inventor [PTCI; 50]. The German version of the PTCI is a 33-item questionnaire that assesses dysfunctional cognitions of traumatic events on a seven-point rating scale (1 = “totally disagree”, 7 = “totally agree”). In a clinical sample, the three subscales negative cognitions about the self (21 items), negative cognitions about the world (seven items), and self-blame (five items) showed satisfactory to very good internal consistencies: $\alpha = .97$, $\alpha = .88$, and $\alpha = .86$, respectively.

Inventory of Complicated Grief [ICG-D; 51]. The German version of the ICG [52] measures the extent of complicated grief symptoms [synonyms: prolonged grief, persistent complex bereavement disorder; 53] with 19 items on a five-point rating-scale (1 = “never”, 5 = “always”). Cronbachs Alpha was $\alpha = .87$ in a clinical sample.

Grief Experience Questionnaire [GEQ; 54]. The GEQ is a questionnaire that measures reactions to grief and symptoms that are typical for suicide bereavement. In the current study, only the stigmatization subscale is taken. This scale has ten items on a five-point rating scale (1 = “never”, 5 = “almost always”) with a good Cronbach’s Alpha ($\alpha = .86$) in a sample with bereaved students. The original items were translated into German by the last author and another research assistant using back and forth translation (see Appendix C).

Stigma of Suicide and Suicide Survivor [STOSASS; 55]. To evaluate the level of perceived stigmatization towards completed suicide, we applied the STOSASS, which comprises the two subscales “stigma towards the suicidal person” and “stigma towards the suicide survivor”. Participants indicate their agreement with 17 items on a four-point rating scale (1 = “strongly disagree”, 4 = “strongly agree”). Internal consistencies for the subscales in non-clinical and clinical samples were good (between .79 to .83). The original items were translated into German by the last author and another research assistant using back and forth translation (see Appendix D).

H-Scales [56]. The H-Scales are a German translation of the hopelessness scale by Beck, Weissman, Lester, & Trexler [57]. The short version with ten items to measure the participants’ negative expectations of themselves, the environment and their future life on a six-point rating scale (1 = “completely wrong”, 6 = “completely correct”) will be used. Cronbach’s alpha ranged between $\alpha = .74$ and $\alpha = .92$ in clinical and non-clinical samples.

Berlin Social Support Scales [BSSS; 58]. The BSSS assesses social support via five subscales: *perceived available social support* (eight items, $\alpha = .83$), *actually received social support* (eleven items, $\alpha = .83$), (3) *need for support* (four items, $\alpha = .63$), *mobilization of social support* (five items, $\alpha = .819$, and *protective buffering* (six items, $\alpha = .82$). The questionnaire was validated in a clinical sample and uses a four-point rating scale (1 = “is not correct”, 4 = “is completely correct”). In the current study, only the subscales *perceived available social support*, *need for support*, and *mobilization of social support* will be used.

Questionnaire on Police Delivery of Death News (QPDDN; Hofmann & Wagner). The PDDN is a newly constructed questionnaire to examine how mourners perceive the behavior of the officers who transmitted the death news. The questionnaire consists of 34 items with items of perceived stigmatization, experienced emotional support and perceived behavior of the police (see Appendix E) with 2 items using a six-point rating (1 = “not correct at all”, 6 = “completely correct”). 7 items assess additional information regarding received information material, how the message was delivered, if there was any support (e.g. doctor, pastor), which behavior they found most disturbing and what they would have wished for. Information on the validity and reliability will be provided once the data have been analyzed.

Process measures. In addition to the primary and secondary outcomes, we are also interested in variables that relate to the therapeutic process and the development of suicidal or depressive markers from one treatment session to another. We expect that the depressive and suicidal symptoms will reduce over the course of the intervention. After each session, depression will be assessed with the depression subscale from the PHQ-D [46]. Suicidality will be measured with the “suicide item” from the BDI-II [43].

Furthermore, the therapeutic relationships within the intervention groups were assessed using the German version of the Group Questionnaire [GQ-D; 59]. This inventory consists of the subscales *positive bonding*

relationship ($\alpha = .92$), *positive working relationship* ($\alpha = .89$), and *negative relationship* ($\alpha = .79$) and differentiates between group members, group leaders, and the group as a whole. Agreement with the statements is indicated on a seven-point rating scale (1 = “is not correct at all”, 7 = “is completely correct”).

Data management and storage

Personal Data. As part of the registration process, participants provide their name, telephone number, email, and home address. This information is pseudonymized using encrypted codes. The pseudo-anonymization will be saved in a coding list, which exists on paper and only in one version. This list will be kept locked up with no third-party access. As long as the coding list exists, the study participants are able to request the deletion of all data collected from them. The coding list will be destroyed after data collection. Then all data of the study will be completely anonymous and the personal data of participants can no longer be identified.

Furthermore, we assess socio-demographic data, symptoms of general psychopathology, grief or suicidality within the telephone interview and the online surveys. We conduct all surveys using the program Unipark[®]. The storage and evaluation of the study-related data is carried out according to legal provisions without the participants name or IP address. The data will be transferred to the statistical programs SPSS 20. We keep the data in a place that only employees of this study have access to. We store the digital data on secured servers at the Medical School Berlin for at least ten years. After expiration of the retention obligation, we will delete the data.

The audio recordings that were made in the context of the focus groups will be deleted after the transcription has been completed. The transcription has been anonymized.

Statistical analysis

We will use a repeated measures ANOVA to analyze the changes in the primary endpoint variables (suicidality and depression) and the secondary outcomes from baseline to post-measurement and the two follow-up assessments (3-months, 6-months), whereby the dependent variable will be the treatment condition (treatment group vs. waitlist control group). In addition, we will control for the baseline levels of depression and suicidality using an ANCOVA. The predictor analyses will be conducted using multiple regressions.

Handling of Missing Data

We will follow the principles of intention-to-treat analyses. Participants who drop out of the study after randomization are asked to state their reasons for doing so and are asked to continue the assessments. Missing values will be imputed using the Last Observation Carried Forward approach.

Monitoring, ethical considerations, and safety

The group leaders record each session so that the study employees can randomly examine the adherence to the intervention manual. In addition, the group leaders document each session (e.g. attendance, mood of participants, disturbances) and contact participants individually in case of absence, problematic behavior, suicidality or deterioration of symptoms via the study online portal. In addition, the study employees receive an automatic E-Mail when participants report increased levels of suicidality in the questionnaires after each session. If suicidality or adverse effects are suspected, the study employees will call the participants once a week to monitor and assess the mood and offer support.

The randomized controlled trial was approved by the ethics committee of Medical School Hamburg (March 3, 2018). Participants are informed in a written form (i.e. study information, consent form) about the procedure of the program, the aims of the study, the inclusion and exclusion criteria, risks and costs of participation, confidentiality and data storage. They have the opportunity to drop out of the program at any time without giving reasons. They are also allowed to use other assistance (e.g. psychotherapy) in addition to the study participation.

The participants are also informed about the chance to detect abnormalities in the clinical interview (before treatment) or during the data analysis. In that case, we contact participants for a more detailed clinical assessment. If we find clinically relevant aspects or diagnoses, we inform participants about it. However, we point out that study assessments do not substitute for clinical diagnostics by a medical doctor or psychotherapist.

During treatment, participants may experience a worsening in mood and sadness at first when they deal with the suicide of their loved ones. Such mood aggravations are normal in an intensive grief process and usually exist only for a short time. In case of acute suicidality (i.e. corresponding hints in the suicidality item of the BDI-II), we contact the participant by telephone and offer counselling. He or she may be excluded from the program and referred to local professionals. However, the scientific evidence so far suggests that the proposed online program can reduce difficulties in coping with grief reactions and symptoms. Hence, we do not expect any unwanted side effects or lasting psychopathological worsening at the end of the program. External supervisors will accompany the process of the treatment at regular intervals (every 4th session).

There will be no external Data Monitoring Committee because the sponsor as well as cooperation partners will function as instances where procedures, results and modifications have to be communicated to on a regular basis (at least twice a year). Although the execution of the study and the data analyses are independent of these institutions, we will write several interim reports about the achievement of project aims, results, and finances and justify deviations. If adverse events arise in the suggested procedures (e.g. eligibility criteria, randomization strategy, parts of intervention, etc.) the study coordination will discuss the necessity and impact of possible changes to the study protocol. An audit is not scheduled in our study.

Discussion

The primary aim of the study is to reduce the suicidality and depression in people bereaved by suicide with an online-group intervention. Furthermore, the intervention should reduce secondary parameters such as

prolonged grief, anxiety, or PTSD. Last but not least, we are interested in sociodemographic predictors (e.g. age, sex, relationship to the deceased) that predict a successful treatment as well as the cognitive processes (e.g. experience of stigmatization, guilt) that influence the participants' general psychopathology.

People bereaved by suicide have a high risk of developing mental illnesses and committing suicide themselves [10]. For this reason, it is important to provide adequate lowthreshold support. One of the main advantages of the program is that it is easy to access and geographically independent. The attendance of the participants and the group leaders is possible without much technical knowledge and without any special equipment. Furthermore, participants can largely remain anonymous, which might lower hesitation to seek professional help, because after the suicide people often face stigmatization in their environment. The same applies to the group leaders. Further, the intervention offers the unique opportunity to meet other people after suicide bereavement, which reduces social isolation.

With a planned sample size of more than 70 participants, this trial is adequately powered for detecting a medium effect size for the comparison between the treatment and the waitlist group. Additionally, we explore multiple predictors of treatment outcomes moderator variables to define detailed processes of the effectiveness.

The study has multiple methodological strengths such as block randomization or the use of a standardized manual with precise procedures and instructions that are based on cognitive-behavioral principles. The group leaders receive detailed training and regular supervision so we can ensure treatment fidelity. Because the intervention is led by a psychologist *and* a self-help counsellor who has also experienced suicide loss, both perspectives are considered, which complements each other's work. Last but not least, this study uses validated questionnaires and an additional clinical interview in the diagnostic process so we can make sure that the participants meet the inclusion criteria.

Despite its strength, some limitations of the current study design are worth mentioning. First, the study does not test whether the online group intervention is more effective than standard psychotherapy or self-help groups, because we use a waitlist control group design. Future research should expand this approach to active treatment conditions. Second, the organization of groups is not always without difficulties (e.g. temporary delays, schedule difficulties). This could mean that participants have to be randomized a second time if they could not take part in the assigned group appointment finding appointments. Further, participants may seek professional support in addition to our program. This might affect the effect sizes of our intervention although we control for such influences (e.g. record additional psychotherapy, medication, self-help groups). Follow-up studies or dismantling studies might further investigate which aspects of the intervention in particular drive the effects.

Taken together, this study and its results will help to better understand the problems people bereaved by suicide face. We expect our online group intervention to be effective in reducing parameters like depression, suicidality and prolonged grief disorder. Hopefully, the gained knowledge can be used for further studies on this target group.

Dissemination

We will present the results of the study to the scientific community in peer-reviewed journals and on international and national conferences. We will report the results to the non-scientific community by publishing them on our website, in newspaper articles, in newsletters for VEID and AGUS and in magazines for practitioners. Participants interested in the study results will receive a report via email.

Trial Status

(Version 1 19/08/2019)

We started recruitment in October 2018.

Recruitment will be finished approx. May 2020.

Abbreviations

ACSS-FAD: Revised Acquired Capability of Suicide Scale; AGUS: Angehörige um Suizid e.V.; BDI-II: Beck Depression Inventory; BPD: Borderline Personality Disorder; BSSI: Beck Scale for Suicide Ideation; BSSS: Berlin Social Support Scales; GEQ: Grief Experience Questionnaire; GQ: Group Questionnaire; H-Scales: Hopelessness Scale; ICG-D: Inventory of Complicated Grief-German Version; IES-R: Revised Impact of Event Scale; STOSASS: Stigma of Suicide and Suicide Survivor; PHQ-D: Short Version of the Patient Health Questionnaire-German Version; PTCI: Posttraumatic Cognitions Inventory; PTSD: Posttraumatic Stress Disorder; QPDDN: Questionnaire on Police Delivery of Death News;

SkPTBS: Screening for Complex PTSD; SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials; VEID: Bundesverband Verwaiste Eltern und trauernde Geschwister e.V.

Declarations

Ethics approval and consent to participate

Ethical approval for this study was obtained from the Medical School Hamburg Ethical Committee (reference number MSB-2018-11). The Ethics committee approved the research protocol (date of approval: 2018/03). Written informed consent will be obtained from all subjects prior to their participation in the study.

Consent for publication

Not applicable.

Availability of data

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

Not applicable.

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Authors' contributions

BW is the grant holder, conceived the study, initiated and implemented the design. *UM* and *LH* helped with the development of the treatment manual, and participant recruitment. All authors drafted the study protocol and contributed to refinement of the manuscript. All authors read and approved the final manuscript.

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Tables

Table 1

Schedule of enrollment, interventions, and assessments (SPIRIT Figure)

	Enrolment	Baseline	Treatment (Weekly Sessions 1-12)												Follow-Up	
Timepoint	$-t_1$	t_0	t_1	t_2	t_3	t_4	t_5	t_6	t_7	t_8	t_9	t_{10}	t_{11}	t_{12}	t_{13}	t_{14}
		<i>Pre</i>	<i>Middle</i>						<i>Post</i>	<i>3 months</i>		<i>6 months</i>				
Enrollment	X															
Eligibility Screen		X														
Informed consent	X															
Allocation		X														
Online Group Intervention																
Assessments																
Demographics		X														
SCID-I: Major Depression		X														
SCID-I: Bipolar Disorder		X														
SCID-I: Posttraumatic Stress Disorder		X														
SCID-I: Alcohol and Substance Misuse		X														
SCID-II: Borderline Personality Disorder		X														
SDPD: Schizophrenia		X														
SRAI: Suicidality		X														
SBQR: Suicidality		X														
PHQ-D: Anxiety / Depression		X						X					X	X	X	
BDI-II: Depression		X						X					X	X	X	
SkPTBS:		X														

PTSD													
IES: Traumatic events	X					X				X	X	X	
PTCI: Posttraumatic Cognitions	X					X				X	X	X	
ICG-D: Grief	X					X				X	X	X	
GEQ: Grief	X					X				X	X	X	
STOSASS: Stigmatization	X									X	X	X	
BSSI: Suicide Ideation	X					X				X	X	X	
H-Scales: Hopelessness	X					X				X	X	X	
ACSS-FAD: Anxiety of death	X					X				X	X	X	
BSSS: Social Support	X					X				X	X	X	
Transmission of Death News	X												
Evaluation of the Intervention										X			
GQ-D: Therapeutic Relationship in Groups		X	X	X	X	X	X	X	X	X	X	X	X
PHQ-D: Depression		X	X	X	X	X		X	X	X	X	X	
BDI-II: Suicide Item		X	X	X	X	X		X	X	X	X	X	

Note. SCID I = Structured Clinical Interview for DSM-IV Axis I; SCID-II = Structured Clinical Interview for DSM-IV Axis II; SDPD = Dutch Screening Device for Psychotic Disorder; SRAI = Suicide Risk Assessment Interview; SBQR = Suicide Behaviors Questionnaire Revised; PHQ-D = German Patient Health Questionnaire; BDI-II = Becks Depression Inventory II; SkPTBS = Screening for complex PTSD ; IES = Impact of Event Scale; PTCI = Posttraumatic Cognitions Inventory; ICG = Inventory of Complicated Grief; GEQ = Grief Experience Questionnaire; STOSASS = Stigma of Suicide and Suicide Survivor Scale; BSSI = Beck Scale Suicide Ideation; H-Scales = H-Scales to Assess Hopelessness; ACSS-FAD = Revised Acquired Capability of Suicide Scale; BSSS = Berlin Social Support Scale; GQ-D = German Group Questionnaire

Table 2

No.	Content	Structure
1	Introduction	<ul style="list-style-type: none"> § Group discussion: Participants introduce themselves and the deceased § Group guides introduce the program § Individual writing assignment: Set grief-related therapy goals
2	The suicide mode	<ul style="list-style-type: none"> § Video: A psychiatrist explains physical and psychological aspects of a suicide § Group discussion on the suicide § Individual writing assignment: Circumstances of the suicide
3	My grief	<ul style="list-style-type: none"> § Psychoeducation: Grief tasks [36] § Group discussion on grief § Individual writing assignment: Relationship with the deceased person
4	Suicide as traumatic event	<ul style="list-style-type: none"> § Psychoeducation: Symptoms of post-traumatic stress reactions § Group discussion on symptoms § Individual writing assignment: Last hours of the deceased person
5	Meaning and the why-question	<ul style="list-style-type: none"> § Video: A wife talks about meaning-making after the suicide § Group discussion on rumination § Individual writing assignment: Positive behavioral activation
6	Guilt	<ul style="list-style-type: none"> § Video: A mother talks about coping with guilt § Group discussion on the functionality of guilt § Individual writing assignment: Letter to a friend
7	Own suicidality	<ul style="list-style-type: none"> § Video: A mother talks about coping with her own suicidality § Psychoeducation: Warning signs, coping strategies § Group discussion on suicidality § Individual writing assignment: Crisis plan
8	Shame and stigmatization	<ul style="list-style-type: none"> § Video: A father talks about coping with stigmatization § Group discussion on stigmatization § Individual writing assignment: Coping with stigmatizing reactions
9	To communicate the suicide	<ul style="list-style-type: none"> § Video: A brother talks about his way to communicate with others about the suicide of his sibling § Psychoeducation: Gender differences, communication styles § Group discussion on communication § Individual writing assignment: Letter to a friend
10	Grief rituals	<ul style="list-style-type: none"> § Psychoeducation: Grief rituals § Group discussion on rituals § Individual writing assignment: Letter to the deceased person
11	Finding a new role in the	<ul style="list-style-type: none"> § Video: A daughter talks about how she regained her life after the loss of her

future

father

§ Group discussion on coping with grief in the future and plans for the future

§ Individual writing assignment: Letter from the deceased person

12 Goodbye

§ Group discussion about the intervention, changes and the group experience

§ Individual writing assignment: Goal attainment

Figures

Potential participants...

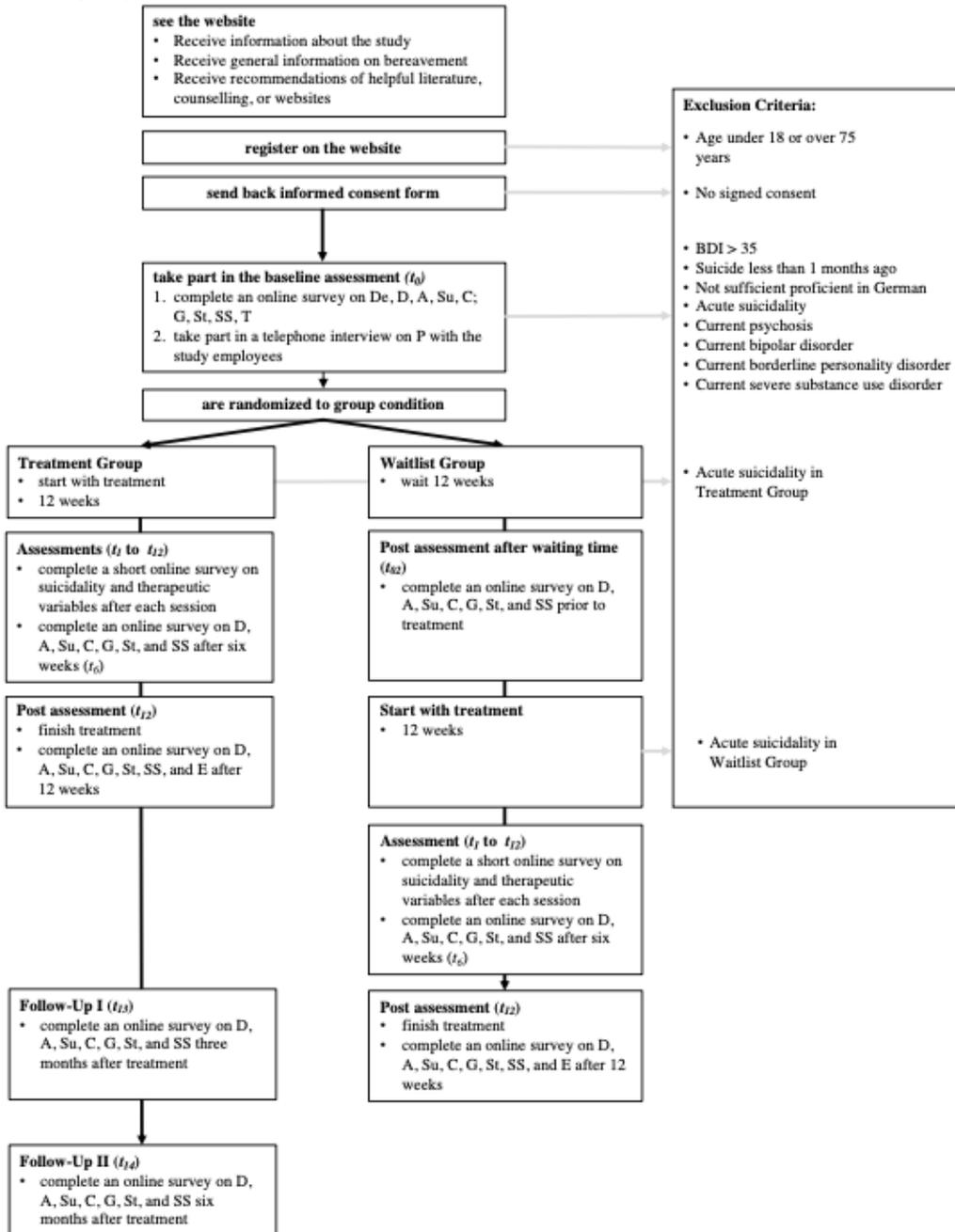


Figure 1

Participant Flow. De = Demographics, T = Transmission of the death news, P = psychopathology: Major Depression, Bipolar Disorder, Manic Episode, Borderline Personality Disorder, Posttraumatic Disorder, Alcohol or Substance misuse, Psychotic Episode, D = depression, A = anxiety, Su = suicidality, C = cognitions; G = grief, St = stigmatization; SS = social support, E = Evaluation of the intervention

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