



Design and rationale for a technology-based healthy lifestyle intervention in older adults grieving the loss of a spouse



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ARTICLE INFO

Keywords:

Grief (normal, Complicated)

Bereavement

Aging

Sleep

Exercise

Diet

ABSTRACT

Introduction: Experiencing the death of a spouse during late life is associated with an increased risk of developing debilitating mental health problems. Healthy lifestyle practices, such as regular exercise, healthy eating, and good sleep hygiene are promising strategies to influence the mental health and associated physical symptoms of late-life spousal bereavement.

Objective: This paper describes the design and rationale of an intervention development study addressing selective and indicated prevention of depression, anxiety, and/or complicated grief disorder(s) among adults 60 years and older who are grieving the recent loss (within 8 months) of a spouse or partner.

Methods: In Phase I, now complete, we developed and standardized behavioral self-monitoring of daily lifestyle choices via an electronic diary (BSM) and the combined BSM + motivational interviewing-based lifestyle coaching (BSM + MI) to be administered to participants grieving the loss of loved one. In Phase II, we have been implementing the interventions in a randomized controlled trial and addressing challenges related to recruitment. Randomization is to one of three cells: BSM, BSM + MI, or an enhanced usual care condition.

Discussion: Several challenges in implementing our lifestyle interventions to older widow(er)s who are at risk for common mental disorders have been identified. Direct outreach to hospice organizations is an effective way to identify older adults in the early months following spousal death. Results from study may advance the field of grief support and promote a healthy adaptation to widowhood.

In this report we describe the design, rationale, and initial feasibility of a mental illness prevention intervention pilot study focused on older adults who are grieving the loss of a loved one, entitled “Widowed Elders’ Lifestyle after Loss” (WELL). We focus on bereaved adults because experiencing the death of a spouse during later life is associated with an intense period of suffering and an increased risk of developing debilitating mental health problems. Approximately 10–20% of older adults are diagnosed with major depression, anxiety, and/or prolonged grief disorder(s) [1–4] in the context of losing their spouse. Preventing mental health problems is important because these conditions are highly prevalent and have lasting adverse consequences for the well-being of the bereaved survivor including physical disability, morbidity, and excess mortality [1,5].

Apart from the emotional strain of losing a spouse, there are profound changes to bereaved survivors’ lifestyle and daily routine (wake time, meal time, activity time, bed time, etc.) [6–8]. Losing a spouse leads to the absence of social cues that once kept daily routines properly

entrained; bereaved elders suddenly feel no reason to wake up, eat meals, or go to bed at a particular time [6,9]. These changes disrupt the stability of individuals’ internal chronobiological rhythms, placing them at high risk for mood disorders like depression [8]. Observational research shows that among the bereaved, changes in daily routines associated with physical activity, food preparation/eating, and sleep/wake regularity are correlated with symptoms of depression and complicated grief [10–18].

For this pilot intervention study, we chose to develop and implement an intervention that we hypothesized might prevent depression, anxiety, and/or prolonged grief disorders in bereaved elders via re-entraining a regular daily routine: behavioral self-monitoring of daily lifestyle choices and motivational interviewing-based lifestyle coaching. Interventions such as behavioral self-monitoring (BSM) offer a promising, nonstigmatised strategy to equally target physical activity, healthy eating, and good sleep hygiene practices [19–21]. BSM teaches older adults to become mindful of their daily lifestyle practices and the

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conditions in which they occur. The steps of BSM include: (1) selecting a goal, (2) paying attention to some aspect of behavior, and (3) recording that behavior in a diary. We implemented a technology-based approach using personalized tablets to decrease participant burden and improve participant retention [22,23]. Improving lifestyle practices can be challenging, requiring effort and motivation. Therefore, the effects of BSM to promote healthy lifestyle change may be enhanced by using motivational interviewing (MI) – a patient-centered approach to strengthen bereaved elders' motivation and commitment to change. MI facilitates healthy lifestyle change by helping patients resolve ambivalence about lifestyle change in an empathetic and encouraging climate [24–26].

We designed this pilot study to inform researchers about whether a healthy lifestyle intervention designed to target the daily routine of bereaved elders is feasible and acceptable when offered alone, and when offered in combination with MI. In this report we: 1) describe the development of a BSM + MI intervention using personalized tablet technology to increase engagement in and adherence to physical activity, healthy eating, and good sleep practices; 2) report on our experience with participant recruitment and retention; and 3) discuss intervention implementation challenges.

1. Methods

1.1. Overall study design

We conducted an intervention development study to examine the following:

- The feasibility and acceptability of behavioral self-monitoring (BSM) of physical activity, diet, and sleep behaviors for 12 weeks in adults 60 + who are at risk for common mental disorders (depression, anxiety, and prolonged grief) following the recent death of a spouse or partner (within 8 months).
- The feasibility and acceptability of motivational interviewing-based lifestyle coaching (MI) added to BSM for 12 weeks.
- The pattern of interrelationships between healthy lifestyle practices and symptoms of depression, anxiety, and/or complicated grief in adults 60 years and older who are grieving the recent loss of a spouse or partner.

This project consists of two phases. Phase I, now complete, focused on developing and standardizing BSM and BSM + MI to be delivered to participants via an electronic diary (on a tablet device). In an open case-series ($n = 10$), we collected feasibility and acceptability data, monitored participant progress, and adjusted the delivery of BSM, alone and in combination with MI to meet the needs of older bereaved adults. Phase II focuses on implementing BSM and BSM + MI in a randomized clinical trial, relative to enhanced usual care (i.e., usual care enhanced by the provision of research assessment and monitoring).

The study design for Phase II is shown in Fig. 1. After the baseline assessment (T1), participants are randomized using a 2:2:1 allocation to behavioral self-monitoring (BSM), behavioral self-monitoring + motivational interviewing-based lifestyle coaching (BSM + MI), or enhanced usual care (EUC). We allocated fewer participants to enhanced usual care so that feasibility of intervention components could be evaluated. The interventions are described below. After the 12-week intervention period, participants complete a post-intervention interview (T2) and are assessed every 3 months (T3–T5) for up to 9 months (total study time = 12 months). The Institutional Review Board at the University of Pittsburgh and a data safety and monitoring board have reviewed all protocols and procedures. Recruitment began in June 2015, and follow-up will be completed in December 2018 ([ClinicalTrials.gov](https://clinicaltrials.gov); NCT02631291).

1.2. Participants

Inclusion criteria required participants to be (1) aged 60 years and older; (2) having experienced the loss of a spouse or partner within the last 8 months; and (3) at-risk for mental illness, based on having at least one of the following high risk markers: high medical comorbidity ($> = 2$ on at least two items of the CIRS-G), low social support (no family/friends to open up to or rely upon), functional disability (requiring help with at least 1 activity of daily living); or subthreshold symptoms of depression (HRSD of 9–14), anxiety (GAD-7 = 10), and/or complicated grief (ICG = 20), together with absence of current major depression, generalized anxiety, post-traumatic stress, or suicidality. These markers align with the Institute of Medicine's framework for selective and indicated prevention interventions ('selective' prevention focuses on persons at risk for developing the disorder, while 'indicated' prevention focuses on individuals who have subsyndromal symptoms, but are below the symptom threshold for clinical disease) [27,28]. Exclusion criteria specify: (1) current DSM-5 criteria for syndromal mood, psychosis, anxiety, eating disorder, or substance abuse/dependence; (2) cognitive impairment (3MS < 80); and (3) new psychotropic medication after spousal death (including antidepressants and benzodiazepines) or regular use of anxiolytics (low and/or stable dosage ok permitted, e.g., 1 mg Lorazepam prn ≤ 4 times/week).

1.3. Recruitment

Recruitment for both Phases I and II takes place in community senior centers, grief support centers, and primary care physician (PCP) offices. In addition, we collaborated with Pitt + Me, a research registry program of the University of Pittsburgh's Clinical and Translational Science Institute, who referred appropriate participants to our study.

1.4. Intervention

All participants receive written education about grief (NIA Age Page: *Mourning the death of a Spouse*) and healthy lifestyle choices for older adults (recommendations from the National Sleep Foundation, USDA's *Choose My Plate*, and the NIH's *Getting Fit for Life*) at baseline. All participants chose a personal health goal on which to focus over the course of the 12-week intervention. Personal health goals are related to physical activity, diet, and/or sleep hygiene; examples included: engage in 150 min of moderate-intensity activity/week; eat 2–3 servings of fruits and 3–4 servings of vegetables; and sleep 7–8 h per night, among others. After the 12-week intervention, participants receive a lifestyle 'report' that summarizes their typical activity and sleep patterns (using objective data collected from Actigraphy).

BSM. Participants randomized to BSM record their physical activity, diet, and sleep behaviors twice daily using a diary-like app on a tablet, for 12 weeks.

The diary includes a morning report, an evening report, and a section that provided the user feedback about their recorded behaviors. The diaries include questions to re-entrain a regular daily routine; including items from the Pittsburgh Sleep Diary [29]; the morning report asked about the previous night's sleep including 1) bedtime (hh:mm); 2) time to fall asleep (minutes); 3) number of nighttime awakenings; 4) mood at bedtime (alert, sleepy, worried, anxious; scale 1–10); 5) quality of sleep (scale 1–10); 6) time of morning awakening (hh:mm), 7) time out of bed to start daily activities (hh:mm); and 8) mood at morning awakening (scale 1–10; very good – very bad). The evening report asks about physical activity, diet, and sleep behaviors throughout the day including 1) time daily activities started (hh:mm); 2) time of first contact with another person via phone or in-person (hh:mm); 3) time of breakfast, lunch, and dinner (hh:mm); 4) number of servings of whole grains, fruits, vegetables, calcium-rich foods, proteins, and alcohol); 5) number of meals at a sit-down/take out restaurant; 6) number of naps; 7) time spent in light, moderate, and vigorous activity (minutes); time

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