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Digital Monitoring of Sleep, Meals, and Physical Activity for Reducing Depression in Older Spousally-Bereaved Adults: A Pilot Randomized Controlled Trial

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Abstract

Objectives: To evaluate the feasibility and acceptability of a behavioral intervention and explore its impact on depression symptom burden among older spousally-bereaved adults.

Methods: Participants were age ≥ 60 years, bereaved ≥ 8 months, and at high risk for depression. Participants were randomized to 12 weeks of digital monitoring of sleep, meals, and physical activity; digital monitoring plus health coaching; or enhanced usual care and followed for 9 months for new-episode depression.

Results: We enrolled 57 participants, 85% of eligible adults and 38% of all adults screened. We observed high levels of adherence in both digital monitoring (90%) and health coaching (92%); 88% of participants were retained. In linear mixed-effects models, depression symptoms significantly decreased, but the interaction between time and intervention was not significant.

Conclusions: A behavioral intervention that uses both digital monitoring and motivational health coaching is feasible and acceptable to older bereaved adults.

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Author Contributions:

STS designed the study and acquired the data. STS and SFS completed the statistical analysis. All authors contributed to the interpretation of the data; the drafting and revising of the paper; and they approved the final version.

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Keywords

Depression; prevention; older adults; circadian rest-activity rhythms; bereavement

The death of a spouse is a life-altering event that is associated with disruption in routine daily activities. Many older adults feel no reason to wake up, eat meals, or go to bed on a regular schedule. Disruptions of these key social timekeepers (or zeitgebers) decrease the stability of circadian rhythms, placing these individuals at high risk for mood disorders like major depressive disorder (MDD).¹ Approximately 20–30% of older adults meet criteria for MDD in the first year after spousal death.² High regularity in the timing of daily activities may protect against MDD, presumably by strengthening circadian rhythms.³

The aim of this pilot trial was to establish the feasibility of conducting a behavioral intervention to stabilize time cues (sleep, meals, and physical activity) in older spousally-bereaved adults at risk for MDD, while exploring circadian rest-activity rhythm mechanisms. We explored preliminary efficacy of the behavioral intervention and examined links between depression symptoms and the regularity, timing, and shape of behavioral patterns over a 24-hour period.

METHODS

Participants

Participants were age ≥60 years; bereaved ≥8 months; and at high risk for MDD, based on one of the following markers: high medical comorbidity (score ≥2 on at least two items of the CIRS-G⁴); low social support; impairment in at least 1 of 6 activities of daily living; or subthreshold symptoms of depression (HRSD score of 9–14⁵), anxiety (GAD-7 score ≥10⁶), and/or complicated grief (ICG score ≥20 but less than 30⁷), together with absence of current DSM-5 defined MDD, generalized anxiety disorder, post-traumatic stress, or suicidality. Exclusion criteria included: current DSM-5 criteria for syndromal mood disorder, psychosis, anxiety disorder, eating disorder, or substance use disorder (based on the PRIMEMD/MINI); cognitive impairment (MSE score <80⁸); and new psychotropic medication after spousal death (including antidepressants and benzodiazepines) or regular use of anxiolytics (4+ times per week).

Procedures

Participants were randomized using a 2:2:1 allocation to (a) digital monitoring of sleep, meals, and physical activity (DM); (b) DM plus motivational health coaching (DM+coach); or (c) enhanced usual care (EUC). Participants were assessed at baseline, directly after the intervention period (12 weeks after baseline), and then 3, 6, and 9 months later. All procedures were approved by the University of Pittsburgh Institutional Review Board and the trial was registered with [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02631291) (NCT02631291).

Interventions

Participants randomized to DM recorded the timing of sleep, meals, and physical activity behaviors twice daily using a diary-like app on a tablet, for 12 weeks. The app also provided

feedback in real time about participants' sleep, meals, and physical activity (see Stahl et al., 2017 for design and pilot testing of app).⁹ Participants randomized to DM + coach received weekly calls from a health coach who used motivational interviewing (MI) techniques to strengthen participants' intrinsic motivation to engage in a regular behavioral routine. Using the MI Treatment Integrity Coding Manual – four components of MI were met during each session: open-ended questions, affirmations, reflective listening, and summarizing statements.¹⁰ The control condition was considered —enhanced because participants were followed on the same assessment schedule as intervention participants and were referred to medical and or grief specialty care, as needed.

Outcome Measures

Depression symptoms.—We assessed symptom levels of depression using the Patient-Health Questionnaire (PHQ-9), and incidence of PRIME MD/MINI-defined MDD.

Rest-activity rhythm (RAR).—Participants wore an ActiGraph GT9X activity watch on their non-dominant wrist during week 1 and 12 of the intervention. EUC participants wore the activity watch on the same assessment schedule. We derived RAR measures using in-house SAS and R code implementing the sigmoidally transformed cosine and non-parametric approaches.¹¹ Modeled parameters included measures of *timing* (time participant 'gets going' in the morning, time of peak activity level, and time participant 'settles down' in the evening); *regularity* (inter-daily stability and intra-daily variability); and *shape* (height of the rhythm or peak-trough differences).

Statistical Analyses

We compared baseline characteristics of the three groups using F-tests, Fisher's exact tests, and chi-square tests. To compare depression symptom trajectories between treatment arms, we employed a mixed effects model using treatment assignment, time (pre-and post-intervention), and assignment X time interaction. We assessed associations between each RAR variable and depression symptom severity using Spearman correlations. All analyses were conducted using SPSS Statistical software.

RESULTS

Feasibility

A total of 152 adults were screened. Of these, 95 (62.5%) did not meet inclusion criteria and 10 (6.6%) were not interested, leaving 57 (38%) who completed the baseline assessment and were enrolled in either stage 1A (n=10) or stage 1B (n=47) – 18 to DM, 18 to DM+coach, and 9 to EUC. Participants were mostly white women whose mean age was 75; about 7% were nonwhite. Participant retention and loss to follow-up are shown in Figure 1. Among the 47 participants enrolled in stage 1B, 2 withdrew consent and did not complete the baseline, 3 discontinued the intervention (DM group), 1 was lost to follow-up (DM group), and 1 died (DM+coach group).

Implementation of Intervention Components

In stage IA, issues launching the electronic diary led to low adherence (61% or an average of 104 diary sessions out of a possible 168 sessions [2 times per day for 84 days]). We fixed these issues (see Stahl et al., 2017) and in stage IB, adherence increased to 152 diary sessions (90%). Implementation of health coaching was excellent: coaches completed an average of 11 calls out of a possible 12 (92%). Implementation of actigraphy was satisfactory: 45 participants (82%) wore the Actigraph watch during week 1 and week 12 of the intervention. Of the 45 participants, 37 (82%) had usable data from which to calculate RAR variables. This number reflects difficulty deriving RAR measures from the raw activity time series (e.g., not providing >72 hours of data without substantive hours (>3 or 4 hours) of missing data).

Acceptability

Acceptability of study components, based on written feedback, was high. One comment speaks for many: —“I became more aware of what I was doing. I could focus on my health.” Participants believed health coaches to be “motivating,” “encouraging,” and found the sessions to be “an opportunity to share difficult times without burdening family/friends.”

Depression symptoms

In our mixed effects model, we found a significant fixed effect for time ($F_{[4, 183]} = 10.76$, $p < .001$). PHQ-9 scores significantly declined from baseline to post-intervention in all groups by an average of 3.0 points (SD: 2.5) ($t_{[183]} = 3.23$, $p = 0.001$). This mean change yielded a Cohen's d of 0.70. The fixed effect for group ($F_{[2, 183]} = 0.62$, $p = .542$) and group X time interaction did not reach statistical significance ($F_{[8, 183]} = 0.34$, $p = .947$). Over 9 months of follow-up, zero participants (0%) met diagnostic criteria for MDD.

Rest-activity rhythms

Lower inter-daily stability of the RAR (representing the inconsistency of activity patterns across days) was significantly associated with more depression symptoms (Spearman's correlation = -0.33 , $p < .05$). Improvements in the consistency of activity patterns across days (greater inter-daily stability) was marginally associated with improvements in depression symptoms (Spearman's $r = -0.31$, $p = .06$). More active periods (greater alpha) was significantly associated with improvements in depression symptoms (Spearman's $r = -0.38$, $p < .05$).

DISCUSSION

Our pilot study showed that a behavioral intervention that incorporates digital monitoring and motivational health coaching was feasible and acceptable to older spousally-bereaved adults who were at high risk for MDD. Notable strengths include the high levels of implementation adherence in both digital monitoring and health coaching, retention of study participants, and novel use of actigraphy-measured circadian rest-activity rhythm to index rhythm stability in this context. Depression symptoms decreased from pre- to post-intervention; however, our sample was small, which affected power to detect differences

between the three treatment arms. Depression symptoms were associated with inconsistent behavioral patterns across days (or less inter-daily stability of the circadian RAR).

Our findings are limited by the small sample size, brief follow-up period, and disproportionate representation of white participants relative to black/African American participants. The sample was also predominantly female (although this is consistent with samples of older bereaved adults). Additional research should recruit a larger and more representative sample to ensure generalizability to the population of older spousally-bereaved adults. We deliberately recruited individuals who had any number of high-risk markers for MDD. This resulted in a very heterogeneous group of individuals. The interventions may not have benefited individuals all to the same degree, but we could not examine this issue given our small sample. Several participants disliked the Actigraph watch, which resulted in non-usable actigraphy data. We did not get a true baseline assessment of participants' circadian RAR (i.e., prior to randomization), which likely affected our ability to detect change in RAR measures from pre to post-intervention.

This pilot study demonstrated feasibility and acceptability of digital monitoring and motivational health coaching in older spousally-bereaved adults at high risk for MDD. Technology challenges were overcome and intervention implementation was excellent. The association between stable behavioral patterns across days (inter-daily stability of the RAR) and reductions in depression symptoms is a promising avenue for future large-scale studies to explore.

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Highlights

- **What is the primary question addressed by this study?** — Is a behavioral intervention that targets sleep, meals, and physical activity feasible and acceptable to older spousally bereaved adults who are at high risk for major depressive disorder.
- **What is the main finding of this study?** — We observed high levels of adherence in both intervention arms (90–92%); and 88% of participants were retained. In linear mixed-effects models, findings indicated a significant reduction in depression symptoms, but a test of the interaction between time and intervention was not significant.
- **What is the meaning of the finding?** — A behavioral intervention that uses both digital monitoring and motivational health coaching is feasible and acceptable to older bereaved adult, with resulting improvement in symptoms of depression

Figure 1.
CONSORT diagram.