STUDY PROTOCOL

ClinicalTrials.gov Identifier: NCT05309577

Self-Care for Dementia Caregivers Using the myRhythmWatch

Organization's Unique Protocol ID: STUDY21060122

Study Type: Interventional

11/21/2025

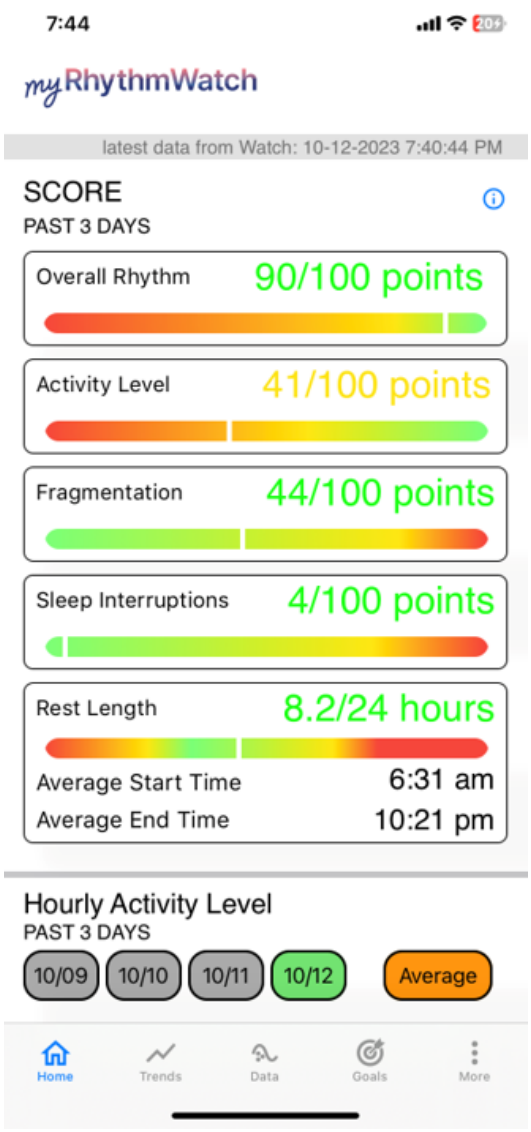
PARTICIPANTS

Participants enrolled as caregiver singletons or caregiver-care recipient dyads. Eligibility criteria for caregivers included 1) aged 50+ years; 2) being a primary caregiver for a patient with Alzheimer's Disease (AD) or a related dementia (ADRD); 3) experiencing stress/strain related to caregiving; 4) the person being cared for had problems with sleep or keeping a consistent routine; 5) experiencing depression symptoms, defined as a score ≥5 on the PHQ-9; 6) living with their care recipient; and 7) being willing to try the app and participate in assessments and calls. Eligibility criteria for care recipients included 1) 60+ years; 2) having been diagnosed with Alzheimer's disease, vascular dementia, mixed Alzheimer's/vascular dementia, or frontotemporal dementia; 3) living with their caregiver; and 4) being willing to wear the watch and participate in assessments and calls. The requirement of at least mild depression symptoms was added after the study began, based on stakeholder feedback that the program worked was most appropriate for caregivers with at least some depression symptoms.

PROCEDURES

This single-arm pilot trial enrolled participants between March 2023 and April 2024 in Pittsburgh, PA. The University of Pittsburgh Institutional Review Board approved all procedures (STUDY21060122) and the trial was registered with ClinicalTrials.gov (NCT05309577). Participants were recruited from university-affiliated research registries (ctsi.pitt.edu) at the University of Pittsburgh. Participants provided electronic consent in REDCap. To include individuals representative of the population of PWD, we allowed individuals who did not have the capacity to give informed consent to enroll, provided they gave verbal assent and proxy consent signed by a legally authorized representative.

After enrollment, participants received one-on-one technology training with a research staff person on wearing the Apple Watch and using the myRW app. Participants were provided a Apple Watch Series 8 and asked to wear it over the six-week trial, except when they were bathing/showering, when we asked them to charge the watch. As needed, we also followed up with participants two days after the technology training visit to troubleshoot any issues that arose. Eleven of the 15 caregivers also completed pre- and post-treatment assessments and were included in the health outcome analysis.



Intervention: The myRW system uses raw accelerometry data from the Apple Watch to compute standard RAR metrics which are displayed to users on their mobile phone (Figure 1). Therapists accessed information on participant's RARs via a HIPPA-compliant clinician dashboard, which displayed participant's RAR metric data and graphs including raw accelerometer data plots. Therapists used this information in six sessions, one per week, each lasting about 30-45 minutes. Caregivers facilitated sessions for themselves and for their care recipients, and when care recipients were involved, the sessions were approximately 60 minutes.

In each session, therapists used the RAR monitoring results and motivational interviewing techniques to identify targets and plan activities, with the overall goal of adhering to *4 Rules for Healthy Rhythms*: (1) get up at the same time every day; (2) engage in rewarding morning activity (preferably with exposure to sunlight and physical activity); (3) limit naps to less than 30 minutes and ending before 4:00pm; and (4) maintain active periods of around 15-16 hours per day. In the first session, and as needed thereafter, therapists reviewed standardized educational materials about circadian rhythms. In subsequent sessions, therapists reviewed participant's daily routine, progress/challenges with their activity plans, developed ideas about areas to target, and made future activity plans focused on optimizing rhythms.

Feasibility and acceptability measures: Feasibility was assessed with process outcomes including the (1) proportion of users providing sufficient data for assessing RARs (i.e., ≥3 consecutive valid days defined as days with at least 20 hours of data); (2) the total number of valid days of accelerometer data collected; and (3) the number of completed health coaching sessions. Acceptability was assessed with open-ended questions that asked participants to describe their likes and dislikes of the myRW app and intervention procedures. Participants also rated satisfaction with intervention components on a 5-point Likert scale, ranging from "very dissatisfied" (1) to "very satisfied" (5). Scores ≥4 indicate adequate levels of intervention acceptability.

Mood and Sleep: Initially our plan was to focus an intervention on promoting self-care and reducing caregiving burden. However, in designing the trial, we switched the focus to the circadian-informed, behavioral activation-based approach (described above) that aimed to

improve sleep and mood in caregivers. Therefore the two main outcomes of interest were measures of (1) depression symptom severity assessed using the Patient-Health Questionnaire (PHQ-9) and (2) insomnia symptom severity assessed using the Insomnia Severity Index (ISI).