

Official Title: Sleep Well 24 (SWELL24): Promoting Healthy Sleep-wake Behaviors Across a 24-hour Cycle in Frail Older Adults
NCT05780983
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SWELL24 (PI: Hughes, J.)
Pilot Feasibility Trial
Analysis Plan

In preparation for a larger trial, we will collect the following: *Retention rate*. This will be defined as the number of participants who complete all intervention sessions out of the total number enrolled. *Adherence to personalized recommendations*. Adherence to personalized behavioral recommendations is a key measure of acceptability. This information will be gathered through process notes recorded after each intervention session and in sleep and activity diaries completed on a daily basis during the course of the intervention. *Response to intervention*: In order to determine dose, sequencing, and timing of intervention components to be used in a larger trial, participants will report daily sleep-wake behaviors using a daily diary. This information will be reviewed qualitatively for potential signals of change. In preparation for a full trial, we will evaluate whether selected measures are sensitive to change over the intervention period. This will include examining percent change in both objective and subjective sleep-activity measures. Specifically, this will include changes in objective sleep efficiency (Fitbit: sleep efficiency) and activity levels (Fitbit: total daily steps) in addition to self-reported insomnia severity (Insomnia Severity Index) and daytime dysfunction resulting from poor sleep (Pittsburgh Sleep Quality Index, 3-component scoring).