Statistical Analysis Plan
I-STAND R21: Reducing Sedentary Time in Older Adults
NCT02692560
2/12/2018

Excerpted from:
Rosenberg DE, Lee AK, Anderson M, Renz A, Matson TE Kerr J, Arterburn D, McClure JB. Reducing Sedentary Time for Obese Older Adults: Protocol for a Randomized Controlled Trial. *JMIR Res Protoc* 2018 (Feb 12); 7(2):e23.

Statistical Analysis

The primary outcome will be defined as the change between baseline and 12 weeks in daily sitting time during waking hours, adjusted for wear time. Sitting time adjusted for wear time is a percentage calculated per day as: 100*(sitting time/hours device was worn during waking hours). This measure is averaged across valid wear days within an assessment period. Linear regression models will estimate the difference in mean change in adjusted daily sitting time from baseline to 12 weeks between the healthy living and I-STAND intervention groups. We will adjust for baseline sitting time and important potential confounders. Our primary analysis will include participants with valid sitting time outcome data at both baseline and 3-months data (complete case approach). We will conduct sensitivity analyses including all randomized participants and assuming no change (baseline value carried forward) for participants lost to follow-up. Similar analyses will assess the impact of the intervention at 3 months on secondary outcomes. If linear regression normality assumptions are violated, we will consider transformation of the outcome measures.

Power

Based on preliminary data from our prior work [Rosenberg et al. 2015], we estimated the change from baseline in sitting time adjusted for wear time would have a standard deviation of 8.3%. Assuming an 80% follow-up rate, a sample of 60 (30 in each arm) was estimated to provide 80% power to detect a between-group difference in sitting time adjusted for wear time of ~60 minutes per day.

Conflicts of Interest

None declared. This study was funded by the National Institutes of Health (R21 AG043853; Rosenberg, PI).

References

Rosenberg DE, Gell NM, Jones SM, Renz A, Kerr J, Gardiner PA, et al. The Feasibility of Reducing Sitting Time in Overweight and Obese Older Adults. Health Educ Behav. 2015 Oct;42(5):669-76. PMID: 25794518.