Clinical Protocol
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.e

Methods

Trial Design
A 12-week single-blind, randomized two-arm trial design was employed to evaluate the efficacy of the I-STAND intervention for decreasing sitting time compared to a healthy living control group. Enrollment began in February 2016 and data collection finished in February 2017.

Setting
The study is being conducted by the Kaiser Permanente Washington Health Research Institute (formerly, Group Health Research Institute). All activities were reviewed and approved by the Kaiser Permanente Washington (KPWA) Institutional Review Board.

Recruitment
Potential participants were identified using electronic health records from members of Kaiser Permanente Washington. Participants were limited to members whose primary care clinics were located in King County, WA to facilitate in-person appointments. Individuals were deemed potentially eligible if their: electronic medical records indicated they were aged 60-89, body mass index was ≥ 30 (to select for a group at risk for chronic conditions who may benefit the most from sedentary time reduction), and enrollment in the health plan was continuous for the prior 12 months. Individuals were excluded if they resided in long-term care or a skilled nursing facility in the prior 12 months, had a new cancer or heart failure diagnosis, or had a new diagnosis of dementia or serious mental health disorder.

Study invitation letters were mailed to a random selection of potentially eligible individuals who met the criteria above. Those who were interested in learning more were asked to call study staff for more information. Up to three mailings were sent to potential participants if they did not respond to the initial invitation or opt out of further contact. Interested responders were screened for eligibility by phone. Additional eligibility requirements were: self-report of sitting ≥ 7 hours per day, able to stand, and able to walk one block with or without an assistive device.

Contacts and Procedures
Persons screened as potentially eligible by phone provided oral consent to participate and were scheduled for an in-person appointment. They were then mailed an activPAL device to wear on the front middle part of the thigh with a waterproof dressing. Participants were provided with clear instructions and photos showing them how to adhere the device to their leg. The device was worn on the leg 24 hours a day to assess

active and sitting time; participants wore the device for at least 7 days prior to coming to an in-person baseline assessment. Participants completed a log to record their sleeping hours.

At the in-person baseline visit, participants met with a study staff member who collected written informed consent, downloaded their activPAL data, and collected other baseline assessment data (including a questionnaire, biometric assessments, and a fasting blood draw). A separate study health coach then randomized individuals and met with them to inform participants of their randomization group. Participants then completed their first health coach visit in person. Participants randomized to the I-STAND intervention arm were also provided a Jawbone UP band and trained on how to use it. The baseline visit lasted 1.5-2 hours.

Participants also completed an in-person assessment at 3 months post-randomization. Similar to baseline, each person wore an activPAL device for 7 days prior to the visit to assess active and sedentary behavior. During the 3-month visit, the biometric assessments and blood draw were repeated by a blinded study staff member, and a follow-up questionnaire was also administered. Participants received $50 each for completing the baseline and 3-month visit. A subsample of I-STAND participants (n = 22) were invited to participate in a separate qualitative exit-interview following study completion. Interviews were conducted by phone within 10 days of the final session. Additional study contacts are outlined as part of the descriptions of the intervention and control conditions (below).

Randomization & Blinding

Randomization occurred during the in-person baseline visit. The health coach used an automated macro, developed and overseen by the study statistician in Stata, to process the participant's downloaded baseline activPAL data. The macro computed preliminary estimates of activity metrics such as average daily sitting and standing time. Participants were randomized in a 1:1 allocation to I-STAND or the healthy living control. Randomization was stratified by baseline average daily sitting time (≥9 hours vs. <9 hours), in permuted blocks of randomly varying size (2 or 4). Staff responsible for collecting baseline and follow-up data were blinded to participants' treatment arm. Participants and health coaches were aware of treatment assignment, since individuals received a different intervention depending on their assignment.

I-STAND Intervention

Theoretical framework. The experimental I-STAND intervention was based on relevant behavioral theories including social cognitive theory, the ecological model, and habit formation. Social cognitive theory posits that the interaction of individual, social, and environmental influences impact behavior. Specifically, constructs such as self-efficacy, social support, goal-setting and action planning, and cues were deemed important for inducing changes in sitting behavior. The ecological model specifies the importance of considering influences at the built environment level including the home and neighborhood environment which could shape sitting behaviors (Sallis, 2008). Principles of habit formation suggest that unconscious and automatic processes typically underlie decisions to sit. Bringing these decisions into conscious awareness will help make decisions to stand (instead of sit) more automatic over time (Lally, 2011).

Intervention Development. In our prior work we developed a theory-based ST reduction intervention (using the theories above) and tested it over 8 weeks among older adults

with obesity (Rosenberg et al., 2015). We then conducted in-depth qualitative interviews to refine and improve the program (Greenwood-Hickman et al., 2016). The program resulted in a 30-minute reduction in sitting time, comparable to other preliminary studies in older adult populations. The interviews suggested that sitting is a highly ingrained habit often performed unconsciously and additional prompts were suggested to help constantly remind participants to bring their sitting habits into conscious awareness. These findings further informed the design of the I-STAND intervention.

Format. I-STAND consisted of 2 in-person health coaching sessions (the first immediately following their baseline measurement visit and the second 1 week later), 4 follow-up health coaching phone calls (every 2 weeks after the first 2 in-person sessions), and written materials. Participants were also offered email reminders to work on their individual goals on the off-weeks of the biweekly calls.

Key Components. I-STAND combined the behavioral theories into an approach that focused on using inner, outward, and habit reminder strategies to enhance awareness of sitting behavior and enabled participants to make simple changes that would enhance self-efficacy and reduce sitting time (see Table 1). One of the main tools provided to participants was a Jawbone UP band (Jawbone®, San Francisco, CA) to provide gentle vibrations every 15 minutes of inactivity to remind participants to take breaks from sitting regularly throughout the day (serving as an outward reminder) (Rosenberg, 2017). In addition to reminder strategies, key components included: 1) a workbook with biweekly content focusing on the various types of reminder strategies, which was used with each health coaching session; 2) feedback charts were provided to participants based on their activPAL wear at baseline and wearing the device at 2 additional check-in points 1 week following the baseline week and at the study mid-point (~week 6). The feedback charts included both numeric and graphic depictions of average daily waking time spent sitting, standing, and stepping, as well as their total breaks from sitting, sitting bouts lasting longer than 30 minutes, and step count; and, 3) health coaching sessions as described below. Table 1 provides an overview and descriptions of the I-STAND intervention components.

Health coaching sessions. Sessions focused on using different types of reminders, building self-efficacy through motivational interviewing strategies, problem-solving barriers, and setting an action plan consisting of graded individualized goals using the workbook which contained action planning and goal-tracking worksheets. At the first in-person intervention visit, health coaches met with participants for 1 hour to develop rapport, learn more about their daily activities, elicit motivations for joining the study, provide an intervention overview, and introduce and review study tools, including the workbook, feedback chart, and Jawbone UP wristband. They also reviewed safety information to ensure that participants would not injure themselves by standing more (e.g. stand on a cushioned surface, gradually build the amount of standing time). Health coaches then worked with the participants to set an action plan with obtainable goals, using tailored reminder strategies. During the week following the baseline week, participants wore another activPAL monitoring device and returned in person to meet with the health coach. The second in-person visit, which lasted about 45 minutes, focused on reviewing participant progress on their goals and problem-solving barriers with the assistance of a second feedback chart from wearing the activPAL the prior week; learning about additional reminder strategies; and setting goals for the next 2 weeks. Thereafter, health coaches met with participants by phone every 2 weeks (for approximately 20-40 minutes for each session) to review progress on goals, problem-

solve barriers, use the workbook to guide participants on different types of reminders, and set new action plans at the end of the visit. Additional topics covered in the workbook and health coaching sessions included social support, social environment and norms, conducting a home environment audit, and making home and/or work environment changes based on the audit results.

Table 1. Overview of I-STAND Intervention Components	
Component description	**Examples of content**
Health coaching sessions: 2 in-person and 4 phone calls	• Motivational interviewing to identify values and support goal attainment • Learning about reminder strategies and selecting personalized reminders to help achieve goals • Enhancing self-efficacy for sitting reduction • Problem-solving identified barriers to achieving goals • Reviewing feedback charts at in-person sessions and at mid-point • Action planning including setting stepped goals building towards a 1-hour reduction in sitting time
Feedback charts: Provided 3 times during the intervention	• Color graphs and tables showing sitting time, standing time, breaks from sitting, steps, number of sitting bouts lasting longer than 30 minutes • Reviewed during health coach sessions at baseline, 1 week, and 6 weeks
Workbook: Provided at first in-person session	• Written educational materials • Action-planning pages • Goal-tracking forms • Home environment audit form
Reminder strategies Inner: Internal or bodily cues	• Using mindfulness to be more aware of how body feels when sitting • Standing up anytime you notice your body feeling uncomfortable
Outward: Cues in the environment	• Using the Jawbone UP band, a kitchen timer, or another identified environmental cue • Making environmental changes to the home based on audit results (e.g. setting up a standing work space, finding a counter on which to read the newspaper, moving furniture to create room to stand)
Habit: Ingrained daily habits that can be used as cues	• Standing for 5 minutes while engaging in daily habits such as drinking coffee, reading the newspaper, talking on the phone • Standing for 5 minutes after doing a daily habit like taking medication or going to the bathroom

Healthy Living Control Condition

Participants in the control condition received 1 in-person health coaching session (after the baseline measurements were completed) followed by 5 mailed contacts. The program was based on usual care that is available to members of KPWA. At the in-

person session, participants were provided with a workbook consisting of health education on a variety of topics relevant to aging including depression, advance directives, nutrition, sleep, pain, and bladder control. Participants were instructed to select 1 topic to work on every 2 weeks. Content was derived from online educational information available to KPWA members, which was approved by Kaiser Permanente physicians. During the in-person health coaching session, participants then worked through a goal-setting worksheet with the health coach to help get them oriented to their program. Every 2 weeks, participants received a check-in letter and were asked to complete a form to mail back regarding their progress with their goals.

Health Coach Training and Fidelity

The I-STAND and Healthy Living conditions were delivered by 2 health coaches who had relevant degrees but no prior experience with health coaching. They were trained by the study principal investigator who is a licensed clinical psychologist to use motivational interviewing strategies (e.g. reflective listening, open-ended questions, affirmations, and summaries) and problem-solving techniques to support behavior change. Fidelity was enhanced by using structured scripts for each session and materials in a study workbook specific to the intervention and control group. Initial sessions were audio-recorded and reviewed to support health coach training. All intervention contacts were tracked in a Microsoft Access tracking database.

Assessment Measures

The primary outcome was total daily waking hours spent sitting measured by the activPAL micro device (PAL Technologies Ltd, Glasgow, UK). The activPAL was used because it has been feasible in other studies with older adults (Rosenberg et al., 2015; Lewis et al., 2016; Grant et al., 2008), is sensitive to change, (Rosenberg et al., 2015; Kozey-Keadle et al., 2012) and has high validity in comparison to direct observations (Kozey-Keadle et al., 2011; Larkin et al., 2015; Lyden et al., 2012). The device was initialized, sealed in a waterproof casing and then adhered to the front center thigh with a waterproof medical adhesive (Tegaderm™). Participants were instructed not to remove the device but they were given additional materials for affixing the device in the event that the adhesive became compromised or if they developed any irritation. They were provided with logs to track their sleep time each day they wore the device. The data were downloaded and processed using proprietary activPAL software and programs developed for Stata and R statistical software packages. The processing programs removed logged sleep time from the data to calculate waking hours spent sitting. Similar to standard procedures for accelerometer processing, data were considered valid if wear time was greater than 10 hours per day with a minimum of 4 valid days of data for each assessment period (Troiano et al., 2008; Matthews et al., 2012; Ward et al., 2005). To account for variations in wear time, activPAL outcomes will be adjusted for wear time. In addition to sitting time, activPAL will be used to assess secondary outcomes including average daily sit-to-stand transitions, standing time, steps, and bouts of sitting longer than 30 minutes.

Other secondary outcomes included physiologic measures and a battery of physical measures thought to be sensitive to changes in sedentary time and relevant for chronic disease. Physical function was measured by the Short Physical Performance Battery (SBBP). The SPPB objectively evaluated lower extremity function with tasks for balance, gait speed, and lower-extremity strength (chair rise) (Guralnik, 1995; Gurnalik, 1994). Cardiometabolic outcomes (fasting glucose and a cholesterol panel) were assessed by finger prick using an Alere Cholestech LDX System machine and Lipid + Glucose

cassettes. This device has shown very good agreement with established laboratory methods (Donato, 2015; Carey, 2006; Shepard, 2007). Blood pressure was measured on the left arm using an Omron HEM-907XL digital monitor. Blood pressure was assessed 3 times and the average of the latter 2 measures used. .

Exploratory outcomes included cognitive function as measured by the Trail Making Test (TMT) Parts A and B (to assess psychomotor speed and fluid cognitive abilities) (Salthouse, 2011; Lezak, 2004). Time to complete each task as a raw score will be used in analyses. weight which was measured with a calibrated portable digital scale (Tanita HD-351) and height with a stadiometer (Seca 213). Waist circumference was measured twice at the superior border of the iliac crest. The average of 2 measurements will be used in our analyses (Valsamakis, 2004). Additional exploratory outcomes were self-reported and included benefits and barriers of sitting reduction (Gardiner, 2011), self-efficacy for reducing sitting time (Gardiner, 2011; Salmon et al., 2006; Norman et al., 2005; Norman et al., 2004), habit formation (Self-Report Habit Index) (Verplanken et al., 2003), quality of life with the PROMIS global scale (Hays et al., 2009), and depressive symptoms with the Patient Health Questionnaire-8 (Kroenke et al., 2010; Kroenke et al., 2009).

Qualitative Assessment

Qualitative exit-interviews lasted about 45 minutes and followed a semi-structured interview guide. The semi-structured interview guide was intended to capture feedback on the acceptability of the intervention, barriers and facilitators to sitting reduction, and perceived health impacts of sitting reduction. Only I-STAND participants were interviewed. Due to scheduling and other logistics, 22 of the 29 intervention participants were interviewed. The interviews were audio-recorded and transcribed. A formal qualitative analysis using thematic analysis and a group of coders will be undertaken to identify barriers and facilitators to sitting reduction and guide future refinements to the I-STAND intervention.

Conflicts of Interest

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

Abbreviations

RCT: randomized controlled trial
ST: Sedentary time
MVPA: moderate-to-vigorous physical activity

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