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ORIGINAL RESEARCH

Reducing Sitting Time After Stroke: A Phase II Safety and Feasibility Randomized Controlled Trial

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Abstract

Objective: To test the safety, feasibility, and effectiveness of reducing sitting time in stroke survivors.

Design: Randomized controlled trial with attention-matched controls and blinded assessments.

Setting: Community.

Participants: Stroke survivors (N=35; 22 men; mean age, 66.9±12.7y).

Interventions: Four counseling sessions over 7 weeks with a message of sit less and move more (intervention group) or calcium for bone health (attention-matched control group).

Main Outcome Measures: Measures included safety (adverse events, increases in pain, spasticity, or fatigue) and feasibility (adherence to trial protocol). Secondary measures included time spent sitting (including in prolonged bouts ≥30min), standing, and stepping as measured by the thigh-worn inclinometer (7d, 24h/d protocol) and time spent in physical activity of at least moderate intensity as measured by a triaxial accelerometer. The Multimedia Activity Recall for Children and Adults was used to describe changes in use of time.

Results: Thirty-three participants completed the full protocol. Four participants reported falls during the intervention period with no other adverse events. From a baseline average of 640.7±99.6min/d, daily sitting time reduced on average by 30±50.6min/d (95% confidence interval [CI], 5.8−54.6) in the intervention group and 40.4±92.5min/d in the control group (95% CI, 13.0−93.8). Participants in both groups also reduced their time spent in prolonged sitting bouts (≥30min) and increased time spent standing and stepping.

Conclusions: Our protocol was both safe and feasible. Participants in both groups spent less time sitting and more time standing and stepping postintervention, but outcomes were not superior for intervention participants. Attention matching is desirable in clinical trials and may have contributed to the positive outcomes for control participants.

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Between 1990 and 2010 worldwide prevalence rates for stroke increased by 84% (by 27% in high-income countries), making stroke the third leading cause of disability.[1] Up to a third of people who survive a first stroke will suffer a recurrent stroke within 5 years, with this figure increasing to 43% for people surviving ≥10 years.[2] Both lack of adequate levels of physical activity and high sedentariness (ie, too much sitting) in this population are likely contributing factors to recurrent stroke rates. Lack of adequate physical activity (<150min/wk of moderate-to-vigorous physical

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activity [MVPA]) is the second highest population attributable risk factor for stroke,[3] whereas spending long periods of the day sitting down, particularly in long bouts of uninterrupted sitting, is an independent risk factor for cardiovascular disease, morbidity, and mortality in otherwise healthy adults, even after taking into account the time spent in MVPA.[4,5] Studies have shown that people with stroke are typically both highly sedentary and physically inactive,[6-11] placing them at the greatest risk of the consequences arising from these conditions. In a recently completed observational study using high precision activity monitors, people with stroke were more sedentary and less activity than age-matched controls, spending 75% of their waking hours sitting down each day and <5min/d in MVPA.[6]

Experimental studies[12] and epidemiologic studies[13] have shown that breaking up sitting time with periods of light intensity physical activity (eg, walking at a comfortable pace) leads to reductions in cardiovascular disease risk factors[12] and mortality.[13] Therefore, interventions aimed at reducing daily sitting time may be a promising new target for reducing recurrent stroke risk. However, there are many reasons why people with stroke spend long periods sitting down, including mobility impairments, post-stroke fatigue, pain, and spasticity. This means that people with stroke may find it difficult to sit less each day. Furthermore, encouraging people with stroke to move more each day may lead to increased exposure to risk of falls.

The aim of this pilot randomized controlled trial was to assess the safety, feasibility, and effectiveness of an intervention to reduce sitting time in people with stroke. Our primary hypotheses were that the intervention would be both safe (not lead to adverse events, including falls, negative changes in pain, spasticity, and fatigue) and feasible (have a high adherence to the measurement protocol, in particular the activity monitor wear time). Our secondary hypotheses were that the intervention would lead to a reduction in sitting time, a reduction in prolonged sitting time (bouts ≥30-min duration),[14] and an increase in standing and stepping time and time spent in MVPA. We considered a 30-min/d reduction in sitting time as the minimal clinically important difference. In healthy, inactive adults, replacing 1h/d of self-reported sitting with light-intensity activity has been linked to lower all-cause mortality.[13] As the dose-response relation between sedentary physical activity and health is nonlinear,[13] it is possible that even smaller reductions in sitting time will have health benefits for people who are both more sedentary (spend more time sitting) and more inactive (spend less time in MVPA), particularly when measured accurately and objectively as opposed to self-report.

Methods

This was a pilot randomized controlled trial with an attention-matched control group, concealed allocation, and blinded assessment of outcome. The trial was registered with the Australian and New Zealand Trial Registry (ACTRN12612000958886). Participants were unaware of the intervention of interest. They were told only that this was a trial of healthy living after stroke. A 1:1 randomization sequence was prepared by a statistician independent of the project. A research assistant independent of the project prepared a set of sequentially numbered, opaque, sealed envelopes with the group allocation inside. Participants were recruited from outpatient clinics, databases of participants from previous trials, stroke exercise classes, and social media. Research staff repeatedly visited outpatient clinics and stroke exercise classes to identify potential participants. Flyers were also placed in clinics, and frequent phone calls were made to therapy staff within these centers to assist in recruitment. A trained assessor who was unaware of group allocation assessed participants at baseline (pre-intervention) and postintervention. Ethical approval was obtained from the relevant ethics committees, and participants provided written, informed consent. Because the primary outcomes were safety and feasibility, we did not power the trial to detect statistically significant changes in sitting time. Changes in sitting time were interpreted in light of what we considered the minimal clinically important difference in daily sitting time (30min/d).[13]

List of abbreviations:

CI	**confidence interval**
MARCA	**Multimedia Activity Recall for Children and Adults**
MVPA	**moderate-to-vigorous physical activity**

Participants

We recruited people living at home after stroke. Inclusion criteria were as follows: at least 6 months since last stroke (to minimize the impact of rapid improvement in functional recovery after stroke); living at home for at least 3 months since last hospital discharge; some residual walking and/or balance deficits (self-reported); and sufficient cognitive and language ability to provide informed consent and participate in the motivational interviewing sessions.

Intervention

Participants were randomly assigned to the intervention or control group. Participants in the intervention group received a series of 4 counseling sessions with the main message being to sit less and move more, with encouragement to regularly break up sitting time with short bursts of light-intensity activity (standing, walking at a comfortable pace). Interventions specifically targeted at reducing sitting time have been found to be more effective than those aimed at general lifestyle advice or advice to increase MVPA.[15] The counseling sessions were provided by 2 researchers (C.E., E.B.), both of whom were formally trained in motivational interviewing techniques through accredited courses. Motivational interviewing is a form of goal-directed counseling that aims to strengthen a person's own motivation and commitment to change and is particularly effective in eliciting behavior change for people who are reluctant or ambivalent about change.[16] The first session was provided face-to-face in the participant's home. At this first session, participants were presented with an individualized written report which provided feedback regarding daily sedentary time and breaks in sedentary time based on the baseline hip-worn accelerometer data. This report was used as the starting point for discussions. The counseling sessions used key motivational interviewing techniques (decisional balance sheets, importance and confidence rulers) to initiate and reinforce change talk. Action plans, goals, and strategies were elicited from the participants, rather than imposed by the counselors. Follow-up counseling sessions were delivered by phone and occurred 1, 3, and 7 weeks after the initial session. We chose to deliver the intervention via a face-to-face home visit and follow-up telephone calls, rather than in groups to avoid transport being a barrier to participation.[17] To match the groups for