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Running head: Reducing sitting time after stroke

Title: Reducing sitting time after stroke. A Phase II safety and feasibility randomised controlled trial.

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Preliminary data were presented as part of poster at the European Stroke Organisation Conference, Glasgow, United Kingdom, April 17-19 2015. Main results were presented at Stroke 2015 (a combined conference of the Stroke Society of Australasia and Smartstrokes NSW). Melbourne, Australia September 1-5 2015.

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There are no conflicts of interest to declare.

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Trial registration

The trial was registered with the Australian and New Zealand Trial Registry (ACTRN12612000958886).

1 Running head: Reducing sitting time after stroke

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3 Title: Reducing sitting time after stroke. A Phase II safety and feasibility randomised

4 controlled trial.

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7

8 **Abstract**

9 *Objective*

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

11 *Design*

12 Randomised controlled trial with attention-matched control and blinded assessments.

13 *Setting*

14 Community

15 *Participants*

16 Thirty-five stroke survivors (22 male, mean age 66.9 ± 12.7 years).

17 *Interventions*

18 Four counselling sessions over seven weeks with a message of ‘sit less, move more’
19 (intervention group) or ‘calcium for bone health’ (attention-matched control group).

20 *Main outcome measures*

21 Safety (adverse events, increases in pain, spasticity or fatigue) and feasibility (adherence to
22 trial protocol). Secondary measures included time spent sitting (including in prolonged bouts
23 ≥ 30 mins), standing, and stepping as measured by the thigh-worn activPAL3 activity monitor
24 (7 days, 24hrs/day protocol) and time spent in physical activity of at least moderate intensity
25 as measured by the actigraph GT3x+. The Multi-Media Activity Recall for Children and
26 Adults (MARCA) was used to describe changes in use-of-time.

27 *Results*

28 Thirty-three participants completed the full protocol. Four participants reported falls during
29 the intervention period with no other adverse events. From a baseline average of 640.7 (SD
30 99.6) min/day, daily sitting time reduced on average by 30.0 (SD 50.6) min/day (95% CI 5.8
31 to 54.6) in the intervention group and 40.4 (SD 92.5) min/day in the control group (95% CI
32 13.0 to 93.8). Participants in both groups also reduced their time spent in prolonged sitting
33 bouts (≥ 30 minutes) and increased time spent standing and stepping.

34 *Conclusions*

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

39

40

41 **Key words:**

42 stroke, sedentary behaviors, sitting time, physical activity, objective activity monitoring

43

44

45 **Introduction**

46

47

48 Between 1990 and 2010 worldwide prevalence rates for stroke increased by 84% (by 27% in
49 high income countries), making stroke the third leading cause of disability. ¹ Up to a third of
50 people who survive a first stroke will suffer a recurrent stroke within five years, with this
51 figure increasing to 43% for people surviving 10 years or more. ² Both lack of adequate
52 levels of physical activity and high sedentariness (i.e. too much sitting) in this population are
53 likely contributing factors to recurrent stroke rates. Lack of adequate physical activity - less
54 than 150 minutes a week of moderate to vigorous intensity physical activity (MVPA) - is the
55 second highest population attributable risk factor for stroke, ³ while spending long periods of
56 the day sitting down, particularly in long bouts of uninterrupted sitting, is an independent risk
57 factor for cardiovascular disease morbidity and mortality in otherwise healthy adults, even
58 after taking into account the time spent in moderate to vigorous intensity physical activity. ^{4,5}
59 Studies have shown that people with stroke are typically both highly sedentary and physically
60 inactive, ⁶⁻¹¹ placing them at the greatest risk of the consequences arising from these
61 conditions. In a recently completed observational study utilising high precision activity
62 monitors, people with stroke were more sedentary and less active than age-matched
63 controls, spending 75% of their waking hours sitting down each day and less than five
64 minutes a day in MVPA. ⁶

65

66 Experimental studies ¹² and epidemiological studies ¹³ have shown that breaking up sitting
67 time with periods of light intensity physical activity (such as walking at a comfortable pace)
68 leads to reductions in cardiovascular disease risk factors ¹² and mortality¹³. Therefore,

69 interventions aimed at reducing daily sitting time may be a promising new target for reducing
70 recurrent stroke risk. However, there are many reasons why people with stroke spend long
71 periods sitting down, including mobility impairments, post-stroke fatigue, pain and spasticity.
72 This means that people with stroke may find it difficult to sit less each day. Furthermore,
73 encouraging people with stroke to move more each day may lead to increased exposure to
74 risk of falls.

75

76 The aim of this pilot randomised controlled trial was to assess the safety, feasibility and
77 effectiveness of an intervention to reduce sitting time in people with stroke. Our primary
78 hypotheses were that the intervention would be both safe (not lead to adverse events
79 including falls, negative changes in pain, spasticity and fatigue) and feasible (have a high
80 adherence to the measurement protocol, in particular activity monitor wear time). Our
81 secondary hypotheses were that the intervention would lead to a reduction in sitting time,
82 prolonged sitting time (bouts ≥ 30 min duration¹⁴ and increases in standing and stepping time,
83 as well as time spent in MVPA. We considered a 30-min/day reduction in sitting time as the
84 minimal clinically important difference. In healthy, inactive adults, replacing one hour a day
85 of self-reported sitting with light intensity activity has been linked to lower all-cause
86 mortality¹³. As the dose-response relationship between sedentary physical activity and health
87 is non-linear¹³ it is possible that even smaller reductions in sitting time will have health
88 benefits for people who are both more sedentary (spend more time sitting) and more inactive
89 (spend less time in MVPA), particularly when measured accurately and objectively as
90 opposed to self-report.

91

92 **Method**

93

94

95 This was a pilot randomised controlled trial with an attention-matched control group,
96 concealed allocation and blinded assessment of outcome. The trial was registered with the
97 Australian and New Zealand Trial Registry (xxxx). Participants were unaware of the
98 intervention of interest. They were told only that this was a trial of ‘healthy living after
99 stroke’. A 1:1 randomisation sequence was prepared by a statistician independent of the
100 project. A research assistant independent of the project prepared a set of sequentially
101 numbered, opaque, sealed envelopes with the group allocation inside. Participants were
102 recruited from outpatient clinics, databases of participants from previous trials, stroke
103 exercise classes and social media. Research staff repeatedly visited outpatient clinics and
104 stroke exercise classes to identify potential participants. Flyers were also placed in clinics,
105 and frequent phone calls were made to therapy staff within these centres to assist in
106 recruitment. A trained assessor who was unaware of group allocation assessed participants at
107 baseline (pre-intervention) and post-intervention. Ethical approval was obtained from the
108 relevant ethics committees and participants provided written, informed consent. As the
109 primary outcomes were safety and feasibility, we did not power the trial to detect statistically
110 significant changes in sitting time. Changes in sitting time were interpreted in light of what
111 we considered the minimal clinically important difference in daily sitting time (30
112 min/day).¹³

113

114 Participants

115

116

117 We recruited people living at home after stroke. Inclusion criteria were: at least six months
118 since last stroke (to minimise the impact of spontaneous neurological recovery after stroke);
119 living at home for at least three months since last hospital discharge; some residual walking
120 and/or balance deficits (self-reported); and, sufficient cognitive and language ability to
121 provide informed consent and participate in the motivational interviewing sessions.

122

123 Intervention

124

125

126 Participants were randomly assigned to the intervention or control group. Participants in the
127 intervention group received a series of four counselling sessions with the main message being
128 to ‘sit less and move more’, with encouragement to regularly break up sitting time with short
129 bursts of light intensity activity (standing, walking at a comfortable pace). Interventions
130 specifically targeted at reducing sitting time have been found to be more effective than those
131 aimed at general lifestyle advice, or advice to increase MVPA.¹⁵ The counselling sessions
132 were provided by two researchers (xx and xx) both of whom were formally trained in
133 motivational interviewing techniques through accredited courses. Motivational interviewing
134 is a form of goal-directed counselling that aims to strengthen a person’s own motivation and
135 commitment to change and is particularly effective in eliciting behaviour change for people
136 who are reluctant or ambivalent about change.¹⁶ The first session was provided face-to-face
137 in the participant’s home. At this first session, participants were presented with an
138 individualised written report which provided feedback regarding daily sedentary time and
139 breaks in sedentary time based on the baseline hip-worn accelerometer data (see below). This
140 report was used as the starting point for discussions. The counselling sessions used key

141 motivational interviewing techniques (decisional balance sheets, importance and confidence
142 rulers) to initiate and reinforce change talk. Action plans, goals and strategies were elicited
143 from the participants, rather than imposed by the counsellors. Follow-up counselling sessions
144 were delivered by phone and occurred one, three and seven weeks after the initial session.
145 We chose to deliver the intervention via a face-to-face home visit and follow-up telephone
146 calls, rather than in groups to avoid transport being a barrier to participation.¹⁷ In order to
147 match the groups for attention, control group participants received the same schedule of
148 interviews, with a placebo message of increasing calcium for bone health. Data from a food
149 frequency questionnaire were used to create personalised feedback for control participants.¹⁸
150 The food frequency questionnaire was used to reinforce the credibility of the attention-
151 matched control group and data were not analysed.

152

153 Outcome measures

154

155

156 Baseline measures were collected at the first face-to-face appointment and included stroke
157 type (Oxfordshire Stroke Classification¹⁹), stroke severity (National Institutes of Stroke
158 Scale, score 0 to 42 with higher scores indicating more severe stroke) side of stroke, height,
159 weight, walking speed (self-selected, measured over the middle 5 m of a 9 m walkway), use
160 of walking aids, living arrangements (alone/with spouse), degree of independence in
161 activities of daily living (self-reported as independent or requiring some assistance in daily
162 tasks such as showering, dressing and cooking), and cognitive function (Montreal Cognitive
163 Assessment, score range 0 to 30, scores <22 indicate cognitive dysfunction²⁰). All
164 participants completed a food frequency questionnaire.¹⁸ At this appointment, participants

165 were fitted with three activity monitors and provided with instructions regarding keeping
166 diaries of sleep/wake time and when monitors should be removed. Participants wore all three
167 monitors for seven days at baseline and again one week after the final counselling session
168 (post-intervention).

169

170 *Safety* was assessed by recording changes in self-reported pain and spasticity (visual analogue
171 scale, anchored at 0 [no pain/spasticity] and 10 [severe pain/spasticity]), and fatigue
172 (Checklist Individual Strength, score 8 to 56, higher scores indicating greater fatigue
173 symptoms²¹). Falls incidence and any other adverse events were ascertained by asking
174 structured questions (“have you fallen or tripped over in the last 2 months”) at each
175 assessment point. While simple recall of falls can underestimate falls incidence, it does not
176 underestimate injurious falls (specificity 87-100%)²².

177 *Feasibility* was assessed via adherence to counselling sessions (actively engaged in all
178 scheduled counselling sessions) and completion of all assessments at baseline and post-
179 intervention, including activity monitor wear time.

180

181 *Time spent sitting, standing and stepping* was measured using the activPAL3 device (PAL
182 Technologies Ltd), which was waterproofed and attached to the participants’ anterior thigh
183 on the non-hemiparetic leg. Participants wore this monitor continuously (24 hours/day) for
184 seven days including during showering/bathing and water-based activities. The activPAL3
185 contains an inclinometer and a tri-axial accelerometer. In studies of both healthy adults and
186 people with stroke it has been shown to be 99-100% accurate in classifying sitting/lying and
187 standing postures^{23, 24} The activPAL3 data were processed using activPAL3 software
188 (version 7.2.32). Sleep/wake diaries were entered into a Microsoft Access database. A

189 custom built SAS program linked activPAL3 data to the sleep wake diaries to identify and
190 remove sleep and non-wear time. This program also identified periods of prolonged,
191 uninterrupted sitting of ≥ 30 minutes duration.

192

193 *Physical activity* was measured using the Actigraph GT3+ triaxial accelerometer, which was
194 worn on an elastic waist belt and positioned over the non-hemiparetic hip. Participants were
195 asked to wear the monitor 24 hours a day for seven days, removing it for showering/bathing
196 or any other water-based activities. Participants also wore the Sensewear arm band around
197 their non-hemiparetic upper arm. In this trial, the Sensewear arm band was used purely to
198 determine non-wear time for the Actigraph. As the Sensewear arm band switches off when
199 not in contact with the skin and also had to be removed for water-based activities, we made
200 the assumption (backed up by review of participant diaries) that the Actigraph and Sensewear
201 monitors were always removed at the same time. Actigraph data were processed by Actilife
202 software (version 6.3.2), and periods of sleep (matched to activPAL data) and non-wear (as
203 detected by the Sensewear arm band) were removed using custom filters. In line with the
204 most commonly used cut-points for classification of activity intensity of older adults²⁵
205 activity of at least moderate intensity was defined as ≥ 1952 counts per minute.²⁶

206

207 *Use of time* was measured using the Multimedia Activity Recall for Children and Adults
208 (MARCA)²⁷ This computerised use of time tool asks participants to recall their previous day
209 from midnight to midnight and classifies activities according to a pre-determined list of 520
210 separate items. Activities are then classified into time spent in various 'superdomains' such as
211 transport, screen time and chores. The superdomains are further categorised into 'macro-
212 domains', for example active and passive transport, computer and TV time. Participants were

213 phoned at a pre-determined time during the week they were wearing the monitors at baseline,
214 and post-intervention and the MARCA was administered by interview, which took
215 approximately 20 minutes. In a previous observational study, agreement between repeated
216 administration of the MARCA on the same day, ranged from 0.834 (95% confidence interval
217 [C] 0.681 to 0.918) and 0.946 (95% CI 0.890 to 0.974) for the different MARCA
218 superdomains⁶ The MARCA has been validated against doubly-labelled water in young
219 adults, with a correlation of $r = 0.70$ for daily energy expenditure.²⁸

220

221 **Statistical Analyses**

222

223

224 Paired t-tests (or Wilcoxon Signed Rank tests where data were not normally distributed) were
225 used to examine within group differences between baseline and post-intervention in safety
226 and feasibility measures (pain, spasticity, fatigue, monitor wear-time and falls). To adjust for
227 waking hours, activPAL3 and Actigraph derived activity variables (time spent in sitting,
228 prolonged sitting, standing, stepping and MVPA) were standardised to a 16-hour/day waking
229 wear time period. Paired t-tests (or Wilcoxon Signed Rank tests where data were not
230 normally distributed) were used to examine within group differences between baseline and
231 post-intervention in activity variables. Univariate analyses of variance (with adjustment for
232 multiple comparisons) were used to examine between group differences in change scores
233 (post-intervention minus baseline) in time spent sitting, standing, stepping and in MVPA.
234 Independent t-tests were used to examine between group differences in MARCA-derived
235 variables between intervention and control groups. Sequential Bonferroni corrections were
236 applied to account for multiple comparisons. All analyses were by intention to treat.

237

238 **Results**

239

240

241 Participants were recruited between February 2013 and February 2014 with final data
242 collected in May 2014. Figure 1 presents the flow of participants through the trial. Table 1
243 presents baseline characteristics of the 35 participants. Four (n=2 intervention and n=2
244 control) participants reported falls during the intervention period. None of the falls were
245 injurious. There were no other adverse events reported. Pain, spasticity and fatigue did not
246 change between baseline and post-intervention for either group (Table 2). Compliance with
247 wearing the activity monitors was high. At baseline n=23 and n=31 participants had seven
248 days of valid data from the activPAL3 and the GT3x+ monitors respectively. All other
249 participants had at least four days of wear time for both monitors, with the exception of three
250 participants for whom the GT3x+ monitor did not record any valid data on any days. At post-
251 intervention, n=33 and n=25 had seven days of valid data from the activPAL3 and the GT3x+
252 monitors respectively. All other participants had at least four valid wear days for both the
253 activPAL3 and GT3x+ monitors, with the following exceptions; two participants (both in the
254 control group) did not complete the post-intervention assessment for reasons of ill health not
255 related to the trial, and a further three participants did not have any valid wear days for the
256 GT3x+ monitor. Table 2 presents average wear days and monitored hours for all participants.
257 There was 100% compliance with counselling sessions – that is all participants engaged in all
258 scheduled counselling sessions.

259

260 At baseline participants spent an average of 640.7 (SD 99.6) min/day sitting, 436.2 (SD147.0)
261 min/day in prolonged sitting (un-interrupted sitting bouts of ≥ 30 mins), 153.6 (SD 63.9)
262 min/day standing, 59.3 (SD 36.8) min/day stepping and 7.4 (SD 8.6) min/day in MVPA.
263 Table 3 presents baseline and follow-up values for intervention and control groups
264 (unadjusted for wear-time). Table 4 presents data standardised to a 16-hour waking wear
265 time, including within-group and between group effects. Here, daily sitting time reduced on
266 average by 30.0 (SD 50.6) min/day (95% CI 5.8 to 54.6) in the intervention group and 40.4
267 (SD 92.5) min/day (95% CI 13.0 to 93.8) in the control group. Prolonged sitting time reduced
268 on average by 36.1 ± 65.0 min/day (95% CI 4.8 to 67.5) in the intervention group and $44.2 \pm$
269 134.2 min/day (95% CI 33.3 to 121.7) in the control group. Reductions in sitting time were
270 replaced with increases in time spent standing (intervention 22.5 [SD 35.5] min/day, control
271 33.8 [SD 59.0] min/day) and stepping (intervention 7.8 [SD 19.2] min/day, control 6.6 [SD
272 9.9] min/day). No differences were statistically significant following sequential Bonferroni
273 adjustments. On average, both intervention and control group participants exceeded the target
274 of reducing sitting time by at least 30 min/day, with effect sizes of 0.62 and 0.46 respectively.
275 At less than 10 min/day, average time spent in MVPA (GT3X+ data) remained very low for
276 all participants at baseline and post-intervention. Regarding reported use of time (MARCA
277 data), participants reported reductions in sedentary activities, in particular TV viewing (-46
278 min/day and -38 min/day for the intervention and control groups respectively), but there were
279 no significant between group differences in any of the domains (Table 5).

280

281 **Discussion**

282

283

284 Stroke survivors are both sedentary (spending large proportions of their day sitting down),
285 and physically inactive. Previous research has largely focused on encouraging stroke
286 survivors to increase their time in physical activity of at least moderate intensity. This is the
287 first clinical trial to investigate an intervention aimed at encouraging stroke survivors to
288 replace sitting time with light intensity activity – i.e. ‘sit less and move more’. Our protocol
289 was both safe and feasible, with no adverse events (apart from four non-injurious falls, two in
290 the control and two in the intervention group) and high compliance. On average, participants
291 in both groups reduced their sitting time by at least 30 min/day and replaced sitting time with
292 standing and stepping. However, there was considerable intra-individual variability in the
293 magnitude of change, and, participants in the intervention group did not show superior
294 outcomes relative to the control group.

295

296 The trial was not powered to detect statistically significant intervention effects. However, the
297 attention-matched control group may have played a role in the lack of between group
298 differences. Participants in the control arm of the trial received the same number of
299 counselling sessions as intervention participants. In an attempt to further reduce bias,
300 participants were unaware of the intervention of interest; they were told the trial was about
301 ‘healthy living after stroke’, and that they would receive counselling based on either diet or
302 exercise. While the content of the counselling sessions in the control group focussed on a
303 dietary message, anecdotally many participants reported changing physical activity habits, for
304 example going for more regular walks or recommencing gym programs. The activity
305 monitors worn by all participants did not provide any real-time feedback, however, it is
306 possible that they could have impacted on activity levels in all participants. Determining the
307 key active elements in any intervention is important.

308

309 Currently, the evidence for the effectiveness of behaviour change interventions and self-
310 management programs for increasing physical activity in people with stroke is limited.²⁹
311 Very few high quality trials have been conducted to date, and there is little similarity in the
312 content of the interventions delivered.²⁹ We chose to use a motivational interviewing
313 intervention to target behaviour change in this study. While one previous study found this
314 approach to be effective in increasing physical activity in people after stroke,³⁰ more high
315 quality trials are needed to evaluate the relative effectiveness of different behaviour change
316 interventions for people with stroke.

317

318 The barriers for people with stroke to exercise regularly at moderate intensity are often
319 insurmountable,^{17,31} and efforts to address this have been largely ineffective.^{32,33} Reducing
320 daily sitting time may be a more achievable target with significant health benefits. We
321 recently modelled the impact of replacing sitting with standing or stepping time or both,
322 using accelerometer (activPAL3) based measures of sitting time in a large sample of healthy
323 adults³⁴. Replacing two hour/day of sitting with either standing or stepping was associated
324 with important reductions in cardiovascular disease risk.³⁴ Furthermore, experimental work in
325 healthy adults has demonstrated that reductions in sitting time leads to clinically worthwhile
326 reductions in cardiovascular disease risk factors such as improved glucose metabolism,
327 reduced insulin resistance and decreased blood pressure, at least in the short term.^{12,}

328 ³⁵However, the longer term benefits of changes in sitting time are not known.

329

330

331 Limitations

332 The lack of difference between intervention and control participants suggests the intervention
333 requires development. We did not formally evaluate the degree to which our intervention
334 adhered to motivational interviewing principles, or if there were any differences related to the
335 two individual counsellors delivering the intervention. This may also have contributed to the
336 fact that the intervention expected to change behaviour the most, was not more effective.
337 Furthermore, seasonal variations in habitual physical activity levels have also been well
338 documented³⁶ and may have played a role in this trial as data were collected across an 15-
339 month time period. While both modelling of epidemiological data¹³ and experimental work¹²
340 suggest that changes in sitting time may lead to clinically meaningful reductions in
341 cardiovascular disease risk, this requires testing in large-scale clinical trials. The study was
342 not powered to detect a difference in safety measures between groups, and therefore we
343 cannot exclude the possibility of modest harms. Future trials should carefully monitor fall
344 rates and fear of falling. Accelerometers such as the Actigraph GT3x+ tend to underestimate
345 step counts in people with slow walking speeds.³⁷ This may have affected the accuracy of the
346 absolute values of physical activity in some of our participants, but is not likely to have
347 affected estimations of change over time. Finally, while all participants self-reported they had
348 residual walking or balance deficits, 17% of participants recorded no symptoms on the
349 National Health Institute of Stroke Severity Scale indicating minimal to no disability.

350

351

352 **Conclusion**

353

354

355 This is the first clinical trial to demonstrate that it is possible for people with stroke to sit less
356 each day. We have demonstrated that the clinical trial protocol is both safe and feasible and
357 leads to reductions in daily sitting time. However, the health benefits associated with sitting
358 less each day remain unclear.

359

360

361 **Suppliers**

362 PAL Technologies Ltd. 50 Richmond St Glasgow G1 1XP, Scotland, United Kingdom
363 (activPAL monitors).

364 Actigraph LLC. 49 E Chase Street Pensacola, Florida 32502, United States of America
365 (GT3x+ monitors).

366 Temple Healthcare Pty Ltd. PO Box 299 Bowral 2576, New South Wales, Australia
367 (sensewear am band monitors).

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- 472
- 473

1 Running head: Reducing sitting time after stroke

2

3 Title: Reducing sitting time after stroke. A Phase II safety and feasibility randomised
4 controlled trial.

5

6

7

8 **Abstract**

9 *Objective*

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

12 *Design*

13 Randomised controlled trial with attention-matched control and blinded assessments.

14 *Setting*

15 Community

16 *Participants*

17 Thirty-five stroke survivors (22 male, mean age 66.9 ± 12.7 years).

18 *Interventions*

19 Four counselling sessions over seven weeks with a message of 'sit less, move more'
20 (intervention group) or 'calcium for bone health' (attention-matched control group).

21 *Main outcome measures*

22 Safety (adverse events, increases in pain, spasticity or fatigue) and feasibility
23 (adherence to trial protocol). Secondary measures included time spent sitting
24 (including in prolonged bouts ≥ 30 mins), standing, and stepping as measured by the
25 thigh-worn activPAL3 activity monitor (7 days, 24hrs/day protocol) and time spent in
26 physical activity of at least moderate intensity as measured by the actigraph GT3x+.
27 The Multi-Media Activity Recall for Children and Adults (MARCA) was used to
28 describe changes in use-of-time.

29 *Results*

30 Thirty-three participants completed the full protocol. Four participants reported falls
31 during the intervention period with no other adverse events. From a baseline average
32 of 640.7 (SD 99.6) min/day, daily sitting time reduced on average by 30.0 (SD 50.6)
33 min/day (95% CI 5.8 to 54.6) in the intervention group and 40.4 (SD 92.5) min/day in
34 the control group (95% CI 13.0 to 93.8). Participants in both groups also reduced their
35 time spent in prolonged sitting bouts (≥ 30 minutes) and increased time spent standing
36 and stepping.

37 *Conclusions*

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

42

43

44 **Key words:**

45 stroke, sedentary behaviors, sitting time, physical activity, objective activity

46 monitoring

47

48

49 **Introduction**

50

51

52 Between 1990 and 2010 worldwide prevalence rates for stroke increased by 84% (by
53 27% in high income countries), making stroke the third leading cause of disability.¹

54 Up to a third of people who survive a first stroke will suffer a recurrent stroke within
55 five years, with this figure increasing to 43% for people surviving 10 years or more.²

56 Both lack of adequate levels of physical activity and high sedentariness (i.e. too much
57 sitting) in this population are likely contributing factors to recurrent stroke rates. Lack
58 of adequate physical activity - less than 150 minutes a week of moderate to vigorous
59 intensity physical activity (MVPA) - is the second highest population attributable risk
60 factor for stroke,³ while spending long periods of the day sitting down, particularly in
61 long bouts of uninterrupted sitting, is an **independent** risk factor for cardiovascular
62 disease morbidity and mortality in otherwise healthy adults, **even after taking into**
63 **account the time spent in moderate to vigorous intensity physical activity.**^{4,5} Studies
64 have shown that people with stroke are typically both highly sedentary and physically
65 inactive,⁶⁻¹¹ placing them at the greatest risk of the consequences arising from these
66 conditions. In a recently completed observational study utilising high precision
67 activity monitors, people with stroke were more sedentary and less active than age-
68 matched controls, spending 75% of their waking hours sitting down each day and less
69 than five minutes a day in MVPA.⁶

70

71 Experimental studies¹² and epidemiological studies¹³ have shown that breaking up
72 sitting time with periods of light intensity physical activity (such as walking at a

73 comfortable pace) leads to reductions in cardiovascular disease risk factors ¹² and
74 mortality¹³. Therefore, interventions aimed at reducing daily sitting time may be a
75 promising new target for reducing recurrent stroke risk. However, there are many
76 reasons why people with stroke spend long periods sitting down, including mobility
77 impairments, post-stroke fatigue, pain and spasticity. This means that people with
78 stroke may find it difficult to sit less each day. Furthermore, encouraging people with
79 stroke to move more each day may lead to increased exposure to risk of falls.

80

81 The aim of this pilot randomised controlled trial was to assess the safety, feasibility
82 and effectiveness of an intervention to reduce sitting time in people with stroke. Our
83 primary hypotheses were that the intervention would be both safe (not lead to adverse
84 events including falls, negative changes in pain, spasticity and fatigue) and feasible
85 (have a high adherence to the measurement protocol, in particular activity monitor
86 wear time). Our secondary hypotheses were that the intervention would lead to a
87 reduction in sitting time, prolonged sitting time (bouts ≥ 30 min duration ¹⁴ and
88 increases in standing and stepping time, as well as time spent in MVPA. We
89 considered a 30-min/day reduction in sitting time as the minimal clinically important
90 difference. In healthy, inactive adults, replacing one hour a day of self-reported sitting
91 with light intensity activity has been linked to lower all-cause mortality¹³. As the
92 dose-response relationship between sedentary physical activity and health is non-
93 linear ¹³ it is possible that even smaller reductions in sitting time will have health
94 benefits for people who are both more sedentary (spend more time sitting) and more
95 inactive (spend less time in MVPA), particularly when measured accurately and
96 objectively as opposed to self-report.

97

98 **Method**

99

100

101 This was a pilot randomised controlled trial with an attention-matched control group,
102 concealed allocation and blinded assessment of outcome. The trial was registered with
103 the Australian and New Zealand Trial Registry (xxxx). Participants were unaware of
104 the intervention of interest. They were told only that this was a trial of ‘healthy living
105 after stroke’. A 1:1 randomisation sequence was prepared by a statistician
106 independent of the project. A research assistant independent of the project prepared a
107 set of sequentially numbered, opaque, sealed envelopes with the group allocation
108 inside. Participants were recruited from outpatient clinics, databases of participants
109 from previous trials, stroke exercise classes and social media. **Research staff**
110 **repeatedly visited outpatient clinics and stroke exercise classes to identify potential**
111 **participants. Flyers were also placed in clinics, and frequent phone calls were made to**
112 **therapy staff within these centres to assist in recruitment.** A trained assessor who was
113 unaware of group allocation assessed participants at baseline **(pre-intervention)** and
114 post-intervention. Ethical approval was obtained from the relevant ethics committees
115 and participants provided written, informed consent. As the primary outcomes were
116 safety and feasibility, we did not power the trial to detect statistically significant
117 changes in sitting time. Changes in sitting time were interpreted in light of what we
118 considered the minimal clinically important difference in daily sitting time (30
119 min/day).¹³

120

121 **Participants**

122

123

124 We recruited people living at home after stroke. Inclusion criteria were: at least six
125 months since last stroke (to minimise the impact of spontaneous neurological
126 recovery after stroke); living at home for at least three months since last hospital
127 discharge; some residual walking and/or balance deficits (self-reported); and,
128 sufficient cognitive and language ability to provide informed consent and participate
129 in the motivational interviewing sessions.

130

131 Intervention

132

133

134 Participants were randomly assigned to the intervention or control group. Participants
135 in the intervention group received a series of four counselling sessions with the main
136 message being to 'sit less and move more', with encouragement to regularly break up
137 sitting time with short bursts of light intensity activity (standing, walking at a
138 comfortable pace). Interventions specifically targeted at reducing sitting time have
139 been found to be more effective than those aimed at general lifestyle advice, or advice
140 to increase MVPA.¹⁵ The counselling sessions were provided by two researchers (xx
141 and xx) both of whom were formally trained in motivational interviewing techniques
142 through accredited courses. Motivational interviewing is a form of goal-directed
143 counselling that aims to strengthen a person's own motivation and commitment to
144 change and is particularly effective in eliciting behaviour change for people who are
145 reluctant or ambivalent about change.¹⁶ The first session was provided face-to-face in

146 the participant's home. At this first session, participants were presented with an
147 individualised written report which provided feedback regarding daily sedentary time
148 and breaks in sedentary time based on the baseline hip-worn accelerometer data (see
149 below). This report was used as the starting point for discussions. The counselling
150 sessions used key motivational interviewing techniques (decisional balance sheets,
151 importance and confidence rulers) to initiate and reinforce change talk. Action plans,
152 goals and strategies were elicited from the participants, rather than imposed by the
153 counsellors. Follow-up counselling sessions were delivered by phone and occurred
154 one, three and seven weeks after the initial session. We chose to deliver the
155 intervention via a face-to-face home visit and follow-up telephone calls, rather than in
156 groups to avoid transport being a barrier to participation.¹⁷ In order to match the
157 groups for attention, control group participants received the same schedule of
158 interviews, with a placebo message of increasing calcium for bone health. Data from a
159 food frequency questionnaire were used to create personalised feedback for control
160 participants.¹⁸ The food frequency questionnaire was used to reinforce the credibility
161 of the attention-matched control group and data were not analysed.

162

163 Outcome measures

164

165

166 Baseline measures were collected at the first face-to-face appointment and included
167 stroke type (Oxfordshire Stroke Classification¹⁹), stroke severity (National Institutes
168 of Stroke Scale, score 0 to 42 with higher scores indicating more severe stroke) side
169 of stroke, height, weight, walking speed (self-selected, measured over the middle 5 m

170 of a 9 m walkway), use of walking aids, living arrangements (alone/with spouse),
171 degree of independence in activities of daily living (self-reported as independent or
172 requiring some assistance in daily tasks such as showering, dressing and cooking),
173 and cognitive function (Montreal Cognitive Assessment, score range 0 to 30, scores
174 <22 indicate cognitive dysfunction²⁰). All participants completed a food frequency
175 questionnaire.¹⁸ At this appointment, participants were fitted with three activity
176 monitors and provided with instructions regarding keeping diaries of sleep/wake time
177 and when monitors should be removed. Participants wore all three monitors for seven
178 days at baseline and again one week after the final counselling session (post-
179 intervention).

180

181 *Safety* was assessed by recording changes in self-reported pain and spasticity (visual
182 analogue scale, anchored at 0 [no pain/spasticity] and 10 [severe pain/spasticity]), and
183 fatigue (Checklist Individual Strength, score 8 to 56, higher scores indicating greater
184 fatigue symptoms²¹). Falls incidence and any other adverse events were ascertained
185 by asking structured questions (“have you fallen or tripped over in the last 2 months”)
186 at each assessment point. While simple recall of falls can underestimate falls
187 incidence, it does not underestimate injurious falls (specificity 87-100%)²².

188 *Feasibility* was assessed via adherence to counselling sessions (actively engaged in all
189 scheduled counselling sessions) and completion of all assessments at baseline and
190 post-intervention, including activity monitor wear time.

191

192 *Time spent sitting, standing and stepping* was measured using the activPAL3 device
193 (PAL Technologies Ltd), which was waterproofed and attached to the participants’

194 anterior thigh on the non-hemiparetic leg. Participants wore this monitor continuously
195 (24 hours/day) for seven days including during showering/bathing and water-based
196 activities. The activPAL3 contains an inclinometer and a tri-axial accelerometer. In
197 studies of both healthy adults and people with stroke it has been shown to be 99-100%
198 accurate in classifying sitting/lying and standing postures^{23, 24} The activPAL3 data
199 were processed using activPAL3 software (version 7.2.32). Sleep/wake diaries were
200 entered into a Microsoft Access database. A custom built SAS program linked
201 activPAL3 data to the sleep wake diaries to identify and remove sleep and non-wear
202 time. This program also identified periods of prolonged, uninterrupted sitting of ≥ 30
203 minutes duration.

204

205 *Physical activity* was measured using the Actigraph GT3+ triaxial accelerometer,
206 which was worn on an elastic waist belt and positioned over the non-hemiparetic hip.
207 Participants were asked to wear the monitor 24 hours a day for seven days, removing
208 it for showering/bathing or any other water-based activities. Participants also wore the
209 Sensewear arm band around their non-hemiparetic upper arm. In this trial, the
210 Sensewear arm band was used purely to determine non-wear time for the Actigraph.
211 As the Sensewear arm band switches off when not in contact with the skin and also
212 had to be removed for water-based activities, we made the assumption (backed up by
213 review of participant diaries) that the Actigraph and Sensewear monitors were always
214 removed at the same time. Actigraph data were processed by Actilife software
215 (version 6.3.2), and periods of sleep (matched to activPAL data) and non-wear (as
216 detected by the Sensewear arm band) were removed using custom filters. In line with
217 the most commonly used cut-points for classification of activity intensity of older

218 adults²⁵ activity of at least moderate intensity was defined as ≥ 1952 counts per
219 minute.²⁶

220

221 *Use of time* was measured using the Multimedia Activity Recall for Children and
222 Adults (MARCA)²⁷ This computerised use of time tool asks participants to recall
223 their previous day from midnight to midnight and classifies activities according to a
224 pre-determined list of 520 separate items. Activities are then classified into time spent
225 in various ‘superdomains’ such as transport, screen time and chores. The
226 superdomains are further categorised into ‘macro-domains’, for example active and
227 passive transport, computer and TV time. Participants were phoned at a pre-
228 determined time during the week they were wearing the monitors at baseline, and
229 post-intervention and the MARCA was administered by interview, which took
230 approximately 20 minutes. In a previous observational study, agreement between
231 repeated administration of the MARCA on the same day, ranged from 0.834 (95%
232 confidence interval [C] 0.681 to 0.918) and 0.946 (95% CI 0.890 to 0.974) for the
233 different MARCA superdomains⁶ The MARCA has been validated against doubly-
234 labelled water in young adults, with a correlation of $r = 0.70$ for daily energy
235 expenditure.²⁸

236

237 **Statistical Analyses**

238

239

240 Paired t-tests (or Wilcoxon Signed Rank tests where data were not normally
241 distributed) were used to examine within group differences between baseline and

242 post-intervention in safety and feasibility measures (pain, spasticity, fatigue, monitor
243 wear-time and falls). To adjust for waking hours, activPAL3 and Actigraph derived
244 activity variables (time spent in sitting, prolonged sitting, standing, stepping and
245 MVPA) were standardised to a 16-hour/day waking wear time period. Paired t-tests
246 (or Wilcoxon Signed Rank tests where data were not normally distributed) were used
247 to examine within group differences between baseline and post-intervention in
248 activity variables. Univariate analyses of variance (with adjustment for multiple
249 comparisons) were used to examine between group differences in change scores
250 (post-intervention minus baseline) in time spent sitting, standing, stepping and in
251 MVPA. Independent t-tests were used to examine between group differences in
252 MARCA-derived variables between intervention and control groups. Sequential
253 Bonferroni corrections were applied to account for multiple comparisons. All
254 analyses were by intention to treat.

255

256 **Results**

257

258

259 Participants were recruited between February 2013 and February 2014 with final data
260 collected in May 2014. Figure 1 presents the flow of participants through the trial.

261 Table 1 presents baseline characteristics of the 35 participants. Four (n=2 intervention
262 and n=2 control) participants reported falls during the intervention period. None of the
263 falls were injurious. There were no other adverse events reported. Pain, spasticity and
264 fatigue did not change between baseline and post-intervention for either group (Table
265 2). Compliance with wearing the activity monitors was high. At baseline n=23 and

266 n=31 participants had seven days of valid data from the activPAL3 and the GT3x+
267 monitors respectively. All other participants had at least four days of wear time for
268 both monitors, with the exception of three participants for whom the GT3x+ monitor
269 did not record any valid data on any days. At post-intervention, n=33 and n=25 had
270 seven days of valid data from the activPAL3 and the GT3x+ monitors respectively.
271 All other participants had at least four valid wear days for both the activPAL3 and
272 GT3x+ monitors, with the following exceptions; two participants (both in the control
273 group) did not complete the post-intervention assessment for reasons of ill health not
274 related to the trial, and a further three participants did not have any valid wear days
275 for the GT3x+ monitor. Table 2 presents average wear days and monitored hours for
276 all participants. There was 100% compliance with counselling sessions – **that is all**
277 **participants engaged in all scheduled counselling sessions.**

278

279 At baseline participants spent an average of 640.7 (SD 99.6) min/day sitting, 436.2
280 (SD147.0) min/day in prolonged sitting (un-interrupted sitting bouts of ≥ 30 mins),
281 153.6 (SD 63.9) min/day standing, 59.3 (SD 36.8) min/day stepping and 7.4 (SD 8.6)
282 min/day in MVPA. Table 3 presents baseline and follow-up values for intervention
283 and control groups (unadjusted for wear-time). Table 4 presents data standardised to a
284 16-hour waking wear time, including within-group and between group effects. Here,
285 daily sitting time reduced on average by **30.0 (SD 50.6) min/day (95% CI 5.8 to 54.6)**
286 in the intervention group and **40.4 (SD 92.5) min/day (95% CI 13.0 to 93.8)** in the
287 control group. Prolonged sitting time reduced on average by **36.1 \pm 65.0 min/day**
288 **(95% CI 4.8 to 67.5)** in the intervention group and **44.2 \pm 134.2 min/day (95% CI**
289 **33.3 to 121.7)** in the control group. Reductions in sitting time were replaced with
290 increases in time spent standing (intervention 22.5 [SD 35.5] min/day, control 33.8

291 [SD 59.0] min/day) and stepping (intervention 7.8 [SD 19.2] min/day, control 6.6 [SD
292 9.9] min/day). No differences were statistically significant following sequential
293 Bonferroni adjustments. On average, both intervention and control group participants
294 exceeded the target of reducing sitting time by at least 30 min/day, with effect sizes of
295 0.62 and 0.46 respectively. At less than 10 min/day, average time spent in MVPA
296 (GT3X+ data) remained very low for all participants at baseline and post-intervention.
297 Regarding reported use of time (MARCA data), participants reported reductions in
298 sedentary activities, in particular TV viewing (-46 min/day and -38 min/day for the
299 intervention and control groups respectively), but there were no significant between
300 group differences in any of the domains (Table 5).

301

302 **Discussion**

303

304

305 Stroke survivors are both sedentary (spending large proportions of their day sitting
306 down), and physically inactive. Previous research has largely focused on encouraging
307 stroke survivors to increase their time in physical activity of at least moderate
308 intensity. This is the first clinical trial to investigate an intervention aimed at
309 encouraging stroke survivors to replace sitting time with light intensity activity – i.e.
310 ‘sit less and move more’. Our protocol was both safe and feasible, with no adverse
311 events (apart from four non-injurious falls, **two in the control and two in the**
312 **intervention group**) and high compliance. On average, participants in both groups
313 reduced their sitting time by at least 30 min/day and replaced sitting time with
314 standing and stepping. However, there was considerable intra-individual variability in

315 the magnitude of change, and, participants in the intervention group did not show
316 superior outcomes relative to the control group.

317

318 The trial was not powered to detect statistically significant intervention effects.
319 However, the attention-matched control group may have played a role in the lack of
320 between group differences. Participants in the control arm of the trial received the
321 same number of counselling sessions as intervention participants. In an attempt to
322 further reduce bias, participants were unaware of the intervention of interest; they
323 were told the trial was about 'healthy living after stroke', and that they would receive
324 counselling based on either diet or exercise. While the content of the counselling
325 sessions in the control group focussed on a dietary message, anecdotally many
326 participants reported changing physical activity habits, for example going for more
327 regular walks or recommencing gym programs. The activity monitors worn by all
328 participants did not provide any real-time feedback, however, it is possible that they
329 could have impacted on activity levels in all participants. Determining the key active
330 elements in any intervention is important.

331

332 Currently, the evidence for the effectiveness of behaviour change interventions and
333 self-management programs for increasing physical activity in people with stroke is
334 limited.²⁹ Very few high quality trials have been conducted to date, and there is little
335 similarity in the content of the interventions delivered.²⁹ We chose to use a
336 motivational interviewing intervention to target behaviour change in this study. While
337 one previous study found this approach to be effective in increasing physical activity

338 in people after stroke,³⁰ more high quality trials are needed to evaluate the relative
339 effectiveness of different behaviour change interventions for people with stroke.

340

341 The barriers for people with stroke to exercise regularly at moderate intensity are
342 often insurmountable,^{17, 31} and efforts to address this have been largely ineffective.^{32,}

343 ³³ Reducing daily sitting time may be a more achievable target with significant health
344 benefits. We recently modelled the impact of replacing sitting with standing or
345 stepping time or both, using accelerometer (activPAL3) based measures of sitting
346 time in a large sample of healthy adults³⁴. Replacing two hour/day of sitting with
347 either standing or stepping was associated with important reductions in cardiovascular
348 disease risk.³⁴ Furthermore, experimental work in healthy adults has demonstrated
349 that reductions in sitting time leads to clinically worthwhile reductions in
350 cardiovascular disease risk factors such as improved glucose metabolism, reduced
351 insulin resistance and decreased blood pressure, at least in the short term.^{12,}

352 ³⁵However, the longer term benefits of changes in sitting time are not known.

353

354

355 Limitations

356 The lack of difference between intervention and control participants suggests the
357 intervention requires development. We did not formally evaluate the degree to which
358 our intervention adhered to motivational interviewing principles, or if there were any
359 differences related to the two individual counsellors delivering the intervention. This
360 may also have contributed to the fact that the intervention expected to change
361 behaviour the most, was not more effective. Furthermore, seasonal variations in

362 habitual physical activity levels have also been well documented³⁶ and may have
363 played a role in this trial as data were collected across an 15-month time period.
364 While both modelling of epidemiological data¹³ and experimental work¹² suggest that
365 changes in sitting time may lead to clinically meaningful reductions in cardiovascular
366 disease risk, this requires testing in large-scale clinical trials. The study was not
367 powered to detect a difference in safety measures between groups, and therefore we
368 cannot exclude the possibility of modest harms. Future trials should carefully monitor
369 fall rates and fear of falling. Accelerometers such as the Actigraph GT3x+ tend to
370 underestimate step counts in people with slow walking speeds.³⁷ This may have
371 affected the accuracy of the absolute values of physical activity in some of our
372 participants, but is not likely to have affected estimations of change over time.
373 Finally, while all participants self-reported they had residual walking or balance
374 deficits, 17% of participants recorded no symptoms on the National Health Institute of
375 Stroke Severity Scale indicating minimal to no disability.

376

377

378 **Conclusion**

379

380

381 This is the first clinical trial to demonstrate that it is possible for people with stroke to
382 sit less each day. We have demonstrated that the clinical trial protocol is both safe and
383 feasible and leads to reductions in daily sitting time. However, the health benefits
384 associated with sitting less each day remain unclear.

385

386

387 **Suppliers**

388 PAL Technologies Ltd. 50 Richmond St Glasgow G1 1XP, Scotland, United

389 Kingdom (activPAL monitors).

390 Actigraph LLC. 49 E Chase Street Pensacola, Florida 32502, United States of

391 America (GT3x+ monitors).

392 Temple Healthcare Pty Ltd. PO Box 299 Bowral 2576, New South Wales, Australia

393 (sensewear am band monitors).

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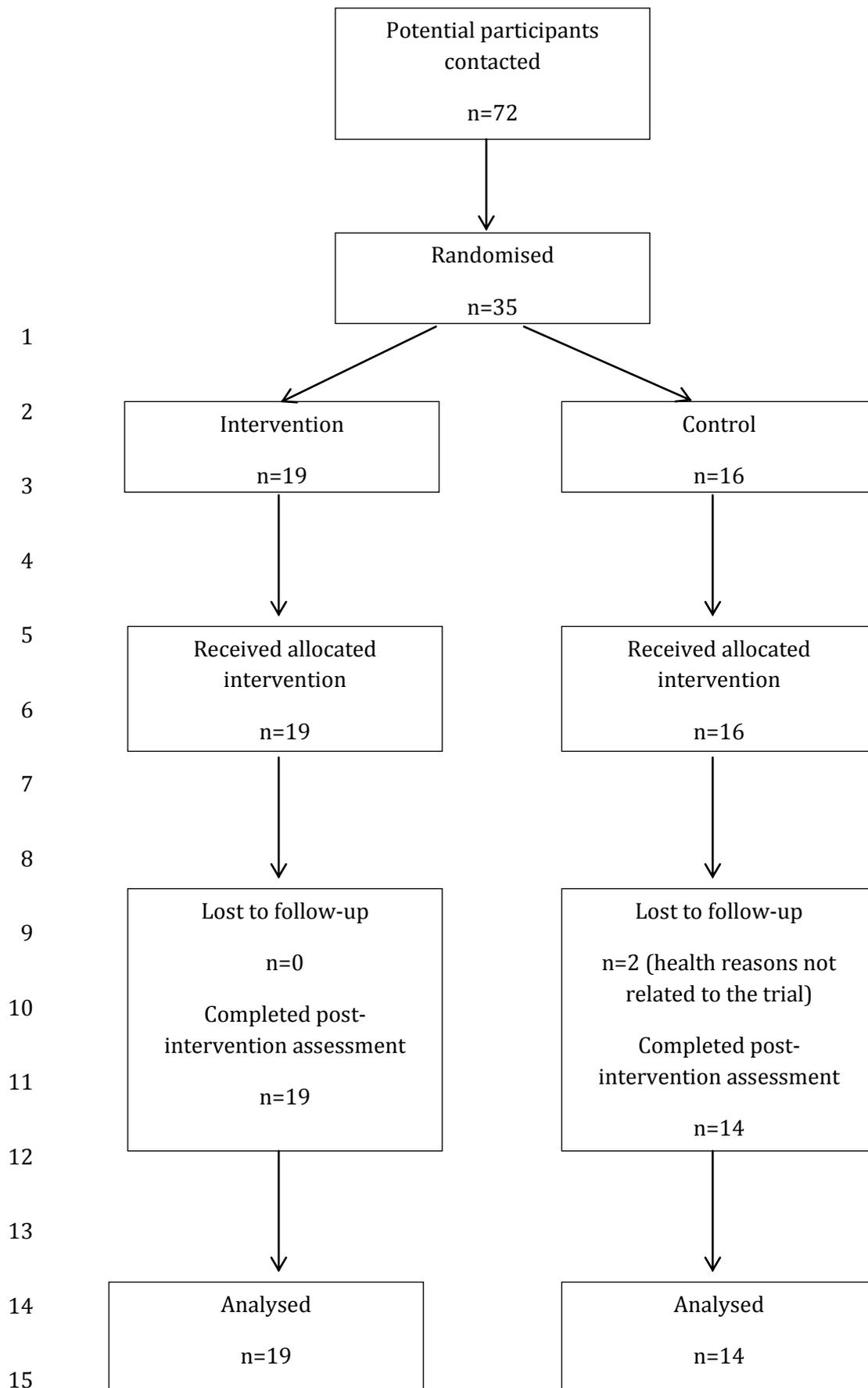
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502

503

Figure 1 CONSORT statement flow chart



1 **Table 1 Participant characteristics**

Characteristic	Whole sample	Intervention	Control
N(%) or mean (SD)	(n=33)	(n=19)	(n=14)
Age (years)	66.9 (12.7)	65.4 (12.3)	67.8 (13.8)
Males	22 (62.9)	13 (68.4)	9 (64.3)
First stroke	28 (80.0)	12 (63.2)	14 (100)
Stroke type*			
TACI	6 (17.1)	5 (26.3)	1 (7.1)
PACI	13 (37.1)	9 (47.4)	3 (21.4)
LACI	7 (20)	3 (15.8)	4 (28.6)
Haemorrhage	9 (25.7)	2 (10.5)	6 (42.9)
Stroke severity (NIHSS)(score)			
No symptoms (0)	6 (17.1)	3 (15.8)	3 (21.4)
Mild (1 to 4)	20 (57.1)	11 (57.9)	7 (50.0)
Moderate/severe (>4)	9 (25.7)	5 (26.3)	4 (28.6)
Time since stroke (years)	3.2 (3.4)	2.8 (2.6)	4.1 (4.3)
Living arrangement			
Spouse/other	27 (77.1)	14 (73.7)	12 (85.7)
Alone	8 (22.9)	5 (26.3)	3 (14.3)
Independence in ADLs			
Independent	23 (65.7)	14 (73.7)	7 (50.0)

Requires assistance	12 (34.3)	5 (26.3)	7 (50.0)
Use of walking aid			
No aids	23 (65.7)	13 (68.4)	9 (64.3)
Walking stick	10 (28.6)	5 (26.3)	4 (28.6)
Frame	2 (5.7)	1 (5.3)	1 (7.1)
Walking speed	0.81 (0.41)	0.80 (0.36)	0.82 (0.51)
(m/s)			
BMI (kg/m ²)	28.6 (4.8)	29.3 (5.8)	27.5 (3.0)
MoCA (score)	24.2 (3.6)	24.0 (4.2)	24.4 (2.7)

*Oxfordshire Stroke Classification. TACI = total anterior circulation infarct, PACI = partial anterior circulation infarct, LACI = lacunar infarct, NIHSS = National Institutes of Health Stroke Scale, ADL = activities of daily living, BMI = body mass index, MoCA = Montreal Cognitive Assessment

1 **Table 2 Safety and feasibility measures**

Outcomes mean (SD)	Intervention		Control	
	Baseline (n=19)	Post- intervention (n=19)	Baseline (n=14)	Post- intervention (n=14)
Pain (cm, VAS)	3.4 (2.8)	3.2 (3.1) [¥]	3.7 (3.5)	3.4 (3.3) [¥]
Spasticity (cm, VAS)	3.0 (2.8)	2.4 (2.4) [¥]	3.6 (3.2)	3.8 (2.7) [¥]
Fatigue (score, CIS)	34.1 (9.3)	32.3 (8.3) ^{¥¥}	32.9 (11.7)	35.3 (10.7) ^{¥¥}
Number falls [§]				
None		16 (84.2)		11 (78.6)
One		1 (5.3)		1 (7.1)
Two		1 (5.3)		1 (7.1)
Missing		1 (5.3)		1 (7.1)
Valid wear days activPAL3 (n)	6.1 (0.8)	6.9 (0.2)	5.6 (0.9)	6.9 (0.4)
Waking wear hours ^{§§} activPAL3 (hr/day)	14.4 (1.2)	14.1 (1.3)	14.1 (1.2)	14.0 (1.6)
Valid wear days GT3x+ (n)	6.5 (0.9)	6.6 (0.8)	6.7 (0.6)	6.8 (0.6)

Waking wear hours^{§§} GT3x+ 14.6 (1.1) 14.1 (1.4) 14.5 (1.5) 14.2 (1.4)
(hr/day)

VAS = visual analogue scale, CIS = Checklist Individual Strength, [¥]No significant difference, Wilcoxon Signed Rank Test, ^{¥¥} significant difference, paired t-test, [§]Number of falls reported during the intervention period, ^{§§}waking hours monitored

1 **Table 3 Sitting time and physical activity. Mean (SD) of intervention and control groups, not adjusted for wear time.**

Outcomes mean (SD)	Groups			
	Intervention (n=19)		Control (n=14)	
	Baseline	Post-Intervention	Baseline	Post-Intervention
Total sitting time (min /day)	645.8 (99.9)	609.7 (121.0)	633.8 (102.5)	589.9 (111.5)
Sitting time accumulated in bouts \geq 30 mins (min/day)	431.1 (155.7)	396.0 (177.3)	443.2 (139.8)	396.4 (162.6)
Standing time (min/day)	154.8 (66.8)	171.3 (73.9)	151.9 (62.1)	183.5 (90.8)
Stepping time	59.6 (40.6)	64.3 (45.0)	59.0 (32.4)	65.5 (42.3)

(min/day)

MVPA (≥ 1952 cpm)

8.2 (10.5)

6.6 (9.5)

6.6 (5.9)

9.9 (10.4)

min/day

2 MVPA = moderate to vigorous physical activity

3

- 1 **Table 4** Sitting time and physical activity, standardised to 16 hour-day waking wear time. Mean (SD) of intervention and control groups,
- 2 **differences within groups and mean (95% CI) of difference between groups.**

	Groups		Difference within groups		Difference between groups in change scores		
	Intervention (n=19)	Control (n=14)	Post-intervention - Baseline mean difference (95% CI) §		Intervention – Control mean difference (95% CI) §§		
Outcomes mean (SD)	Baseline	Post- Intervention	Baseline	Post- Intervention	Intervention (n=19)	Control (n=14)	
Total sitting time (min/day)	722.3 (107.5)	692.1 (124.8)	720.7 (99.5)	680.2 (133.1)	-30.2 ± 50.6 (- 54.6 to -5.8)	-40.4 ± 92.5 (-93.8 to 13.0)	-10.2 (-62.2 to 41.9) p=0.693

					p=0.018	p=0.126	
Sitting time	484.4 (186.6)	448.2 (206.4)	501.9 (146.7)	457.7	-36.1 ± 65.0 (-	-44.2 ±	-8.1 (-81.4 to 65.1)
accumulated in				(188.5)	67.5 to -4.8)	134.2 (-	p=0.821
bouts ≥30 mins,					p=0.026	121.7 to	
(min/day)						33.3)	
						p=0.24	
Standing time	171.0 (71.2)	193.4 (79.7)	171.9 (67.1)	205.7 (93.5)	22.4 ± 35.5 (5.4	33.8 ± 59.3	-11.3 (-45.5 to 22.9)
(min/day)					to 39.6) p=0.013	(0.3 to 67.9)	p=0.504
						p=0.051	
Stepping time	66.8 (48.8)	74.5 (57.8)	67.5 (38.1)	74.1 (45.3)	7.8 ± 19.2 (-1.5 to	6.6 ± 36.9	1.2 (-19.3 to 21.7)
(min/day)					17.0) p=0.096	(-14.6 to	p=0.907
						27.9)	
						p=0.516	
MVPA (≥ 1952	8.8 (11.2)	7.7 (11.4)	7.2 (6.3)	10.9 (11.0)	-0.6 ± 10.9 (-6.4	4.1 ± 9.7 (-	-3.8 (-11.8 to 4.1)

cpm) min/day

to 5.3) p=0.842

1.9 to 10.3)

p=0.332

p=0.161

3 [§]Paired t-test ^{§§}univariate analysis of variance, MVPA = moderate to vigorous intensity physical activity. Sitting, prolonged sitting, standing, and

4 stepping were derived from activPAL3 data; MVPA was derived from GT3X+ data.

1 **Table 5 Use of time data measured by the MARCA**

2

	Control		Intervention		Difference between groups in change scores	
Activity, min/day	Baseline	Post- intervention	Baseline	Post- intervention	Intervention – Control mean difference (95% CI) §	P
mean (SD)						
Total sitting time	679 (167)	667 (217)	668 (136)	593 (170)	63	0.28
Television	221 (157)	183 (133)	303 (183)	257 (120)	8	0.13
Passive Transport	36 (41)	62 (58)	50 (64)	42 (49)	34	0.10
Reading	45 (61)	75 (69)	47 (78)	51 (92)	26	0.42
Sit and talk	87 (109)	58 (51)	50 (62)	72 (92)	26	0.42

3

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