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6 **Title: Ergometer Cycling improves the Ambulatory Function and Cardiovascular**  
7 **Fitness of Stroke Patients – A Randomized Controlled Trial.**

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9 Ernest Kwesi Ofori<sup>1</sup>, PT, MSc, Emmanuel Frimpong<sup>2\*</sup>, Adeolu Ademiluyi, PT<sup>3</sup> PT, Physiol, MPhil,  
10 Olajide Ayinla Olawale<sup>4</sup>, PT, Physiol, PhD

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12 <sup>1</sup>Department of Physical Therapy, College of Applied Health Sciences University of Illinois at  
13 Chicago, 1919 W Taylor St, Chicago IL, 60612 USA, Phone: +16183032470, Email:  
14 eofori4@uic.edu

15 <sup>2</sup>Movement Physiology Research Laboratory, School of Physiology, Faculty of Health Sciences,  
16 University of the Witwatersrand, Johannesburg, South Africa, E-mail: frimemma@gmail.com/  
17 [efrimpong@ug.edu.gh](mailto:efrimpong@ug.edu.gh).

18 <sup>3</sup>Department of Physical Therapy, College of Applied Health Sciences, University of Illinois at  
19 Chicago, USA, Email: aademi3@uic.edu

20 <sup>4</sup>Department of Physiotherapy, Faculty of Clinical Sciences, College of Medicine, University of  
21 Lagos, Nigeria, Email: jideolawale@yahoo.com

22

23 \* Corresponding author: Emmanuel Frimpong

24 Email address: **frimemma@gmail.com**

25

27 **ABSTRACT.**

28 **[Purpose]** The aim of this study was to assess the effects of ergometer cycling on the ambulatory  
29 function and cardiovascular fitness of patients with stroke in the sub-acute phase.

30

31 **[Subjects and Methods]** Twenty (20) patients with stroke in the sub-acute phase were randomly  
32 allocated to either an ergometer cycling group (n=10) or a control group (n=10). The experimental  
33 (ergometer cycling) group performed cycling exercises in addition to conventional physiotherapy for 60  
34 minutes per session, three times per week for 8 weeks. The control group only received conventional  
35 physiotherapy for the same duration as the experimental group. Assessments of participants' functional  
36 ambulatory category, ambulatory velocity, 6-minute walk test, heart rate and blood pressure were  
37 conducted at baseline and at the end of the 8-week intervention.

38

39 **[Results]** The means of the ambulatory velocity and distance walked in 6 minutes were significantly  
40 higher in the ergometer cycling group than those of the control group at week 8. However, the increase  
41 in the FAC score was not significant. The means of heart rate, systolic and diastolic blood pressures  
42 significantly decreased in the ergometer cycling group compared to the control group at the end of the 8-  
43 week of intervention.

44

45 **[Conclusion]** This study demonstrated that ergometer cycling improved the ambulatory function  
46 and cardiovascular fitness of patients with stroke in the sub-acute phase.

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48 **Key words: Stroke, Ergometer cycling, Ambulatory function.**

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51 **INTRODUCTION**

52 Stroke is a leading cause of long-term disabilities in adults. It is characterized by hemiparesis,  
53 walking inability without assistance and dependence on others for the performance of activities of  
54 daily living (ADL)<sup>1</sup>. Performing continuous and smooth reciprocal movements such as ambulation  
55 (walking), is a very difficult task for hemiparetic patients with stroke<sup>2</sup>. This may be due to residual  
56 motor weakness or paresis, spasticity, poor motor control and lower limb coordination, postural  
57 imbalance and loss of sensation<sup>3, 4, 5</sup>. In addition to neurological impairments, walking dysfunction  
58 after stroke is also associated with the cardiovascular and musculoskeletal consequences of the  
59 disease and physical inactivity<sup>6</sup>.

60

61 Musculoskeletal deficits (including muscle atrophy and contractures) and cardiovascular problems  
62 (such as decreased maximal oxygen consumption) as well as low aerobic endurance significantly  
63 affect stroke patients' ADL performance and in severe cases, may lead to death<sup>7</sup>. Thus, the physical  
64 deconditioning along with age-associated declines in fitness and muscle mass can further contribute  
65 to activity intolerance, compromising patients' capacity to meet the high-energy demands of  
66 hemiparetic walking<sup>8, 9</sup>. Furthermore, multiple comorbidities associated with first time and  
67 recurrent strokes including hypertension, coronary heart disease, impaired glucose tolerance,  
68 diabetes, depression and obesity worsen recovery and compound the loss in movement and overall  
69 function<sup>10, 11</sup>.

70

71 Although physical fitness is important for the performance of everyday activities, muscle strength  
72 and cardiorespiratory fitness are impaired in patients with stroke<sup>12</sup>. However, aerobic exercise  
73 reduces the cardiovascular demands that walking makes on patients with stroke<sup>6</sup>. Increased fitness

75 levels may benefit a range of post-stroke problems by reducing fatigue, the energy cost of  
76 hemiparetic gait, and the incidence of falls and fractures as well as improve patients' independence,  
77 mood and quality of life<sup>13)</sup>.

78

79 A major rehabilitation objective for patients with motor impairments in the lower limbs is recovery  
80 of walking capacity<sup>14)</sup>. Thus, restoring walking ability is the major objective of lower limb  
81 rehabilitation after stroke<sup>14)</sup>. However, the degree of recovery depends on several factors such as  
82 location and severity of lesion, capacity for adaptation through training, and the duration of stroke,  
83 recovery is higher in the early months after stroke<sup>4)</sup>. Therefore, motor function recovery strategies  
84 after stroke must include methods directed towards recovery of walking capacity<sup>15)</sup>. Several studies  
85 have employed different exercise interventions to restore ambulatory capacity or function and  
86 cardiovascular fitness after stroke<sup>16, 17, 18, 19, 20, 21, 22, 23, 24)</sup>. Most of these studies used exercise training  
87 on a treadmill with or without weight-support as an intervention for improving ambulatory function  
88 and cardiovascular fitness. The outcome measures commonly used were blood pressure (BP), heart  
89 rate (HR), the six-minute walk test (6-MWT), ambulatory velocity (AV) or the ten-metre walk test  
90 (10-MWT), and the functional ambulatory category (FAC) score<sup>17, 18, 19, 20, 25, 26)</sup>.

91

92 The current approach towards stroke rehabilitation emphasizes task-specific training, which  
93 involves intense practice of functional tasks<sup>4)</sup>. Cycling can improve functional mobility and can act  
94 as a pseudo-walking task-oriented exercise<sup>27)</sup>. Cycling shares a similar kinematic pattern with  
95 walking because both are cyclical, require reciprocal flexion and extension movements of the hip,  
96 knee, and ankle, and both require alternating and coordinated antagonist muscle activation<sup>28, 29)</sup>.  
97 Cycling can be used as a method to counter the consequences of immobility<sup>7)</sup>. This type of training

99 improves the aerobic capacity, strength, and cardiopulmonary function of subjects<sup>15)</sup>. In addition,  
100 cycling exercise also facilitates muscle control of the lower limbs, which may allow putting more  
101 weight on the affected leg while standing<sup>30)</sup>. Moreover, ergometer cycling requires less balance  
102 ability, which makes it useful for training patients with or without neurological deficits who have  
103 difficulty in maintaining balance and independent gait<sup>29)</sup>. Furthermore, the ability to exercise while  
104 sitting means cycling is well-tolerated by patients with stroke in the acute, sub-acute or chronic  
105 phases<sup>31)</sup>. Cycling exercise has elicited positive outcomes for walking performed by patients with  
106 chronic stroke<sup>7, 30, 32, 33)</sup>, and patients with incomplete spinal cord injury<sup>34)</sup>. However, few studies  
107 have evaluated the therapeutic effects of ergometer cycling on the ambulatory function and  
108 cardiovascular fitness of patients with stroke in the sub-acute phase. Moreover, studies have shown  
109 that there is greater chance of recovery during the sub-acute stage after stroke<sup>4, 5)</sup>. Therefore, the  
110 purpose of this study was to assess the effects of ergometer cycling on the ambulatory function and  
111 cardiovascular fitness of patients with stroke in the sub-acute phase.

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### 113 **SUBJECTS AND METHODS**

114 The study was conducted at the Physiotherapy Department of the Korle Bu Teaching Hospital  
115 (KBTH) in Accra, Ghana. KBTH is the largest referral hospital in Ghana and has over 1600 beds.  
116 The hospital receives referrals from all over the country and neighboring West African countries.  
117 KBTH also serves as the teaching hospital of the College of Health Sciences (CHS) of the  
118 University of Ghana. The study population comprised patients with stroke receiving care at the  
119 hospital. The participants were hemiparetic patients with recent stroke referred to the Physiotherapy  
120 Department for rehabilitation. Patients were recruited into the study if they had: first or second

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123 stroke resulting in right or left side hemiparesis, muscle power of at least grade three, and could  
124 walk at least 10 meters with or without assistive devices. Patients were excluded from the  
125 study if they had bilateral hemiparesis, an FAC score of less than grade three, muscle power of less  
126 than grade three, fracture of the lower limb, aphasia and cognitive impairment, cardiac arrhythmias,  
127 or any condition for which exercise is contraindicated<sup>16</sup>.

128

129 The Ethical and Protocol Review Committee (EPRC) of the University Of Ghana School Of Allied  
130 Health Sciences approved the study protocol. All participants gave their written informed consent  
131 after receiving explanations of the study protocol and the potential risks that could be encountered.  
132 The study was advertised via posters and verbal invitation. Eligible patients were randomly divided  
133 into two (2) groups: an experimental group or ergometer cycling group (ErCG), and a no-ergometer  
134 cycling or control group (CG). Randomization was done using cards bearing the names of the  
135 groups and the number of participants. Ten participants were allocated to each group (Fig. 1). Both  
136 groups received three sessions of treatment per week for eight weeks.

137

138 The cycling exercises began with familiarization sessions in which participants were introduced to  
139 the protocol and acquainted themselves with ergometer cycling. The Enraf Nonius ergometer  
140 bicycle (EN cycle 970, Holland) was used in this study. Based on the familiarization session, the  
141 initial revolutions of pedaling and resistances were individually set for each participant. In addition,  
142 participants were instructed on what to do during the study period including: resting periods during  
143 cycling, hydration, communicating adverse symptoms, and prevention of falls.

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146 Treatments for participants in the ErCG comprised warm-ups, cycling exercise and cool-downs.  
147 The warm-up (5 minutes) included overground walking and cycling at a self-selected pedaling  
148 speed. The cool-down sessions (5 minutes) involved slow pedaling, passive stretching of the lower  
149 limbs and controlled breathing exercises. Prior to the exercise, the resting heart rate (HR) and blood  
150 pressure (BP) of the participants were monitored to ensure they were clinically stable before  
151 exercise. Participants were assisted to safely mount the ergometer bicycle. The height of the seat  
152 was adjusted to ensure postural balance, upright seating and firm contact of the feet with the pedals.  
153 Participants who could not grip firmly had their hands strapped to the handle of the ergometer  
154 bicycle. The foot of the affected limb was buckled onto the pedal.

155

156 Treatment for the ErCG lasted for 60 minutes per session. In addition to ergometer cycling, the  
157 participants also received conventional physiotherapy. The cycling was performed for 30 minutes  
158 per session, three times per week for 8 weeks. Thus, a total of 720 minutes of cycling exercises  
159 were performed over the 8-week period. The intensity of the cycling was targeted between 10  
160 (light) and 15 (hard or heavy) on the Borg scale of rating of perceived exertion (RPE)<sup>35</sup>. A low  
161 resistance set at 1 of 4 on the ergometer bicycle was applied to allow a cycling speed of 40 to 60  
162 revolutions per minute (rev/min). Thus, participants performed the cycling at 40 rev/min at the  
163 beginning and 60 rev/min towards the end of the study. Participants were encouraged to increase the  
164 number of revolutions per minute throughout the study. The control group (CG) received only  
165 conventional physiotherapy comprising passive, active assisted, active and strengthening exercises  
166 as well as balance and walking re-training for the same duration as the ErCG. The ErCG and CG  
167 were assessed at baseline and at the end of the 8<sup>th</sup> week for the following outcome measures: heart  
168

170 rate, blood pressure, 6-minute walk test, ambulatory velocity measured by the 10-metre walk test,  
171 and functional ambulatory category (FAC) score.

172

173 Resting heart rate was measured at rest with an electronic monitor (Omron, UK). Following 10  
174 minutes of resting in a seated position, BP was measured using an aneroid sphygmomanometer at  
175 the brachial artery with the arm supported at the level of the heart. The BP was recorded as a ratio  
176 of systolic blood pressure (SBP) mmHg to diastolic blood pressure (DBP) mmHg.

177 The 6-minute walk test was performed to assess the muscular endurance and walking capacity of  
178 the participants. Participants walked around the 40-metre walkway of the therapeutic gymnasium  
179 for 6 minutes. The total distance covered during the 6 minutes was then calculated in metres. Prior  
180 to the test, subjects were told that they could rest by either sitting or standing upon request and that  
181 they could walk with or without walking aids<sup>36</sup>.

182 The 10-MWT was conducted to assess the ambulatory velocity of the participants over a ten-metre  
183 walkway. A 14-meter walkway was marked on the floor of the gymnasium. This was done to  
184 eliminate acceleration and deceleration affecting the test. Participants were told before the test that  
185 they could walk with or without a walking aid at self-selected walking speed<sup>37</sup>. A stop-watch was  
186 used to record the time taken by the subjects to cover the ten-metre distance in the middle of the 14-  
187 metre walkway. The stop-watch was started when the participants crossed the 2-metre line, and  
188 stopped when they crossed the 12-metre line, and the time was recorded in seconds. Three trials  
189 were performed and the average time calculated<sup>16</sup>.

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192 The functional ambulatory category was assessed while participants were walking to evaluate the  
193 level of dependency of participants in performing functional activities. The FAC is a six-point  
194 ordinal rating scale that reflects the assistance a person requires when walking. This scale allows  
195 easy classification of patients in respect of their walking ability, and the maximum score signifies  
196 the ability to ambulate independently on uneven surfaces<sup>38</sup>.

197

198 The data were analyzed using the Statistical Package for Social Sciences (SPSS) version-20. The  
199 paired *t*-test was used to determine significant differences in the means of the outcome measures  
200 (HR, BP, 6-MWT, AV and FAC) within groups between baseline and week 8, and the un-paired *t*-  
201 test was used to determine significant differences between the groups at baseline and week 8. A *p*-  
202 value of less than 0.05 ( $p < 0.05$ ) was considered significant.

203

## 204 **RESULTS**

205 This study had twenty participants: 12 (60%) males and 8 (40%) females. The mean age of the  
206 participants was  $60.6 \pm 8.5$  years. Their mean duration of stroke was  $3.8 \pm 2.8$  months. Sixteen (80%)  
207 and four (20%) of the participants had ischaemic and haemorrhagic strokes, respectively. Ten  
208 (50%) of the participants presented with left hemiparesis and the other half with right hemiparesis.  
209 Five (25%) of the participants had a history of smoking and drinking alcohol, whereas 75% had no  
210 history of smoking and drinking alcohol. Sixteen (80%) of the participants were married, 2 (10%)  
211 were widows, and 2 (10%) were single. Ten (50%) of the participants were retirees,

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213 7 (35%) were working and 3 (15%) were unemployed. The characteristics of the study participants  
214 are shown in Table 1.

215

216 In ErCG, the paired *t*-test indicated there were significant differences in the means of FAC, AV, 6-  
217 MWT, SBP and DBP from baseline to week 8 ( $p<0.03$ ), but the mean value of HR had not changed  
218 significantly at week 8 ( $p=0.2408$ ) (Table 2). Likewise, there were no significant differences in the  
219 means of FAC, AV, 6-MWT, HR, SBP and DBP between baseline and week 8 ( $p>0.05$ ) in CG  
220 (Table 2).

221

222 Analyses with the unpaired *t*-test indicated there were no significant differences in the means of  
223 FAC, AV, 6-MWT, HR, SBP and DBP between the ErCG and CG at baseline ( $p>0.05$ ) (Table 2).  
224 However, there were significant differences in the means of AV, 6-MWT, HR, SBP and DBP  
225 between the ErCG and CG at week 8 ( $p<0.05$ ) (Table 2).

226

## 227 **DISCUSSION**

228 This study investigated the effects of ergometer cycling on the ambulatory function and  
229 cardiovascular fitness of patients with stroke in the sub-acute phase. The findings of the study  
230 demonstrate that ergometer cycling in conjunction with conventional physiotherapy improved the  
231 ambulation and cardiovascular fitness of twenty patients with stroke. The cardiovascular fitness of  
232 the participants improved more in ErCG than in CG as measured by resting heart rate and blood  
233 pressure. The HR and BP were significantly lower in ErCG than in CG at week 8. These results are  
234 in agreement with the results of previous studies<sup>27, 39, 40</sup>. Bateman et al. reported that patients with  
235 stroke showed improved cardiovascular fitness after 12 weeks of cycle ergometer aerobic training.

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237 The observed improvements in cardiovascular fitness may be related to improvements in  
238 sensorimotor function<sup>41</sup>). Other studies have shown that aerobic capacity or peak oxygen  
239 consumption (VO<sub>2</sub> peak) and walking performance are reduced in elderly patients with stroke and  
240 that low oxygen consumption levels are associated with limited physical function when performing  
241 daily activities<sup>42</sup>). However, endurance exercise beneficially affects ambulatory blood pressure<sup>43</sup>).  
242 Thus, increasing the fitness levels of patients with stroke may avert post-stroke problems including  
243 fatigue, increased energy cost of ambulation, falls and fractures, and poor quality of life<sup>13</sup>).

244

245 In this study, ambulatory velocity (AV) measured by the 10-MWT significantly increased in ErCG  
246 and also in comparison to CG at week 8. Similarly, the 6-MWT significantly increased in ErCG  
247 than in CG. These results support the findings of previous studies<sup>7, 27, 33</sup>). Both ambulatory velocity  
248 and walking capacity in the experimental group showed greater improvement than in control group.  
249 The superior improvements in ambulatory velocity in ErCG may be attributable to the improved  
250 gait performance, strength and aerobic capacity of participants<sup>15, 44</sup>). The improvement in walking  
251 capacity may also be due to increased cardiovascular fitness and facilitation of motor learning<sup>44</sup>).  
252 Furthermore, cycling exercise facilitates muscle control of the lower limbs, which may allow  
253 putting more weight on the affected leg while standing<sup>30</sup>). Since the range of motion (ROM) in  
254 cycling is superior to that in walking, pedaling helps maintain the functional ROM of the lower  
255 limbs required to walk<sup>45</sup>). One advantage of cycling is that it involves the affected limb thereby  
256 facilitating use and limb control<sup>41</sup>). Seki et al. observed significant increases in the muscle activities

258 of the rectus femoris, tibialis anterior and soleus muscles in the affected leg of stroke patients  
259 during cycling compared with baseline isometric contraction<sup>46</sup>). Thus, given the ambulatory velocity  
260 and walking capacity of patients in ErCG, they could safely perform community ambulation.

261

262 The FAC assesses the level of support or dependency a patient requires for ambulation<sup>44</sup>). In this  
263 study, although FAC significantly increased in the ErCG, the mean difference was not statistically  
264 significant between the two groups at baseline and at week 8 (Tables 2). These findings are similar  
265 to observations of previous studies<sup>24, 27</sup>). Improvement in functional ambulatory ability in ErCG may  
266 have been due to improvements in the participants' aerobic capacity, strength and cardiopulmonary  
267 function as well as their increased AV of participants having been elicited by ergometer cycling<sup>15</sup>).  
268 The FAC score of ErCG at the end of 8 weeks meant the participants could independently walk or  
269 ambulate freely especially, on level surfaces<sup>38</sup>). Stationary cycling has been found useful for  
270 counteracting the consequences of immobility<sup>7</sup>). Katz-Leurer et al. reported that improvements in  
271 balance and motor abilities were greater in an experimental group (with less than a one-month  
272 history of stroke) than in a control group after three weeks of cycling exercises<sup>27</sup>). These findings  
273 suggest that early cycling exercise at the sub-acute phase may improve balance and motor  
274 performance<sup>15</sup>).

275

276 In conclusion, this study showed that ergometer cycling improved the ambulatory function and  
277 cardiovascular fitness of twenty patients with stroke in the sub-acute phase. Therefore, ergometer  
278 cycling may be used to improve walking ability and cardiovascular health in stroke rehabilitation.  
279 However, due to the small sample size and the short duration of the intervention, further trials are  
280 needed to confirm or refute the effectiveness of ergometer cycling for the ambulatory function and  
281 cardiovascular fitness of patients with stroke in the sub-acute phase.

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404

## 406 TABLES

407 Table 1: Characteristics of the study participants

Characteristics	ErCG	CG
N (%)	10 (50)	10 (50)
Age (Mean $\pm$ SD) (years)	58.8 $\pm$ 8.3	62.4 $\pm$ 8.8
Duration of stroke (Mean $\pm$ SD) (month)	3.5 $\pm$ 2.6	4.1 $\pm$ 3.0
<b>Type of stroke n (%):</b>		
Ischaemic	9 (45)	7 (35)
Haemorrhagic	2 (10)	2 (10)
<b>Side of Stroke n (%)</b>		
Left	5 (25)	5 (25)
Right	5 (25)	5 (25)

408 N - number of participants; % - Percentage; ErCG - Ergometer Cycling Group; CG - Control  
409 Group; Mean  $\pm$  SD - Mean plus or minus Standard Deviation.

412

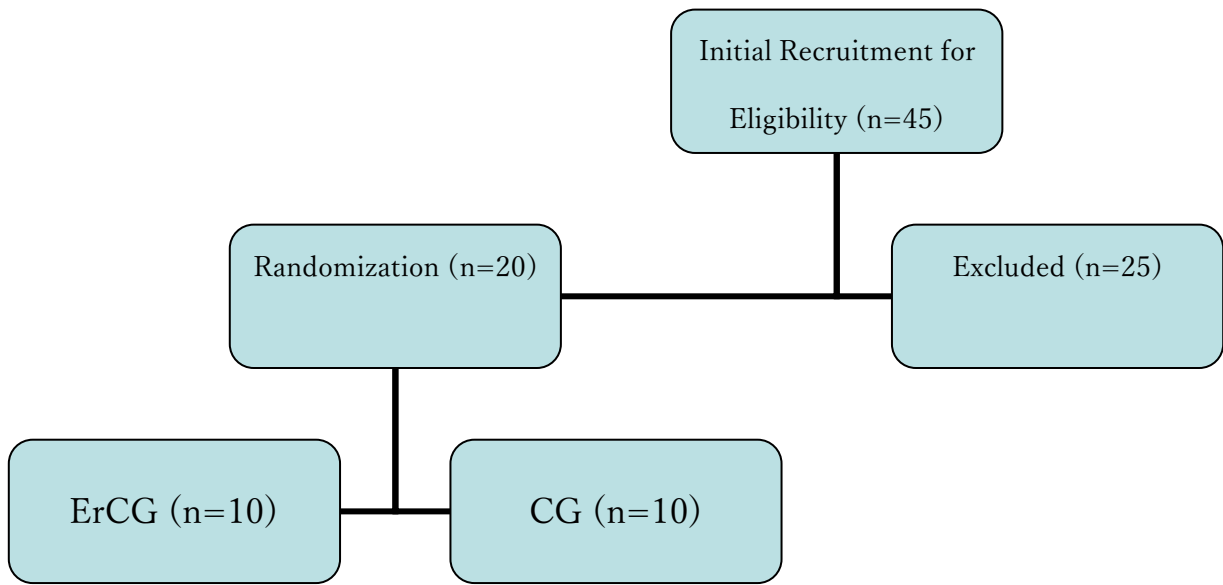
413 **Table 2: Comparison of outcome measures between and within ErCG and CG at both**  
414 **baseline and week 8**

Outcome Measure	ErCG (Mean ± SD)	CG (Mean ± SD)
<b>FAC</b>		
Baseline	2.8 ± 0.6	2.9 ± 0.7
Week 8	4.0 ± 0.8 <sup>#</sup>	3.1 ± 1.3
<b>AV (m/s)</b>		
Baseline	0.64 ± 0.18 <sup>*</sup>	0.46 ± 0.22
Week 8	0.74 ± 0.18 <sup>#*</sup>	0.49 ± 0.24
<b>6-MWT (m)</b>		
Baseline	278.7 ± 58.06	251.7 ± 56.1
Week 8	310.6 ± 63.9 <sup>#*</sup>	268.5 ± 55.1
<b>HR (bpm)</b>		
Baseline	75.0 ± 9.1	81.2 ± 4.0
Week 8	72.3 ± 6.3 <sup>*</sup>	79.3 ± 1.9
<b>SBP (mmHg)</b>		
Baseline	133.9 ± 12.2	134.0 ± 8.1
Week 8	123.0 ± 7.4 <sup>#*</sup>	133.1 ± 8.3
<b>DBP (mmHg)</b>		
Baseline	82.0 ± 7.2	83.6 ± 7.5
Week 8	73.2 ± 9.0 <sup>#*</sup>	81.8 ± 8.7

415 ErCG – Ergometer Cycling Group; CG – Control Group; FAC – Functional Ambulatory Category;  
416 AV – Ambulatory Velocity; 6-MWT – 6-Minute Walk Test; HR - Heart Rate; bpm – Beats Per  
417 minute; SBP – Systolic Blood Pressure; DBP – Diastolic Blood Pressure; mmHg – Millimetres of  
418 Mercury; Mean ± SD - Mean plus or minus Standard Deviation.  
419

420 \* Indicates significant differences in outcome measures between ErCG and CG at both baseline and

421 week 8. # Indicates significant differences in outcome measures from baseline to week 8 in ErCG.



425 **Fig. 1. Flow chart of the study design.**