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**ORIGINAL RESEARCH** 

Effect of the provision of a cane on walking and social
participation in individuals with stroke: protocol for a
randomized trial<sup><sup>(</sup></sup>

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13	KEYWORDS	Abstract
14	Clinical trial;	Background: Canes are usually prescribed for individuals with stroke with the purpose of improv-
15	Stroke;	ing walking and increasing safety. However, there is no consensus regarding the clinical effects
16	Gait;	of these aids on walking and participation.
17	Cane;	Objective: This study will examine the efficacy of the provision of a cane to improve walking
18	Rehabilitation	and increase participation after stroke.
19		Methods: This is a two-arm, prospectively registered, randomized trial with concealed alloca-
20		tion, blinded measurers, and intention-to-treat analysis. Fifty individuals with chronic stroke,
21		categorized as slow or intermediate walkers (walking speeds $\leq 0.8  \text{m/s}$ ), will participate. The
22		experimental group will receive a single-point cane and instructions to use the cane anytime
23		they need to walk. The control group will receive a placebo intervention, consisting of self-
24		stretching exercises of the lower limb muscles and instructions to not use assistive devices. The
25		primary outcome will be comfortable walking speed. Secondary outcomes will include walking
26		step length, walking cadence, walking capacity, walking confidence, and participation. Out-
27		comes will be collected by a researcher blinded to group allocation at baseline (Week 0), after
28		intervention (Week 4), and one month beyond intervention (Week 8).
29		

 Q1 <sup>↑</sup> Trial registration: Clinical Trials, NCT03150979. Registered on May 11th, 2017 (https://clinicaltrials.gov/ct2/show/NCT03150979).
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*Conclusion:* The provision of a single-point cane may help improving walking of slow and intermediate walkers after stroke. If walking is enhanced, the benefits may be carried over to participation, and individuals may experience greater free-living physical activity at home and in the community.

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### 37 Introduction and rationale

Stroke is the leading cause of adult disability worldwide.<sup>1</sup> 38 Amongst the limitations in daily living activities, the ability 39 to walk is reported by patients as the most important activ-40 ity to recover after a stroke.<sup>2,3</sup> In addition, higher walking 41 ability is related to greater independence and social partici-42 pation; both performance and capacity of walking have been 43 shown to predict participation.<sup>4</sup> Thus, recovery of walking 44 after stroke is one of the most important goals in neurolog-45 ical rehabilitation.<sup>5</sup> 46

Assistive devices, such as canes and crutches, are usually 47 prescribed for individuals after stroke with the purpose of 48 improving walking and increasing safety.<sup>6</sup> Previous studies 49 have examined the effects of assistive devices on walk-50 ing parameters in individuals with stroke.7-11 The results 51 suggested that assistive devices increase step length<sup>8</sup> and 52 comfortable and maximum walking speeds,<sup>7,11</sup> decrease 53 cadence,<sup>7</sup> and improve walking symmetry.<sup>9</sup> No significant 54 changes in maximum joint angles<sup>7</sup> or trunk movements<sup>10</sup> 55 have been found. A narrative review<sup>12</sup> summarized the 56 effects of using a cane on walking in people with stroke. 57 Although 19 experimental studies were included, method-58 ological shortcomings, such as the absence of randomized 59 trials and the predominance of cross-sectional studies with 60 small samples (n < 20 participants), prevent the drawing 61 of convincing conclusions regarding the effects of using 62 a cane on walking. In addition, many of these studies 63 included participants, who had been habitually using a 64 cane, so that the magnitude of the benefits may have been 65 overestimated. 66

More recently, Nascimento et al.<sup>13</sup> conducted an experi-67 mental study to investigate the effects of the provision of a 68 single-point cane in a heterogeneous group of community-69 dwelling people with stroke, who were naïve to the use 70 of assistive devices for walking. Overall, the provision of 71 72 a cane did not improve walking speed or cadence, and pro-73 duced a small benefit in step length. However, sub-group analyses demonstrated clinically meaningful increases in 74 walking speed, step length, and cadence for individuals clas-75 sified as slow and intermediate walkers, i.e., walking speeds 76 <0.8 m/s. These results reinforce the need to target inter-77 ventions to those who will most benefit and avoid the risk 78 of not implementing worthwhile interventions.<sup>13,14</sup> 79

It has also been suggested that the provision of a cane
can improve walking confidence.<sup>15</sup> Even though walking abil ity is an important predictor of participation in people with
stroke,<sup>4</sup> there were not found any studies on the bene fits of using a cane on community participation. The most

logical time to prescribe walking aids to people with stroke is after their independent walking has stabilized, since, at this stage, there would be no likelihood of interfering with the development of independent walking. A randomized trial to investigate the effects of the provision of a cane to ambulatory individuals with chronic stroke, naïve to the use of assistive devices, on walking and participation after stroke is, therefore, warranted. The specific research questions are:

- 1. Does the provision of a cane improve walking (speed, step length, cadence, capacity, confidence) in ambulatory individuals with chronic stroke?
- 2. Are the benefits carried over to participation?

#### Methods

Design

A prospective, randomized controlled trial with concealed allocation, blinded measurers, and intention-to-treat analysis will be carried-out (Fig. 1). Community-dwelling people with chronic stroke will be recruited from the general community, by means of advertisements and by screening public rehabilitation services and lists of previous research projects. Participants will be randomly allocated into either experimental group (i.e., provision of a cane) or control group (i.e., placebo intervention). Outcome measures will be collected by trained researchers at baseline (Week 0), at the end of the intervention (Week 4), and one month beyond the intervention (Week 8). Analyses of inclusion criteria, getting the informed consent, data collection, and statistical analyses will be carried-out by researchers, who will be blinded to group allocation. All the participants will be evaluated and receive all the information regarding the interventions in a research laboratory. The study obtained ethical approval from the Research Ethical Committee (CAAE: 65765817.3.0000.5149) of the Universidade Federal de Minas Gerais, Belo Horizonte, Minas Gerais, Brazil. The trial was prospectively registered at the www.ClinicalTrials.gov (NCT03150979).

## Participants and therapists – inclusion and exclusion criteria

Participants will be individuals with stroke, who will be eligible, if they:

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