A Community-Based, Bionic Leg Rehabilitation Program for Patients with Chronic Stroke: Clinical Trial Protocol

Amy Wright, MSc,* Keeron Stone, MSc,† Danielle Lambrick, PhD,‡ Simon Fryer, PhD,† Lee Stoner, PhD,§ Edward Tasker, MSc,* Simon Jobson, PhD,* Grace Smith, PhD,‖ John Batten, MSc,* Jo Batey, MSc,* Vicky Hudson, BSc (Hons),¶ Helen Hobbs, PGDip,¶ and James Faulkner, PhD*

Stroke is a major global health problem whereby many survivors have unmet needs concerning mobility during recovery. As such, the use of robotic-assisted devices (i.e., a bionic leg) within a community setting may be an important adjunct to normal physiotherapy in chronic stroke survivors. This study will be a dual-center, randomized, parallel group clinical trial to investigate the impact of a community-based training program using a bionic leg on biomechanical, cardiovascular, and functional outcomes in stroke survivors. Following a baseline assessment that will assess gait, postural sway, vascular health (blood pressure, arterial stiffness), and functional outcomes (6-minute walk), participants will be randomized to a 10-week program group, incorporating (1) a physiotherapy plus community-based bionic leg training program; (2) physiotherapy only; or (3) usual care control. The training program will involve participants engaging in a minimum of 1 hour per day of bionic leg activities at home. Follow-up assessments, identical to baseline, will occur after 10 weeks, and 3 and 12 months postintervention. Given the practical implications of the study, the clinical significance of using the bionic leg will be assessed for each outcome variable. The potential improvements in gait, balance, vascular health, and functional status may have a meaningful impact on patients' quality of life. The integration of robotic devices within home-based rehabilitation programs may prove to be a cost-effective, practical, and beneficial resource for stroke survivors.
Key Words: Robotic assisted—stroke survivors—walking—gait—blood pressure.

From the *Department of Sport & Exercise, University of Winchester, Winchester, UK; †School of Sport & Exercise, University of Gloucestershire, Gloucester, UK; ‡Faculty of Health Sciences, University of Southampton, Southampton, UK; §School of Sport & Exercise, University of North Carolina, Chapel Hill, North Carolina; ‖Department of Sport & Exercise Sciences, University of Chester, Chester, UK; and ¶Hobbs Rehabilitation, Martyr Worthy, Winchester, UK.

Received May 26, 2017; revision received August 16, 2017; accepted September 7, 2017.

Grant support: The research study is funded by the University of Winchester (RKE/10/2015-16). Bionic legs have been provided by Alter G (Fremont, CA).

Address correspondence to Amy Wright, MSc, Department of Sport & Exercise, University of Winchester, Winchester, UK. E-mail: amyrwright23@gmail.com.

1052-3057/$ - see front matter

https://doi.org/10.1016/j.jstrokecerebrovasdis.2017.09.002

Introduction

By 2030, stroke burden is expected to double, with increasing survival rates as medical care and treatment techniques improve.[1] This leads to an increasing population with diverse stroke-related disabilities, which may include limitations in communication, activities of daily living, coordination, balance, and mobility.[2] It is estimated that following a stroke only 15% of sufferers will gain complete functional recovery for both the upper and lower extremities.[3] As such, many stroke survivors continue to have unmet needs, especially concerning mobility.[4] Although some individuals with stroke will have received some rehabilitation during the acute and subacute phases, rarely does rehabilitation extend beyond 1 year postinjury due to a lack of resources for long-term services.[5]

Gait impairment, and therefore a reduction in functional ability, leads to many stroke survivors becoming sedentary. Objective activity monitoring of stroke survivors has shown that more than 80% of time is spent sedentary, independent of functional ability, and that in the first year poststroke there is minimal behavior change.[6] With this increased sedentary time, there is a concurrent reduction in fitness and an increased risk of cardiovascular and all-cause mortality and morbidity.[7] A reduction in poststroke fitness could arise from the accumulation of low prestroke physical activity and fitness, direct neurological effects of stroke, and the effect of poststroke physical inactivity.[8] For many stroke survivors, improving walking ability and mobility is widely regarded to be an important rehabilitation goal.[9,10]

Recent advances in medical technology have helped to develop robotic devices to aid gait training in order to restore prestroke movement patterns and improve quality of gait for stroke survivors.[11] Robotic rehabilitation may help to promote limb function in stroke patients by stimulating neuroplasticity[12] and has the potential to provide intensive, repetitive, and task-specific practice that could enhance functional restitution and improve motor performances.[13] Although some robotic devices are large, complex, and cumbersome, which necessitates that the therapist be present during use,[14] externally wearable commercially available devices that can be independently used during home-based poststroke rehabilitation are available.[15] The integration of robotic therapy into current practice could increase the efficiency and effectiveness of therapists by alleviating the labor-intensive aspects of physical rehabilitation and by enabling novel modes of exercise not currently available. Robotic-assisted gait training has been shown to exhibit significantly greater improvements in gait and balance, as measured by the functional ambulation capacity scale, when compared with regular physiotherapy alone.[16] Furthermore, with significant increases in physical activity, step count, and walking capacity observed with the use of lower-limb robotic devices,[17] such applications may elicit important cardiovascular benefits for stroke survivors.[8] Increases in ambulatory activity has been shown to improve cardiorespiratory fitness and reduce the risk of recurrent cardiovascular events.[18]

Research into robotic devices has focused on the implementation within a clinical setting. As patient access to such devices may be constrained by both the accessibility and the availability, community-based programs may be efficacious as patients could use such devices more frequently. Despite this, to date, research into robotic devices within a community setting is limited for patients with stroke. Further, studies either have small (n = 1) sample sizes[19] or are nonrandomized controlled trials.[20] Accordingly, this study will investigate the acute and longer-term effects of using a lower-limb robotic device in a community setting on pertinent biomechanical (gait, postural sway), vascular (blood pressure, arterial stiffness), and functional (lower-limb strength, 6-minute shuttle walk test) measures in chronic stroke survivors. It is hypothesized that a 10-week community rehabilitation program with a robotic device (bionic leg) will lead to greater changes in the aforementioned outcome measures compared with stroke survivors receiving stand-alone physiotherapy or usual care.

Methods

Research Design

This is a dual-center, randomized, parallel group clinical trial. Stroke survivors will be identified from a neuro-physiotherapy practice and/or community-based, stroke support groups (Fig 1). All participants will have been diagnosed with stroke by a specialist neurologist/stroke consultant from a UK National Health Service Foundation Trust and will have undertaken normal inpatient and outpatient rehabilitation in accordance with National Institute for Health and Care Excellence guidelines.[21] Participants with a Functional Ambulation Score of 2-5[22] and who meet the inclusion criteria in the next subsection are eligible to participate in the study.

Inclusion Criteria

The inclusion criteria are as follows:

- patients with a diagnosis of stroke within 3 months to 5 years of study start date
- community patients who are medically stable and are either (1) currently receiving physical therapy from a neurophysiotherapy practice or (2) attending a community-based, stroke support group and do not actively receive physical therapy
- individuals who are able to stand and step with an aid or with assistance
- patients who are cognitively aware to undertake rehabilitation exercises, physical therapy, and physical activity
- patients whose height is 1.58-1.92 m
- patients whose weight is less than 159 kg.

Exclusion Criteria

The exclusion criteria are as follows:

- unresolved deep-vein thrombosis, unstable cardiovascular conditions, open wounds, active drug-resistant infections, recent fractures of involved limb, peripheral arterial disease, incontinence, severe osteoporosis, and non–weight bearing.

Randomization

Web-based randomization procedures will be prepared by an investigator with no clinical involvement in the trial. Participants receiving physical therapy from the