PROTOCOL CERITER – STRIDE ONE

Research Report: CERITER Clinical Study - Stride One

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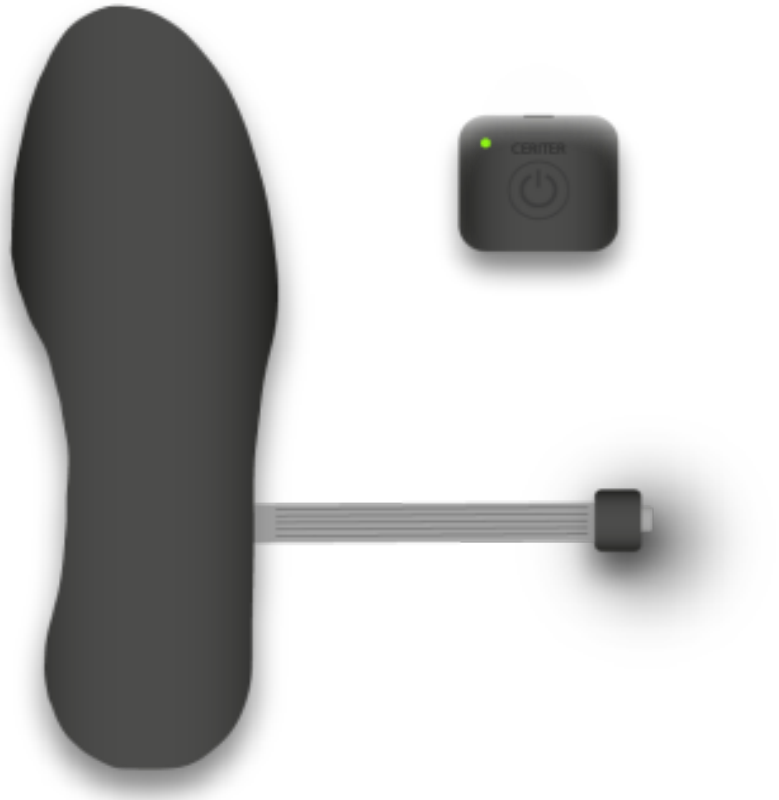


I. GENERAL

Study number	**f/2023/109**
Title study	The effect of the stride one on the gait pattern of people after a stroke
Principal investigator	Dr. Vander Plaetse, M.
Client	CERITER
Protocol version number	Version 2

II. BACKGROUND AND RATIONALE

Cerebrovascular accidents (CVA) are multifactorial disorders that affect both cognitive and physical/motor parameters. One of the most important problems in rehabilitation after CVA (due to hemiplegia) is difficulties in walking, which leads to mobility problems and dependency of the patient on others. When walking, a patient with CVA shows a clear abnormality at the level of the foot, namely an abnormal roll-off pattern. This causes the patient to compensate in other parts of the body. However, if the roll-off pattern of the foot can be influenced or improved, the patient's gait pattern will show an overall qualitative improvement. Ensuring a good foot roll-off is therefore a primary objective in gait rehabilitation after CVA.

Already on the market, Ceriter Stride One is a CE-certified medical device for qualitatively better and more independent walking. The device helps people with walking problems caused by neurological disorders such as Parkinson's disease or CVA. Stride One detects a deviating gait pattern via a smart insole and generates individually tailored audio feedback, for example to prevent or correct a deviating roll-off pattern in the foot as a result of the CVA.

To date, no extensive clinical research has been conducted with Stride One in people with a CVA. In analogy with previously published scientific literature regarding the influence of audio feedback on the gait pattern in CVA and the intensity of exercise, it is expected that Stride One will ensure a better gait pattern in this patient population (see Bibliography 1-4).

FRAME, the clinical test center of the Jessa Hospital (Belgium), was asked by CERITER to perform a Stride One clinical scientific assessment.

III. OBJECTIVES

The aim of this pilot study is to investigate whether patients with a CVA show a qualitatively better gait pattern after training with a Stride One insole and whether patients can maintain this improvement in gait pattern without audio feedback at the end of the training.

Primary endpoints:

- Complete and correct foot roll-off (detected and interpreted in the accompanying software)
- Improved walking speed/greater number of steps per minute

Secondary endpoints:

- Improved functional tests: sit-to-stand, 3min walking test
- Subjective experiences: questionnaires

IV. STUDY POPULATION

In the context of this pilot study, 10 patients with a CVA were recruited between December 2023 and April 2024 from the rehabilitation center of the Jessa hospital (campus Sint-Ursula) in Herk-de-Stad, Belgium, using the following criteria:

Inclusion criteria:

- CVA, residentially admitted to the rehabilitation center
- Older than 18 years of age
- Gait problems as a result of the CVA
- Able to walk safely and independently (possibly with a walking aid)
- Able to understand and sign an information and consent form

Exclusion criteria:

- Severe cognitive problems (attention) that make it difficult to understand instructions or follow feedback
- Hearing problem

The study was approved by the Jessa Hospital Medical Ethics Committee (2023/c/109).

V. RECRUITMENT AND INFORMED CONSENT

Potential participants for this study will be identified by the head of the paramedic department and his team of therapists. Participants consist of patients who have been admitted to the rehabilitation center of Herk-de-Stad, Belgium as a result of a CVA.

If the head of the paramedic or one of the members of his team finds a suitable candidate (impaired gait pattern due to CVA), who they think is suitable for participation in the study, the therapist will approach the patient him/her self to ask whether he or she is interested in participating in the study. After this, the local researcher will approach the patient with an informed consent and additional explanation about the study. After the local researcher has received confirmation from the patient through oral questioning that all information is clear, the informed consent will be signed. As stated in the informed consent, the patient can withdraw from the study at any time, without further consequences.

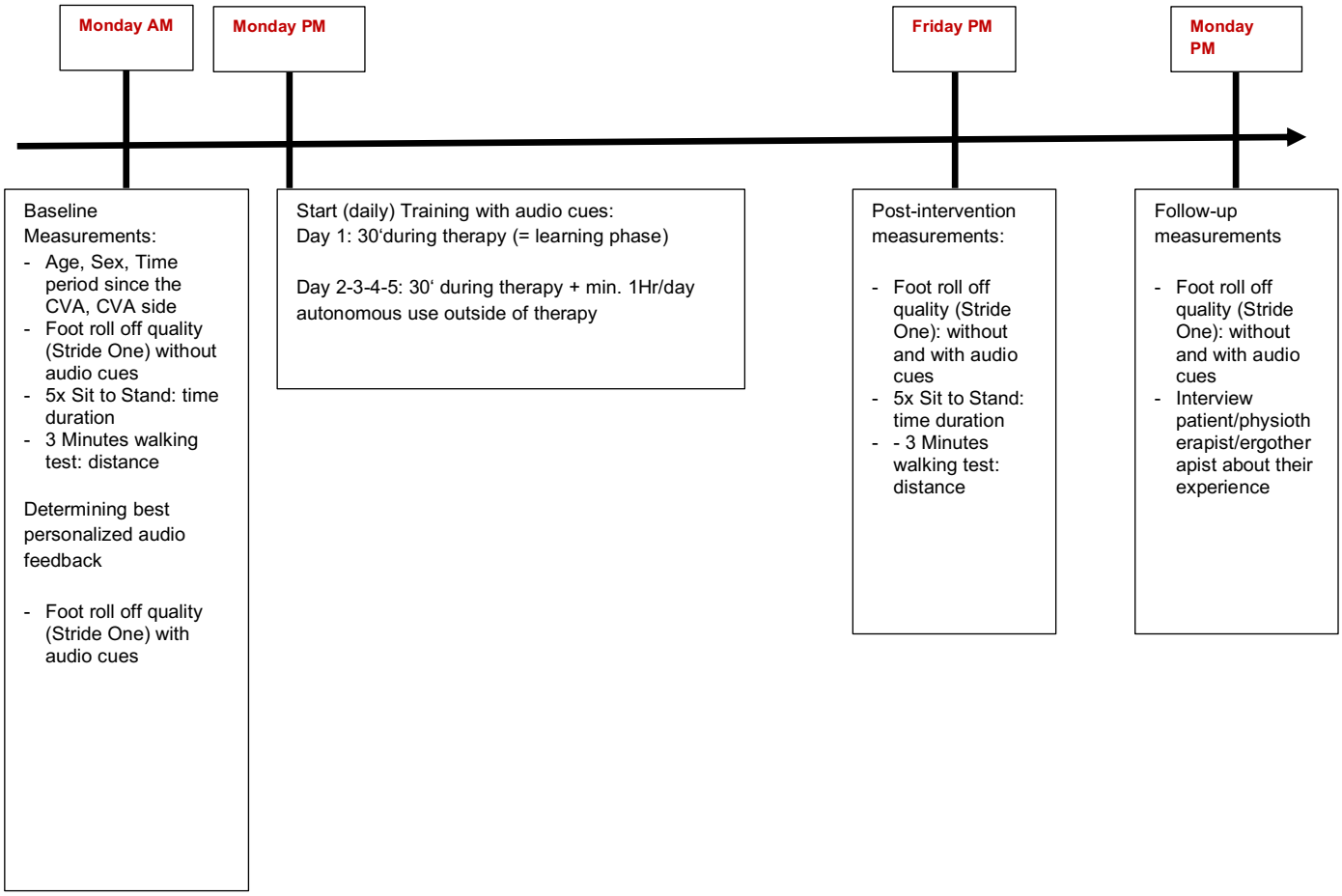
VI. METHODOLOGY

In this study, 10 subjects with impaired gait quality due to a CVA will be recruited. After signing the informed consent, the subjects will undergo baseline measurements (see outcome parameters). Subsequently, the subjects will walk with the Ceriter insole: this provides auditory feedback to the patient, stimulating/helping the patient to achieve a good foot roll-off. During the first gait training, the feedback from the insole is personalized for the patient by the head therapist and employees of Ceriter. After this first measurement/training, the patients will use the insole (+ feedback) daily during rehabilitation with a physiotherapist, as well as on their own (outside therapy) for 5 days. The same post-measurements as at baseline will take place on the last day. This will allow us to determine whether training with the Ceriter insole has a positive effect on the patient's gait pattern. Two days after the post-measurements (and without using the insole in/outside therapy) the patient will be evaluated one last time to determine whether such an intervention also has a lasting effect on the gait pattern.

In addition to the objective measurements (see timeline below), subjective questions will also be asked in the form of questionnaires. Here, the patient will be asked about his/her findings regarding the use of the sole while walking.

Goal of the therapy: to teach patients to place their feet correctly, in order to achieve a better roll-off, and therefore a better gait pattern:

- Help patients to use all areas of the foot correctly during walking
- Help patients to improve specific parts of the foot roll-off during walking
- Help patients to have a completely correct roll-off during walking
- Help patients to again walk symmetrically



VII. RISK-BENEFIT BALANCE

There are no risks associated with participating in this study where an insole will be used to improve the gait pattern of people with a stroke.

VIII. DATA-ANALYSIS

This is a pilot study where aggregated data will be analyzed and displayed to see if this intervention has an effect on objective measurements (gait pattern and functionality) within 1 subject (pre-post wash out). Furthermore, qualitative data will be collected, from which we can gather insights around subjective experiences of the patient.

IX. FINANCIAL ASPECTS

This study was financed by Ceriter BV.

X. REFERENCES

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3. *The Effects of Auditory Feedback Gait Training Using Smart Insole on Stroke Patients.* **J. Kim, S. Jung, C. Song.** 2021.

4. *Intensity of practice after stroke: More is better.* **Kwakkel, Gert et al.** 2009.