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Trans-spinal Electrical Stimulation in Individuals with Spinocerebellar Ataxia

October, 2023

Abstract

The main goal of this pragmatic clinical trial is to investigate the effects of trans-spinal tDCS in individuals with spinocerebellar ataxia (SCA) over some parameters of gait and postural control in real-world conditions, reflecting daily clinical practice. The main questions it aims to answer are: (i) If an extended number of tDCS sessions, beyond the typical 5 to 10 sessions described in scientific literature, applied concomitantly with exercises with progressive challenges, to yield positive outcomes over some parameters of gait and postural control in individuals with SCA and if there is retention of possible benefits one month later the end of this protocol; (ii) If there is specific characteristics (including balance, gait, mobility, severity of ataxia, DNA test characteristics and non-ataxic signs) in individuals with SCA that can predict their improvement in postural control and gait following the 20 tDCS sessions. Participants will receive 20 tDCS sessions concomitantly with exercises for gait and postural control with progressive challenges. Postural control and gait of the participants will be assessed in two big sessions before (#assessment 1) and after the 20 sessions (#assessment 5) and 3 small sessions after every 5 sessions (#assessments 2, 3 and 4). Also, as a follow-up, they will be assessed a month after the end of the intervention (#assessment 6).

1. Scientific background

Spinocerebellar ataxias (SCA) comprise a group of progressive degenerative diseases, currently lacking pharmacological treatments. These conditions produce gait and balance disorders, ultimately necessitating the use of assistive devices, culminating in wheelchair dependency upon the loss of ambulatory function during the clinical progression of SCA. This significantly impacts the individual's independence and quality of life. Recent clinical trials have demonstrated that the application of transcranial direct current stimulation (tDCS) over the cerebellum and spinal cord (trans-spinal stimulation) has led to improvements in upper limb coordination, gait ataxia severity, motor scores (including balance), cognitive abilities, and quality of life in individuals with degenerative ataxias, including SCA. However, it is not yet known whether all patients with SCA demonstrate significant improvement with this intervention. Moreover, if there is no improvement, it remains unclear whether specific characteristics of individuals with SCA, such as balance, gait, mobility, ataxia severity, DNA test results, and non-ataxic signs, can be identified to predict their response to tDCS sessions. Additionally, tDCS studies in individuals with SCA typically involve 5 to 10 stimulation sessions without associating stimulation with exercises of progressive difficulty. One of the main benefits of using tDCS is the

plastic modulation of the nervous system. Therefore, the lack of challenges concomitant with the use of tDCS limits its results.

2. Aim

The main goal of this pragmatic clinical trial is to investigate the effects of trans-spinal tDCS in individuals with SCA over some parameters of gait and postural control in real-world conditions, reflecting daily clinical practice. The specific aims of this study are: (i) Determine whether particular characteristics of individuals with SCA (including balance, gait, mobility, severity of ataxia, DNA test characteristics and non-ataxic signs) can be identified to predict their improvement in balance and gait following tDCS sessions; (ii) to investigate if an extended number of tDCS sessions, beyond the typical 5 to 10 sessions described in scientific literature, applied concomitantly with exercises with progressive challenges, to yield positive outcomes over some parameters of gait and postural control in individuals with SCA; (iii) To investigate, through semi-structured interviews, the subjective experience of the participants regarding the use of trans-spinal tDCS, about changes in health and quality of life, as well as the expectations that were achieved or frustrated with the intervention used; (iv) To investigate if there is retention of benefits a month after the end of the intervention; (v) propose a specific test to detect postural control deficits during head and limb movement; and (vi) analyze whether the specific characteristics evaluated in individuals correlate with each other.

3. Design and Methods

This is a pragmatic clinical trial that will be carried out using the CONSORT-Pragmatic Trials. The present study will be carried out at the Deolindo Couto Institute of Neurology, at the Federal University of Rio de Janeiro - UFRJ (Avenida Venceslau Brás, 95 - Botafogo, Rio de Janeiro - RJ). Individuals with spinocerebellar ataxia of any type, who are part of the records of public hospitals, doctors' offices, and physiotherapists, will be invited to participate in the study.

Initially, individuals will be interviewed to research the eligibility criteria, by filling out an anamnesis form, which will also contain questions about their

demographic data. Those who are eligible and agree to participate must express their consent by signing an informed consent form.

Up to 45 patients with SCA of different types will undergo a non-invasive stimulation plus gait and postural control training. The total duration of sessions will last 30 minutes during which participants will simultaneously receive 20 min of trans-spinal tDCS and perform a gait training protocol with progressively greater difficulties, previously tested in patients with SCA. The trans-spinal tDCS will be applied at an intensity of 2mA, with the anodic electrode positioned over the cerebellar region and the cathodic electrode over the thoracic region of the spinal cord (approximately vertebra T11). The intervention will be applied over four consecutive weeks on weekdays except weekends, totaling 20 sessions.

All participants will receive real stimulation, so there will be no control group. Given that it may be difficult to recruit additional SCA individuals willing to participate in a control group or to find patients with similar characteristics who do not receive treatment during the study period, also due to the progressively debilitating condition of the participants (SCA) and given their socio-economic conditions that limit their transportation, it would be ethically questionable to deprive a group of patients of receiving a potentially beneficial treatment, especially when there is no established standard therapy or other effective treatment options available to them.

The equipment to be used for stimulation will be an NKL Stimulator. The continuous current offered will be supplied through a pair of 5x7 cm (35 cm2) electrodes wrapped in sponges moistened with saline solution. The anode electrode will be positioned over the cerebellar region. To do this, the inion region will be located. Using a measuring tape, the point 2cm above the inion will be identified and the electrode will be fixed to the scalp, using appropriate adjustable bands. The cathode electrode will be positioned over the spinal region, more precisely, at the level of T8. To precisely find this position, the thoracic spinous processes will be palpated, and the 11th process located. Using a measuring tape, identify the point located 2 cm below T11 and fix the electrode with adhesive tape at this point. The stimulation intensity will be 2mA.

Initially, participants will be evaluated (ASSESSMENT 1) through the application of the SARA scale; modified dynamic gait index (mDGI); The Berg Balance Scale; Timed up and go (TUG); Inventory of non-ataxic signs (INAS);

The four-stage test; Ten-meter walk test with an accelerometer; and perform other three tasks using an accelerometer of a mobile phone: (i) 5 times sit-to-stand; (ii) Functional Reach Test; and (iii) a test consisted in move arms and head standing with foot together. Three physiotherapist experts in these evaluations who will not participate in the intervention sessions will conduct this part. Then, 20 successive tDCS sessions will be applied to the participants. Every 5 tDCS sessions, the mDGI and TUG assessment will be reassessed (ASSESSMENT 2, 3, and 4). At the end of the 20 sessions, all instruments will be reapplied except for INAS (ASSESSMENT 5). A month after the end of the intervention the individuals will be reassessed except for the tests using the accelerometer (ASSESSMENT 6).

Before and after each session, individuals will be evaluated using the one-leg stand test proposed in the miniBestest instrument. In this test, the individual must remain standing, with their eyes open and fixed on a point 1.6 to 3m away with their hands on their waist. The participant must remove a lower limb from the support, without assistance, flexing it backward and remaining there. The time spent in the position will be measured in seconds, from the moment the evaluator says "now" until the elevated foot touches the ground again, or the upper limbs move from the initial position. The test will be repeated twice for each lower limb. Both times will be noted, and the highest time will be considered.

At the end of 20 sessions, individuals who complete the intervention will be also interviewed with a semi-structurally questionary by a researcher who did not take part in the study. The method that will be used to analyze the interviews will be the framework approach, which consists of a deductive form of analysis that starts from pre-defined research objectives. The framework approach is a systematic method that allows for in-depth analysis, in which the researcher extracts codes from the interviewees' statements, forms categories, and finally acquires refined themes useful for describing the participants' ideas and perceptions. All interviews will be conducted face-to-face. The interviews will be recorded for future transcription, using a smartphone. Once the interviews have been transcribed, the content will be analyzed using ATLAS.ti® software, and, finally, the themes that most faithfully represent the concepts found in the interviews will be chosen.

Inclusion Criteria:

1. Individuals aged 18 to 70, without distinction of gender or ethnicity;
2. Diagnosed with spinocerebellar ataxia, of any type, by a neurologist;
3. With mild to moderate ataxia severity;
4. Able to walk 2 meters even when using a walker, cane or crutch;
5. Score ≥21 (BERTOLUCCI et al., 1994) on the Mini-Mental State Examination (MMSE; FOLSTEINet al., 1975; ALMEIDA, 1998);
6. No other concomitant neurological changes.

Exclusion Criteria:

1. Illiterate;
2. Being subjected to any other experimental physiotherapeutic or medicinal intervention during the clinical trial;
3. Skin condition that may affect the electrode placement site
4. Musculoskeletal, neurological or cardiorespiratory disorders that prevent the tests from being carried out;
5. Epilepsy;
6. Pregnancy;
7. History of brain surgery;
8. History of seizures;
9. Metallic implants in the skull that interfere with neuromodulation;

Outcome Measures

Primary Outcome Measure:

1.Postural control

The Berg Balance Scale (BBS) measures functional balance and fall risk in 14 tasks. Each item is given a score of 0-4, with a total score between 0 and 56, being the higher the score, the better the individual's performance. The Berg scale also predicts the risk of falls. A score equal to or less than 45 points indicates a greater risk of falls.

The four-stage test (4-stage) assesses static balance and measures an individual's ability to hold a series of four balance positions, each more challenging than the previous, for at least 10 seconds each.

[Time Frame: (i) Baseline, (ii) after 20 sessions and (iii) in follow up (one month).]

2.Mobility

Timed up and go (TUG) assesses mobility, balance, walking ability and the risk of falling. On the command "go", the patient gets up from the chair, walks 3 meters, turns around, returns to the chair, and sits down. The time is calculated in seconds. The longer the time taken, the greater the risk of falling

[Time Frame: (ii) Baseline, (ii) at the end of sessions 5, 10, 15 and 20 (each session is 1 day) and (iii) in follow up (one month)]

3.Gait performance

Measured by the Modified Dynamic Gait Index (mDGI) which total score is from 0 (severe gait impairment) to 64 (no gait impairment) and a Ten-meter walk test with an accelerometer fixed at the sacrum to assess step and stride time, speed, and gait cadence.

[Time Frame: (ii) Baseline, (ii) at the end of sessions 5, 10, 15 and 20 (each session is 1 day) and (iii) in follow up (one month)]

4.Accelerometry

To perform three tasks using an accelerometer of a mobile phone fixed on the participant's waist: (i) 5 times sit-to-stand; (ii) Functional Reach Test; and (iii) a test consisted in move arms and head standing with foot together. The accelerometer will register how the body is moving and changing speed over time while performing tasks.

[Time Frame: (i) Baseline and (ii) after 20 sessions.]

Secondary Outcome Measures:

The subjective experience of the participants regarding the protocol.

Semi-structured interview regarding subjective experience of the participants relative to the study intervention

[Time Frame: At the end of session 20 (each session is 1 day)]

The presence of non ataxic signals (INAS) and the disease severity (SARA)

INAS is an inventary to detect the presence or absence of 16 non-ataxic signs and symptoms through a clinical physical examination. SARA is an instrument to

evaluate the disease severity through eight tasks including gait, balance, speech and coordination that produce a total score of 0 (no signs of ataxia) and 40 (more severe ataxia).

[Time Frame: (i) Baseline and (ii) after 20 sessions.]

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INFORMED CONSENT FORM

Developed based on Resolution No. 466 of December 10, 2012, by the National Health Council

You are being invited to participate in the research " TRANS-SPINAL ELECTRICAL STIMULATION IN INDIVIDUALS WITH SPINOCEREBELLAR ATAXIA."

Transcranial Direct Current Stimulation (tDCS) is a technique that involves the use of a gentle electric current, generated by a small device. This current is applied to a specific part of the brain. This is done by placing electrodes, which are like small electric cables, on the scalp. The low-intensity electric current is sent from the device to the brain through the electrodes. This electric current can affect brain activity and, in some cases, may help improve certain symptoms or abilities, such as balance and gait. Thus, the objectives of this study are to investigate: (i) if there are specific characteristics (including balance, gait, mobility, severity of ataxia, characteristics of the DNA test, and non-ataxic signs) in individuals with SCA that may predict their improvement in balance and gait after 20 sessions of tDCS; (ii) if a greater number of tDCS sessions, beyond the typical 5 to 10 sessions described in the literature, continue to produce positive results in terms of balance and gait performance in individuals with SCA; (iii) through semi-structured interviews, the subjective experience of participants regarding the use of tDCS, in relation to changes in health and quality of life, as well as the expectations that were achieved or frustrated with the intervention used; (iv) if there is retention of benefits one month after the end of the intervention; (v) to propose a specific test to detect deficits in postural control during head and limb movement; and (vi) to analyze if the specific characteristics evaluated in individuals correlate with each other. This study is the responsibility of the researcher ANNA FONTES BAPTISTA, who can be contacted by phone at (21) 98270-7759.

Procedures: To participate, initially, some questions will be asked about you and your health. This information will help us determine if you can participate in this research. Then, if you have the desired profile and agree to participate, we will ask you to sign this form, called IC form, to confirm your participation. Then, an experienced physiotherapist will conduct an initial assessment through five tests (ASSESSMENT 1): the Scale for the Assessment and Rating of Ataxia (SARA), the modified Dynamic Gait Index (mDGI), the Timed up and go (TUG), the Berg Balance Scale (BBS), and the Inventory of Non-Ataxic Signs (INAS). These tests will help measure your overall status and track changes throughout the study. The SARA Scale evaluates ataxia in eight categories, such as gait, posture, speech, and hand movements, determining the severity of ataxia. The mDGI evaluates the ability to adapt to different demands during gait in eight different tasks, such as walking at different speeds, turning the body, and climbing stairs, which indicate the degree of difficulty in gait.

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The BBS assesses balance, and the TUG evaluates your mobility when getting up from a chair, walking 3 meters, returning, and sitting down again. Finally, the INAS assesses signs and symptoms not related to cerebellar ataxia. In addition to these assessments, you will perform 4 tasks using an accelerometer from a cell phone attached to your waist by an elastic support. An accelerometer is a device that measures movement acceleration. The tasks will be to walk 10 meters at the fastest speed possible without running (TC10m); sit and stand up five times as quickly as possible while the time spent on the task is timed (5TSTS); reach forward with your feet standing in the same place (TAF) while the distance you can reach is measured; and finally, perform a test that involves moving your arms and head while standing with your feet together, trying to maintain balance. When attached to your waist, the accelerometer will record how your body moves and changes speed over time during the tasks. This information captured by the accelerometer is useful for better understanding how you move and behave during different activities. After the assessments, daily sessions will be conducted (from Monday to Friday, always at the same time, to be arranged) of 20 minutes of tDCS application with an intensity of 2mA, combined with gait and balance exercises. During treatment, we will use a device called NKL Stimulator. The device provides a continuous current through two electrodes positioned in specific areas of the body. The placement of tDCS electrodes in this study will be on the back and head. This positioning has already been proven beneficial for the gait and balance of people with cerebellar ataxia. The placement of the electrodes will be based on individual measurements of head size. Before and after each session, individuals will be assessed using the one-legged support test proposed in the miniBestest instrument. In this test, the individual must stand with eyes open and fixed on a point 1.6 to 3m away, with hands on the waist. The participant must remove one lower limb from support, unaided, flexing it backward and remaining there. The time spent in the position will be measured in seconds, from the moment the evaluator says "now" until the raised foot touches the ground again, or the upper limbs move from the initial position. The test will be repeated twice for each lower limb. Both times will be recorded, considering the longest time. A total of 20 sessions will be conducted. After every 5 sessions of tDCS, the evaluation of mDGI and TUG will be repeated (ASSESSMENT 2, 3, and 4). At the end of the 20 sessions, all instruments will be reapplied, except for the INAS (ASSESSMENT 5). One month after the end of the intervention, individuals will be reassessed using the same instruments, except for the INAS and accelerometer tests (ASSESSMENT 6). At the end of the 20 sessions, individuals who complete the intervention will be interviewed with a questionnaire about what you thought of the treatment.

Potential risks, discomforts, and benefits: There may be effects such as itching or local redness that will disappear quickly, without any other major risk to the participant. To avoid such problems, the equipment to be used has an operating mode that prevents these discomforts. The expected benefits will be the improvement of gait and balance.

Guarantee of confidentiality, privacy, anonymity, and access: Your privacy will be respected, meaning your name or any other data or element that could in any way identify you will be kept confidential. Anonymity and privacy will be guaranteed. If interested, you will have access to the results.

Clarification guarantee: Assistance will be provided throughout the research, as well as the guarantee of your free access to all information and additional clarifications about the study and its consequences.
Responsibility and disclosure guarantee: The results of the examinations and research data will be the responsibility of the researcher, and these results will be disclosed in the scientific community without mentioning any form that may identify your name.
Researcher and institution responsibility: The researcher ANNA FONTES BAPTISTA, who can be contacted by phone at (21) 98270-7759 and the proposing institution (UNISUAM) will be responsible for any personal or moral damage related to the physical and ethical integrity that the research may entail. UNISUAM CEP (No. 5325): Rua Dona Isabel 94, Bonsucesso, Rio de Janeiro, RJ, CEP 21032-060 Institutional phone and email: (021) 3882-9797 ext. 9943, comitedeetica@souunisuam.com.br
Expense reimbursement guarantee: You will not have personal expenses at any stage of the study, nor financial compensation related to your participation. In case of personal damage directly caused by the procedures proposed in this study, you will be referred to the SUS and for medical treatment.
Criteria for suspending or terminating the research: The study will be suspended in the event of any methodological or technical failure observed by the researcher, who will be responsible for informing all participants of the reason for the suspension. The study will also be suspended if any risk or harm to the health of the participating subjects, resulting from the research, is perceived, which was not foreseen in this document. When the expected number of participants is reached, data collection will be terminated.
Infrastructure demonstration: The institution where the study will be conducted has the necessary infrastructure for the development of the research with an adequate environment.
Property of generated information: There is no restrictive clause for the disclosure of research results, and the collected data will be used solely for the purpose of proving the experiment. The results will be submitted for publication, whether favorable or not to the study hypotheses.
About refusing to participate: If you wish, you may refuse to participate in the study, or withdraw your consent at any time, without needing to justify yourself, without suffering any prejudice to the assistance you receive.
Contact of the responsible researcher and the ethics committee: At any stage of the study, you may have access to the responsible professional, ANNA FONTES BAPTISTA, who can be contacted by phone at (21) 98270-7759. If you have any considerations or doubts about the ethics of the research, you can contact the Research Ethics Committee. Rua Dona Isabel 94, Bonsucesso, Rio de Janeiro, RJ, CEP 21032-060 Institutional phone and email: (021) 3882-9797 ext. 9943, comitedeetica@souunisuam.com.br
The responsible researcher guarantees: compliance with the requirements of Resolution No. 466/2012; that the results of the research data will be their responsibility; that the data will be used exclusively for scientific purposes; and that the data will be submitted for publication.
If this form is clear enough to provide you with all the information about the study and if you understand its purposes, the procedures to be performed, its discomforts and risks, and the guarantees of confidentiality and permanent

clarification. You may declare your free consent to participate, being fully aware of the study proposals. We guarantee that you will receive a copy of this form.

Important guidelines:

- Try not to miss any session so that the benefits are achieved.
- During treatment, do not consume alcoholic beverages, nor coffee or drugs.
- Do not come to treatment with wet hair, or with leave-in conditioner or gel, as this interferes with the passage of electric current.
- It is important to notify if there is a change in any medication during the process.
- Try to tell us how your day was after the stimulations.

Date: _____ / _____ /_____

Participant NAME:_____
Signature:_____

Responsible researcher: ANNA FONTES BAPTISTA
Signature:_____