Translation from the original document in Brazilian Portuguese

Participant Information Sheet

Research study: REAC NEUROBIOLOGICAL MODULATION IN POST TRAUMATIC INJURIES

I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

Who we are and what this study is about:

We are researchers of the Center of Adaptive Neuro Psycho Physiopathology and Neurobiological Optimization with REAC Technology, at Amapa University, in cooperation with Rinaldi Fontani Institute and Foundation in Florence Italy.

Why we are doing this study:

There is scientific evidence that neuropsychic components are the basis of origin, or are conditioning factors in the evolution of pathological or symptomatic conditions in the field of orthopedic, traumatological and sports medicine. The aim of this study is based on the consideration that physical traumas can lead to unconscious neuropsychical alterations which can compromise the rehabilitation result and complete functional recovery.

In this study, we intend to verify if specific neurobiological treatments with Radio Electric Asymmetric Conveyer (REAC) named Neuro Postural Optimization (NPO) and Tissue Optimization (TO) can induce effects on recovery process in post trauma/accident injuries.

What will taking part involve?

Participation in this clinical evaluation implies that you commit yourself, not to spontaneously carry out other treatments (including analgesic and physical treatments), without having first consulted the researchers, who will decide if you can continue the study. Specific clinical evaluations and self-assessment tests will be made before to start the treatments, after the end of the treatments and 30 days after the last treatment session. In order to receive the treatments proposed in this study, you will have to be available to go to the study facility, five days a week, in the morning and/or in the afternoon for 2 consecutive weeks, and be available to participate in the follow up visit, 30 days after the last treatment.

In the first session, you will receive a first REAC neuromodulation treatment, named Neuro Postural Optimization (NPO) that consists of a noninvasive and painless single treatment of 250 milliseconds administered on a specific area of the auricle pavilion. In the following sessions, you will receive a second REAC neuromodulation treatment, named Tissue Optimization (TO) which is administered by applying the REAC device probe (ACP) on your injured knee. The ACP is held in place by a tubular elastic bandage. Each TO treatment requires about 15 minutes. You will receive up to four TO treatments per day, with an interval of at least one hour from each other, for a total of 18 sessions.

Why have you been invited to take part?

You are invited to be part of this study because you have reported a very recent injury to the medial collateral ligament of the knee and you have the proper characteristics to be included in this study.

Do you have to take part?

Participation is completely voluntary and you have the right to refuse participation, refuse any question and withdraw at any time without any consequence whatsoever.

What are the possible risks and benefits of taking part?

Until now, REAC treatments have not shown any risk, or adverse side effects. If any physical or psychological harm should arise, you will have to contact immediately the study supervisor who will assess the situation and decide if you can continue to participate in the study. The treatments will be carried out using medical devices approved by ANVISA (BENE 110, ASMED, Florence, Italy). The possible benefits of the treatments might be reduction of pain and shortening of healing time for lesions as yours (second and third degree post-traumatic lesions of the medial collateral ligament of the knee).

Will taking part be confidential?

To guarantee confidentiality and anonymity of the participants, the data collected in this study will be only the initials of the name and surname, the gender and age and the degree of severity of the injury. These data can be reported as supplemental material to support scientific publications. Non-anonymized data in the form of signed consent forms are collected and retained as part of the research process.

How will information you provide be recorded, stored and protected?

Anonymized and non-anonymized information collected in this study will be preserved for a period of 5 years by the researcher in charge of the study according to the Resolution No. 466, December 12, 2012 of the Brazilian Ministry of Health - National Health Council. Data obtained from research participants may not be used for purposes other than those provided for in the protocol and / or informed consent.

What will happen to the results of the study?

The results of the study might be disseminated through scientific publications, conferences and congresses, seminars and courses.

Funding and conflict of interest

This study does not require any funding. It will be conducted in cooperation with Rinaldi Fontani Institute & Foundation, which will provide the medical devices. There is potential Competing Interest as Rinaldi and Fontani are the inventors of REAC technology. They are also the founders of the company that manufactures REAC technology. The other researchers report no conflicts of interest in this study.

Who should you contact for further information?

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