Webinar title: What it Takes to be a Clinical Trial Participant

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Neurotech Reports
The Institute for Functional Restoration has the mission to restore function to people with neurologic disorders by creating a sustainable commercial model for neuromodulation technologies. Founded in 2013, the IFR is a non-profit based at Case Western Reserve University (Cleveland, OH).
The mission of NASCIC is to bring about unified achievements in research, care, cure, and policy by supporting collaborative efforts across the spinal cord injury community.

To achieve this mission, NASCIC will identify gaps, communicate resources, and be a conduit for collaboration between the community of people living with SCI and the many stakeholders.
DISCLAIMERS

The information presented in this webinar is not meant to replace the advice from a medical professional. You should consult a health care professional familiar with your specific case, concerns and condition.

Neurotech Network and its representatives do not endorse, rate, sell, distribute, prescribe, administer or recommend any products, procedures or services. We highly suggest for you to take information to a trained medical professional familiar with your case to discuss options that are best for you.
TODAY’S AGENDA

• Basics about Clinical Trials
• How to Find Clinical Trials
  • Introducing SCITrials.org
• Be Informed
**WHAT IS A CLINICAL TRIAL?**

**Clinical Research**

Research with human subjects that is:

1. Patient-oriented research, which includes:
   - (a) mechanisms of human disease,
   - (b) therapeutic interventions,
   - (c) clinical trials, or
   - (d) development of new technologies.

2. Epidemiologic and behavioral studies.

3. Outcomes research and health services research.

**Clinical Trial**

- A prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).

- Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective.

- Long-term goal is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care.

- The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy.
How is it different from treatment?

- **Clinical Study**
  - Specific goal
  - Strict Protocol

- **Usual Health Care**
  - Care or monitor of condition
  - Flexible for treatment
Take our Poll
Have you ever participating in a clinical trial?
1. Reason for conducting the study
2. Who may participate in the study (eligibility criteria)
3. Number of participants needed
4. Schedule of tests, procedures, or drugs and dosages
5. Length of the study
6. What information will be gathered about the participants
BASICS: CLINICAL STUDY PARTICIPANT

ELIGIBILITY CRITERIA

Inclusion

Exclusion

Eligible

Expanded Access
The majority of academic research is in the “Pre-Discovery” and “Discovery” phases.
“My girlfriend read an article in the paper.”

“I was on a routine visit to my doctor.”

“It was my girlfriend who learned about the project. She persisted until she found the right connections.”
CONNECTING SCIENTISTS & THE SCI COMMUNITY

- FIND SCI TRIALS
- EASY TO READ LANGUAGE
- GET UPDATES ON NEW TRIALS
- APPLY ONLINE
- CUSTOMIZE YOUR PREFERENCES

WWW.SCITRIALS.ORG
SEARCHING FOR TRIALS

CLOSED-LOOP DEEP BRAIN STIMULATION FOR REFRACTORY CHRONIC PAIN

The trial is to study a new form of deep brain stimulation (DBS) to relieve chronic pain. It will use personalised targeting of brain regions using the Medtronic Summit RC+S device.

INFLUENCE OF WEARABLE INTENSIVE NERVE STIMULATION ON SPASTICITY AND FUNCTION IN PERSONS WITH SPINAL CORD INJURY

This study aims to identify if wearable intensive nerve stimulation decreases spasticity in the legs of people with SCI, and if this intervention is usable and desirable to individuals with SCI.
FILTER BASED ON YOUR INTEREST

**Treatments**
- Acupuncture
- Brain Machine Interface (BMI)
- Brain Stimulation
- Devices
- Drugs
- Electrical Stimulation
- Epidural Stimulation
- Exoskeleton
- Functional Electrical Stimulation (FES)
- Intermittent Hypoxia
- Neuromuscular Electrical Stimulation (NMES)
- Nutrition
- Observational
- Rehabilitation
- Safety
- Stem Cells
- Surgical Procedure
- Transcranial Direct Current Stimulation (tDCS)
- Transcranial Magnetic Stimulation (TMS)
- Transcutaneous Stimulation

**Outcomes**
- Arm Movement
- Bladder Function
- Blood Pressure
- Bone Strength
- Bowel Function
- Breathing Function
- Hand Movement
- Leg Movement
- Motor Function
- Mental Health
- Neuroprotection
- Pain Management
- Plasticity
- Pressure Sores
- Quality of Life
- Regeneration
- Sensory Function
- Sexual Function
- Spasticity
- Temperature Control
- Trunk Control
- Walking Function
EASY TO READ OVERVIEW

EFFECTS OF HYDROTHERAPY ON NEUROPATHIC PAIN AND PAIN CATASTROPHIZATION IN SPINAL CORD INJURY

What's the trial about?
The trial is to see if hydrotherapy has benefits on neuropathic pain.

Who can take part?

Injury Details

- **Injury Levels**
  - C4-S5

- **AIS Grade**
  - A, B, C, D

- **Time since injury**
  - Sub-Acute, Acute, Chronic

- **Gender**
  - All

- **Age**
  - From 18 Years

The full details are provided on the Trial Details page.

What will be required for the trial?

Sessions will be done by 3 physical therapists specialized in hydrotherapy under different modalities, and a pool equipped to perform this type of intervention. The most commonly used techniques in the institution are Bad Ragaz, for motor control, and the Watsu technique for relaxation and spasticity work.

The full details are provided on the Trial Details page.
CREATE YOUR INJURY PROFILE

Spinal Cord Injury Trials
Connecting Scientists & the SCI community

YOUR INJURY PROFILE

Used to Find Trials
Receive Relevant Updates
Used When Applying
Lessons Learned

BEWARE

Of “trials” that are unapproved, even if a US doctor is doing the study does not mean it is legitimate!

DO YOUR RESEARCH

Get a second or third opinion from a research center or hospital that specializes in current SCI

NEVER

Never pay for experimental treatments.

KNOW

Your rights, the risks, your commitments, and your informed consent

MANAGE

Your expectations and your own health
RISK-BENEFIT
• Increased and long-lasting pain and/or muscle spasticity
• Further loss of function
• Increased disability
• Medical complications or death
• Loss of health care coverage should complications occur after unapproved treatment
• Exclusion from future SCI clinical trials
• A form of medical travel to purchase unproven therapies (ex. Stem cells; epidural stimulation). These unproven treatments hold significant risk for people.

• There is no evidence yet that stem cells or epidural stimulation have a reparative effect or who they reliably work in.

• It is unethical to charge people money for unproven, risk-laden medical interventions.

• Be aware of selling Hope for Money

• No Oversight/Reporting
Experimental treatments for spinal cord injury: What you should know (Version 2)

A guide for people living with spinal cord injury, their family, friends and health care professionals

https://www.themiamiproject.org/research/research-participation/experimental-treatments/
Anyone interested in participating in a clinical study should know as much as possible about the study and feel comfortable asking the research team questions about the study, the related procedures, and any expenses.

What is being studied?

Why do researchers believe the intervention being tested is effective?

How do the possible risks, side effects, and benefits of this trial compare with those of my current treatment?

What are my out of pocket costs?

How will it be determined which intervention is effective?
APPENDIX B: What to ask before taking part in a clinical trial or human study? (Your participation checklist)

Note: most of these questions should be answered during the informed consent process.

<table>
<thead>
<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
<th>Additional Information</th>
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<tbody>
<tr>
<td><strong>1. Safety</strong></td>
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<tr>
<td>a. Are there safety risks associated with this experimental treatment?</td>
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<td>b. Could my condition or my health get worse after this experimental treatment?</td>
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<td>c. If so, can you describe the possible risks associated with this experimental treatment?</td>
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<td><strong>2. Possible benefits</strong></td>
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<td>a. Can you describe the possible specific benefits of this experimental treatment?</td>
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<td>b. Can you describe the maximum level of recovery I might see after this treatment?</td>
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<td>c. Can you describe how any potential benefit will be measured?</td>
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<td><strong>3. Clinical trial protocol</strong></td>
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<td>a. Is this study registered as a clinical trial with an appropriate qualified regulatory body?</td>
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<td>b. Can you describe what clinical trial phase this particular human study falls within (Phase 1, 2, or 3) and what is the emphasis of study for this phase of the trial program?</td>
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<td>c. Is there a control group in this study?</td>
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<td>d. Could I be randomly assigned to the control group?</td>
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<td>e. Can you tell me how long I will be assessed for any change in outcome?</td>
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<td>f. Will I be blinded to whether I have received the experimental or control treatment?</td>
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<td>g. Will the investigators and examiners be blind to what treatment I have received?</td>
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<tr>
<td>Question</td>
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<td>Additional Information</td>
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<td>4. Payments and costs</td>
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<td>a. Do I have to pay for this treatment?</td>
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<td>b. As a possible participant, are there other costs I have to pay to be involved in this study?</td>
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<td>c. Will my expenses associated with participating in this study be paid (e.g. travel to center for follow-up assessment)?</td>
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<td>5. Participation in Other Trials</td>
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<td>a. Will my participation in this clinical trial limit my participation in other SCI clinical trials?</td>
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<td>b. If I am assigned to the control group and the experimental treatment is subsequently shown to be an effective therapy for my type of SCI by this clinical trial program, will I be eligible to receive this treatment later?</td>
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<td>6. Preclinical or prior clinical evidence</td>
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<td>a. Can you describe the preclinical or prior clinical evidence that indicates this experimental treatment might be beneficial?</td>
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<td>b. Have these findings been independently confirmed by other researchers?</td>
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<td>c. Are there any dissenting opinions and do these arguments have some validity for not going forward with this treatment?</td>
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<td>7. Independent assessment of the treatment and investigator</td>
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<td>a. Can you provide me several names of scientists and clinicians (not involved with this study) who can provide me independent advice about this treatment and your reputation?</td>
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