Reviewer's report

Title: Electrical Stimulation for Chronic Non-specific Low Back Pain in a Working-Age Population: A 12-Week Double Blinded Randomized Controlled Trial

Version: 1 Date: 17 November 2012

Reviewer: Yocheved Laufer

Reviewer’s report:

Overall, the study design is appropriate for determining the study's objective. However several issues must be further clarified in order to enable replication of the work by others or comparison with other studies. It seems the authors stressed in this report the methods for randomization, blindness and statistical analysis, while not providing sufficient details allowing the replication of the intervention and assessments.

Major compulsory revisions;

1. Intervention time not clear. While it is clear from the manuscript that assessment will be conducted at enrollment and at week 1, 4, 8 and 12, it is not clear what the treatment period is?
2. Page 6. In general the entire section on outcome measures is not clear and not sufficiently specific. (page 6-7)
   a. VAS score will refer to what period (day of assessment? overall period between assessments? etc.)
   b. It is stated that physical activity levels will be measured with accelerometers. When and for what period? Is it throughout the entire treatment period, a few hours, days before assessment time?
   c. How is strength measured? Some details are provided on page 7, but these are not specific enough. For example what is meant by pushing and pulling strength test?
   d. What is meant by the term "up to maximum baseline pain level"
   e. How is "duration of time standing comfortably" measured? They will stand quietly until uncomfortable?
   f. What walking endurance test is used? What is meant by duration and distance walking comfortably mean? Again they will walk until uncomfortable.
   g. More detail is necessary for describing the "standardized protocol on a BTE system" at least what functions are assessed.
   h. The description does not seem consistent. Will all these tests be performed twice at each visit as implied by the sentence "assessments will be measured pre and post treatment at these visits? This does not seem quite feasible!
   i. On page 7, it is stated that all measures will be assessed electronically or
administered electronically. I assume that what is meant is using electronic equipment? How can these then be measured on week 8 on the phone?

k. Details on validity and reliability of at least the major outcomes should be provided

3. Page 8. What are the stimulation parameters used with the H-Wave, the pulse duration? and pulse frequency? What is meant by "patients will be required to reach near maximal intensity on low frequency" Is it maximally tolerated intensity, or maximal intensity offered by the device? Will the maximal intensity induce only sensory stimulation, or muscle contractions and painful stimulation as well?

4. Page 8. More details are required to describe the TENS stimulation as well. How many channels/electrodes will be used. Where will they be placed. What is the pulse duration and waveform? Will subjects be encouraged to increase intensity to level of sensory, motor or painful stimulation?

Minor Essential Revisions

Abstract
Abstract should include more details as to intervention – intervention parameters, number of visits and contact time

Introduction
1. Unique characteristics of the H-Wave device not well described (what pulse duration or frequency).
2. The rational for this comparison is not well substantiated. Unique characteristics of the H-Wave device noted are related primarily to changes in circulation and lymphatic system. How are changes in these systems expected to affect chronic pain syndrome
3. More references should be included to substantiate various claims made both regarding the effect of TENS and H-Wave.

Methods and Materials
Regarding use of pacemakers etc..It is stated that "patients will be dissuaded from using these devices if not actively using at the time of enrollment" – can't dissuade an individual from using a pacemaker if he needs one. Treatment should be terminated

Discretionary Revisionnnns

Why used both the Oswestry Index and the Roland Morris Instrument? Both are self reported questionnaires regarding function, measuring pretty much the same thing.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being
published

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I declare that I have no competing interests