Consensus agreement on the design and conduct of clinical studies with low level laser therapy and light therapy for musculoskeletal pain and disorders.

Approved by the World Association of Laser Therapy at the 5th World Congress, in Guaruja, Brazil, November 27th 2004.

Definition.
Low level laser therapy (LLLT) in musculoskeletal disorders refers to monochromatic light therapy with lasers which have a mean optical output of larger than 1 mW, i.e. lasers in classes III and IIIa. A similar definition applies for light therapy with light emitting diodes (LEDT) when the mean optical output is larger than 1 mW. Trial reports should make explicit whether LLLT or LEDT is being used.

1.
In general, clinical trials with low level laser therapy (LLLT) should have a **control group** where patients receive placebo-LLLT or another reference treatment, and include procedures for **randomization** and **patient-blinding**,

2.
The reporting of a trial should be presented according to the **CONSORT guidelines** from The Lancet (http://www.consort-statement.org).

3.
Several leading journals require, or will in the near future require, that the trial is **registered** in a public trials register, **prior** to the start of the trial to ensure that not only positive results are being published. Several registers exist, and one such register can be found at http://www.controlled-trials.com

4.
In particular, item 4 in the CONSORT guidelines, calls for a **specific description of the intervention**. A specific description of LLLT should include the number of treatment session and the frequency of sessions per week, and the following parameters from one treatment session mandatory [1, 2]:

Application procedure:

1) Stationary in skin contact
or
2) Stationary with distance from skin described
or
3) Scanning mode

Wavelength reported in nanometers

Average output of the laser reported in milliWatts (mW)

Treatment time in seconds

Energy Dose delivered reported in Joules (reporting in J/cm^2 should be confined to studies with small animals and cell cultures)

In addition, the following parameters should be reported

spot size on the skin in square cm (cm^2),
and
power density in mW/ cm^2

Accumulated energy delivered from all sessions in Joules

5.
Testing of optical output should be performed regularly and at least before, and after the end the trial.
6.
Co-intervention with steroids should be avoided as steroids block the effect of LLLT [3].

7.
The review should explicitly state which **possible biological action(s**) of LLLT that are intended.
The site of laser exposure should be clearly stated and include either:

a) **the site of pathology** (tendon, joint capsule, cartilage, ligament, muscle, bone, wound, etc)
b) **the nerve supplying the painful and/or paralysed area**
c) **the acupuncture or trigger points**
d) **or other sufficiently described locations**

WALT musculoskeletal advisory board has acknowledged that optimal doses exist for several musculoskeletal when treatment administered to the site of the pathology, complaints [1, 4]. Scientific evidence is graded at two levels, optimal dose and likely optimal dose, and a list diagnoses is available at WALT website. These parameters are based on imaging studies that provide data for estimation of energy loss and statistical testing that has verified that these parameters are significantly more effective than other parameters. Using dosage outside the optimal parameters in trials, requires a detailed hypothesis and rationale for the treatment parameters used in the trial report. Authors should be aware that trials with non-optimal doses according to WALT standards should not be included or subgrouped as non-optimal dosage in systematic reviews and meta-analyses of LLLT.

8.
Outcomes should be selected from current **valid and reliable** measures as recommended by organisations like the American College of Rheumatology, European League Against Rheumatism. Preferably outcomes of **pain, physical function and quality of life** should be provided if the material allows for this. Outcome measures should be quantified either by continuous scales or categorical scales of at least 5 categories. Examples of valid pain measures are pain at rest, pain during physical activities or pain at palpation measured by a pressure algometer [5]. Examples of physical function are painfree muscle strength[5], maximal walking distance in 6 minutes, and the Back Performance Scale[6]. Examples of health-related measures of quality of life is Short-Form 36. For systemic inflammatory conditions, measures of disease activity should be included. Other valid outcome measure instruments are Western Ontario and McMasters Universities Osteoarthritis Index (WOMAC)[7], Visual Analogue Scale (VAS) for pain, Arthritis Impact Measurement Scale 2

(AIMS2), AUSCAN for hand osteoarthritis, Shoulder Pain and Disability Index (SPADI)[8], Roland Morris disability index or Oswestry Pain and Disability index.

9.
Statistical analysis of results should preferably be made according to current standards as used by either European League Against Rheumatism (EULAR), Cochrane Collaboration, or British Medical Journal. As such, the reporting of means for pre-treatment and post-treatment outcomes and the mean difference in change between groups and their respective variance data and parametric tests of p-values for significance, is expected for normally distributed data. For outcome data that are not normally distributed, medians and quartile should be used together with non-parametric tests.

10.
This Consensus agreement is valid until further notice. Updates on optimal treatment will be continuously considered and subject to alteration if the WALT musculoskeletal advisory board finds it necessary. Such updates will be made available on the WALT website www.walt.nu.

References

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