

## Standard for the design and conduct of systematic reviews with low level laser therapy for musculoskeletal pain and disorders.

Approved by the World Association of Laser Therapy at the 5<sup>th</sup> World Congress, in Guaruja, Brazil, November 27<sup>th</sup> 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, IIIa and IV. A similar definition applies for light therapy with light emitting diodes (LEDT) when the mean optical output is larger than 1 mW. It should be made explicit whether the systematic review or meta-analysis includes either LLLT or LEDT, or both.

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 **randomisation** and **patient-blinding**,

2.

The reporting of a systematic review should be presented according to the **QUORUM statement** from (<http://www.thelancet.com>) The Lancet, Moher et al. 1999; **354**:1896-1900.

3.

The **inclusion criteria** should be clearly stated.

Patient selection criteria should ensure that the hypothesis is tested on a **homogeneous patient sample**.

**Co-intervention with steroids** in more than 15% of the patients, is a valid reason for exclusion of trials, as steroids block the anti-inflammatory effect of LLLT.

**Diagnostic inclusion criteria** should be subjected to a limited focus on disorders that have fairly similar pathological manifestation.

The review should explicitly state which **possible biological action(s)** of LLLT that are expected and under investigation.

The site of laser exposure should 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**

and the review should explicitly evaluate and label each trial in one of these categories.

SR&MA should only **focus on one category**, as the biological actions of LLLT are most likely to be different for each of the categories. If **more than one category** is included, SR&MA should make distinctions between the categories. In such cases, **subgroup analyses** for each category, and if needed an additional category for trials using a mixture of exposure sites, **should always be performed**.

**Adequate dosage reporting** should not in itself lead to lack of inclusion of a trial. WALT acknowledges incomplete dosage reporting as a major problem, and has instituted future standards for dosage reporting. However, WALT has detailed knowledge on the specifications of older laser models, and in many cases it has been possible to calculate missing data. If

needed, WALT musculoskeletal advisory board can be contacted, and will try to be of assistance in calculating missing data on treatment parameters [1].

**Dose limitations** should either be used as inclusion criteria, or as a tool for sub-grouping trials for separate analyses. WALT musculoskeletal advisory board has acknowledged that optimal doses exist for several musculoskeletal complaints[2, 3]. Scientific evidence is graded at two levels, optimal dose and likely optimal dose interval, and a list diagnoses is available at WALT website. Trials with non-optimal doses according to WALT standards should be not be included or subgrouped as non-optimal dosage in SR&MA.

**Language restrictions** should be avoided as LLLT- trials are being published in different languages in all six continents of the world. Reviewers should rather seek linguistic assistance for translation of trial reports, than excluding them for linguistic reasons. WALT musculoskeletal advisory board can be contacted, and will try to be of assistance to overcome linguistic problems with translation of trial reports.

4.

**Methodological assessments should include assessment of randomization and blinding procedures.** This may either be performed through inclusion criteria assessments or in the methodological assessments or it can be performed with checklists or other instruments later in the review. **Exclusion of trials** from statistical analysis and conclusions by poor methodological assessment results, **should be avoided** as checklists have proved to be rather unreliable in general [4] and particularly **unreliable** for the LLLT-literature [5]. Analysis of methodological quality may have some value in increasing the precision of effect size calculations[6], and may be subjected to sub-group analyses.

5.

**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. Examples of valid instruments are Western Ontario and McMasters Universities Osteoarthritis Index (WOMAC), Visual Analogue Scale (VAS) for pain, Arthritis Impact Measurement Scale 2 (AIMS2), AUSCAN for hand osteoarthritis, Shoulder Pain and Disability Index (SPADI).

6.

**Statistical pooling of results** should preferably be made according to current standards as used by either European League Against Rheumatism (EULAR), Cochrane Collaboration, British Medical Journal or the Oxford Internet Pain site ([www.jr2.ox.ac.uk](http://www.jr2.ox.ac.uk) oxford league pain). In cases of **missing data** and graphical data presentation only, data can be imputed from visual inspection of graphs. In cases of missing variance data, a reasonable estimate from other similar trial data can be acceptable if handled conservatively by using the largest reasonable variance data from other studies which are similar in size and patient selection criteria. However, in both cases of missing data, the imputing of virtual data should be stated.

7.

The 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 in the WALT website

[www.walt.nu](http://www.walt.nu)

## References

1. Bjordal, J.M., et al., *A systematic review of low level laser therapy with location-specific doses for pain from chronic joint disorders*. Aust J Physiother, 2003. **49**(2): p. 107-16.
2. Bjordal, J., C. Couppé, and A. Ljunggreen, *Low level laser therapy for tendinopathy. Evidence of a dose-response pattern*. Physical Therapy Reviews, 2001. **6**(2): p. 91-99.
3. Tuner, J. and L. Hode, *It's all in the parameters: a critical analysis of some well-known negative studies on low-level laser therapy*. J Clin Laser Med Surg, 1998. **16**(5): p. 245-8.
4. Juni, P., et al., *Direction and impact of language bias in meta-analyses of controlled trials: empirical study*. Int J Epidemiol, 2002. **31**(1): p. 115-23.
5. Bjordal, J.M., *A quantitative study of bias in systematic reviews*. Advances in Physiotherapy, 2003. **5**(2): p. 83-96.
6. Verhagen, A.P., et al., *Impact of quality items on study outcome. Treatments in acute lateral ankle sprains*. Int J Technol Assess Health Care, 2000. **16**(4): p. 1136-46.