Appendix 2. Recommendations to Facilitate Blinding in PT trials

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| Blinding | Minimize bias by | Practicalities: examples |
| Assessors | * Blind assessors to treatment allocation: External personnel perform sequence generation and allocation concealment of study participants to different treatment groups. Thus assessors will not be aware of random allocation. * Assessors should be independent of research team. * Use objective outcome measures in combination with self-reported or more subjective measures. * Blind assessors to study hypothesis as well * Request to participants not to reveal any information of the study to assessors. * Request clinicians and/or research team not to reveal any information to assessors. * Request clinicians and/or research team to prepare same conditions for evaluation for all subjects regardless treatment allocation (e.g. space, time, duration, instrumentation) * Ideally use instrumentation to provide automated data that could be fed into a computer or outcomes that can be analyzed from images, recordings, or videos. * Use trained, experienced, and calibrated assessors. * When the outcome is the presence or not of an event: * Ideally use 2 reviewers or an event adjudication committee which should agree on the presence of an event or not, without providing details of treatment assignment. * Provide objective and clear criteria for describing the event of interest: Make a check list. | * If the therapeutic modalities generate changes in appearance (e.g. skin of participants) make sure to cover body parts when assessors are performing data collection. * For example, generally diathermia causes changes in the skin of participants immediately after treatment. Make sure to mask treated region to ensure blinding of assessors. |
| Participants | * Blinding participants to random allocation can be done in certain situations such as when generating a credible placebo. In this case, blinding of participants to treatment allocation can be done easily by having an external personnel performing the sequence generation and allocation concealment of study participants. * When placebo treatment is not possible or of no interest to the research team, blind participants to research hypotheses. This can be achieved by providing partial information regarding the interventions or the way the interventions work. * Do not provide details of the comparison groups * Try to establish a neutral environment to participants, so they do not have high expectations for any of the applied treatments. * The use of a Zelen design[1](#_ENREF_1) could also help minimize bias, especially decreasing resentful demoralization and the “Hawthorne” effect. * Reduce contamination biases by avoiding interaction between subjects assigned to different groups. | **Credible placebo:** Generally credible placebos in PT are difficult to perform. However, the use of electro physical agents such as TENS, interferential current (IFC), US, diathermia, laser therapy and acupuncture among others can be used for that purpose applying a “sham” intervention. Most of the placebos generated with these modalities can be achieved by using either leads that are not truly connected to the devices (IFC treatment), having the US not really ON, or prepare special devices that are not providing any type of stimulus (TENS).[2](#_ENREF_2),[3](#_ENREF_3) In the case of acupuncture, there are some available needles that can create a credible placebo effect. [4](#_ENREF_4),[5](#_ENREF_5)For example, the location of the needles do not correspond with the described points of acupuncture or the needles used are not inserted in the skin.  The main issue with sham applications is the difficulty to blind subjects effectively because the use of a device is usually associated with a sensation, such as during TENS. Therefore, subjects with previous experience with that device might be easily unblinded.[6](#_ENREF_6) That is the reason why subjects with previous experience usually are excluded from studies exploring mechanisms of placebo in physical therapy.[2](#_ENREF_2),[3](#_ENREF_3)  In cases of placebo use with different modalities, therapists participating in the trial should use a particular informational context in which participants are informed that they may or may not feel any sensation related to the treatment. [2](#_ENREF_2),[3](#_ENREF_3)  A non-therapeutic tape or prosthetic devices can also be used as a placebo effect in some conditions. |
| Therapists | * Generally blinding of therapists is difficult to achieve in PT trials. * Therapists can be potentially blinded to random allocation when physical modalities are used. * Therapists can be blinded to the study hypotheses. * Having different therapists performing different treatments when possible will decrease the possibility of performance bias since therapists will be instructed to follow the same protocol for the group assigned and there would not be differences in care provided. * Research team can give therapists specific information for treatments that they have to perform but they can omit/or provide limited information regarding the comparison group. * A strategy to decrease the possibility for biases, especially at the therapist level would be the use of expertise-based randomized controlled trials. This type of randomized trials minimize the differential-expertise bias by allocating participants to clinicians with expertise in the specific interventions under investigation. | A way to blind therapists would be the use of physical modalities equipment such as TENS, IFC, US, etc. In the case of using these type of equipment, a trained research assistant can set up the equipment for the therapist. So, if the equipment is ON or OFF or it is providing non-therapeutic treatment can be manipulated by another person and not directly by the therapist.  In the case of acupuncture, a new needle called the “Takakura device” shows promising results to blind both participants and therapists. [5](#_ENREF_5) |
| Statistician | * Blinding statistician to random allocation, research hypotheses, intervention details and outcome assessment is generally possible in any RCT. * Information provided to statisticians regarding random allocation, data collection, intervention details should be minimal. * Blinding statisticians could be done by coding subjects and groups. So the analysist does not have any knowledge of the meaning of the codes and cannot have any influence in the study results. |  |
| Investigators | * Blind research team to treatment allocation: This can be done easily by having an external personnel performing the sequence generation and allocation concealment of study participants to different treatment groups. Thus investigators will not be aware of random allocation. * Ideally the research team should not be involved in recruitment, allocation, intervention delivery, data collection, and analysis of their trial. Qualified personnel should be hired to perform these activities. In this way, biases are minimized. This will facilitate blinding of the research team to all of the components of the trial. |  |

References

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