Appendix 1

CLEAR NPT: A Checklist for Scoring the Methodology of Nonpharmacological Trials

1. Was the generation of allocation sequences adequate?
2. Was the treatment allocation concealed?
3. Were details of the intervention administered to each group made available?
4. Was care providers' experience or skill in each arm appropriate?
5. Was participant (i.e., patients) adherence assessed quantitatively?
6. Were participants adequately blinded?

6.1. If participants were not adequately blinded

6.1.1. Were all other treatments and care (i.e., cointerventions) the same in each randomized group?

6.1.2. Were withdrawals and lost to follow-up the same in each randomized group?

7. Were care providers or persons caring for the participants adequately blinded?

7.1. If care providers were not adequately blinded

7.1.1. Were all other treatments and care (i.e., cointerventions) the same in each randomized group?

7.1.2. Were withdrawals and lost to follow-up the same in each randomized group?

8. Were outcome assessors adequately blinded to assess the primary outcomes?

8.1. If outcome assessors were not adequately blinded, were specific methods used to avoid ascertainment bias (systematic differences in outcome assessment)?

9. Was the follow-up schedule the same in each group?
10. Were the main outcomes analyzed according to the intention-to-treat principle?

Our Scoring Criteria

The scoring criteria for the CLEAR NPT.

1. We considered this adequate if a random process was used to generate treatment sequence (i.e. computer, table, dice, coin). Pseudorandomization was considered inadequate (i.e. date of enrollment, birthdate, alternating, chart number). We considered unclear those studies in which insufficient data were given.

2. We considered the following methods for allocation concealment adequate: central randomization; numbered coded vehicles; opaque, sealed, and sequentially numbered envelopes; and other methods containing convincing means of concealment. Inadequate methods concerned open or predictable sequences of allocation (for example, alternation), date of birth, case record number or similar, and open tables of random numbers. We categorized studies as unclear if they did not fall into one of these categories or that provided no information[18].

3. The answer should be ''yes'' for this item if these data were either described in the report or made available for each arm (reference to a preliminary report, online addendum, etc.).

4. Appropriate experience or skill should be determined according to published data, preliminary studies, guidelines, run-in period, or a group of experts and should be specified in the protocol for each study arm before the beginning of the survey. For the purposes of this study, we considered this adequate if any type of statement was made regarding operator skill.

5. Treatment adherence will be assessed only for treatments necessitating iterative interventions (e.g., physiotherapy that supposes several sessions, in contrast to a one-shot treatment such as surgery). For one-shot treatments, this item is not relevant and should be removed from the checklist or answered ''unclear''.

6. We considered blinding unclear unless explicit statement was made otherwise, or unless the nature of the intervention would make it impossible. Cointerventions were considered the same if the rehabilitation protocol, post-op analgesia, antibiotic treatment and deep-vein thrombosis (DVT) prophylaxis were the same, when relevant. Withdrawals were considered the same if the loss to follow-up between groups was within 5% of each other.

7. We considered blinding unclear unless explicit statement was made otherwise, or unless the nature of the intervention would make it impossible. Cointerventions were considered the same if the rehabilitation protocol, post-op analgesia, antibiotic treatment and DVT prophylaxis were the same, when relevant. Withdrawals were considered the same if the loss to follow-up between groups was within 5% of each other.

8. We considered blinding unclear unless explicit statement was made otherwise, or unless the nature of the outcome would make it impossible.

In cases where there were multiple outcomes, the following algorithm was used:
If blinding was unclear for one or more outcomes, blinding was considered unclear.
If blinding of outcomes was never unclear, and explicitly mentioned as not done in one or more outcomes, then blinding was considered not done.
If explicit mention was made of blinding in all outcomes, then blinding was considered done.

8.1. The answer should be ‘‘yes’’ for this item if the main outcome is objective or hard, if outcomes were assessed by a blinded or at least an independent end-point review committee, or if outcomes were assessed by an independent outcome assessor trained to perform the measurements in a standardized manner, or if the outcome assessor was blinded to the study purpose and hypothesis.

This question was answered in regards to the main outcome of interest, if one was defined. In situations where it was unclear what the main outcome was, or in situations where there were multiple outcomes, the following algorithm was used:
If use of methods to avoid ascertainment bias was unclear for one or more outcomes, then this was considered unclear.
If use of methods to avoid ascertainment bias was never unclear, and explicitly mentioned as not done in one or more outcomes, then this was considered not done.
If explicit mention was made of use of methods to avoid ascertainment bias in all outcomes, then this was considered done.

9. This item is not relevant for trials in which follow-up is part of the question. For example, this item is not relevant for a trial assessing frequent versus less frequent follow-up for cancer recurrence. In these situations, this item should be removed from the checklist or answered ‘‘unclear.’’

10. Scored as “yes” if patients were analyzed in the groups to which they were assigned. Scored as “unclear” if no mention of non-compliance to treatment was made, and groups in which patients were analyzed could not be ascertained.

Note: Terms like single blinding and double-blinding were scored as unclear since previous studies have shown that they mean different things to different investigators[9].

Appendix 2

Questionnaire to Authors

What is the primary outcome(s) you were looking at in your study:	
How was the treatment sequence for your study determined?	
☐Chart number	☐Computer generated number
☐Birth date	☐Dice
☐Determined by a professional statistician	☐Uncertain
☐Other:_____	
Prior to randomization, how did you ensure that investigators were unaware of upcoming treatment assignments?	
☐Posted list	☐Centralized telephone system
☐Internet based system	☐Envelopes
☐Containers	☐Uncertain
☐None	☐Other:_____
If envelopes were used, were they:	
☐Sealed	☐Opaque
☐Serially numbered	☐Sealed AND Opaque
☐Sealed AND Serially numbered	☐Opaque AND Serially numbered
☐Sealed AND Opaque AND Serially numbered	☐Other:_____
How did you ensure that the treatment protocol was adhered to by caregivers? (Check all that apply.)	
☐Explicit written instructions	☐Meeting with caregivers
☐Third party supervision of caregivers	☐Uncertain
☐None	☐Other:_____
How did you ensure that care providers' experience or skill was appropriate? (Check all that apply.)	
☐Care providers had all performed a minimum number of cases	
☐Care providers all performed a minimum number of cases per year	
☐Care providers' results were compared to good clinical practice outcomes	
☐Uncertain	
☐None	
☐Other:_____	
Was patient adherence to the treatment protocol assessed? (Does not apply to trials investigating one-shot treatments.)	
☐Yes	☐No
☐Not applicable	☐Uncertain
If yes, how was patient adherence assessed?	
In your study, who was blinded to treatment? (Check all that apply.)	
☐Patient	☐Individual performing intervention (i.e. surgeon)
☐Ward Staff (i.e. nurses)	☐Rehabilitation team (i.e. physiotherapists)
☐Data analyst	☐None
☐Other:_____	
In your opinion, who would it have been feasible to blind in your study? (Check all that apply.)	
☐Patient	☐Individual performing intervention (i.e. surgeon)
☐Ward Staff (i.e. nurses)	☐Rehabilitation team (i.e. physiotherapists)
☐Data analyst	☐None
☐Other: _____	
It is often impossible to blind outcome assessors. Which statement is true for your study (Note: Do not take self-reported outcomes into consideration since these would not require any outcome assessors.):	

Regarding clinical outcomes (i.e. physical exam, morbidity, mortality):

☐ALL clinical outcome measures were assessed by blinded assessors

☐ALL clinical outcome measures were assessed by blinded assessors WHEN FEASIBLE

☐SOME clinical outcome measures were assessed by blinded assessors

☐NO clinical outcome measures were assessed by blinded assessors

☐It was NOT possible to blind clinical outcome assessors

☐There were no clinical outcomes

Regarding non-clinical outcomes (i.e. x-rays, lab tests):

☐ALL non-clinical outcome measures were assessed by blinded assessors

☐ALL non-clinical outcome measures were assessed by blinded assessors WHEN FEASIBLE

☐SOME non-clinical outcome measures were assessed by blinded assessors

☐NO non-clinical outcome measures were assessed by blinded assessors

☐It was NOT possible to blind non-clinical outcome assessors

☐There were no non-clinical outcomes

When it was impossible to blind outcome assessors, did your study attempt any other methods to try and minimize bias? (Check all that apply.)

☐Objective measures

☐Third party outcome assessors (Individuals who were independent of study investigators)

☐Adjudication committee (A group of individuals who were independent of study investigators)

☐Uncertain

☐Not applicable

☐None

☐Other:_____

If applicable, please specify which method of minimizing bias was used for each outcome measure that did not have a blinded assessor:

With the constraints currently being placed upon authors, information originally intended for publication is sometimes left out of the final manuscript. What elements of your original study went unreported? (Check all that apply.)

☐Aspects of the methods	☐Aspects of the data-analysis
☐Aspects of the outcomes	☐Certain discussion points
☐None	☐Other:_____

If applicable, please describe in as much detail as possible the material that went unreported in the final manuscript:

It can be very difficult to ensure that all patients are treated identically outside of the treatment under investigation. In your study, what aspects of care were ensured to be identical between treatment groups? (Check all that apply.)

☐Post-procedure analgesia	☐Antibiotics
☐Antithrombotic therapy	☐Post-procedure rehabilitation
☐Follow up protocols	☐Uncertain
☐None	☐Other:_____

Was the follow up schedule the same in each group?

☐Yes	☐No
☐Uncertain	

Was the difference in the number of withdrawals and loss to follow up between groups a concern?

☐Yes	☐No
☐Uncertain	
If no, why not?	
☐No dropouts	☐Dropouts calculated to be not significant
☐Dropout rate felt to be similar between groups	☐Not applicable
☐Other:_____	

Were the main outcomes analyzed according to the intention-to-treat principle? (i.e., Individuals were analyzed according to the group to which they have been randomized, even if they never received the treatment they were assigned.)

☐Yes	☐No
☐Uncertain	

How was the sample size for your study determined?	
☐All patients between a set time frame	☐From a power calculation
☐Other:_____	
How many centres were involved in your study:_____	
How was your study funded? (Check all that apply.)	
☐Industry	☐Government
☐Foundation	☐Association
☐Non-funded	☐Other:_____
Would you like to declare any possible conflict of interest issues?	
Comments or Questions:	