TRAUMATIC BRAIN INJURY REHABILITATION: AN OVERVIEW OF SYSTEMATIC REVIEWS OF INTERVENTION EFFECTIVENESS. A PRE-PUBLISHED PROTOCOL.

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BACKGROUND

Many authors are in favour of using systematic reviews as a method for evidence synthesis in rehabilitation (Brown et al., 2012; Dijkers et al., 2012; Glasziou et al., 2004, Johnston et al., 2006; Paul&Leibovici, 2014) and the last decade has introduced several guidelines to help with their implementation in rehabilitation contexts (Brown et al., 2012; Johnston&Dijkers, 2012; Pollock&Berge, 2018). At present, however, there is little clear information about the quantity and quality of systematic reviews on TBI rehabilitation interventions.

The quality of systematic reviews in general is known to vary. Almost 15 years ago, Moher et al. (2004) presented a study on epidemiological and reporting characteristics of systematic reviews indexed in Medline during November 2004. The same methodology was used a decade later by Page et al. (2016). While there were about three times more systematic reviews indexed, the quality of published reviews still showed remarkable deficiencies, i.e. methods used were poorly reported, unpublished data were seldom sought, and statistical methods not in accordance with recognized best standards, despite the increase in using and reporting risk of bias assessment practices (Page et al., 2016). Gianola et al. (2013) used Moher’s methodology to examine rehabilitation-related systematic reviews and drew conclusions which were not vastly different from those previously mentioned. Although Jesus (2016) showed that the increase in rehabilitation clinical trials and systematic reviews, especially for the neurological conditions, has been higher than that in medical research, there is no published analysis available about the trends or quality of neurorehabilitation systematic reviews.

Furthermore, Lei et al. (2012) investigated Cochrane reviews on medical interventions for management of acute TBI. Their conclusions were stark: there is no high-level evidence to support practiced interventions for TBI populations. To our knowledge there is no similar review or overview of reviews investigating the evidence base for TBI rehabilitation interventions.

In order to advance research in TBI rehabilitation— as is the main aim of the overall PhD project – it is crucial to have a thorough knowledge about the existing evidence and evidence gaps in this knowledge base. On one hand this provides a basis for further discussions about developments needed within research. On the other, the results will directly inform clinical practitioners and other relevant stakeholders – i.e. funders, policy-makers, patients and families – about available evidence and its quality for TBI rehabilitation.

We aim to conduct an overview of systematic reviews published on TBI rehabilitation interventions in order to summarise the current state of evidence in this area of clinical practice. In addition to providing information on strength of evidence for intervention effectiveness, our goal is to research and summarise two additional domains: reviews’ characteristics and evidence gaps.

We will synthesise the systematic review evidence on the effectiveness of rehabilitation interventions and service provision practices for adults with TBI in order to describe the current state of evidence and provide comprehensive evidence-map for stakeholders (i.e. clinicians, patients, researchers, policy-makers etc.). This systematic overview will concentrate on the adult TBI population (regardless of severity, stage of recovery, or other aspects of clinical presentation), any kind of rehabilitation interventions (regardless of setting, uni- or multidisciplinarity etc), comparisons with no treatment, placebo or sham treatment, and usual care; and variety of common outcomes used by the review authors to measure quality of life, activity and participation – as per International Classification of Functioning, Disability & Health (ICF) (World Health Organization, 2001) – residential status, family burden, and adverse effects. As a result, we aim to produce a comprehensive evidence map of TBI rehabilitation interventions according to their effectiveness.
OBJECTIVES OF THE OVERVIEW

The objectives of this overview are to:

- To describe publishing and reporting trends in systematic reviews on TBI rehabilitation interventions
- To describe the content characteristics of systematic reviews on TBI rehabilitation interventions
- To describe and critically appraise the review methods used in systematic reviews of TBI rehabilitation interventions
- To provide an overview of the extent and quality of evidence of effectiveness of rehabilitation intervention for people with TBI
- To highlight the gaps in the systematic review evidence for TBI rehabilitation effectiveness

METHODS

CRITERIA FOR CONSIDERING REVIEWS FOR INCLUSION

TYPES OF REVIEWS TO BE INCLUDED

We will include systematic reviews that have examined the effectiveness of one or more rehabilitation interventions on health outcomes for adults with TBI. We define a systematic review as a research process in which literature relevant to a stated question is identified and synthesised using explicit methods, including methods for selecting studies, evaluating quality of studies, extracting data and analysing data (Moher et al., 2007). We will include systematic reviews of quantitative studies and mixed-method studies with intended quantitative analysis. We will exclude studies not published in English.

TYPE OF PARTICIPANTS

We will include systematic reviews on adult populations (18+ years at time of injury) with TBI, regardless of injury severity, including concussion. TBI is “an alteration in brain function, or other evidence of brain pathology, caused by an external force” (Menon et al., 2010, p.1637). For the purposes of this review, we intend to exclude from this definition the appearance of neurological symptoms due to psychological issues; psychiatric disorders; medication, alcohol or drug use; treatment for other injuries; or other co-existing medical conditions.

We will include reviews with more varied patient populations, i.e. neurotraumas or acquired brain injuries, provided that data on TBI can be extracted and reported on separately. If data on TBI is not separable, the review will be excluded. If a review includes both paediatric and adult population, it will be included, if data on adults is presented separately.

TYPES OF INTERVENTIONS

We will include any systematic review of rehabilitation interventions for people with TBI. World Health Organization defines rehabilitation as “a set of interventions designed to optimize functioning and reduce disability in individuals with health conditions in interaction with their environment.” (WHO, 2017; p.1). We will include reviews on all types of rehabilitation interventions provided, prescribed or led by mainstream rehabilitation specialists (doctors, nurses, physiotherapists, occupational therapist, speech language therapist, orthoptists, social workers, counsellors and psychologists, orthotists) or rehabilitation teams – regardless of the setting, modality or the method of service provision. We will include reviews on different aspects of the same intervention as well as on more complex multi-dimensional approaches, i.e. goal-setting, if the reviews look at intervention effectiveness. Furthermore, we will also include reviews on approaches to rehabilitation service provision, i.e. early supported discharge. We will exclude reviews on diagnostic or surgical procedures, prognostic studies, or observational studies on the burden of TBI (i.e. personal and societal consequences). We will include all reviews that meet these criteria regardless of intervention context (e.g. hospital, residential care, outpatient, home, work).
TYPES OF COMPARATOR(S)/CONTROL
For the purposes of providing a descriptive overview of reviews’ characteristics, we will extract general data about comparisons used from all systematic reviews considering the before-mentioned population and interventions. We will collect data on finding on effectiveness from any systematic reviews that collate or syntheses evidence from studies which include a no intervention control, an attention control (i.e. a Hawthorne control), or a comparison to ‘usual care’ as defined by the study authors. We will not collect data on effectiveness from any systematic reviews that compares two different rehabilitation interventions or different approaches of the same intervention (i.e dosage).

TYPES OF OUTCOMES
For the purposes of providing a descriptive overview of reviews’ characteristics, we will extract general data on outcomes used from all systematic reviews considering before-mentioned population and interventions. We will collect data on effectiveness related to quality of life and participation (as per the ICF) as primary outcomes, and as secondary outcomes have: activity (as per the ICF), mortality, cost of service delivery, residential status (home, residential care, supported accommodation), family burden, and adverse effects.

SEARCH METHODS FOR IDENTIFICATION OF REVIEWS
We will carry out a comprehensive search of the Cochrane Library database (including Database of Abstracts and Reviews of Effectiveness) MEDLINE, CINAHL, EMBASE, Epistemonikos, PDQ-evidence, and PubMed to find relevant systematic reviews. We also will make efforts to identify ongoing reviews by searching for protocols in the Cochrane Library database and in PROSPERO. We are not going to search grey literature because the aim of the study is to analyse the reviews which inform clinical practice and grey literature, particularly non-peer reviewed grey literature, is much less likely to have been accessed or used for that purpose.

For search terms in electronic databases we will use subject headings and text word synonyms for ‘traumatic brain injury’ combined with those for ‘systematic review’. The search strategy is based on the practices of previously undertaken research. The search for ‘traumatic brain injury’ is based on Cochrane reviews done by Synnot et al (2017) and Kumar et al (2017). The search for ‘systematic review’ is based on a recommendation by Lee et al (2012) who suggest to exploit the search from health-evidence.ca. We have decided to act according to the strategy, but leave out the term ‘intervention$.ti’ which, based on our trial searches, do not add extra value to specificity of the search. Our search strategy in Medline is presented in Box 1.

Box 1: Search strategy in Medline (Ovid)

1  exp brain injuries/
2  exp craniocerebral trauma/
3  exp cerebrovascular trauma/
4  exp brain edema/
5  ((head or cerebr* or brain* or intra?cran* or inter?cran*) adj3 (injur* or trauma* or damag* or oedema* or edema* or contusion* or concus*)).ab,ti.
6  1 or 2 or 3 or 4 or 5
7  MEDLINE.tw.
8  systematic review.tw.
9  meta-analysis.pt.
10  7 or 8 or 9
11  6 and 10
DATA COLLECTION AND ANALYSIS

SELECTION OF REVIEWS
We will use Covidence (https://www.covidence.org/home) to manage review selection. Two review team members (KE and WL) will independently review all titles and abstracts and categorise them as either ‘retrieve’ (eligible or potentially eligible/unclear) or ‘do not retrieve’. We will retrieve the full-text reviews, and two review authors (KE and WL) will independently screen the full-text publications and identify studies for inclusion, identifying and recording reasons for exclusion of the ineligible studies. All disagreements will be discussed until consensus is found. A third reviewer (JHS or AP) will be involved where necessary. Full papers will be obtained if titles and abstracts remain unclear for decision-making or if both selectors have agreed that a publication should be included to our study.
All included reviews. Data extraction on review characteristics. AMSTAR-2, PRISMA

Comparisons which are not relevant.

Relevant comparisons (no treatment, placebo, usual care)

categorization of outcomes according to ICF

Outcomes which are not relevant

Outcomes about activities and participation, QoL, cost, residential status, family burden, adverse effects

categorization of outcomes according to ICF domains in ICF check list

Statistical analysis

GRADE

No statistical analysis

Chart 1: The flow of our overview’s activities.
DATA EXTRACTION AND MANAGEMENT

We will use an online membership database, built using Knack software (https://www.knack.com/), to extract data on review characteristics and review findings. The review characteristics will be extracted for all included reviews. The review findings on effectiveness will be extracted for reviews with certain comparisons and outcomes as described in the previous sections on “Types of comparison(s)/controls” and “Types of outcomes”. We will have two authors independently extract data. KE will extract data on all included reviews, with WL and JHS sharing the role of second author. We will discuss differences in opinions until a consensus is reached. We will consult a third reviewer (AP) to resolve disagreements where needed.

For review methodological and content characteristics, we will extract data on:

- Full citation
- Date published
- Methodological characteristics:
  - Date of the last search
  - Existence of a pre-published protocol (yes/no)
  - Whether the review is a Cochrane review (yes/no), and which Cochrane Review Group if it is a Cochrane Review
  - Whether the review is limited to TBI only (yes/no) as stated by the authors in the results section
    - Total number of participants in included studies, as reported by review authors
    - Number of TBI participants in included studies, as reported by review authors
  - Number of studies included in the review
  - Methodology of included studies
  - Number of meta-analyses conducted
    - If none conducted, the authors’ comments on the reasons
    - Number of meta-analysis for primary outcome(s)
    - Number of studies and participants contributing to the meta-analysis on primary outcome(s)
  - Method used by the review authors for grading the evidence (e.g. GRADE, PEDro, etc)
  - Risk-of-bias assessments by the review authors – general comments
    - If risk of bias assessment was done (yes/no)
    - What method/tool/approach was used for risk of bias assessment
    - How were the results of the risk of bias assessment used
- Review authors’ comments on methodological issues
  - Review limitation as stated by authors
  - Review authors’ conclusions regarding the effectiveness of the interventions under consideration
  - Review authors’ recommendations for future research
- Intended review question or objective
- Content characteristics:
  - PICO components of the review, as defined by the review authors
    - Population
    - Intervention(s)
      - Content – what, how, tailoring and modifications
      - Setting – where, when, and how much
      - Provider – by whom
    - Comparison(s), if no care, usual care, attention control or placebo, then the same items as for intervention(s) – content, setting, provider – will be extracted
      - Number of comparisons presented
Outcomes – primary and secondary

For review findings we will extract data on:

- Information on specific outcomes relevant to the objectives of our review
  - References (first author’s name and publication year) for the primary publication associated with outcomes of a study
  - Number of studies and participants behind each outcome presented
  - Intervention effects for the outcomes presented by the review authors
    - risk ratios (RRs), odds ratios (ORs), or mean differences (MDs), or standardised mean differences (SMDs); 95% confidence intervals (CIs)
    - \( I^2 \) statistic for heterogeneity
  - Narrative text of results if no statistical results presented.
  - Population behind the outcome – age, severity, time post-injury – as stated by the review authors
  - Intervention behind the outcome as stated by the review authors
  - Rehabilitation setting of the outcome as stated by the review authors
  - Comparison for the intervention with the outcome as stated by the review authors
  - Reason for evidence being downgraded or upgraded for the outcomes presented as stated by the review authors
- Risk of bias assessments as assessed by original review authors
  - Randomization (selection bias)
  - Blinding of outcome assessors (detection bias)

**Assessment of methodological quality of included reviews**

We will assess the quality of reporting with PRISMA (Transparent Reporting of Systematic Reviews and Meta-Analysis) (Moher et al, 2009). We will apply PRISMA in accordance with the updated version of PRISMA Explanation and Elaboration document (Liberati et al, 2009; Page et al, 2018) by making a judgement of “yes/no/unclear” without further descriptions. We will present the results of our PRISMA assessments in a dedicated table.

We will use Covidence to extract data on methodological quality. We will have two authors independently extract data on methodological quality before comparing findings. KE will extract data on methodological quality of all included reviews, with WL and JHS sharing the role of second author. We will discuss differences in opinions until a consensus is reached. We will consult a third reviewer (AP) to resolve disagreements where needed. We will assess the methodological quality of included reviews with AMSTAR 2 (A Measurement Tool to Assess Systematic Reviews) instrument (Shea et al, 2017). AMSTAR 2 is an update of the AMSTAR instrument which is aimed at critically appraising systematic reviews. AMSTAR 2 has 16 items (10 of those the same as were in AMSTAR) which are presented in Table 1. The critical items are important in giving the overall confidence rating for the results of a systematic review. (Shea et al, 2017). We will present all information in an ‘AMSTAR 2 Assessment’ table.

Table 1: The sixteen domains in AMSTAR 2 (Shea et al, 2017)

<table>
<thead>
<tr>
<th>No.</th>
<th>AMSTAR 2 question</th>
<th>Critical item</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Did the research questions and inclusion criteria for the review include the components of PICO?</td>
<td></td>
</tr>
</tbody>
</table>
2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol? ✓

3. Did the review authors explain their selection of the study designs for inclusion in the review? ✓

4. Did the review authors use a comprehensive literature search strategy? ✓

5. Did the review authors perform study selection in duplicate? ✓

6. Did the review authors perform data extraction in duplicate? ✓

7. Did the review authors provide a list of excluded studies and justify the exclusions? ✓

8. Did the review authors describe the included studies in adequate detail? ✓

9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review? ✓

10. Did the review authors report on the sources of funding for the studies included in the review? ✓

11. If meta-analysis was performed, did the review authors use appropriate methods for statistical combination of results? ✓

12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis? ✓

13. Did the review authors account for RoB in primary studies when interpreting/discussing the results of the review? ✓

14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review? ✓

15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review? ✓

16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?

We will not reassess the quality of studies included within reviews but instead will report study quality according to review authors’ assessments. We will collect this information during the data extraction process as described above.

We will categorise all outcomes on the basis the ICF. Where possible, we will classify outcomes by their ICF components, (i.e. 1) body functions and body structures, 2) activity and participation, or 3) environmental factors) and by their full alphanumeric code according to chapters (level 1 headings) in ICF checklist. We will categorise outcomes not fitting into any category, as “not fitting the ICF”.

**Quality of evidence in included reviews**

We will score the quality of evidence for the quantitatively presented intervention effects reported in the second stage of the study – overview of reviews – using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach (Guyatt, 2008), which considers the following aspects: (a) risk of bias due to flawed design or conduct of studies; (b) imprecision (e.g. when confidence intervals for treatment effect are wide); (c) inconsistency (e.g. when point estimates vary widely, I² is large); (d) indirectness (e.g. variations in participants, interventions, comparisons and outcomes); (f) publication bias (may be explored with the use of funnel plots and classed as not suspected, suspected, strongly suspected or very strongly suspected). However, as practiced by Pollock et al. (2014) to guarantee higher level of objectivity in the GRADE scores, we are similarly going to use objective criteria for grading evidence. We will take the Pollock algorithm (Pollock et al., 2014)
and use this as a starting point for exploring criteria and cut-offs which are relevant and meaningful to this body of TBI evidence we will find.

Two review authors (KE and WL or JHS) will determine whether the evidence arising from each comparison is of high, moderate, low or very low quality within GRADE, based on the following definitions (Guyatt 2008):

- **High quality**: when further research is very unlikely to change our confidence in the estimate of effect.
- **Moderate quality**: when further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
- **Low quality**: when further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
- **Very low quality**: when we are very uncertain about the estimate.

The overview authors resolve the disagreements with discussions and will involve the third author (WL or JHS) when necessary.

**DATA SYNTHESIS**

We will provide a report on the characteristics of all included reviews using simple statistical analyses and narrative accounts. We present these results as tables, charts or schemes depending on which format supports the clearest descriptive summary possible. We aim to produce infographics to spread the most practically relevant results in a convenient manner. The report will include, but will not be limited to, the following information:

- Publication trends of systematic reviews on TBI rehabilitation intervention effectiveness over the years.
- Summary of interventions targeted in published systematic reviews.
- Summary of populations and rehabilitation settings contributing data to the published systematic reviews.
- Summary of comparisons reported in the published systematic reviews.
- Summary of outcomes selected by reviewers to reported in the published systematic reviews.
- Summary of systematic review authors’ comments on the quality of included studies and recommendations for future research.

We will separately comment and provide tabulated information on methodological quality of included reviews based on our AMSTAR 2 assessments. We will discuss the common problems with the quality and highlight existing good practices. We will provide the overall conclusions on the ratings of confidence – high, moderate, low, critically low – in the results from the reviews according to intervention groups. We will summarise common problems in the development of systematic review level evidence for TBI rehabilitation interventions and solutions to these problems suggested by the review authors. Also, we will make similar efforts in summarising and commenting on the quality of reporting of systematic reviews based on our PRISMA assessments.

We will present the main summary of results based on intervention effectiveness (Table 4). We will present data on intervention effects according a framework adapted from Shepherd et al. (2016) and Farquhar & Marjoribanks (2018) as follows:

- **Effective intervention** - indicating that the review found evidence of effectiveness for an intervention.
- **Promising interventions (more evidence needed)**: indicating that the review found some evidence of effectiveness for an intervention, but that more evidence is needed.
• Ineffective interventions: indicating that the review found evidence of lack of effectiveness for an intervention.
• Probably ineffective interventions (more evidence needed): indicating that the review found evidence suggesting lack of effectiveness for an intervention, but that more evidence is needed.
• No conclusions possible: indicating that the review found insufficient evidence for review authors to comment on the effectiveness of an intervention.

We will base our categorization on our GRADE assessments for quality of evidence (see chapter “Quality of evidence in included reviews”). If an original review presented only narrative conclusions and no quantitative conclusions, we will base our categorization on the conclusion of original review authors. This approach is summarized in Table 3. Two overview authors (KE and WL or JHS) resolve the disagreements with discussions and will involve the third author (WL or JHS) when necessary to reach a consensus.

Table 3: Classification of interventions by their effect for quantitative findings. Adapted from Shepherd et al. (2016) and Farquhar & Marjoribanks (2018)

<table>
<thead>
<tr>
<th>Effective interventions</th>
<th>indicating that the review found evidence of effectiveness for an intervention.</th>
<th>high-quality evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Promising interventions (more evidence needed)</td>
<td>indicating that the review found some evidence of effectiveness for an intervention, but that more evidence is needed.</td>
<td>moderate-quality evidence</td>
</tr>
<tr>
<td>Ineffective interventions</td>
<td>indicating that the review found evidence of lack of effectiveness for an intervention.</td>
<td>high-quality evidence</td>
</tr>
<tr>
<td>Probably ineffective interventions (more evidence needed)</td>
<td>indicating that the review found evidence suggesting lack of effectiveness for an intervention, but that more evidence is needed.</td>
<td>moderate-quality</td>
</tr>
<tr>
<td>No conclusions possible</td>
<td>indicating that the review found insufficient evidence for review authors to comment on the effectiveness of an intervention.</td>
<td>low- or very low-quality</td>
</tr>
</tbody>
</table>

Table 4: The main summary of results.

<table>
<thead>
<tr>
<th>Effective interventions</th>
<th>Probably effective</th>
<th>Not effective</th>
<th>Probably not effective</th>
<th>No information for making decision of effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>List of interventions we have categorized as effective*.</td>
<td>List of interventions we have categorized as probably effective*.</td>
<td>List of interventions we have categorized as not effective*.</td>
<td>List of interventions we have categorized as probably not effective*.</td>
<td>List of interventions for which we haven’t found enough evidence for making decision on effectiveness.*</td>
</tr>
</tbody>
</table>

* If we find relevant evidence, we will consider organize it according to patient group (ie mild TBI, moderate TBI, severe TBI) and/or rehabilitation setting (ie early acute setting, active rehabilitation setting, chronic community-based rehabilitation setting)
Also, we aim to present conclusions specific to each intervention in terms of the current evidence base: statistical and/or narrative descriptions of effects and the evidence quality, relevant contextual factors, population, rehabilitation setting, and comparisons researched. We anticipate there are interventions, such as cognitive rehabilitation, where there will be more than one review published. If the reviews do not have overlapping primary studies we will report results from all reviews, and aim to comment on similarities or differences within the results. If overlaps between primary studies exist we will decide as a group how best to avoid ‘counting’ findings from the same studies more than once in our reported findings. We will base these decisions on: PICO components related to review questions and AMSTAR-2 scores. We will not perform meta-analysis. Where possible and clinically meaningful we will discuss results according to TBI severity, time post-injury, rehabilitation setting (acute in-patient rehabilitation, subacute inpatient rehabilitation, outpatient services, community-based rehabilitation, home/work/study or training environment, long-term solutions), and outcomes such as ICF-component-based outcomes, quality of life, adverse effects, etc.

In order to example gaps in the current evidence of TBI rehabilitation, we will separately summarise the information on ICF categorizations covered with low or very-low quality evidence or no evidence at all from existing systematic reviews.

To support knowledge translation, we will organise the overview of reviews’ findings as comprehensive evidence maps. The specific format of these evidence maps will depend on the results of our research, but will include intervention-specific information related to researched outcomes and presenting statistical or narrative results from original reviews in order to highlight information on effectiveness and evidence gaps. Our ideal aim is to create an interactive evidence maps to assure wider knowledge translation possibilities. In addition, we will consider creating relevant infographics on about effective and ineffective interventions, research gaps, interventions targeting activity and participation outcomes, interventions targeting quality of life, and interventions resulting with adverse event, quality of systematic reviews, and recommendations for future research.
REFERENCES


