Physical rehabilitation interventions in non-ambulatory people with Multiple Sclerosis: a systematic review

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Background

- Expanding body of literature in multidisciplinary rehabilitation and exercise in MS *(Dalgas et al 2008; Khan et al 2007; Rietberg et al 2005; Garrett and Coote 2009)*
- Focus on mild – moderate MS (EDSS ≤6.5)

DESPITE.....

- Higher costs associated with increasing disability *(Kobelt et al 2006)*
  - €18000 for EDSS <4 - €62000 for EDSS >7
- Significant proportion of PwMS are severely disabled/non-ambulatory
  - 23% = non-ambulatory in Einarsson et al. 2003
  - 26% = non-ambulatory in Coote et al. 2010

Objective of review

- The objective of this review was to assess the evidence surrounding physical rehabilitation interventions in non-ambulatory people with Multiple Sclerosis

Methodology - Criteria

Included articles:

- Non-ambulatory men and women of all ages with a diagnosis of MS
- Non-ambulatory was defined as requiring a wheelchair to mobilise indoors and outdoors, or bed-bound (EDSS scores of ≥7.0)
- Inpatient and outpatient interventions
- All types of MS

Excluded articles:

- Pharmacological, surgical, and medical trials
- Interventions using assistive devices when the device served purely to compensate for lack of function rather than attempting to restore function, e.g. wheelchairs
- Studies that did not analyse results of non-ambulatory PwMS separately to ambulatory PwMS

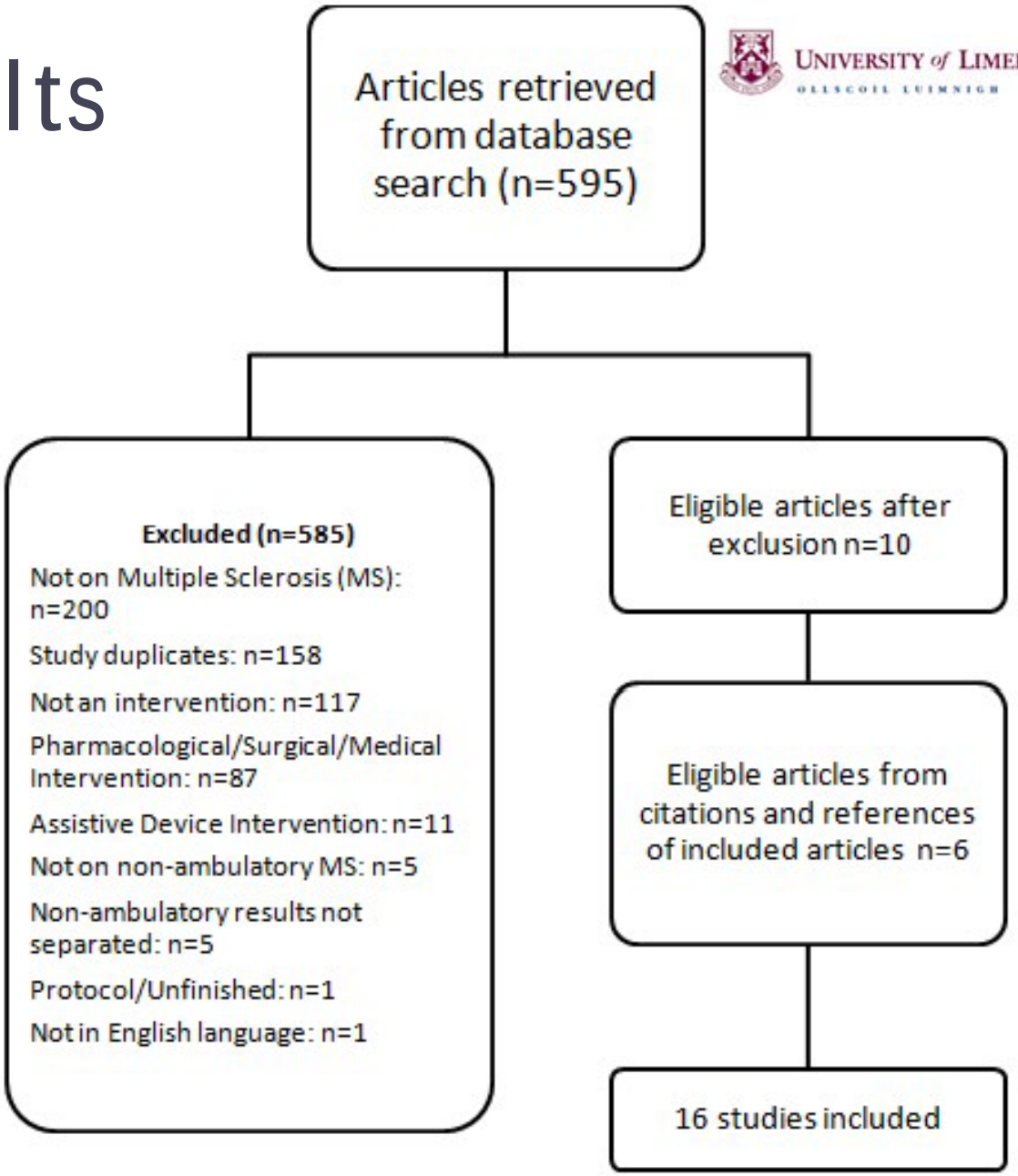
Methodology – Search methods

- Electronic searches up to 31st May 2011
  - AMED, CINAHL, MEDLINE, PSYCHarticles, Google Scholar, EMBASE and PEDro
- Hand searched reference lists
- Citations of retrieved articles searched
- Known experts with special interest in severe MS contacted

Methodology – Data collection and analysis

- Selection of studies and data extraction
  - Second reviewer checked retrieved articles against selection criteria
  - Study design and description, participant characteristics, recruitment details, outcome measures, results and limitations systematically extracted
- Assessment of risk of bias
  - Cochrane Handbook for Systematic Review of Interventions version 5.1.0 used *(Higgins and Green 2011*
  - Performance, selection, attrition, reporting, detection bias
- Data synthesis and interpretation
  - GRADE approach recommended by Cochrane Handbook

Results


Articles retrieved from database search (n=595)
Excluded (n=585)
Not on Multiple Sclerosis (MS): n=200
Study duplicates: n=158
Not an intervention: n=117
Pharmacological/Surgical/Medical Intervention: n=87
Assistive Device Intervention: n=11
Not on non-ambulatory MS: n=5
Non-ambulatory results not separated: n=5
Protocol/Unfinished: n=1
Not in English language: n=1
Eligible articles after exclusion n=10
Eligible articles from citations and references of included articles n=6
16 studies included

Results

- 16 studies of overall low quality
- 3 RCTs, 10 case studies, 2 before-and-after comparison studies, 1 randomised crossover study
- Only 8 studies consisted of entirely non-ambulatory PwMS

Exercise Interventions

- 2 RCTs
- 3 case studies

Rehabilitation Interventions

- 1 RCT
- 1 before-and-after comparison study
- 3 case studies

Cooling Suit Interventions

- 1 before-and-after comparison study
- 4 case studies

Other Interventions (Therapeutic Standing)

- 1 crossover study

Results – Exercise Interventions

- Respiratory muscle training: 2 RCTs *(Gosselink et al 2000; Klefbeck et al 2003)*
  - Inspiratory or expiratory muscle training improves respiratory muscle strength with no changes in function
- Aerobic exercise: 2 case studies (*Smith and Hale 2006; Giesser et al 2007*)
  - May improve impairment level, no evidence for carryover into function
- Strengthening exercise: 1 case study (*Svensson et al 2004*)
  - Subjective improvements, objective disimprovement but confounded by additional aquatic treatment

Results – Rehabilitation Interventions

- 1 RCT *(Freeman et al 1997)*
  - Non-ambulatory PwMS only analysed separately in locomotion section of FIM
  - Non-ambulatory improved significantly in contrast to ambulatory
- 1 before-and-after comparison study *(Grasso et al 2005)*
  - Significantly more improvement in mild to moderate MS for mobility and ADLs than non-ambulatory
- 3 case studies *(Peterson 2001; Hamer & Hills 1991; Baer & Lewis 1987)*
  - Qualitative improvements in impairment and activity measures

BUT

  - Participants experiencing severe deterioration on admission (*Hamer & Hills 1991; Baer & Lewis 1987)*
  - Confounding use of aquatic treatment *(Peterson 2001)*

Results – Cooling Suit Interventions

- 4 case studies *(Flensner &Lindencrona 2002; Flensner & Lindencrona 1999; Kinnmann et al 2000; Capello et al 1995)*
- 1 before-and-after comparison *(Kinnmann et al 1997)*
- Impairment measures:
  - Results varied and inconclusive regarding strength
- Activity measures:
  - Varied, with general trend towards improvements in gait and mobility
  - Two studies that evaluated fatigue found improvements
  - Different outcome measures and conflicting results for effect on ADLs

Results – Therapeutic Standing

- Randomised crossover trial *(Baker et al 2007)*
- Significant improvements in hip and ankle RoM
- Non-significant improvements in lower limb spasticity
- No functional outcomes at activity or participation level used

GRADE quality

Reference (Year):	Design:	Initial Grade:	Grade Reduced/Increased:	Final GRADE Quality:
Smith & Hale (2006)	Case report	Very Low	n/a	Very Low
Giesser et al. (2007)	Case series	Very Low	n/a	Very Low
Svensson et al. (1994)	Case report	Very Low	n/a	Very Low
Gosselink et al. (2000)	RCT	High	Detection bias – High risk; Performance bias – High risk; Attrition bias – Unclear risk; Reporting bias – Unclear risk	Low
Klefbeck et al. (2003)	RCT	High	Selection bias – Unclear risk; Detection bias – High risk; Performance bias – High risk; Attrition bias – High risk; Reporting bias – Unclear risk	Low
Baer and Lewis (1987)	Case report	Very Low	n/a	Very Low
Hamer and Hills (1991)	Case report	Very Low	n/a	Very Low
Freeman et al. (1997)	RCT	High	Selection bias – Unclear risk; Detection bias – High risk; Performance bias – High risk; Reporting bias – Unclear risk	Low
Peterson (2001)	Case report	Very Low	n/a	Very Low
Grasso et al. (2005)	Before-and-after comparison study	Low	Selection bias – High risk; Performance bias – High risk; Reporting bias – Unclear risk	Very Low
Capello et al. (1995)	Case Report	Very Low	n/a	Very Low
Kinnmann et al. (1997)	Before-and-after comparison study	Low	Selection bias – High risk; Detection bias – High risk; Performance bias – High risk; Reporting bias – High risk	Very Low
Flensner and Lindencrona (1999)	Case series	Very Low	n/a	Very Low
Kinnmann et al. (2000)	Case report	Very Low	n/a	Very Low
Flensner and Lindencrona (2002)	Case series	Very Low	n/a	Very Low
Baker et al. (2007)	Randomised crossover trial	Moderate	Selection bias – Unclear risk; Performance bias – High risk; Reporting bias – Unclear risk	Low

Conclusions

- Effectiveness of physical rehabilitation interventions in non-ambulatory PwMS remains unclear
- Though results suggest positive benefits, conclusions cannot be drawn due to **small numbers** and **poor quality studies**

Implications of the review

- Lack of focus on effects of interventions on carers
- Apparent lack of suitable outcome measures
  - Lack of outcome measures at participation level
- Importance of evaluating non-ambulatory PwMS separately
- Challenging population to research
  - Varied and complex disabilities
  - Cognition, memory and communication difficulties
- Despite the challenges, attempts must be made to improve quality and quantity of research in non-ambulatory PwMS

How can we build the evidence base?

- Medical Research Council framework:
  - Development
    1. Qualitative and quantitative
    2. Appropriate outcome measures
    3. Suitable interventions
  - Piloting
  - Evaluating
    - High quality methodologies
  - Reporting
  - Implementation

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