The methodological quality of aphasia research: an investigation using the PsycBITE™ database

Evidence based practice (EBP) poses challenges to clinicians and researchers. The quantum of information on the Internet results in clinicians being faced with the time consuming nature of doing searches, and then the daunting task of judging the methodological quality of papers (Vallino–Napoli & Reilly 2004). Additionally, there is a lack of explicit standards to judge the quality of designs. This paper presents a database resource called the Psychological database for Brain Injury Treatment Efficacy (PsycBITE™) which was developed to help clinicians and researchers address these issues. It promotes efficient evaluation and implementation of evidence-based interventions for people with acquired brain injury (ABI). PsycBITE™ is modelled on the Physiotherapy Evidence Database (PEDro)(Herbert, Moseley & Sherrington, 1998/99) and is freely available on the internet (http://www.psycbite.com).

The method for establishing PsycBITE™ has been described elsewhere (McDonald, Tate, Togher et al., 2006; Tate, Perdices, McDonald, et al, 2004) and is summarised as follows: Seven existing databases (Medline, PsycINFO, EMBASE, ERIC, AMED, CINAHL and The Cochrane library) are auto-searched using 85 reference terms. Results of these searches are manually screened and included in PsycBITE™ if they meet 5 criteria: (1) the report is a full length paper published in a peer-reviewed journal, (2) the participants are human with ABI and (3) over 5 years of age, (4) treatment comprises at least one intervention that is psychologically based and/or targets at least one psychological consequence of ABI, and (5) the report provides empirical data regarding treatment efficacy. Selected reports are indexed using 73 terms that cover 5 broad domains: (1) target area (e.g., aphasia), (2) intervention (e.g., communication treatment), (3) neurological group (e.g., stroke), (4) method (e.g., RCT), and (5) age group.

Reports on PsycBITE™ of randomised controlled trials (RCTs), non –RCTs (NRCTs) and Case series (CSs) are then rated for methodological rigor using the 11-point PEDro scale (Maher, Sherrington, Herbert, Moseley & Elkins, 2003). This scale assesses the internal validity of a trial and whether it contains sufficient statistical information to make it interpretable (Appendix 1). The first item relates to external validity, and is not counted in the final methodological quality rating score which is out of 10. It has acceptable inter-rater reliability (Maher et al, 2003) and has been extensively used to rate research reports published on PEDro. As single subject design studies are different to RCTs, requiring a different set of criteria for judging methodological rigor, a rating scale is being designed for this purpose.

This paper provides a preliminary investigation of methodologies and methodological quality ratings of a sample of RCTs, NRCTs and CS papers used to study aphasia treatment efficacy. The following questions are addressed:

1. What type and frequency of research designs are used in aphasia treatment studies as listed on PsycBITE™?
2. What is the methodological quality of RCTs, NRCTs and CS of aphasia treatment efficacy as measured by the methodological quality rating (MQR) using the PEDro scale?
3. What proportion of RCTs, NRCTs and CS aphasia treatment studies meet each of the criteria on the PEDro scale?
Method
A search was completed on 19 December, 2006, of all papers in the target area Communication/Language/Speech on the PsycBITE™ database. Papers were excluded if they were indexed for dementia, motor speech disorders, voice and/or social skills. Papers were then listed according to the methodology used (i.e., Systematic review (SR), RCT, NRCT, CS, single subject design (SSD)) and a mean methodological quality rating (MQR) score was determined for RCTs, NRCTs and CS, based on the PEDro scale. Maximum MQR scores for RCT, NRCT and CS are 10/10, 8/10 and 2/10 respectively. SR receives no MQR, and an SSD rating scale is in development. Finally, the rate of compliance of RCTs, NRCTs and CSs for the criteria on the PEDro scale was analysed. All papers included in this paper had confirmed ratings indicating that two raters agreed on 100% of ratings or, in the case of disagreement, a third independent rater also rated the paper to reach 100% agreement.

Results
Of the 1683 papers currently listed on PsycBITE™, 407 were listed in the target area Communication/Language/Speech and, of these, 310 investigated aphasia treatment efficacy. Of these, 8 were Systematic Reviews (SR) (3%), 22 were RCTs (7%), 17 were NRCTs (5%); 48 were CS (15%) and 215 Single Subject Designs (SSD) (69%) (Figure 1). Of these, 26 papers have confirmed ratings including 9 RCTs, 5 NRCTs and 12 CS papers (Appendix 2).

The mean methodological quality ratings (MQR) for RCTs (n=9) was 4.4 (S.D. = 1.2, range = 2-6), for NRCTs (n=5) was 2.2 (S.D. = 0.8, range 1-3) and for CS (n=12) the mean MQR was 0.8 (S.D. = 0.7, range = 0-2).

The rate of compliance with each of the PEDro criteria varied across research designs (Figure 2). With RCTs 67% of papers addressed eligibility criteria (Criterion 1), all were randomised (Criterion 2), but only 22% of papers concealed allocation (Criterion 3), 44% of papers matched the groups statistically at baseline (Criterion 4), none blinded the participants or therapists (Criterion 5 & 6); 56% blinded the assessors (Criterion 7), 67% provided data on ≥ 85% of the participants post treatment (Criterion 8), none addressed intention to treat (Criterion 9), 89% provided between group statistical comparison data (Criterion 10) and 67% provided statistical variability data (Criterion 11). Results for NRCTs and CSs are in Table 2. NRCTs can only receive a score of up to 8 out of 10 (losing two points due to lack of randomisation and lack of concealed allocation). However, none of the NRCTs used blinded assessors, or intention to treat analysis, and only 60% provided data regarding variability of their findings. Similarly, CS were poorly described, with incomplete eligibility criteria, high drop-out rates and poor statistical reporting.

Discussion
Incorporating EBP into clinical practice is a complicated process. The challenges include describing acceptable forms of evidence, accessing these effectively and reasonably applying EBP to the satisfaction of clients, administrators and funding agencies (Bernstein Ratner, 2006). PsycBITE™ was developed by a multidisciplinary team of clinician/researchers to begin to address these challenges. It has proven to be a valuable research tool in investigating the research
design types and methodological quality of ABI treatment studies (Perdices et al., 2006). The PsycBITE™ database is also being used by clinicians in EBP networks in Australia who use the results of PsycBITE™ searches to determine the papers upon which they will base their critically appraised topics (Worrall & Bennett, 2001).

Moseley, Sherrington, Herbert & Maher (2000) suggest a score of 5 or above on the PEDro Scale is indicative of a well designed, well conducted RCT. While this is a small sample of papers, the mean MQR for aphasia RCTs was 4.4/10. Some criteria, such as blinding participants and therapists, are only possible in pharmacological trials. However, it is possible, to blind the assessor. Just over half the aphasia papers (56%) complied with this criterion, therefore for the remaining papers, observer bias may have been a confounding influence. There was poor compliance with other fundamental criteria such as groups being statistically similar at baseline and presentation of statistical data. Compliance was even poorer in NRCT and CS designs. Clearly, there is much to be done in improving research design in the field of aphasia treatment research.

References


Figure 1. Methodological designs used in aphasia treatment

SR = Systematic review
RCT = Randomised controlled trial
NRCT = Non Randomised controlled trial
CS = Case Series
SSD = Single subject design
Figure 2. Percentage of Randomised controlled trials, Non-RCTS and Case Series meeting criteria on the PEDro scale

- **Pedro criteria**
  1 = eligibility criteria, 2 = random allocation, 3 = concealed allocation, 4 = groups similar at baseline, 5 = blinded subjects, 6 = blinded therapists, 7 = blinded assessor, 8 = $\geq 85\%$ of subjects data at post treatment, 9 = intention to treat analysis, 10 = between group statistical comparison, 11 = measures of variability

- **Percentage of papers meeting criterion**
- **PEDro criteria**
  - RCT n=9
  - NRCT n=5
  - CS n=12
Appendix 1: Criteria comprising the PEDro Scale
(Herbert, Moseley & Sherrington, 1998/99)

1. eligibility criteria of subjects were specified (not included in MQR Score)
2. subjects were randomly allocated to interventions (in a crossover study, subjects were randomly allocated an order in which treatments were received)
3. allocation was concealed
4. the intervention groups were similar at baseline regarding the most important outcome measures and prognostic indicators
5. there was blinding of ≥ 95% of subjects
6. there was blinding of ≥ 95% of therapists who administered the therapy
7. there was blinding of ≥ 95% of assessors who measured at least one key outcome
8. measures of at least one key outcome were obtained from ≥ 85% of the subjects initially allocated to groups
9. all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”
10. the results of between-intervention group statistical comparisons are reported for at least one key outcome
11. the study provides both point measures and measures of variability for at least one key outcome
## Appendix 2: Details of aphasia treatment efficacy studies (N=26)

<table>
<thead>
<tr>
<th>Author/s</th>
<th>Year</th>
<th>Title</th>
<th>Citation</th>
<th>Research design</th>
<th>PEDro rating (/10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aftonomos LB, Appelbaum JS, Steele RD</td>
<td>1999</td>
<td>Improving outcomes for persons with aphasia in advanced community-based treatment programs</td>
<td>Stroke 1999 30(7):1370-1379</td>
<td>CS</td>
<td>1</td>
</tr>
<tr>
<td>Aftonomos LB, Steele RD, Wertz RT</td>
<td>1997</td>
<td>Promoting recovery in chronic aphasia with an interactive technology</td>
<td>Archives of Physical Medicine and Rehabilitation 1997 78(8):841-6</td>
<td>CS</td>
<td>0</td>
</tr>
<tr>
<td>Buckwalter KC, Cusack D, Beaver M, Sidles E, Wadle K</td>
<td>1988</td>
<td>The behavioral consequences of a communication intervention on institutionalized residents with aphasia and dysarthria</td>
<td>Archives of Psychiatric Nursing 1988 2(5):289-95</td>
<td>CS</td>
<td>1</td>
</tr>
<tr>
<td>Crerar MA, Ellis AW, Dean EC</td>
<td>1996</td>
<td>Remediation of sentence processing deficits in aphasia using a computer-based microworld</td>
<td>Brain and Language 1996 52:229-275</td>
<td>RCT</td>
<td>3</td>
</tr>
<tr>
<td>Elman RJ, Bernstein-Ellis E</td>
<td>1999</td>
<td>The efficacy of group communication treatment in adults with chronic aphasia</td>
<td>Journal of Speech Language and Hearing Research 1999 42(2):411-419</td>
<td>RCT</td>
<td>4</td>
</tr>
<tr>
<td>Hartman J, Landua WM</td>
<td>1987</td>
<td>Comparison of formal language therapy with supportive counselling for aphasia due to acute vascular accident</td>
<td>Archives of Neurology 1987 44:646-649</td>
<td>RCT</td>
<td>5</td>
</tr>
</tbody>
</table>
Hickin J, Best W, Herbert R, Howard D, Osborne F
Hinckley JJ, Patterson JP, Carr TH
Hoen M, Golembiowski M, Guyot E, et al
Kagan A, Black SE, Duchan FJ, Simmons-Mackie N, Square P
Katz RC, Wertz RT
Lincoln NB, McGuirk E, Mulley GP, Lendrem W, Jones AC, Mitchell JR
Marshall RC, Karow CM, Freed DB, Babcock P
Voinescu I, Mihailescu L
Shewan C, Kertesz A
Sparks R, Helm N, Albert ML
Voinescu I, Mihailescu L

2002 Phonological therapy for word-finding difficulties: A re-evaluation
2001 Differential effects of context- and skill-based treatment approaches: Preliminary findings
2003 Training with cognitive sequences improves syntactic comprehension in agrammatic aphasics
2001 Training volunteers as conversation partners using "Supported Conversation for Adults with Aphasia" (SCA): A controlled trial
1992 Computerized hierarchical reading treatment in aphasia
1984 Effectiveness of speech therapy for aphasic stroke patients. A randomised controlled trial
2002 Effects of personalised cue form on the learning of subordinate category names by aphasic and non-brain damaged subjects
1981 Efficiency of methods based on the divergent principle in the therapy of aphasia
2001 Constraint-induced therapy for chronic aphasia after stroke
1984 Effects of Speech and language treatment on recovery from aphasia
1974 Aphasia rehabilitation resulting from melodic intonation therapy
1980 Grammar disorders in aphasics' narrative speech and their treatment
1986 Comparison of clinic, home, and deferred language treatment for aphasia: A Veterans Administration cooperative study

Phonasiology 2002 16(10-11):981-999
Neuroreport 2003 14(3):495-9
Journal of Speech Language and Hearing Research 2001 44(3):624-38
Aphasiology 1992 6(2):165-177
Lancet 1984 1(8388):1197-1200
Aphasiology 2002 16(7):763-771
Stroke 2001 32(7):1621-6
Brain and Language 1984 23:272-299
Cortex 1974 10:303-316
Neurologie et Psychiatrie 1980 18(2):107-114
Archives of Neurology 1986 43(7):653-658

RCT = randomized controlled trial. Non RCT = Non randomized controlled trial, CS = Case Series