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 (Appendix2).

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 (Criteria 5 & 6); 56% blinded the assessors (Criterion 7), 67% provided data on $\geq$ 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.

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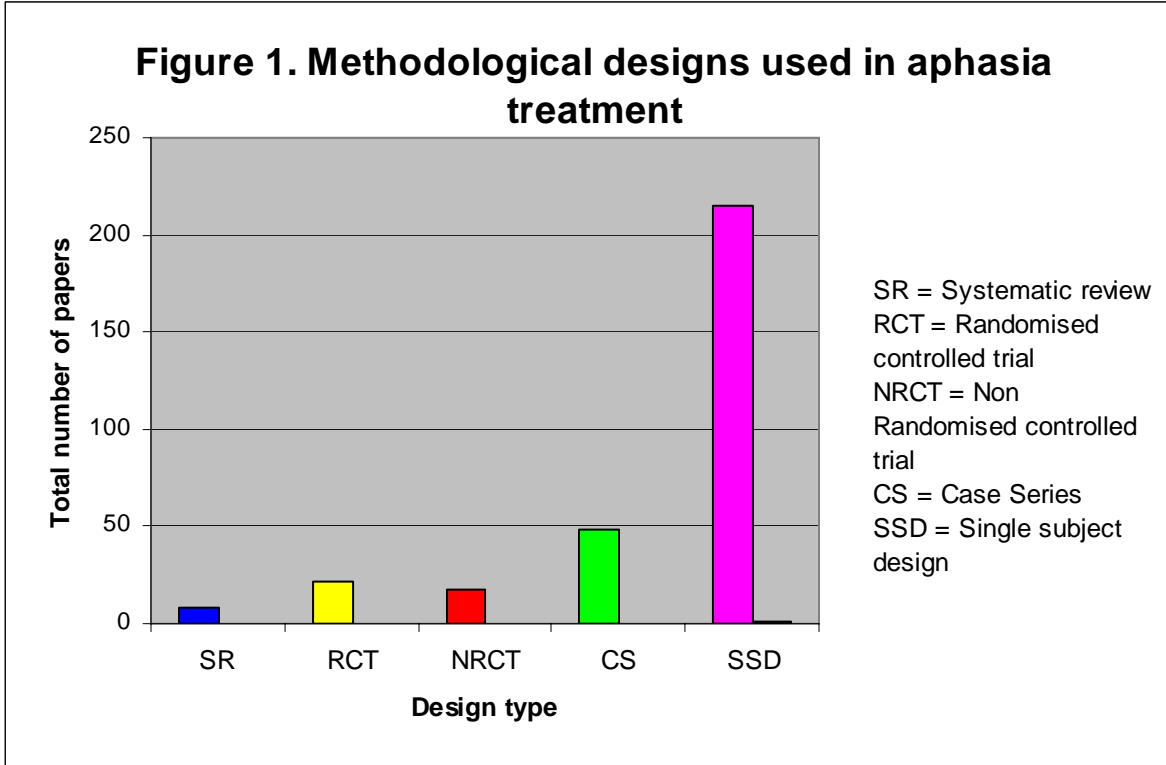
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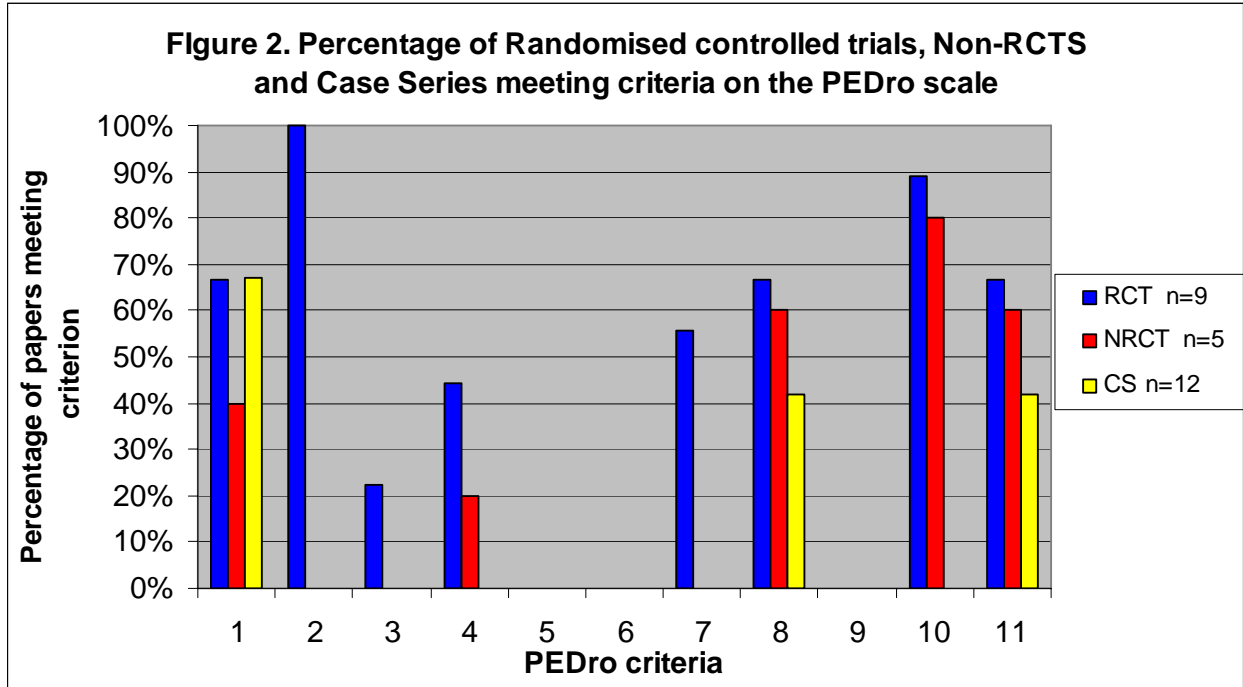
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Figure 1. Methodological designs used in aphasia treatment

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

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

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 $\geq$ 95% of subjects

6. there was blinding of $\geq$ 95% of therapists who administered the therapy

7. there was blinding of $\geq$ 95% of assessors who measured at least one key outcome

8. measures of at least one key outcome were obtained from $\geq$ 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)

Author/s	Year	Title	Citation	Research design	PEDro rating (/10)
Aftonomos LB, Appelbaum JS, Steele RD	1999	Improving outcomes for persons with aphasia in advanced community-based treatment programs	Stroke 1999 30(7):1370-1379	CS	1
Aftonomos LB, Steele RD, Appelbaum JS, Harris VM	2001	Relationships between impairment-level assessments and functional-level assessments in aphasia: Findings from LCC treatment programmes	Aphasiology 2001 15(10-11):951-964	CS	2
Aftonomos LB, Stelle RD, Wertz RT	1997	Promoting recovery in chronic aphasia with an interactive technology	Archives of Physical Medicine and Rehabilitation 1997 78(8):841-6	CS	0
Aten JL, Caligiuri MP, Holland AL	1982	The efficacy of functional communication therapy for chronic aphasic patients	Journal of Speech and Hearing Disorders 1982 47(1):93-96	CS	2
Avent JR, Wertz RT	1996	Influence of type of aphasia and type of treatment on aphasic patients' pragmatic performance	Aphasiology 1996 10(3):253-265	Non RCT	3
Avent JR, Wertz RT, Auther LL	1998	Relationship between language impairment and pragmatic behavior in aphasic adults	Journal of Neurolinguistics 1998 11(1-2):207-221	Non RCT	3
Best W, Herbert R, Hickin J, Osborne F, Howard D	2002	Phonological and orthographic facilitation of word-retrieval in aphasia: Immediate and delayed effects	Aphasiology 2002 16(1-2):151-168	CS	1
Buckwalter KC, Cusack D, Beaver M, Sidles E, Wadle K	1988	The behavioral consequences of a communication intervention on institutionalized residents with aphasia and dysarthria	Archives of Psychiatric Nursing 1988 2(5):289-95	CS	1
Buckwalter KC, Cusack D, Sidles E, Wadle K, Beaver M	1989	Increasing communication ability in aphasic/dysarthric patients	Western Journal of Nursing Research 1989 11(6):736-47	CS	0
Carlomagno S, Pandolfi M, Labruna L, Colombo A, Razzano C	2001	Recovery from moderate aphasia in the first year poststroke: Effect of type of therapy	Archives of Physical Medicine and Rehabilitation 2001 82(8):1073-80	CS	1
Crerar MA, Ellis AW, Dean EC	1996	Remediation of sentence processing deficits in aphasia using a computer-based microworld	Brain and Language 1996 52:229-275	RCT	3
Elman RJ, Bernstein-Ellis E	1999	The efficacy of group communication treatment in adults with chronic aphasia	Journal of Speech Language and Hearing Research 1999 42(2):411-419	RCT	4
Hartman J, Landua WM	1987	Comparison of formal language therapy with supportive counselling for aphasia due to acute vascular accident	Archives of Neurology 1987 44:646-649	RCT	5

Hickin J, Best W, Herbert R, Howard D, Osborne F	2002	Phonological therapy for word-finding difficulties: A re-evaluation	Aphasiology 2002 16(10-11):981-999	CS	1
Hinckley JJ, Patterson JP, Carr TH	2001	Differential effects of context- and skill-based treatment approaches: Preliminary findings	Aphasiology 2001 15(5):463-476	RCT	2
Hoen M, Golembiowski M, Guyot E, et al	2003	Training with cognitive sequences improves syntactic comprehension in agrammatic aphasics	Neuroreport 2003 14(3):495-9	CS	1
Kagan A, Black SE, Duchan FJ, Simmons-Mackie N, Square P	2001	Training volunteers as conversation partners using "Supported Conversation for Adults with Aphasia" (SCA): A controlled trial	Journal of Speech Language and Hearing Research 2001 44(3):624-38	RCT	6
Katz RC, Wertz RT	1992	Computerized hierarchical reading treatment in aphasia	Aphasiology 1992 6(2): 165-177	RCT	5
Lincoln NB, McGuirk E, Mulley GP, Lendrem W, Jones AC, Mitchell JR	1984	Effectiveness of speech therapy for aphasic stroke patients. A randomised controlled trial	Lancet 1984 1(8388):1197-1200	RCT	5
Marshall RC, Karow CM, Freed DB, Babcock P	2002	Effects of personalised cue form on the learning of subordinate category names by aphasic and non-brain damaged subjects	Aphasiology 2002 16(7):763-771	CS	0
Voinescu I, Mihailescu L	1981	Efficiency of methods based on the divergent principle in the therapy of aphasia	Neurologie et Psychiatrie 1981 19(2): 151-157	Non RCT	1
Pulvermuller F, Neininger B, Elbert T, et al	2001	Constraint-induced therapy for chronic aphasia after stroke	Stroke 2001 32(7):1621-6	RCT	5
Shewan C, Kertesz A	1984	Effects of Speech and language treatment on recovery from aphasia	Brain and Language 1984 23:272-299	Non RCT	2
Sparks R, Helm N, Albert ML	1974	Aphasia rehabilitation resulting from melodic intonation therapy	Cortex 1974 10:303-316	CS	0
Voinescu I, Mihailescu L	1980	Grammar disorders in aphasics' narrative speech and their treatment	Neurologie et Psychiatrie 1980 18(2):107-114	Non RCT	2
Wertz RT, Weiss DG, Aten JL, et aL.,	1986	Comparison of clinic, home, and deferred language treatment for aphasia: A Veterans Administration cooperative study	Archives of Neurology 1986 43(7):653-658	RCT	5

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