RHSC 501-RS705 Assignment 2 CAT

At this time, there is insufficient evidence to determine whether bilateral arm training (BAT) or modified constraint - induced therapy (mCIMT) is more effective in producing improved ADL performance of older adults with stroke.

Prepared by: Ardith L. Richter, B.Sc.(O.T.), UBC M.R.Sc. Student
                      a.p.richter@telus.net
Date: Nov. 11, 2010
Review date: Nov. 11, 2012

CLINICAL SCENARIO:
Many Canadians will suffer from a stroke - approximately 2 out of every 1000 residents. (2006 Canadian Census indicates ± 32,000,000 residents. The Heart and Stroke Foundation of Canada (2010) reports > 50,000 Canadians suffering a stroke/year.)   Up to 75% of these individuals are left with some level of disability (Canadian Heart and Stroke Foundation, 2010).   Many of these individuals will require some form of rehabilitation.   This is a comparison of the effectiveness of two of the more recently developed, often used, treatment approaches for people who have had upper extremity issues post stroke.

FOCUSED CLINICAL QUESTION: Is BAT or mCIMT more effective in producing improvement in affected UE ADL performance post stroke/CVA?

SUMMARY of Search, 'Best' Evidence' Appraised, and Key Findings:
- Despite an in depth search, only two studies were found that compared BAT to mCIMT.
- The best study met all of the inclusion criteria except the age of the clients. They ranged from 23 to 81 years.   Unfortunately, no good quality study was available to address this question exclusively for older adults.   As such, the focused clinical question changed slightly to reflect this.
- Two very recent Cochrane Database systematic reviews were acquired. Neither of them compared BAT to mCIMT. Both reviews stated that no BAT or mCIT research has good enough evidence to justify either treatment approach.

CLINICAL BOTTOM LINE: Much more research utilizing randomized controlled trials (RCT's) with much larger sample sizes and much longer follow up periods is required to determine which treatment is most effective – if either actually is.

Limitation of this CAT: This critically appraised topic was prepared for a graduate course assignment and has not been peer-reviewed by any other independent person such as an instructor.

SEARCH STRATEGY:
Terms used:
- **P**atient/Client Group: older adult > 65 years of age, 6-12 months post CVA with residual motor impairment
- **I**ntervention (or Assessment):   BAT (bilateral arm training)
- **C**omparison: mCIMT/dCIT (modified/distributed constraint induced movement therapy)
- **O**utcome(s): maximizing independence in ADL as measured by the FIM

Databases/Sites Searched	Search Terms	Limits
1st CINAHL (Ebsco Host) Medline Embase PubMed Scopus	"Stroke or cerebrovascular accident or CVA" AND >65 years of age AND * "Bilateral upper extremity therapy OR upper extremity treatment" AND FIM OR FIM Instrument, or "functional status" (*second search was the same, however used mCIMT instead of bilateral treatment/therapy)	English language Reports occurring in the last 15 years Only human studies
2nd Ebsco Host Alerts	These were requested and sent to me regarding the most recent advances in treatments for CVA/stroke	Adults >65 English
Gather pertinent articles from reference lists of first articles found	BAT mCIMT	Adults 2003 and newer English
3rd PEDro OT Seeker Cochrane Database	Bilateral Upper Extremity Therapy Bilateral Upper Extremity Treatment Constraint Induced Therapy (or TX.) modified CIT (mCIMT)	Adult English

INCLUSION and EXCLUSION CRITERIA
- Inclusion:
  - 6-12 months post CVA
  - ≥ 24/30 MMSE
  - Able to give consent
  - Mild to moderate impairment of affected upper extremity

- Exclusion:
  - Medically unstable
  - Severe impairment or excessive spasticity of affected upper extremity/hand
  - Other significant pain, neurological, or orthopaedic conditions affecting the "affected" upper extremity
  - Involvement of the cerebellum or the brainstem
  - Visual field deficits

RESULTS OF SEARCH

4 relevant studies were located and categorised as shown in Table 1, based on Levels of Evidence from Oxford Centre for Evidence-based Medicine, March 2009**.
(Two articles specifically addressed the focused clinical question, Cochrane Reviews gave an important overall view of where BAT and mCIMT research is at present).

Table 1: Summary of Study Designs

Study Design/ Methodology of Articles Retrieved	Level**	Author (Year)	Sources of Evidence
RCT (randomized control trial)	1b	Lin, K., Chang, Y., Wu, C., and Chen, Y. (June, 2009).	Medline Embase Pub Med CINAHL
Low Quality RCT	2b	Hayner, K., Gibson, G., and Giles, G.M. (2010)	Pub Med CINAHL
Systematic Review of RCT's and "quasi" RCT's	1a, 1b, 2b	Sirtori, V., Corbetta, D., Moja, L., and Gatti, R. (2009)	Cochrane Library/ Database
Systematic Review	1a, 1b	Coupar, F., Pollock, A., van Wijck, F., Morris, J., and Langhorne, P. (2010)	Ebsco Host Alert followed by Cochrane Library/Database

BEST EVIDENCE

Lin et al. (June, 2009) was identified as the 'best' evidence and selected for critical appraisal. Reasons for selecting this study were:

- Provided a comparison between the relevant treatment approaches, BAT vs mCIMT

- Randomized control trial with an "attention control group" (Law et al., 1998, p. 341 in Law and MacDermid [EDs.], 2008).

- Baseline comparison of the three groups indicated no significant differences statistically.

SUMMARY OF BEST EVIDENCE

Table 2: Description and appraisal of: Effects of constraint-induced therapy versus bilateral arm training on motor performance, daily functions, and quality of life in stroke survivors. **RCT by Lin et al., 2009.**

Objective of the Study/Systematic Review:
To examine the current literature regarding two very commonly used neurological upper extremity treatment options, comparing which is most effective for maximizing a person's abilities to function in daily activities, post stroke.

Study Design:
RCT with blinding of assessors. Randomized allocation was concealed. Outcome measures (FMA, FIM, MAL, and SIS) were utilized pre-intervention, and after 3 weeks of intervention.

Setting:
- Outpatient departments of three urban hospitals and one urban rehabilitation clinic.
- At home practice for only the mCIMT/dCIT group.

Participants:
- 60 participants; 20 participants randomly allocated to one of three treatment groups (mCIMT, BAT, control). Groups were similar in demographics as well as clinical characteristics prior to the interventions, there were no dropouts.

- 34 men, 26 women mean age of 52.14 years
- purposive recruitment of participants from outpatient programs in these rehabilitation centers. Consent was obtained from participants.
- diagnosis of unilateral stroke, deemed eligible through screening by trained occupational therapists. Both hemorrhagic and ischemic CVAs included.

Therapists ensured participants:
- > 6 months post CVA.
- ≥ 24 on the MMSE
- significant nonuse of affected upper extremity (UE) - (<2.5 on the MAL)
- no excessive spasticity in any part of affected UE – MAS ≤2
- score above Brunnstrom III for proximal and distal parts of UE
- no balance problems that would jeopardize a participant's safety
- no participation in any experimental rehabilitation or drug studies in previous 6 months.

Interventions Investigated:
- all participants had intensive outpatient treatment from an occupational therapist (O.T.), 2 hours/day x 5 days/week x 3 weeks, in addition to participant's other interdisciplinary treatments.

1) – **control group** involved training for hand function, coordination, balance, and movements of the affected UE, as well as compensatory practice for functional tasks.

2) - **BAT group** used both affected and unaffected arms to do either symmetrical or alternating UE tasks – i.e. picking up two cups, picking up 2 pegs, reaching upwards or forwards to move items, grasping and releasing 2 towels etc.

3)- **mCIMT group** wore mitten on unaffected UE. Involved in activities such as: reaching upwards and forwards whilst moving a cup, picking up coins, using utensils whilst eating, grasping and releasing blocks, and other daily activities with the affected UE. The level of difficulty was increased as client's affected UE abilities increased. *mCIMT group also did therapy at home. They wore constraint mitten on unaffected limb 6 hours/day whilst performing daily activities.*

Outcome Measures *(used pre- intervention and after 3 weeks tx.):*
1) FMA (Fugl-Meyer Assessment): evaluates motor impairment.
a) composite, b) proximal, and c) distal UE motor scores.   Maximum composite score is 66.   Each subtest for the score uses a 3 pont ordinal scale.   Higher scores indicate better motor control.   Test–retest and interrater reliability, and construct validity are well established.
2) FIM (Functional Independence Measure): 18 items of daily functioning, 6 subscales - self-care, sphincter control, transferring, locomotion, communication, & social cognition. Scores range from 1-7 for each of the 18 items, lower scores indicate the need for more assistance. Max. Score 126.   Good interrater reliability and validity.
3) MAL (Motor Activity Log): evaluates use of affected arm in real world situations – uses semistructured interview. Assesses amount of use (AOU) and quality of movement (QOM) of affected UE in 30 important daily activities. Uses 6 point ordinal scale, and higher scores indicate better performance.   MAS has good interrater reliability, construct validity, internal consistency. Overall score not clarified by researchers.
4) SIS (Stroke Impact Scale) Verson 3:   measures changes in quality of life.   Self-report scale. 8 functional domains (59 items) including strength, memory, emotion, communication, activities of daily living (ADL)/(IADL), mobility, hand function and participation.   Uses 5 point ordinal scale. Higher scores indicate better recovery. Good reliability and validity.   Authors did not clarify maximum score.

3 certified O.T.'s trained to give these four assessments, each of whom evaluated for competence by the senior certified O.T..   There was high interrater reliability >0.95 for the FIM and FMA scores.

MAIN FINDINGS:

		PRETREATMENT			POST TREATMENT			ANCOVA	
		(•n=20 for all groupings in table below)							
		•mCIMT	•BAT	•Con	•mCIMT	•BAT	•Con	P	Effect Size r
FMA (overall)	Mean and SD	46.05 ±8.30	45.50 ±10.35	49.75 ±12.10	52.30 ±7.17	52.25 ±9.06	51.25 ±12.59	<.001	.51
	95% C.I.	42.17 To 49.93	40.66 To 50.34	44.09 To 55.41	48.94 To 55.65	48.01 To 56.49	45.36 To 57.14		0.088 To 1.038
FIM	Mean and SD	119.4 ±8.34	116.7 ±12.83	114.3 ±10.27	122.05 ±5.60	119.2 ±10.7	116.65 ±8.34	.350	.19
	95% C.I.	115.50 To 123.30	110.70 To 122.70	109.49 To 119.11	119.43 To 124.67	114.1 To 124.2	112.75 To 120.55		0.283 To 0.667
MAL (AOU)	Mean and S.D.	1.03 ±0.81	1.11 ±1.09	0.85 ±1.07	1.76 ±0.86	1.31 ±0.95	0.99 ±1.16	.012	.38
	95% C.I.	0.651 To 1.409	0.600 To 1.620	0.349 To 1.351	1.358 To 2.162	0.865 To 1.755	0.447 To 1.532		0.075 To 0.875

MAL (QOM)	Mean and S.D.	1.02 ±0.74	1.14 ±0.86	0.90 ±1.21	1.96 ±0.85	1.45 ±1.00	1.16 ±1.27	.005	.41
	95% C.I.	0.674 To 1.366	0.738 To 1.542	0.344 To 1.466	1.562 To 2.358	0.982 To 1.918	0.566 To 1.754		0.039 To 0.911
SIS	Mean and S.D.	66.26 ±10.04	64.36 ±15.77	64.36 ±9.33	73.29 ±10.78	64.22 ±15.6	64.92 ±13.08	.005	.42
	95% C.I.	61.56 To 70.96	56.98 To 71.74	59.99 To 68.73	68.24 To 78.34	56.94 To 71.50	58.80 To 71.04		0.027 To 0.923

Original Authors' Conclusions:

a) BAT improved motor function of the affected proximal UE better than mCIMT.

b) mCIMT improved functional use of the affected arm in ADL/IADL, improved functional independence such as locomotion, and also improved quality of life better than BAT

c) The authors felt it necessary to closely scrutinize the results of different components/factors of each of the 4 main outcome measures – to see what treatment had the most beneficial effect.

CRITICAL APPRAISAL: From table above.

1) The confidence intervals (C.I's) for the 5 main composite scores indicate that FMA improved most with BAT. For FIM, MAL (AOU & QOM), and SIS – mCIMT was the best treatment.

2) Effect sizes (r) indicate a significant difference (improvement) for those individuals who received either mCIMT or BAT (independent variables) with respect to FMA, MAL (AOU AND QOM), and SIS scores (dependent variables). This would be supported by the considerably smaller than 0.05 P values for these four composite scores - indicating that these positive outcomes did not occur just by chance (Greenhalgh, 1997, Article 5, p. 423).

3) In contrast, appears as if only statistically small improvements in functioning (FIM) occurred with either mCIMT or BAT. The r value was small and the P value was >>0.05. Whatever improvements were noted could have been entirely due to chance.

4) It appears as if both treatments help, BAT can assist with motor improvement, real functional change and improvement occurs with use of mCIMT. This interpretation agrees with the author's interpretation. One word of caution, however, with this positive interpretation.

The sample size was relatively small per group (only 20 each) and 11/21 of the P values in the author's original table were >>0.05, indicating that statistically, many of the subtest results were not significant. The power of the study was poor due to low sample size and this results in an elevated risk of type II errors – false negatives (as per MacDermid and Law, 2008, p. 127 in Law and MacDermid [Eds.], and Munro, 2005, p. 89). Due to low power it is difficult to determine the true effectiveness of these treatments. It would have been better if more subjects had been studied.

Validity:

I have chosen to use the Quality Index Score reviewed by Downs and Black (1998, pp. 377 – 384) as this tool evaluates more components of a research study than the PEDro Scale (June 21, 1999, Physiotherapy Evidence Database, Centre for Evidence-Based Physiotherapy, Australia).

Based on the Quality Index, this study scored 10/11 for Reporting, 2/3 for External Validity, 5/7 for Internal validity (bias), 5/6 Internal validity (looks at confounding), and 3/5 for power.   Overall score 25/32 = 78%.   This study seems to be fairly methodically sound.   The main areas of weakness were:

1) subjects and treating therapists were not blind to the study
3) principles of intention to treat were not utilized i.e. deviation from protocol esp. at home
4) Potential harms/ill effects of these two treatment approaches were not mentioned
5) power of the study was low to moderate
6) study of long term treatment effects was not done
7) all calculations were not completed i.e. confidence intervals for the treatment effects and the r values.   These would have significantly enhanced interpretation of the study results.

IMPLICATIONS FOR PRACTICE, EDUCATION and FUTURE RESEARCH

A) Based on the above critical appraisal, there seems to be some possibility of benefits to both of these treatment methodologies.   Much more research comparing the effectiveness of both of these treatment approaches is required.

B) In addition to determining which treatment approach is most effective, it appears that both methodologies need a considerable amount of study to ensure that they really are effective.   This as per the outcomes of the two Cochrane Reviews.   Certainly much larger sample sizes, much longer follow up after interventions, the reduction in potential bias, and utilizing intention to treat principles would certainly assist in generating a better evaluation of the potential usefulness of these two treatment methodologies. This is imperative to be able to provide excellent evidence-based care for our clients.

C) Currently, only a scaled down version of BAT and something similar to the study's control treatment are being used in our region. If better evidence justifying use of BAT and/or mCIMT becomes available, then there may be more of an impetus to educate therapists and treat CVA clients in this regard.

REFERENCES

Center for Evidence-Based Physiotherapy.   Musculoskeletal Division.   The George Institute for Global Health. P.O. Box M201, Missenden Rd. NSW   2050, Australia. (June 21, 1999). The PEDro Scale.   Retrieved November 3, 2010, from http://www.pedro.org.au/english/downloads/pedro-scale/

Coupar, F., Pollock, A., van Wijck, F., Morris, J., & Langhorne, P. (2010). Simultaneous bilateral training for improving arm function after stroke. *Cochrane Database of Systematic Reviews, 4.* Art. No.: CD006432. DOI:10.1002/14651858.CD006432.pub2.

Downs, S.H., & Black, N.   (1998). The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. *Journal of Epidemiological Community Health, 52,*377-384.

Greenhalgh, T. (1997) How to read a paper.   Statistics for the non-statistician.II: "Significant" relations and their pitfalls. *British Medical Journal, 315*, 422 – 425.

Hayner, K., Gibson, G., & Giles, G.M. (2010).   Research Scholars Initiative - Comparison of constraint-induced movement therapy and bilateral treatment of equal intensity in people with chronic upper-extremity dysfunction after cerebrovascular accident*.   American Journal of Occupational Therapy, 64,* 528 – 539. DOI: 10.5014/ajot.2010.08027

Heart & Stroke Foundation of Canada.   Statistics.   Stroke. Deaths, Prevalence and Effects.   Retrieved November 7, 2010, from
http://www.heartandstroke.com/site/c.ikIQLcMWJtE/b.3483991/k.34A8/Statistics.htm

Law, M., Stewart, D., Pollock, N., Letts, L., Bosch, J., & Westmorland, M. (2008). Appendix B: Guidelines for critical review form.   Quantitative studies.   In M. Law & J. MacDermid (Eds.), Evidence-based rehabilitation: A guide to practice (pp.335 - 346). Thorofare, NJ: Slack Incorporated.

Lin, K., Chang, Y., Wu, C., & Chen, Y. (2009).   Effects of constraint-induced therapy versus bilateral arm training on motor performance, daily functions, and quality of life in stroke survivors. *Neurorehabilitation and Neural Repair, 23,* 441-448. DOI:10.1177/1545968308328719.

MacDermid, J., & Law, M. (2008).   Evaluating the evidence.   In M. Law & J. MacDermid (Eds.), Evidence-based rehabilitation: A guide to practice (pp.121-142).   Thorofare, NJ: Slack Incorporated.

Munro, B.H. (2005).   Statistical Methods for Health Care Research, Fifth Edition (p.89). Philadelphia: Lippincott Williams & Wilkins.

REFERENCES CONTINUED… **p.2**

Oxford Centre for Evidence-based Medicine Levels of Evidence (March 2009).   Produced by Bob Philips, Chris Ball, Dave Sackett Doug Badenoch, Sharon Strauss, Brian Haynes, Martin Dawes since November 1998.   Updated by Jeremy Howick March 2009.   Retrieved September 7, 2010, from http://www.cebm.net

Sirtori, V., Corbetta, D., Moja, L., & Gatti, R. (2009). Constraint-induced movement therapy for upper extremities in stroke patients. *Cochrane Database of Systematic Reviews, 4.*   Art. No.: CD004433. DOI: 10.1002/14651858.CD004433.pub2.

Statistics Canada.   Population and dwelling counts, for Canada, provinces and territories, 2006 and 2001 censuses – 100% data.   Retrieved November 7, 2010, from
http://www12.statcan.gc.ca/census-recensement/2006/dp-pd/hlt/97-550/Print.cfm?T=101…