There is some Level 2b evidence (RCTs) of low methodological quality to support the use of Constraint-Induced Movement Therapy with children who have a hemiparesis

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CLINICAL SCENARIO:

Constraint-induced movement therapy (CIMT) and forced use therapy refer to restraining the unaffected arm of people with hemiplegia to "force" the affected arm into use. Restraint may range from wearing of a mitt which restricts grasp to immobilization of the limb in a plaster cast and/or a sling. The constraint may be in place for a few hours per day to most of the waking hours. In the form advocated by its chief proponent, Edward Taub, CIMT (but not forced use therapy) is also accompanied by intensive therapy (massed practice) to facilitate function in the affected arm. The underlying rationale for CIMT is that 'forcing' use of the affected arm reverses the learned non-use of the limb. Several reports of CIMT used with the adult stroke population have been published including a systematic review (Hakkennes & Keating, 2005), but it is not clear whether there is a place for CIMT in paediatrics.

FOCUSSED CLINICAL QUESTION: What is the evidence that constraint induced movement therapy (CIMT) is effective in improving upper limb function in children?

SUMMARY of Search, Best Evidence appraised, and Key Findings:

Three references reporting two randomised controlled trials (RCTs) were located:

- 1 published crossover design RCT - Level 2b evidence, PEDro score 2/10 (Willis et al., 2002).
- 1 unpublished crossover design RCT (a PhD dissertation) - Level 2b evidence, PEDro score 4/10 (DeLuca, 2002). This dissertation appears the have been published as Taub et al (2004) - Level 2b evidence, PEDro score 5/10.
- The first arm of both crossover design RCTs were appraised for this CAT. See 'Summaries of Best Evidence".

Results:

- Willis et al (2002) reported statistically significant improvement (without reporting variance), measured using the Peabody Developmental Fine Motor Scale (PDMS), at 1 and 6 months, in the treatment group receiving forced use therapy (1 month of casting) when compared with standard therapy.
- DeLuca (2002) found no difference between groups receiving CIMT (constraint plus massed practice) vs standard therapy at follow up (3 weeks) on the Quality of Upper Extremity Skills Test (QUEST), the Child Arm Use Test (CAUT) or on parent rating of quality of movement. There was some difference between groups on parent report of frequency of movement and emerging behaviours.
- In Taub et al.'s report of DeLuca's dissertation (2004) there was no mention that the QUEST was used an as outcome measure. Taub reported significant differences between groups on the CAUT. Taub also reported more improvement in emerging behaviours and frequency of use in the CIMT group. Thus, there are some inconsistencies between the DeLuca and Taub reports of the same study.

There were significant methodological weaknesses in each of these reports that reduces the confidence with which these results can be accepted.

CLINICAL BOTTOM LINE: There is weak evidence that CIMT, involving use of plaster cast with or without intensive practice, appears to improve upper limb function more than routine therapy alone, when used with children up to 8 years of age who have a hemiparesis.

Limitation of this CAT: This critically appraised paper has been peer-reviewed by one external person.

SEARCH STRATEGY:

Terms used to guide Search Strategy:

- **P**atient/Client: Nil
- **I**ntervention: Constraint induced movement therapy OR Forced use
- **C**omparison: Nil
- **O**utcome(s): Nil
- **L**imits: Terms relating to children and the arm/upper limb were used to limit searches in the databases where articles retrieved were too numerous to search,.

Sources Searched:
American Academy of Pediatrics
American Academy of Cerebral Palsy and Developmental Medicine
Centre for Clinical Effectiveness – Monash University
CINAHL
Cochrane Library
Embase
Medline
OT Seeker
PEDro
PsycINFO
University of Ottawa

INCLUSION and EXCLUSION CRITERIA

- Inclusion: Studies that evaluated upper limb outcomes of CIMT or forced use treatment in children.

RESULTS OF SEARCH

The most recent searches were conducted on May 5th 2006. Fourteen relevant studies were located and categorised as shown in Table 1 based on Levels of Evidence, Centre for Evidence Based Medicine (Phillips et al., 2001). The protocol for a Cochrane Systematic Review was also located (Hoare & Wasiak, 2002).

Table 1: Summary of Study Designs of Articles retrieved

Level of Evidence	Study Design/ Methodology of Articles Retrieved	Number Located
2b	RCT	*3 located* but 2 reported same study. (DeLuca, 2002; Taub et al., 2004; Willis et al., 2002)
3b	Non-randomised clinical trials	*2 located* (Eliasson et al., 2005; Sung et al., 2005)
4	Case series and studies	*10 located* (Charles et al., 2001; Crocker et al., 1997; DeLuca et al., 2003; Eliasson et al., 2003; Glover et al., 2002; Gordon et al., 2006; Karman et al., 2003; Naylor & Bower, 2005; Pierce et al., 2002; Yakusawa, 1990)

BEST EVIDENCE

The following articles were identified as the 'best' evidence and selected for critical appraisal. The reasons for selecting these papers were that they constitute the highest level of evidence on the topic and the only two RCTS in the area.

SUMMARY OF BEST EVIDENCE

Study 1 by Willis et al. (2002)

NB: This is a crossover trial; only the first arm of the study is appraised

Aim of the Study
To evaluate the effects of forced use therapy with children with hemiplegia.

Sample: 25 children with hemiparesis for at least 1 year, aged 1 to 8 years, were randomly allocated to the experimental or control group. Diagnoses included stroke, cerebral malformation, trauma and unknown.

Intervention Investigated: Experimental group: Plaster cast to the unaffected arm (proximal to the elbow to the fingertips) for 1-month plus children's routine upper limb physiotherapy and occupational therapy (mean = 1.4 visits per week). The control group continued with their routine upper limb physiotherapy and occupational therapy (mean = 2.1 visits per week). There was no information provided on the nature of this therapy.

Outcome Measures: Measured at baseline, 1 month and 6 months.
The sole outcome measure was the Peabody Developmental Motor Scales (PDMS) – Fine Motor. A fine motor quotient was obtained excluding bimanual tasks. It is not clear how this score would have been achieved nor what the range of possible scores for this scoring system would be. No variance was provided.

Results

Table 2: All recruited children – PDMS Fine Motor scores

	Baseline	**1 month**	
CIMT N=12	143.2	155.8	ANOVA P<0.0001
Control N=13	102.2	104.7	

Table 3: Children who returned at 6 months[#] - PDMS fine motor scores

	Baseline	**1 month**	**6 months**
CIMT N=7	140	153.9*	149*
Control N=10	117	114.4	112.8

[#] As this was a cross-over trial, there was incentive for the control participants to return for the 6-month assessment.
* Statistically Significant difference from baseline

Adverse events
This study reported no medical complications of casting but 15% of casts required repair or reapplication. No further mention of the presence or absence of adverse events was made.

Original Authors' Conclusions

One month of casting improved upper limb function in children with hemiplegia immediately after removal of the plaster cast (4 weeks) and at 6 months.

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Critical Appraisal of study by Willis et al (2002):

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Validity: *PEDro score = 2/10 (points allocated for random allocation and between group comparison for PDMS Fine Motor).*

- No power calculation was reported and the sample size (N=25) appears small.
- Baseline equivalence: It appears that the baseline scores for age and the PDMS scores are very different.
    - Age: The mean ages were not reported however the median and ranges for the groups were: treatment group - median = 4.5yrs, range = 3-6yrs; control group - median = 2yrs, range = 1-8yrs.
    - See Table 2 for the difference between groups on the baseline PDMS scores, which appears extremely large.
    - The authors report, however, that although there appears a difference between groups in the ages and PDMS scores at baseline the differences were not statistically significant. Despite this a PEDro scale point was not

awarded for baseline equivalence. No other demographic or baseline details were provided.

- No variance was provided so it was not possible to calculate CI or treatment effect.
- Readers assume that the all participants were assessed at 1 month (see legend of Figure 1 of paper). However, they also reported that "several" children withdrew from the study and had casts removed because of irritability – these numbers were not specified. The adequacy of follow up at 1 month is therefore not entirely clear. At 6 months only 7/12 experiment group participants and 10/13 control group children were followed up, a large total drop out rate of 32%.
- There was no blinding of any parties.
- It is not possible to determine the nature and possible range of PDMS scores and how the administration and scoring differed from the standardized approach.

Results: Poor reporting of this study makes interpretation of the results difficult. This is study of low methodological quality provides weak evidence in support of forced use therapy using casting for children with hemiparesis.

SUMMARY OF BEST EVIDENCE

Study 2a by DeLuca et al. (2002)

NB: This is a crossover trial; only the first arm of the study is appraised.

Aim of the Study

To evaluate effects of CIMT using plaster casting and massed practice.

Subjects: 18 children with CP with assymetric upper limb involvement. Mean age 41.5 months (ie. 3.5 years, range 7 months to 8 years); 13 males, 5 females. Children were recruited from local early interventions programmes (Birmingham, Alabama, USA).

Design: Cross over trial: Phase I involved random assignment (not described) of participants to either CIMT or Traditional Services (TS). In Phase II the TS group crossed over to CIT with casting. Only Phase I results are considered here.

Interventions Investigated:

- CIMT - casting with intensive movement therapy for 21 consecutive days. The less-involved arm was casted from the upper arm to fingertips and bivalved for weekly checks of skin and ROM. The intervention also included massed practice, that is, very intensive therapy (6 hours per day including operant training) to increase functional ability of the involved arm.
- Traditional Service (TS) = continued participation in existing upper limb interventions - mean of 2 hours / week.

Outcome Measures: Measured at baseline, 3 weeks (immediately after removal of plaster cast) and 6 weeks post baseline.

1. QUEST - Dissociated Movement Scale.

2. Child Arm Use Test (CAUT) - 21 items are videoed and rated according to Amount of Use (AOU) *[0 = no use to 2 = functional use]* and Quality of Movement (QOM) *[0 = no*

use to 5 = age appropriate use]. The videotapes were rated blinded to order and group by 2 raters; moderate to good interrater agreement was achieved. The test was developed by the research group and it has no other established psychometric properties.

3. Pediatric Motor Activity Log (PMAL). The PMAL lists 22 distinct upper limb functional tasks which parents rate on 2 scales: Frequency of Use *[0 = doesn't use to 5 = exclusive use of involved arm]* and Quality of Movement *[0 = doesn't use arm to 5 = normal quality]*. The test was developed by the research group and it has no established psychometric properties.

4. The Emerging Behaviours Scale (EBS) was developed by the researchers based on the observation that children receiving CIMT rapidly acquire new skills. The presence or absence of 31 motor patterns or functional activities are recorded. The EBS has no established psychometric properties.

Results

1. QUEST

Table 4: QUEST (Dissociated Movement Scale) for baseline and 3 weeks scores. Scale of scores is unknown

	CIMT	**TS**	**Diff bet means**	**95%CI***
Mean at Baseline (SD)	23.27 (18.02)	33.34 (29.07)		
Mean at 3 weeks (SD)	37.5 (24.06)	31.6 (31.58)	5.9	-22.2 to 34
Mean change at 3 weeks	14.23 (17.48)	-1.74 (16.02)	15.97	-0.8 to 32.7
Within group diffs	*p*=0.04 sig. diff	*NS*		

*Note that confidence intervals were calculated from available data.

Interpretation:
Although the within group analysis indicated that the CIMT group improved significantly whereas the TS group did not, analysis using ANCOVA indicated no significant differences between groups. Further, the 95% CI reinforces the lack of clinically important change for either the mean scores at 3 weeks or the mean change at 3 weeks.

2. CAUT

The author reported that there were no statistically or clinically important differences between groups.

3. PMAL – Frequency of Use and Quality of Movement.

Table 5a: PMAL - Frequency of use at baseline and 3 weeks. Scale of this test is from 0 to 5.

	CIMT	TS	Diff bet means	95 CI*
Mean at Baseline (SD)	0.79 (0.45)	1.11 (0.75)	1.66	0.6 to 2.7
Mean at 3 weeks (SD)	2.84 (1.14)	1.18 (0.82)		
Within group diffs	$p < 0.0001$	NS		

*Note that confidence intervals were calculated from available data.

Interpretation:
Using ANCOVA, analysis indicated that the CIMT group improved significantly more than the TS group (p<0.0001). The 95% CI supports this conclusion with seemingly clinical important differences being observed.

Table 5b: PMAL Quality of Movement at baseline and 3 weeks. Scale of this test is from 0 to 5.

	CIMT	TS	Diff bet means	95 CI*
Mean at Baseline (SD)	1.02 (0.62)	1.6 (1.2)	0.75	-0.4 to 1.9
Mean at 3 weeks (SD)	2.68 (0.97)	1.93 (1.12)		
Within group diffs	$p = 0.001$	NS		

*Note that confidence intervals were calculated from available data.

Interpretation:
Although analysis using ANCOVA indicated a significant improvement in the CIMT group (p<0.0001), the 95% CI indicates that there is no clinically important differences between groups.

4. EBS

Table 6: Emerging Behaviours Scale at baseline and 3 weeks. Scale of test is 0 to 31

	CIMT	TS	Diff bet means	95 CI*
Mean at Baseline (SD)	12.11 (5.64)	12.78 (6.51)	6.56	1.7 to 11.4
Mean at 3 weeks (SD)	21.56 (4.45)	15 (5.66)		
Mean change at 3 weeks	9.44 (2.19)	2.22 (1.86)	7.22	5.2 to 9.3
Within group diffs	$p = 0.001$	NS		

*Note that confidence intervals were calculated from available data.

Interpretation:
Analysis using ANCOVA indicated a significant improvement in the CIMT group. The 95% CI also indicate a clinically important difference between groups with the CIMT demonstrating more new behaviours than the TS group.

Adverse events
No mention was made of the presence or absence of adverse events.

Original Authors' Conclusions
Children demonstrated significant changes in many areas of upper extremity function in response to CIMT.

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Critical Appraisal of study by DeLuca (2002):

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Validity: PEDro score = 4/10 (points allocated for random allocation, assessor blinding for 1 outcome of interest (CAUT), between-group comparisons and reporting point estimates and variability).

The only outcome measure to have established psychometric properties is the QUEST.

Although the CAUT has not established properties, it was evaluated blinded to group membership, thus reducing some possible bias.

No analysis of demographic and baseline data was reported, however, the data appear to be equivalent between groups at baseline with the exception of the QUEST scores, see Table 4. Because the QUEST is the only standardised measure, the PEDro point for baseline equivalency was not awarded. There was no justification of the sample size nor was the follow up rate specifically reported.

Results
The cautious conclusion following appraisal of this study is that there is some promising evidence that the CIT group improved over time where the TS group did not.

On the stronger outcome measures, that is the QUEST which is standardised and the CAUT which was rated by blinded assessors, there was no difference between groups at the 3 weeks follow up. The only measures where there was a difference between groups at follow up were the PMAL – Frequency of Use and the Emerging Behaviours Scale. Neither of these tests have established psychometric properties and both are by parent report.

Note: Data from this dissertation were published in the following article by Taub et al. (2004).

SUMMARY OF BEST EVIDENCE - Study 2b by Taub et al. (2004)

NB: This paper is the published version of the DeLuca (2002) PhD dissertation reported above. There are, however, some inconsistencies and differences between these reports. These are noted throughout the summary and appraisal.

Aim of the Study - As for Study 2a by DeLuca et al. (2002)

Subjects: As for Study 2a by DeLuca et al. (2002)

Design: Paper reports an RCT with participants randomised to either CIMT using casting plus intensive movement therapy or Traditional Services (TS). The crossover component of DeLuca's study was not mentioned.

Interventions Investigated - As for Study 2a by DeLuca et al. (2002)

Outcome Measures: Measured at baseline, 3 weeks (immediately after removal of plaster cast) and 6 weeks post baseline. Some PMAL data were also reported for 3 months and 6 months follow up.

These were the measures reported by Taub.

1. Toddler Arm Use Test (TAUT) - 22 items are videoed and blindly rated accordingly to Amount of Use (AOU) *[0 = no use to 2 = functional use]* and Quality of Movement (QOM) *[0 = no use to 5 = age appropriate use].* DeLuca reported use of the 21-item CAUT.

2. Pediatric Motor Activity Log (PMAL) - 21 distinct upper limb functional tasks which parents rate on 2 scales: Amount of Use *[0 = doesn't use to 5 = exclusive use of involved arm]* and Quality of Use *[0 = doesn't use arm to 5 = normal quality]*. DeLuca's report of the PMAL was similar but reported 22 items.

3. Emerging Behaviours Scale - developed by the researchers based on the observation that children receiving CIMT rapidly acquire new skills. The presence or absence of 31 motor patterns or functional activities are recorded. As per DeLuca.

Thus the use of the QUEST reported by DeLuca was not reported by Taub.

Results

1. TAUT

Despite reporting "large and statistically significant between-group differences" (Taub et al., 2004; p. 308) for percentage of items where the affected arm was used without prompts, there was successful accomplishment of tasks and improved overall quality of use; the authors did not report any data. Taub et al. reported large within-group differences in favour of the CIMT group for increased first-time use of the affected upper limb and increased independent functional use. See Table 7
NB: De Luca thesis reported no difference between groups on this outcome measure.

Table 7: Toddler Arm Use Test – percent increase at 3 weeks

	CIMT group	**Control group**	**95% CI***
First time use %(SD)	53% (35.64)	18% (31.12)	2.5 to 69.3
Independent Functional use %(SD)	16.8% (21.53)	5% (15.4)	-6.9 to 30.5

*CI for differences in proportions was calculated from data given in paper

The percentage change for the CIMT group is larger in each domain than for the control group. The confidence intervals however are wide and do not demonstrate clinical importance at the lower ends of the intervals.

2. **PMAL – see tables following**

Statistical analysis indicated a significant difference between groups for both the Amount of Use and Quality of Use scales, which was maintained at 6 weeks. (multivariate ANCOVA: $p<0.0001$). The confidence intervals, however, indicate that there appears to be some clinical importance of the results of the Amount of Use scale but no clinically important results for the Quality of Use scale.

Table 8: PMAL – Amount of Use and Quality of Movement scales at baseline, 3 weeks, and 6 weeks. * The scale of the PMAL is from 0 to 5.

	CIMT group Mean (SD)	**Control group** Mean (SD)	**95% CI[+]**
Amount of Use			
Baseline	0.8 (0.44)	1.1 (0.75)	
Follow up – 3 weeks	2.8 (1.14)	1.2 (0.82)	0.6 to 2.6
Follow up – 6 weeks	2.6 (1.29)	1.2 (0.67)	0.4 to 2.4
Quality of Use			
Baseline	0.9 (0.62)	1.6 (1.20)	
Follow up – 3 weeks	2.7 (0.97)	1.9 (1.13)	-0.3 to 1.9
Follow up – 6 weeks	2.6 (1.25)	1.8 (1.01)	-0.3 to 1.9

* Data for this table were extracted from Table 3 from Taub et al., 2004.
[+] Confidence intervals were calculated from data provided in Taub et al.

3. Emerging Behaviours Scale – see Table 9 following

The scale for this test is 0 to 31. The CIMT group made significantly more gains than control group at 3 weeks (ANCOVA; $p<0.0001$). Not reported at 6 weeks.

Table 9: Emerging Behaviours Scale at baseline and 3 weeks.

	CIMT group Mean (SD)	**Control group** Mean (SD)	**95% CI***
Baseline	12.2 (5.64)	12.7 (6.51	
Follow up – 3 weeks	21.5 (4.45)	15 (5.66)	1.4 to 11.6

Adverse events
The only reported events were related to upset during the initial cast application and minor cast complications – all sounding usual for cast application and wear. No specific data were reported for these outcomes.

Original Authors' Conclusions
CIMT therapy produced major and sustained improvement in motor function.

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Critical Appraisal of study by Taub et al., (2004)
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Validity: *(PEDro score = 5/10 with points awarded for random allocation, equivalency at baseline, blinding of assessors for the TAUT, between group comparisons, reporting of point estimates and variability.)*
The adequacy of follow up was not specifically mentioned. There was no mention of intention to treat analysis. The sample size was not justified.

Equivalency at baseline. Raw data were provided for demographic information; this appears to be equivalent between groups. The authors report that 1-way ANOVA was conducted with the baseline scores of the outcomes measures and that there were no differences between groups on the measures. Although the authors did not report this statistical analysis, there appears no difference in the baseline scores on any of the outcome measures.

<u>Comparisons with DeLuca (2002)</u>

There are some concerns regarding the differences in reporting between DeLuca's PhD dissertation and Taub's article. The concerns are:

- DeLuca used the QUEST, but Taub doesn't mention its use. This may be because of the failure to detect a treatment effect using the QUEST and is despite the QUEST being the only outcome measure used which has any established psychometric properties. There were no between-group differences at 3 weeks follow-up reported in the DeLuca paper, either using statistical analysis, or as reflected by the 95% CI of the mean scores at 3 weeks. There was a large and probably clinically significant difference between the groups at baseline. Despite the apparently large increase in scores in the CIMT group and the lack of a change in the TS group this does not appear significant as reflected in the 95% CI for the mean change scores; the variability (SD) was very large. Thus, based on these QUEST results, the evidence for CIMT is not convincing.
- There is inconsistency surrounding the CAUT (DeLuca) and TAUT (Taub).

- Firstly this measure is referred to as the CAUT by DeLuca (with 21 items) and as both the TAUT (in text with 22 items) as well as the CAUT (in Appendix II with 21 items).
- DeLuca reported no difference between groups on the CAUT. It appears Taub looked at the data in a different way for between-group differences and found a significant difference (although data largely unreported).
- It may be worth considering how appropriate it is to use a test designed for toddlers when evaluating a group of children between the ages of 7 months and 8 years.

Results

There is some preliminary evidence that the CIMT group improved over time where the TS group did not. The conclusion is tempered by the suspicions raised by the inconsistent reporting of the same study by Taub et al (2004) and DeLuca (2002) and the lack of established psychometric properties of the outcome measures used in this study.

OVERALL CLINICAL IMPLICATIONS

Taking these two RCTs into consideration it appears that there is preliminary evidence to support the further evaluation of CIMT. It would be responsible to carefully evaluate any implementation of CIMT as there is insufficient evidence to adopt it as standard clinical practice at this point. This is not only because the evidence is not strong, but also because of the highly intensive nature of involvement in CIMT for both families and their children, and for therapists.

In Australia it has been more usual for researchers to adopt a modified form of constraint-induced therapy. Eliasson and colleagues (2005) from Sweden have led the way with modified constraint-induced therapy by using a mitt worn on the unaffected hand that prevents grasp and release. They also propose shorter periods of daily constraint (eg 2 hours) for more extended periods of time (eg 8 weeks). Eliasson and colleagues have conducted a non-randomised trial of this intervention and reported promising results. Therapists exploring constraint-induced therapy may be interested to consider this model.

A major weakness of the reported RCTs was the lack of standardised measures of either upper limb function per se or of the impact of intervention on children's ability to participate in meaningful daily occupations. There are at least three upper limb measures which have been specifically designed for populations of children with cerebral palsy and/or hemiplegia. These are the QUEST (DeMatteo et al., 1992), the Assisting Hand Assessment (Krumlinde-sundholm & Eliasson, 2003) and the Melbourne Assessment of Unilateral Upper Limb Function (Randall et al., 1999). Further, two possible measures exist which are useful for evaluating the effects of intervention on occupational performance: The Canadian Occupational Performance Measure (Law et al., 2005) and Goal Attainment Scaling (Kiresuk et al., 1994). All of the tools can be used in clinical and research settings to evaluate the outcomes of constraint-induced movement therapy.

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