Outcomes 12 months after a constraint induced movement therapy program were maintained for an additional year

Synopsis


Question: What is the retention of improvements 24 months after a 2-week constraint-induced movement therapy (CIMT) intervention in stroke survivors? Design: Follow-up 24 months after a single blind, cross over, randomised controlled trial of CIMT. This paper reports follow-up data for the intervention group that received CIMT without delay only. Setting: Seven US academic clinical sites. Participants: 106 out of 222 participants with mild to moderate post-stroke impairment who had experienced the stroke in the previous 3 to 9 months. Interventions: CIMT was delivered for two weeks. During the two weeks, participants wore a padded protective mitt that covered their less impaired wrist and hand up to 6 h per day, 5 days per week. The mitt was to be worn for 90% of waking hours. During that time participants did adaptive task practice or repetitive practice of specific tasks, such as grooming or eating, continuously for 15–20 minutes. Contracts with participants and caregivers were used to promote adherence to mitt use. Outcomes: Primary outcomes were function of the paretic upper limb, measured with the Wolf Motor Function Test (WMFT) and the Motor Activity Log (MAL) measured at 12, 12.5, 16, 20, and 24 months. Health-related quality of life, measured with the Stroke Impact Scale (SIS), was a secondary outcome assessed at 12, 16, and 24 months. WMFT is a laboratory-based measure of upper limb motor function that consists of 15 timed movement tasks and two strength-based tasks. The MAL is a structured interview that assesses 30 activities of daily living on a 6-point scale when using the paretic arm. Results: 34% of the participants who received CIMT immediately after allocation had dropped out at 24 months. From month 12 to month 24, the time taken to complete the WMFT did not decline significantly (mean difference 0.32 s longer, 95% CI –3.06 to 3.70). Over the same period, outcomes improved for weight lifted in the WMFT (1.39 kg, 95% CI 0.04 to 2.74) and for WMFT grip strength (4.39 kg, 95% CI 1.86 to 6.91). There were no significant differences in the amount of use in the MAL (0.17, 95% CI –0.04 to 0.38) and how well the limb was used in the MAL (0.14, 95% CI –0.06 to 0.34). Conclusion: Outcomes that had improved significantly 12 months after a 2-week CIMT program were maintained for an additional year.

Commentary

Since the 1990s, CIMT has been examined in several small trials and in the large multisite EXCITE trial (Wolf et al 2006). The results from the EXCITE trial showed significantly greater functional improvement for the CIMT group compared to the control group at 12-months follow-up. The aim of the present study was to evaluate the retention of the treatment effect 24 months after CIMT. The authors conclude that the functional improvements found at 12-months follow-up were retained for an additional year.

In our view, retention of the treatment effect has not been evaluated because there was no comparison against a control group in the present report from this study. In addition, the paper does not define ‘partially analysed’ and ‘changed condition’ in the trial flow diagram, and this may cause bias if some participants’ data were not included in the analysis because their condition had worsened. Finally, the functional ability scale on the Wolf Motor Function Test showed no significant differences between the groups at 12-month follow-up, and it is appropriate to ask why this scale is excluded from the present analysis. In summary, these methodological shortcomings question the validity of the authors’ conclusion.

However, if CIMT is superior to standard treatment in the long run, this might be explained by motor learning mechanisms and corresponding motor network changes, as repetitive use alone is unlikely to induce long-lasting changes in cortical networks (Nudo 2006). This topic should be investigated further.

The optimal time for this treatment to be applied after the onset of stroke is not determined in this report. In the overall EXCITE trial, however, CIMT was given with a one-year delay to the control group. This provides the opportunity to compare the effect of this treatment given at two different time points. We look forward to publication of this comparison. Although a lot of questions remain unanswered about the efficacy of CIMT, the EXCITE trial has renewed the hope for stroke survivors and moved the research of stroke rehabilitation into the area of evidence-based treatments.

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References

NIPSV for acute cardiogenic pulmonary oedema does not increase the risk of myocardial infarction compared to CPAP

Synopsis


Question: Acute cardiogenic pulmonary oedema (ACPO) can be managed with either non-invasive positive pressure ventilation (NIPSV) or non-invasive continuous positive airway pressure (CPAP). Does management with NIPSV increase the risk of myocardial infarction compared to management with CPAP? Design: Randomised controlled trial with concealed allocation. Setting: High-dependency unit of a hospital emergency department in Turin, Italy. Patients: 52 adults with severe ACPO, defined as acute dyspnoea, > 30 breaths per minute, use of accessory respiratory muscles, oxygen saturation (SpO₂) < 90% with FIO₂ 60%, and radiological signs of ACPO. Patients with signs of acute coronary syndrome (ACS) on hospital admission were excluded from the study. Interventions: All patients received standard medications (diuretic, nitroglycerin, morphine) and oxygen. NIPSV was applied by a Pulmonetics Systems LTV 1000 ventilator. CPAP was administered by means of a flow generator (Whisper-Flow) with an expiratory (PEEP) valve. Patients randomised to NIPSV (n = 25) received sufficient inspiratory pressure (IPAP) to generate a tidal volume of ~7 mL/kg, and oxygen to maintain SpO₂ at ~93%, via an oronasal mask. Expiratory pressure (EPAP) was gradually increased until SpO₂ ≥ 96% (maximum of 12 cmH₂O). Those randomised to CPAP (n = 27) commenced at 5 cmH₂O via an oronasal mask with oxygen to maintain SpO₂ at ~93%. The CPAP was gradually increased until SpO₂ ≥ 96% (maximum of 12 cmH₂O). Treatment failure was defined as cardiac arrest, respiratory distress and arterial blood gas deterioration for > 60 min, PaO₂/FIO₂ < 100 mmHg, coma or psychomotor agitation, haemodynamic instability, or life-threatening arrhythmias. Otherwise, treatment continued until the participant met objective criteria of recovery. Outcomes: The primary outcome was the rate of acute myocardial infarction (AMI). Secondary outcomes included rate of endotracheal intubation, death, duration of ventilatory assistance, and lengths of stay in the hospital and high-dependency unit. Results: In the NIPSV group, the average EPAP and IPAP applied were 7 ± 1 and 15 ± 3 cm H₂O, respectively. In the CPAP group, the mean pressure applied was 9 ± 2 cm H₂O. AMI occurred in four patients on NIPSV and eight patients on CPAP, which was not significantly different, absolute risk reduction (ARR) 0.14, 95% CI –0.10 to 0.34. Also not significantly different were the number of intubations with only one in the NIPSV group, ARR –0.04, 95% CI –0.20 to 0.09, and the number of deaths with three in the NIPSV group and two in the CPAP group, ARR –0.05, 95% CI –0.23 to 0.13. The lengths of stay in hospital and in the high-dependency unit also did not significantly differ between the groups. Conclusion: This study demonstrated no significant difference in AMI among patients with ACPO managed with NIPSV versus CPAP.

[ARRs and CIs calculated by the CAP Co-ordinator.]

Commentary

ACPO is a vital emergency that usually occurs in the elderly population with a high prevalence of coronary artery disease. The most frequent precipitant cause has been reported to be ACS, especially AMI. Typically, this is a non-extensive non-Q wave AMI that occurs in a patient with previous infarction, diabetes, and hypertension. On other occasions, however, myocardial necrosis is due to either coronary flow imbalance or cardiac overload, secondary to the stress of ACPO. This secondary mechanism is silent, usually generates lower increases in cardiac biomarkers than primary ACS, and has been described in patients with normal coronary arteries.

In patients with ACPO, non-invasive ventilation has been shown to produce a rapid improvement in physiologic parameters and a reduction in the intubation rate and mortality (Masip 2005). Most of the series analysing this technique have reported the overall incidence of AMI considering both primary and secondary mechanisms.

The study by Ferrari et al excluded patients with ACS and therefore it should be inferred that all new cases of AMI were secondary. The trial was specifically designed to clarify the confusion introduced by some previous biased trials that described a higher AMI rate with the use of NIPSV compared to CPAP (Mheta 1997). Conversely, the authors found a nearly double AMI rate in the CPAP group, but the difference was not significant. The study does not provide extensive information about ACS exclusions or new cases of AMI and it is not conclusive because of the small sample size, but provides, like previous trials (Bellone 2004) and meta-analyses, greater evidence about the neutral effect of NIPSV on the incidence of AMI.

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References

Hydrotherapy and Tai Chi each provide clinical improvements for older people with osteoarthritis

Synopsis


Question: For people with osteoarthritis of the hip or knee, do hydrotherapy or Tai Chi give worthwhile improvements in pain and physical function? Design: Randomised, 3-arm, parallel, controlled trial with concealed allocation, assessor blinding, and intention-to-treat analysis. Setting: Tertiary hospital, Sydney, Australia. Participants: Adults aged 59–85 years, with osteoarthritis of the hip or knee meeting American College of Rheumatology criteria, recruited through advertisements, social clubs for older people, and referral from local general practitioners and rheumatologists. 55 participants were randomised to hydrotherapy, 56 to Tai Chi, and 41 to a control group. Interventions: Participants in either of the two treatments groups were required to attend classes (max 15 participants) for one hour, twice per week for 12 weeks. Hydrotherapy involved lower limb exercise in waist-deep water, including walking, free-standing and bar work, running, and stairs. Tai Chi included a 10-minute warm-up followed by a modification of 24 forms of Sun style Tai Chi. Participants were allowed to purchase, if they desired, a Tai Chi video to assist with home practice. The control group were wait-listed for 12 weeks and then randomly allocated to one of the two treatments. Outcomes: The primary outcomes were pain and physical function measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). Secondary outcomes included the SF-12 general health status questionnaire; the Depression, Anxiety and Stress Scale of psychological well being; the participant’s global assessment of treatment effectiveness and current status of the joint that had originally been the most painful; and physical performance measures (50-foot walk test, stair climb test, and Up and Go test). Outcomes were assessed at the end of the 12-week treatment period, and 12 weeks later.

Results: At the end of treatment, pain had improved by 6 points (95% CI 0 to 13) more in the hydrotherapy group than the control group. Similarly, physical function had improved by 10 points (95% CI 4 to 14) more in the hydrotherapy group and by 10 points (95% CI 3 to 17) more in the Tai Chi group. The hydrotherapy group also showed significant treatment benefits in the physical component summary of the SF-12 and the three physical performance measures. Twelve weeks later, comparisons with a no-treatment control group were not possible, but the outcomes that had improved significantly during treatment had mostly been maintained.

Conclusion: Older people with osteoarthritis of the hip or knee can obtain clinically worthwhile improvements in physical function from hydrotherapy or Tai Chi.

Commentary

This Australian study investigated 12 weeks of hydrotherapy or Tai Chi classes for sedentary older people with chronic osteoarthritis of the hip or knee. The study concurs with the growing body of knowledge suggesting that a variety of exercise-based interventions may be beneficial to reduce pain and improve physical function in this client group.

There have been relatively few high quality studies investigating hydrotherapy for osteoarthritis. Bartels et al (2007), in their Cochrane review, concluded that while aquatic exercise provided short-term beneficial effects for people with hip or knee osteoarthritis, the longer term benefits had not been investigated. The current study demonstrated significant improvements in pain, function, walking speed, and stair climbing over 12 weeks of hydrotherapy and these outcomes were largely maintained for the next 12 weeks. A strength of the current study is that the hydrotherapy protocol is outlined clearly and may be reproduced by any organisation with hydrotherapy facilities and a physiotherapist.

This is one of the few studies investigating Tai Chi for people with osteoarthritis. Compared to the no-intervention control, the 12-week Tai Chi exercise significantly improved function and stair climbing and these outcomes were largely maintained for a further 12 weeks. Once again, the Tai Chi program could be replicated by an organisation if the video is purchased and Tai Chi instructors are available.

A comparison between the exercise modes was not part of the current paper; however, effect sizes were larger for the hydrotherapy group. Adverse events were uncommon with only 2 of 111 participants withdrawing because of an exacerbation of pain (2%). Therefore, while both modes of exercise have positive effects with few adverse effects, further analysis is needed to determine if one mode is superior to the other. In the meantime, client preference, availability of a hydrotherapy pool, or access to qualified Tai Chi instructors may determine which mode is chosen with a particular client.

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References

No difference in cost-effectiveness of intensive group training for chronic back pain compared with usual physiotherapy care

Synopsis


**Question:** Is an intensive group training protocol cost-effective compared to usual care physiotherapy for chronic low back pain? **Design:** Economic evaluation alongside a randomised controlled trial comparing two physiotherapy interventions for chronic low back pain. **Setting:** Primary care physiotherapy clinics in and around Amsterdam, the Netherlands, involving 85 physiotherapists. **Participants:** 114 participants with a new episode of non-specific low back pain of more than 12 weeks duration and aged 18 to 65 years were included. Patients with specific spinal pathology were excluded. **Interventions:** Participants in the intensive group performed 10 individual and 20 group sessions consisting of graded exercises and back school based on behavioural principles. Those allocated to usual care received an average of 9 sessions of individual physiotherapy treatments according to the Royal Dutch College for Physiotherapy Low Back Pain Guidelines. **Outcomes:** Treatment effectiveness was measured using the following pre-specified outcomes: functional status (24-item Roland-Morris Disability Questionnaire), pain intensity (11-point numerical rating scale), general perceived effect (6-point GPE scale) and quality of life (EuroQol-5D) at baseline, 6, 13, 26, and 52 weeks after randomisation, with 89% follow-up at 1 year. Diaries were used to measure costs associated with utilisation of health care, non-health care, medications, and loss of productivity due to work absenteeism. Multilevel analyses were performed to determine the difference in effects. The mean differences in costs between groups and 95% confidence intervals (CIs) were obtained by bias corrected and accelerated bootstrapping. Quality of life was expressed in utilities based on the Dutch tariff. **Results:** The differences in effects were small and not significant. Although the direct health care costs were higher for the intensive training group, (between-group difference per patient €233, 95% CI 2185 to 2764), there were no differences between the groups in terms of total health costs. **Conclusion:** The intensive group training protocol is not cost-effective compared with usual care physiotherapy carried out according to the guidelines. Whilst there is no clinical contraindication to the use of the intensive group training program, the results do not support implementation of the intensive program for back pain in primary care in the Netherlands.

Commentary

Economic evaluation is the systematic comparison of the costs and consequences of alternative interventions, programs, or services. It is used to provide information about the relative value for money provided by options under consideration. A common vehicle for an economic evaluation is a randomised controlled trial.

A wide range of techniques and programs to treat back pain have been developed, many of which have not been evaluated systematically. It is particularly important to assess the cost-effectiveness of an intervention that is designed to be more intensive than the alternative; even if effectiveness is improved, costs are likely to be higher and therefore understanding what additional benefits are being gained for what cost is important.

In the trial reported here, there were no differences in the clinical effectiveness measures between the intensive and usual care groups. However, the costs were higher, due mainly to the increased costs of providing additional physiotherapy input. However, the importance of collecting information about the use of health care other than physiotherapy is illustrated by the finding that more members of the intensive program group used more secondary and complementary care.

The cost per additional point of functional status was €16 349 (SA27 728) and the cost per quality-adjusted life year (QALY) gained was €5141 (S8405). These results are only useful if they can be compared with a threshold, usually set by a government agency to indicate how much society is willing to pay for new interventions or technologies. Although there is no official threshold in Australia, decisions made by the Pharmaceutical Benefits Advisory Committee (PBAC) indicate that ~ $A70 000 per QALY gained is a reasonable benchmark. Although this seems to indicate that the intensive program was relatively cost-effective, the use of cost-effectiveness planes (which are used to show the distribution of costs and effects) indicated no significant differences in effectiveness or cost-effectiveness. A more practical reason for not using an intensive program is the finding that 22 patients either did not start or dropped out of the intensive program.

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