Controlled randomised crossover trial of the effects of physiotherapy on mobility in chronic multiple sclerosis

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of physiotherapy, administered either at home or as outpatient therapy, for patients with multiple sclerosis (MS) and problems with walking. Patients received physiotherapy sessions of 45 minutes twice a week, either at home (focusing more on specific functional activities) or at the hospital (focusing more on specific facilitation techniques).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with MS who complained of difficulties with walking, who were at least 18 years old, and were able to walk 5 metres with or without a mechanical aid. In addition, they were not to be in a current relapse of MS, and they had to be free from other major general medical or surgical disorders or pregnancy.

Setting
The settings were a hospital and community care. The economic study was performed in Cardiff, Wales, UK.

Dates to which data relate
The dates to which the effectiveness and cost data related were not reported. The price year was not stated.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing appears to have been performed prospectively on the same sample population as that used in the effectiveness analysis.

Study sample
Power calculations were performed in the planning phase of the study in order to assure a certain power. On the basis of a prior study, a sample size of 42 patients was required to detect a clinically relevant change of one unit difference of the primary outcome measure with 90% of power at a 5% level of significance. Among 45 patients referred to the centre where the study was performed, 42 were considered for inclusion in the study. Two patients refused to participate. The final study sample was composed of 40 patients. Each of these patients was allocated to one of the six
permutations of home care, outpatient care and no therapy, administered as three 8-week treatment periods, separated by 8-week intervals. Two neurophysiotherapists administered the therapy, while a different neurophysiotherapist assessed the effectiveness. The authors did not show evidence that the study sample was representative of the study population.

Study design
The study was a randomised, controlled crossover trial, which was carried out in a single centre. The patients were assigned to one of the six possible treatment permutations by randomisation with sealed envelopes. The patients were followed up over 45 weeks. The authors did not report any loss to follow-up. The doctor who performed the assessments (which were always made at home) was unaware of the treatment allocation, except for 28 of the 283 home visits delivered, as stated by the authors.

Analysis of effectiveness
The basis of the analysis of the clinical study was intention to treat. The primary health outcome assessed in the effectiveness analysis was the change in the Rivermead mobility index on one therapy compared with that in the other therapy. The authors also reported the results of comparisons among the alternative therapies in terms of:

the balance, walking, upper limb and global impression of mobility, as judged by the assessor physiotherapist before and after each of the interventions;

the Hospital Anxiety and Depression Scale (HALS) for anxiety and depression, the Visual Analogue Scale (VAS) on mobility, as reported by patients and carers, and the VAS on falls;

the preferences of patients, carers and physiotherapist in relation to the therapy that benefited more, and the most preferred therapy, when home and hospital therapies were compared.

Also reported were the number of missed therapy sessions and other outcomes related to therapy delivery, such as the total number of hours of therapy. The authors also assessed the degree of achieving four targets, as rated by the treating therapist, although they did not report what these targets were. The patients were not shown to be comparable at analysis since the clinical study analysed patient variability of outcomes derived from the administration of the different therapies, rather than variability between different groups of patients receiving different therapies.

Effectiveness results
When home therapy and hospital therapy were compared with no therapy, there were statistically significant improvements in the Rivermead mobility index. There was an increase of 1.4 in the score when hospital therapy was administered (95% confidence interval, CI: 0.62 - 2.14; p<0.001), and an increase of 1.5 in the score when home therapy was administered (95% CI: 0.73 - 2.26; p<0.001).

The balance, walking, and global mobility scores, as assessed by the assessor physiotherapist, were significantly improved with home and hospital therapies in comparison with no therapy, (p<=0.004). However, there were no significant differences between the scores obtained when home and hospital therapies were compared, (p=0.38).

In comparison with no therapy, there was a reduction of 1.48 in the HADS-anxiety score with hospital therapy (95% CI: -2.44 - -0.51; p=0.003) and a reduction of 1.24 with home therapy (95% CI: -2.23 - -0.26; p=0.014). There were no significant differences when hospital and home therapies were compared, (p=0.64).

In comparison with no therapy, the HADS-depression score was significantly reduced by 2.22 when hospital therapy was administered (95% CI: -3.25 - -1.18; p<0.001), and it was significantly reduced by 1.70 when home therapy was administered (95% CI: -2.73 - -0.66; p=0.002). There were no significant differences between home and hospital therapies in terms of the changes in the HADS-depression score, (p=0.32).

In comparison with no therapy, the VAS scores for mobility, as assessed by patients, were increased by 25.2 (95% CI: 18.3 - 32.0; p<0.001) with hospital therapy and by 24.2 (95% CI: 17.3 - 31.0; p<0.001) with home therapy. There were...
no statistically significant differences in the variations of the VAS scores for mobility between the home and hospital therapies, (p=0.77).

The VAS scores for mobility, as assessed by carers, also improved significantly with hospital therapy (16.0, 95% CI: 6.7 - 25.3; p=0.001) and home therapy (17.6, 95% CI: 8.1 - 27.1; p<0.001) when compared with no therapy. There were no significant differences in the VAS scores for mobility between the hospital and home therapies, (p=0.73).

The VAS scores for falls improved significantly with hospital therapy (18.3, 95% CI: 9.0 - 27.6; p<0.001) and home therapy (20.7, 95% CI: 11.2 - 30.2; p<0.001), compared with no therapy. There were no significant differences between the home and hospital therapies, (p=0.62).

When hospital and home therapies were compared, home therapy was preferred, although this result was significant only for the assessment made by the carers, (p=0.005).

The number of missed therapy sessions was 10 out of 640 (i.e. 1.6%) with home therapy, and 37 out of 640 (i.e. 5.8%) with hospital therapy.

Clinical conclusions
In comparison with no therapy, mobility was shown to improve with home and hospital therapies in terms of the Rivermead mobility index, the HADS anxiety and depression scores, and the VAS scores for mobility and fall. There were no significant differences between the results obtained when both the home and hospital therapies were compared, although the carers preferred home treatment. There were less therapy sessions missed with home therapy than with hospital therapy.

Measure of benefits used in the economic analysis
No summary measure of benefit was used in the economic analysis. The study was therefore categorised as a cost-consequences analysis.

Direct costs
The resource quantities were reported separately, although the unitary costs applied to these resource quantities were not reported. The direct costs considered for the economic analysis were those of the health service. These included the costs of the physiotherapist in terms of the time for administering the therapy and travel costs for the case of the home therapy. For the hospital therapy, the authors also reported the travel costs of the patients, although these were not included in the final cost. The source of the unitary costs applied to resource utilisation was not reported. Therefore, it could not be known whether or not the costs were estimated from actual data. The authors did not report any discounting, but it was irrelevant since the costs were incurred in less than two years. The study reported the average costs per session. The price year was not reported.

Statistical analysis of costs
No statistical analysis of the costs was reported.

Indirect Costs
No indirect costs were reported.

Currency
UK pounds sterling (€).

Sensitivity analysis
No sensitivity analyses were reported.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
A home therapy session cost 25 and a hospital therapy session cost 11 (without considering patient travel costs). The patient travel costs associated with hospital therapy were 7 per session.

**Synthesis of costs and benefits**
The estimated costs and benefits were not combined due to the cost-consequences approach adopted.

**Authors' conclusions**
Physiotherapy, either at home or as outpatient care, resulted in significant improvements in mobility, subjective well-being, and mood in patients with chronic multiple sclerosis (MS), in comparison with no therapy. Home-based therapy was more costly when compared to hospital-based therapy.

**CRD COMMENTARY - Selection of comparators**
The comparator chosen was a 'do-nothing' alternative, which was justified because the evidence of the effectiveness of rehabilitation for MS patients with difficulties in walking is conflicting. Therefore, a 'no therapy' alternative allowed the active value of the therapies to be evaluated. You should decide whether there is an alternative health technology for the treatment of these patients in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis used a randomised controlled crossover trial. This seems to have been appropriate for the study question since this approach allows the outcome variation generated by the alternative therapies under study to be compared in the same patient. Moreover, MS is a chronic condition, the therapies provided temporary rather than permanent relief, and the benefits of the therapies did not seem to have lasted until the other periods of therapy. These facts support the use of this design. The authors did not provide evidence that the study sample was representative of the study population, which may limit the external validity of the clinical study. Some of the methods used to evaluate the effectiveness of the therapies seem to have been appropriate, such as the Rivermead index (as reported by the authors) and the HADS and the VAS scores. However, the authors did not report the methods used by the assessing physiotherapist to evaluate balance, walking, upper limb and global impression of mobility.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of health benefit. The analysis was therefore categorised as a cost-consequences study.

**Validity of estimate of costs**
All the costs related to the therapies under study appear to have been considered in the economic analysis. The resource quantities were reported separately. However, the source of the unitary costs used to value resource utilisation was not reported and the authors did not perform statistical analyses on the quantities and costs. These factors introduce uncertainty into the reliability of the conclusions. Moreover, the price year was not reported, which hinders reflation exercises to other settings. The reporting on the costs was very brief. Discounting does not seem to have been performed, but was irrelevant since the costs were incurred in less than two years.
Other issues
The authors compared their findings with those from other studies, and they reported that some of them failed to show significant benefits. The issue of the generalisability of the results was not addressed. The authors’ conclusions reflected the scope of the study.

Implications of the study
The authors recommend further research to investigate the appropriate dose of treatment necessary to obtain a significant benefit from physiotherapy for patients with MS and difficulties with walking.

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Bibliographic details

Other publications of related interest


Indexing Status
Subject indexing assigned by NLM

MeSH
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