A pragmatic parallel arm multi-centre randomised controlled trial to assess the effectiveness and cost-effectiveness of a group-based fatigue management programme (FACETS) for people with multiple sclerosis


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.

CRD summary
The study objective was to assess the effectiveness and cost-effectiveness of a six-session group-based programme (FACETS) to manage fatigue in people with multiple sclerosis. The authors concluded that the FACETS programme was effective at reducing fatigue severity and increasing fatigue self-efficacy but the cost-effectiveness of the programme was unclear. The study methodology and reporting were good. The authors’ conclusion appears to be appropriate.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
The study objective was to assess the effectiveness and cost-effectiveness of a six-session group-based programme (FACETS) to manage fatigue in multiple sclerosis (MS) patients. The study population was MS patients with a Fatigue Severity Scale total score greater than 4.

Interventions
The comparator was current local practice. This ranged from general advice and information to detailed individualised management advice from various health professionals. The intervention (FACETS) consisted of current local practice plus six 90-minute group-based sessions, which included cognitive behavioural and energy effectiveness techniques. The sessions were delivered by two health professionals routinely involved in managing MS (such as occupational therapists, nurses or physiotherapists).

Location/setting
UK/primary and secondary care

Methods
Analytical approach:
An economic evaluation was conducted alongside a multicentre randomised controlled trial (RCT) in which 164 patients were randomised to current local practice or FACETS and observed for four months post intervention. The authors stated that the perspective was of the NHS and personal social service provider (third party payer).

Effectiveness data:
The primary effectiveness outcomes were fatigue severity and self-efficacy for managing fatigue. Fatigue severity was measured using the Global Fatigue Severity (GFS) subscale of the Fatigue Assessment Instrument (FAI) questionnaire. Self-efficacy was measured using the Multiple Sclerosis Fatigue Self-Efficacy scale questionnaire. Outcomes in both arms were measured at one week (baseline) before the start of FACETS, one month (follow-up one) and four months (follow-up two) after the final FACETS session. All questionnaires were self-reported and administered and returned through the post. Disease-specific quality of life was measured using the total score on the Multiple Sclerosis Impact Scale.

Monetary benefit and utility valuations:
Overall quality of life was measured using the EQ-5D and SF-6D questionnaires. Measurements were taken at the same
time as for the effectiveness outcomes. Utility values were derived from the questionnaires. Quality-adjusted life years (QALYs) were calculated from the utility values at different time points using the under the curve method assuming linear extrapolation between points. Differences in QALYs between trial arms were adjusted for baseline values to avoid bias.

Measure of benefit:
The health benefit was measured in terms of the improvement in GFS scores, the number of persons with a clinically significant improvement in GFS (defined as a 0.5 point improvement) and quality-adjusted life-years (QALYs).

Cost data:
The cost categories included intervention training, equipment and delivery costs, a range of health care worker consultation costs, treatment costs, accident and emergency visit costs and hospital admission and stay costs. Costs were calculated for the three-month period prior to follow-up two in each arm. Health care service use data were derived from the trial using sampling forms completed by clinical staff who delivered the programme. Unit costs applied to resource data were derived from national sources (including the Personal Social Services Research Unit, NHS Reference costs and local NHS Trust cost data). Costs were reported in 2010 GBP (£).

Analysis of uncertainty:
Standard deviation and 95% confidence intervals values were reported alongside relevant outcome data. Non-parametric bootstrapping methods were used to estimate confidence intervals around cost estimates for healthcare service use. Sensitivity analyses were conducted to assess the affect of uncertainties around cost estimates on the results.

Results
The mean difference in the change from baseline GFS score was -0.03 (95% CI -0.33 to 0.28; p=0.86) at follow-up one and -0.36 (95% CI -0.63 to -0.08; p=0.01) at follow-up two, which indicated that FACETS produced a larger fatigue reduction. Forty per cent of FACETS participants had a clinically important GFS improvement compared to 19% in current local practice (p=0.009). The mean difference in self-efficacy score was 9 (95% CI 4 to 14; p=0.001) at follow-up one and 6 (95% CI 0 to 12; p=0.048) at follow-up two, which indicated that FACETS resulted in a larger increase in fatigue control than current local practice. There were no statistically significant mean differences in EQ-5D or SF-6D scores. Observed differences in QALYs marginally favoured the current local practice arm.

Assuming a mean group size of eight, mean cost per participant per FACETS session was estimated to be £453 (95% CI 331 to 585). The total NHS and private payer costs over three months was £218.03 for current local practice and £265 for FACETS. The incremental cost-effectiveness ratio (ICER) was £1,259 per one-point improvement in GFS fatigue or £2,157 per additional person with a clinically significant improvement in fatigue. In terms of cost per QALYs, current local practice dominated FACETS as it produced more QALYs at lower cost.

Authors’ conclusions
The authors concluded that the FACETS programme was effective at reducing fatigue severity and increasing fatigue self-efficacy but that the cost-effectiveness of the programme was unclear.

CRD commentary
Interventions:
A comprehensive description of the intervention and comparator was reported. Standard care was an appropriate comparator. The authors highlighted that there would inevitably have been variations in the exact composition of standard care. The authors argued that this variation could be seen as a strength of the study as it increased the generalisability of the results to a wider range of centres. The authors discussed an alternative intervention (one-to-one therapy as opposed to group sessions) and argued that this was not a practical option for the UK because psychologists working with MS patients were scarce.

Effectiveness/benefits:
Effectiveness outcomes and the methods used to derive them were reported clearly. In the trial, an appropriate form of randomisation was used and should minimise the risk of bias in the results. Patient blinding to treatment was not possible due to the nature of the treatments but this is not expected to significantly affect the effectiveness outcomes.
Methods used to calculate the utility scores were reported clearly and appropriate.

**Costs:**
The cost categories were reported clearly and were appropriate for the setting and perspective. Appropriate sources were used to derive costs and these were reported clearly in an online supplement. The price year was reported. Future costs and effects were not discounted which was reasonable given the short time horizon.

**Analysis and results:**
Details of the analysis were reported clearly. An intention-to-treat analysis was conducted and this was the appropriate method to adopt.

Results of the analysis were reported clearly with full results in an online supplement. The authors suggested that the QALY may have been insufficiently sensitive to pick up the relevant treatment effect (fatigue reduction). They suggested two further reasons why there was no apparent QALY affect: the relatively small sample size may have contributed to the insensitivity of QALY measures to differences in fatigue; and quality of life effects may only be apparent over a longer time scale as changes in attitudes and lifestyle central to the programme were likely to take time to incorporate into daily routines.

**Concluding remarks:**
The study methodology and reporting were good. The authors' conclusion appears to be appropriate.

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