RESEARCH PAPER

Randomised feasibility study of physiotherapy for patients with functional motor symptoms

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ABSTRACT

Objective To determine the feasibility of conducting a randomised controlled trial of a specialist physiotherapy intervention for functional motor symptoms (FMS).

Methods A randomised feasibility study was conducted recruiting patients with a clinically established diagnosis of FMS from a tertiary neurology clinic in London, UK. Participants were randomised to the intervention or a treatment as usual control. Measures of feasibility and clinical outcome were collected and assessed at 6 months.

Results 60 individuals were recruited over a 9-month period. Three withdrew, leaving 29 intervention and 28 controls participants in the final analysis. 32% of patients with FMS met the inclusion criteria, of which 90% enrolled. Acceptability of the intervention was high and there were no adverse events. At 6 months, 72% of the intervention group rated their symptoms as improved, compared to 18% in the control group. There was a moderate to large treatment effect across a range of outcomes, including three of eight Short Form 36 (SF36) domains (d=0.46–0.79). The SF36 Physical function was found to be a suitable primary outcome measure for a future trial; adjusted mean difference 19.8 (95% CI 10.2 to 29.5). The additional quality adjusted life years (QALY) with intervention was 0.08 (95% CI 0.03 to 0.13), the mean incremental cost per QALY gained was £12 087.

Conclusions This feasibility study demonstrated high rates of recruitment, retention and acceptability. Clinical effect size was moderate to large with high probability of being cost-effective. A randomised controlled trial is needed.

Trial registration number NCT02275000; Results.

INTRODUCTION

Functional neurological disorder (conversion disorder), accounts for 15% of all new patients seen in general neurology clinics.[1 2] Approximately 10–50% present with functional motor symptoms (FMS), typically weakness, tremor and gait disorder.[1 2] These patients experience disability and distress equivalent to those suffering from degenerative neurological disease.[3] Prognosis is poor; at an average of 7 years follow-up, 40% have similar or more severe symptoms, and the majority remain symptomatic.[4]

Despite the prevalence and impact of symptoms, there is limited evidence regarding effective treatment. Psychological therapy is traditionally proposed as the treatment modality of choice, but physically based interventions have emerged as a promising treatment. A randomised delayed-start study of 3 weeks inpatient physical rehabilitation 'with a cognitive behavioural framework', found an improvement in measures of physical functioning which were maintained at 12 months follow-up.[5] A systematic review of physiotherapy for FMS (including 564 participants) supports the view that physiotherapy outcomes are promising and warrant further investigation with a randomised controlled trial (RCT).[6] The interventions employed in this literature differ from physiotherapy for typical neurological disease which we have described in consensus recommendations for physiotherapy practice.[7] This approach has been tested in two cohort studies which report improvement in physical functioning.[8 9]

We aimed to determine the feasibility of an RCT of specialist physiotherapy for FMS. Specific aims were to test acceptability and feasibility of a treatment protocol based on consensus recommendations; to test the utility of a range of outcome measures; and to collect outcome data to determine the sample size required for a large scale trial.

METHODS

Study design and setting

We conducted a two parallel arm, randomised feasibility study of a 5-day specialist physiotherapy-led intervention versus a treatment as usual control for patients with FMS. This study took place at the National Hospital for Neurology and Neurosurgery, London, UK. Approval was obtained from the National Research Ethics Service Committee London—City Road & Hampstead (14/LO/0572). All participants gave written informed consent. A trial steering committee oversaw the conduct of the trial. The trial was registered at ClinicalTrials.gov (NCT02275000).

Participants

Sixty participants were recruited from new patients attending an outpatient neurology clinic specialising in movement disorders and FMS. Inclusion criteria were: a clinically established diagnosis of FMS according to Fahn-Williams criteria;[10] age 18 years or older; completed diagnostic investigations; acceptance of the diagnosis on the balance of probability (ie, we did not exclude patients who continued to express some doubt over the diagnosis); FMS duration of at least 6 months; symptoms severe enough to cause distress or impairment in social or occupational functioning. Exclusion criteria were: unable to understand English; pain or

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fatigue that we judged to be the primary cause of the patient's disability; prominent dissociative seizures for which the patient required assistance to manage; clinically evident anxiety or depression that we felt required assessment before starting physiotherapy treatment; high level of disability that prevented participation in an outpatient/day hospital environment; and unable to attend five consecutive days of treatment.

Prior to enrolment, all participants attended a consultation with the study neurologist (MJE) where the diagnosis of FMS was made. Each patient received a standard comprehensive explanation of the diagnosis.[11] The patient was also referred to online sources of information (http://www.neurosymptoms.org, http://www.FNDHope.org). Patients meeting the selection criteria were provided with written information about the trial and invited to return for consent and baseline assessment.

Randomisation and blinding

Eligible consenting participants were randomly allocated (1:1) to the intervention or control group using a secure online randomisation application (Sealed Envelope, London, UK). The randomisation procedure was completed after baseline assessment by the study lead physiotherapist (GN) or independent research physiotherapist (MD). Participants were immediately informed of their treatment allocation. Both participants and clinicians were unmasked to treatment allocation.

Procedures

The intervention was a protocolised 5-day programme, delivered by a neurophysiotherapist (KH) who had undertaken additional specific training (from GN). Participants were admitted to a day hospital for five consecutive days, within 4 weeks of baseline assessment. The first session was a joint consultation with the neurologist and physiotherapist where diagnostic information was reviewed and the aims of the programme discussed. These were explained as retaining movement and learning how to manage symptoms in the longer term. The programme consisted of eight sessions over five consecutive days, each lasting 45–90 min. Each session included education, movement retraining and development of a management plan. Education was centred on a physical biased aetiological model for functional motor symptoms.[8] The physiotherapist and participant collaboratively devised a symptom formulation taking into account triggering events, comorbidity, psychological factors, self-focussed attention and unhelpful reinforcement of symptomatic movement patterns. Movement retraining aimed to restore normal movement during problematic activities by redirecting the focus of motor attention.[7] The participant and physiotherapist made notes in a workbook, documenting the individualised symptom formulation, information about FMS, specific symptom management strategies, daily reflections, a personal self-management plan and what to do in case of symptom exacerbation.

For controls, a referral was made to the participant's local neurophysiotherapy service. The referral letter contained information about the diagnosis, specific treatment goals and welcomed contact for further information regarding the diagnosis or treatment advice. No attempt was made to standardise treatment provided. Input received was recorded, based on patient report.

Participants were reassessed at 4 weeks and 6 months by MD. For the intervention group, the 4-week assessment coincided with the final day of treatment.

Outcome measures

Measures of feasibility were: recruitment rate; retention; intervention fidelity; and acceptability of the intervention. Safety was assessed by participant reported adverse events. We did not specify a primary clinical outcome measure as the primary aim of this study related to feasibility. Clinical outcome measures collected were: Short Form 36 (SF36);[12] Hospital Anxiety and Depression Scale (HADS);[13] EQ-5D-5L;[14] Work and Social Adjustment Scale (WSAS);[15] 5-point patient rated Clinical Global Impression Scale (CGI);[16 17] Disabilities of the Arm Shoulder and Hand (DASH);[18] Functional Mobility Scale;[19] Berg Balance Scale;[20] Brief Illness Perception Questionnaire (B-IPQ);[21] and 10 m timed walk. The CGI was collapsed into two groups: good outcome (ratings of much improved and improved) and poor outcome (ratings of no change, worse or much worse). We collected additional data on the economic impact of symptoms as well as qualitative data related to the intervention, which will be reported elsewhere. Participants in the intervention group completed a feedback form to assess acceptability of the intervention.

Statistical analysis

A power calculation was not performed as the primary aim of this study was to assess feasibility. The sample size of 60 was predetermined and considered sufficient to meet the objectives of collecting data on outcome measure variation, recruitment and retention. For continuous measures, the difference between groups was assessed using a linear regression model, adjusting for the baseline scores of the measure. Treatment effect was calculated using Cohen's d to allow comparisons between outcome measures.[22] Incomplete cases due to drop out were excluded from analysis. Data were analysed using SPSS V.22. The EQ-5D-5L utility scores[23] were converted to Quality Adjusted Life Years (QALYs) by calculating the area under the curve adjusting for baseline differences.[24] Physiotherapist and neurologist salaries, on-costs and overheads were obtained from the Personal Social Services Research Unit[25] and multiplied by the average contact time per patient. Other costs were obtained from trial costings documentation and were for the 2014/2015 financial year. The estimated mean cost per patient of the intervention minus the mean cost of control neurophysiotherapy services was divided by the difference in QALYs gained between groups to calculate the incremental cost-effectiveness ratio (ICER).

RESULTS

The trial profile is shown in figure 1. Between 8 September 2014, and 4 June 2015, 210 new patients were screened and 143 excluded. The commonest reasons for exclusion were dominant pain (n=57, 27% of screened patients), clinically evident anxiety or depression requiring assessment (n=50, 24% of screened patients) and dominant fatigue (n=22, 10% of screened patients). Seven patients declined to participate and the remaining 60 were recruited and randomly assigned to the intervention (n=30) and control (n=30) groups. About 31.9% (95% CI 25.6% to 38.2%) of screened patients met selection criteria. Ninety per cent of eligible patients consented to participate. The number assessed at the primary end point was 29 for the intervention group and 28 for the control group. The dropout rate was 5%. One participant from the intervention group was unable to attend the final assessment but they agreed to complete questionnaires by post; their final physical assessment measures (Berg Balance Scale and 10 m walk time) were therefore missing. Three participants from the control group did not attend the interim 4-week assessment.

Baseline characteristics of the participants are shown in table 1. The mean age was 43 years, 72% were women and approximately

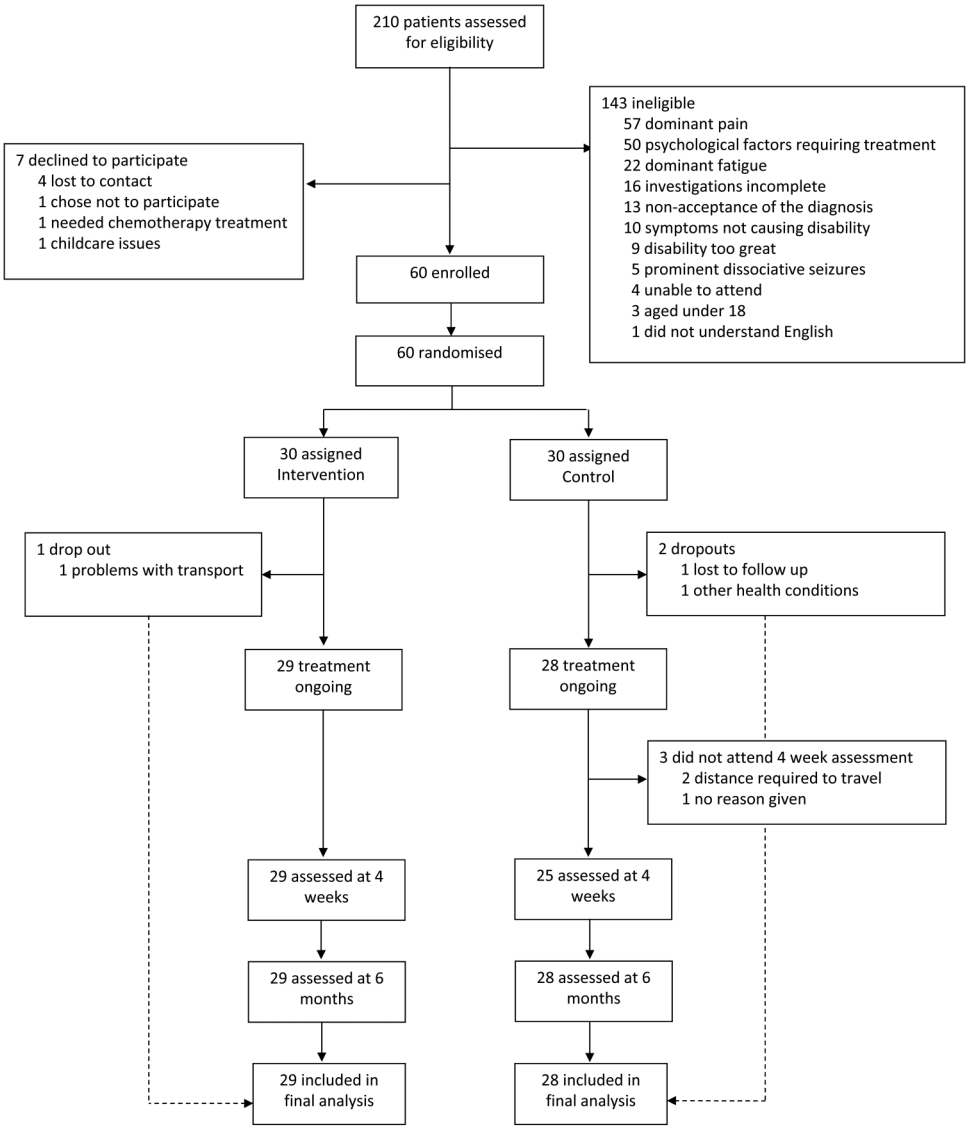

Figure 1 Trial profile.

half the participants were not working due to ill health. Mean FMS duration was 5.8 years (SD 7.3) and mean age of symptom onset was 37 (SD 12.0).

Continuous clinical outcome measures for baseline and 6-month outcome are reported in table 2, (see online supplementary data for 4-week outcome scores). Inspection of baseline data suggested that the control group had generally worse scores than the intervention group, which were accounted for in the analysis.

We tested the assumptions of the regression model, which were met. After adjusting for baseline scores, at 6 months the intervention group had superior scores (representing better health) in three domains of the SF36 (Physical function, Physical role and Social function); the Berg Balance Scale, the 10 m walk time, the Functional Mobility Scale, the DASH and the composite B-IPQ score. Two outliers skewed the results of the 10 m walk time, inflating the treatment effect. After removing outliers, the mean difference remained significant. Effect sizes were medium to large, ranging from d=0.46 to 0.79. Outcomes that were not different between groups were the remaining five domains of the SF36, HADS anxiety and depression scores and the WSAS.

The CGI data are presented in table 3. At 6 months 72% of the intervention group reported a good outcome, compared to 18% in the control group. Thirty-two per cent of the control group felt that their symptoms had got worse from baseline to 6-month follow-up, compared to 3% in the intervention group.

The mean EQ-5D-5L utility scores at baseline, 4 weeks, and 6 months are presented in figure 2. Adjusting for baseline differences, the mean QALYs over 6 months for the intervention group was 0.34 (95% CI 0.31 to 0.37) and 0.26 (95% CI 0.22 to 0.30) for the control group with a mean gain in QALYs per patient of 0.08 (95% CI 0.03 to 0.13). The cost of the intervention was estimated to be £1200 per patient. Costs included consultant neurology time, physiotherapy time (NHS band 7), equipment and consumables (including intervention workbook and issuing less supportive splints or walking aids for some patients only), lunch for 5 days and hotel accommodation for four nights (costs are itemised in online supplementary data). The cost of control was on average 4.8 sessions per patient multiplied by the cost of 1 hour of a neurophysiotherapist band 7 (£49) or £233 per patient. Based on this data, the mean incremental cost per QALY gained was £12 087.

Table 1 Baseline demographic and clinical characteristics

	Intervention n=30	Control n=30	Overall
Demographic data			
Age, mean (SD)	44 (13.1)	41 (13.1)	43 (13.1)
Female sex	22 (73%)	21 (70%)	43 (72%)
Marital status			
Married/partner	19 (63%)	18 (60%)	37 (62%)
Single	11 (37%)	12 (40%)	23 (38%)
Employment status			
In paid work or full-time study	14 (48%)	12 (40%)	26 (43%)
Not working due to ill health	14 (45%)	15 (50%)	29 (48%)
Retired	2 (7%)	3 (10%)	5 (8%)
Education level (years)			
<16	2 (7%)	1 (3%)	3 (5%)
Up to 16	8 (27%)	13 (43%)	21 (35%)
Up to 18	4 (13%)	6 (20%)	10 (17%)
Degree level qualification	13 (43%)	9 (30%)	22 (37%)
Post graduate qualification	3 (10%)	1 (3%)	4 (7%)
Clinical data			
Symptom duration in years, mean (SD)	5.9 (8.3)	5.6 (6.2)	5.8 (7.3)
Age at symptom onset, mean (SD)	38 (12.9)	36 (11.2)	37 (12.0)
Primary symptom, frequency			
Weakness	3 (10%)	4 (13%)	7 (12%)
Gait disturbance	9 (30%)	7 (23%)	16 (27%)
Upper limb tremor	3 (10%)	3 (10%)	6 (10%)
Head tremor	2 (7%)	1 (3%)	3 (5%)
Fixed dystonia	0	1 (3%)	1 (2%)
Jerks	2 (7%)	1 (3%)	3 (5%)
Mixed movement disorder	11 (37%)	13 (43%)	24 (40%)
Sensory symptoms, frequency			
Visual disturbance	11 (37%)	12 (40%)	23 (38%)
Hearing difficulties	8 (27%)	6 (20%)	14 (23%)
Pins and needles	15 (50%)	23 (77%)	38 (63%)
Numbness	14 (47%)	20 (67%)	34 (57%)
Dizziness	15 (50%)	14 (47%)	29 (48%)
Other symptoms			
Weakness*	20 (67%)	23 (77%)	43 (72%)
Headache	14 (47%)	22 (73%)	36 (60%)
Sleep disturbance	18 (62%)	20 (67%)	38 (63%)
Gastrointestinal symptoms	9 (30%)	6 (20%)	15 (25%)
Bladder problems	9 (31%)	11 (37%)	20 (33%)
Speech disturbance	13 (43%)	16 (53%)	29 (48%)
Concentration or attention problems	23 (77%)	22 (73%)	45 (75%)
Dissociative seizures	6 (20%)	3 (10%)	9 (15%)
Pain self-rating			
None	6 (20%)	1 (3%)	7 (12%)
Slight to moderate	10 (34%)	14 (47%)	24 (40%)
Severe to extreme	13 (45%)	15 (50%)	28 (47%)
Fatigue self-rating			
None	2 (7%)	1 (3%)	3 (5%)
Slight to moderate	13 (43%)	14 (47%)	27 (45%)
Severe to extreme	15 (50%)	15 (50%)	30 (50%)
Patients reporting falls	10 (33%)	19 (63%)	29 (48%)
Previous physiotherapy	23 (77%)	23 (77%)	46 (77%)
Previous psychological therapy	9 (31%)	10 (33%)	19 (32%)

*Participants who reported weakness that was in addition to their primary symptom (eg, gait disturbance and subjective symptom of weakness).

In the post-treatment feedback form, all participants in the intervention group reported they were either completely satisfied (86%) or satisfied (14%) with their treatment and they would be extremely likely (93%) or likely (7%) to recommend the programme to family and friends if they required similar treatment. The intensity of treatment was considered about right (38%) or very intense but manageable (48%). Treatment fidelity data is reported in online supplementary data and was considered satisfactory.

All control participants but one had been seen by a community physiotherapist in the period from baseline to 6-month

Table 2 Continuous outcome measure scores at baseline and 6-month follow-up

	Intervention group Mean (SD)		Control group Mean (SD)			
	Baseline	Follow-up	Baseline	Follow-up	Regression coefficient for group, baseline as covariate (95% CI)	Cohen's d
SF36 domains						
Physical function	34.8 (23.7)	51.9 (27.2)	23.7 (19.0)	23.2 (21.3)	**19.8** (10.2 to 29.5), p<0.001	0.70
Physical role	31.7 (28.9)	47.0 (30.3)	19.4 (21.7)	26.8 (22.5)	**13.0** (0.8 to 25.2), p=0.037	0.46
Bodily pain	45.6 (33.5)	47.4 (33.1)	32.1 (25.3)	33.9 (27.4)	3.6 (–8.0 to 15.3)	0.12
General health	47.3 (23.9)	54.1 (28.3)	40.7 (23.4)	39.6 (22.6)	9.0 (–0.1 to 18.2)	0.34
Vitality	32.3 (21.4)	39.2 (27.3)	26.6 (17.6)	28.3 (20.2)	6.2 (–3.6 to 15.9)	0.25
Social function	39.7 (33.2)	56.9 (30.2)	34.4 (29.8)	37.0 (25.1)	**17.1** (5.0 to 29.2), p=0.007	0.58
Role emotional	70.1 (29.5)	68.7 (34.5)	61.0 (32.6)	62.5 (35.4)	0.1 (–15.1 to 15.4)	0.00
Mental health	65.5 (21.1)	67.9 (23.8)	58.4 (23.8)	59.3 (25.2)	3.4 (–6.4 to 13.2)	0.14
Physical Summary score	33.1 (11.1)	38.7 (10.8)	28.7 (7.9)	29.5 (9.2)	**5.9** (2.1 to 9.7), p=0.003	0.54
Mental Summary score	45.2 (13.0)	45.9 (13.6)	42.6 (13.3)	43.3 (14.2)	0.9 (–4.9 to 6.8)	0.06
HADS anxiety	6.5 (3.8)	6.9 (4.8)	7.7 (4.9)	7.9 (5.6)	–0.1 (–2.1 to 2.0)	–0.02
HADS depression	5.4 (4.0)	5.2 (3.9)	8.0 (4.5)	8.4 (5.0)	–1.4 (–3.2 to 0.5)	–0.30
WSAS	24.7 (7.9)	20.2 (10.5)	27.6 (7.5)	26.9 (10.2)	–4.2 (–8.4 to 0.1)	–0.39
Berg Balance Scale	39.0 (13.8)	47.7 (13.8)	35.7 (13.2)	37.0 (14.7)	**8.0** (2.9 to 13.1), p=0.003	0.53
10 m walk time*	16.8 (10.0)	9.6 (3.8)	24.6 (17.3)	19.0 (10.6)	**–6.7** (–10.7 to –2.8), p=0.001	–0.72
Functional Mobility Scale	11.7 (4.1)	14.5 (3.5)	10.0 (3.6)	10.0 (3.9)	**3.4** (1.9 to 5.0), p<0.001	0.79
DASH	51.8 (19.6)	39.6 (25.6)	51.2 (15.0)	48.1 (21.4)	**–9.1** (–17.4 to –0.8), p=0.031	–0.38
B-IPQ composite score	50.0 (10.8)	39.4 (16.1)	54.6 (10.6)	51.0 (13.0)	**–8.0** (–14.4 to –1.6), p=0.015	0.51

*Two outliers removed from the intervention group (baseline times of 197 and 182 s). Removing these outliers decreased the treatment effect by 1.4 s. Higher scores represent better health in the SF36, Berg Balance and Functional Mobility Scale. Higher scores represent worse health for HADS, Work and Social Adjustment, 10 m timed walk and DASH.
DASH, Disabilities of Arm Shoulder and Hand; HADS, Hospital Anxiety and Depression Scale; WSAS, Work and Social Adjustment Scale.

Table 3 Clinical Global Impression Scale at 6 months

	Intervention group	Control group
Much worse	0	3 (11%)
Worse	1 (3%)	6 (21%)
No change	7 (24%	14 (50%)
Improved	11 (38%)	5 (18%)
Much improved	10 (35%)	0
Collapsed scores		
Good outcome	21 (72%)	5 (18%)
Poor outcome	8 (28%)	23 (82%)

We defined a good outcome as a rating of improved or much improved, and a poor outcome as a rating of no change, worse or much worse.

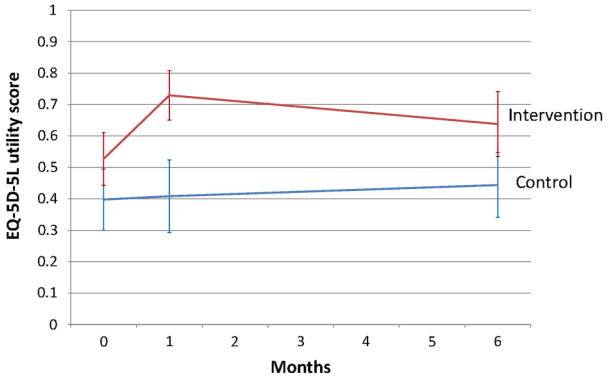

Figure 2 Mean EQ-5D-5L utility scores at baseline, 4 weeks and 6 months for the intervention and control groups. A utility score of 1.0 represents full health.

follow-up. The number of sessions ranged from 1 to 17; the median number was 5 (IQR 3–7.5). The content of physiotherapy sessions (reported by participants) included gait retraining, stair practice, balance, non-specific cardiovascular exercise, specific strengthening exercises and stretching. Four participants were provided with a walking aid or splint. One participant had fatigue management education and one participant was given specific strategies aimed at controlling a functional tremor.

No serious adverse incidents were reported during the study period. Some participants from the intervention group reported exacerbation of chronic pain or fatigue during, and the week following treatment. These resolved without the need for a new intervention. No participants reported deterioration of mental health associated with treatment.

DISCUSSION

We report a large randomised feasibility study of a specific physiotherapy-based treatment for FMS. Recruitment rate, enrolment and retention were high and clinical outcomes were promising, providing evidence that an appropriately powered RCT is feasible, timely and important. Thirty-two per cent of new patients presenting to our clinics with FMS met the selection criteria and there was a 90% enrolment rate. Given the high prevalence of such patients in general neurology clinics it follows that there are sufficient patients to run a larger version of this trial.[1 2] High rates of recruitment and retention point to the intervention being acceptable, and this is supported by participant feedback forms.

An important aim was to test the utility of a range of outcome measures and determine which to use in a power calculation for a future clinical trial. Measuring outcome in FMS is complicated by the variable nature of symptom severity inherent to the diagnosis. For this reason, snapshot measures of disability are likely to have problems with test–retest reliability, limiting their usefulness. Gait and balance outcome measures are restrictive as they are not applicable to patients with upper limb symptoms only. The SF36 Physical Function domain was the most promising primary outcome. It had a medium-to-large effect size (d=0.70), and it is not as vulnerable to symptom fluctuation, as answers are given based on the respondent's perception of the average experience within the set recall period.

There were no reported serious adverse incidents during the trial period. We did not identify any mental health-related adverse events associated with physiotherapy treatment. Patients with clinically evident anxiety and depression warranting intervention were excluded from the study and referred to more appropriate treatment. Measures of mental health did not change in either group. Some participants in the intervention group reported an exacerbation of chronic fatigue related to the intensity of treatment, which resolved spontaneously over several days. We suspect the relatively high intensity and short duration is an important therapeutic element of our intervention, allowing gains made in therapy to be built on in subsequent sessions, minimising time for symptom relapse or interference from environmental symptom maintaining factors. This intensity may make it unsuitable for some patients and with this in mind we excluded those for whom chronic pain or fatigue was the dominant problem. Despite this, half the enrolled participants still rated their pain or fatigue as severe to extreme.

To the best of our knowledge, this is the first reported randomised study of physical rehabilitation for FMS with a control period >4 weeks. With the caveat that this research was primarily designed to assess feasibility, we report a moderate to large treatment effect size across a range of measures of physical function, controlled over a 6-month period. A larger proportion of the intervention group rated their symptoms as improved (72%) compared to the control group (18%), while 32% of the control group felt their symptoms had worsened over the follow-up period, compared to 3% in the intervention group. The effect size of the intervention is consistent with those of similar published studies in FMS, including our cohort study of 47 patients during the development phase of the 5-day programme;[8] a 5-day physiotherapy and occupational therapy-based intervention;[26] and a randomised delayed-start trial of a 3-week inpatient physical-based rehabilitation programme.[5] The improvement reported in the current study occurred in a sample of patients with characteristics usually associated with a poor prognosis. The average FMS duration was 5.8 years (SD 7.3), participants had multiple coexisting symptoms, and high rates of unemployment due to ill health. It is possible that if the intervention occurred earlier in the course of their disorder, it may have been more effective.

The B-IPQ total score is thought to represent the threat value of an illness. In our study, the intervention was associated with a reduction in the B-IPQ total score in the intervention group and there was little change in the control group (table 2). We hypothesise that the intervention helped patients to understand their symptoms and improve control over their movement, both of which resulted in diminished concern. This may represent one mechanism by which the intervention affects change, although we recognise that the total B-IPQ score may have problems with internal consistency.[27]

The EQ-5D-5L is the preferred instrument for generating QALYs by the UK organisation the National Institute for Health and Care Excellence (NICE). The average difference in QALYs between the groups adjusting for baseline differences was 0.08 QALYs and the resulting ICER of £12 087 suggests the intervention is most likely cost-effective. In general, an ICER below £20 000 is considered cost-effective.[28] This is without accounting for a potential reduction in the costs of health and social care usage, reduction in disability benefits and return to paid employment.

We recognise a number of limitations in our study. It was not specifically designed or powered to detect a treatment effect. However, given the absence of controlled trials in the literature we considered reporting outcome appropriate. At baseline, the control group had scores that represented worse health than the intervention group. Our analysis accounted for baseline differences and there was still a large treatment effect with the intervention and little or no change with the control condition. A future trial could consider a randomisation procedure that involved minimisation to account for baseline severity. Participants and assessors were not masked to treatment allocation, which may have introduced bias. Most outcomes were subjective patient-reported outcomes, which may be influenced by many factors, including the lack of blinding. We did not use a standardised diagnostic schedule to ascertain clinically significant anxiety or depression as a basis for exclusion from the study. This may have led to exclusion of some patients who might have benefitted from the programme. The intervention included an additional consultation with the study neurologist that was not offered to the control group. This may have enhanced the therapeutic benefit of the intervention, limiting generalisability to services where this is unavailable. Finally we did not standardise the control condition. A strength of the study is that the selection criteria were relatively inclusive (we did not exclude on the basis of age, FMS duration or phenomenology), making results more transferable to a real world clinical context.

In summary, this study demonstrates the feasibility of performing a large trial of specialist physiotherapy for FMS. We report a large treatment effect and evidence of cost benefit in a group of patients that are prevalent, have poor quality of life and have a poor prognosis with the current available treatment. The study data strongly support the need for a multicentre randomised trial of this intervention.

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Contributors GN and MJE devised the physiotherapy treatment programme. GN, MJE, MB, FS, EJ, RH, LR and JM contributed to the design of the study. KH delivered the intervention. MD took part in data collection. GN took part in data analysis. RH contributed to health economic analysis. GN and ME prepared the first draft of the manuscript, all authors reviewed and revised the subsequent versions of the manuscript.

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REFERENCES

1 Ahmad O, Ahmad KE. Functional neurological disorders in outpatient practice: an Australian cohort. *J Clin Neurosci* 2016;28:93–6.
2 Stone J, Carson A, Duncan R, *et al*. Who is referred to neurology clinics? The diagnoses made in 3781 new patients. *Clin Neurol Neurosurg* 2010;112:747–51.
3 Carson A, Stone J, Hibberd C, *et al*. Disability, distress and unemployment in neurology outpatients with symptoms 'unexplained by organic disease'. *J Neurol Neurosurg Psychiatr* 2011;82:810–13.
4 Gelauff J, Stone J, Edwards M, *et al*. The prognosis of functional (psychogenic) motor symptoms: a systematic review. *J Neurol Neurosurg Psychiatr* 2014;85:220–6.
5 Jordbru AA, Smedstad LM, Klungsøyr O, *et al*. Psychogenic gait disorder: a randomized controlled trial of physical rehabilitation with one-year follow-up. *J Rehabil Med* 2014;46:181–7.
6 Nielsen G, Stone J, Edwards MJ. Physiotherapy for functional (psychogenic) motor symptoms: a systematic review. *J Psychosom Res* 2013;75:93–102.
7 Nielsen G, Stone J, Matthews A, *et al*. Physiotherapy for functional motor disorders: a consensus recommendation. *J Neurol Neurosurg Psychiatr* 2015;86:1113–19.
8 Nielsen G, Ricciardi L, Demartini B, *et al*. Outcomes of a 5-day physiotherapy programme for functional (psychogenic) motor disorders. *J Neurol* 2015;262:674–81.
9 Matthews A, Brown M, Stone J. Inpatient physiotherapy for functional (psychogenic) gait disorder: a case series of 35 patients. *Mov Disord Clin Pract*. Published Online First: 2 Jan 2016 doi:10.1002/mdc3.12325
10 Fahn S, Williams DT. Psychogenic dystonia. *Adv Neurol* 1988;50:431–55.
11 Stone J, Edwards M. Trick or treat? Showing patients with functional (psychogenic) motor symptoms their physical signs. *Neurology* 2012;79:282–4.
12 McHorney CA, Ware JE, Raczek AE. The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. *Med Care* 1993;31:247–63.
13 Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983;67:361–70.
14 Herdman M, Gudex C, Lloyd A, *et al*. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727–36.
15 Zahra D, Qureshi A, Henley W, *et al*. The work and social adjustment scale: reliability, sensitivity and value. *Int J Psychiatry Clin Pract* 2014;18:131–8.
16 Carson AJ. The outcome of neurology outpatients with medically unexplained symptoms: a prospective cohort study. *J Neurol Neurosurg Psychiatr* 2003;74:897–900.
17 Sharpe M, Walker J, Williams C, *et al*. Guided self-help for functional (psychogenic) symptoms: a randomized controlled efficacy trial. *Neurology* 2011;77:564–72.
18 Hudak PL, Amadio PC, Bombardier C. Development of an upper extremity outcome measure: the DASH (disabilities of the arm, shoulder and hand) [corrected]. The Upper Extremity Collaborative Group (UECG). *Am J Ind Med* 1996;29:602–8.
19 Graham HK, Harvey A, Rodda J, *et al*. The Functional Mobility Scale (FMS). *J Pediatr Orthop* 2004;24:514–20.
20 Berg KO, Wood-Dauphinee SL, Williams JI, *et al*. Measuring balance in the elderly: validation of an instrument. *Can J Public Health* 1992;83(Suppl 2):S7–11.
21 Broadbent E, Petrie KJ, Main J, *et al*. The brief illness perception questionnaire. *J Psychosom Res* 2006;60:631–7.
22 Sedgwick P. Effect sizes. *BMJ* 2012;345:e7370.
23 Devlin N, Shah K, Feng Y, *et al*. Valuing health-related quality of life: an EQ-5D-5L value set for England. *Office of Health Economics* 2016. https://www.ohe.org/publications/valuing-health-related-quality-life-eq-5d-5l-value-set-england (accessed 12 Jul 2016).
24 Hunter RM, Baio G, Butt T, *et al*. An educational review of the statistical issues in analysing utility data for cost-utility analysis. *Pharmacoeconomics* 2015;33:355–66.
25 Curtis L, Burns A. Unit costs of health and social care 2015. Personal Social Services Research Unit, The University of Kent. http://www.pssru.ac.uk/project-pages/unit-costs/2015/ (accessed 28 Apr 2016).
26 Czarnecki K, Hallett M. Functional (psychogenic) movement disorders. *Curr Opin Neurol* 2012;25:507–12.
27 Broadbent E, Wilkes C, Koschwanez H, *et al*. A systematic review and meta-analysis of the Brief Illness Perception Questionnaire. *Psychol Health* 2015;30:1361–85.
28 National Institute for Health and Clinical Excellence (NICE). *Social value judgements: principles for the development of NICE guidance*. 2nd edn. 2008. https://www.nice.org.uk/media/default/about/what-we-do/research-and-development/social-value-judgements-principles-for-the-development-of-nice-guidance.pdf (accessed 12 Apr 2016).