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A pilot randomised controlled trial of a home based exercise programme aimed at improving endurance and function in adults with neuromuscular disorders (NMD)

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ABSTRACT

Background: We investigated the feasibility and effect of a home-based exercise programme on walking endurance, muscle strength, fatigue and function in individuals with neuromuscular disorders (NMD).

Methods: Twenty adults with NMD were recruited to a control (11) or exercise group (9) in this single-centre randomised controlled pilot study. Blinded assessors assessed individuals at baseline and week eight. The exercise group received an eight-week home exercise program of walking and strengthening exercises. Main outcome measure was 2-minute walk distance; secondary measures included isometric muscle strength, fatigue and function.

Results: Two-minute walk distances did not change in either group ($p>0.05$) (control, mean ± SD: 14.50 ± 22.06; exercise, 2.88 ± 20.08), with no difference in the change scores between groups ($p>0.05$). Leg muscle strength measures increased in the exercise group ($p<0.05$) but not the control group ($p>0.05$). The difference in change in muscle strength scores reached significance between the groups in the right quadriceps ($p<0.05$): control, -2.82 ±4.87 and exercise -7.08 ± 2.82 ($p<0.05$). There was no change in fatigue or function scores ($p <0.05$).

Conclusions: This pilot study suggests a home-based approach is feasible. Further investigation is warranted in a larger sample.

INTRODUCTION

Individuals with neuromuscular diseases may lead a relatively sedentary lifestyle, causing secondary detraining. [1] Participation in regular exercise leads to health and social benefits even in people with disease. [2] The limited clinical research in adults with neuromuscular disease suggest that they benefit from targeted aerobic and muscle training exercise programmes. [3] [4] These interventions may be effectively provided in the community setting [5] [6]and have been shown to be more effective if supported by a therapist. [7]

Patients with neuromuscular disease in the UK receive specialist support from regional centres, which may be some distance from their home. We developed a training programme that could be delivered with a single demonstration of exercises in the clinic with follow up support delivered through a leaflet and by phone. We set out to carry out a pilot investigation of the effect of an exercise programme specifically developed for a range of neuromuscular disorders upon walking distance in adults with NMD. Our secondary aims were to investigate the effect on fatigue, isometric muscle strength and performance, and perceived ability in targeted functional activities.

METHOD

Adults were sixteen years and over with a diagnosis of primary muscle disease attending a regional neuromuscular clinic with abnormal gait pattern, or 10 metre time exceeding “normal” age related time by >= 2s but able to walk 10m without physical assistance, aids being permitted. People who had physical, cognitive, sensory or psychological impairments, or other conditions precluding full engagement with the experimental paradigm were excluded. Informed consent was obtained before participation.

On first assessment the following measures were obtained:

1. Gender and age.
2. Anthropometrical data [height (cm), weight (kg) and leg length (cm)].
3. Presenting pathology, medication and past medical history
4. Rivermead Mobility Index (standard version, 0-15).[8]
5. Barthel Index (standard 0-100 version). [8]
6. Fatigue [Fatigue Severity Scale]. [9]
7. Self reported capability of performing a functional activity [using a 10cm Visual Analogue Scale]. [10] [11]
8. Physical Activity Scale for the Elderly (PASE). [12]
9. Maximal isometric muscle strength, best of three attempts (hip flexor/extensor, knee flexor/extensor and ankle flexor/extensor) using a myometer (Lafayette, US). [13]
10. Ten metre and two minute walk times. [8]

The Control group patients had: Becker Muscular Dystrophy (BMD) 3, Myotonic Dystrophy 3, Polymyositis 1, Facioscapulohumeral muscular dystrophy (FSH) 1, inclusion body myositis 1, Congenital myopathy 1 and the Exercise group: Limb girdle muscular dystrophy 4, FSH 2, BMD 1, Myotonic Dystrophy 1. Ages ranged from 18- 81 with mean of 44 (SD ± 12). There were seven men in the control group and four in the exercise group. At baseline one individual in each group used a wheelchair for long distance mobility, with three using a walking aid in the exercise group and four in the control group.

Following initial assessment individuals were randomly allocated to an exercise or control group. Randomisation occurred in blocks of 4 using consecutively numbered sealed envelopes containing the group derived from computer generated random numbers. The control group received standard physiotherapy (advice and support). The training group received an additional exercise intervention for 8 weeks. After 8 weeks both groups were reassessed (see figure 1) by a blinded assessor. At this point the control group were offered the intervention.

Intervention

Individuals allocated to the exercise programme were introduced to the intervention (walking and strengthening exercises) performed on alternate days. They were familiarised with Borg's CR10 exercise symptom rating scale using a standard method [14] and asked to walk for as long as possible up to 20 minutes at a light subjective exercise intensity, taking breaks if required. When individuals achieved the full 20 minutes they were encouraged to increase walking intensity towards a 'moderate' level using the CR10 scale.

Individuals were given two leg muscle endurance and two core stability exercises. Individuals were encouraged to increase gradually the number of repetitions, decreasing the number and length of rest breaks until they could perform each exercise for 2 ½ minutes. At this point, they were guided to increase the difficulty by increasing the range performed. In sessions when the difficulty was increased individuals were guided to perform as many repetitions as possible and in subsequent sessions to increase this number until they could exercise for 2 ½ minutes. When the full range was achieved, difficulty was increased by performing exercises against resistance, using gravity, with individuals again guided to perform as many repetitions as possible and in subsequent sessions to increase this number.

In order to measure exercise compliance during the intervention period, pedometer counts and self reported compliance diaries (exercises and walking) were recorded. [15]

Individuals were given a handout with their exercises detailed. The day following the initial assessment and each week, individuals were contacted by phone by a researcher and supported in their exercise progression.

Sample characteristics were summarised using descriptive statistics. Data were examined for initial between group differences and for between group differences in change scores.

Due to the small sample sizes, and rejection of normality assumptions non-parametric tests (Mann-Whitney U and Wilcoxon tests) were used, with the significance level set at 5%. Data were analysed using SPSS version 12.01.

RESULTS

Figure 1 shows the time line and flow of individuals recruited to the study. One individual dropped out from each arm of the study for reasons unrelated to the intervention.

Self-reported compliance by the exercise group rendered a mean walking exercise of 106% (range: 78-160%) and endurance exercises of 104% (67-152%). Pedometer counts taken in the intervention period were a mean count of 6098 (SD ± 1901) steps (range 2798-8331) in week one with no significant increase seen during the following weeks of the intervention: mean change -1485 (SD ± 2681) ($p>0.05$).

At baseline we observed no difference between groups (Table 1). The exercise group improved significantly in all strength measures. The difference in change in muscle strength scores reached significance between the groups in the right quadriceps ($p<0.05$) (Table 1). We observed no effects on walking measures, disability, mobility or fatigue.

Table one

Measures at baseline and re-assessment [mean (SD) range]

	Week 1 **Baseline**		**Change in score week 1– week 8** **Re - assessment**			
Mean (SD) *Range*	**Control Group**	**Exercise Group**	**Control Group**		**Exercise Group**	
Disease Duration (yrs)	15.3 (17.2) 0.5-52	25.6 (18.9) 3-56				
Height (cm)	177.6 (10.9) 191.2-157.5	172.5 (8.9) 182.5-163.2				
Weight (kg)	79.1 (13.9) 110-64	79.1 (17) 59-103				
10-metre walk (seconds)	11.93 (4.85) 5.19-21.18	11.03 (3.82) 6.25-18	0.43 (2.06) -3.96 - 4.07	***I***	-0.30 (0.91) -2.34 -0.40	***D***
2-minute walk (metres)	93.67 (29.11) 53-136	97.06 (43.62) 48-184.57	14.50 (22.06) -8.00- 64.00	***D***	2.88 (20.08) -18.00 -41.00	***D***
Strength Quadriceps L	9.83 (6.25) 3.8 - 22.4	9.3 (4.00) 2.6 - 15.5	-2.26 (4.85) -12.00- 4.70	***I***	-5.08 (3.18) -7.47- 1.00	***I*** †**
Strength QuadricepsR	10.28 (6.69) 3.2 - 22.4	9.1 (3.53) 2.5 -14.5	-2.82 (4.87) -13.40 - 2.60	***I***	-7.08 (2.82) -12.30 - ¯3.20	***I*** † *
Strength Iliopsoas L	11.08 (5.26) 4.5- 20.3	9.01 (2.63) 3.9 -12.5	-2.20 (4.57) -9.30 - 6.70	***I***	-5.59 (5.58) -14.90- 0.02	***I*** †
Strength Iliopsoas R	12.68 (4.17) 7.2 - 21	9.28 (3.73) 2 - 14.8	-2.13 (5.57) -13.30- 7.30	***I***	-4.20 (5.91) -13.80 -3.77	***I*** †
Strength TA L	6.85 (4.66) 1.5 - 14.7	4.88 (4.63) 0 11.2	-1.93 (2.04) -6.60- 0.50	***I*** †	-5.35 (5.20) -13.80 - ¯ 0.10	***I*** †
Strength TA R	7.03 (4.88) 1.3 - 16.8	3.65 (3.14) 0 - 8.4	-2.07 (5.38) -16.50 - 3.40	***I***	-4.90 (5.92) -13.80 - 3.95	***I*** †
RMI	12 (2) 9-15	11 (2) 9-15	0.20 (1.48) -2.00 - 3.00	***D***	-0.88 (1.46) -4.00- 0.00	***I***
Fatigue Severity Scale	5 (1) 3 - 6	5 (1) 4- 5	0.08 (0.90) -1.03- 1.88	***I***	0.30 (0.74) -0.68 - 1.63	***I***
Visual Analogue Scale	7 (3) 1 -10	8 (1) 6 -9	1.96 (1.83) -1.10 - 4.80	***I***	1.13 (1.73) -0.60 - 4.20	***I***
Barthel Index	97 (3) 90 -100	96 (7) 80 -100	-0.50 (4.38) -10.00 - 5.00	***I***	-2.5 (7.56) -20 – 5	***I***
PASE	112 (75) 43 - 295	145 (103) 64 - 302	-43.49 (100.74) -237.10- 60.74	***I***	-11.64 (38.31) -74.02- 41.35	***I***

RMI Rivermead Mobility Index
PASE Physical Activity Scale for the Elderly
***** Mann- Whitney U test p-value < 0.05
****** Mann- Whitney U test p-value < 0.1
† Wilcoxon test p-value < 0.05

Improvement = ***I*** Deterioration = ***D***A power calculation to determine the sample size required to observe between group differences in the measure of walking distance, taking a power of 0.9, and alpha of 0.05, SD of 21.07 and difference between groups of 11.62 suggests a sample size of 70 would be needed.

DISCUSSION

We found individuals tolerated and were compliant with the exercise program. All muscles in the exercise group increased in strength, with statistical significance over the control group achieved in the right quadriceps. Walking distance and speed did not significantly change in either group. There was no observed change in disability or fatigue. Analysis reveals that a sample of 70 would be required to show between group differences in walking distance with smaller numbers to show significant differences in muscle measures. Our findings are promising and an adequately powered study investigating delivery of a home exercise programme from current neuromuscular clinics is indicated.

There are certain limitations to the study. The sample size was small. Individuals recounted their own compliance and step count to the researchers during the weekly phone support. Further we were unable to monitor the control group; informally reported activity levels increased in the control group, which may have been a consequence of mention of the possible benefits of exercise while gaining informed consent.

Whilst our findings are encouraging, there is scope for investigating other systems for delivering exercises. Future studies with a bigger sample of individuals with a range of conditions and impairment levels should observe the natural time course of the disease on specific strength, community mobility measures and quality of life prior to examining delivery and long term follow up of an exercise programme and its effect.

CONCLUSION

We found the programme feasible and well tolerated. Home delivery of such a programme is novel, practical and easily implemented within busy outpatient clinics in the NHS. Further investigation is warranted.

Figure 1 Flow of people through the study

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