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Pragmatic exercise intervention in people with mild to moderate multiple sclerosis: A randomised controlled feasibility study

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ABSTRACT

Background: People with Multiple Sclerosis (PwMS) are less physically active than the general population and pragmatic approaches designed to equip them with the skills and confidence to participate in long-term physical activity are required.
Objective: The objective of this study was to determine the feasibility of a pragmatic exercise intervention in PwMS.
Methods: A voluntary sample of 30 PwMS (male $n = 4$, female $n = 26$; mean age = 40 years; range = 24–49 years), with mild to moderate disability (EDSS ≤ 5.5), were recruited from eligible participants attending outpatient clinics. A total of 28 participants were randomised to a 10 week pragmatic exercise intervention (2× supervised and 1× home-based session per week) or usual care. Clinical, functional and quality of life (MSQoL-54) outcomes were assessed at baseline, immediately and 3 months after the intervention.
Results: Attrition was low (2 participants lost to immediate follow-up and 4 participants lost to 3 month follow-up), with high compliance rates (>75% of all sessions). The intervention group achieved progression of exercise volume (24.3 ± 7.0 to 30.9 ± 5.5 min per session), intensity (60.4 ± 8.8 to 67.7 ± 6.9% HR max) and training impulse (min × average HR = training impulse/load [arbitrary units; AU]) (2600 ± 1105 to 3210 ± 1269 AU) during the intervention, whilst significantly increasing($P = 0.050$) their physical composite score (MSQOL-54) at 10 weeks and readiness to exercise ($P = 0.003$) at 3 months compared with usual care.
Conclusion: This pragmatic intervention was feasible for PwMS, but further research is needed to assess its long-term impact on physical activity behaviour.

1. Introduction

Evidence suggests that People with Multiple Sclerosis (PwMS) are less physically active than the general population [1], but exercise self-efficacy has consistently been reported to influence participation [2,3]. Current research supports the health benefits of supervised, one to one facility based exercise interventions for people with mild to moderate disability from Multiple Sclerosis (MS). These include, increased muscle

Abbreviations: PwMS, People with Multiple Sclerosis; QoL, Quality of life; NHS, National Health Service; EDSS, Expanded Disability Status Score; RPE, Rate of Perceived Exertion; TRIMP, Training impulse; AU, Arbitrary units; GNDS, Guy's Neurological Disability Scale; BMI, Body Mass Index; MSFC, Multiple Sclerosis Functional Composite; MSQOL-54, Multiple Sclerosis Quality of Life-54; HRQOL, Health Related Quality of Life; EM, Expectation Maximisation

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strength and aerobic capacity, improved mood state and enhanced quality of life (QoL), with no evidence of patient harm [4,5]. In the long-term, this approach may prove difficult for PwMS and is unlikely to be cost effective. More high quality randomised control trials (RCTs) to assess the efficacy of pragmatic interventions for equipping PwMS with the skills and confidence needed to exercise independently long-term are required [6]. This is important as despite the benefits of exercise, PwMS appear to find long-term exercise behaviour change difficult and interventions based on behaviour change theories are likely to optimise the chances of long term behaviour change. One approach to this is the Transtheoretical Model [7] of behaviour change, which outlines a series of stages that people move through in the behaviour change process and suggests strategies or processes that can be used to facilitate movement through the stages. This model has been used to promote physical activity behaviour change in other populations but not in PwMS [8].

The primary aim of this study was to investigate the feasibility of a 'pragmatic' exercise intervention, that included cognitive–behavioural strategies within the framework of the Transtheoretical Model, to facilitate long term physical activity behaviour change in PwMS. In this study 'pragmatic' is defined as a practical, achievable and flexible programme that allows for individual choice and utilises behaviour change tools to enhance self-efficacy and promote long-term behaviour change. Feasibility was measured in terms of recruitment, acceptability of the intervention, compliance and attrition, safety and suitability of exercise dose and appropriateness of outcome measures. The secondary aim was to obtain preliminary data on the impact of the intervention on key health outcomes by comparison with PwMS randomised to a usual care control group. We hypothesized that PwMS will find a pragmatic approach to exercise feasible, with results indicating improvements in physical function and quality of life.

2. Methods

2.1. Participant inclusion/exclusion criteria

A total of 30 participants were recruited from MS clinics at Sheffield Teaching Hospitals NHS Foundation Trust (UK). All participants were aged 18–65 years, fulfilled the modified McDonald diagnostic criteria for MS [9], had an Expanded Disability Status Score (EDSS; [10]) $\leq$5.5 and were stable on disease modifying treatment for $\geq$3 months prior to recruitment. Participants who experienced relapses within the preceding 3 months, had other illnesses substantially affecting their ability to exercise (confirmed by consultant physician) or who were physically active ($\geq$2$\times$ per week, $\geq$30 min per session, during the previous 3 months) were excluded. Ethics and research governance approval for this study were obtained through Sheffield Research Ethics Committee and the Sheffield Teaching Hospitals NHS Foundation Trust, respectively.

2.2. Study design

This feasibility study was a parallel randomised controlled trial (RCT). Following completion of baseline assessments, 28 participants were randomly assigned to either pragmatic exercise or usual care control groups. The randomization list was computer generated by an independent researcher and was concealed from those conducting assessments. Both groups had access to usual medical care.

2.3. Pragmatic exercise therapy intervention

Participants attended two supervised sessions and undertook one home session per week for 10 weeks. Supervised sessions were delivered one-to-one and led by an exercise researcher, qualified up to postgraduate level in sport and exercise science, with applied accreditation in exercise delivery. The project lead observed the delivery of the intervention at the start to ensure that protocols were interpreted correctly and consistently. Each session lasted approximately 1 h, with participants being offered a range of aerobic exercise options (rowing, walking, upright cycle, recumbent bike and cross-trainer), delivered as short bouts (e.g. 5$\times$ for 3 min, with 2 min rest) at 50 to 69% age predicted maximum heart rate (ratings of perceived exertion [RPE] 11 to 13 on the Borg RPE Scale). Training impulse (TRIMP), calculated as average exercise heart rate (beats/min) $\times$ duration (min), and expressed in arbitrary units (AU), was used to quantify overall exercise training load [11]. TRIMP is a method used to quantify aerobic exercise training load and is useful for expressing the total "dose" of exercise achieved during an intervention and rate of progression.

The exercise programme was progressive and tailored towards individual capabilities and preferences. Participants were encouraged to try all appropriate exercise options, but were given a choice over the exact modality, duration and intensity of the sessions. Sessions were then designed and progressed on the basis of individual preferences. Each session contained a warm-up, followed by an aerobic component, tailored functional body conditioning exercises based on individual need (balance, strength and flexibility) and a cool down, with content recorded (exercise modality, heart rate, RPE and duration). Body conditioning exercises included supported body resistance exercises (e.g. squats against the wall), gym ball exercises for core stability and static stretching for large muscle groups. This type of tailored approach is recommended for PwMS [6]. Using the Transtheoretical Model [7] as a guiding framework, a variety of cognitive behavioural techniques (e.g. consciousness raising, goal setting and finding social support for exercise) were also used during sessions to promote motivation and confidence for exercise. Exercise researchers were trained in the delivery of the intervention and detailed guidelines on weekly content were provided. The behavioural techniques were integrated into the exercise sessions and the instructor used strategies appropriate to the conversation, the stage of change participants were at, and difficulties/questions participants raised during sessions. Full details of the behaviour change strategy have been published previously [12].

Home session content comprised both aerobic exercise and body conditioning activities, and was agreed with the participant after taking into account their needs, preferences, goals and exercise opportunities in their community. The duration and intensity of the home exercise sessions mirrored the level and progression achieved in the supervised sessions. Home sessions were included to promote independent exercise participation following the intervention. Participants completed a physical activity diary to log compliance and diaries were