RCT of a Behavioral Intervention Targeting Physical Activity and Symptoms in MS

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INTRODUCTION

• Exercise training results in improved fitness, fatigue, depression, mobility, and quality of life among persons with MS; [1,2] however, persons with MS do not engage in sufficient amounts of exercise or physical activity.

• Lifestyle physical activity defined as daily accumulation of 30 minutes or more of moderate-to-vigorous physical activity may be an alternative to exercise training.[3]

• We previously designed and tested a lifestyle physical activity intervention delivered through the Internet and grounded in social cognitive theory (SCT). This intervention has effectively increased self-reported and objectively measured physical activity.[4-7]

• To date, there is minimal evidence regarding the efficacy of this intervention for improving secondary symptomatic and quality of life (QOL) outcomes.

AIMS

1. To examine the efficacy of a behavioral intervention delivered through the Internet for improving outcomes of fatigue, depression, anxiety, pain, sleep quality, and QOL among ambulatory persons with MS.
2. To replicate previous effects of the intervention on self-reported and objectively measured physical activity.

METHODS

Participants:
• Clinically definite diagnosis of MS
• Relapse-free during past 30 days prior to testing
• Age 18-64 years
• Internet access
• Ambulatory with or without an assistive device
• Inactive (≤ 60 minutes of MVPA per week
• Minimal risk for engaging in physical activity

Outcomes:
• <u>Physical Activity</u>: Godin Leisure-Time Exercise Questionnaire (GLTEQ) and accelerometer (minutes of MVPA).
• <u>Fatigue</u>: Fatigue Severity Scale (FSS) and Modified Fatigue Impact Scale (MFIS).
• <u>Depression and Anxiety</u>: Hospital Anxiety and Depression Scale (HADS).
• <u>Pain</u>: short-form McGill Pain Questionnaire (SF-MPQ).
• <u>Sleep</u>: Pittsburgh Sleep Quality Index (PSQI).
• <u>Health Related Quality of Life</u>: Multiple Sclerosis Impact Scale-29 (MSIS-29).

INTERVENTION

The goal of the intervention was to increase lifestyle physical activity, primarily walking, and was based on previous versions of the intervention.[4-7] This was accomplished through: (1) a study website with information on becoming more physical active based on SCT; (2) self-monitoring and goal-setting using a pedometer activity logs, and Goal Tracker Software; (3) and one-on-one web-based video coaching sessions with a behavioral coach.

RESULTS

TABLE 1. Participant characteristics and tests for pre-trial differences between randomized groups. Values are means (SD) unless otherwise noted.

Variable	Intervention (n=41)	Control (n=41)	*P* value
Age, years	48.4 (9.1)	49.5 (9.2)	.61
Sex, female/male	30/11	32/9	.61
Height, cm	169.4 (9.3)	167.6 (7.2)	.34
Weight, kg	79.8 (21.4)	77.6 (18.6)	.63
PDDS, mdn (IQR)	2.0 (4.0)	3.0 (3.0)	.12
SR-EDSS, mdn (IQR)	3.5 (4.25)	3.5 (4.5)	.69
Disease duration, years	10.6 (7.1)	13.0 (9.1)	.18
Disease course, RRMS/SPMS/PPMS	31/8/2	34/2/5	.08
Assistive device use, number (%)			.95
No assistive device	31 (75.6%)	30 (73.2%)	
Cane	5 (12.2%)	5 (12.2%)	
Walker or rollator	5 (12.2%)	6 (14.6%)	
Physical activity			
GLTEQ	15.6 (19.9)	17.2 (15.2)	.69
MVPA, minutes	17.0 (22.4)	16.2 (17.7)	.87
Symptoms			
FSS	5.0 (1.4)	5.2 (1.4)	.51
MFIS	38.8 (20.9)	42.2 (20.1)	.45
HADS Depression	6.3 (4.1)	6.3 (4.0)	.98
HADS Anxiety	5.5 (4.2)	5.5 (3.3)	.93
SF-MPQ	8.3 (7.0)	10.6 (7.7)	.16
PSQI	6.9 (4.1)	8.4 (4.3)	.12
Health-Related Quality of Life			
MSIS-29 Physical	42.9 (20.1)	47.6 (19.6)	.28
MSIS-29 Psychological	18.8 (7.7)	21.2 (8.4)	.19

TABLE 2. Post-trial data from intervention and control conditions and tests for condition effect controlling for pre-trial outcome scores. Values are adjusted marginal means (SE). *Notes significant difference between groups (*p*<.05).

| Outcome	Intervention (n=37)	Control (n=39)	η_p^2
Physical activity			
GLTEQ	27.2 (3.0)	13.0 (3.0)	.13*
MVPA, minutes	19.5 (2.3)	13.8 (2.2)	.05
Symptoms			
FSS	4.6 (0.2)	5.4 (0.2)	.15*
MFIS Total	35.7 (1.8)	40.5 (1.8)	.05
MFIS Physical	16.0 (0.9)	19.3 (0.8)	.09*
MFIS Cognitive	16.7 (1.0)	18.0 (0.9)	.01
MFIS Psychosocial	3.0 (0.2)	3.3 (0.2)	.01
HADS Depression	5.0 (0.4)	6.6 (0.4)	.10*
HADS Anxiety	4.1 (0.4)	5.6 (0.4)	.10*
SF-MPQ	8.1 (0.7)	9.8 (0.6)	.04
PSQI	6.4 (0.4)	7.4 (0.4)	.05
Health-Related Quality of Life			
MSIS-29 Physical	43.3 (1.2)	46.6 (1.2)	.05
MSIS-29 Psychological	18.9 (0.9)	20.9 (0.8)	.04
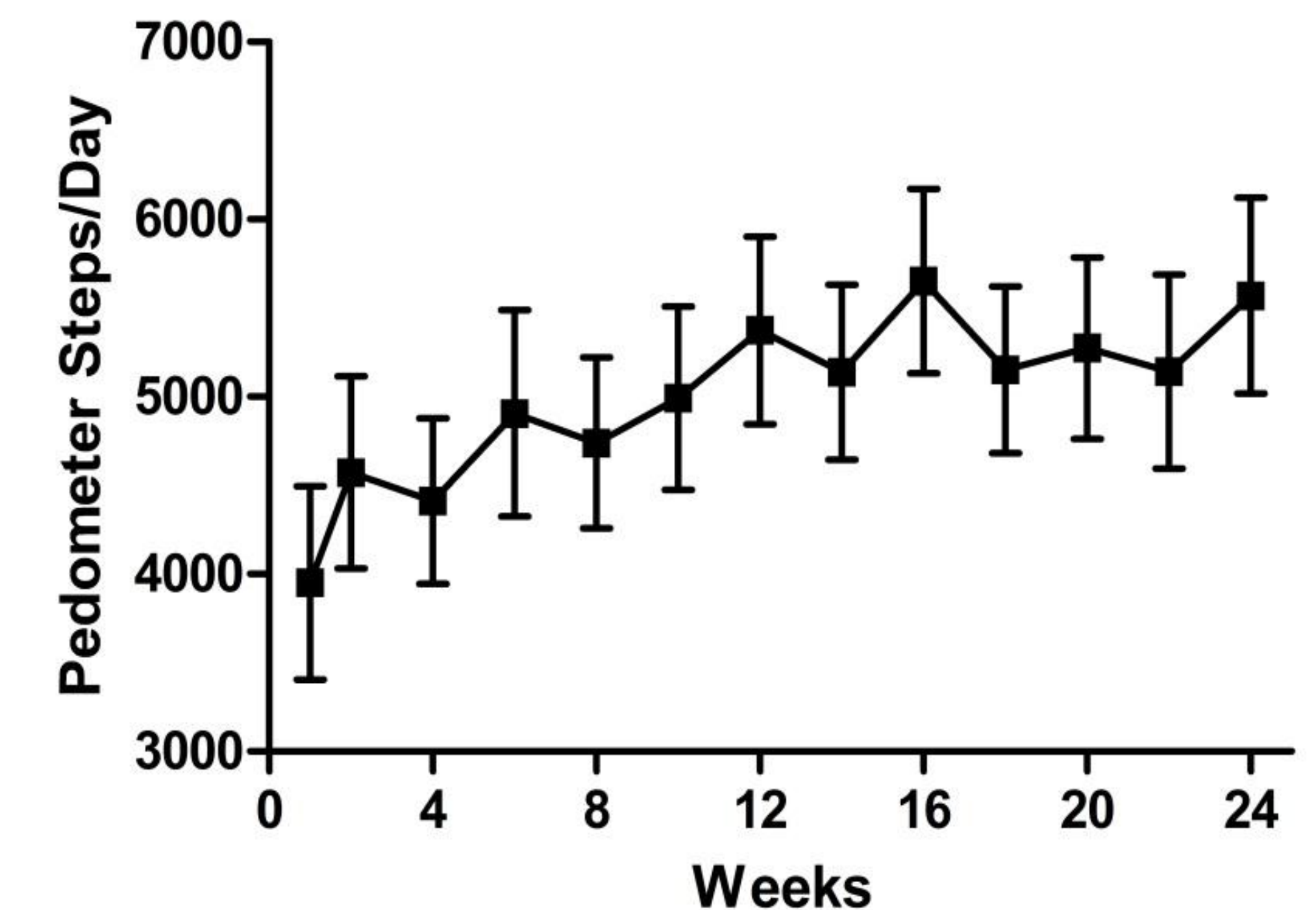
FIGURE 1. Average daily pedometer step counts for the intervention group.

DISCUSSION & CONCLUSIONS

• This is the first study to examine the effects of a 6-month behavioral intervention on symptomatic and QOL outcomes.

• The lifestyle physical activity intervention significantly improved symptomatic outcomes including fatigue severity and its physical impact, depression, and anxiety.

• Importantly, we replicate the results of our previous behavioral interventions by demonstrating a significant increase in self-reported physical activity.

• Overall, behavioral interventions are effective for increasing physical activity in persons with MS, and this might translate into important benefits in symptomatic outcomes that are comparable with exercise training.

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