ORIGINAL ARTICLE

The Efficacy of Telephone Counseling for Health Promotion in People With Multiple Sclerosis: A Randomized Controlled Trial

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ABSTRACT. Bombardier CH, Cunniffe M, Wadhwani R, Gibbons LE, Blake KD, Kraft GH. The efficacy of telephone counseling for health promotion in people with multiple sclerosis: a randomized controlled trial. Arch Phys Med Rehabil 2008;89:1849-56.

Objective: To determine if motivational interviewing-based telephone counseling increases health promotion activities and improves other health outcomes in people with multiple sclerosis (MS).

Design: Randomized controlled trial with wait-list controls and single-blinded outcome assessments conducted at baseline and at 12 weeks.

Setting: MS research and training center in the Pacific Northwest.

Participants: Community-residing persons (N=130) with physician confirmed MS aged 18 or older who were able to walk unassisted at least 90m (300ft).

Intervention: A single in-person motivational interview followed by 5 scheduled telephone counseling sessions to facilitate improvement in 1 of 6 health promotion areas: exercise, fatigue management, communication and/or social support, anxiety and/or stress management, and reducing alcohol or other drug use.

Main Outcome Measures: Health Promotion Lifestyle Profile II plus fatigue impact, subjective health, and objective measures of strength, fitness, and cognition. Intent-to-treat analyses of change scores were analyzed using nonparametric tests.

Results: Seventy persons were randomized to treatment and 60 to the control condition. The treatment group reported significantly greater improvement in health promotion activities, including physical activity, spiritual growth, and stress management as well as in fatigue impact and mental health compared with controls. In addition, the exerciser subgroup showed greater improvement than controls in self-selected walking speed.

Conclusions: A less intensive, more accessible approach to health promotion based on telephone counseling and motivational interviewing shows promise and merits further study.

Key Words: Exercise; Fatigue; Health promotion; Multiple sclerosis; Rehabilitation.

MULTIPLE SCLEROSIS IS a demyelinating disease of the central nervous system affecting an estimated 400,000 persons in the United States and is more common in women.[1] The disease causes demyelination and axonal loss in an unpredictable pattern and may result in a relapsing or progressive clinical course.[2] MS causes a wide variety of symptoms including fatigue, weakness, sensory impairments, cognitive impairment, and depression.[3]

Eventually, MS almost always leads to increasing disability. Several medications that modulate the immune system can reduce the underlying inflammatory disease process, mitigate disability, and maintain QOL.[4] Aspects of MS that adversely impact functioning and QOL such as deconditioning, depression, and fatigue may be ameliorated through other treatment paradigms, including rehabilitation. Evidence is mounting that rehabilitation and health promotion interventions can alter the clinical course of MS in meaningful ways.[3,5] Activity-based interventions have been shown to improve strength,[6,7] endurance,[8-10] fatigue,[11,12] functional abilities,[9,11-14] mental and physical health,[9] and health-related QOL.[14] Thus far, interventions to improve the health of people with MS have included multidisciplinary inpatient rehabilitation,[14-16] outpatient rehabilitation,[11,17] clinic-based aerobic exercise programs,[9] clinic-based strengthening programs,[7] aquatic exercise,[18] and outpatient lifestyle change classes.[19] All these interventions are resource intensive, expensive, and available only to people located near MS specialty centers.

List of Abbreviations

EDSS	Expanded Disability Severity Scale
HPLP II	Health Promoting Lifestyle Profile II
ITT	intention-to-treat
MCS	mental components summary
MFIS	Modified Fatigue Impact Scale
MS	multiple sclerosis
MSFC	Multiple Sclerosis Functional Composite
PCS	physical components summary
QOL	quality of life
SF-36	36-Item Short-Form Health Survey
TMT-A	Trail-Making Test Part A
TMT-B	Trail-Making Test Part B

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A logical next step in this line of research is to determine whether alternative treatment models can produce similar positive effects, but in a manner that is more feasible, accessible to a wider range of persons with MS, and potentially less costly. Therefore, we designed a health promotion intervention based on the principles of motivational interviewing primarily delivered by telephone. Motivational interviewing is a brief evidence-based behavior change counseling approach with over 70 randomized controlled trials and several meta-analyses supporting its efficacy.[20,21] Motivational interviewing has theoretical roots in client-centered counseling, values discrepancy approaches, self-perception theory, the theories of reactance, choice, and self-efficacy.[22,23] We chose a telephone-based intervention because this approach is increasingly used to overcome geographic and other logistic barriers to treatment in patients with chronic medical problems such as traumatic brain injury,[24] arthritis,[25] lupus erythematosus,[26] and heart disease.[27] Telephone counseling has been used to increase compliance with medication[28,29] and to increase physical activity.[30]

The content of the program was derived from consumer preferences and the research literature on what health promotion activities are empirically valid for people with MS. Numerous studies show that physical activity and exercise have good potential to improve functioning and QOL in persons with MS. In addition to exercise, Stuifbergen and Roberts[31] found that social support, stress management, and spiritual growth (ie, finding meaning, contentment, peace) as measured by the HPLP II[32] mediated the relationship between illness-related disability and QOL. A survey of health promotion interests among 739 community-residing persons with MS found that 86% of the sample reported wanting help to exercise, 85% to manage fatigue, 69% to manage stress, 56% to improve social support, and 10% to reduce substance abuse problems.[33] Therefore, the study was designed to assist people in each of the following target areas: exercise, fatigue management, anxiety and stress management, improving communication and social support, or reducing alcohol or drug use. Rather than providing all subjects with a generic health promotion intervention as done in many studies, we reasoned that it would be more efficient, clinically relevant, and effective to provide participants with counseling tailored to help them in the target area of their choosing.

The a priori study hypotheses were: (1) telephone counseling will result in significant improvements in the primary outcome, self-reported health promoting behaviors as measured by a multifactorial measure, the HPLP II; (2) improvements on the HPLP II in the treatment group will be significantly greater than in a waiting list control group; and (3) telephone counseling will result in significantly greater improvements in secondary outcomes (fatigue impact, subjective health, social support, community integration and objective measures of strength, fitness, cognition) compared to wait-list controls.

METHODS

Study Participants

The study sample was composed of 130 community-residing persons with clinically definite MS. Participants were identified from a variety of sources, including the Western MS Center at the University of Washington, advertisements and articles in local newspapers and MS newsletters, flyers sent to neurologists' offices, and MS support groups in the Puget Sound region. Participants were also recruited from a large survey of persons with MS, the methods of which are described elsewhere.[34]

We included participants who were 18 years of age or older, reported they had a diagnosis of MS confirmed by a neurologist or physiatrist specializing in MS including magnetic resonance imaging, were able to walk 90m (300ft) without assistance (equating to an EDSS[35] score of 5.5 or better) and endorsed interest in 1 or more of the health promotion target areas. The level of disability was limited to EDSS score of 5.5 in order to assure that subjects would be able to perform all the required outcome measures. All types of MS—relapsing remitting, secondary progressive, primary progressive, and benign course—were included. Potential participants were excluded if they reported significant depressive symptoms on the PRIME MD[36] or reported medical conditions that were contraindications to increased exercise such as severe cardiorespiratory disease, bone or joint disease, or severe Uhthoff's phenomenon (temporary blindness in people with MS triggered by exercise).

Procedures

The research study protocol was approved by the institutional review board at the University of Washington. Potential subjects were screened by telephone interview. Those meeting initial inclusion and exclusion criteria were invited to come to our center for a baseline assessment. Participants had the study fully explained to them and were required to sign the study consent form before data collection. The baseline and outcome assessments were conducted in person at our center by trained research assistants supervised by study investigators. After undergoing the baseline assessment, participants were also asked to choose a single health promotion target area on which to focus.

On completion of the baseline assessment, participants met with the research care manager who carried out the intervention. The research care manager opened the next numbered randomization envelope and informed the participant that they were assigned either to the 3-month wait list control group or to the treatment group. The randomization sequence was computer generated and blocked to yield equal allocation of every 50 participants without stratification.

Those randomized to the treatment group immediately underwent a 60- to 90-minute motivational interview and goal-setting meeting with the research care manager. Participants in the treatment group subsequently received a series of 5 follow-up telephone counseling sessions (planned to be $\approx$30min each), conducted at weeks 1, 2, 4, 8, and 12, to promote follow-through with the plan. Treatment sessions are described in detail in a later section. Those randomized to the control condition were thanked for participating, informed that we would contact them for a re-evaluation in 12 weeks and sent home. As an incentive for participation they were offered the opportunity to receive the intervention after their 12-week outcome assessment. Outcomes were assessed during in-person examinations at 12 weeks postrandomization by another trained research assistant who was kept unaware of the participant's group assignment.

Baseline and Outcome Measures

Demographic and medical variables. Demographic and medical information were obtained during the telephone screen. Demographic variables included age, race and ethnicity, marital status, and educational level. Medical history variables included date of diagnosis and self-reported MS subtype.

Primary Outcome Measure

Health promotion behaviors. We assessed the impact of the intervention on health-promoting behaviors using the HPLP II.[32] The HPLP II is a 52-item measure comprised of 6 sub-

scales: health responsibility, physical activity, nutrition, interpersonal relations, spirituality, and stress management. The nutrition subscale was not used because it has not tended to correlate with functional outcomes.[31] Subjects were asked to indicate how often they presently engaged in specific health-promoting activities on a 4-point response scale (1 [never] to 4 [routinely]). Higher total scores indicate more frequent performance of the health-promoting behaviors.

Secondary Outcome Measures

Fatigue impact. We measured fatigue using the 21-item MFIS.[37] The MFIS measures the perceived impact of fatigue in physical, cognitive, and social domains over the past 4 weeks. Subjects respond on a 0 (never) to 4 (almost always) scale. Item scores are equally weighted and summed to form a total score ranging from 0 (low fatigue impact) to 84 (high fatigue impact).

Subjective health. The Medical Outcomes Study SF-36[38] was used to assess self-reported health status. The SF-36 is a widely used measure shown to detect significant treatment effects in a variety of populations.[39] Two summary scales, the PCS scale and the MCS scale, were derived from transformation of the aggregate score of the 36-item measure. Higher scores on each scale indicate better health.

Medical Outcomes Study modified social support scale. This 18-item measure of perceived social support was developed based on the Medical Outcomes Study[40] and modified for the Multiple Sclerosis Quality of Life Inventory.[41] The questionnaire produces a total social support score as well as tangible support, emotional/informational support, affectionate support, and positive social interaction. Subjects indicate how often someone is available to provide each type of social support from 1 (none of the time) to 5 (all of the time).

Community integration. We measured community integration through the Craig Handicap Assessment and Reporting Technique.[42] This well-established measure was designed to assess 5 domains of handicap: (1) physical independence; (2) mobility; (3) occupation; (4) social integration; and (5) economic self-sufficiency. Only the first 4 domains were administered (25/27 items). A total score was generated by averaging the subscores for each domain, permitting a maximum score of 100, which would indicate no handicap at all.

Objective measures of strength, fitness, and cognition. Lower-limb strength was measured on an isokinetic dynamometer as the average peak torque for the right and left legs, for both extension and flexion. A Cybex 6000 dynamometer[a] was used to measure peak torque. It was calibrated weekly using manufacturer's procedures. Standard testing procedures as outlined by Cybex were used. Each subject was given 5 submaximal trial repetitions before testing. To obtain peak torque output for knee flexion and extension, 10 maximal repetitions were performed by both right and left legs at a rate of 60° per second.

A bicycle ergometer was used to measure fitness (aerobic capacity). Subjects were instructed to pedal the ergometer at 60rpm as long as possible while the pedal resistance was increased. Resistance began at 0W and was increased by 0.5W every 2 minutes until the participant could no longer sustain 60rpm. The number of seconds the subject could sustain pedaling at 60rpm was the dependent variable. All ergometric activities were conducted in a laboratory, temperature controlled between 19°C and 22°C.

Self-selected walking speed was measured by asking subjects to walk 90m (300ft) at a self-selected pace along an indoor track traced in a hospital corridor. Speed was determined by measuring the time taken for participants to walk the 90m. Tests of self-selected walking speed have high retest reliability and can provide an indication of functional impairment in persons with disabilities.[43]

The MSFC was developed by the MS clinical outcomes task force charged with the mission of creating a quantitative outcome measure for clinical trials in people with MS.[44] The MSFC is comprised of a test of leg function (Timed 25-foot Walk), arm function (9-Hole Peg Test), and cognitive function (Paced Auditory Serial Addition Test−3 minute version).

The TMT-A and TMT-B are widely used measures of psychomotor speed, concentration, and cognitive flexibility. TMT-A requires the subject to follow a simple number sequence in a paper and pencil format. TMT-B is similar but requires the subject to follow an alternating sequence (1-A-2-B-3-C. . .). Time to complete the sequence was the main dependent measure.[45]

Intervention

In preparation for the study, the research care manager completed a standard 2-day training program in motivational interviewing and received additional training plus ongoing supervision from a clinical psychologist experienced in motivational interviewing. The FRAMES model of motivational interviewing was used to guide this intervention. FRAMES is an acronym for 6 key elements of effective brief therapies: providing personally relevant feedback, emphasizing the person's freedom to choose and responsibility for change, giving advice with permission, presenting the person with a menu of options regarding ways to change, expressing empathy, and enhancing self-efficacy and optimism about change.[22,46] First, motivational interviewing principles are used to build motivation to change a given behavior and, second, when appropriate, a specific change plan is negotiated.

As applied in this study, during the initial session the research care manager helped the subject build motivation to change in the target area of the subject's choosing (either exercise, fatigue management, anxiety or stress management, improving communication or social support, or reducing alcohol or drug use). The research care manager elicited the importance and confidence the person associated with the proposed behavior change. The research care manager helped the subject consider various change strategies and explored the advantages and potential barriers of each. Next, if appropriate during the first session, concrete steps to begin changing were negotiated. The research care manager attempted to elicit commitment to specific change strategies. Participants were asked what, if any, involvement from significant others might be indicated. Goals and plans were written for the participant to take home, with assistance from the research care manager if needed. After the initial session the research care manager wrote a short letter to the participant that summarized the goals and plans agreed on in the session. The letters affirmed the participant's strengths and motivation and expressed confidence in their abilities to successfully accomplish their goals.

Subsequently the research care manager made 5 scheduled telephone counseling calls to the subject to monitor progress toward goals, adjust goals, and problem-solve using the FRAMES model. Participants were permitted to have additional telephone contact with the research care manager between sessions through a toll-free number. The research care manager provided some direct assistance if desired by the participant, such as referrals to medical specialists, or educational information on stress management and resources such as loaning Pilates or yoga videotapes for people to trial. We used published resources to inform our advice regarding exercise, fatigue management, stress management, and communication strategies appropriate for people with MS.[47-50]

Statistical Analyses

Analyses were conducted using SAS software[b] and Stata.[c] The primary analyses were conducted under ITT, in the sense that data were analyzed by the treatment group to which they had been assigned, whether or not they participated in or completed treatment. In addition, baseline values were carried forward for those missing posttreatment tests. As a sensitivity analysis, data were also analyzed using only the observed data.

Normality assumptions were untenable for most of the clinical measures, so we used nonparametric Kruskal-Wallis tests to assess the effectiveness of the randomization with respect to age, duration of MS, and the clinical measures. The Fisher exact test was used for categorical demographics. Treatment groups were not comparable at baseline for some measures. Therefore, Kruskal-Wallis tests on the change scores (posttreatment minus pretreatment) were used for the principal outcome analyses. Regression modeling with outcome variables transformed to improve normality assumptions were conducted to confirm nonparametric findings when possible. Transformed pretreatment values of the outcome were included in the regression models. Potential confounders were entered into the model if they differed by treatment group at baseline, and retained if the coefficient of the treatment effect changed by more than 15%. For all significant outcomes, treatment effect was quantified using the effect size *d*.[51] In exploratory analyses, any subscales that existed for the significant outcome measures were also analyzed.

Power. The study was designed to randomize 235 participants and have 80% power to detect a moderate (0.4 SD) change in the clinical outcomes due to treatment (α=.05, 2-sided). With a final enrollment of 70 in treatment and 60 controls, we had 81% power to detect .05 SD changes. Among the completers, there was 80% power to detect .50 SD treatment effects.

RESULTS

Sample Characteristics

As depicted in figure 1, 359 potential participants were screened, 112 declined to participate, 117 were excluded, and 138 consented. Of the 117 excluded, 8 were nonrandomized pilot subjects used to develop the motivational interviewing-based intervention. These people were the first 8 to consent to the study and were not included in the outcome analyses. One hundred thirty participants were randomized: 70 into the treatment condition and 60 as wait-list controls. The average age of participants was 46.2±9.9 years old and the range was 19 through 70 years. The majority of participants (70%) reported having been diagnosed with a relapsing-remitting subtype, 10% had secondary progressive, 5% had primary progressive, 2% had a benign course, and for the remainder the course was not recorded. Seventy-eight percent were women, 52% were married, and 70% had at least a 4-year college degree. Whites constituted 95.4% of the sample, 1.5% were blacks, 1.5% were of Semitic/Arabian origin, and less than 1% were either Asian/Pacific Islanders or Hispanic/Latino.

Forty-one (58.6%) of the participants chose to work on exercise promotion activities whereas 11 (15.7%) chose stress management, 5 (7.1%) chose fatigue management, and 7 (10%) chose to work on communication or social support. No participants chose substance abuse and 6 (8.6%) dropped out without deciding on a health promotion target. The mean total time the research care manager spent in telephone counseling with each participant was 117.1±56.6 minutes. The average time spent among those who completed the intervention was 128.8±44.7 minutes. Overall, 53% received less than 2 hours of direct telephone contact time with the research care manager.

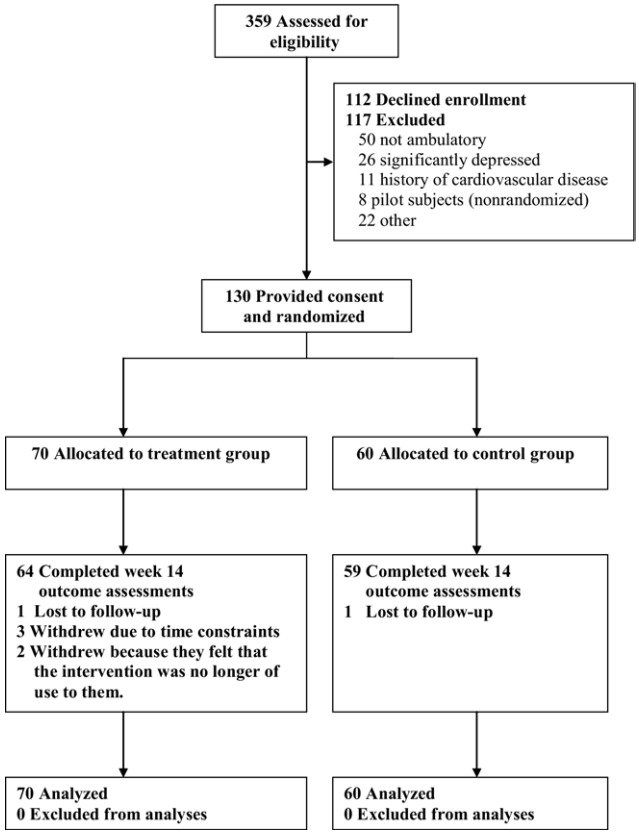

Fig 1. CONSORT flowchart.

Effectiveness of the Randomization

We compared the 2 randomized groups to judge the effectiveness of the randomization (table 1). The treatment and control groups did not differ on age, education, sex ratio, years since diagnosis, or percent with the relapsing-remitting type of MS. Groups were also equivalent on most of the outcome measures at baseline. However, the treatment group reported significantly greater total fatigue impact and significantly slower performance on a test of psychomotor speed (TMT-B). Therefore, principal outcome analyses were conducted on change scores.

Primary Outcome

Overall self-reported health promotion activities as measured by the total HPLP II score increased for the treatment group and remained unchanged for the control group (table 2). Regression analysis using the square of total HPLP II scores confirmed this finding (likelihood ratio test for treatment χ^2_1=7.47, P<.01). The treatment effect was not confounded by baseline differences in MFIS or TMT-B. The effect size was .57, a large effect according to Cohen.[52] Post hoc analyses of the subscales within the HPLP II showed that improvements were significantly greater in the treated group on the physical activity (P<.001), spiritual growth (P<.01), and stress management (P=.03) subscales (see table 2).

Secondary Outcomes

Fatigue impact decreased significantly in the treated group and remained unchanged among the controls (see table 2). In the

Table 1: Sample Demographic and Baseline Clinical Characteristics for the 2 Study Groups

Characteristic	Health Promotion (n=70)	Control (n=60)	P*
Age (y)	47.5 (41 to 54)	45 (40.5 to 52)	.28
Sex, women (%)	75.7	80.0	.67
Education (%)			
≤ High school	32.9	26.7	
Bachelor's degree	42.9	50.0	
Graduate/professional degree	24.3	23.3	.69
Ethnicity, white non-Hispanic (%)	94.3	96.7	.69
Married or living with partner (%)	52.9	60.0	.48
Duration of MS	6.3 (3.4 to 10.5)	6.4 (2.8 to 13.1)	.49
Relapsing-remitting MS (%)	69.6	75.0	.56
HPLP II (5 domains)	2.7 (2.4 to 3.0)	2.7 (2.5 to 3.1)	.16
MFIS	39.5 (30 to 50)	32 (16 to 46)	.03
SF-36 MCS scale	50.0 (42.9 to 56.8)	52.2 (44.5 to 56.4)	.69
SF-36 PCS scale	39.1 (32.2 to 45.7)	41.9 (32.5 to 48.9)	.32
Modified Social Support Scale	72.4 (61.5 to 87.0)	77.0 (63.3 to 90.8)	.32
CHART total score	97.5 (86.4 to 99.9)	96.7 (89.5 to 99.8)	.72
MSFC	0.4 (−1.6 to 1.5)	0.9 (−0.3 to 1.7)	.08
TMT-A (s)	27.0 (21.0 to 34.0)	28.0 (21.0 to 37.0)	.92
TMT-B (s)	67.5 (54.0 to 91.0)	57.0 (44.5 to 74.5)	<.01
Isokinetic dynamometer leg extension peak torque (ft/lb)	57.5 (41.5 to 77.5)	64.5 (45.5 to 85.0)	.37
Isokinetic dynamometer leg flexion peak torque (ft/lb)	30.0 (17.0 to 45.0)	33.0 (20.0 to 48.5)	.19
Bicycle ergometer time (s)	535 (453 to 586)	535 (398 to 627)	.37
Self-selected walking speed (s)	26.0 (23.3 to 28.7)	25.3 (22.3 to 28.6)	.20

NOTE. Values are mean (upper and lower quartile) or as otherwise indicated.
Abbreviation: CHART, Craig Handicap Assessment and Reporting Technique.
*P associated with the Fisher exact test for categorical variables, with the Kruskal-Wallis test for ordinal variables.

regression analysis, the mean treatment effect for the MFIS (untransformed) was 3 points, the same as the difference observed in the medians, but the likelihood ratio test for treatment was not significant ($\chi^2_1=1.30$, $P=.25$). Post hoc comparisons on the MFIS subscales showed that the physical subscale improved significantly in the treatment group compared with controls ($P=.02$), but not the cognitive or psychosocial subscales.

Subjective mental health as measured by the SF-36 MCS improved significantly more in the treated group than in controls. Regression analysis using the cube of the SF-36 MCS

Table 2: Median Change Scores for the Primary and Secondary Outcomes, Under ITT

Outcome	Health Promotion (n=70)	Control (n=60)	P*
Primary outcome			
HPLP II total	0.2 (0.0 to 0.3)	0.0 (−0.2 to 0.2)	<.01
Health responsibility subscale	0.0 (−0.3 to 0.4)	0.0 (−0.3 to 0.3)	.19
Physical activity subscale	0.4 (0.0 to 0.9)	0.0 (−0.3 to 0.3)	<.01
Spiritual growth subscale	0.1 (0.0 to 0.4)	0.0 (−0.3 to 0.3)	<.01
Interpersonal relations subscale	0.0 (−0.1 to 0.2)	0.0 (−0.3 to 0.3)	.33
Stress management subscale	0.2 (0.0 to 0.3)	0.0 (−0.2 to 0.2)	.03
Secondary outcomes			
MFIS total	−1 (−9.5 to 0.5)	0 (−7 to 5)	.02
Physical subscale	−1 (−4 to 1)	0 (−3 to 3)	.02
Cognitive subscale	−1 (−4 to 0)	0 (−4 to 4)	.11
Psychosocial subscale	0 (−1 to 0)	0 (−1 to 1)	.31
SF-36 MCS scale	3.6 (0.3 to 8.0)	0.7 (−2.7 to 6.3)	.02
SF-36 PCS scale	−0.3 (−3.4 to 2.1)	1.0 (−2.8 to 5.1)	.11
Modified Social Support Scale	0.7 (−2.1 to 6.8)	−0.3 (−7.8 to 5.9)	.20
CHART total	0.0 (−2.6 to 0.7)	0.0 (−2.7 to 1.8)	.93
MSFC	0.5 (0.0 to 1.2)	0.4 (−0.3 to 0.7)	.26
TMT-A (s)	0.0 (−6.0 to 2.0)	−2.0 (−8.5 to 0.5)	.15
TMT-B (s)	−3.5 (−23.0 to 2.0)	−2.0 (−14.5 to 9.0)	.14
Isokinetic dynamometer leg extension peak torque (ft/lb)	0.0 (−2.5 to 5.5)	0.0 (−3.0 to 8.0)	.79
Isokinetic dynamometer leg flexion peak torque (ft/lb)	0.5 (−0.5 to 7.0)	1.0 (−0.5 to 8.5)	.95
Bicycle ergometer time (s)	0 (−45 to 23)	0 (−34 to 31)	.62
Self-selected walking speed (s)	−0.4 (−2.0 to 0.5)	0.0 (−1.7 to 1.0)	.28

NOTE. Values are median (upper and lower quartile). A positive value indicates a higher posttreatment score, compared with baseline.

scores produced a likelihood ratio test for treatment of (χ^2_1=4.84, P=.03). Effect sizes for the SF-36 MCS and the total MFIS were in the moderate range (d=.32, d=.33, respectively). There were no significant between group differences observed on the SF-36 PCS, measures of social support, community integration, strength, fitness, or cognition.

Completers Analyses

Sixty-four of the 70 treatment participants and 59 of 60 controls completed the study. Results based on the observed data were very similar to results from ITT, as would be expected. The statistical significance of the primary outcome, and the total HPLP II scores, as well as the MFIS total score and the SF-36 MCS score were stronger (P<.001, P=.01, P<.01, respectively). No additional outcomes were statistically significant.

Analyses of Exercisers

Finally, for several reasons we wanted to examine the effect of the intervention on those who chose to exercise. Exercise was the most popular health promotion activity chosen. Forty-one persons (59%) assigned to the treatment group and 47 controls (78%) indicated prior to randomization that they would like to work on exercise. Also we had reason to suspect that exercise has potential to produce widespread physical and emotional benefits among people with MS.[9] Because all subjects were asked to indicate which health promotion activity they would like help with before randomization, we could compare treatment versus control subjects within the group that intended to exercise. Therefore, we conducted exploratory ITT analyses comparing those who wanted to exercise within the treatment group to those who wanted to exercise among the control group. On the primary outcome, the HPLP II total score, exercisers in the treatment group reported significantly greater health promotion activities than those who wanted to exercise in the control group (P<.01) with the differences on the physical activity subscale highly significant (P<.001). Improvement in self-reported minutes of exercise per week was greater among treated subjects (130min) versus controls (24min) (P=.02). Results revealed less fatigue impact and higher SF-36 MCS scores among those treated compared with controls. In addition, among those interested in exercise the group that received treatment improved significantly more on self-selected walking speed compared with the control group (treatment, -1.7 ± 3.2s; control, 0.0 ± 2.8s; P=.04). Finally, there was a nonsignificant trend for treated participants to improve more than controls on the MSFC (P=.06). On other measures the groups did not differ significantly.

DISCUSSION

This study extends previous research showing that health promotion interventions can improve the lives of people with MS. Existing research proved that health-promoting activities, especially exercise, have beneficial effects on strength, endurance, functioning, and health-related QOL in this population. These interventions appear time intensive, labor intensive, and costly, however, and they typically required the participant either to be hospitalized or to attend outpatient sessions at the study site. This study shows that a less intensive telephone-delivered intervention also can increase health-promoting behaviors and improve salient outcomes such as fatigue impact and mental health-related QOL in people with MS. The effect size this intervention had on the HPLP II total score (d=.57) is quite favorable compared with the magnitude of effect associated with another intervention consisting of eight 90-minute lifestyle change classes plus 3 months of telephone counseling (d=.54 at 5mo).[19] Nevertheless, we did not find differential improvement on measures of social support, community integration, strength, fitness, or cognition.

The intervention tested in the present study seems quite feasible from the perspective of the participant. Fifty-four percent of those eligible for the study participated and 91% of those assigned to the treatment group completed the study. The intervention was brief, consuming on average less than 2 hours of direct contact time between the therapist and participant. Based on a therapist cost of $50 an hour, the intervention would have cost approximately $150 per subject on average and up to $200 if the subject received the maximum dose planned. Most importantly, the intervention was delivered to participants without requiring them to leave their home environment more than once. The results of this study suggest that simple telephone technology can be use to extend the expertise found in specialized MS rehabilitation centers such as ours to people with MS over a very large geographic area.

The results of this study underscore the interest in and potential benefits of increased physical activity among people with MS. Increased exercise was the most popular goal of the study participants representing the choice of the majority of the sample. The effect of the intervention was most pronounced in the area of improving self-reported physical activity. Moreover, those who chose to exercise achieved somewhat greater benefit by showing significantly greater improvement in self-selected walking speed compared with controls who also intended to exercise. In addition there was a trend toward greater improvement in functioning on the MSFC among exercisers in the treated group compared with controls. The combination of strong consumer interest in exercise[53] combined with the widespread potential benefits of increased physical activity makes this health-promotion activity especially promising among people with MS.

Study Limitations

Before we conclude, several study limitations should be discussed. The primary outcome measure for the study was a self-report measure of health-promoting activities. This measure, like all self-report measures, can be challenged on the basis of its subjective nature and uncertain relationship to meaningful outcomes. In the case of the HPLP II, there is reason to believe that the physical activity subscale strongly impacted by this intervention is related to clinically significant outcomes. In a longitudinal descriptive study, Stuifbergen et al[5] reported that higher levels of physical activity on the HPLP II subscale predicted slower accumulation of functional limitations over a 5-year time period. Additional research is needed to determine whether boosting physical activity using our methodology is of sufficient magnitude and durability to influence changes in functional limitations.

Our study used a single-blinded design and a waiting list control group that received no therapist attention. Therefore, we cannot rule out the potential effects of simple time spent with the participant or the effects of differential participant expectations on the outcomes observed. Future studies should consider including an attention control group or nonspecific treatment condition. The outcome assessment was conducted immediately after the end of the trial. Ethical considerations regarding withholding a potentially beneficial treatment from the wait-list control group for an extended time led us not to use a longer, for example, 6- to 12-month follow-up period. As a result we are not certain how durable the treatment effects might be. Based on the most recent meta-analysis of motivational interviewing studies, the average short-term effect size

was .77 whereas the effect size for longer term outcomes was .30.[21] The effects of the intervention used in the present study, therefore, should be thought of primarily as initiating significant changes or short-term outcomes in the target areas. Future studies should examine how well any improvements in health promotion activities are maintained or how to maintain them.

Although the study utilized motivational interviewing, a replicable evidence-based approach to behavior change counseling, no objective measure of therapist adherence to the principles and strategies of this method was used. The research care manager who carried out the intervention completed standard training in motivational interviewing and was supervised by a trained motivational interviewing practitioner. In addition, intervention was scripted to use motivational interviewing strategies systematically. Objective measures of motivational interviewing skill and treatment fidelity have been developed in recent years,[54] but were not widely used when this study was designed. Future research should include audio recordings of counseling sessions to permit motivational interviewing treatment fidelity ratings.

We excluded people who had significant depressive symptoms and persons unable to ambulate at least 90m (300ft) (EDSS score >5.5). Therefore, the results of this study may not be generalizable to people with more severe disability or to those who have significant depressive symptoms. Future researchers could reconsider these exclusions. Major depression is highly prevalent among people with MS[34] and people with significant depression symptoms are interested in having help to exercise.[33] Exercise is emerging as an evidence-based treatment for major depression.[55] Therefore, exercise interventions may be a promising approach to treating depression in this population. With regard to ambulatory ability, future studies should consider including people with greater disability.

A strength of this study was that we allowed participants to choose from among several potential health-promotion activities. People with MS have different health promotion needs and interests and by offering to help change multiple target behaviors we were able to intervene with more people. This intervention also probably enhanced adherence to treatment and ecological validity by tailoring treatment to the individual preferences of the participants. Nevertheless, testing an intervention that allowed participants to choose from several disparate target behaviors posed significant challenges to outcome measurement. This design required us to use multiple multidimensional outcome measures. Fortunately a single measure, the HPLP II, could capture self-reported changes in many of our target areas and serve as our primary outcome. As noted above, the HPLP II has been used extensively in people with MS and is related to clinically significant outcomes. Future research may be able to use more rigorous subjective and objective outcome measures and produce more convincing results by focusing on a single health promotion area such as increasing physical activity or exercise.

CONCLUSIONS

This initial randomized controlled trial of telephone-based motivational interviewing suggests it may be an effective approach to health promotion in people with MS. This type of intervention may help overcome important and common barriers to effective treatment such as cost, inconvenience, distance to specialty MS sites, and transportation difficulties. By using an evidence-based replicable behavior change counseling method this study also responds to calls for more theoretically and empirically sound health promotion models for people with MS.[19] More rigorous tests of the efficacy of this approach are needed to replicate these findings and answer additional questions such as: Is motivational interviewing more effective than nonspecific counseling in improving health-promotion activities? How durable are the observed treatment effects? What is the range of people for whom this type of intervention is appropriate? What therapy process variables are associated with more effective health behavior change in this population?

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