

Effect of 2-Arm Intervention on Emotional Outcomes in Informal Caregivers of Individuals With Multiple Sclerosis: A Randomized Pilot Study Trial

Sara L. Douglas, PhD, RN; Matthew Plow, PhD; Tanya Packer, PhD; Amy R. Lipson, PhD; and Michelle J. Lehman, MSc

ABSTRACT

BACKGROUND: Caregivers of people with multiple sclerosis (MS) report poor emotional outcomes yet few interventions have been tested. The goal of this study was to compare the effectiveness of a remotely delivered intervention with 2 arms (ie, website and telecoaching vs website only) aimed at reducing depression, anxiety, stress, and distress in informal caregivers of individuals with MS.

METHODS: From March 2021 through August 2021, 151 caregivers were enrolled in the study. The intervention occurred over a 4-month period. The website plus telecoaching arm received (a) a monthly coaching session focused on information, skill building, and support that was delivered by a licensed social worker via videoconference or telephone, and (b) had access to a study-designed website for caregivers of individuals with MS. The website-only arm did not receive coaching sessions and had the same website access. Data were obtained at baseline, immediately after the intervention period, and 6 weeks after the intervention.

RESULTS: A linear mixed-effects model using an autoregressive covariance structure was used. It showed that the group by time interaction was statistically significant for the overall composite emotion score (depression, anxiety, stress) ($P = .037$) and the stress subscale score ($P = .047$), and it indicated that the website plus telecoaching arm demonstrated greater effectiveness at reducing the overall composite emotion and stress subscale scores.

CONCLUSIONS: Use of a remotely delivered psychoeducational intervention that included individual coaching sessions as well as website access demonstrated preliminary efficacy in improving emotional outcomes in caregivers of individuals with MS. Further testing of the intervention with a larger sample is recommended.

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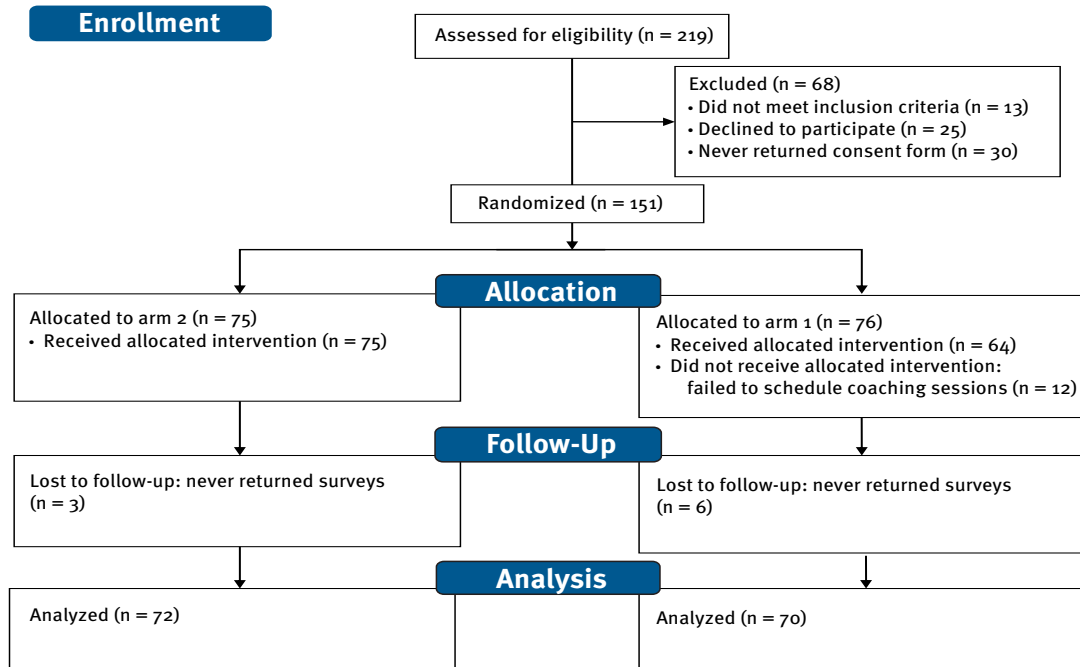
There are approximately 1 million people with multiple sclerosis (MS) living in the United States and more than half a million receive support from informal caregivers (ie, unpaid family member or friend).^{1,2} For many people, the nature of this neurodegenerative disease leads to an unpredictable course of care with periodic exacerbations and physical deterioration over an extended period of time. Informal family caregivers are considered key members of the care team and play a crucial role in providing the majority of home care needs (eg, transportation, shopping, personal care, emotional support) for individuals with MS at no cost to the health care system.^{3,4} It has been well documented that caregivers for individuals with MS experience poor outcomes such as poor health-related quality of life, increased depressive symptoms, and high levels of anxiety and distress.⁵⁻⁷ These poor outcomes tend to increase as the disease progresses and the care needs of the individual with MS increase. In addition, caregivers report frustration due to a lack of information regarding how to manage their loved one's changing needs, deal with the uncertainty of the illness, and find support for their own emotional and physical needs.^{3,7}

Research examining the needs of informal caregivers to individuals with MS has highlighted the need to reduce caregivers' poor emotional outcomes⁷⁻¹⁰ and provide information relevant to caring for individuals with MS.^{7,11,12} Psychoeducational programs providing information and support have shown some efficacy in reducing elevated emotional outcomes (eg, anxiety, depression) in other caregiver groups (eg, cancer⁷, ALS¹³) and the inclusion of tailored strategies (eg, coaching) to increase caregiver self-efficacy and provide emotional support been shown to decrease poor emotional outcomes.¹⁴⁻¹⁶ To date, however, few interventions have focused solely on reducing depression, anxiety, stress, and distress in informal caregivers of individuals with MS and a majority have focused solely on

From the Frances Payne Bolton School of Nursing, Case Western Reserve University, Cleveland, OH (SLD, MP, ARL); School of Occupational Therapy (TP) and School of Health Administration (MJL), Dalhousie University, Halifax, Nova Scotia, Canada. Correspondence: Sara L. Douglas, PhD, RN, School of Nursing, Case Western Reserve University, 10900 Euclid Avenue, Cleveland, OH, 44106; email: sld4@case.edu.

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FIGURE 1. Consolidated Standards of Reporting Trials Diagram

spousal caregivers and not included other caregivers.^{4,17} Therefore, the purpose of this study was to compare the effectiveness of an intervention with 2 arms aimed at reducing depression, anxiety, stress, and distress in informal caregivers of individuals with MS.

METHODS

The study was approved by the institutional review boards of the study site (Case Western Reserve University; approval number: STUDY20201484) and the supporting site (Dalhousie University Research Ethics Board approval number: 2021-5484) and was registered at ClinicalTrials.gov (NCT04662008). Participants were recruited using 2 convenience sampling strategies and met the following eligibility criteria: (1) self-identified as an adult (18 years or older) informal caregiver for a person with MS; (2) capable of providing informed consent; (3) identified English as their primary language; and (4) able to access the internet. There were no exclusion criteria. Of the 206 eligible caregivers who were approached, 151 (73.3%) consented and signed the online consent form (FIGURE 1). The Consolidated Standards of Reporting Trials checklist guided the report of the study.

Procedures

All potential participants were recruited using convenience sample strategies with specific details described in the protocol publication.¹⁷ One strategy involved contacting individuals with MS who had given consent to be recontacted for future research studies (Patient-Centered Outcomes

Research Institute, Multiple Sclerosis-1610-37015). If the person with MS had an informal caregiver who might be interested, they were instructed to ask the caregiver to contact the study office for further information. A second strategy was a direct email from the National Multiple Sclerosis Society to all informal caregivers in their database and a Facebook advertisement describing the study. Interested caregivers completed an online information form, were screened by a research assistant (RA), and completed an online consent form (for those who agreed to participate), which they signed in Research Electronic Data Capture (REDCap).¹⁸ All study data were collected and managed using REDCap tools.

After caregivers provided online consent, a survey was sent via REDCap to obtain baseline demographic (eg, age, sex, race, relationship to patient) and study outcome data. Participant self-reporting was used to identify participants' race and ethnicity and was obtained for the purposes of describing the sample. Participants were then randomly assigned (1:1) to 1 of the 2 study arms using a computer-generated randomization procedure.¹⁹ The project director (ARL) generated the randomization assignments and emailed the participants their group assignment; all investigators were blind to group assignment.

Intervention Arms

Both study arms were delivered remotely over a period of 4 months, which is a time frame consistent with other psychoeducational interventions for informal caregivers.^{11,14-16} Specific details of the components in each

arm have been described in the protocol publication.¹⁷ Each study arm had access to different levels of intensity of information and support. Participants in arm 1 (website and telecoaching) received 2 components: (a) 4 personalized coaching sessions, and (b) access to the study-designed website. Personalized coaching sessions were delivered by 2 independent social workers via videoconference or telephone per each participant's preference. The key components of the coaching sessions were session 1: identifying informal caregivers' needs for information and support; session 2: strategies for caring for a loved one with MS; session 3: caring for yourself; and session 4: planning and decision-making for the future. While aligned with specific landing pages on the website, each session was tailored to the individual and involved discussion, skill development, and support from the social workers who worked with the same participant throughout the intervention to maintain consistency.

Participants in arm 2 (website only) received a unique password to the study-designed website. The password allowed for website usage tracking (eg, whether the participant ever logged on to the site, areas within the website that were viewed, etc). The website materials consisted of text information, links, and video scenarios designed specifically for informal caregivers of people with MS in the following areas: (1) information about MS, (2) obtaining reliable information about MS on the web, (3) practical strategies for caring for a loved one with MS, (4) COVID-19 concerns specific to people with MS and their caregivers, (5) self-care strategies for caregivers, and (6) planning and decision-making issues and strategies. Specific details about landing pages and content are described in the protocol publication.¹⁷ The main landing pages for the website were based on descriptions of key informational topics provided in web-based psychoeducational interventions as well as findings from a previous psychoeducational study focused on informal caregivers of persons with cancer.^{20,21}

Caregiver-Reported Outcome Measures

The primary outcome was an overall index of negative emotion that included depression, anxiety, and stress measured with the composite score of the Depression Anxiety Stress Scales (DASS) instrument.²² The DASS has 3 subscales of 14 items each that assess the presence and intensity of depression, anxiety, and stress. The items are based on a 4-point Likert scale ranging from 0 ("Did not apply to me at all") to 3 ("Applied to me very much, or most of the time"). The instrument shows good internal consistency ($\alpha = .91$) and construct validity.²³ DASS Total Composite scores range from 0 to 126 with higher scores representing greater overall negative emotions. In the present study, Cronbach's α for Total Composite scores was .98.

Secondary outcome measures were the separate depression ($\alpha = .90$), anxiety ($\alpha = .88$), and stress ($\alpha = .88$) scores

as measured by the subscales of the DASS.²² Total scores for each scale range from 0 to 42 with higher scores representing greater amounts of each attribute. Cutoff scores for each subscale have been validated and classify scores as normal, mild, moderate, severe, or extremely severe.²³ Distress was measured using the Distress Thermometer (DT), a single-item, self-report measure of psychological distress that has excellent psychometric properties for caregivers.²⁴ Participants rated their distress in the past 7 days using an 11-point visual analog scale ranging from 0 (no distress) to 10 (extreme distress) with higher scores indicating higher levels of distress. Scores equal to or above 4 represent clinically elevated levels of distress for caregivers.²⁵

Statistical Considerations

This trial was designed to compare MS informal caregiver negative emotional outcomes (ie, depression, anxiety, stress, distress) before and after an intervention with 2 study arms. Based on findings from a trial testing a similar psychoeducational intervention for long-distance caregivers of cancer patients,¹⁶ our hypothesis was that study arm 1 (website and 4 coaching sessions) would have a greater reduction in negative emotional outcomes. A mixed-effects model²⁶ a priori power analysis indicated that a sample size of 75 individuals in each group was needed to have a power of 0.8, assuming a correlation of 0.5 among 3 repeated measurements, a small Cohen's d of 0.35, and a 20% attrition rate. These estimates are consistent with a prior randomized controlled trial of psychoeducational interventions on stress ($d = 0.35$) and anxiety ($d = 0.32$) in caregivers of individuals with cancer¹⁶ and a meta-analysis of internet interventions plus clinical support via videoconferencing on depression ($d = 0.34$) and anxiety ($d = 0.36$) in caregivers.^{15,27} A posttest sample of 120 was found to have a power of 0.8 to detect medium moderation effects.²⁸

Missing data for DASS items were imputed using the multiple imputation procedure in SPSS Statistics (IBM Corp). Using intent-to-treat principles, linear mixed-effects models were employed to test whether there was a significant difference between arms on the DASS composite score (primary outcome) over time from baseline (before the intervention) to immediately after the intervention, and then at 6 weeks after the intervention. The linear mixed-effects model included the variables of group assignment, time, and the interaction of time by group, along with the participant-specific random intercept and slope. If the group by time interaction was significant, we conducted a post hoc analysis using the univariate F-statistic to determine whether there were significant differences after the intervention or at the 6-week follow-up when compared with baseline. The same approach was used to test for differences by intervention arm for the DASS subscale scores and the DT score.

The moderated regression analysis used separate multiple linear regression models for each baseline characteristic and dependent outcome variable. The primary dependent

TABLE 1. Demographic and Clinical Baseline Characteristics by Study Arm

Caregiver variables (N = 151)	Arm 1 (website and coaching) (n = 76)	Arm 2 (website only) (n = 75)	P
Age, years [mean (SD)]	53.2 (14.1)	51.9 (13.8)	.57
Distress Thermometer, mean (SD)	3.9 (2.7)	3.9 (2.6)	.98
DASS Composite, mean (SD)	23.9 (22.9)	26.3 (21.9)	.53
DASS Depression, mean (SD)	7.3 (8.3)	8.2 (8.3)	.95
DASS Anxiety, mean (SD)	4.9 (6.6)	4.6 (6.0)	.51
DASS Stress, mean (SD)	11.8 (9.3)	13.5 (9.4)	.42
Gender: Female, sample size (%)	40 (52.6)	40 (53.3)	.59
Race: White (sample size [%])	65 (86.7)	69 (92.0)	.51
Black	4 (5.3)	4 (5.3)	
Asian	2 (2.7)	0 (0.0)	
American Indian	1 (1.3)	0 (0.0)	
Other	3 (4.0)	2 (2.7)	
Ethnicity: Not Hispanic or Latino*	55 (94.8)	60 (95.2)	.43
Hispanic or Latino	3 (5.2)	3 (4.8)	
Spouse/partner to individual with MS, sample size (%)	62 (81.6)	58 (77.3)	.94
Employed: Yes, sample size (%)	49 (64.5)	50 (66.7)	.52
Income (annual household): > \$50,000, sample size (%)	52 (68.4)	47 (62.7)	.69
Time spent providing care to individual with MS, sample size (%)			.98
• ≤ 20 h/wk	38 (50.0)	38 (50.7)	
• 21-40 h/wk	7 (9.2)	7 (9.3)	
• > 41 h/wk	30 (39.5)	31 (41.3)	
Individual with MS variables	Arm 1	Arm 2	P
Age, years (mean [SD])	50.6 (13.2)	49.9 (12.0)	.74
Time since MS diagnosis, years (mean [SD])	13.1 (10.6)	12.1 (9.7)	.27
Gender: Female, sample size (%)	51 (67.1)	48 (64.0)	.69
MS Type: Relapse (other group Progressive), sample size (%)	39 (53.4)	48 (65.7)	.62
Patient Determined Disease Step score, median (range, IQR)	4 (1-9, 5)	4 (1-8, 3)	.68

DASS, Depression Anxiety Stress Scales; MS, multiple sclerosis.

*Missing data for this variable: n = 17 (arm 1), n = 12 (arm 2)

variable (DASS Total Composite score) after the intervention was regressed on the moderator variable at baseline, arm assignment (website and telecoaching or website only), and the moderator by intervention group interaction. If the interaction was significant, it was probed using a simple slopes analysis. The specific variables at baseline that were tested for moderation and whether they had an influence on the primary outcome after the intervention and at the 6-week follow-up were age, gender, race/ethnicity, type of community, income, geographic distance between the informal caregiver and the individual with MS, number of hours the informal caregiver spent caring for the individual with MS, perceived caregiving burden, baseline levels of anxiety, depression, and distress, and the age, gender, and disability level of the individual with MS.

Finally, to further explore the efficacy of the 2 arms, we planned to examine cumulative distribution functions (CDF) for any outcome variables that demonstrated significant group-by-time interactions. The use of CDFs to

examine the effect of treatments, particularly when using patient-reported outcomes as the outcomes of interest in a trial, has been recognized as an appropriate method for exploring clinical effects of treatments under study.²⁹ All analyses were conducted using SPSS Version 28 (IBM Corp) and all outcome variables met the assumptions of the various statistical tests.

RESULTS

A convenience sample of 151 informal caregivers was enrolled from March 2021 to August 2021 with follow-up data collection continuing until January 2022. As seen in Figure 1, of the 151 participants enrolled, 76 were randomly assigned to arm 1 and 75 to arm 2 and 142 enrollees completed the study period with no significant differential attrition. As seen in **TABLE 1**, baseline characteristics of the caregivers were well balanced between arms and clinical characteristics of the individuals with MS who were being cared for by the participating caregivers were also well balanced.

Baseline DASS Composite, Depression, Anxiety, Stress, and DT Scores

The group mean DASS composite score at baseline was 25.1 (22.4) with scores ranging from 0 to 115. There currently are no validated threshold scores indicating elevated levels of this composite score. When examining the percentage of MS caregivers with DASS subscale scores that exceeded validated thresholds for normal levels of the attribute (depression, anxiety, stress),^{22,23} we found that 33.8% had elevated DASS Stress scores, 31.1% had elevated DASS Depression scores, 19.2% had elevated DASS Anxiety scores, and 41.7% had elevated DT scores. As seen in Table 1, there were no significant differences by study arm for primary or secondary outcomes at baseline.

Primary and Secondary End Points

FIGURE S1 shows DASS Total Composite (A), Stress (B), Depression (C), Anxiety (D), and DT (E) scores over time by group. The linear mixed-effects model using an autoregressive covariance structure showed that the group-by-time interaction (Type III tests of fixed effects) was statistically significant for the DASS Total Composite score ($P = .037$) and the DASS Stress subscale ($P = .047$). The DASS Anxiety subscale approached significance ($P = .052$) while the DASS Depression subscale ($P = .26$) and DT score ($P = .136$) were nonsignificant.

The post hoc pairwise comparison analyses showed that participants in arm 1 significantly improved on the DASS Total Composite score after the intervention ($P < 0.01$) and at the 6-week follow-up ($P < 0.01$), whereas those in arm 2 did not have significant improvements after the intervention ($P = .41$) or at the 6-week follow-up ($P = .12$). The post hoc pairwise comparison analyses showed that participants in arm 1 significantly improved on the DASS Stress subscale after the intervention ($P < 0.01$) and at the 6-week follow-up ($P < 0.01$), while those in arm 2 did not have significant improvements after the intervention ($P = .195$), but did have a significant improvement at the 6-week follow-up ($P = .019$). As seen in **TABLE S1**, effect sizes (d) were largest for DASS Total Composite (after the intervention) ($d = 0.41$; 95% CI, 0.07-0.75) and DASS Stress subscale after the intervention) ($d = 0.41$; 95% CI, 0.07-0.74).

FIGURE S2 shows the CDF of DASS Stress scores for participants in arm 1 and arm 2. The CDF was used to examine stress scores because stress was significantly reduced in arm 1 and, unlike the composite score, had the normed cutoff thresholds needed for CDF analysis. No other outcome variables met these criteria and presenting their CDFs is not indicated. The x-axis represents the change in scores from baseline to immediately after the intervention period and the y-axis represents the cumulative proportion of patients who experienced these levels of change. Currently, there are no standards for the best point difference that indicates a change of state in DASS subscale scores. However, given the validated cut-points for classifications of stress using the DASS subscale

PRACTICE POINTS



Clinicians caring for individuals with multiple sclerosis should assess caregiver emotional status (eg, anxiety, stress) over the trajectory of the disease and treatment.

Evidence shows that psychoeducational interventions can reduce stress and anxiety in other caregiver groups; our pilot study provides preliminary evidence that this also may apply to caregivers of individuals with multiple sclerosis.

Caregivers with poor emotional outcomes should be encouraged to speak with their primary care practitioners or mental health professionals for more in-depth evaluation. ■

(normal, mild, moderate, severe, extremely severe), we decided that an improvement of 10 points (which would lower an individual's score by 1 or 2 categories) and an improvement of 7 points (which would lower an individual's score by 1 category in all but 1 classification) would be considered relevant change thresholds.

As seen in Figure S2, a reduction (or negative) change in score on the DASS Stress subscale represents a reduction (improvement) in stress over time. As shown, 18.8% of arm 1 participants and 7.1% of arm 2 participants achieved at least a 10-point reduction in their DASS Stress score; 27.5% in arm 1 and 15.7% in arm 2 achieved at least a 7-point reduction; and 79.7% in arm 1 and 58.6% in arm 2 had no worsening of their DASS Stress scores from baseline to immediately after the intervention.

The results of the moderated regression analysis indicated that all variables tested for moderation had a small and nonsignificant relationship with changes in the DASS and distress scores immediately after the intervention and at the 6-week follow-up.

DISCUSSION

The goal of this study was to test the effect of 2 remotely delivered intervention arms on depression, anxiety, stress, and distress for informal caregivers of individuals with MS. There were several key findings. First, we found that a significant number of informal caregivers had baseline levels of stress, depression, and distress that fell above clinical thresholds. Our reported prevalence of stress, depression, and

distress was similar to rates in prior research with caregivers of individuals with MS^{6,7,11,30} and exceeded rates reported for informal caregivers of individuals with cancer^{15,17,18} and informal caregivers of persons with a variety of chronic health conditions.³¹ It is well established that informal caregivers of individuals with MS often play an important role over time in their care and that the psychological and physical health of the caregiver has an impact on the quality of life of the individual with MS.³⁰ As informal caregivers are important members of the care team, helping them to recognize and to seek help for elevated stress, anxiety, depression, and distress is recommended.^{7,16}

Second, we found that the arm 1 intervention had a significant and clinically meaningful impact, reducing informal caregiver stress and overall emotion composite score (depression, anxiety, stress), when compared to arm 2. The reduction was sustained over an additional 6-week follow-up period. While few studies of interventions for caregivers of individuals with MS have been conducted, our findings of improving psychological outcomes align with several prior interventions.^{6,7,11-13} The effect sizes associated with arm 1 align with those reported in prior psychoeducational interventions for informal caregivers of other chronic conditions^{11,15,16,21} and provide preliminary support for the use of this remotely delivered intervention, which also was found to be effective in informal caregivers of individuals with cancer.¹⁶ For caregivers who live in remote areas, feel unable to leave the family members they attend to, or have schedules that do not allow in-person attendance, the website and remote coaching are convenient. For a group of caregivers without many psychoeducational support interventions, this is a first step to provide needed support.

CONCLUSIONS

Several limitations of this study should be noted. First, convenience sampling was used, which limits generalizability of study results. Second, the sample was very homogeneous in terms of race (89% White) and income (66% with an annual income > \$50,000), also limiting generalizability of results. The eligibility criterion that required informal caregivers to have access to the internet may have yielded a self-selected sample of participants with access to and comfort with technology. Finally, there were 2 interventionists, and although study results did not differ by interventionist and ongoing fidelity checks showed no difference in protocol fidelity by interventionist, study generalizability is limited by the small number of interventionists.

Although this study demonstrated the efficacy of a website-plus-coaching intervention, more research is needed before clinical implementation can be considered. First, we recommend that the website-plus-coaching intervention be tested with a sample of informal caregivers of individuals with MS who have lower incomes and are non-White. Second, we recommend that the intervention be tested in a larger sample to enhance generalizability and statistical power.

In conclusion, while the importance of assessing the emotional status of informal caregivers of individuals with MS has been recognized,^{2-9,11-13} the use of evidence-based interventions to reduce untoward psychological outcomes is rare. We need to continue to test interventions aimed at improving the poor emotional outcomes reported for a significant portion of informal caregivers. Improving their emotional and mental health will not only improve their physical and emotional quality of life, but will improve the care received and the quality of life of their loved ones with MS as well.^{15,30} If health care providers are to ensure support of individuals with MS throughout their disease course, then we must facilitate the support of their informal caregivers as well. ■

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