Feasibility and efficacy of an at-home, technology-supported mindfulness program in people with Multiple Sclerosis: a proof-of-principle study

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May 15, 2023

Abstract

Background: Multiple Sclerosis (MS) is a chronic disease with a high prevalence of neuropsychiatric symptoms. Mindfulness is a practice that encourages individuals to cultivate a present-focused, acceptance-based approach for managing neuropsychiatric symptoms. Its positive effect on MS has been demonstrated, but learning such technique is expensive and time-consuming. In this study, we investigated the feasibility and efficacy of an 8-week, at-home, technology-supported mindfulness program in a cohort of MS patients. Methods: The study included two visits, one at baseline and another after the mindfulness program. We measured adherence to the proposed mindfulness treatment and its effect on different neuropsychological scales and in terms of quantitative EEG parameters. All participants received a smart biofeedback device to be used during the therapeutic program consisting of daily meditative exercises. Results: Twenty-nine patients were recruited for the present study. Among them, 27 (93%) completed the entire program and 17 (63%) completed more than 80% of the scheduled sessions. We observed a statistically significant reduction of the Ruminative Response Scale score and a significant increase in the Digit Span Backward. Regarding neurophysiological data, we found a significant reduction of the whole-scalp beta and parieto-occipital theta power post intervention. Conclusion: Our results show that an at-home, technology-supported mindfulness program is feasible for people with MS. The efficacy in terms of reappraisals of stress, cognitive and emotional coping responses is also supported by our neurophysiological data. Further studies are warranted to better explore the role of such approaches in managing the psychological impact of MS diagnosis.

Introduction

Multiple Sclerosis (MS) is the most common non-traumatic cause of disability in young adults (1). It is a condition with great clinical heterogeneity and thus emotional distress about the uncertainties relating to disease progression takes a considerable toll. Not surprisingly, neuropsychiatric symptoms are common in MS, occurring in almost 60% of patients over the course of the disease (2). Among them, major depressive disorder (MDD) is the most frequent psychiatric comorbidity, with a prevalence ranging from 15–25% of patients (2), and anxiety disorders are also common (3). The high prevalence of depression and anxiety disorders in people with MS (PwMS) finds an answer in several factors, including disease severity, disability and psychosocial aspects such as inadequate coping or insufficient social support (4,5). Depression, anxiety disorders and fatigue – another extremely common symptom of MS (6,7) – constitute a vicious cycle that may lead to an increase in symptom burden and disability worsening and could affect treatment compliance (4,8).
Improving coping skills might help patients manage negative emotions related to their condition and develop resilience with a positive impact on their psychological status and quality of life. Thus, taking care of PwMS should pay attention to psychological support for dealing with the challenges of the disease.

Psychological counselling and psychotherapeutic treatments, such as cognitive-behavioural therapy (CBT), significantly affect psychological symptoms in MS, even in the long-term (9). In this regard, mindfulness has become recognised as a powerful tool in psychotherapy. This technique is defined as the ability to bring one’s attention to experiences occurring in the present moment, with complete acceptance and without judgment (10). Mindfulness encourages individuals to cultivate a present-focused, acceptance-based approach to managing their symptoms and helps to reduce anxiety, depression and stress (11). Several reviews and meta-analyses have demonstrated that it can alleviate psychological symptoms, fatigue and pain in PwMS with a positive impact on the quality of life and coping strategies (12–14). However, traditional mindfulness-based interventions are time-consuming and expensive because they require frequent face-to-face meetings with the therapist and daily at-home practice. Moreover, disability can further reduce the accessibility to mindfulness programs. Waiting lists, treatment acceptability and the lack of clinicians with specific expertise in many MS centres are other potential limiting factors.

For all these reasons, it is important to explore alternative approaches based on the support of technology to increase the accessibility to mindfulness programs for PwMS.

To date, only some data are available in the literature regarding the feasibility and efficacy of this approach and there is a discussion in the MS community about the benefits and the limitations of technology-supported, at-home mindfulness programs (14). Indeed, if this approach can reduce the limitations related to physical access for face-to-face, hospital-based mindfulness programs (necessity of long journeys, time and money consuming for patients and caregivers), it raises questions and concerns about internet security, IT accessibility and reduced patient engagement.

To address these issues, it is not only important to evaluate whether technology-supported mindfulness is feasible and effective but also to understand the mechanisms underlying treatment response. In this regard, electroencephalogram (EEG) could be a valuable tool for non-invasively exploring the effects of mindfulness on brain activity.

In this study, we investigated the feasibility and efficacy of an 8-week, at-home, technology-supported mindfulness program in a cohort of MS patients. In particular, we measured adherence to the proposed mindfulness treatment and its effect on different neuropsychological scales – exploring depression, anxiety, quality of life, stress perception, cognitive status and fatigue – before and after our intervention. Also, we explored changes in terms of quantitative EEG (qEEG) measures between the two time points.

Methods

Study design and population

This was an interventional study on a cohort of patients affected by Multiple Sclerosis (MS), diagnosed according to current clinical criteria (15). Patients were recruited from the MS outpatient clinic of the Policlinico Campus Bio-Medico, Rome (Italy), from October 2020 to July 2021. Severe disability (defined as Expanded Disability Status Scale score >8) and cognitive (defined as Mini-Mental State Examination < 27), visual or hearing impairment were the exclusion criteria. All participants gave written informed consent. This study was performed according to the declaration of Helsinki and was approved by the local ethics committee.

The study included two visits, one at baseline and the other after the 8-week home mindfulness program. Both visits consisted of a clinical and neuropsychological evaluation, together with the recording of a high-density resting-state (rs) EEG. After the first visit, participants received a smart biofeedback device – i.e., a headband with EEG sensors placed along the forehead – to be used during the mindfulness program (Figure 1).
Patients received adequate training on how to use the device and how to perform mindfulness exercises by qualified personnel who supported participants throughout the study. At the final visit, patients had to give back the device.

Clinical and Neuropsychological evaluation

The clinical evaluation included reviewing patients’ clinical and pharmacological history and the neurological examination.

Regarding the neuropsychological evaluation, a battery of eight validated tests was administered to each patient. This battery included:

- The 12-Item Short Form Survey (SF-12), which is a self-reported outcome measure assessing the impact of health on an individual’s everyday life. It is often used as a quality-of-life measure and investigates the patient’s state of health via eight dimensions (general health perception, physical health, limited physical role function, physical pain, vitality, mental health, limited emotional role function and social functioning) (16).
- The Perceived Stress Scale (PSS) is the most widely used psychological tool for assessing stress perception. It measures the degree to which situations in one’s life are appraised as stressful (17).
- The Ruminative Response Scale (RRS) is a self-reported questionnaire about rumination, i.e., repetitive negative thinking about an idea, situation, or choice interfering with normal mental functioning. Subjects are asked to report what they generally do when they feel sad or depressed, describing the factors of brooding and reflection (18). Rumination is not a unitary process but rather a multidimensional construct associating adaptive and maladaptive components (19). There is growing evidence that brooding, i.e., “a passive comparison of one’s current situation with some unachieved standard” and reflective pondering or reflection, i.e., “a purposeful turning inward to engage in cognitive problem-solving to alleviate one’s depressive symptoms”, are two distinct components of rumination (20). Brooding may represent a more maladaptive aspect of rumination than reflection, with stronger links to depression and suicide attempts (21,22)
- The Hospital Anxiety and Depression Scale (HADS) is a frequently used self-rating scale developed to assess psychological distress in non-psychiatric patients. It consists of 14 items and two subscales for anxiety (HADS Anxiety) and depression (HADS Depression) (23). Scores above 11 indicates the presence of anxiety and/or depressive symptoms.
- The pain-visual analogue scale (VAS) is a unidimensional measure of pain intensity used to record patients’ pain. It is applied to assess pain intensity among the adult population with chronic conditions (e.g., MS, rheumatologic diseases, chronic pain and cancer).
- The Modified Fatigue Impact Scale (MFIS) is a structured, self-report questionnaire which provides an assessment of the effects of fatigue in MS in terms of physical (9 items), cognitive (10 items) and psychosocial functioning (2 items) (25).
- The perceived self-efficacy scale explores personal action control or agency: a person who believes in being able to produce a desired effect can conduct a more active and self-determined life course. In terms of feeling, a low sense of self-efficacy is associated with depression, anxiety and helplessness. In terms of thinking, a strong sense of competence facilitates cognitive processes and performance in a variety of settings, including quality of decision-making and academic achievement (26).

Mindfulness home treatment

After the neuropsychological evaluation, patients enrolled in the study received training about the 8-week mindfulness program. Specifically, they had to perform meditative exercises daily for the entire study period – 30 minutes per day for the first week and 45 minutes per day from the second week until the end.

The daily meditation session was supported by the headband (Muse 2<sup>®</sup>, Interaxon Inc., Toronto, Canada), which was capable of detecting brain activity through EEG electrodes placed on the forehead (AF7, AF8),...
behind the ears (TP9, TP10) and on Fpz. A mobile app to manage the headband was provided by the manufacturer and was installed during baseline visit on patients’ smartphones. The headband’s application transforms the EEG signal into different components (i.e., decomposing noise, oscillations, non-periodic characteristics and transient and event-related brain events), which change in relation to the detected brain activity. When one finds a deep, restful state, the singing of birds begins, while a thunderstorm sound of variable intensity is associated with an activated state. Signal processing and machine learning techniques are applied to the brain signal components to control the experience in real-time. Biofeedback sensors (plethysmography, pulse oximetry, accelerometer, gyroscope) also register signals about heart and respiratory rate, posture and breathing. These data help patients to evaluate their progress and improve meditation techniques. Patients were asked to wear the headband every time they performed the meditation exercises. Similar to previous experiences (37), we planned a weekly virtual session with the psychologist (D.S.) to carry out self-observation on meditation performed.

### EEG recording

Sixty-two channel-EEG was acquired with a prewired head cap (g.GAMMAcap, g.tec medical engineering GmbH). Electrodes were placed according to the international extended 10–20 system with two-ear reference electrodes (A1 and A2). The ground was placed on FCz. Impedance was kept below 5 kOhm for all electrodes. The sampling rate was set to 48 KHz (g.HIamp, g.tec medical engineering GmbH, Austria) and data acquisition were controlled by the software g.HIsys Highspeed Online Processing for Simulink (The MathWorks Inc., Massachusetts, USA). A/D conversion was made at 16 bits; the preamplifier amplitude range was ±3200 μV. Hardware acquisition filters were used: high pass =0.2 Hz. The rs-EEG recording was performed with the patient seated in a comfortable armchair in a quiet room and was composed of 10 min with closed-eyed and 5 minutes with open eyes.

### Quantitative EEG analysis

Quantitative EEG analysis was performed using the EEGLAB and Brainstorm Toolbox for Matlab (27) and in-home Matlab code (The MathWorks Inc., Massachusetts, USA, Version: R2020a). Offline data preprocessing was performed using the EEGLAB toolbox through a semiautomatic homemade MATLAB script. EEG data were visually inspected to reject massive artefacts – e.g., discontinuities and jumps in the EEG signal such as “electrode pop” - DC artefact was removed and EEG was re-referenced to average. A third-order Butterworth 0.5 Hz high-pass filter was then used to remove slow drifts in the EEG signal and data were resampled to 128 Hz. Bad channels were automatically recognised using the clean_rawdata plugin in EEGLAB and spherical interpolation was performed. We then applied the Independent Component Analysis method to recognise non-brain-derived components. The latter were processed through the IClabe plugin in EEGLAB to identify artefacts – such as EKG or eye blinks – which were manually checked before rejection (based on topography and spectral features) (28). EEG was filtered again at 70 Hz low-pass (third-order Butterworth filter). Finally, epochs were visually reviewed to reject residual macroscopic artefacts. Cleaned data free from relevant artefacts were then exported for the subsequent analysis.

### EEG power spectrum analysis

To assess the effect of our mindfulness program on PwMS brain networks, we performed a measure of resting-state brain activity. Cleaned data were imported in Brainstorm and analysed through a semiautomatic homemade MATLAB script. As a measure of activity, we estimated the Power Spectrum Density (PSD) by the standard Welch method – i.e., an average of non-overlapped windows with a duration of 2 s for the following frequency bands: i) Delta: 2–4 Hz; ii) Theta: 5–7 Hz; iii) Alpha: 8–12 Hz; iv) Beta: 13–30 Hz. To measure global cortical activity, we averaged PSD measures over all channels. Then, we focused the PSD analysis on specific regions of interest (ROI). In particular, we identified three ROIs: i) Frontal (Fp1, Fpz, Fp2, AF7, AF3, AF4, AF8, F5, F3, F1, Fz, F2, F4, F6 ); ii) Frontocentral (FC5, FC3, FC1, FCz, FC2, FC4, FC6, C5, C3, C1, Cz, C2, C4, C6 ); and iii) Parietal (CP5, CP3, CP1, CPz, CP2, CP4, CP6, P7, P5, P3, P1, Pz, P2, P4, P6, P8, POz, PO7, PO3, PO4, PO8 ). Finally, we measured the individual alpha frequency (IAF) – the predominant frequency of alpha-band oscillations – using an automated peak-detection
algorithm embedded in Brainstorm (29). IAF is a neurophysiological marker of cognitive performance and is altered in several neurological and psychiatric conditions (30,31).

Compliance outcomes

First, we measured the number of drop-outs, defined as patients that never used the headband at home or did not return for the final visit. Moreover, we measured how much time each patient used the headband, compared to the total time of mindfulness meditation planned to be performed in this study – i.e., 2415 minutes; this ratio was transformed into a percentage. Compliance was then classified as i) optimal (values ranging from 81-100%), ii) good (values ranging from 61-80%), iii) moderate (values ranging from 41-60%) and iv) poor (values less than 40%).

Statistical analysis

Statistical analysis was performed using the software JASP (version 0.12.1, University of Amsterdam, 2020). Data were analysed for normality of distribution using the Shapiro-Wilk test and were expressed as mean (±standard deviation [SD]). Categorical factors were reported as frequency (%). The effect of the mindfulness program on neuropsychological and neurophysiological measures was assessed using the Wilcoxon signed-rank test for non-parametric data. The significance level was set at $p < 0.05$. No formal sample size calculation was performed considering the proof-of-principle nature of the study.

Results

The demographic and clinical data are displayed in Table 1. Twenty-nine (n=29) patients were recruited for the present study. The study participants were predominantly female (69%), with a mean age of 46.1 years (SD 8.7). On average, participants have been living with MS for 7.9 years (SD 5.9). A total of 75.9% of the participants had Relapsing-Remitting MS (RRMS), 13.8% Secondary Progressive MS (SPMS) and 10.3% Primary Progressive MS (PPMS). The majority of the patients (86.2%) were on MS treatment during the study. Also, four patients (13.8%) were taking anti-depressant drugs, while one (3.5%) was taking benzodiazepine.

At the end of the study, we recorded two dropouts. Both patients (F47; F48) did not perform the meditation exercises included in the program. They returned to give back the headband but did not perform the final visit. Among the patients who completed the program (n=27), seventeen patients presented optimal adherence (81–100%), three patients showed good adherence (61–80%), five patients presented moderate adherence (41–60%) and two patients presented poor adherence (<40%). Overall, thirteen patients (48%) completed more than 90% of the scheduled program and twenty-three (85%) completed at least 50% of the program.

To evaluate the efficacy of our intervention – i.e., the smart device-aided mindfulness program – the neuropsychological evaluation was performed at the baseline (T0) and the end of the study (T1) after the 8-week study period. We only considered the patients who completed the program in the analysis (n=27). Mean values and the comparison between T0 and T1 are summarised in Table 2. According to the Shapiro-Wilk test results, we compared the scores of the individual scales and questionnaires using the Wilcoxon-signed rank. We observed a statistically significant reduction of the RSS mean score after the mindfulness program (43.4 vs 35.9) ($W=295; p<0.05$) and a significant increase in the mean score of the Digit Span Backward (4.3 vs 4.9) ($W=42.5; p<0.05$) after the intervention. Of note, we also observed a reduction in the mean score of the cognitive subitems of the MFIS (14.9 vs 10.9), although there was borderline statistical significance ($W=307.5; p=0.0053$). No other statistically significant difference was found in the neuropsychological tests (Figure 2).

Regarding neurophysiological data, after the pre-processing and processing stage, we compared the EEG signal at T0 and T1 using the paired-t test. We only considered the patients who completed the program in the analysis (n=27). After the pre-processing, the EEG dataset from twenty-three patients (n=23) was analysed, while the data from the other four patients (n=4) were discarded for technical reasons (e.g., excessive artefacts, acquisition mistakes, etc.). These EEG data are summarised in Table 3. No modification
of IAF was found (W=124; p=0.25). With regard to the individual EEG band power, a significant reduction in beta power between time points was found for both the whole scalp and for the individual ROIs (See Table 3 for mean power values and the related statistic). In addition, we observed a statistically significant reduction in the mean value of theta power for the parieto-occipital ROI only (0.047 vs 0.039) (W=188; p<0.05) (Figure 2).

Discussion

In this study, we investigated the feasibility and efficacy of an 8-week, at-home, technology-assisted mindfulness program in a cohort of PwMS, exploring different neuropsychological domains and qEEG measures. To date, several studies have been published focusing on the effect of mindfulness in PwMS; however, to the best of our knowledge, this is the first study based on the use of a technology-assisted neurofeedback method to help patients’ at-home meditation. First, we found excellent adherence among participants since 27 patients (93%) completed the program, 23 patients (85%) completed at least 50% of the scheduled at-home sessions and 17 patients (63%) completed more than 80% of the scheduled at-home sessions. These results are particularly relevant, considering the heavy commitment required (30–45 min per day for eight consecutive weeks) and the social characteristics of our sample (most of the participants were employed and married, thus with familiar and work commitments).

As for potential efficacy, we found that meditative exercises improved rumination and cognitive functioning, as demonstrated by the reduction of beta power (32), confirming the data already present in the literature (33).

A diagnosis of MS comes with many uncertainties relating to disease progression and the potential disability, significantly impacting patients’ quality of life and leading to dysfunctional mood regulation and ruminative thinking (34). Indeed, emotional distress and inadequate coping strategies might result in depression and anxiety disorders. The recent SARS-CoV-2 pandemic has shown that PwMS are less resilient to psychological stressors (35,36).

Mindfulness is a type of meditation whose benefit on stress management and the cognitive and emotional profile has been proven on several occasions. It originates in ancient Buddhist meditative tradition and is defined as the awareness that arises through “paying attention in a particular way: on purpose, in the present moment and nonjudgmentally” (37). Since the 1970s, the translation of these meditation techniques within western culture has led to a new conceptualisation (38). In fact, this definition now describes practices that require both the regulation of attention (to maintain the focus on immediate experiences) and the ability to approach one’s experiences with openness and acceptance (39,40). Mindfulness meditation has been widely applied to multiple health conditions as a form of behavioural intervention (41,42). Regarding MS, previous research showed a significant positive effect of different mindfulness practices on global quality of life, mental health (e.g., anxiety, depression), physical (e.g., balance, pain, fatigue) and psychosocial self-report measures (33,43–46). In addition, a reduction in pain perception and improved physical mobility and balance have been reported after mindfulness practice or yoga (44). Meditative training not only has beneficial effects on the psychological and motor profile, but it might also induce structural modifications of the brain (47–50). Functional neuroimaging studies found that mindfulness could modify brain activity, reducing bilateral amygdala and prefrontal cortex activation, which are brain regions involved in emotional processing and implicated in the pathogenesis of mood disorders (51).

In line with these data, we found a reduction of rumination after the intervention. Ruminative thought style is characterised by repetitive and intrusive negative thinking – e.g., hopelessness, pessimism, self-criticism and neediness – leading to maladaptive emotion regulation strategies (52). It is considered a cognitive vulnerability to depression (53) and rumination can maintain and exacerbate depression (52). It also reduces social support and interferes with problem-solving and instrumental behaviour. In our study, improving emotional response led to reduced rumination and improved performance in the digit span test, a rough but validated measure of cognitive efficacy. We also observed a trend towards improving the MFIS cognitive sub-items. This is not surprising since repetitive negative thinking impacts cognitive performances...
and, indeed, has been associated with dementia and cognitive decline (54).

Despite the positive effects of meditative practices, different factors may hamper their diffusion. Learning meditation techniques might be expensive and time-consuming because of the steep learning curve. Thus, to minimise the impact of distractors and better tailor the intervention, we exploited the potential of a neurofeedback method (55, 56) to help patients to enhance meditative attitudes, focusing on external (e.g., the sound of the device) rather than internal stimuli (e.g., the breathing pattern). The brain-sensing headset was crucial because it allowed the patient to identify whether they were resting or in an activated mood during meditation (55,57). The headset is embedded with electrodes that are capable of recording frontotemporal electroencephalographic activity. This brain signal is then processed through an algorithm that identifies a resting or activated state which is eventually translated into auditory feedback. This device is primarily validated (57,58) and has already been used in several studies (55,59,60). The support given by the device allows us to shorten the learning curve without compromising the beneficial effects of mindfulness training.

To investigate neurophysiological correlates of the effect of meditation on the brain, we performed high density-EEG before and after the mindfulness practice. The reduction of beta activity power found in our study is of interest since it has been correlated with both cognitive and executive functions and many studies have demonstrated the role of beta rhythm in anticipation, executive functions and cognitive processes (32,61). Some reports suggest a possible link between beta activity and emotional distress, insomnia, attention deficit and anxiety (62–65). Indeed, an excess of beta waves is related to hypervigilance and alertness which might, in turn, lead to fear, overthinking, anxiety and stress (66,67). The reduction in beta activity observed in our study can be interpreted as a neurophysiological confirmation of our clinical outcome. Indeed, mindfulness helps patients avoid ruminative and negative thoughts on the disease. Such thoughts might overload neural networks, emphasising anxiety and over-worrying. This could, in turn, cause increased beta activity, which is reduced after effective mindfulness training.

Moreover, we found a reduction in the mean value of theta power for the parieto-occipital ROI. Frontal theta has been associated with anxious rumination, reflecting the putative activation of the anterior cingulate cortex in conflict situations (68). However, Andersen and co-workers (69) have also observed an increase in parieto-occipital theta power during a task inducing personally meaningful rumination. Our finding of a reduced theta and beta band power activity could be then considered the epiphenomena of improved neural network functioning.

This study has some limitations to be acknowledged. Firstly, there was no active control group because the study was primarily devoted to demonstrating the feasibility of an at-home, smart device-aided mindfulness program in PwMS. Secondly, the sample size is limited to draw definite conclusions regarding efficacy. However, we also have to acknowledge that this was the first study to test the performance of a brain-sensing device in a real-life cohort of PwMS. Exploiting the role of new technologies in real-life scenarios is extremely important in light of the recent SARS-CoV-2 pandemic.

In conclusion, our study confirms that mindfulness training stimulates adaptive psychological functioning, even in vulnerable subjects such as PwMS. Meditative exercises help patients change their perspective on their condition, improving emotional response regulation. In turn, this might help with other related aspects, such as cognition or everyday self-efficacy. The major barrier to the diffusion of such practices is that mindfulness requires long and expensive training with specialised instructors. New technologies might help to improve compliance and the efficacy of mindfulness programs, as shown in the present paper. However, more studies are warranted to better explore the role of at-home, technology-supported mindfulness programs in managing the psychological impact of MS diagnosis in patients’ lives.

References


Legends

Figure 1. Adherence to the mindfulness program

Adherence to the program was classified as i) optimal (values ranging from 81–100%), ii) good (values ranging from 61–80%), iii) moderate (values ranging from 41–60%) and iv) poor (values <40%). Among patients who completed the program (n=27), seventeen patients (63%) presented optimal compliance (pie chart on the left), of which thirteen (48%) completed more than 90% of the scheduled program (pie chart on the right).

Figure 2. Study experimental design.

SF-12: 12-item Short Form Survey; PSS: Perceived Stress Scale; RRS: Ruminative Response Scale; HADS: Hospital Anxiety and Depression Scale; BDS: Backward Digit Span; FDS: Forward Digit Span; VAS: Visual Analogue Scale; MFIS: Modified Fatigue Impact Scale; GSE: General Self-Efficacy Scale; EEG: 64-channel Electroencephalogram.

Figure 3.

The figure on the left shows how psychological tests score changes after mindfulness intervention. On the right, the changes in EEG band power between the two time points is shown. * p<0.05

**EEG**

**Bio-feedback guided Mindfulness sessions**

- **Week 1**: 30 minutes/day
- **Week 2-8**: 45 minutes/day

**ASSESSMENT**

SF-12; PSS; RRS; HADS; BDS; FDS; VAS; MFIS; GSE

**T0**

- EEG

**T1**

- EEG
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