

Meditation training for people with Amyotrophic Lateral Sclerosis: a Randomized Clinical Trial

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ABSTRACT

Background: There is a lack of studies about psychological interventions for the promotion of well-being in people with Amyotrophic Lateral Sclerosis. We aimed to test the efficacy of an ALS-specific mindfulness-based intervention on the improvement of quality of life.

Methods: We conducted a randomized, open-label and controlled clinical trial of the efficacy of an ALS-specific meditation program in promoting quality of life. Adults who received a diagnosis of ALS within 18 months were randomly assigned to an 8-week meditation training based on the original mindfulness-based stress reduction program and tailored for people with ALS, or to the usual care. Quality of life, assessed with the ALS-Specific Quality of Life Revised, represented the primary outcome, while secondary outcomes included anxiety and depression, assessed with the Hospital Anxiety and Depression Scale, and specific quality of life domains. Participants were assessed at the recruitment and after 2, 6, and 12 months. The efficacy of the treatment was assessed on an intention-to-treat basis in a linear mixed model.

Results: One hundred participants were recruited between November 2012 and December 2014. Over time, there was a significant difference between the two groups in term of quality of life ($\beta=0.24$, $p=0.015$, $d=0.89$). Significant differences between groups over time were also found for anxiety, depression, negative emotions, and interaction with people and environment.

Conclusion: An ALS-specific meditation program is beneficial to quality of life and psychological well-being of people with ALS.

INTRODUCTION

Amyotrophic lateral sclerosis (ALS) is a neurodegenerative disease that affects upper and lower motor neurons. It is clinically characterized by progressive muscle atrophy, weakness, fasciculation and spasticity (1). Life expectancy is generally 2-4 years from symptoms onset, with only 5-10% of patients surviving beyond 10 years (2). It affects about two individuals per 100,000 every year, with an overall prevalence of 5-6 individuals per 100,000 (3).

While current medical knowledge cannot stop the progression of the disease, the enhancement of quality of life is considered the primary goal in ALS care (4). Several psychological issues, including depression, hopelessness, distress, anxiety, and fear of the death, have been reported to be serious challenges to quality of life (QOL) (5, 6). Although these issues have been extensively investigated through observational studies, there is an absence of controlled studies concerning interventions aimed to promote psychological well-being in this field (7). Studies that examine how psychological well-being and quality of life can be promoted with psychological interventions are “urgently needed” (8).

To date, some of the most promising clinical treatments for the reduction of distress, the improvement of psychological well-being and help for people dealing with a chronic disorder are based on the concept of mindfulness, which can be considered as the process of bringing attention to moment-by-moment experience, in a non-judgmental way, and by noticing how the present moment is novel, every time (9). Mindfulness was reported to be associated with higher quality of life in both ALS patients (10) and their caregivers (11). In general and clinical populations, common interventions for the promotion of psychological well-being through mindfulness utilize meditation. Specifically, the most commonly used training program is the Mindfulness Based Stress Reduction (MBSR), developed by Jon Kabat-Zinn (12). The goal of this training program is to bring the attention to the present moment (*“what I am doing now; how I feel now”*) and accept feelings, sensations and emotions, without judgment. This allows people to better manage their

feelings and emotions, also improving their abilities to accept their illnesses (12). The practice of meditation leads to an awareness of what is happening in the body and the achievement of a more balanced emotional state. It also increases the ability to remain physically passive (i.e., without movement) for long periods of time and maintain a positive experience.

We developed a specific meditation training, based on the original MBSR protocol and adapted it for people with ALS, aimed at improving their QOL and psychological well-being (13). The study aims to test the efficacy of this protocol in the promotion of QOL and reduction of distress.

METHODS

Study design and participants

We conducted a randomized, open-label and controlled clinical trial of the efficacy of an ALS-specific mindfulness training program in promoting quality of life, compared to the usual care, with a one-year follow-up.

Recruitment and intervention were conducted in a hospital setting, a clinical center specialized in the treatment and management of neuromuscular disorders (NEMO - NEuroMuscular Omnicenter, Milan). Study approval was obtained by the Ethics Committee of Niguarda Ca' Granda Hospital. Study protocol was registered in ISRCTN registry, with the ID n° 88066803.

Individuals were considered eligible when they met the following inclusion criteria: probable or definite ALS diagnosis according to El Escorial criteria (14); aged 18 years or older; an Amyotrophic Lateral Sclerosis Functional Rating Scale-Revisited (ALSFRS-R) score above 24; ALS diagnosis within eighteen months; ability of the patient to speak and understand; and no secondary severe comorbidity, including significant cognitive and/or behavioral impairment, as assessed by the study physicians. Patients with a personal history of psychiatric disorders, as assessed by medical records and clinical interviews, were also excluded. All participants provided

written informed consent before the baseline assessment or, for individuals unable to write, verbal consent was given and a witness signed to acknowledge the consent of the participant.

Randomization

We randomly assigned participants 1:1 to join the meditation program (intervention group) or to receive usual care (control group) using a web-generated (www.random.org) random list.

Procedures

Participants in the experimental group joined an 8-week ALS-specific meditation program based on the original MBSR protocol (12) that was adapted to ALS clinical features (MBSR-ALS). Each of the eight weekly group sessions emphasized accepting the discomfort and physical limitations of ALS, focusing on the resources and abilities that are available. Arguments, metaphors, and sharing moments among participants were adapted to the daily reality of people with ALS. Participants were invited to explore, non-judgmentally, their emotions and the impact that physical limitations may have on stress, with a particular attention to the expression of anger. Physical exercises, such as Hatha Yoga (yoga postures) or Mindful Eating (chewing a raisin fully aware of perceptions and feelings), were removed or changed to make them appropriate for a functionally impaired ALS population. Primary caregivers (one for each patient) were invited to join the intervention. The full clinical protocol was previously reported by our group (13).

Controls received usual care and were not invited to join the intervention afterwards. Usual care was provided in a multidisciplinary setting and it also included individual counseling and psychological support when requested.

Participants from both conditions were assessed at recruitment (T0, baseline), after two months (T1, post-intervention for the experimental group), after 6 (T2) and 12 (T3) months.

Outcomes

Quality of Life represented the primary study outcome. It was assessed with the ALS-Specific Quality of Life Revised (ALSSQoL-R) (15), a questionnaire specifically developed to assess QOL in people with ALS. It is composed of 46 items and each question is rated with a 10-point Likert scale. Together with the total average score (0-10), which represents the primary outcome, the scale produces a single-item QOL score, and 6 domain scores: Negative Emotion, Interaction with People and the Environment, Intimacy, Religiosity, Physical Symptoms and Bulbar Symptoms. All these domains represent secondary outcomes.

Secondary outcomes included depression and anxiety. We assessed them with the Hospital Anxiety and Depression Scale (HADS) (16), a questionnaire designed to screen for the presence and severity of depression and anxiety over the past week in medical patients. It possesses a 7-item depression subscale (HADS-D) and a 7-item anxiety subscale (HADS-A), both on a 4-point Likert scale (range 0–3). Each subscale score is the sum of the respective seven items (ranging from 0 to 21). The scale is comprised primarily of items unrelated to somatic symptoms of depression and anxiety, reducing the interference of physical components that could confound the results (6).

We assessed dispositional trait mindfulness as a potential moderator of the results. It was measured with the Five Facet Mindfulness Questionnaire (FFMQ) (17). The FFMQ is a 39-item scale assessing five components of mindfulness: observing, describing, acting with awareness, non-judging, and non-reacting.

Statistical analysis

Data were analyzed on an intention-to-treat basis with the multilevel growth modeling technique(18). Time (4 repeated measures coded as follows: 0=baseline; 1=2 months (post treatment); 2=6 months; 3=12 months after the end of treatment), mindfulness (time-varying),

treatment (0=control; 1=treatment) and the interactions time*mindfulness and time*treatment were included in all growth models (one for each outcome) using a bottom-up approach starting from the generalized least squares (GLS) model. All fixed effects were tested step-by-step by means of the t-test based on the Satterthwaite approximation for degrees of freedom or the Wald t-test, while random effects were tested by the likelihood ratio test. Also covariance and error structures of models were assessed step-by-step. In particular, it was determined whether model fits improved by incorporating (a) an autoregressive structure with serial correlations, (b) heteroscedastic residuals for each time point and (c) heteroscedastic residuals for each time point in each condition. Treatment effect size was finally calculated for each outcome using the following formula (Feingold, 2009): the ratio of the time*treatment coefficient to the square root of the estimated slope variance. All models were fitted by maximum likelihood (ML). Critical alpha was set to 0.05 for all statistical tests. The R software (release 3.1.2) and RStudio (version 0.99.441, RStudio Inc.) were used for model fitting, in particular the R packages “lmerTest” (version 2.0-30) and “nlme” (version 3.1-119).

Power analysis and Sample size

Given the novelty of the trial (no other study had ever assessed the efficacy of a psychological intervention on ALS patients’ quality of life and well-being) and the multilevel approach that was planned to use for data analysis, necessary parameters for proper power analysis (i.e. between-subject slope variance and error variance) were not available at the time of study planning and sample size was thus calculated for a medium-size interaction effect ($f=0.25$) in a 2 (between) * 4 (within) mixed ANOVA. The G*Power software (release 3.1.3)(19) was used and the output showed that, setting alpha to 0.05, power to 0.95, the correlation among repeated measures to 0.5 and the non-sphericity correction to the lowest value (0.34), a total sample size of 80 was needed to

detect the hypothesized effect with the desired power. Taking into account a possible dropout rate of 25%, the number of patients to be recruited was further increased to 100.

RESULTS

One hundred ALS patients out of 300 eligible were recruited in the period between November 2012 and December 2014. After baseline assessment, they were randomly assigned to receive usual care or to join the meditation training (figure 1).

Insert figure 1 about here

The clinical and psychological baseline characteristics of the sample are shown in Table 1. No significant differences were detected between the two groups at the baseline.

| | Meditation (n=50) | SD | Usual care (n=50) | SD |
|---------------------------------------|------------------------------------|-----------|------------------------------------|-----------|
| Sex | | | | |
| Male (0) | 31 | | 33 | |
| Female (1) | 19 | | 17 | |
| Age | 57.933 | 11.330 | 63.411 | 10.156 |
| Time since symptoms onset (months) | 11.642 | 15.773 | 11.381 | 14.755 |
| ALSFRS | 29.833 | 4.834 | 32.167 | 6.645 |
| Quality of Life | 5.859 | 1.112 | 5.621 | 1.051 |
| Anxiety | 7.840 | 3.222 | 7.242 | 3.662 |

| | | | | |
|---|-------|-------|-------|-------|
| Depression | 5.861 | 2.770 | 6.363 | 2.841 |
| Quality of Life (Single Item Scale) | 5.775 | 1.950 | 5.776 | 2.365 |
| Negative Emotion | 5.938 | 1.508 | 5.701 | 1.544 |
| Interaction with People and the Environment | 7.338 | 1.638 | 7.342 | 1.413 |
| Intimacy | 5.657 | 2.179 | 5.149 | 1.744 |
| Religiosity | 5.425 | 2.910 | 5.371 | 3.599 |
| Physical Symptoms | 6.251 | 2.155 | 6.081 | 1.917 |
| Bulbar Symptoms | 6.772 | 2.731 | 6.124 | 2.470 |
| Mindfulness | 3.623 | 0.429 | 3.510 | 0.499 |

Table 1: Baseline characteristics

Unconditional growth models

Each outcome was firstly regressed on time in a growth model with a random intercept. The likelihood ratio test showed that all growth models with a random intercept were significantly better than their counterparts without random intercepts. With the exception of ALSSQoL single item, Intimacy and Religion, whose average trends were quite flat, the fixed linear effects of time were statistically significant in all other models, showing that, on average, “negative” outcomes (anxiety and depression) increased along time, while “positive” outcomes (ALSQoL-R total score and subscales) decreased. A random slope was then added to all models and the likelihood ratio test indicated that the random linear effect of time was statistically significant for depression, ALSSQoL total score, negative emotions, interactions and religion. Quadratic trends were also tested but did not significantly improve the fit of any model. Autocorrelation and heterogeneity of residuals over time were finally assessed by incorporating autoregressive and heteroscedastic error

structures. Only the model predicting ALSSQoL interactions was significantly improved by allowing for autocorrelation, while models predicting anxiety and depression were improved by modeling heteroscedastic residuals for each time point.

Conditional growth models

Mindfulness was the first predictor to be included in the models that passed the first step. Since the first time period was coded as 0, its main effects represent the cross-sectional correlations between the baseline scores of mindfulness and the baseline scores of each outcome. The t-test based on the Satterthwaite approximation for degrees of freedom showed that, at baseline, mindfulness was significantly related to anxiety, depression and ALSSQoL religion with a negative sign, and to ALSSQoL total score, negative emotions, interactions and intimacy with a positive sign. An interaction between time and mindfulness was then included but it did not result to be statistically significant in any model. Finally, treatment and its interaction with time were included. While the main effect represents the baseline difference in each outcome between the two conditions, the interaction effect is the between-group difference between the means of the slopes and reflects the degree to which treatment moderated the effect of time. All models were firstly extended by allowing for heteroscedastic residuals for each time point in each condition. This improved significantly only the fit of the model predicting depression. Given that no statistically significant difference between conditions was found in any outcome variables at baseline, only interaction effects were examined and results showed that the meditation training was effective in reversing the increasing trends of anxiety ($\beta=-0.96$, $p=0.038$, $d=0.78$, fig. 1) and depression ($\beta=-0.93$, $p=0.013$, $d=1.06$, fig. 2), and the decreasing trends of ALSSQoL total score ($\beta=0.24$, $p=0.015$, $d=0.89$, fig. 3), negative emotions ($\beta=0.38$, $p=0.018$, $d=0.91$, fig. 4) and interactions ($\beta=0.43$, $p=0.009$, $d=1.49$, fig. 5). A statistically significant treatment*time interaction was found also in the model predicting the ALSSQoL single item ($\beta= 0.49$, $p=0.01$, $d= 11.17$, fig. 6).

An intention-to-treat analysis showed a significant improvement of Quality of Life in the mindfulness group, in comparison with the control group. The difference in ALSSQOL-R total score between the two groups averaged in time was statistically significant ($p = 0.000342$). A significant difference over time favoring the intervention group was observed in the primary outcome, which corresponds to a 0.25 points per unit of time increment conditional on average time and treatment effect (CI 95% = 0.09857254 - 0.42565568, $p = 0.002021$). Mindfulness also showed a significant effect on QOL ($p = 0.002718$).

Secondary outcome analyses showed significant group X time effects in all models. Specifically, anxiety showed a significant decrement of -1.0588 points for intervention group against control group (CI 95% = -1.9127710 - 0.2069599, $p = 0.01573$) with a significant Mindfulness effect ($p = 0.01347$). In the analysis of depression scores, the model indicates a significant interaction effect equal to -0.70 points (CI 95% = -1.3757880 - 0.02131412, $p = 0.0411$) and a significant effect of mindfulness (p -value = 0.0233). The improvements of QoL (Single-Item) over time favoring the intervention group versus the control group was equal to 0.5197 points (CI 95% = 0.1277 - 0.9177, $p = 0.0102$). When considering Negative Emotions as dependent variable, the model shows a significant interaction effect equal to an increment of 0.41776 (IC 95% = 0.1418936 - 0.6957470, $p = 0.003616$) and a significant effect of mindfulness ($p < 0.0001$). Similar results were found for Interaction with People and the Environment scores, as we observed a significant increase of 0.4582 points for the intervention group in comparison with the control group (IC 95% = 0.1976038 - 0.71868556, $p = 0.000654$) and a significant effect of mindfulness ($p = 0.000994$). For the Intimacy domain, only a significant effect of mindfulness was observed ($p = 0.00232$). The models that considered Physical and Bulbar Symptoms as dependent variables failed to show significant results for interaction (group x time) and for mindfulness effects. Religiosity scores did not show significant differences in terms of interaction (group x time) and mindfulness effects. All mixed model analyses are shown in Table 2. No participants reported adverse effects.

Insert figures 2-4 about here

| | Fixed | t (df)* | p | Random# | Error structure |
|--------------------------------|-------|------------------------------|--------|---------|-----------------|
| Quality of Life (ALSSQOL-R) | | | | | ns |
| Intercept | 4.14 | 10.696 (235.66) | 0.0000 | 0.93 | |
| Time | -0.22 | -3.302 (56.72) | 0.0017 | 0.27 | |
| Mindfulness | 0.43 | 4.268 (204.32) | 0.0000 | | |
| Treatment | 0.14 | 0.657 (99.26) | 0.5125 | | |
| Time*Treatment | 0.24 | 2.513 (54.3) | 0.0149 | | |
| Residual | | | | 0.55 | |
| Anxiety (HADS) | | | | | b |
| Intercept | 11.81 | 6.936982 (143) ² | 0.0000 | 2.59 | |
| Time | 0.98 | 3.108609 (143) ² | 0.0023 | 1.22 | |
| Mindfulness | -1.29 | -2.792732 (143) ² | 0.0059 | | |
| Treatment | 0.66 | 0.989514 (98) ² | 0.3248 | | |
| Time*Treatment | -0.96 | -2.094526 (143) ² | 0.0380 | | |
| Residual | | | | 2.13 | |
| Depression (HADS) | | | | | c |
| Intercept | 9.68 | 7.803122 (143) ² | 0.0000 | 2.08 | |
| Time | 1.03 | 3.835342 (143) ² | 0.0002 | 0.87 | |
| Mindfulness | -0.90 | -2.686089 (143) ² | 0.0081 | | |
| Treatment | -0.85 | -1.536291 (98) ² | 0.1277 | | |
| Time*Treatment | -0.93 | -2.523899 (143) ² | 0.0127 | | |

| | | | | | |
|---|-------|-----------------|--------|------|----|
| Residual | | | | 1.57 | |
| Quality of Life (ALSSQOL-R Single-Item Scale) | | | | | ns |
| Intercept | 5.81 | 20.396 (102.97) | 0.0000 | 1.56 | |
| Time | -0.33 | -2.449 (155.03) | 0.0154 | 0.04 | |
| Treatment | 0.18 | 0.444 (104.31) | 0.6583 | | |
| Time*Treatment | 0.49 | 2.584 (152.67) | 0.0107 | | |
| Residual | | | | 1.4 | |
| Negative emotions | | | | | ns |
| Intercept | 3.55 | 5.930 (240.1) | 0.0000 | 1.23 | |
| Time | -0.36 | -3.329 (54.41) | 0.0016 | 0.42 | |
| Mindfulness | 0.65 | 4.116 (220.38) | 0.0000 | | |
| Treatment | -0.03 | -0.114 (99.25) | 0.9098 | | |
| Time*Treatment | 0.38 | 2.446 (52.09) | 0.0179 | | |
| Residual | | | | 0.88 | |
| Interaction | | | | | a |
| Intercept | 4.79 | 8.089575 (143) | 0.0000 | 0.77 | |
| Time | -0.20 | -1.747490 (143) | 0.0827 | 0.29 | |
| Mindfulness | 0.74 | 4.679617 (143) | 0.0000 | | |
| Treatment | -0.15 | -0.503921 (98) | 0.6154 | | |
| Time*Treatment | 0.43 | 2.613074 (143) | 0.0099 | | |
| Residual | | | | 1.24 | |
| Intimacy | | | | | ns |
| Intercept | 2.53 | 2.934 (245.62) | 0.0037 | 1.20 | |
| Time | 0.13 | 0.946 (152.63) | 0.3457 | 0.05 | |
| Mindfulness | 0.71 | 3.040 (241.31) | 0.0026 | | |

| | | | | | |
|-------------------|-------|-----------------|--------|------|----|
| Treatment | 0.63 | 1.759 (106.86) | 0.0815 | | |
| Time*Treatment | -0.04 | -0.205 (147.93) | 0.8378 | | |
| Residual | | | | 1.47 | |
| Religion | | | | | ns |
| Intercept | 8.69 | 5.979 (24.3) | 0.0000 | 2.31 | |
| Time | -0.10 | -0.352 (41.54) | 0.7276 | 1.14 | |
| Mindfulness | -0.84 | -2.156 (231.64) | 0.0321 | | |
| Treatment | -0.41 | -0.647 (98.67) | 0.5192 | | |
| Time*Treatment | 0.29 | 0.687 (49.08) | 0.4961 | | |
| Residual | | | | 2.35 | |
| Physical Symptoms | | | | | ns |
| Intercept | 5.96 | 21.909 (100.37) | 0.0000 | 1.74 | |
| Time | -0.41 | -4.159 (48.09) | 0.0001 | 0.23 | |
| Treatment | 0.27 | 0.699 (100.87) | 0.4861 | | |
| Time*Treatment | 0.06 | 0.420 (43.31) | 0.6767 | | |
| Residual | | | | 0.90 | |
| Bulbar Symptoms | | | | | |
| Intercept | 6.14 | 17.545 (97.88) | 0.0000 | 2.16 | ns |
| Time | -0.46 | -2.792 (34.97) | 0.0084 | 0.56 | |
| Treatment | 0.82 | 1.655 (98.59) | 0.1011 | | |
| Time*Treatment | 0.25 | 1.049 (33.28) | 0.3018 | | |
| Residual | | | | 1.35 | |

Table

2.

Conditional Growth Models

*With the exception of anxiety, depression and interaction, all other t-tests used Satterthwaite approximations to degrees of freedom.

Standard deviation

DISCUSSION

Our results indicate that an ALS-specific meditation training improves quality of life of people with ALS. Furthermore, in comparison with those who received the standard care, participants who joined the MBSR-ALS course reported lower levels of anxiety and depression. These results confirm the initial hypothesis. To our knowledge, this is the first RCT that has investigated the effects of a psychological intervention on QOL with people with ALS. Despite the need for exploration of the effects of psychological treatment in the promotion of well-being (7), the available information is currently limited (8). Recent quasi-experimental, non-randomized or limited-sample studies suggest that cognitive-behavioral therapy (20), hypnosis (21), expressive disclosure (22), and dignity therapy (23) may all increase quality of life and psychological well-being. There is currently insufficient evidence, however, to recommend the use of a specific psychological intervention for the promotion of well-being in ALS (8).

Mindfulness-based interventions are currently some of the most commonly used psychological interventions to improve quality of life in people with chronic diseases (9), but no study had explored their effects in the ALS field. We previously reported subjective feedback from a subsample of participants of the current study who joined the meditation training, with a qualitative approach (24). Interviewed patients reported more functional coping strategies and an improvement in resilience, following the training. Specifically, they described a reduction in judgmental attitude, increasing the disposition towards acceptance. These two aspects seem particularly relevant for people with ALS, as they are forced to must cope with the changes of the disease, which are often unpredictable and negatively evaluated. One of the main mechanisms of change that leads meditation to improve psychological well-being is the cultivation of mindfulness as a mental state (9). Mindfulness is a multifaceted construct, which includes being in the present moment,

awareness, flexibility, openness and curiosity. All these aspects have been reported to support psychological well-being, distress tolerance and resilience (25). Current study results are in line with these preliminary findings and they provide evidence of positive effects across different aspects of psychological well-being and QOL. Furthermore, differences between the two groups remained stable or increased through time.

Despite findings from a previous study (10) that suggested a negative relationship between mindfulness and disease progression, we did not find an effect of meditation on physical impairment. This was not expected or anticipated in the study hypothesis, as the treatment focused on the acceptance of symptoms, as well as emotions and feelings. The question whether psychological interventions can affect the course of the disease remains unanswered.

Several limitations of this investigation require mention. First, the control group did not receive any additional treatment to the usual care. It may be argued that patients may improve simply because they received more attention. The reason that justified referring to the usual care was that, at the time the project was designed, there was no study at all that explored psychological interventions. The comparison gold standard was, and it still is (26), multidisciplinary care, which may include a psychologist or a social scientist, who can support patients and their caregivers when requested. Therefore, no structured intervention was available as a comparison. Second, the recruitment process was very challenging. Several patients reported a lack of interest, if not an opposition towards the idea of a psychological intervention, or logistical reasons that prevented their participation to the trial. These are important issues that should be considered when discussing the clinical feasibility and reproducibility of the intervention. Third, we had a high attrition rate, although that seemed similar to other longitudinal non-pharmacological studies conducted in the ALS field (i.e., (27)), and it may be expected given the degenerative nature of the disease.

Despite some limitations, the study is one of the first contributions that provides evidence of the effects of a psychological intervention in the promotion of quality of life in people with ALS.

Further investigations about the effects of psychological and psychotherapeutic programs are warranted. This ALS-specific mindfulness-based intervention could be used as a comparison for future studies that will explore the effects of other treatments. Furthermore, future studies may investigate the underlying neurological mechanisms that change after a psychological intervention, to explore possible interactions with the disease progression mechanisms. Similarly, on a clinical level it may be worth investigating the potential effects of psychological interventions on the perception of symptoms (e.g., pain), if not a direct influence on the neurological processes.

Clinical implications of the study could be relevant in terms of quality of life and well-being promotion. Considering that maintaining a high quality of life is the primary goal of ALS care nowadays (4), this aspect seems particularly important. The protocol is publicly available (13) and further information can be requested to the authors. The ALS-MBSR is safe and easy to be implemented, as it can be conducted by trained personnel and it does not require additional instruments. It can be integrated in current multidisciplinary care and it may represent a new way to enhance quality of life in people with ALS.

CONTRIBUTORS

FP was the principal investigator who oversaw the whole study. FP, AM, GR, MC, GC, PB, EM, VS and CL conceived and designed the study. AT, GG, EV and AP followed up the patients and acquired the data. RG and VF conducted the meditation training. The statistical analyses were done by MM and FG. All the authors were involved in the analysis and interpretation of the data.

COMPETING INTERESTS

We declare no competing interests

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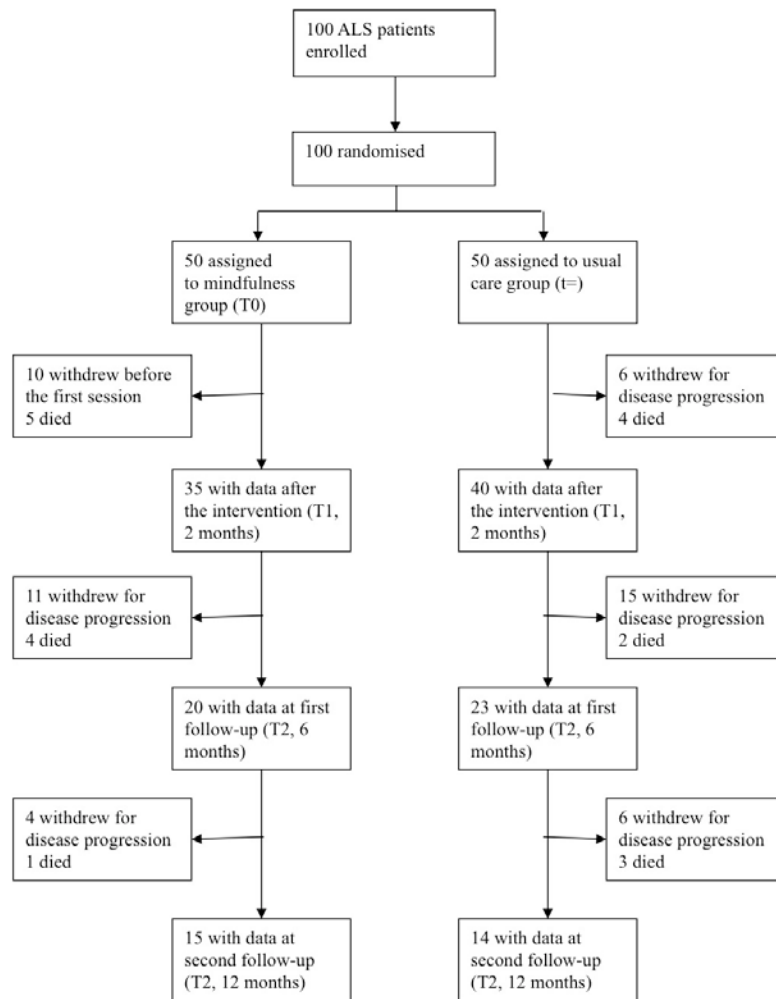


Fig. 1 - Study profile

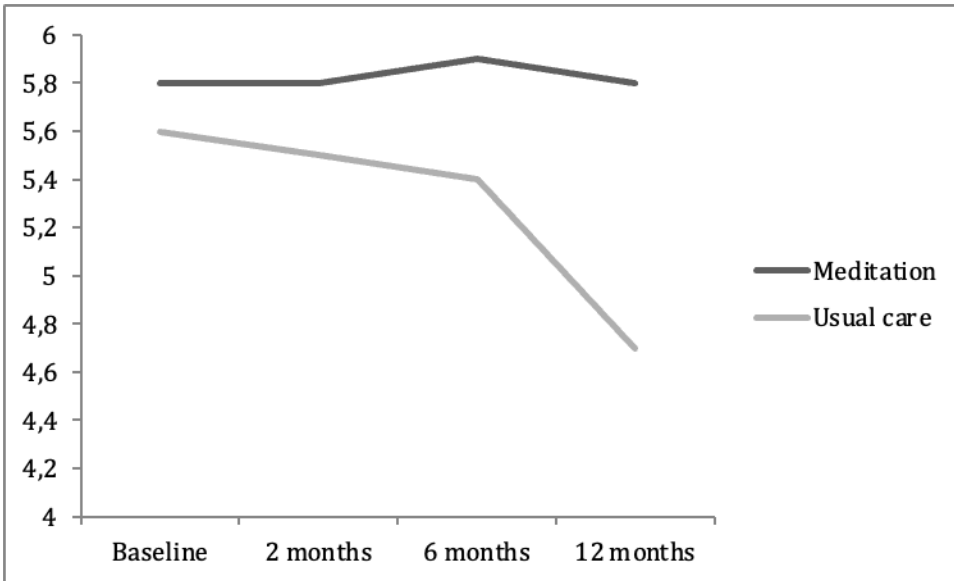


Figure 2 – Quality of life (ALSSQOL-R) scores

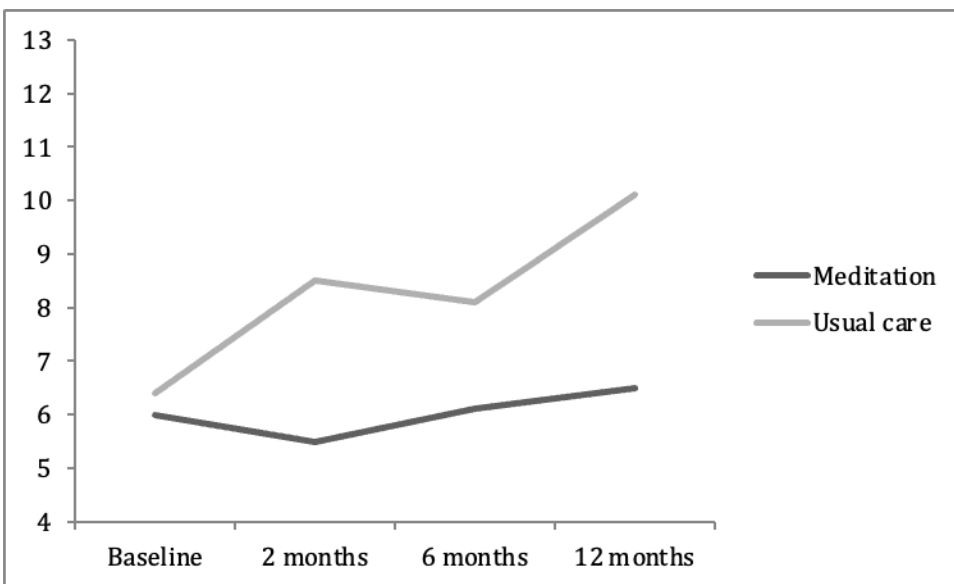


Figure 3- Depression (HADS-D) scores

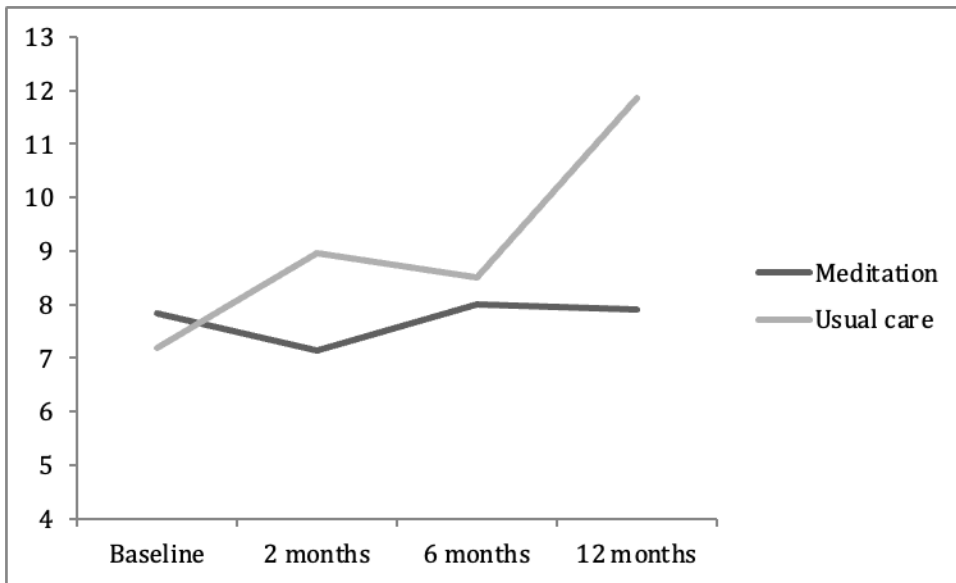


Figure 4 – Anxiety (HADS-A) scores