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This is the author's manuscript

Original Citation:

Availability:

This version is available <http://hdl.handle.net/2318/142480> since

Published version:

DOI:10.1177/0269215513501525

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This is the author's final version of the contribution published as:

F. Graziano;E. Calandri;M. Borghi;S. Bonino. The effects of a group-based cognitive behavioral therapy on people with multiple sclerosis: a randomized controlled trial. *CLINICAL REHABILITATION*. 28 (3) pp: 264-274.
DOI: 10.1177/0269215513501525

The publisher's version is available at:

<http://cre.sagepub.com/cgi/doi/10.1177/0269215513501525>

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<http://hdl.handle.net/2318/142480>

The effects of a group-based cognitive behavioral therapy on people with multiple sclerosis: a randomized controlled trial

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Abstract

Objective: To evaluate the effectiveness of a cognitive behavioral group-based intervention aimed at reducing depression and fostering quality of life and psychological well-being of multiple sclerosis patients through the promotion of identity redefinition, sense of coherence, and self-efficacy.

Design: A randomized controlled trial.

Setting: Non-medical setting, external to the Multiple Sclerosis Clinic Centre.

Subjects: Eighty-two patients: 64% women; mean age 40.5, SD = 9.4; 95% with relapsing-remitting multiple sclerosis; Expanded Disability Status Scale (EDSS) between 1 and 5.5 were included in the study.

Interventions: Patients were randomly assigned to an intervention group (five cognitive behavioral group-based sessions, $n = 41$) or to a control group (three informative sessions, $n = 41$).

Main measures: Depression (CES-D), Quality of life (MSQOL revised), Psychological well-being (PANAS), Identity Motives Scale, Sense of Coherence (SOC), and Self Efficacy in Multiple Sclerosis.

Results: Quality of life increased in the intervention group compared with the control at 6-months follow-up (mean change 0.72 vs. -1.76 , $p < 0.05$). Well-being in the intervention group increased for males and slightly decreased for females at 6-months follow-up (mean change 6.58 vs. -0.82 , $p < 0.05$). Contrasts revealed an increase in self-efficacy in the intervention group at posttreatment compared with the control (mean change 2.95 vs. -0.11 , $p < 0.05$). Depression tended to lower, while identity and coherence increased in the intervention group compared with the control, though the differences were not significant.

Conclusions: Preliminary evidence suggests that intervention promotes patients' quality of life and has an effect on psychological well-being and self-efficacy.

Keywords

Multiple sclerosis, cognitive behavioral therapy, group therapy, identity, sense of coherence, self-efficacy, quality of life, depression, well-being

Introduction

Multiple sclerosis is a chronic neurological disease whose numerous and variable symptoms might affect different aspects of body functioning and might include cognitive impairment and neuropsychiatric problems. The high unpredictability of the illness, along with the fact that it is usually diagnosed in young adulthood, might cause serious psychological consequences for patients. Emotional disturbances, especially depression and anxiety,¹ might have a strong influence, not only on the global quality of life and the psychological well-being experienced by patients,² but they could also affect their social relationships and adherence to treatments and adjustment to the illness.³ For this reason, an increasing number of studies have stressed the importance of supporting multiple sclerosis patients to face psychological difficulties associated with the illness.

Some evidence of effectiveness comes from cognitive behavior therapy as a treatment that is useful not only to manage symptoms, as fatigue, but also to reduce depression and anxiety, promote coping strategies and adjustment, and globally improve quality of life and psychological well-being of the multiple sclerosis patients.⁴ One of the psychological mechanisms through which cognitive behavior therapy interventions resulted in being effective is self-efficacy. More recently, an interest is arising for making sense and identity, as psychological dimensions considered in cognitive behavior therapy interventions. Self-efficacy is the individual's appraisal of the extent to which he/she has the capabilities required to organize and realize actions needed to obtain planned goals in a specific domain.⁵ Its promotion has been demonstrated to be useful for the management of chronic diseases,⁶ such as multiple sclerosis, and it is positively linked to psychological adjustment and to a better quality of life.^{7,8} Sense of coherence is defined by Antonovsky as the global individual way of perceiving and interpreting stimuli coming both from the internal and external world.⁹ The recovery of a sense of coherence in one's life after the diagnosis of a chronic illness, such as multiple sclerosis¹⁰ and cardiovascular disease,¹¹ has proved to positively

influence patients' quality of life. Finally, identity is defined as the sense of continuity and oneness that everyone experiences during one's life, despite the continuous changes of the biological, psychological, and social life.¹² The chronic disease represents a break in the sense of identity, and the restructuring of the patient's identity in diverse domains (physical, psychological, and social) has been demonstrated to be a key aspect for the psychosocial adjustment of multiple sclerosis^{13,14} and HIV-positive patients.¹⁵

All these constructs have been considered separately, and identity in particular has been mainly investigated through qualitative and explorative research designs. Moreover, randomized controlled trials that include all these aspects are lacking and theoretical comprehensive models of psychological constructs contributing to multiple sclerosis adjustment are needed.⁴ The aim of the present study was to evaluate the effectiveness of a cognitive behavioral group-based intervention aimed at reducing depression and fostering quality of life and psychological well-being of multiple sclerosis patients through the promotion of identity redefinition, sense of coherence, and self-efficacy, which are considered as key elements of the individual psychosocial adjustment to the illness by interacting in a circular way.^{16,17} To our knowledge, this model of intervention is yet to be employed among multiple sclerosis patients or other chronically ill populations.

Method

The study was a randomized controlled trial with an intervention group attending group-based cognitive behavioral intervention and a comparison group attending informative sessions.

Participants

Patients with multiple sclerosis were recruited from a Multiple Sclerosis Clinic Centre (Regional Reference Centre for Multiple Sclerosis – CRESM, Turin, Italy). All the subjects had a confirmed diagnosis of multiple sclerosis and the eligibility criteria were: (a) aged between 20 and 65; (b) an Expanded

Disability Status Scale (EDSS)¹⁸ score of between 1.0 (no disability) and 5.5 (limitations in daily activities, able to walk 100 meters without aid or rest) representing patients with mild to moderate levels of disability (EDSS range 1–10); (c) absence of clinically significant cognitive deficits; (d) absence of severe psychiatric deficits; and (e) absence of significant relational difficulties. All the requirements were verified in the patients' case sheets together with a neurologist.

An initial pool of 580 patients were screened and 436 were excluded because they did not meet the inclusion criteria. The remaining 144 patients were registered and allocated to the intervention or comparison group through the drawing of a card from a pack. Seventy-one patients were assigned to the intervention group and 73 to the comparison group. Thirty patients allocated to the intervention group and 32 patients allocated to the comparison group declined to participate, especially because of travel, family, and work reasons. The final number of participants was 41 (58% of the allocated patients) in the intervention group and 41 (56% of the allocated patients) in the comparison group (Figure 1). A considerable number of refusals were expected because of the need of these individuals to reconcile with group participation, work, family, and the necessity to travel to attend the sessions and the possibility of relapses during the intervention period.

The intervention

The intervention group was divided in to six subgroups based on age (20–35, 36–50, and 51–65 years old), because the developmental tasks and challenges are different for people in different periods of their life span¹⁹ and grouping together people of similar ages would facilitate sharing of similar experiences related to the illness. Intervention sessions were held in an external non-medical place, a castle surrounded by a park, away from the Multiple Sclerosis Clinic Centre.

The same psychologist with the experience of running groups based on cognitive behavioral principles conducted the groups. There were four sessions over two months and a fifth follow-up session after 6 months. Each session lasted for about 2 hours

and included a 15-minute break. Participants were also tutored to practice exercises for physical relaxation at the beginning and end of each session: relaxation allowed the participants to feel calm and relaxed before starting the session and leaving the group.

The topics of the four sessions were as follows. First session: identity change and redefinition following the diagnosis of multiple sclerosis (in the family, work, and free-time domains). Second session: life goals that gave people a sense of coherence before the diagnosis and life goals that might give a sense of coherence after the diagnosis (in the family, work, and free-time domains); the definitions of new, realistic, and personally meaningful goals in life. Third session: strategies to reach goals and behavior evaluation; the promotion of self-efficacy over symptoms, in particular, fatigue. Fourth session: the management of negative emotions related to the illness; positive, negative, and illusory thinking related to the illness; effective communication (in personal relationships and with health workers, such as nurses and physicians) and the ability of asking for help. Homework was set to encourage the participants to practice exercises from the group at home. The participants were also asked to do relaxation exercises at home every day. All the participants received copies of sheets that were used during the session.

People in the comparison group attended three informative sessions that were conducted by different therapists about stem cells, complementary and alternative therapies, and nourishment, respectively, over the same period of six months and in the same non-medical setting. People in the comparison group were given the opportunity to have the intervention after the conclusion of the trial.

Measures

Quality of life was assessed through a 9-items scale adapted from the Italian version of the Multiple Sclerosis Quality of Life (MSQOL-54)²⁰ for the purposes of the present study (items on physical health and emotional state, along with specific multiple sclerosis quality of life items on fatigue and energy and illness difficulties, were selected) (Cronbach's alpha 0.85) (range 0–24).

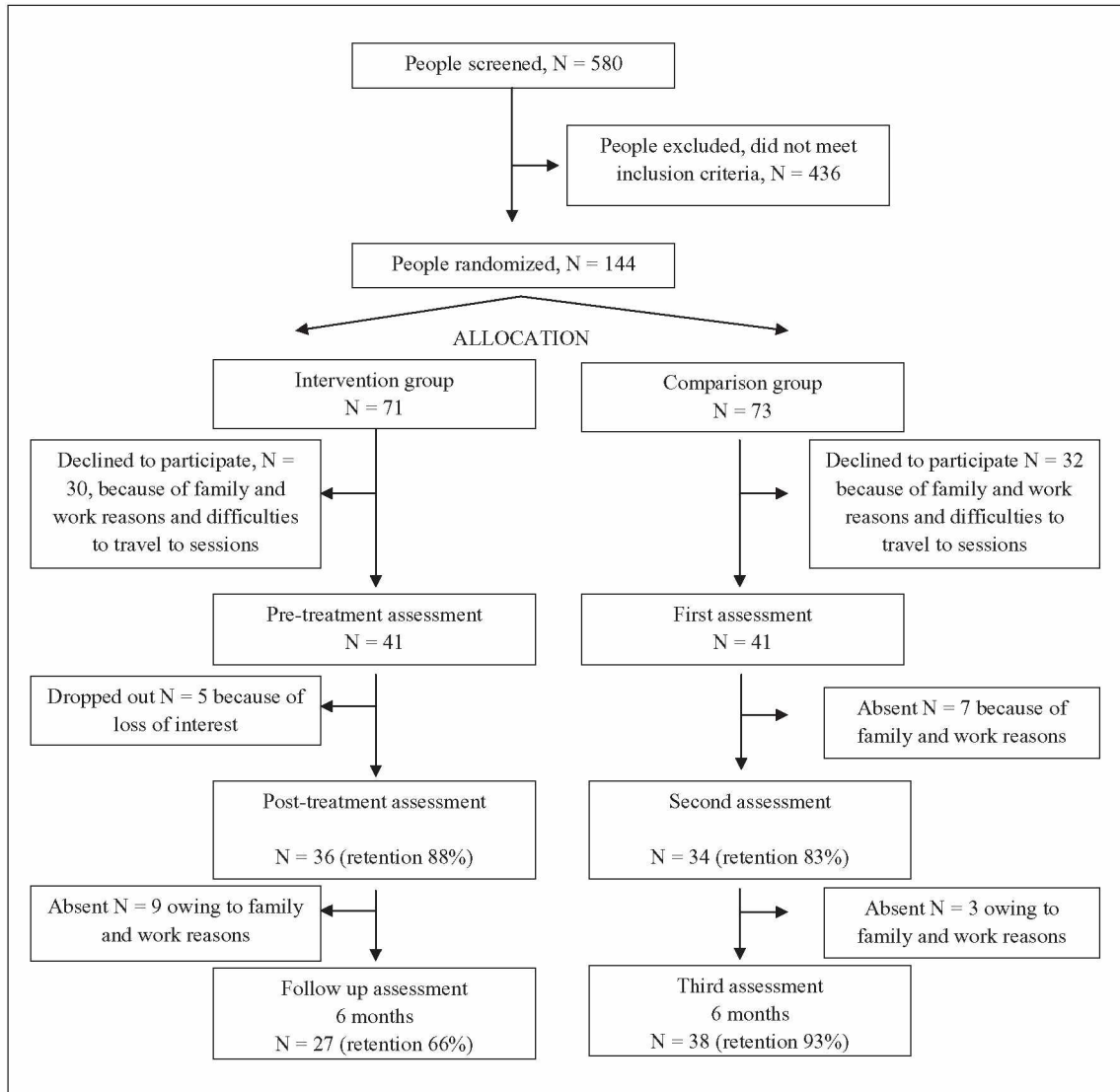


Figure 1. Flow of participants through the study.

Psychological well-being was evaluated through the Italian validation of the Positive Affect Negative Affect Schedule (PANAS)²¹: it comprises of two mood scales, one measuring the positive affect (10 items) and the other measuring the negative affect (10 items); the measure of psychological well-being is derived by subtracting the negative affect from the positive affect (Cronbach's alpha 0.70) (range -40 to +50).

Depression was assessed through the Italian validation of the Center for Epidemiologic Studies Depression Scale (CES-D)²² (20 items; Cronbach's alpha 0.91; range 0-60, a cut off score of 16 or higher indicates the presence of significant depressive symptoms).

Identity was evaluated through the Identity Motives Scale²³ that considers identity in terms of expectations for the future (12 items; Cronbach's

alpha 0.80; range 12–60), while the Sense of Coherence (SOC) was examined through the Italian validation of the Antonovsky's scale (11 items; Cronbach's alpha 0.82; range 11–77).²⁴

A 15-items scale was purposely defined to evaluate the perceived self-efficacy in dealing with multiple sclerosis. The scale evaluates the individuals' perception of his/her ability to face difficult situations related to multiple sclerosis (physical disabilities and fatigue), to set goals and plan activities, to maintain social life and ask for support, and to control negative emotions (range 15–75). Based on the specificity of the construct under examination, the new 15-items scale was defined to investigate specific facets of efficacy considered in the intervention and not included in existing instruments^{25,26} by following Bandura's²⁷ guidelines for constructing self-efficacy scales. The scale had good internal consistency (Cronbach's alpha 0.90) and it was related negatively to depression ($r = -0.60$) and positively to the other outcomes of the study (quality of life $r = 0.52$; psychological well-being $r = 0.76$; identity $r = 0.57$; sense of coherence $r = 0.62$).

The questionnaire was anonymous, patients were only requested to write a self-generated code following the researchers' indications to combine the questionnaires of different waves. For the intervention group, questionnaires were administered to patients before the first session (pretreatment), after the fourth session (immediate posttreatment), and after the fifth session (six-months follow-up) by trained researchers who were not blind to the patients' treatment groups, but were blind to the aims of the study. The posttreatment patients in the intervention group were also asked to fill a second questionnaire that aimed at evaluating the group experience. The questionnaire included the following questions.

1. How satisfied are you with the experience? (4-point scale.)
2. How do you evaluate the experience? (5-point scale from negative to very positive.)
3. Do you think this experience is useful for your life? (5-point scale.)
4. Would you repeat this experience? (Yes/no/don't know.)

5. Would you recommend this experience to other patients? (Yes/no/don't know.)
6. Did you perceive a personal change after the group experience? (Yes/no/don't know.)
7. Was this change positive or negative?
8. Which elements of the group experience did you like the most? (Open-ended question.)
9. Did you do the homework given in each session? (4-point scale.)

For the comparison group, questionnaires were administered before each of the three informative sessions at the same time of the intervention sessions.

Statistical analyses

Statistical analyses were performed by using Statistical Package for Social Science (SPSS), version 18. A series of repeated measures analysis of variance were performed to investigate a significant group-by-time interaction on each outcome measure: time (three levels – pretreatment, posttreatment, and follow-up) was entered as a factor within subjects and Group (2 levels – intervention vs. comparison) as factor between subjects. Years since diagnosis were entered as covariates, and gender and age as moderators. No significant interaction effect of gender and age with the outcomes measured emerged, except for psychological well-being and gender. For this reason, results refer to models with only Group as a factor between subjects and results are reported only for the well-being interaction. Significant group-by-time interaction effects were examined by using repeated contrasts with each category compared with the previous category. Linear interpolation was used as the method to estimate missing values.

Results

Characteristics of the study participants are presented in Table 1.

People in the intervention group and people in the comparison group did not differentiate at the baseline on any socio-demographic characteristics (gender,

Table 1. Characteristics of study participants.

	Intervention (N = 41)		Comparison (N = 41)	
Gender (female)	27	66%	24	60%
Age (mean, SD)	42.3	8.5	38.3	10.1
Years since diagnosis (mean, SD)	8.6	5.2	7.2	5.3
Multiple sclerosis type				
Relapsing remitting	39	95%	38	93%
Primary progressive	2	5%	–	–
Secondary progressive	–	–	3	7%
Marital status				
Married/living with a partner	22	54%	20	49%
Separated/divorced/widow	7	17%	7	17%
Single	12	29%	14	34%
Education				
8 years	17	41%	10	24%
13 years	15	37%	24	59%
More than 13 years	9	22%	7	17%
Employment				
Employed	27	66%	29	71%
Unemployed/student/retired	14	34%	12	29%

Data are reported as N (%) unless otherwise indicated.

age, marital status, education, and employment), in the clinical variables (multiple sclerosis type and years since diagnosis), or in the outcome indicators examined in the study. Cohort group differences were not observed in the intervention group for any variables of the study. The majority of the participants of the intervention group ($N = 36$, 88%) completed treatment and 27 (66%) were present at the six-months follow-up. The attrition was 12% at posttreatment and 34% at six-months follow-up. Differences between patients who completed treatment and patients who dropped out were not significant for gender, age, years since diagnosis, and the other variables considered in the study. Concerning the attendance rate in the comparison group, 34 patients (83%) attended the second session and 38 (93%) attended the third session (Figure 1).

Outcome evaluation

Patterns of change in all the outcome measures for the intervention and the comparison groups across time are presented in Table 2.

For all outcomes, the main effect of time was not statistically significant. Results stressed that the quality of life increased over time in the intervention group and decreased in the comparison group: a significant group \times time interaction was observed ($F(2, 108) = 3.27, p = 0.042$), which shows that the intervention group reported a higher quality of life over time than the comparison group. Repeated contrasts revealed that there was a significant difference between groups at six-months follow-up compared with posttreatment ($F(1, 54) = 4.74, p = 0.034$) suggesting a long-term effect of the intervention.

Psychological well-being showed a tendency to increase in both groups at posttreatment, increased again at six-months follow-up for the intervention group and slightly decreased for the comparison group, though the difference was not significant ($F(2, 108) = 1.20, p = 0.307$). On the contrary, the group \times time \times gender interaction effect attained statistical significance ($F(2, 104) = 3.14, p = 0.047$): in particular psychological well-being in the intervention group increased for males and slightly decreased for females at six-month follow-up when compared with posttreatment ($F(1, 52) = 5.95, p = 0.018$) (Table 3).

Table 2. Scores on outcome measures for intervention and comparison groups across the three assessment points.

Outcome variables/groups	Pretreatment		Posttreatment		Follow-up (6 months)	
	Mean (SD)	CI (95%)	Mean (SD)	CI (95%)	Mean (SD)	CI (95%)
Quality of life						
Intervention	13.39 (4.39)	11.67–15.11	14.24 (3.62)	12.77–15.72	14.96* (4.28)	13.08–16.85
Comparison	12.43 (4.54)	10.77–14.09	13.71 (4.00)	12.28–15.13	11.95* (5.40)	10.13–13.77
Psychological well-being (PANAS)						
Intervention	5.33 (10.34)	0.95–9.72	6.43 (7.99)	2.53–10.32	8.07 (10.48)	3.60–12.55
Comparison	8.41 (12.25)	4.18–12.65	11.93 (11.72)	8.17–15.69	10.19 (12.53)	5.88–14.50
Depression (CES-D)						
Intervention	17.16 (8.60)	13.51–20.81	15.23 (8.47)	12.01–19.04	14.79 (7.61)	10.56–19.03
Comparison	18.59 (10.27)	14.87–22.31	15.60 (9.71)	12.02–19.19	19.25 (13.60)	14.94–23.57
Identity						
Intervention	40.70 (7.24)	37.50–43.91	42.22 (5.93)	39.39–45.06	41.22 (6.74)	38.33–44.12
Comparison	41.80 (9.20)	38.70–44.89	43.22 (8.44)	40.49–45.96	43.76 (8.14)	40.97–46.55
Sense of coherence (SOC)						
Intervention	51.31 (9.43)	46.90–55.71	52.43 (9.19)	47.75–57.10	51.30 (10.60)	47.24–55.35
Comparison	53.21 (13.00)	48.95–57.46	51.73 (14.29)	47.23–56.24	51.44 (10.42)	47.36–55.36
Self-efficacy in multiple sclerosis						
Intervention	44.81 (8.18)	41.18–48.44	47.46* (6.34)	44.24–50.68	47.60 (7.46)	44.28–50.92
Comparison	48.28 (10.07)	44.84–51.71	48.17* (9.54)	45.12–51.22	48.38 (9.23)	45.24–51.52

SD, standard deviation; CI, confidence interval.

N = 56 (27 intervention group, 29 comparison group).

*p < 0.05 repeated contrasts; for quality of life significant six-months follow-up vs. posttreatment; for self-efficacy significant posttreatment vs. pretreatment.

Table 3. Psychological well-being (PANAS) in the intervention and comparison groups separately by gender across the three assessment points.

Groups/Gender	Pretreatment		Posttreatment		Follow-up (6 months)	
	Mean (SD)	CI (95%)	Mean (SD)	CI (95%)	Mean (SD)	CI (95%)
Intervention						
Males	8.11 (11.27)	0.54–15.68	7.20 (8.43)	0.51–13.90	13.78* (11.92)	6.14–21.41
Females	3.94 (9.88)	–0.140–9.30	6.04 (7.98)	1.30–10.77	5.22* (8.67)	–0.18–10.62
Comparison						
Males	11.46 (10.89)	5.16–17.76	15.44 (11.55)	9.87–21.01	11.50 (13.20)	5.15–17.85
Females	5.94 (13.06)	0.26–11.61	9.08 (11.42)	4.06–14.10	9.13 (12.30)	3.40–14.85

SD, standard deviation; CI, confidence interval.

N = 56 (27 intervention group, 29 comparison group).

*p < 0.05 repeated contrasts; significant six-months follow-up vs. posttreatment.

Depression tended to decrease in both groups at posttreatment, while at six-months follow-up it decreased in the intervention group and increased in

the comparison group, even though the group \times time interaction effect was not statistically significant ($F(2, 102) = 1.53, p = 0.224$). At posttreatment

the scores for both groups were below the critical level of 16, which indicates the presence of significant depressive symptoms, while at six-months follow-up only the intervention group's score remained under the cut-off level for depression.

Concerning identity, the means tended to increase for both groups at posttreatment and then tended to slightly decrease for the intervention group and to increase for the comparison group at six-months follow-up even though the pattern of change was not significantly different between the groups ($F(2, 108) = 0.559, p = 0.573$).

Sense of coherence tended to increase in the intervention group at posttreatment and to decrease in the comparison group across time even though the group \times time interaction effect was not significant ($F(2, 108) = 0.493, p = 0.612$).

Self-efficacy showed a tendency to increase in the intervention group and to remain stable in the comparison group across time, even though the group \times time interaction effect was not significant ($F(2, 106) = 1.32, p = 0.272$). Despite the overall non-significant effect, the change from the baseline to immediate postintervention was significant for the intervention group but not for the comparison group, suggesting a short-term effect of the intervention (contrasts $F(1, 53) = 4.26, p = 0.044$).

Process evaluation

Results on process evaluation were based on attendance rate and on the participants' responses to the evaluation questionnaires administered at posttreatment. Patients demonstrated good compliance with the treatment (attrition 12% at posttreatment) while the attrition rate at six-months follow-up was 34% owing to common difficulties in obtaining patients' participation in delayed sessions. Results of the evaluation questionnaires are reported in Table 4; overall, the participants were satisfied and positively evaluated the experience.

Discussion

Quality of life of patients who attended the group-based cognitive behavioral intervention increased

over time compared with the control group. Psychological well-being in the intervention group increased for males and slightly decreased for females at six-month follow-up, suggesting a long-term effect of the intervention moderated by gender. The change in self-efficacy from the baseline to immediate postintervention was significant for the intervention group but not for the comparison group, suggesting a short-term effect of the intervention. Depression showed a trend to decrease, while identity and coherence to increase in the intervention group compared with control group, suggesting the superiority of psychological intervention when compared with the informative sessions even though the differences were not statistically significant. The intervention had a high attendance rate immediately after posttreatment and the participants reported satisfaction and presented a positive evaluation of the group experience.

Results on quality of life, depression, and well-being (even if only the first outcome was statistically significant and the global effects are modest) are consistent with other studies that demonstrated the effectiveness of cognitive behavioral therapy for multiple sclerosis patients.^{2,4} As for the effect on well-being moderated by gender, to our knowledge, this kind of result has not been pointed out in similar studies, and research on gender differences in psychological correlates of multiple sclerosis is still inconclusive.^{28,29} Results of our study should be further investigated through qualitative instruments. Preliminary findings on self-efficacy, even if a global statistically significant effect was not detected, are comparable with the evidence from studies that have evaluated the positive influence of self-efficacy on psychological adjustment and quality of life of multiple sclerosis patients.^{7,8} Correlations between self-efficacy and the other outcome measures of our study have provided preliminary evidence of the positive role of self-efficacy for patients' adjustment. However, further analyses are necessary. As for the sense of coherence and identity, it is likely that the intervention might have produced a change, which therefore needs continuous support for maintenance or increase across time. Both are psychological aspects that are deeply rooted in the person, which might need time and

Table 4. Summary statistics on process evaluation.

Questions	Answers	N (%)
Satisfaction	Quite satisfied	13 (41%)
	Very satisfied	19 (59%)
Evaluation	Negative	1 (3%)
	Quite positive	6 (17%)
	Positive	18 (50%)
	Very positive	11 (30%)
Usefulness	Useless	1 (3%)
	Nor useful nor useless	2 (6%)
	Quite useful	8 (23%)
	Useful	14 (40%)
	Very useful	10 (28%)
Would repeat the experience	Yes	36 (100%)
Would recommend to other patients	Yes	36 (100%)
Perceived change	Yes	21 (64%)
	No	2 (6%)
	Don't know	10 (30%)
Change positive/negative	Positive	21 (100% of people who perceived a change)
Done homework	Never	2 (6%)
	Seldom	8 (25%)
	Often	18 (56%)
	Always	4 (13%)
Most liked aspects	Sharing experiences, learning from others	

N = 36 (percentages are calculated on valid N).

support to be modified. Comparison with similar studies is difficult because they often rely on psychological constructs that are similar to making sense, such as mindfulness and acceptance, and they only report provisional results.³⁰ Identity, to our knowledge, has rarely been pointed out as an outcome indicator in psychological interventions for multiple sclerosis patients. These topics should be further investigated with repeated follow-up across time.

The low attrition rate, at least immediately after posttreatment, along with the positive feedback from patients demonstrate that the patients perceived this experience not only as an important occasion of sharing problems with people with the same illness, but also as an opportunity to acquire abilities and making sense of one's life with multiple sclerosis under the guidance of an expert moderator. As pointed out in literature, the benefits of

the intervention are likely to be because of both the specific contents of the program and the social interaction among the participants.^{31–33}

The study has some limitations. As previously noticed, the small sample size made it difficult to detect statistically significant results, thus the study should be replicated with a larger sample to investigate whether the differential pattern of change in the intervention and comparison groups is confirmed. Reduction in the sample size was because of patients declining to participate owing to work and family commitments. This sample selection is almost unavoidable in the psychological group treatment and other studies have also reported comparable number of refusals.³² The attrition rate at six-months follow-up highlights the difficulties in obtaining patients' participation in delayed sessions of psychological interventions and therefore, future research should investigate possible strategies to

reduce attrition. Moreover, the fact that patients were recruited from only one clinic limits the generalization of results. Limitations concerning measures are mainly linked to our new self-efficacy scale, whose validation is still ongoing. Finally, future studies should investigate the usefulness of this intervention with patients affected by more severe forms of multiple sclerosis.

Despite these limitations, this study provides some preliminary evidence suggesting that a group-based cognitive behavioral intervention focused on identity redefinition, sense of coherence, and self-efficacy might have a positive influence on multiple sclerosis patients' adjustment.

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