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The Unified Protocol as a Transdiagnostic Treatment in Multiple Sclerosis: A Feasibility pilot Study in Chilean Patients in Eating Behaviors and Emotional Regulation Outcomes

Aplicación del Protocolo Unificado como Tratamiento Transdiagnóstico en la Esclerosis Múltiple: Un Estudio Piloto de Factibilidad en Pacientes Chilenos sobre Conductas Alimentarias y Resultados en la Regulación Emocional.

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Abstract

Background: Multiple sclerosis (MS) is a degenerative disease affecting the central nervous system, significantly impacting quality of life. Relapsing-remitting MS (RRMS) is the most common subtype and is often worsened by comorbidities such as obesity, which heighten symptoms and disability. Emotional regulation and eating behaviors are critical areas influencing the progression and management of RRMS. **Objective:** To assess the feasibility and acceptability of the Unified Protocol, a transdiagnostic treatment, in improving psychological symptoms, emotional regulation, andeating behaviours in Chilean RRMS patients, particularly those living with obesity or overweight. **Method:** The sample included 7 RRMS patients who underwent 14 sessions of the UP. The UP aims to manage and prevent emotional symptoms by enhancing emotional regulation skills, crucial for reducing future psychological distress such as anxiety and depression. The intervention focused on disrupting the cycle of emotional eating and enhancing overall quality of life. **Results:** Results showed improvements in emotional regulation and reductions in depression and anxiety. However, these effects diminished over time, with an increase in emotional eating, underscoring the need for continuous support and targeted strategies. **Conclusions:** The findings of this pilot study on feasibility and acceptability highlight the potential of the UP in treating RRMS, emphasizing the importance of comprehensive, multidisciplinary approaches and further research into sustained and tailored treatments. This study is an extension of a wider RCT which has already been pre-registered [osf.io/sr4bx].

Keywords: multiple sclerosis, emotional dysregulation, eating behaviours, transdiagnostic treatments, unified protocol.

Resumen:

Antecedentes: La esclerosis múltiple (EM) es una enfermedad degenerativa que afecta el sistema nervioso central, impactando significativamente la calidad de vida. La EM recurrente-remitente (EMRR) es el subtipo más común y a menudo se agrava por comorbilidades como la obesidad, que intensifican los síntomas y la discapacidad. La regulación emocional y las conductas alimentarias son áreas críticas que influyen en la progresión y el manejo de la EMRR. **Objetivo:** Evaluar la factibilidad y aceptabilidad del Protocolo Unificado, un tratamiento transdiagnóstico, en la mejora de los síntomas psicológicos, la regulación emocional y las conductas alimentarias en pacientes con EMRR chilenos, particularmente en aquellos que viven con obesidad o sobrepeso. **Método:** La muestra incluyó a 7 pacientes con EMRR que participaron en 14 sesiones del PU. El PU tiene como objetivo gestionar y prevenir síntomas emocionales mediante el fortalecimiento de habilidades de regulación emocional, cruciales para reducir el malestar psicológico futuro como la ansiedad y la depresión. La intervención se centró en interrumpir el ciclo de la alimentación emocional y mejorar la calidad de vida general. **Resultados:** Los resultados mostraron mejoras en la regulación emocional y reducciones en la depresión y la ansiedad. Sin embargo, estos efectos disminuyeron con el tiempo, observándose un aumento en la alimentación emocional, lo que subraya la necesidad de un apoyo continuo y estrategias específicas. **Conclusiones:** Los hallazgos de este estudio piloto de factibilidad y aceptabilidad destacan el potencial del PU en el tratamiento de la EMRR, enfatizando la importancia de enfoques integrales y multidisciplinarios y la necesidad de una investigación continua en tratamientos sostenidos y personalizados. Este estudio es una extensión de un ECA más amplio que ya ha sido pre-registrado [osf.io/sr4bx].

Palabras claves: esclerosis múltiple, desregulación emocional, conductas alimentarias, tratamientos transdiagnósticos, protocolo unificado.

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Introduction

Multiple sclerosis (MS) is a degenerative central nervous system disease that damages the myelin sheath and leads to severe symptoms like pain and cognitive impairment (Thompson et al., 2018), decreasing quality of life (Gil-González et al., 2020). MS affects about 2.2 million people globally, with a prevalence of 30 per 100,000 (GBD 2016 Multiple Sclerosis Collaborators, 2019; Habbestad et al., 2024). Relapsing-remitting multiple sclerosis (RRMS), the most common MS subtype, comprises about 80% of cases (Walton et al., 2020). RRMS features episodic neurological impairments with initial high reversibility. Over time, episodes often leave lasting deficits, potentially progressing to the more degenerative secondary progressive multiple sclerosis (SPMS; Thompson et al., 2018).

Chile lacks nationwide MS data but shows regional prevalences of 11.7 and 13.4 per 100,000 in Santiago and Magallanes, respectively (Retamal-Matus et al., 2020). MS severity correlates with biological, socioeconomic, and healthcare factors, with public healthcare users and lower-income individuals facing worse outcomes (Ciampi et al., 2023). It also impacts employment, leading to higher unemployment and lower incomes than healthy individuals (Kavaliunas et al., 2022). All in all, we may have a vulnerable population adversely affected by socioeconomic and healthcare factors, influencing MS prognosis.

MS patients often face comorbidities, including significant rates of obesity and overweight (Marrie et al., 2009).Specifically, a study showed that more than half of RRMS patients live overweight (Guevara et al., 2020). Obesity aggravates disability and increases relapse risk in RRMS (Tettey et al., 2017). Moreover, the unpredictable nature of MS leads to heightened anxiety and depression among patients (Boeschoten et al., 2017), prompting maladaptive coping mechanisms like emotional eating, weight gain, and worsening of symptoms and disability, creating a detrimental cycle impacting their health and quality of life (Dakanalis et al., 2023). Emotional eating is the tendency to overeat in response to arousal states such as anger, fear, and anxiety (Van Strien et al., 1986). This behavior is linked to the consumption of sweet, energy-dense foods (Dakanalis et al., 2023) and is recognized as a potential risk factor for developing obesity (Benbaibeche et al., 2023).

In this way, it is important to emphasize the relation between states of anxiety and depression and eating behaviours like emotional eating, which may increase the risk of living with obesity (Dakanalis et al., 2023). RRMS patients experience elevated levels of anxiety and depression (Boeschoten et al., 2017), in

consequence, it may increase the probability of engaging in emotional eating as a coping mechanism, which could exacerbate disability, elevate the risk of relapses, and deterioration of patients over time (Dakanalis et al., 2023; Tettey et al., 2014). All in all, this may create a vicious cycle that further deteriorates patients' health and quality of life.

Cognitive Behavioral Therapy (CBT) is effective for managing these symptoms in RRMS (Fiest et al., 2016), while the Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders (UP; Barlow et al., 2019) is a cognitive behavioural intervention developed to address different emotional disorders, such as anxiety, depression and related disorders (Bullis et al., 2019). The UP focuses on improving emotional regulation across eight modules training five emotion regulation strategies. In its implementation, traditional CBT techniques, such as cognitive restructuring, are combined with newer approaches, such as mindfulness enhancement, to address deficits in emotion regulation (Barlow et al., 2019). Its efficacy has been proven in recent systematic reviews and meta-analyses (e.g., Longley & Gleiser, 2023). Particularly, randomized controlled trials involving MS-diagnosed participants have been conducted where notable reductions in symptoms like depression, anxiety, and emotional dysregulation were observed (Nazari et al., 2020). Although studies like these exist, it is crucial to evaluate whether this same approach is effective for patients with RRMS and obesity, understanding that this is a significant public health issue as obesity and overweight exacerbates the condition's severity (Guevara et al., 2020). Additionally, evidence of the UP has shown effectiveness in patients with medical conditions like obesity, which is often a comorbid factor in patients with RRMS (e.g., Osma & Farchione, 2023).

In Chile, and to our knowledge globally, there is no study using the Unified Protocol (UP) in a group format that has addressed the issue of overweight and obesity in patients with relapsing-remitting multiple sclerosis (RRMS). Therefore, this study aims not only to evaluate the feasibility and acceptability of the UP in a Chilean population but also to assess how emotional regulation affects eating behavior. This should, in turn, lead to an improved quality of life for this patient group, as better emotional regulation can promote a better prognosis in their treatment for RRMS. Our primary objective, therefore, is to assess whether this intervention is feasible and acceptable among MS patients, making it the first of its kind in a public health group setting in the Chilean context. Additionally, we aim to enhance emotional regulation through the UP, thereby reducing the tendency towards emotional eating. This focus extends beyond weight management to the development of preventive strategies to mitigate the incidence of anxiety and depression. By enhancing emotional regulation, we aspire not only to break the

cycle of emotional eating but also to substantially improve the overall quality of life for these patients.

Methods

Participants

Eight patients were recruited for this initial pilot study, one of whom did not continue due to personal reasons. All seven participants, mostly females (n=6), with an average age of 40±12.65 years old (min=26, max=60) at the beginning of the treatment, took part in the study. Five had higher education at Institutes/Professional Training Centers (n=3) or University (n=2). Other participants completed primary or secondary school. Everyone received the RRMS diagnosis, although three had a recent RRMS diagnosis in the last 12 months.

The inclusion criteria used were: (1) being over 18 years old; (2) having the diagnosis of RRMS and being overweight; (4) speaking fluent Spanish; (5) being up to date with their pharmacological treatment; (6) understanding and accepting what is stated in the informed consent. The exclusion criteria was a score on the Expanded Disability Status Scale (EDSS; Kurtzke, 1983) of less than 6.5.

Detailed description of the cases

Table 1 *Detailed description of the cases*

Participant	Cases							
	Marital Status	Age	Education	Occupation	RRMS Diagnosis	Other Diagnoses	Mental Health Diagnosis	Current Treatment
1	Married with adult children	60	Basic, middle, and technical	Homemaker, cares for nephew	More than a year ago	Hypertension	None	Fingolimod
2	Married with children	32	Technical in accounting	Full-time in payroll department	More than a year ago	None	None	Teriflunomide
3	Married with adult children	51	Basic and middle	Homemaker, sells books on weekends	More than a year ago	Liver cirrhosis	None	None due to liver condition
4	Single, no children	26	Nursing	Full-time nurse	Less than a year ago	None	None	Teriflunomide
5	Married, no children	48	Basic	Full-time truck driver	Less than a year ago	None	None	Ocrelizumab
6	Single, no children	33	Music education	Teacher in a school	More than a year ago	Asthma, depression	Depression, anxiety	Teriflunomide
7	Single, no children	31	Aesthetics in technical institute	Part-time independently	Less than a year ago	Anxiety	Anxiety	Ocrelizumab

Note. The rows represent the participant numbers, and the columns represent the main characteristics.

Instruments

Descriptions of each instrument are in the table below.

Table 2. *Detailed description of the instruments*

Instrument	Description					
	Authors & Validation	Aim	Scale	Reliability (α)	Score interpretation	Direction of Change
Symptom Checklist-90-Revised (SCL-90-R)	Derogatis, 1994; Chilean validation by Gempp & Avendaño, 2008	Assess psychological distress and severity across 9 subscales and 3 global indices	5-point Likert Scale (0 to 4)	0.66 - 0.92	Higher scores indicate presence of symptoms	Decrease indicates improvement
Multidimensional Emotional Disorders Inventory (MEDI)	Rosellini & Brown, 2019; Spanish validation by Osma et al., 2021	Measures 9 transdiagnostic emotional disorder dimensions	9-point Likert Scale (0 to 8)	0.66 - 0.92	Higher scores indicate presence of a emotional disorder dimension	Decrease indicates improvement
Overall Anxiety Severity and Impairment Scale (OASIS)	Norman et al., 2006; Spanish validation by Osma et al., 2019	Assess anxiety symptoms and impact	5-point Likert Scale (0 to 4)	0.87	Scores over 10 indicates the presence of anxiety symptoms	Decrease indicates improvement
Overall Depressive Severity and Impairment Scale (ODSIS)	Bentley et al., 2014; Spanish validation by Osma et al., 2019	Assess depressive symptoms and impact	5-point Likert Scale (0 to 4)	0.94	Scores over 10 indicates the presence of depressive symptoms	Decrease indicates improvement
Dutch Eating Behavior Questionnaire (DEBQ)	Van Strien et al., 1986; Chilean validation by Andrés et al., 2017	Measures dietary restraint, emotional eating, and external eating	5-point Likert Scale (0 to 5)	0.87 - 0.97	Higher scores indicates presence of dietary restraint, emotional eating and external eating	Decrease indicates improvement in emotional and external eating, and in dietary restraint
Multidimensional Body-Self Relations Questionnaire (MBSRQ)	Cash, 1990; Chilean validation by Cruzat-Mandich et al., 2019	Assess attitudes toward body image and related behaviors	Various 5-point Likert Scales	0.70 - 0.92	Higher scores indicate presence of the following dimensions: Orientation to physical activity, Evaluation of appearance, Concern over weight, Orientation towards appearance, Orientation towards health, Evaluation of illness,	Decrease indicates improvement for negative body image dimensions (Evaluation of appearance, Concern overweight, Evaluation of illness, Orientation towards illness); Increase indicates improvement for positive body image dimensions

					Orientation towards illness	(Orientation towards health, Orientation towards physical activity, Orientation towards appearance)
EuroQoL EQ-5D	Brooks, 1996; Chilean validation by Superintendence of Health, 2005	Assesses health status across five dimensions with an additional EQ-VAS.	3-point Likert Scale (1 to 3); EQ-VAS (0 to 100)	ICC = 0.70	Higher index indicate better health	Increase in EQ-VAS indicates improvement; Decrease in dimension scores indicates improvement
Quality of Life Scale (QOLS)	Burckhardt et al., 1989; Spanish validation by Latorre-Román et al., 2014	Evaluates overall life satisfaction.	7-point Likert Scale (1 to 7)	0.88	Higher scores indicate better quality of life	Increase indicates improvement
Rosenberg Self-Esteem Scale (RSS)	Rosenberg, 1965; Chilean validation by Rojas-Barahona et al., 2009	Assess self-esteem	4-point Likert Scale (1 to 4)	0.75	Higher scores indicate better self-esteem	Increase indicates improvement
Difficulties in Emotion Regulation Scale (DERS)	Gratz & Roemer, 2004; Chilean validation by Guzmán-González et al., 2020	Evaluates problems in emotional regulation	5-point Likert Scale (1 to 5)	0.92	Scores over 73 points indicate difficulties in emotion regulation	Decrease indicates improvement
Satisfaction with Treatment Questionnaire (STQ)	Larsen et al., 1979; Spanish adaptation by Ferreres-Galán et al., 2022	Evaluates customer satisfaction with received services	4-point Likert Scale (0 to 4)	Not specified	Higher scores indicate higher satisfaction	Increase indicates improvement

Note. The columns correspond to the characteristics of each scale, and the rows correspond to the names of each instrument.

Focus Group Questions. The study employed a set of structured questions during a focus group to gather qualitative data on the patient's experience with group therapy, and to obtain feedback for future adaptations. These were:

A. Overall Experience: How has it felt to be in therapy?
B. Changes: Have you noticed any changes since starting therapy?
C. Attribution: In general, what do you attribute these changes to?
D. Homework: What are your thoughts on having to do homework every week? How did you feel about filling out the forms?
E. Format: What do you think about therapy being in a group format?
F. Suggestions: Do you have any suggestions regarding the research or therapy? Is there anything else you would like to say?

Procedure

The study was conducted at the Faculty of Social Sciences at the University of Chile. Patients meeting the inclusion criteria were invited through referrals from the clinical hospital of the University of Chile or the San Juan de Dios hospital. This study was approved by the Research Ethics Committee of the Faculty of Medicine at the University of Chile. Their RRMS treating physician contacted them initially, followed by a psychologist via telephone. Patients voluntarily joined the study without monetary incentives, and the intervention was free. Upon agreeing to participate, they signed informed consent forms and completed comprehensive scales before and after the intervention. The 14 weekly therapy sessions, each 1 hour and 45 minutes long, were led by a trained therapist and co-therapist. The lead therapist provided theoretical content, examples, and answered questions, while the co-therapist assisted with the activities.

Both therapists underwent weekly supervision sessions with a specialized psychologist and co-author of this paper (J.O.), who is also a certified-UP trainer and possesses extensive experience in its application. Before each session, preparatory meetings were held to review progress and clarify any ambiguities, thereby setting the stage for future sessions.

After each session, participants received printed exercise sheets and self-reporting documents for completion as homework, which were collectively discussed and corrected in subsequent sessions.

In terms of assessment, evaluations were carried out at three stages using SurveyMonkey online platform: pretreatment evaluation, post-treatment evaluation, and a three-month follow-up.

In relation to the implementation of the Unified Protocol, prior to each intervention session, preparation meetings were held with all therapists involved, during which the objectives, procedures and content of each module of the protocol were reviewed in detail. In addition, weekly supervision meetings were held after the group sessions, in order to address concerns, adjust strategies and detail key aspects. Both meetings were led by a certified psychologist at the PU, who is also a co-author of the study, which contributed significantly to ensuring treatment fidelity.

Participants' attendance was also monitored as a proxy indicator of adherence and acceptability of treatment. On average, participants attended 79.59% of group sessions, a percentage that increased to 92.86% when recovery sessions were

included. This high level of attendance reflects a significant commitment to the intervention.

Intervention

The adaptation of the UP consisted of 14 weekly group sessions, each lasting 1 hour and 45 minutes. We utilized all 8 modules of the original UP (Barlow et al., 2019). For participants who missed a session, a make-up individual session was scheduled within the same week. We were only unable to reschedule one session for Participant 6.

The aim for this patient group was self-care, emotional regulation, and adopting healthy lifestyle habits, with a particular emphasis on emotional eating, motivation to engage in physical activity, and eating healthy.

The initial module was adapted to include psychoeducational material. This new segment covered the topic of emotional eating and delved into the correlation between dietary choices and emotional states. To further enhance patient knowledge and engagement, the inaugural session was designed to provide an overview of MS and its subtypes, along with a workshop focused on healthy eating practices and their effects on their diagnosis. The session also laid out what the entire intervention would entail and clarified the rationale for the specific skills that would be targeted to address their principal concerns. Moreover, the importance of consistent session attendance, adherence to group norms, and doing homework assignments were emphasized. Table 3 shows the main adaptations of the UP made for this sample.

Table 3. *Description of the original UP modules and specific adaptations carried out to personalize the intervention in the present study with the number of sessions in each module*

Modules of the original UP	Adaptations of each module	Number of sessions
Setting goals and maintaining motivation	In this module, the examples regarding motivation and change were made concerning changes in their healthy lifestyle habits and emotions related to their pathology	1
Understanding your emotions: What is an emotion? And following the ARC	The content was applied based on the participants' experiential insights, which bore direct or indirect relevance to dietary practices or the diagnosis of RRMS. A specific portion of the session was allocated for the empirical analysis of the interplay between emotional states and eating behaviors.	2
Mindful emotion awareness	The practice of attentive, non-judgmental awareness of physical discomfort or pain was introduced. This technique involves objectively observing physical sensations, acknowledging their presence. By doing so, patients learn to separate the physical experience of pain	2

	from their automatic emotional responses, allowing them to manage better their symptoms and improving their quality of life.	
Cognitive flexibility	This module required two sessions due to the participants' challenges in understanding its content. The exercises were tailored to the experiences shared by participants during the session. Most of the prevalent irrational automatic thoughts revolved around concerns about physical appearance and weight, a perceived inability to control food intake and maintain a regular exercise regimen, and worries about their health and future.	2
Countering Emotional Behaviors	This module required two sessions due to the participants' challenges in understanding its content. This module aided in identifying and comprehending different behavioral patterns that contribute to avoiding negative emotions. For example, patients learned to recognize patterns such as emotional eating, where they might consume food in response to feelings rather than hunger. The module then demonstrated the short and long-term effects of these emotional behaviors. For instance, avoiding exercise, though it might seem to reduce stress initially, can lead to decreased physical health and lower mood over time. Finally, the module discussed alternative behaviors to approach negative emotions rather than avoiding them., to equip patients with healthier coping mechanisms for their emotional and physical well-being.	2
Understanding and confronting physical sensations	It aimed to develop tolerance towards strong physical sensations, which patients often immediately associate with their MS, leading to strong negative emotions. A key aspect highlighted in the module was the understanding that not all physical sensations are necessarily linked to MS. This approach aimed to help patients realize that physical sensations can be related to various causes, not always linked to their condition. By learning to consider a broader range of possibilities, patients could reduce the immediacy and intensity of negative emotional reactions to such sensations.	1
Emotion Exposures	In this module, each participant created their emotion exposure hierarchy. Among the different hierarchies it was found relevant items for example exposure to physical sensations, to the distress before doing exercise or going to the gym, asking help to their family, or going out alone. All these items are related in some degree to how they lived their diagnosis and the possibility of increasing their quality of life.	2
Moving up from here-Accomplishments and looking to your future	The module aimed to empower participants to adapt their goals in response to their evolving circumstances, ensuring that their objectives remained realistic and achievable despite the challenges posed by RRMS. This was also an opportunity to revisit various techniques learned throughout the therapeutic process.	1

Three months after the intervention, a follow-up session and a focus group were carried out. The follow-up session addressed the status of their objectives, mood, daily life obstacles, and application of techniques learned in the therapy. On the other hand, the focus group's objective was to know the acceptability of the intervention.

Data analysis

This study employed a convergent mixed-methods design, which allows for the combination of qualitative and quantitative data to evaluate the experience and outcomes of the intervention. This approach is particularly useful for assessing the acceptability and preliminary effectiveness of the UP, as it integrates subjective perceptions with objective data.

The Kolmogorov-Smirnov test was used for testing normality. When this assumption is met, repeated measures ANOVA were conducted to analyze effectiveness at the group level. Greenhouse-Geisser epsilon was used as a mean for evaluating departures from sphericity over the p- value of Mauchly's test using 0.90 as the cut-off; Greenhouse-Geisser was employed in case this number was below 0.60 and Huynh-Feldt otherwise (Blanca et al., 2023). Partial eta squared (ηp^2) is reported as an effect size measure. The confidence interval was calculated using an online tool (Uanhoro, 2017). Bonferroni post hoc were carried out as they control for type I error and are robust to sphericity departures (Field, 2013). Cohen ś d was calculated as effect size for a posteriori test.

When normality assumption violations were detected, Friedman's ANOVAs were conducted. Wilcoxon signed rank (Bonferroni adjusted) was used as a post-hoc test, reporting r as an effect size. Due to missing data in the session-by-session measures (i.e., ODSIS and OASIS), blocks were built, each block being the average score of two sessions. In this way, the first block results from calculating the mean of the first and second sessions, and so forth.

In addition to evaluating the change at the group level, change at the individual level was also assessed. For this, the Standardized Individual Difference was calculated (SID) (Payne & Jones, 1957) for each participant as the difference between pre- and post-treatment scores divided by the standard deviation of the difference. This approach produces fewer false positives than other options like the Reliable Change Index or the Individual Effect Size (Ferrer & Pardo, 2014). Additionally, the test re-test liability information is not available for the employed tests in the Chilean population, and using the values obtained from internal consistency instead, tends to produce higher false positive rates (Ferrer & Pardo,

2014). As done previously for pre-post designs, 1.645 was used as a cut-off score for identifying cases that changed reliably (Estrada et al., 2019). In this index, positive values represent a reduction from pre to post, while negative values represent a increase of the scores from pre to post

Attendance to sessions is reported as an indicator of acceptability and feasibility of the treatment. Statistical analyses were performed using R (R Core Team, 2022), mostly through the psych (version 2.2.9; Revelle, 2022) and rstatix (version 0.7.2; Kassambra, 2023) packages. while graphs were built using Graphpad (2018).

Focus group notes were analyzed using template analysis which provides a systematic technique for categorizing qualitative data thematically, emphasizing a hierarchical, structural coding (Brooks et al., 2015). It permits the creation of a priori themes to be used to develop an initial version of the coding template but also allows to refine the coding creation process.

For the qualitative analysis, template analysis was used, which provides a systematic technique for categorizing qualitative data thematically, emphasizing a hierarchical, structural coding (Brooks et al., 2015). Three evaluators participated in an initial independent reading of the data and developed preliminary codes. Subsequently, in an initial meeting, they shared their codes, integrating them into an initial template and discussing differences in their interpretation. Finally, through a detailed review, they refined the categories and reached consensus. This process was part of the triangulation of the data, ensuring a consistent and validated representation of the findings.

Results

Effectiveness at group level

Descriptive statistics as well as effect sizes suggest that patients experienced reductions in depression, anxiety, neuroticism, dietary restriction, external eating, and emotional regulation difficulties from pre - to post-treatment. However, the effect tends to vanish over time -particularly in the last case- tending to rebound. The changes in self-esteem and general health perception reached statistical significance. Although they were reduced from post-treatment to follow-up, the levels were more favorable in the last assessment than prior to the intervention. Contrary to this, health-related quality of life improved at post-treatment but at follow-up presented levels inferior to the pre-treatment, showing a small effect size.

'Orientation towards illness' changed consistently at all moments being compared. An increased emotional eating was detected, as evidenced by the means at the different points. Finally, no relevant effects were detected for overall quality of life. See Table 4 for more details.

Table 4. *Change at pre, post and 3 month follow-up*

	Mean Pre (sd)	Mean Post (sd)	Mean 3m FU (sd)	F	p-value	ηp^2	Cohens'd Pre-Post	Cohens'd Pre-3m FU	Cohens'd Post-3m FU
Depression (SCL)	1.40 (1.13)	0.95 (0.82)	1.02 (1.15)	2.26	0.15	0.27 [0.00-0.52]	-1.05	-0.54	0.12
Depressed mood (MEDI)	32.86 (30.19)	17.86 (14.32)	27.86 (27.78)	2.22	0.15	0.27 [0.00-0.52]	-0.71	-0.3	0.52
Anxiety (SCL)	1.26 (0.91)	0.87 (0.63)	1.01 (1.01)	1.59	0.25	0.21 [0.00-0.48]	-0.65	-0.63	0.2
Autonomic activation (MEDI)	29.29 (22.72)	19.64 (18.84)	23.57 (26.33)	1.87	0.21	0.24 [0.00-0 .53]	-1.09	-0.34	0.31
Neurotic temperament (MEDI)	59.64 (17.29)	38.57 (18.36)	39.64 (28.67)	3.65	0.06	0.38 [0.00-0.58]	-0.88	-0.76	0.06
Orientation towards illness(MBSRQ)	**20.43 (2.70)**	**18.86 (3.48)**	**15.86 (2.73)**	**5.54**	**0.02**	**0.48 [0.02-0.66]**	**-0.36**	**-1.25***	**-1.02**
Dietary restraint (DEBQ)	3.46 (0.67)	2.97 (0.48)	3.03 (0.63)	1.73	0.23	0.22 [0.00-0.55]	-1.05	-0.43	0.08
Emotional eating (DEBQ)	2.44 (0.34)	2.78 (0.48)	2.77 (0.55)	3.18	0.11	0.35 [0.00-0.62]	1.72	0.64	-0.03
External eating (DEBQ)	2.81 (0.42)	2.40 (0.45)	2.71 (0.62)	3.17	0.08	0.35 [0.00-0.55]	-1.14	-0.2	0.64
DERS	60.71 (12.76)	50.43 (4.65)	58.00 (19.95)	2.07	0.18	0.26 [0.00-0.54]	-1.18	-0.19	0.44
Self-esteem (RSS)	**27.71 (5.41)**	**32.71 (3.99)**	**30.71 (6.26)**	**12.87**	**<0.01***	**0.68 [0.24-0.80]**	**2.40***	**0.97**	**-0.78**
Quality of life (QOLS)	83.00 (13.65)	82.86 (9.14)	83.86 (11.71)	0.04	0.96	0.01 [0.00-0.05]	-0.02	0.07	0.1
Health-related quality of life index (EQ-5D)	0.72 (0.16)	0.82 (0.14)	0.68 (0.29)	1.31	0.30	0.18 [0.00-0.54]	1.08	-0.16	-0.46
General health perception (EQ-VAS)	**55.57 (5.97)**	**76.14 (9.35)**	**73.57 (18.87)**	**7.76**	**0.03**	**0.56 [0.00-0 .77]**	**2.67***	**0.89**	**-0.18**

Note. Pre = Pre-treatment; Post = Post-treatment; 3-m FU = 3 months follow-up; SCL-90-R=Symptom Checklist-90-Revised; MEDI=The Multidimensional Emotional Disorders Inventory; DEBQ = Dutch Eating Behavior Questionnaire; DERS=Difficulties in Emotion Regulation Scale; RSS = Rosenberg Self-esteem Scale;QOLS= The Quality of Life Scale; EQ-5D=EuroQoL EQ-5D; Multidimensional Body–Self Relations Questionnaire=MBSRQ; *p<0.05

OASIS and ODSIS

Anxiety, measured over the treatment also showed changes, as evidenced by Friedman's ANOVA ($x^2(6) = 17$, $p=0.01$). Post-hoc comparisons showed a large but not significant, reduction from the first to the last block ($r = 0.90$). See Figure 1.A. Results for depression failed to reach statistical significance ($x^2(6) = 12.10$, $p=0.06$), although a large effect size (r=0.55) was detected for the difference between the first and the last block. Scores session by session can be seen in Figure 1.B.

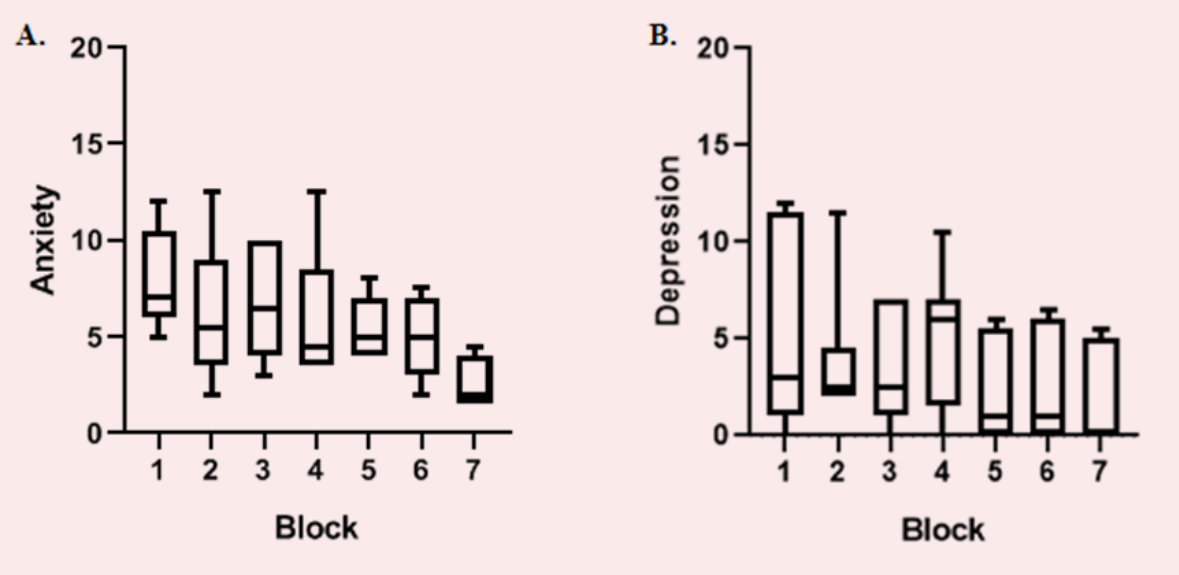

Figure 1. *Anxiety and depression over the treatment (Note.* In both graphs, the central line inside the box represents the median while the bars represent minimum and maximum values. Graph A (left) shows anxiety levels on the y-axis over the blocks (x-axis). Graph B shows depression degrees (y-axis) over blocks).

Change at individual level

Two to four patients reliably improved from pre- to post-treatment in measures of anxiety and depression. Participant #5 showed consistent improvement across all measures. Specifically, depressive symptoms measured by the SCL-90-R and MEDI significantly decreased (SID: 2.69⁎ and 2.01⁎ respectively). Participant #1 and Participant #4 also showed reliable changes in depression (SID SCL-90-R scores: 1.79⁎ and 0.72 respectively). For anxiety, both Participants #5 and #7 exhibited notable reductions (SID SCL-90-R scores: 1.67⁎ and 1.67⁎ respectively).

Addressing eating behaviors, positive changes were detected in dietary restriction and external eating (both with n=2), but an increase in emotional eating was noted in four participants. Specifically, Participants #2 and #3 showed

improvement in dietary restraint (SID DEBQ scores: 1.73* and 2.16* respectively), whereas Participant #2 showed an increase in emotional eating (-2.33*).

Three patients reported reduced difficulties in emotional regulation, with Participant #5 showing the most significant reduction (SID DERS score: 2.41*). Self-esteem improved in five participants, most notably in Participant #2 and Participant #5 (SID RSS scores: -4.32* and -2.88* respectively). General health perception, as measured by the EQ-VAS, improved for five participants as well, with Participant #5 again showing the most considerable improvement (SID GHP score: -1.30).

From pre-treatment to 3 months-follow-up, only one patient showed continued beneficial changes in depression measures, while two patients experienced favorable changes in anxiety. For example, Participant #4 presented a significant reduction in 'autonomic activation' (SID MEDI score: 2.55*). However, improvements in dietary restriction were limited, with only one participant showing desired changes. Emotional eating increased for some participants, with Participant #2 again showing an increase (SID: -2.33*). Participant #3 showed improvement in quality of life (SID: -1.86*), and participant #1 and #5 showed the same tendency in 'Orientation towards illness' (SID: 2.04* and 2.38*, respectively).

From the post-treatment to the 3 months-follow-up, Participant #3 showed improvement in quality of life (SID: -1.86*), and Participant #1 and #5 decreased their 'Orientation towards illness' (SID: 2.04* and 2.38*, respectively). Participant #2 showed detrimental changes in depression and anxiety, dietary restriction, external eating, emotional regulation difficulties, and self-esteem.

Feasibility and satisfaction with the intervention

The participants attended an average of 11.14 group sessions (range = 7-14), representing an attendance rate of 79.59%. This percentage increases when considering individual recovery sessions attended by participants who missed any regular session, with an average of 13 sessions (range = 12-14). Therefore, the overall rate of attendance, including these recovery sessions, was 92.86%.

In the STQ, five participants rated the program as Excellent. Six stated they for sure would definitely recommend the program to family or friends. A seventh person indicated it probably would. All participants reported that the program's content helped them deal with their problems and be satisfied with the treatment. Consequently, they indicated they found the psychological intervention they were looking for, although one of them stated that it did partially.

Just one patient reported high discomfort through the STQ. Regarding treatment format, 4 of them would take a group treatment again while the other 3 indicated they probably would. See Table 5 for more details.

Table 5. *Participant Responses to Treatment Satisfaction and Engagement Aspects*

Category	Number of participants
Program Rating (Excellent)	5
Would Recommend (Definitely)	6
Would Recommend (Probably)	1
Found Helpful Content	7
Satisfied with Treatment	7
Found Desired Intervention	6
Found Desired Intervention (Partially)	1
Reported High Discomfort	1
Would Take Group Treatment Again (Yes)	4
Would Take Group Treatment Again (Probably)	3

Note. This table represents participant responses to various aspects of the treatment program. 'Category' describes the aspect evaluated, such as program rating or willingness to recommend the program. 'Number of Participants' indicates how many participants responded positively to each aspect.

Focus group themes

Emotional stability

Well-being, emotional understanding, emotional stability, present-focused approach in their daily life, socializing their knowledge, and openness to new experiences were reported by patients.

For instance, one patient mentioned she felt distressed when she knew her husband was mugged. She recognized “Even if the feeling was terrible, I embraced it. After the episode, I felt fine and stable. I still go out with my husband”.

Use of techniques

The use of different techniques taught in group therapy in several daily life situations was reported. Such as mindfulness, cognitive flexibility, countering emotion-driven behaviors, confronting their physical sensations, and emotional exposure.

A patient reported that one day she felt a pain behind her eye. She thought “Maybe I am suffering another attack” but then she confronted her physical sensation and applied an alternative thought like “Maybe I’m stressed, I’ve been through a lot of family issues lately”. Shortly, when some of her family issues were resolved, she felt better from her pain. Now she always remembers that feeling pain behind her eye is not equivalent to having an attack.

Socializing knowledge

A different phenomenon was also detected in which patients reported they started to socialize what they had learned in group therapy with their relatives or even in their workplace.

A patient, who is a teacher, said she often uses and teaches the cognitive flexibility principles to her students. When they are in front of a conflict between peers she asks them "Are you describing or interpreting the situation?" then all of them reflect, propose an alternative thought, and successfully resolve the situation in the classroom.

Group therapy format

Participants valued several characteristics of the group therapy, for example, it was presential, they could meet other people with MS with different backgrounds. Also, they stressed that it was a safe place where they solved doubts about the therapeutic techniques, without feeling judged.

For example, a patient mentioned what she liked the most was "the different point of view between peers" that let her "think from a different perspective". She claims "now I try to give a different perspective on a situation. Always remembering the opinions that my peers gave me. This experience is very valuable to me".

Reservations

Patients made some reservations about the intervention. For example, therapeutic techniques were difficult to understand at the beginning. Sometimes, the use of technical concepts was confusing and difficult to grasp. Adaptations may be necessary in the future.

Regarding the homework material, "the instructions were long and often unintelligible" according to patients. They think easier, straightforward instructions may be useful.

Integration of Qualitative and Quantitative Data.

A qualitative and quantitative data integration was conducted to provide a deeper understanding of the effects of the Unified Protocol (UP). Quantitative results indicated improvements in emotional regulation (DERS), self-esteem (RSS), and general health perception (EQ-VAS). Although these outcomes showed a decrease at the three-month follow-up, the scores remained higher than the baseline levels

prior to treatment. These improvements were supported by qualitative data obtained from focus groups, where participants reported feeling more emotionally stable, having greater control over their emotions, and an increased ability to manage stressful situations.

On the other hand, divergences were observed between quantitative and qualitative results regarding emotional eating. While DEBQ scores indicated an increase in this behavior, participants' comments suggested that this change could reflect greater recognition and awareness of their emotions rather than an actual increase in maladaptive behaviors.

Regarding the intervention acceptability, participants reported in the survey that this intervention helped them with their problems. This is concordant with their comments in the focus group session about how they are applying and socializing the techniques taught in group therapy.

Discussion

This pilot study suggests potentially promising outcomes for the Unified Protocol (UP) in treating patients with RRMS and comorbid emotional symptoms, along with overweight/obesity, as evidenced by substantial effect sizes on several measures. However, these findings should be interpreted cautiously, given the preliminary nature of the study. A detailed case-by-case analysis is recommended to identify the most effective aspects of the intervention. Notable but statistically non-significant reductions in depression, anxiety, neurotic temperament, and autonomic activation suggest possible clinical benefits of the UP, though these effects remain to be studied in future research. These reductions may indicate that patients experience less frequent and intense negative emotions, potentially contributing to less stressful lives despite their chronic condition (Barlow et al., 2014). Although baseline anxiety and depression were not clinically significant, the observed reductions hint at the potential of preventive interventions to further enhance benefits, particularly when focusing on early intervention and sustained health management.

The effect sizes observed post-treatment—depression (d = -1.29), anxiety (d = -0.62), neurotic temperament (d = -0.88), and autonomic activation (d = -1.10)—suggest significant changes, although these might be influenced by the small sample size. These results are consistent with the documented benefits of psychological interventions in MS patients (Fiest et al., 2016), reinforcing the case

for incorporating the Unified Protocol (UP) in group settings to improve patient satisfaction and treatment outcomes (Nazari et al., 2020).

While the Quality-of-Life Scale (QOLS) did not show statistically significant changes in overall quality of life, notable improvements in self-esteem and general health perception were observed, highlighting the complex nature of quality of life in RRMS patients. The Unified Protocol (UP) seems effective in enhancing specific well-being aspects but may not fully address others. Measures like EQ-5D and EQ-VAS reported promising results, with stable Health-related Quality of Life Index scores (d = 1.08, d = -0.16) and increasing General Health Perception (d = 2.67, d = 0.89) through pre-treatment, post-treatment, and follow-up phases. Despite the chronic condition's impact, patients with a positive health perception are likely to maintain or adopt health-protective behaviors (Lee et al., 2019). Additionally, increased self-esteem (d = 2.40) serves as a protective mediator, potentially preventing depressive and anxiety disorders, underscoring its importance in treatment outcomes (Mikula et al., 2021; Momenabadi et al., 2020). This suggests a valuable protective factor in these patients, aiding in the avoidance of depressive and anxious symptoms.

The substantial effect sizes in self-esteem (d = 2.81) and general health perception (d = 3.72) indicate a significant impact of the Unified Protocol (UP) on these areas, highlighting its effectiveness. However, the lack of significant long-term improvements in health-related quality of life and certain psychological measures at follow-up underscores the necessity for continued support or booster sessions after the intervention to sustain these gains.

While dietary restriction and external eating decreased post-treatment, emotional eating paradoxically increased. This rise may not reflect an actual increase in emotional eating but rather an improved recognition of it, potentially due to the heightened emotional awareness cultivated by the Unified Protocol (UP) intervention. As patients become more attuned to their emotions, they might more accurately report behaviors like emotional eating. This interpretation is supported by recent studies indicating that mindfulness interventions can enhance awareness of cues linked to emotional eating (Aoun et al., 2025). This complexity in managing emotional regulation and eating behaviors in RRMS patients highlights the need for tailored strategies that more directly address emotional eating nuances.

Another important variable is 'Orientation towards illness,' which showed a decrease across all patients (d = -0.36), indicating reduced reactivity to being or becoming ill. This aligns with the improved general health perception mentioned

earlier. In essence, patients are less focused on their disease and feel healthier, enabling them to engage in other activities.

Despite patients being diagnosed with overweight or obesity, no statistically significant changes were observed in their eating behaviors, such as dietary restriction, emotional eating, and external eating. Several factors, including sample size, might explain these results. Literature suggests that MS patients are not more likely to adopt specific diets than control participants, even when they live overweight or obese (Russell et al., 2020). This condition may not be prioritized by patients due to the high comorbidity and life-changing nature of MS (Magyari & Sorensen, 2020). Therefore, transdiagnostic therapies are needed to address core issues relevant to this disease. For instance, a study on bariatric surgery patients with emotional disorders showed reductions in anxiety, dysregulation, and eating disorder symptoms, but not BMI (Ferreres-Galán et al., 2022).

This pilot study has several limitations. Firstly, the lack of a control group, although typical for pilot studies, limits definitive causal inferences about the effectiveness of the UP intervention. Additionally, resource constraints prevented us from conducting diagnostic interviews at the outset, which might have provided richer data on participants' experiences and mental health status. The specific nature of our target population posed recruitment challenges, resulting in a small sample size. Consequently, we could not selectively include participants with prominent anxiety or depression symptoms, leading to a cohort with less pronounced mental health symptomatology.

An additional limitation of the study is the absence of a formal analysis of adherence to the protocol, such as the use of structured checklists or the systematic review of recorded sessions. Including these tools in future studies would allow for a more accurate assessment of consistency in the implementation of the intervention, which would strengthen the interpretation of the results and improve the internal validity of the study.

Despite the high attendance rate and overall satisfaction with the UP intervention, participant feedback highlighted the complexity of therapeutic techniques and materials, suggesting a need for simplification and clearer communication in future applications. Tailoring content can enhance understanding and engagement, thereby improving therapy effectiveness.

Main conclusions and contributions of the study

- Preliminary findings suggest reductions in anxiety and depressive symptoms, along with increases in self-esteem, self-regulation, and GHP between pre- and post-treatment. These results should be interpreted with caution, as they are exploratory and derived from a pilot study, highlighting the need for further research with larger samples.
- Dietary variables indicated a reduction in the perception of looking for signs of being ill and an increase in emotional eating. The latter may be due to an increase in awareness of the patient's own emotions.

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