

Factors associated with nutritional status and risk factors of metabolic disorders in persons with multiple sclerosis

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Key words: nutritional status, physical activity, metabolic disorders, multiple sclerosis.

Abstract

Introduction: Nutritional status and metabolic health may affect the course of multiple sclerosis (MS), and they are key determinants of a patient's physical ability and well-being.

Aim of the research: The aim of this study was to analyse factors related to the nutritional status and the occurrence of risk factors of metabolic disorders in persons with MS.

Material and methods: The disability status of MS patients ($N = 115$; 75.7% women) was assessed using the Expanded Disability Status Scale (EDSS; 2.6 ± 1.7 pts). The nutritional status was assessed based on anthropometric measurements and a body composition analysis performed using the bioelectrical impedance method. Physical activity (PA) was measured using an accelerometer. Furthermore, selected biochemical parameters of the blood serum were analysed.

Results: A higher percentage of time spent on light PA was associated with lower body mass index, waist to height ratio, adiposity indicators, and triglyceride (TG) concentrations, and with higher high-density lipoprotein (HDL)-cholesterol concentrations ($p \leq 0.05$). A higher intake of fruits and vegetables was associated with lower anthropometric indicators of the nutritional status and adiposity indicators ($p \leq 0.05$). A higher intake of red meat, cold cuts, and sausages showed a positive relationship with the value of the glucose concentration ($p \leq 0.05$).

Conclusions: Our findings suggest that increasing physical activity should be the primary recommended strategy for counteracting excessive adiposity in persons with MS. Dietary habits also seem to be a significant modifiable determinant of the nutritional status and metabolic health in this group. Consequently, persons with MS should be provided with dietary counselling.

Introduction

Low physical activity (PA) is one of the primary risk factors for overweight and obesity [1, 2] and for metabolic disorders [3, 4]. Persons with multiple sclerosis (MS) are less physically active than the general population [5, 6] due to the progressive disability and fatigue associated with the disease [7, 8]. As a result, it seems likely that persons with MS are particularly at risk of developing obesity and metabolic disorders. Some studies indicate that while obesity is a risk factor of MS, after its onset, the mean body mass index (BMI) in adults with MS is significantly lower than the BMI in controls without MS [9], and that adults with MS do not increase their BMI with age, as is typical for the general population [10]. The nutritional status of persons with MS may also be determined to a large extent by factors other than PA, especially dietary habits [11, 12], as well as non-modifiable factors, such as gender [13]. However, an assessment of the nutritional status based on BMI, including the BMI classification, leads to an underestimation of adiposity in persons with MS [14], nor can it be used to

determine the distribution of fat tissue. Few studies have analysed body composition in detail [15, 16]. Consequently, this topic requires further research. The associations between habitual PA and the prevalence of metabolic parameters in persons with MS are also largely unknown. Our earlier study showed that as many as 48.7% of persons with MS had at least 2 metabolic risk factors, and that these may have been caused, at least partially, by low PA [2]. However, our study was self-reported, which prevented a detailed assessment. Furthermore, the prevalence of metabolic parameters in persons with MS may be strongly affected by other lifestyle factors, primarily diet [17].

Aim of the research

The aim of the present study was to assess factors related to the nutritional status and the occurrence of metabolic risk factors in persons with MS. Based on habitual PA, as measured with an accelerometer, and other related modifiers such as gender, age, disability status, and dietary habits.

Material and methods

Study cohort

The study participants comprised 115 persons (75.7% women) aged 42.6 ± 11.6 years with a diagnosis of MS according to the McDonald criteria [18], and with a mean duration of their MS of 11.35 ± 10.10 years. The study was conducted at the Resmedica Neurological Clinic in Kielce, Poland, between 1.09.2020 and 28.02.2021. Recruitment continued for the duration of the research project until the target numbers of participants had been reached. The study project was approved by the Bioethics Committee of the Collegium Medicum at the Jan Kochanowski University in Kielce (No. 24/2020), and all participants provided their written consent for participation in the study. Information about the course of MS was taken from the participants' medical documentation. Most of the participants (88.7%) had relapsing-remitting MS. Persons with secondary progressive and primary progressive MS constituted 4.34% and 6.96% of all the participants, respectively. None of the participants took glucocorticosteroids over the course of the study.

Measurements

Each participant's disability status was assessed by a neurologist based on the Expanded Disability Status Scale (EDSS) [19]. Body height was measured using a stadiometer with an accuracy of 0.1 cm. Waist circumference (WC) was measured using non-elastic tape at a point midway between the lowest rib and the iliac crest. BMI and waist to height ratio (WHtR) were calculated. Body composition was assessed using bioelectric impedance analysis (BIA) performed with a Tanita MC-780MA-N analyser. The concentration of triglycerides (TG) was measured using the phosphoglyceride oxidase peroxidase method. High-density lipoprotein (HDL) and low-density lipoprotein (LDL) cholesterol were measured directly with polyethylene glycol-modified enzymes. Glucose (Glu) concentration was determined with glucose oxidase using the enzymatic method. PA was measured using an ActiGraph GT3X-BT GTIM accelerometer (ActiGraph LLC, Pensacola, USA). The average time of wearing the device was 8 days (min.–max.: 7–9 days). The participants were asked to wear the device on their non-dominant wrist and to maintain their habitual activity over the data registration period. The time when the device was put on and taken off was recorded every day. The data obtained using the device were analysed using ActiLife 6.0. Data Analysis Software. The analysis took into account the days on which the device was worn for at least 10 hours. The PA data were collected in 10-second epochs at a frequency of 30 Hz. Non-wear time was defined as a period of at least 60 consecutive minutes of zero counts. The results were presented as the aver-

age vector magnitude count (VMC), % sitting time, and % time spent on light physical activity (LPA) and moderate-to-vigorous physical activity (MVPA).

The participants' dietary habits were assessed using the Dietary Habits and Nutrition Beliefs Questionnaire (KomPAN) [20]. The analysis was performed based on the food frequencies of the following 6 food groups: fruits and vegetables; total fats; red meat, cold cuts and sausages; sweets and sweetened carbonated or still drinks; and refined grain products and whole-meal grain products. Each response category (from the lowest to highest food frequency) was presented as the number of times eaten per day.

Statistical analysis

Mean values (X), standard deviations (SD), medians (Me), and the interquartile range (IQR) were calculated according to gender groups. The significance of differences between the means was calculated using Student's t -test or the Mann-Whitney U test, depending on the distribution. Percentages were calculated for the categorical variables, and gender-wise differences in the distributions were estimated using a χ^2 test. Generalised linear and non-linear models and a log-normal model with an identity link function were used to determine the effect of each variable on the values of the somatic parameters and adiposity. Gender was a categorical variable. The effects were presented for women, while men were used as a reference group. The following continuous variables constituted a set of predictors: age; EDSS, intake of fruits and vegetables, red meat, cold cuts and sausages presented as times/day; % of LPA and MVPA. Statistical significance was assumed at $p \leq 0.05$. The analyses were conducted using the Polish version of the Statistica 13.3 package (Statsoft, Kraków, PL).

Results

The basic characteristics of person with MS are presented in Table 1. In the multivariate model, a higher LPA was associated with significantly lower BMI, WHtR, and TG, and higher HDL (Table 2). The MVPA and EDSS did not significantly affect any parameters. Gender, age, and intake of some groups also led to significant differences in some somatic and metabolic parameters. The women had a lower WC, WHtR, and LDL and a higher HDL than the men. The BMI, WHtR, LDL, and TG increased with age. A higher intake of fruits and vegetables decreased the somatic indicators of nutritional status but was not associated with metabolic risk factors. The only significant effect of the higher intake of red meat, cold cuts, and sausages in the men was a higher Glu.

Adiposity decreased with LPA (Table 3). The effect of LPA was significant for all analysed indicators. No significant associations between MVPA and

Table 1. Characteristics of the MS group

Variable	Men (n = 28)		Women (n = 87)		P-value
	X ± SD	Me (IQR)	X ± SD	Me (IQR)	
Age	45.39 ±12.59	48.50 (19.00)	41.72 ±11.13	42.00 (15.00)	0.145 ^A
Duration of disease [years]	13.11 ±11.68	9.00 (19.00)	10.77 ±9.53	9.00 (11.00)	0.299 ^A
Form of MS disease (N; %)					
Relapsing-remitting MS	25	89.29	77	88.50	0.307 ^B
Secondary progressive MS	3	10.71	5	5.75	
Primary progressive MS	0	0.0	5	5.75	
EDSS scale	2.89 ±1.76	2.50 (2.50)	2.51 ±1.66	2.00 (2.00)	0.326 ^C
Anthropometric traits and indicators					
Body height [cm]	179.75 ±5.83	179.00 (7.50)	164.38 ±5.90	164.00 (8.00)	< 0.001 ^C
Body mass [kg]	82.75 ±17.70	81.95 (16.00)	63.91 ±13.17	62.30 (14.70)	< 0.001 ^A
BMI [kg/m ²]	25.62 ±5.39	25.85 (5.25)	23.61 ±4.40	22.90 (4.80)	< 0.001 ^C
WC [cm]	104.93 ±48.72	95.00 (32.00)	94.57 ±42.98	80.00 (13.00)	< 0.001 ^C
WHtR	0.54 ±0.09	0.54 (0.12)	0.50 ±0.07	0.49 (0.08)	0.034 ^C
Adiposity indices					
Fat [%]	23.21 ±8.59	23.65 (10.75)	29.30 ±7.24	29.20 (7.80)	0.705 ^C
Fat mass [kg]	19.45 ±8.54	18.10 (8.40)	20.45 ±11.46	20.35 (14.80)	< 0.001 ^C
Trunk fat [%]	25.68 ±9.67	26.50 (12.80)	25.27 ±8.10	25.90 (8.60)	0.848 ^C
Trunk fat mass [kg]	12.99 ±7.69	12.65 (9.35)	9.44 ±4.90	8.40 (4.90)	0.015 ^C
VFL	10.89 ±7.75	10.00 (6.00)	4.45 ±2.52	4.00 (3.00)	0.003 ^C
Σ of fat (%) for limbs	81.67 ±25.48	83.90 (34.15)	137.19 ±27.9	136.30 (25.70)	< 0.001 ^C
Σ of fat mass [kg] for limbs	7.53 ±3.73	7.70 (4.90)	10.01 ±3.80	9.20 (3.30)	< 0.001 ^C
Blood chemistry parameters [mg/dl]					
HDL-cholesterol	54.78 ±13.60	53.00 (20.00)	64.69 ±11.62	64.00 (16.00)	< 0.001 ^A
LDL-cholesterol	146.38 ±43.40	140.50 (60.80)	127.15 ±41.66	122.20 (47.80)	0.024 ^C
TG	104.93 ±48.72	95.00 (32.00)	94.57 ±42.98	85.00 (57.00)	0.273 ^C
Glucose	96.46 ±12.73	94.50 (13.50)	90.66 ±12.02	89.00 (10.00)	0.011 ^C
Physical activity					
VMC [106 counts/day]	3.392 ±0.871	3.233 (1.147)	2.962 ±0.967	2.941 (0.844)	0.012 ^C
% of sitting time	62.45 ±10.26	63.42 (9.00)	61.69 ±6.45	61.18 (10.03)	0.362 ^C
% in LPA	23.26 ±5.46	22.69 (5.38)	21.05 ±3.75	20.16 (5.08)	0.025 ^C
% in MVPA	14.29 ±6.37	14.24 (6.03)	17.26 ±5.42	16.69 (7.91)	0.008 ^C
Nutrition [frequency/day]					
Vegetables and fruit	2.03 ±1.07	1.70 (0.89)	2.86 ±1.47	2.50 (2.08)	0.003 ^C
Fats (total)	1.33 ±1.09	1.04 (1.71)	1.37 ±0.99	1.08 (1.33)	0.666 ^C
Red and processed meat	0.96 ±0.59	1.00 (0.56)	0.71 ±0.57	0.64 (0.77)	0.032 ^C
Sweets and sweetened drinks	0.93 ±0.98	0.64 (0.69)	0.56 ±0.59	0.50 (0.52)	0.012 ^C
Refined grain products	0.93 ±0.98	0.64 (0.69)	0.56 ±0.59	0.50 (0.52)	0.012 ^C
Whole grain products	0.58 ±0.72	0.23 (0.47)	2.05 ±10.82	0.64 (0.92)	.0375 ^C

MS – multiple sclerosis, EDSS – Expanded Disability Status Scale, BMI – body mass index, WC – waist circumference, WHtR – waist to height ratio, VFL – visceral fat level, Σ – sum, HDL – high-density lipoproteins, LDL – low-density lipoproteins, TG – triglycerides, VMC – average vector magnitude counts, LPA – light physical activity, MVPA – moderate-to-vigorous physical activity, X – arithmetic mean, SD – standard deviation, Me – median, IQR – interquartile range, p – significance level, ^AStudent's t-test, ^Bχ² test, ^CMann-Whitney U-tests.

Table 2. Factors related to the value of somatic indicators and metabolic factors in persons with MS – results of regression analysis

Factor	BMI	WC	LDL	HDL	TG	Glucose
% of time spent on LPA						
Parameter	−0.23	−0.77	−0.70	0.99	−1.73	0.06
95% CI	−0.41; −0.07	−1.21; −0.34	−2.27; 0.87	0.46; 1.52	−3.34; −0.11	−0.35; 0.47
SE	0.09	0.22	0.80	0.27	0.82	0.21
P-value	0.007	< 0.001	0.381	< 0.001	0.036	.774
% of time spent on MVPA						
Parameter	0.08	0.31	0.31	−0.05	−0.47	−0.16
95% CI	−0.06; 0.22	−0.05; 0.67	−0.97; 1.60	−0.49; 0.38	−1.79; 0.86	−0.50; 0.18
SE	0.07	0.18	0.66	0.22	0.68	0.17
P-value	0.236	0.097	0.632	0.825	0.492	0.343
EDSS score						
Parameter	0.002	0.89	−0.21	0.58	2.80	0.80
95% CI	−0.51; 0.51	−0.44; 2.21	−4.95; 4.52	−1.02; 2.17	−2.06; 7.66	−0.44; 2.05
SE	0.26	0.68	2.41	0.81	2.48	0.63
P-value	0.995	0.191	0.930	0.479	0.259	0.207
Sex (women)						
Parameter	−0.55	−6.26	−10.02	5.55	−1.55	−2.21
95% CI	−1.47; 0.38	−8.65; −3.86	−18.54; −1.51	2.67; 8.42	−10.43; 7.31	−4.46; 0.03
SE	0.47	1.22	4.34	1.46	4.52	1.14
P-value	0.248	< 0.001	0.021	< 0.001	0.731	0.053
Age						
Parameter	0.10	0.29	1.08	0.001	0.72	0.16
95% CI	0.03; 0.17	0.10; 0.47	0.42; 1.73	−0.21; 0.23	0.04; 1.40	−0.01; 0.33
SE	0.04	0.09	0.33	0.11	0.35	0.08
P-value	0.007	0.002	0.001	0.946	0.037	0.069
Red and processed meat						
Parameter	0.46	0.22	7.49	1.69	−0.24	3.38
95% CI	−0.81; 1.72	−3.04; 3.48	−4.19; 19.17	−2.23; 5.60	−12.26; 11.26	0.51; 6.63
SE	0.64	1.66	5.96	0.71	6.13	1.56
P-value	0.479	0.894	0.209	0.399	0.968	0.022
Vegetables and fruit						
Parameter	−0.60	−1.60	1.20	−0.17	−1.34	−0.09
95% CI	−1.13; −0.08	−2.97; −0.24	−3.57; 5.96	−1.77; 1.43	−6.23; 3.56	−1.35; 1.17
SE	0.27	0.70	2.43	0.82	2.50	0.64
P-value	0.025	0.021	0.622	0.837	0.592	0.892

LPA – light physical activity, MVPA – moderate-to-vigorous physical activity, EDSS – Expanded Disability Status Scale, BMI – body mass index, WC – waist circumference, HDL – high-density lipoproteins, LDL – low-density lipoproteins, TG – triglycerides, CI – confidence interval, SE – standard error, *p* – significance level.

Table 3. Factors related to the values of adiposity indices in persons with MS – results of regression analysis

Factors	Fat %	Fat mass [kg]	Trunk fat %	Trunk fat [kg]	VFL	Σ of fat for limbs (%)	Σ of fat for limbs [kg]
% of time spent on LPA							
Parameter	−0.41	−0.54	−0.42	−0.29	−0.10	−1.36	−0.25
95% CI	−0.68; −0.13	−0.87; −0.21	−0.74; −0.09	−0.48; −0.09	−0.20; −0.003	−3.37; −0.35	−0.39; −0.11
SE	0.14	0.17	0.17	0.09	0.05	0.51	0.07
P-value	0.004	0.001	0.012	0.003	0.043	0.008	< 0.001
% of time spent on MVPA							
Parameter	0.02	0.12	0.01	0.04	−0.02	0.09	0.08
95% CI	−0.20; 0.25	−0.14; 0.39	−0.25; 0.28	−0.11; 0.20	−0.11; 0.05	−0.73; 0.91	−0.04; 0.19
SE	0.11	0.13	0.14	0.08	0.04	0.42	0.06
P-value	0.834	0.360	0.939	0.573	0.494	0.827	0.188
EDSS score							
Parameter	0.59	0.51	0.72	0.28	0.07	1.81	0.24
95% CI	−0.25; 1.42	−0.47; 1.50	−0.27; 1.70	−0.29; 0.87	−0.22; 0.37	−1.24; 4.86	−0.18; 0.66
SE	0.43	0.50	0.50	0.30	0.15	1.58	0.21
P-value	0.167	0.308	0.157	0.338	0.627	0.246	0.261
Sex (women)							
Parameter	3.75	0.20	0.46	−1.23	−1.98	29.20	1.42
95% CI	2.24; 5.26	−1.57; 1.98	−1.32; 2.24	−2.28; −1.18	−2.51; 1.45	23.75; 34.66	0.65; 2.18
SE	0.77	0.91	0.91	0.54	0.27	2.78	0.39
P-value	< 0.001	0.817	0.610	0.022	< 0.001	< 0.001	< 0.001
Age							
Parameter	0.10	0.10	0.10	0.06	0.16	0.36	0.05
95% CI	−0.01; 0.21	−0.03; 0.23	−0.04; 0.23	−0.02; 0.14	0.12; 0.20	−0.06; 0.78	−0.01; 0.11
SE	0.06	0.07	0.07	0.04	0.02	0.21	0.02
P-value	0.079	0.139	0.160	0.176	< 0.001	0.089	0.107
Red and processed meat							
Parameter	−0.43	−0.28	−0.94	−0.34	−0.23	−0.22	0.02
95% CI	−2.48; 1.63	−2.70; 2.14	−3.36; 1.49	−1.77; 1.09	−0.96; 0.49	−7.72; 7.27	−1.01; 1.06
SE	1.05	1.23	1.24	0.73	0.37	3.82	0.02
P-value	0.684	0.819	0.450	0.639	0.524	0.953	0.970
Vegetables and fruit							
Parameter	−0.84	−1.21	−0.98	−0.68	−0.36	−3.62	−0.53
95% CI	−1.70; 0.01	−2.22; −0.19	−1.99; 0.04	−.28; −0.08	−0.66; −0.06	−6.74; −0.49	−0.97; −0.10
SE	0.44	0.52	0.52	0.30	0.15	1.59	0.22
P-value	0.054	0.019	0.059	0.025	0.019	0.023	0.016

LPA – light physical activity, MVPA – moderate-to-vigorous physical activity, EDSS – Expanded Disability Status Scale, VFL – visceral fat level, Σ – sum, CI – confidence interval, SE – standard error, p – significance level.

the EDSS and adiposity indicators were found. Fat mass (kg) and trunk fat% did not differ between men and women. The women showed a higher fat% and limb fat and a lower trunk fat mass in kg and VFL than the men. Trunk fat in kg and VFL increased with age. None of the analysed parameters were affected by the intake of red meat, cold cuts, and sausages. In turn, a higher intake of fruits and vegetables was associated with a significantly lower adiposity.

Discussion

A normal nutritional status throughout a person's life may play a crucial role in MS, and is a key determinant of metabolic health and well-being [21]. This study indicated that objectively measured PA significantly differentiated the nutritional status and lipid profile of persons with MS. Although most intervention studies have confirmed the beneficial effect of physical training on the body composition of persons with MS [22], few studies have investigated the relationship between habitual PA and the BMI or body composition. A study conducted in Israel did not find any relationship between objectively measured leisure time PA and BMI in persons with MS [23]. Ward *et al.* observed that PA (step count) was not associated with the fat% in women with MS [24]. However, the results of our previous studies, which analysed PA using the IPAQ, demonstrated that BMI ≥ 25.0 kg/m² may have resulted from low PA [2].

This study showed that the LPA was associated with a significantly lower TG and higher HDL. A literature review conducted by Ewanchuk *et al.* indicated that evidence for the modification of the lipid profile and vascular comorbidities through physical exercise in persons with MS is inconclusive [22]. On the other hand, according to an intervention study, a 12-week medium-intensity continuous training regime led to an improvement in the concentrations of some lipoproteins [25]. Likewise, an 8-week combined exercise training programme was associated with an improved lipid profile in persons with MS [26]. However, 24 weeks of low- or medium-intensity resistance and endurance training did not improve the blood glucose control in a group of persons with MS [27]. In turn, Motl *et al.* confirmed that both a self-reported and objectively measured habitual PA significantly decreased the number of cardiovascular comorbidities [28].

This study did not demonstrate a significant, independent effect of the disability status on any analysed indicators of the nutritional status or metabolic factors. These results are consistent with those obtained by some other authors. Jeng and Motl also did not observe a relationship between a worse body composition and more severe disability in persons with MS [29]. Likewise, Livne-Margolin *et al.* reported that a more severe disability in persons with MS did not correlate with an increased BMI [30]. Only the mean

WC increased significantly with the EDSS score. Wingo *et al.* concluded that only the lean mass of the leg in women with MS correlated with the EDSS score [14]. Another study conducted in Poland observed that a more severe disability in persons with MS was strongly associated with a lower FFM and higher fat mass, especially in the abdominal area [15]. However, the median score on the EDSS was 4.5 points, i.e. it was significantly higher than in our study (2.6 points). Only prospective studies observed a positive relationship between the disability status and dyslipidaemia in persons with MS [31, 32]. A different, cross-sectional study did not confirm such a correlation [33].

The body composition parameters, fat tissue distribution, and LDL and HDL were strongly associated with gender. Bertapelli *et al.* noted that gender accounted for 29% of the variation in fat% in persons with MS, while the values of fat% were similar to those obtained for persons without MS [13]. The results obtained by other authors confirmed that both hyperlipidaemia and diabetes occurred more often in men with MS than in women with MS [34]. Our study also showed that the values of BMI, WC and WHtR, VFL, trunk fat mass, and dyslipidaemia correlated positively with the participant's age. However, the presence of such a relationship in a cross-sectional study may depend on the age range of the participants. Bertapelli *et al.* did not observe a significant correlation between %BF and age in persons with MS [13]. However, similar relationships between an increasing age and a higher number of atherosclerosis risk factors were noted in another cross-sectional study [34].

A higher intake of fruits and vegetables by the participants in this study was associated with lower values of the BMI, WC, and WHtR, as well as lower adiposity. On the other hand, no significant association was found with any of the analysed metabolic risk factors. A randomised 1-year study among persons with MS demonstrated that the use of a very low-fat, plant-based diet improved the lipid profile and lowered the insulin concentration after just 6 months [35]. Furthermore, monthly decreases in the BMI were observed, amounting to an average of -1.125 kg/m² per month. Consequently, our results are consistent with those obtained in the aforementioned study with respect to the nutritional status. We were unable to find any studies concerning correlations between the intake of such products and the body composition of persons with MS in the literature. In our study, a higher intake of red meat, cold cuts, and sausages significantly increased the Glu. Meat is a source of exogenous amino acids that, in combination with a higher PA, can maintain the normal mass and function of the skeletal muscles [36]. However, research conducted among the general population also confirmed that a higher consumption of red and processed meat may be related to a higher risk of an abnormal Glu concentration [37].

The main limitation of this study was its cross-sectional design and small sample size. In turn, its strengths are the objective assessment of PA and an evaluation of the nutritional status based not only on anthropometric parameters, but also on a body composition analysis.

Conclusions

Increasing PA should be the primary recommended strategy for counteracting excessive adiposity and its associated secondary effects in persons with MS. Future studies should specify the duration and intensity of the habitual PA that may contribute to reduce the risk of excessive adiposity and metabolic risk factors.

Dietary habits seem to be another significant modifiable determinant of the nutritional status and metabolic health among persons with MS. To reduce the risk of abnormal glucose concentration, people should be instructed about healthier sources of complete protein. The results of our study indicate that dietary counselling should be incorporated, as a basic aspect of comprehensive care, in persons with MS.

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Ethical approval

Approval numer: No. 24/2020.

Conflict of interest

The authors declare no conflict of interest.

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