

## ORIGINAL ARTICLE

# Impact of the COVID-19 pandemic on access to healthcare services amongst patients with multiple sclerosis in the Lazio region, Italy

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## Abstract

**Background and purpose:** Multiple sclerosis (MS) is a complex chronic, autoimmune inflammatory disease involving multidisciplinary assessments and interventions. Access to outpatient specialist and home healthcare services was explored during the pandemic outbreak and the lockdown amongst MS patients in the Lazio region. Adherence to disease-modifying therapies (DMTs) is also described.

**Methods:** A population-based study was conducted using regional healthcare administrative databases. A validated algorithm was used to identify MS cases over the period 2011–2018. The numbers of specialist and home-based services were compared between 2019 and 2020. The medication possession ratio was used to measure adherence to DMTs.

**Results:** A total of 9380 MS patients were identified (68% women). A decline in the number of outpatient care services between March and June 2020 compared to the previous year was observed, in particular for rehabilitation (–82%), magnetic resonance imaging (–56%) and neurological specialist services (–91%). Important year-to-year variations were observed in May and June 2020 in home-based nursing and medical care (–91%) and motor re-education services (–74%). Adherence to DMTs was higher in the first 4 months of 2019 compared to the same period of 2020 (67.1% vs. 57.0%).

**Conclusions:** A notable disruption of rehabilitative therapy and home-based services as well as in DMT adherence was observed. Since the pandemic is still ongoing and interruption of healthcare services could have a major impact on MS patients, it is necessary to monitor access of MS patients to healthcare resources in order to ensure adequate treatments, including rehabilitative therapies.

## KEYWORDS

administrative databases, cohort, COVID-19, healthcare, multiple sclerosis

## INTRODUCTION

The novel coronavirus disease 2019 (COVID-19) represents an unprecedented new challenge worldwide, causing large-scale loss of life and

a great impact on economy and society. The COVID-19 pandemic severely affected the organization of health services, and the provision to patients suffering from chronic diseases of timely and optimal care has become increasingly difficult [1–3]. Healthcare systems face a twofold

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challenge, as on the one hand they need to address a growing demand for care of COVID-19 patients and on the other they need to maintain continuity of care for patients with chronic diseases or severe acute conditions. Multiple sclerosis (MS) is a progressive, inflammatory, autoimmune, neurodegenerative disease of the central nervous system and the most common cause of non-traumatic neurological disability in young adults [4]. MS patients require to have a regular access to a wide range of medical services (e.g., infusions, physical therapy, home-care assistance, specialist visits), which may be disrupted during the pandemic exposing MS patients to a high risk of acute exacerbations and disease complications. A recent survey on MS patients' management in the USA and Europe during the COVID-19 pandemic [5] found that most individuals did not discontinue their disease-modifying therapy (DMT) but observed a significant disruption of rehabilitative therapies and homecare services. Italy was the first Western country to experience the COVID-19 emergency and one with the most cases and deaths. The first Italian patient was diagnosed in mid-February in Lombardy (northern Italy). The Italian government put the entire country in lockdown, with a gradual reduction of containment measures starting on 4 May. Preliminary data on the impact of the COVID-19 epidemic on the management of MS patients in Italy show a reduction in access to drug therapies, rehabilitation and homecare services [6].

Patients with MS require long-term treatment with DMT to control their disease course. Non-adherence to DMT has been associated with poorer clinical outcomes, including higher relapse rates and disease progression [7]. Individuals with MS receiving long-term treatment with immunotherapies have been hypothesized to be at increased risk of infection and mortality from COVID-19 [8]. However, it has also been reported that the proportion of patients at high risk of mortality is below 1% [9]. Additionally, Louapre et al. in their registry-based study observed no association between DMT exposure and COVID-19 severity [10]. Recent reports highlight the importance of maintaining DMTs when indicated during the pandemic associated with patients' follow-up and risk mitigation strategies, especially amongst those treated with immunosuppressive drugs [11–13].

Due to conflicting evidence of the effect of DMTs on the frequency of SARS-CoV-2 infection and the course of COVID-19, the decision whether to initiate or discontinue or maintain medication is a critical issue for both the patient and the physician. With the recent lockdown and unavoidable changes to healthcare delivery, patients with MS may have had limited access to usual medical services (infusions, physical therapy, occupational therapy and homecare services), because of either unavailability or the fear of SARS-CoV-2 infection. In the Lazio region, health administrative databases are comprehensive and contain high-quality information, allowing for region-wide public health monitoring and research [14,15]. A validated algorithm is used to identify MS cases within healthcare administrative databases, for healthcare planning and monitoring purposes [16]. In 2019, 10,400 individuals affected by MS were identified; amongst those, 5200 resided in the metropolitan area of Rome [17]. The objective of the present study was to evaluate access to outpatient specialist and home healthcare services during the pandemic outbreak and the lockdown amongst MS patients in the Lazio region. The impact of the pandemic on adherence to DMTs is also described.

## METHODS

### Ethics statements

The Department of Epidemiology of the Regional Health Service is the referral centre for epidemiological research in the Lazio region and has full access to anonymized health administrative databases. Data were analysed through a standardized methodology according to the national privacy law. Consent was not necessary because information already collected at the beginning of the study was used and the data were analysed anonymously; individuals cannot be identified directly or through identifiers and results are shown in aggregate form.

### Study population and data sources

A population-based retrospective cohort study was conducted using linked healthcare administrative databases of the Lazio region (an Italian region in the central part of the country, including the city of Rome, and with about 6,000,000 inhabitants).

Information on hospitalizations, drug prescriptions, co-payment exemption due to severe conditions, outpatient specialist and homecare services is available for everyone registered in the regional Health Care Assistance Registry (approximately 97% of residents). All regional administrative databases include a unique person-based identifier allowing for deterministic record-linkage procedures (description of healthcare administrative databases is given in Appendix S1).

A validated case-finding algorithm [16] was used to identify MS cases over the period 2011–2018, including the following criteria: (a) at least one prescription claim for an MS-specific DMT (beta-interferon, glatiramer acetate, fingolimod, natalizumab, teriflunomide, dimethyl fumarate, alemtuzumab, ocrelizumab, peginterferon); or (b) at least one hospital discharge diagnosis of MS, coded 340.xx according to the International Classification of Diseases, Ninth Revision, Clinical Modification (ICM-IX-CM); or (c) a claim registered with the MS specific code (046.340) in the regional co-payment exemption registry.

To describe access to outpatient specialist and home healthcare services, all MS patients living in Lazio on 31 December 2018 who were still alive and resident in the region on the same day the following year were included in the study population. To analyse adherence, only patients with MS using DMTs at any time during 2018 and who were still on disease-modifying medication in 2019 were selected. This approach was used to select patients with MS who are supposed to be treated continuously with DMTs.

### Statistical analysis

The numbers of outpatient specialist services provided in 2020 from 1 January to 30 June were compared with those of the same 6-month period in 2019. In particular, the following outpatient services were considered: rehabilitative therapy, magnetic resonance imaging and specialist neurological care services. Moreover, the number of home

services (nursing/medical care, home-based motor re-education) provided in the period from January 2020 to September 2020 were compared with those performed in the same period of 2019. The percentage changes per month were calculated to compare the number of outpatient specialist services and home healthcare services in 2019 and 2020. The medication possession ratio (MPR) was used to measure adherence to DMT over a period of 4 months, from January to April, in 2019 and 2020. The MPR was defined as the number of days of medication supplied divided by the total number of follow-up days in the study period. An adequate adherence was considered as MPR  $\geq 0.80$ . To calculate adherence to DMTs, additional drugs, other than those used to identify MS cases, were included in the analysis: mitoxantrone, azathioprine, cyclophosphamide, rituximab and methotrexate. Baseline demographic data (age, gender and place of residence) and clinical characteristics (concomitant diseases, number of emergency department discharges in the previous year, outpatient services and medication use in the previous year) were described for all study participants. Details on ICD-IX-CM codes for comorbidities and Anatomical Therapeutic Chemical (ATC) codes for drugs are reported in Appendix S2. Since MS centres are heterogeneously distributed throughout the region, adherence to DMTs was also described by patient's place of residence, comparing the municipality of Rome and the surrounding area with the remaining provinces of the Lazio region.

All statistical analyses were conducted using SAS, version 9.2.

## RESULTS

A total of 9380 individuals with MS were identified (73% registered in the drug prescription database) residing in the Lazio region on 31 December 2018 and still present on 31 December 2019. The baseline demographic and clinical characteristics of MS patients are detailed in Table 1. The average age was 49 years, 68% of the patients were women, and over half were living in the metropolitan area of Rome. Only 2%–3% of people had been hospitalized for causes other than MS in the previous 2 years and 1.2% were affected by another autoimmune disease. Twenty per cent had accessed an emergency room at least once in the previous 12 months whilst most patients had accessed outpatient neurological services (60%). Moreover, 21% of MS patients were taking antihypertensive medications and 10% drugs for obstructive airway diseases.

Amongst the overall population of patients, 90% received specialist care from outpatient clinics and 11% home healthcare services (data not shown). A reduction in the number of overall outpatient care services was observed starting from March 2020, compared to the same period of the previous year (Figure 1). This reduction persisted throughout the period and reached its peak in April, when a percentage change of 79% compared to 2019 was observed.

Figure 2a,b,c shows, respectively, the number of physical medicine and rehabilitation, magnetic resonance imaging, and neurological specialist services provided from January to June in 2019 and 2020, and the percentage variations of 2020 versus 2019. A strong decline was observed in the period from March to June 2020 compared to 2019 ( $N = 10,130$  and

**TABLE 1** Sociodemographic and clinical characteristics of MS patients ( $N = 9380$ )

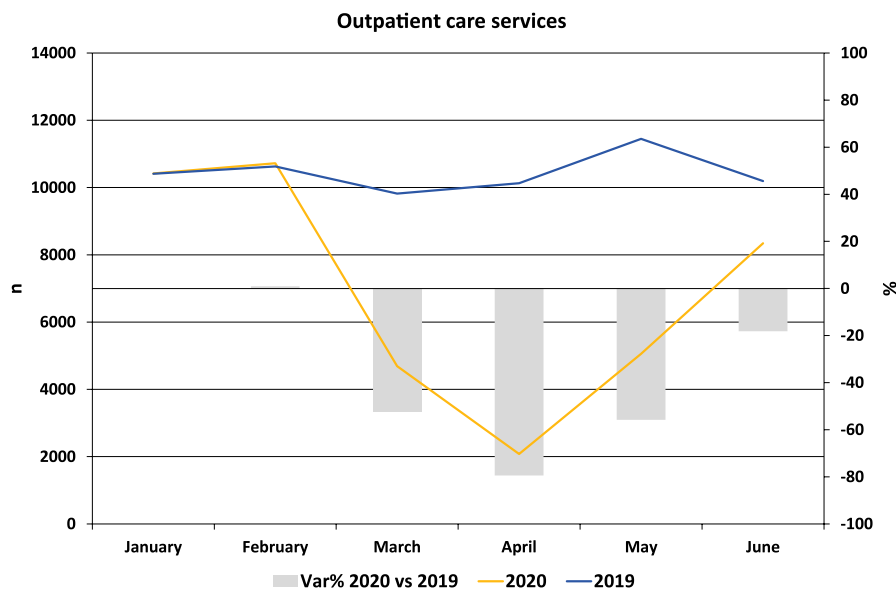
	N	%
Gender		
Females	6369	67.9
Age, years		
<30	814	8.7
30–44	2704	28.8
45–59	3857	41.1
60+	2005	21.4
Residence		
Rome	4705	50.1
Province of Rome	2248	24.0
Rest of Lazio region	2427	25.9
Condition 24 months before enrolment		
Comorbidity <sup>a</sup>	264	2.8
Cardiovascular risk factors <sup>b</sup>	207	2.2
Other autoimmune disease <sup>c</sup>	116	1.2
Number of emergency department discharge (1 year before enrolment)		
0	7408	79.0
1	1322	14.1
2–4	598	6.4
5+	52	0.5
Outpatient services (1 year before enrolment)		
Neurological services		
None	3676	39.2
1	839	21.0
$\geq 2$	1896	39.8
Other services		
None	6380	68.0
1	438	11.7
$\geq 2$	709	20.3
Medication drugs		
Antidiabetics	289	3.1
Cardiac therapy	141	1.5
Antihypertensives	1943	20.7
Drugs for obstructive airway diseases	1005	10.7
Patients identified in prescription claims database at enrolment	6841	72.9

Note: Lazio region, 31 December 2018.

<sup>a</sup>Anxiety, depression, diabetes, chronic obstructive pulmonary disease, respiratory failure, neoplasm, renal failure, chronic disease of liver, pancreas and intestine.

<sup>b</sup>Hypertension, ischaemic heart disease, cerebrovascular disease, arrhythmias, peripheral vascular diseases.

<sup>c</sup>Chronic lymphocytic thyroiditis, inflammatory bowel disease, ankylosing spondylitis, idiopathic thrombocytopenic purpura, myasthenia gravis, Sjögren's syndrome, systemic lupus erythematosus.



**FIGURE 1** Outpatient care delivery. Trend January to June and percentage change 2019–2020 [Colour figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

$N = 2083$  in April 2019 and 2020, respectively) with major reductions in April ( $-82\%$  for physical medicine and rehabilitation,  $-56\%$  for magnetic resonance imaging and  $-91\%$  for neurological specialist services).

There was also a decrease in homecare services delivery in 2020 compared to 2019 (Figure 3).

Important year-to-year variations were observed in May and June 2020 (respectively  $-90\%$ ,  $-92\%$ ) in nursing and medical care provision, as shown in Figure 4a; for home-based motor re-education the largest variations were observed in June ( $-74\%$ ) (Figure 4b).

Amongst 4192 MS patients who were taking any DMT on 31 December 2018, 3680 were still receiving any kind of DMT on the same date of the following year. Most patients (50.1%) were between ages 45 and 59 years (mean age 47) and 67% were females. About 75% of patients were residing in the city of Rome or the surrounding area, and the remaining in other provinces of the region. Patients' demographic and clinical characteristics did not vary within the 1-year timeframe (data not shown). Univariate analysis highlighted a greater adherence to treatment in the first 4 months in 2019 compared to the same period of 2020 (67.1% in 2019 vs. 57.0% in 2020,  $p < 0.0001$ ). Adherence to DMT was lower in 2020 than in 2019 for Rome (64.2% in 2019 vs. 62.8% in 2020,  $p < 0.0001$ ) (Table 2), as well as in the rest of the region where an important change in adherence, decreasing from 75% in 2019 to 40% in 2020 ( $p < 0.0001$ ), was observed.

Finally, no differences were observed between years in the distribution of adherent patients by type of DMT (Appendix S3).

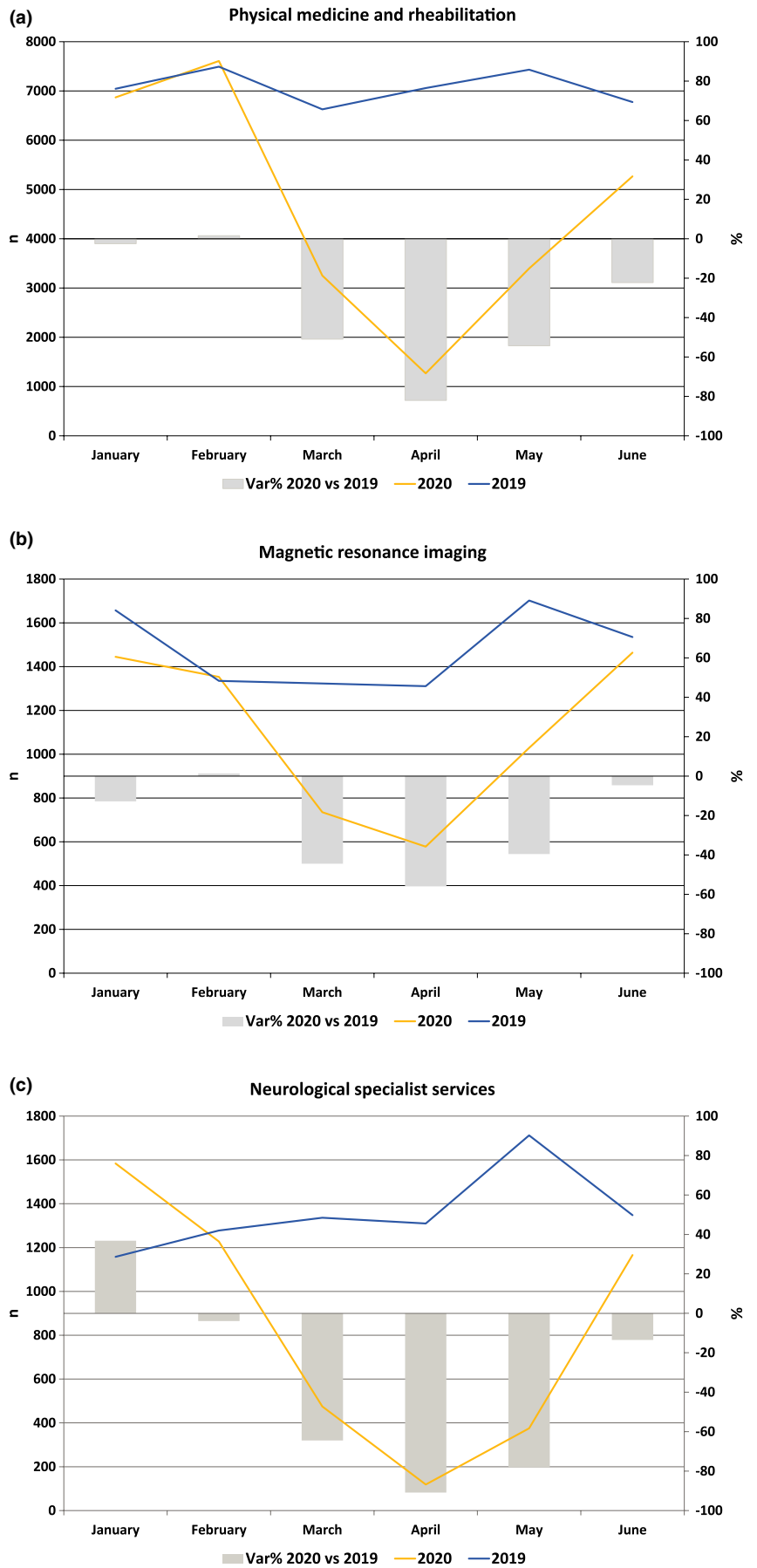
## DISCUSSION

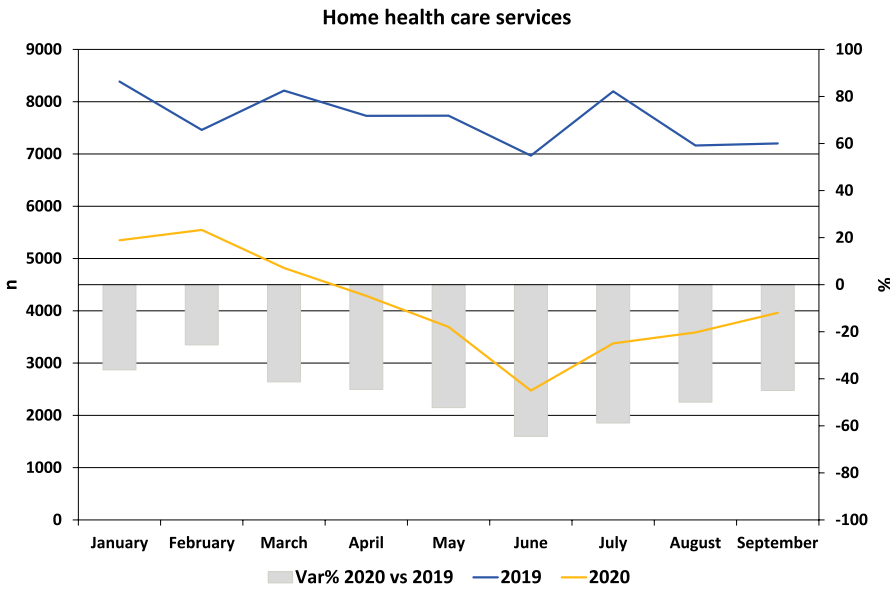
This population-based study shows how the widespread COVID-19 pandemic and the measures adopted to face the emergency severely affected the treatment and care of people living with MS in the Lazio region. During the COVID-19 outbreak they experienced a substantial decrease in adherence to DMTs, although varying by residence,

and a remarkable reduction in the number of visits to ambulatory care practices and provision of healthcare services at home.

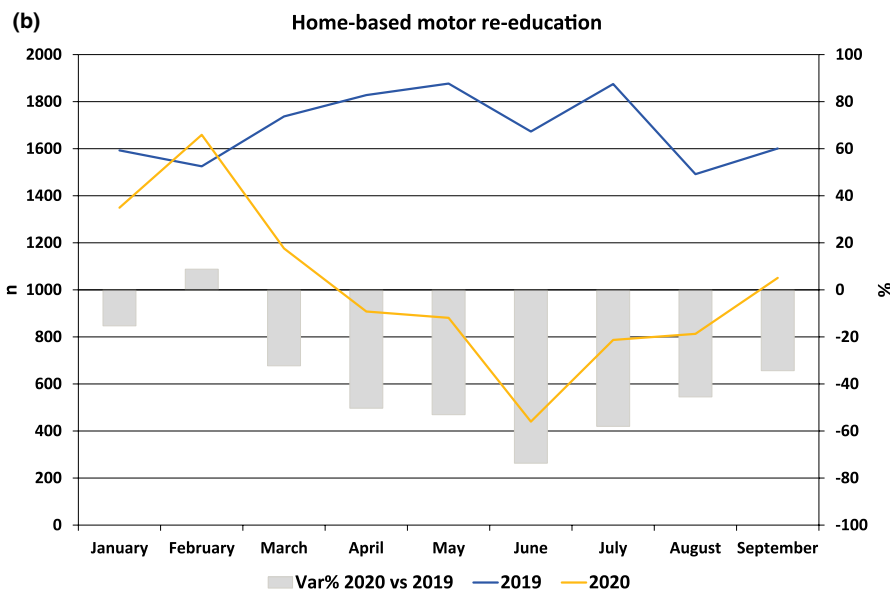
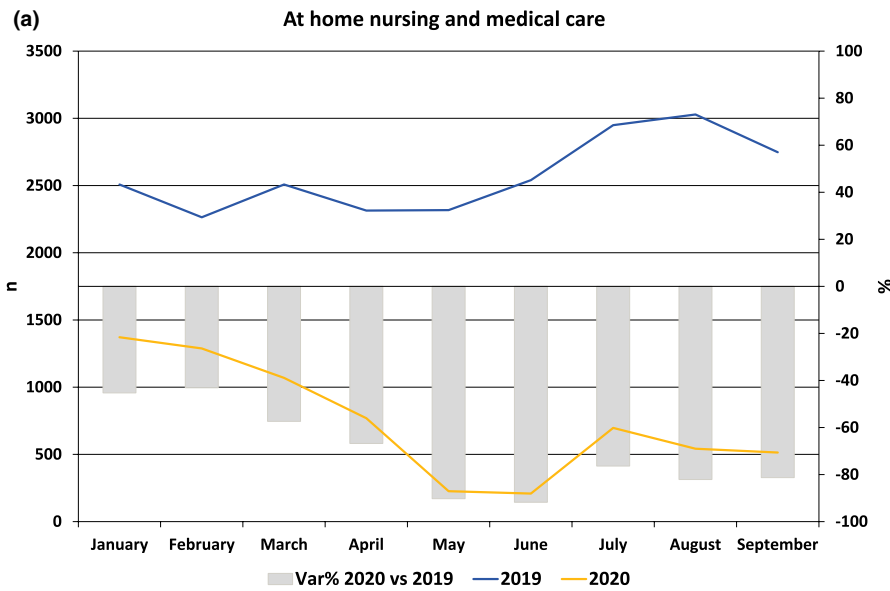
Several factors may have caused the broad disruption to usual care of MS patients, related both to the quick reorganization of healthcare resources and to patients' behaviours. Few studies documented changes in therapy plans amongst individuals with MS during the COVID-19 pandemic, mainly deriving from surveys of patients or healthcare professionals at specialist clinics [18]. In particular, limited information is available on the provision of rehabilitative therapy and homecare services, for which the continuity is of paramount importance [19]. Moss et al. reported a disruption of rehabilitative therapies and to an even greater extent of homecare services, mainly amongst older patients, patients with progressive MS and patients with disability and comorbidity conditions [5]. The most common reason for stopping or decreasing access to healthcare services was fear of acquiring the infection. Some studies showed that in a few cases patients' decision to avoid hospital visits was an autonomous choice [20,21]. Interesting findings were reported by an Italian study showing that most patients with MS were compliant with social restriction rules during the lockdown period, and 16% reported subjective worsening of neurological conditions; about one-third suspended hospital treatments or physiotherapy [22]. Conversely, difficulties in obtaining pharmacological treatments were reported only by a small percentage of patients (3%). A cross-sectional online survey launched in Italy after the institution of the national lockdown reported that disruptions in care amongst MS patients varied across different levels of disability, with more severe patients experiencing a higher proportion of lack of usual care and support, rehabilitation and specialist services [6]. About 14% of respondents declared problems in receiving medication therapies with no differences amongst disability groups. Considering findings from other studies, it is supposed that the decreasing adherence observed may reflect patients' concerns due both to an increased risk of infection with SARS-CoV-2 and more severe disease due to DMTs with immunosuppressive effects. Indeed, at the start of the pandemic there was uncertainty as to the specific risks of SARS-CoV-2 infection in

**FIGURE 2** Trend January to June and percentage change 2019–2020 in physical medicine and rehabilitation (a), magnetic resonance imaging (b) and neurological specialist services (c) [Colour figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]





**FIGURE 3** Home care services delivery. Trend January to September and percentage change 2019–2020 [Colour figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]



**FIGURE 4** Trend January to September and percentage change 2019–2020 in home-based nursing and medical care, and motor re-education [Colour figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

**TABLE 2** Adherence to disease-modifying therapy amongst MS patients in the Lazio region, by year (January–April)

	Overall adherence			
	MPR $\geq$ 80			
	2019		2020	
	N	%	N	%
	2467	67.1	2098	57
	Adherence by patient residence			
	N	%	N	%
	Rome and its province	1763	64.2	1724
Other provinces	704	75.2	374	40.0

people with MS and concerns about the effect of immunosuppressant or immune-modifying medications on COVID-19 course and outcome. However, at the beginning of March 2020, different international societies, and organizations, including the Society of Italian Neurologists and the Association of British Neurologists, published guidelines for the use of DMTs during the pandemic [23,24], which have been gradually updated on the basis of available evidence providing a support for the management of DMTs [25]. General recommendations for patients on a DMT were to continue the treatment and to consider extended-interval dosing for cell-depleting therapies and natalizumab. Recommendations also stressed the need to discuss individual risks and benefits when considering changes in therapy regimen. Still, in our study population, most patients (about 55%) were taking interferons or glatiramer (data not shown), considered to be safe with respect to the novel coronavirus infection. Difficulties in keeping in touch with the treating physician and/or the referral MS centre may have contributed to the reduction in adherence that was observed. This hypothesis seems to be supported by the lower drop in adherence in the city of Rome and its surrounding areas, where the main specialist centres are concentrated, relative to the rest of the region.

Some limitations of this study must be highlighted. To identify MS patients, a validated algorithm [16] was applied capturing only cases diagnosed and recorded in administrative databases and accounting for about 85% of the total affected population. Moreover, regional administrative databases, although having an optimal coverage and including high-quality data, miss information on relevant clinical characteristics, such as MS phenotype, disease severity and level of disability. Indeed, record linkage between different databases may help in describing the clinical profile of patients but only if a contact with any service within the regional health systems has occurred (e.g., hospital admission, medication prescriptions). The main strength of this study is its population-based approach, allowing for a comprehensive description of the provision of and access to healthcare services at the regional level. The study relies on good quality administrative data currently used not only for descriptive but also for analytical purposes [26,27]. It is noteworthy that the timely availability of information coming from administrative databases allows healthcare delivery in the region to be monitored and critical points in the provision

of and access to healthcare to be identified in order to implement corrective measures. This aspect is particularly relevant in the current public health emergency due to the COVID-19 pandemic.

In conclusion, our data suggest that during the COVID-19 outbreak and lockdown restriction measures there was a notable disruption of rehabilitative therapy and homecare services as well as in DMT adherence amongst MS patients residing in the Lazio region. Since the pandemic is still ongoing and interruption of healthcare services could have downstream consequences for MS-related outcomes, there is a need to monitor access of MS patients to healthcare resources and to eventually reorganize services in order to ensure adequate treatments, including rehabilitative therapies.

## CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest.

## AUTHOR CONTRIBUTIONS

Paola Colais: Conceptualization (equal); formal analysis (lead); methodology (equal); validation (lead); writing original draft (supporting); writing review and editing (supporting). Silvia Cascini: Conceptualization (equal); data curation (supporting); formal analysis (supporting); methodology (equal); validation (equal); writing original draft (supporting); writing review and editing (supporting). Maria Balducci: Conceptualization (equal); data curation (equal); formal analysis (supporting); methodology (equal); validation (supporting); writing original draft (supporting); writing review and editing (supporting). Nera Agabiti: Conceptualization (equal); methodology (equal); project administration (equal); writing original draft (supporting); writing review and editing (equal). Marina Davoli: Methodology (equal); project administration (equal); writing review and editing (supporting). Danilo Fusco: Methodology (equal); writing review and editing (supporting). Enrico Calandrini: Data curation (equal); investigation (equal); writing review and editing (supporting). Anna Maria Bargagli: Conceptualization (equal); investigation (equal); methodology (equal); project administration (equal); supervision (lead); validation (equal); writing original draft (lead); writing review and editing (lead).

## ETHICAL APPROVAL

The Department of Epidemiology of Lazio Regional Health Service is the regional referral centre for epidemiological research and has full access to anonymized health information systems. Consent was not necessary because the authors used data already collected at the beginning of the study and the data were analysed anonymously through a standardized methodology according to the national privacy law (national legislative decree on privacy policy no. 196/30 June 2003). Individuals cannot be identified directly or through identifiers and results are shown in aggregate form.

## DATA AVAILABILITY STATEMENT

Data related to the findings reported in our paper are available to all interested researchers upon request because of stringent legal restrictions regarding privacy policy on personal information in Italy (national legislative decree on privacy policy no. 196/30 June



2003). For these reasons, our dataset cannot be made available on public data deposition. All interested researchers can contact the following persons to request the data: Nera Agabiti, Department of Epidemiology, Lazio Regional Health Service, Rome, Italy, email: n.agabiti@deplazio.it; Damiano Lanzi, Department of Epidemiology, Lazio Regional Health Service, Rome, Italy, email: d.lanzi@deplazio.it.

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## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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