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CROSS-SECTIONAL STUDY

The dedicated nurse in the multiple sclerosis centre: effects on the self-management capacity in home therapy patients

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ABSTRACT

BACKGROUND: Multiple sclerosis (MS) is a chronic inflammatory disease of the central nervous system with wide clinical variability among patients and an overall progressive disability. People affected by it require a continuous system of care. The optimum position to coordinate care can be obtained with dedicated nurses, within an MS Centre, who provide a range of skills and abilities for patients and caregivers oriented toward living with the pathology, self-management of the pathology and maintaining patients' state of health.
AIM: To assess whether the presence of a dedicated nurse (DN) in MS Centres can affect patients' ability to self-manage the disease.
METHODS: Cross-sectional, observational, multicentric study. The twelve MS Italian Centers that participated in this study have been divided into the two sample groups based on the presence or not of a DN. Through the self-administered Multiple Sclerosis Self-Management Scale (MSSM-R), the degree of self-management achieved by the patient in the charge of the center was measured.
RESULTS: The results of the MSSM-R Scale did not show any statistically significant differences in the self-management capacity of the disease between patients belonging to the two arms. Patients recognize the nurse's skills and competence as indispensable within the centers.
CONCLUSIONS: The study showed no differences between the two groups. However, from patients' responses, the importance of DN and the consequent need for recognition of this professional figure emerges, as well as the need to further demonstrate the nurse's role in the management of the disease with further scientific studies.

KEYWORDS: *Nurses, Chronic Disease, Multiple Sclerosis, Self-Management*

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STUDIO TRASVERSALE

L'infermiere dedicato nel centro sclerosi multipla: effetti sulla capacita' di autogestione del paziente

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ABSTRACT

INTRODUZIONE: La sclerosi multipla (SM) è una patologia infiammatoria cronica del sistema nervoso centrale, caratterizzata da un'elevata eterogeneità clinica tra i pazienti e da una disabilità progressiva nel tempo. Le persone affette da SM necessitano di un sistema di assistenza continuativo. Un ruolo ottimale nel coordinamento dell'assistenza può essere svolto dall'infermiere dedicato (ID), operante all'interno di un Centro SM, in grado di offrire competenze specifiche a supporto del paziente e del caregiver, orientate alla convivenza con la patologia, all'autogestione della stessa e al mantenimento dello stato di salute del paziente.
OBIETTIVO: Valutare se la presenza di un infermiere dedicato (ID) nei Centri SM possa influenzare la capacità dei pazienti di autogestire la malattia.
METODI: Studio osservazionale trasversale, multicentrico. I dodici Centri SM italiani partecipanti sono stati suddivisi in due gruppi, in base alla presenza o meno di un ID. Attraverso la somministrazione della *Multiple Sclerosis Self-Management Scale – Revised* (MSSM-R), è stato misurato il livello di autogestione raggiunto dai pazienti in carico presso ciascun centro.
RISULTATI: I risultati della scala MSSM-R non hanno evidenziato differenze statisticamente significative nella capacità di autogestione della patologia tra i pazienti appartenenti ai due gruppi. Tuttavia, i pazienti riconoscono le competenze e l'expertise dell'infermiere come elementi imprescindibili all'interno del centro.
CONCLUSIONI: Lo studio non ha rilevato differenze tra i due gruppi rispetto alla capacità di autogestione. Tuttavia, dalle risposte dei pazienti emerge l'importanza dell'infermiere dedicato e la conseguente necessità di un riconoscimento formale di tale figura professionale. Si evidenzia inoltre il bisogno di ulteriori studi scientifici per dimostrare l'effettivo ruolo dell'infermiere nella gestione della sclerosi multipla.

KEYWORDS: *Infermieri, Patologia Cronica, Sclerosi Multipla, Autogestione*

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BACKGROUND

Multiple Sclerosis (MS) is a chronic disease of the central nervous system (CNS) with autoimmune and degenerative inflammatory characteristics with wide clinical variability among patients and an overall progressive disability. Symptomatology depends to the localization of CNS lesions that interrupt the conduction of nerve impulses and the functionality of multiple areas and systems, thus determining their clinical course. In 85% of cases, the disease begins with a relapsing-remitting progression. Relapses can involve physical and cognitive symptoms and present psychosocial and emotional challenges that can compromise patient's quality of life [1].

People affected by the disease need a continuous, multidimensional, multidisciplinary and multilevel long-term care system, aimed at improving the quality of life and reducing the evolution of the disease by preventing disabilities [2].

Although there is no cure for MS, in recent years scientific research has radically changed the possibilities of treatment, having several disease-modifying therapies (DMT) that reduce relapse rate and slow the progression of disability [3]. The precocity of these treatments, administered by injection or oral, the correct administration and their continuity are prerequisites for their effectiveness [4].

The chronicity and variable course of MS can make the effects and benefits of prescribed treatments and behaviors less appreciable for patients. The side effects of therapies, the stability of the disease for long periods with no relapses or, worse, the progression of symptoms, can lead to the abandonment of the treatment plan (therapies, diet, behaviors, clinical monitoring, visits, examinations) [5]. This clearly limits the effectiveness of treatment, compromising the quality of life, increasing hospitalization (related to MS) and mortality, increasing health costs [6].

The nurse in MS centers is in an ideal position to coordinate a personalized care plan, aimed at providing a series of skills and abilities to the patient and caregiver, oriented to the ability to cope with pathology, to maintain of the state of health (self-care) and, progressively, to the real self-management of the pathology (self-care management) [7].

In Italy, the care of the patient affected by MS is managed by hospital MS centers where, in terms of organization and professional composition, a variety of different disciplinary teams operate. The presence of the DN within the multi-disciplinary team is not formally considered necessary, and therefore is not present in all MS centers. Where a DN is present, their role and participation is not well defined because they are not formally recognized as a provision for the benefit of the outpatient. MS centers are generally located within the hospitals and the DN, where present, carries out specifically nursing interventions of assessment, planning, prevention, and education aimed at the patient and the care giver [8]. There is no path in Italy to train nurses specifically dedicated to the care of patients with multiple sclerosis, nor a definition of a DN. In the past, in 2008 and 2009, university masters have been implemented for specific training for MS, but they have not been followed up. Only for this study, we define the requirements for being a DN in methods paragraph, based on our experience inside the MS centres.

AIM

The purpose of this study is to assess whether the presence of DN within the team of MS centres can affect the patient's ability to self-manage the disease. At the same time, the study investigates about the relationship between patient and nurse, through the administration of a questionnaire for patients.

METHODS

A cross-sectional, observational, multicentric study was designed and carried out. For this study it was necessary to define in detail the characteristics of the DN, in order to distinguish between the participating centers within the two sample groups. Thus, a DN is defined as a trained and certified nurse who has educational competence and interacts with the patient aimed at the following nursing objectives: health education for people with MS, planning of therapeutic and care diagnostic procedures, assessment and education to the home management of oral or injective DMT in the person affected by MS, evaluation of specific symptoms of MS (for example, those arising from neurological bladder pathology with EcoBladderScan), education given to the person with MS and to the

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caregiver for the management of some problems (for example, bladder self-catheterization).

Furthermore, DN must also be in possession of a Master's Degree in the management of people with MS or must have attended a specific course for the management of people with MS and have a continuous and extensive experience in the field of MS for at least 5 years.

The twelve participating centres differ greatly from each other in terms of organization. Furthermore, the role of the nurse within them is highly variable. To better understand the specific role of the nurse and the benefits provided to patients within the MS center, it was necessary to ask each participating center for information on the number of DN present, their actual activity in the clinic, the nursing services provided to outpatients and the CV's of each of the DN.

The overall characteristics of the participating centers have been defined:

Sample Group 1: The DN is present in the MS center making available to the patient and family members their profession at the time of periodic neurological visits; The DN provides nursing advice when the patient/family member or another team professional requests a nursing need.

Sample Group 2: The DN is not present in the MS center and he can't establish a relationship with the patient with home treatement.

The participating centers have been divided into two sample groups depending on the information provided (Table 1).

Table 1. Sorting the centers into two sample groups and number of patients enrolled.

Centre N.	Sample Group	Enrolled Patients
01-Coordinating centre: Centro SM XXX	**1**	11
02-Centro SM XXX	**1**	8
03-Centro SM XXX	**2**	9
04-Centro SM XXX	**1**	13
05-Centro SM XXX	**2**	12
06-Centro SM XXX	**2**	10
07-Centro SM XXX	**1**	13
08-Centro SM XXX	**2**	8
09-Centro SM XXX	**1**	20
10-Centro SM XXX	**1**	7
11-Centro SM XXX	**1**	11
12-UO Neurologia XXX	**2**	10
	Tot.	132

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In participating centers, where outpatients in DMT home management therapy were enrolled, the following questionnaires were delivered in paper format for self-administration:

MSSM-R: questionnaire widely used in the clinical field as a self-assessment tool for the evaluation of the degree of self-management achieved by the patient which consists of 24 statements that according to the degree of agreement of the compiler provides a score on the relationship and communication with healthcare staff, adherence to treatment and the presence of any barriers, social and family support, knowledge and education about MS, behaviors deemed useful for maintaining health [9].

QUESTIONNAIRE FOR PATIENTS (Image 1) It was drafted for this study to gather the practical experience of the patient in the relationship with the nurse of the MS centre. The questionnaire investigates nurse's knowledge of the disease and the treatment, the availability of nurse for clarification on symptoms or doubts about relapses, availability of nurses for help in health practices, availability of nurses for management of terapy.

1	Ritiene che nel suo Centro ci siano infermieri che conoscono molto bene la malattia e le cure disponibili?
2	Nel suo centro può rivolgersi a infermieri preparati per chiarimenti su sintomi o problemi legati alla malattia o dubbi su possibili ricadute?
3	Se ha risposto "sì", è soddisfatto dell'aiuto che possono darle in queste situazioni?
4	Se ha risposto "no", ritiene che le sarebbe di aiuto poter contare su infermieri specializzati nella cura della SM?
5	Nel suo centro può rivolgersi a infermieri preparati per informazioni e chiarimenti sulla terapia (come e quando assumerla, problemi, dubbi su interazioni con cibi, farmaci o altre cure, effetti collaterali...)?
6	Se ha risposto "sì", è soddisfatto dell'aiuto che possono darle in queste situazioni?
7	Se ha risposto "no", ritiene che le sarebbe di aiuto poter contare su infermieri specializzati nella cura della SM?
8	Nel suo centro può rivolgersi a infermieri per essere aiutato in pratiche sanitarie? (Ad esempio, programmazione vaccinazioni, reperimento ausili, rinnovo patente…)
9	Se ha risposto "sì", è soddisfatto dell'aiuto che possono darle in queste situazioni?
10	Se ha risposto "no", ritiene che le sarebbe di aiuto poter contare su infermieri specializzati nella cura della SM?

Image 1. Patient questionnaire regarding the relationship with the nurse

In addition to the self-administered questionnaires, the following information about the participant was collected: age, gender, years of schooling, number of members of the cohabiting household, DMT in use and date of beginning, number of previous therapies, date of onset of disease, EDSS.
All collected data were entered by each center on an excel sheet with password anonymized.
This sample size satisfied an effect size of 0.20 with a statistical power of 95% at a significance level of 5% (α=0.05). A 20% data entry error was also considered. Calculations were obtained using G*Power 3.1.9.7 software.

Included in the study were persons with MS aged between 18 and 60, with EDSS between 0 and 5.5, in home management DMT therapy undertaken from 6 months to 6 years, without relapses in the last 3 months, able to understand and complete the questionnaires and give informed consent to inclusion. The coordinating centre have guaranteed the management and analysis of data in anonymous, aggregated form and only for statistical purposes. Data were collected within the centers between January and July 2022.

ETHICAL CONSIDERATIONS: The present study (No. 139 of 2021) was approved by the Ethics Committee of

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RESULTS

A total of 132 patients were enrolled; 83 followed by centers belonging to sample group 2 and 49 belonging to sample group 1 (tab. 4).

Despite center n. 01, belonging to sample group n. 1, it didn't provide personal data about the participants, the sample is, thus, designated as homogeneous between the two sample groups: considering biographical elements such as age, gender, and clinical characteristics, such as EDSS, age of illness, n. previous therapies and time of therapy (*Table. 2*).

Table 2. Sample characteristics: comparison between the two sample groups.

CHARACTERISTIC		GROUP 1	GROUP 2
Age at start (years), mean ± sd		42,3 ± 11,4	42,8 ± 8,6
Female, n (%)		30 (61%)	56 (75%)
Literacy, n (%)	Middle school	12 (25%)	31 (37%)
	Secondary/graduation	33 (67%)	44 (53%)
Disease duration (years), mean ± sd		8.4 ± 6.5	8,0 ± 7.6
Edss, median (iqr)		1,4 [1-2]	1,7 [1-2]
Oral therapy, n (%)		40 (82%)	68 (82%)
Smss total score *, mean ± sd		9.6 ± 10.5	12.3 ± 12.27
Smss score (item 9+ item 10), mean ± sd		1.5 ± 2,2	2.0 ± 2,4

From MSSM-R score, there are no substantial differences between the patients followed by centers with a DN and those followed by centers without a DN.

This occurs both in the total score of the scale, and in the various subscales that consider aspects of self-management ability. (table 3) The results were analysed with Wilcoxon rank-sum test.

Table 3. Score from MSSM-R questionnaire: comparison between the two sample groups.

		GROUP 1	GROUP 2	p-value*
MSSM-R TOTAL SCORE, MEDIAN (IQR)		85.4 [76-88]	83.3 [79-87]	0,98
SUBSCALE SCORES	Relationship and communication	26,0 [25-26]	26,0 [25-26]	0.06
	Adherence to treatment	32.0 [30-35]	32 [30-35]	0,47
	Social and family support	14 [10-15]	13 [12-15]	0.69
	Knowledge and education on MS	19 [17-20]	17 [19-20]	0.79
	Behaviors deemed useful for maintaining health	16 [13-18]	16 [14-18]	0,96

** = Wilcoxon rank-sum test*

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Patient questionnaire provided an overview of practical experience of the patient in the relationship with the nurse (Image 2). All patients consider it necessary to have a specialized nurse inside the centre and 98% of the respondent were satisfied with the help received from the nurses, when present in the centres. This was investigated regarding clarifications on symptoms or problems related to the disease, doubts about possible relapses, information on therapies, help in health practices.

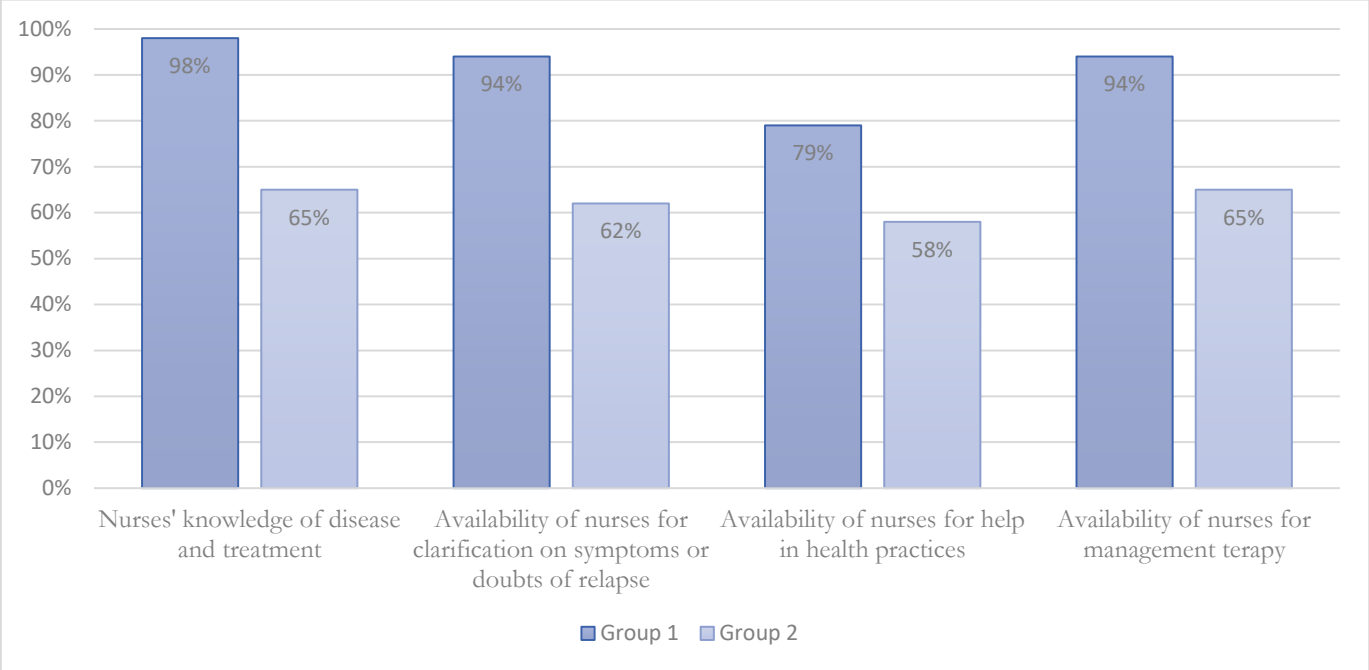

Image 2. Patient's experience detected by patient questionnaires.

DISCUSSION

The main objective of the study was to measure and demonstrate through MSSM-R the impact of the DN on self-management capacity of patients with MS. The patients' self-management capacity, measured through the MSSM-R questionnaire, did not show statistically significant differences between the group with the DN within the team and the one without the DN (Tab.3).

Recent literature studies [10] highlight the difficulties for research which measures qualitative factors, such as self-efficacy and self-management in chronic diseases. Indeed, self-management is not a linear phenomenon, it is constantly evolving with characteristics of fluidity and multidimensionality. The numerous and complex interactions of factors that determine it entail a high level of complexity in the data collection, assessment and measurement process [11]. Furthermore having included only subjects attending the outpatient unit resulted in a relatively low disability sample, that is in patient whose self-management is less challenging compared to more disabled people with MS.

The patient questionnaire (Tab. 4) clearly shows the appreciation by patients of the DN. Firstly, the questionnaire indicates an appreciation for a health figure able to recognize and satisfy patient's needs for education. In addition, the questionnaire highlights the DN's ability to provide help, support, and advice in the various dimensions of care and assistance that the disease presents. Patient satisfaction for the intervention of the dedicated nurse emerges and this factor, in addition to those described above, is considered fundamental in the literature to improve self-management [12]. Comparable data are not available.

However, the analysis of our study reveals some critical issues that may have influenced the results. The figure of

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DN, as defined for the purposes of the study, can be interpreted differently in the various MS centers. In Italy the DN is not defined or required, neither at the regulatory level, nor contractual. Moreover, further doubts have emerged regarding the use of the MSSM-R scale, not so much for its reliability and validity, that appears well documented in the literature [13,14], but rather regarding its applicability and appropriateness to a multicentric observational study with transverse design.

Moreover, aspects such as continuity, personalization, fairness, and access to care have not been considered. The relationship with family members or caregivers has not been investigated: an aspect in which the figure of the DN is present and should be documented.

Finally, the Covid emergency has certainly created difficulties, both in the phase of preparation and in the operational phase of the study, such as, the normal attendance by patients of MS centers, in follow up or in relationship with health personnel. This may have caused confusion in the study.

There are no self-management models in the literature for MS and even less scientific studies that document evidence about the cost/benefit ratio due to the presence of the DN [15]. This is currently the greatest obstacle, but also a necessity for recognition of the DN by government agencies that design structures, services and health legislation. Therefore, it is the task of research to fill this gap and make it available to the system.

It is estimated that the care of people with chronic diseases worldwide absorbs about 70-80% of health resources. This seems alarming with epidemiological projections predicting a dizzying increase in the number of Italians and Europeans (from 88 to 152 million) over 65 years for 2060 [16]. Health services run by nurses are one of the solutions suggested by research to cope with increasing economic pressure on the health system, as they are considered potentially capable of making the health system more accessible, less expensive and to guarantee quality and safe care [17].

The study has revealed that DN can play a fundamental role in the transformation, change and reprogramming of chronic disease care and treatment, however, the figure of the DN in MS is not present in the organisation of the Italian healthcare system and not even a specific academic path that can better define it. In the past, in the years 2008 and 2010, two editions of a master's degree in patient management with MS at the University of Genova were implemented, which were not continued in subsequent years.

For this to happen, a social, cultural, educational and contractual recognition of the role, participation and requirement of a DN must begin with a scientifically based confirmation of the profession.

CONCLUSIONS

The study showed no differences between the two groups. However, from patients' responses, the importance of DN emerges with his knowledge of the disease and treatments and nurse's capacity to help the patients in the different phases of healtcare. Consequently emerges the need of more recognition of this professional figure, as well as the need to further demonstrate the nurse's role in the management of the disease with further scientific studies.

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