

# BMJ Open Development and psychometric properties of a self-assessed knowledge questionnaire for caregivers of people with multiple sclerosis (CareKoMS): a cross-sectional study

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## ABSTRACT

**Objectives** Knowledge about multiple sclerosis (MS) is crucial for those who provide care and support as caregivers. However, despite the key benefits of acquiring relevant information to properly assume the caregiving role, caregivers' knowledge of MS is poorly investigated. The aim of this study was to develop and validate the Caregivers' Knowledge of Multiple Sclerosis (CareKoMS), a self-assessed questionnaire, to test MS knowledge in caregivers of people with MS.

**Design** Cross-sectional study.

**Setting** Italy.

**Participants** Two-hundred caregivers (female: 49%) were asked to self-administer the 32-item CareKoMS questionnaire; they had a median age of 60 years (IQR: 51–68 years) and a medium–high educational level (36.5% primary school and 63.5% high school/university). Item analysis using item difficulty index, item discrimination index, Kuder–Richardson–20 coefficient and item–total correlation were assessed. Once excluding less useful items, reliability, floor and ceiling effects and construct validity were calculated on the 21-item CareKoMS final version.

**Results** Psychometric evaluation indicates that the 21-item CareKoMS was a good questionnaire with no ceiling or floor effects registered. Internal consistency was satisfactory and acceptable as indicated by the mean value of 0.74 of Kuder–Richardson–20. No ceiling or floor effects have been observed. Interestingly, educational level and disease duration correlated with MS knowledge.

**Conclusion** CareKoMS is a valid self-assessed questionnaire on MS knowledge for caregivers that may be used in clinical practice and research. Assessing knowledge of MS among caregivers is essential to facilitate their caregiving role and thus decrease the burden of disease management.

## INTRODUCTION

Multiple sclerosis (MS) is a chronic inflammatory disease of the central nervous system characterised by demyelination and axonal loss.<sup>1</sup> About 2.3 million people are estimated to live

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Multiple sclerosis (MS) caregivers were directly involved alongside a multidisciplinary expert panel to the design and development of Caregivers' Knowledge of Multiple Sclerosis (CareKoMS) through an iterative approach contributed.
- ⇒ CareKoMS investigates a broad range of domains in the expertise of MS caregivers: aetiopathogenesis, epidemiology, diagnosis, disease course, symptoms and treatment.
- ⇒ Although CareKoMS is not a comprehensive assessment scale, it does offer a general view of a caregiver's knowledge of MS.
- ⇒ CareKoMS does not include topics such as genetic risk, use of supplements, daily variability of symptoms and cognitive impairments which is a limitation.

with MS globally,<sup>2</sup> which is the main cause of neurological disability in young and middle-aged adults in Europe and North America. As the disease progresses, the majority of people with MS (pwMS) experience the accumulation of permanent long-term disability, which results in the loss of functional independence and the increased need for personal assistance to manage the challenges of daily life and to maintain independence.<sup>3</sup> The burden of providing this support falls primarily on unpaid family members, often referred to as caregivers, who provide as much as 80% of the home care needed by individuals with MS.<sup>4</sup> Caregivers undertake various forms of support, including personal care, practical help, emotional support, help in obtaining information, that enable pwMS to participate in daily life activities and remain functioning within their home amidst gradual disease progression.<sup>5</sup>

The long disease progression allows time for caregivers to prepare and adjust to their carer roles. However, as time passes, ageing of both patient and caregiver, and the possible onset of comorbidities, add to the complexity of the disease management and to the care burden.<sup>6</sup> A large body of literature shows that MS caregivers are at risk of experiencing considerable ‘burdens’.<sup>7,8</sup> Caregiver burden is not directly related to disease duration, but appears to be associated with the extent of disease progression, MS course, disability level, psychological distress and cognitive disturbances of the care recipient.<sup>9</sup> In particular, evidence shows that slow information processing of pwMS is a major determinant of poorer mental health status in caregivers. Thus, the relationship between caregivers’ depression and pwMS information processing speed should be taken into account when planning treatment programmes for both MS caregivers and care recipients.<sup>10</sup>

Caregivers often feel overburdened with care, and lack information on how to deal with some of the complex symptoms of their relatives. Knowledge may help both pwMS and their caregivers to make sense of the disease within a holistic and constructive view of their present and future life. After all, having adequate information and MS-related knowledge has been shown to generally improve diagnosis and secondary preventive strategies in both pwMS and caregivers, such as shared decision-making,<sup>11 12</sup> disease-modifying therapy choices<sup>13</sup> treatment adherence and satisfaction with care.<sup>14</sup>

The need for consistent, reliable and current information about the disease as well as healthcare services available to both pwMS and caregivers has been greatly reported.<sup>15</sup> Research on MS caregivers showed widespread need for information in different domains, including disease progression, prognosis, treatment, general care, impact on other family members, caregiver rights and what to expect.<sup>6</sup> Qualitative evidence shows that knowledge plays an important role in reducing fear and uncertainty towards MS progression and its consequences.<sup>16</sup> Caregivers unsure about how the disease may progress or how to navigate formal care can feel overwhelmed from lacking the knowledge they need to provide adequate care. Furthermore, the main benefit of information and knowledge about MS is enabling caregivers in taking on their caregiving role and in supporting other caregivers in similar situations.<sup>17</sup> Evidence highlights the need for strategies to reduce burden and leverage positive adaptations in caregivers.<sup>7</sup>

Although attempts to assess MS knowledge in patients have been made,<sup>18 19</sup> data on disease knowledge among caregivers are scarce. In the context of caregivers and the role of disease knowledge, a study by Messmer Uccelli and colleagues<sup>20</sup> was conducted with parents of children with MS that assessed their knowledge of the disease using the Multiple Sclerosis Knowledge Questionnaire,<sup>18</sup> a self-assessment questionnaire of disease knowledge, specifically developed for use in individuals with a recent diagnosis of MS. In this study, lower knowledge of MS correlated with lower satisfaction for couple relationship

and quality of communication within the couple. Moreover, there was a significant correlation between limited knowledge about the child’s illness and the overall sense of competence as a parent of a son or daughter with MS.<sup>20</sup>

Even though existing scales shed light on the key role of caregivers’ knowledge throughout the disease evolution to provide adequate care and support, they were first developed specifically for assessing information needs of the care recipient. Thus, there is a risk that some aspects that are truly pivotal for caregivers may be overlooked. Considering the above considerations, this study aimed to develop and validate the Caregivers’ Knowledge of Multiple Sclerosis (CareKoMS), a self-assessed questionnaire to investigate disease knowledge in caregivers of pwMS.

## METHODS

The study was composed by two stages:<sup>21</sup> (1) the CareKoMS design and development and (2) the psychometric evaluations of the questionnaire.

### Patient and public involvement

Multidisciplinary expert panel and MS caregivers were collaboratively involved in the earlier stages of the study (eg, questionnaire design and development). The multidisciplinary expert panel consisted of two psychologists, one social worker, one physical therapist, one neurologist, one psychiatrist and one nurse, working at the Italian MS Society (AISM) Rehabilitation Service in Genoa. Six caregivers of pwMS (three females) were recruited from the AISM Rehabilitation Service in Genoa, as relatives providing care and help in daily activities to outpatients with MS. Caregivers were selected also considering the level of independence of the pwMS they provided care to. Panel experts and caregivers were involved in the development of the preliminary 32-item version of CareKoMS to ensure representation of the broadest possible range of relevant MS expertise.

### CareKoMS design and development

The design and development stage was carried out in two phases at the Italian MS Foundation (FISM) based in Genoa (Italy).

#### Phase I

Based on a comprehensive review of the literature and caregiver-targeted guidelines defined by global network of MS organisations (MSIF),<sup>22</sup> which includes AISM,<sup>23</sup> the research team and the expert panel jointly identified six domains: aetiopathogenesis, epidemiology, diagnosis, disease course, symptoms and treatment.

The multidisciplinary expert panel built a bank of 43 multiple-choice questions selecting from existing tools and questionnaires.<sup>18</sup> The questions covered the six domains as follows—aetiopathogenesis: 11 items; epidemiology: 6 items; diagnosis: 5 items; disease course: 7 items; symptoms: 9 items; treatment: 5 items. All 43 items

allowed three answer options and one 'I do not know the answer' option. The latter was included to avoid the respondents guessing. Only one response was correct.

### Phase II

The six caregivers completed the questionnaire in two rounds of cognitive interviews.<sup>24</sup> Caregivers were asked to 'think aloud' to comment whether and to what extent the 43-items and answer options fulfilled the following criteria: appropriateness, accuracy and relevance. Comments were collected and analysed thematically using MS Excel to identify common themes, points of feedback, challenges to the items and queries about wording and then presented to the expert panel. Modifications to the questionnaire were made between the first and the second round. Items were deleted if full agreement among caregivers could not be reached regarding its relevance, whereas items found to be unclear (ie, readability criterion) were reviewed by the experts. As a result of this process, 11 items were eventually removed and 10 were reviewed for clarity. The second round of cognitive interviews only led to minor changes in the questionnaire. A debriefing meeting was held with the six caregivers and resulted in the preliminary version of 32-item CareKoMS.

### Psychometric evaluation

The psychometric evaluation stage was also carried out in two phases.

#### Phase I

The preliminary version of the 32-item CareKoMS was analysed in order to delete items with low performance scores. The analysis was run considering the following outcomes:

1. Item difficulty index (P) was calculated as the percentage of correct responses to the test item. An item was considered difficult when P was <10% and easy when was >90%.<sup>24</sup>
2. Discrimination index (D) was calculated as described by Kline.<sup>25</sup> Based on their total score, the respondents were divided in two groups, high total score versus low total score, with 27% of respondents in each group. For every item, the percentage correct answers of the lower 27% group was subtracted from the % correct answers of the upper 27% group. D may range from -1 to +1, with 1 being a perfect correlation between respondents selecting the correct response and also scoring high marks on the test and -1 being for questions where respondents answered incorrectly, but scored highly overall. Based on Ebel's (1972) guidelines on classical test theory item analysis, items were categorised in their discrimination indices.<sup>26 27</sup> The item with negative D was considered to be discarded (D: 0.0 to 0.19—poor item, to be revised; D: 0.2 to 0.29—acceptable; D: 0.3 to 0.39—good; D: >0.4—excellent).
3. Item-total correlation was calculated for each item.<sup>28</sup> This is the Pearsonian correlation coefficient of each

individual test item with the total of scores on all other items, ranging from -1.00 to +1.00. Higher values indicate that items are well correlated with the total score. Items with an item-total correlation <0.2 have been identified as candidates for removal.

#### Phase II

After removing worse performing items at previous outcomes, we evaluated reliability, presence of floor and ceiling effects and construct validity of the final version of CareKoMS. Reliability was assessed through estimation of internal consistency, using the Kuder-Richardson-20 coefficient for dichotomously scored items, with values above 0.70 considered as acceptable.<sup>29</sup> Floor and ceiling effects were explored by examining the frequency of highest and lowest possible scores in both subscales. Floor and ceiling effects were considered present if >15% of participants achieved either the lowest or highest scores.<sup>30</sup> Construct validity was analysed using known groups technique.

### Recruitment, data collection and measures

Caregivers were recruited through pwMS in the caseload of psychologists who participate in the AISM promoted network 'Rete Psicologi' (ie, Psychologists Network) that includes professionals with expertise on MS. Caregivers were identified by psychologists based whether they would provide one or more of the following care tasks as defined by Buchanan and colleagues<sup>4</sup>: personal care, homemaking, assistance with daily activities, mobility, and leisure activities.

Caregivers were invited to take part in the study in person or by telephone if necessary, from May 2021 to December 2021.

The project was approved by the local Ethics Committee of Azienda Ospedaliera 'San Martino' (protocol name: Competence in MS Caregivers; number 400/2019) and all caregivers signed an informed consent form prior to their inclusion in the study.

All caregivers completed the self-administered CareKoMS and filled a sociodemographic form including information such as sex, age and education level. Care recipient's disease duration and disability level according to the self-Expanded Disability Status Scale<sup>31</sup> (self-EDSS) were also collected. At the end of administration session, psychologists checked that CareKoMS, caregivers' and care recipients' forms were entirely fulfilled by each participant to prevent missing data.

### Data analysis

To establish the initial psychometric properties of the questionnaire, the minimum sample size has been estimated based on five participants per item.<sup>32</sup> As the number of preliminary version is 32, a minimum of 160 participants has been required to complete the questionnaire initially (T0).

Descriptive statistics were used to summarise socio-demographic information such as sex, age and education level and single items. Items were recoded into a

**Table 1** CareKoMS scale and items properties

Items	D	P (%)	Item-total correlation	KR-20*	Topic
Items included in the final scale					
CareKoMS 4	0.24	46	0.25	0.76	Aetiopathogenesis
CareKoMS 5	0.35	29	0.21	0.75	Epidemiology
CareKoMS 7	0.44	81	0.38	0.73	Epidemiology
CareKoMS 10	0.56	42	0.32	0.74	Disease course
CareKoMS 11	0.57	46	0.36	0.73	Disease course
CareKoMS 12	0.54	68	0.37	0.73	Disease course
CareKoMS 13	0.56	48	0.31	0.74	Disease course
CareKoMS 14	0.46	66	0.33	0.74	Disease course
CareKoMS 15	0.43	70	0.29	0.74	Disease course
CareKoMS 16	0.48	78	0.38	0.73	Symptoms
CareKoMS 17	0.41	74	0.25	0.74	Symptoms
CareKoMS 19	0.52	75	0.41	0.73	Symptoms
CareKoMS 20	0.35	87	0.39	0.73	Symptoms
CareKoMS 25	0.54	62	0.34	0.73	Treatment
CareKoMS 26	0.20	90	0.20	0.74	Treatment
CareKoMS 27	0.43	68	0.26	0.74	Symptoms
CareKoMS 28	0.30	82	0.27	0.74	Symptoms
CareKoMS 29	0.33	86	0.34	0.74	Symptoms
CareKoMS 30	0.39	74	0.29	0.74	Treatment
CareKoMS 31	0.43	52	0.24	0.74	Symptoms
CareKoMS 32	0.44	48	0.24	0.74	Symptoms
Items removed from the final scale					
CareKoMS 1	0.11	96	0.22	0.75	Aetiopathogenesis
CareKoMS 2	0.28	92	0.08	0.74	Aetiopathogenesis
CareKoMS 3	0.19	88	0.11	0.75	Aetiopathogenesis
CareKoMS 6	0.28	70	0.17	0.75	Epidemiology
CareKoMS 8	0.17	44	0.08	0.76	Diagnosis
CareKoMS 9	0.11	95	0.16	0.75	Diagnosis
CareKoMS 18	0.19	82	0.14	0.75	Symptoms
CareKoMS 21	0.07	90	0.06	0.75	Symptoms
CareKoMS 22	0.30	72	0.13	0.75	Treatment
CareKoMS 23	0.06	97	0.16	0.75	Treatment
CareKoMS 24	0.26	86	0.17	0.74	Treatment

\*Corrected internal consistency calculated using Kuder-Richardson-20 coefficient obtained removing one item in turn. CareKoMS, Caregivers' Knowledge of Multiple Sclerosis; D, discrimination index; KR-20, Kuder-Richardson-20 coefficient; P, item difficulty.

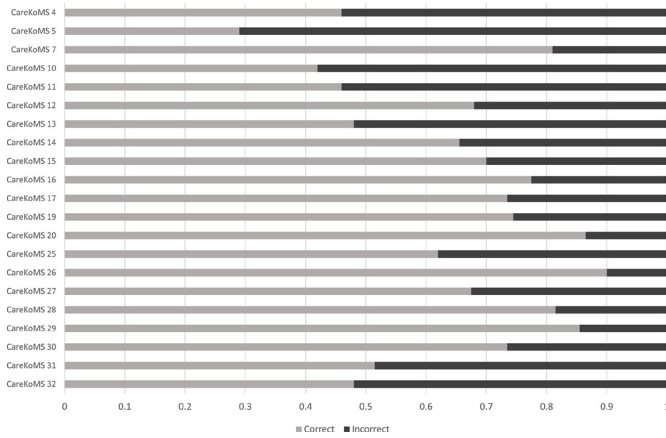
dichotomous variable (correct–not correct). The 'I do not know' option was recoded as 'not correct'. Instrument total score was obtained by summing each correct answer. The independent non-parametric test (Wilcoxon or Kruskal-Wallis test) was used to compare the knowledge scores between the predefined groups (known groups technique). In particular, associations between CareKoMS and caregivers' characteristics as sex, age class codified as <60 and ≥60 years (median sample aged) and educational level were assessed. Care recipients'

self-EDSS scores were stratified in three levels: mild (self-EDSS 0–3), moderate (self-EDSS 4–6.5) and severe (self-EDSS ≥7) disability and disease duration codified as <23 and ≥ 23 years (median sample illness duration). Data were analysed using the STATA Statistical Software V.15 (StataCorp LP, College Station, Texas, USA).

## RESULTS

Two-hundred caregivers (female: 49%) participated in the study; they had a median age of 60 years (IQR: 51–68





**Figure 1** Distribution of MS caregivers' answers to each CareKoMS questionnaire item. Percentage of correct responses provided by caregivers of pwMS to each item is represented in light grey scale colour, while incorrect responses are in dark grey colour. CareKoMS, Caregivers' Knowledge of Multiple Sclerosis.

years) and a medium–high educational level (36.5% primary school and 63.5% high school/university). No missing data were found.

**Psychometric evaluation of the 32-item CareKoMS**

Results from the psychometric analysis are presented in table 1. P ranged between 29% and 97%, average percentage was 71%. None of the questions had  $p < 10\%$ , while four items had  $p > 90\%$ .

Overall, D ranged from 0.06 to 0.57, mean was 0.34 ( $\pm 0.15$ ). None of the items had a negative D and seven items had  $D < 0.20$ .

Besides, 10 items had an item-total correlation  $< 0.20$ . Finally, overall Kuder-Richardson-20 value was 0.75, and values obtained excluding each item in turn ranged from 0.73 to 0.76 (see table 1).

This resulted in the final version of 21-item CareKoMS.

**Psychometric evaluation of the final 21-item CareKoMS**

The mean score of the 21-item CareKoMS was 13.7 (SD: 3.7; median: 14; IQR: 11–16), no ceiling or floor effects were registered. Score distribution was skewed, and the normality assumption rejected ( $p = 0.042$ ). Kuder-Richardson-20 coefficient was 0.74, indicating good

internal consistency. Figure 1 shows the percentages of the correct and incorrect answers provided by the participants in each item (final 21-item CareKoMS and its English translation are presented in online supplemental material 1).

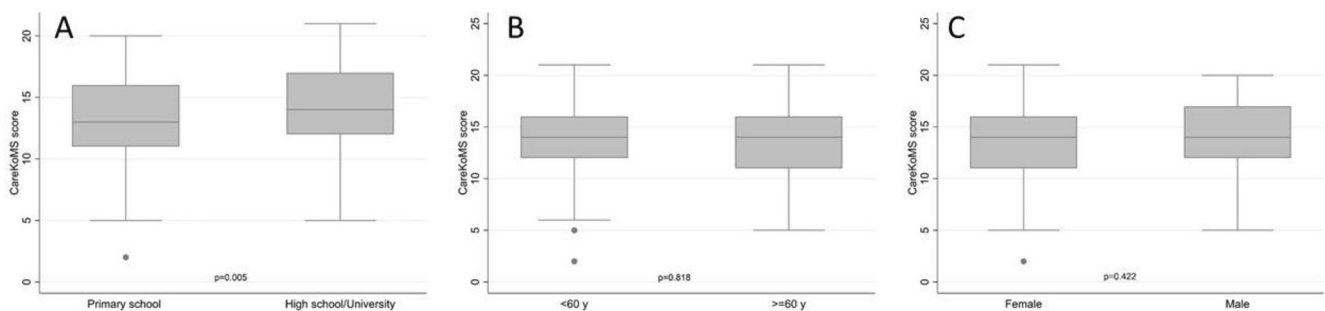
Known groups technique to test construct validity indicates that group scores of the caregivers with a high educational level were significantly higher than those of the caregivers with lower educational level ( $p = 0.005$ ) (see figure 2A), while age class ( $p = 0.818$ ) (figure 2B) and sex ( $p = 0.422$ ) (figure 2C) were not associated with CareKoMS total score. By analysing the characteristics of care recipients, we observed that caregivers who took care of pwMS with longer disease duration showed higher CareKoMS total scores than ones who took care of pwMS with shorter disease duration ( $p = 0.007$ ) (figure 3A), while no difference was observed for disability level ( $p = 0.060$ ) (figure 3B). All procedures necessary to replicate these analyses are available via request to the corresponding author of the present study.

**DISCUSSION**

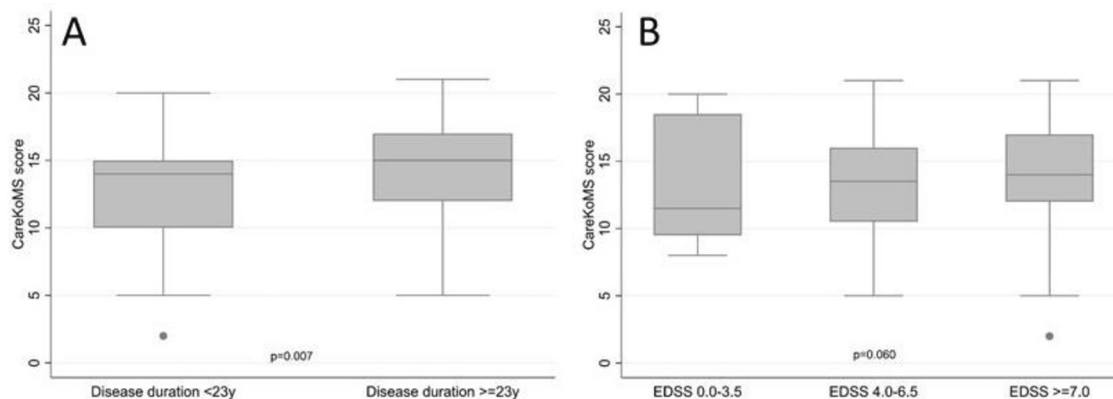
Information needs about MS are crucial for those who provide care and support. In this context, it is essential to obtain a reliable assessment of caregivers' knowledge. Therefore, we developed the CareKoMS questionnaire, a self-assessed instrument to investigate disease knowledge among caregivers of pwMS.

As far as we know, this is the first study to validate a tool to measure knowledge of MS in caregivers of pwMS. Psychometric evaluation indicates that the 21-item CareKoMS questionnaire was good with no ceiling or floor effects registered. Internal consistency was satisfactory and acceptable as indicated by the mean value of 0.74 of Kuder-Richardson-20.

Four items, related to symptoms (items 20, 28, 29) and treatment (item 26), were answered correctly by the majority of caregivers as indicated by item difficulty index ( $p > 85\%$ ). In line with literature, basic symptoms and typical course of the disease are generally well known, so it is not surprising that, as disease progresses adding burden to pwMS, caregivers were aware of the most



**Figure 2** Known groups technique to compare CareKoMS scores between educational level, age and sex. Box-plot graphs show associations between CareKoMS scores (vertical axis) and caregivers' characteristics as educational level (panel A), age (panel B) and sex (panel C) (horizontal axis). Dots represent outliers. CareKoMS, Caregivers' Knowledge of Multiple Sclerosis.



**Figure 3** Known groups technique to compare CareKoMS scores between disease duration and self-EDSS. Box-plot graphs show associations between CareKoMS scores (vertical axis) and disease-related characteristics of the care recipient as disease duration (panel A) and self-EDSS (panel B) (horizontal axis). Dots represent outliers. CareKoMS, Caregivers' Knowledge of Multiple Sclerosis; self-EDSS, self-Expanded Disability Status Scale.

common symptoms (items 20, 28, 29) and aids for pwMS (eg, a cane, walker, straps, magnifying glasses) (item 26).

Interestingly, caregivers' educational level was positively associated with MS knowledge. This is in line with a study by Iyer *et al*,<sup>33</sup> who found that lower education in caregivers of people with epilepsy led to higher risk of inadequate factual knowledge. This could be explained by the 'knowledge-gap hypothesis' which points to the faster acquisition of knowledge by people of higher compared with people of lower educational level when information is given to any social system thereby increasing the knowledge gap between them.<sup>34</sup> The fact that individuals with higher levels of education scored better on care understanding was also confirmed by Jorge *et al*<sup>35</sup> and Eshbaugh and Stratton<sup>36</sup> who investigated knowledge of caregivers of people with Alzheimer disease. Interestingly, a positive association between education and disease knowledge has been reported in pwMS as well as with other chronic conditions as diabetes and rheumatoid arthritis.<sup>18 37 38</sup>

Furthermore, we found an association between MS knowledge and disease duration of care recipient, suggesting that longer disease duration would give the caregiver more time to learn about the disease. However, previous studies report contradictory results about the relationship between disease knowledge and disease duration in patients. Barlow and colleagues (1999) found that people with longer experience of rheumatoid arthritis had similar levels of knowledge compared with those with a shorter disease duration.<sup>39</sup> However, it is generally believed that people in the early stages of their disease feel that they are given more information than they can cope with.<sup>40</sup> For instance, patients with diabetic retinopathy with a disease duration of 5 years or more showed a better knowledge compared with individuals with a recent diagnosis.<sup>41</sup> It is reasonable to speculate that caregivers could accrue enough knowledge to provide care from experience as the disease of their relative progresses over time.

Following Giordano and colleagues (2010), test-retest reliability of the CareKoMS was not assessed since a

questionnaire about caregivers' knowledge of MS is not expected or required to be stable over time. Indeed, assessing test-retest reliability could lead to the risk of observing an increase in knowledge as a result of repeated exposure to the same questionnaire contents.<sup>18</sup>

### Strengths and limitations

One possible limitation is that CareKoMS does not include some topics such as the genetic risk, use of supplements and daily variability of symptoms. Furthermore, only one item (item 12) investigated knowledge about cognitive difficulties, such as language problems. Since caregiver burden has been shown to be predicted by care recipient's working memory, information processing speed, executive functioning and verbal fluency,<sup>9</sup> having proper knowledge about cognitive deficits could be helpful for caregivers in dealing with the cognitive consequences of MS and thus may therefore be particularly beneficial in reducing burden. However, it is therefore important to acknowledge that, although the CareKoMS is not a comprehensive assessment scale, it does offer a general view of a caregiver's knowledge of MS. One strength of the instrument is represented by the direct engagement of MS caregivers and multidisciplinary expert panel through an iterative approach from the earlier stages of CareKoMS design and development.

### CONCLUSION

Having adequate MS-related information may help caregivers to assume their caregiving role, gain awareness about aspects of MS that they were previously unaware of and adopt proper decisions about one's own health. Furthermore, investigating MS knowledge is important for planning effective educational strategies to reduce burden and leverage positive adaptations in MS caregivers. Thus, CareKoMS may play a valuable role in identifying when and where caregivers need tailored interventions. In this view, both AISM and FISM actively protect the collective interest of pwMS, their caregivers

and people with correlated and similar pathologies (eg, neuromyelitis optica). Their commitment is clearly stated in the ‘*Carta dei Diritti delle persone con sclerosi multipla e patologie correlate, loro familiari e caregiver*’,<sup>42</sup> that asserts the right to accurate and reliable information for both pwMS and their caregivers, closely linked to the sphere of personal freedom and self-determination.

Overall, our findings suggest that providing education to bridge the knowledge gap, promoting appropriate intervention and supporting media for information transfer should be highly recommended to ensure caregivers’ self-management skills mastery.

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**Contributors** JP was responsible for study concept and design. JP undertook a literature review, developed the questionnaire, conducted and analysed data collected from the multidisciplinary expert panel and focus groups with MS caregivers and drafted the original paper. AT contributed to study design and concept and provided methodological expertise in the interpretation of results. AV cleaned the original data and produced the database used for analysis. She was involved in data extraction and analysis. MAB was responsible for funding acquisition. GB supervised the study and appraised the paper. MP was the principal investigator and the guarantor of the study. She also provided methodological expertise in assessing the psychometric properties, including the approach to analysis and interpretation of the results. She obtained ethical and governance approvals for this study. All authors critically reviewed and approved the final version of the manuscript.

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**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

**Patient consent for publication** Not applicable.

**Ethics approval** This study involves human participants and was approved by the local Ethics Committee of Azienda Ospedaliera ‘San Martino’ (protocol name: Competence in MS Caregivers; protocol number 400/2019). Participants gave informed consent to participate in the study before taking part.

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**Data availability statement** Data are available upon reasonable request. Data are available upon reasonable request to MP (michela.ponzio@aism.it).

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## REFERENCES

- Kamm CP, Uitdehaag BM, Polman CH. Multiple sclerosis: current knowledge and future outlook. *Eur Neurol* 2014;72:132–41.
- Thompson AJ, Banwell BL, Barkhof F, *et al*. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol* 2018;17:162–73.
- Rivera-Navarro J, Benito-León J, Oreja-Guevara C, *et al*. Burden and health-related quality of life of Spanish caregivers of persons with multiple sclerosis. *Mult Scler* 2009;15:1347–55.
- Buchanan R, Radin D, Chakravorty BJ, *et al*. Perceptions of informal care givers: health and support services provided to people with multiple sclerosis. *Disabil Rehabil* 2010;32:500–10.
- Hughes N, Locock L, Ziebland S. Personal identity and the role of ‘carer’ among relatives and friends of people with multiple sclerosis. *Soc Sci Med* 2013;96:78–85.
- Borreani C, Bianchi E, Pietrolongo E, *et al*. Unmet needs of people with severe multiple sclerosis and their carers: qualitative findings for a home-based intervention. *PLoS One* 2014;9:e109679.
- Buchanan RJ, Radin D, Huang C. Caregiver burden among informal caregivers assisting people with multiple sclerosis. *Int J MS Care* 2011;13:76–83.
- McKenna O, Fakolade A, Cardwell K, *et al*. A continuum of languishing to flourishing: exploring experiences of psychological resilience in multiple sclerosis family caregivers. *Int J Qual Stud Health Well-Being* 2022;17:2135480.
- Maguire R, Maguire P. Caregiver burden in multiple sclerosis: recent trends and future directions. *Curr Neurol Neurosci Rep* 2020;20:18.
- Labiano-Fontcuberta A, Mitchell AJ, Moreno-García S, *et al*. Anxiety and depressive symptoms in caregivers of multiple sclerosis patients: the role of information processing speed impairment. *J Neurol Sci* 2015;349:220–5.
- Colligan E, Metzler A, Tiryaki E. Shared decision-making in multiple sclerosis. *Mult Scler* 2017;23:185–90.
- Brown H, Gabriele S, White J. Physician and patient treatment decision-making in relapsing-remitting multiple sclerosis in Europe and the USA. *Neurodegener Dis Manag* 2018;8:371–6.
- Kasper J, Köpke S, Mühlhauser I, *et al*. Informed shared decision making about immunotherapy for patients with multiple sclerosis (ISDIMS): a randomized controlled trial. *Eur J Neurol* 2008;15:1345–52.
- Solari A, Martinelli V, Trojano M, *et al*. An information aid for newly diagnosed multiple sclerosis patients improves disease knowledge and satisfaction with care. *Mult Scler* 2010;16:1393–405.
- Queluz FNFR, Kervin E, Wozney L, *et al*. Understanding the needs of caregivers of persons with dementia: a scoping review. *Int Psychogeriatr* 2020;32:35–52.
- Kirkpatrick Pinson DM, Ottens AJ, Fisher TA. Women coping successfully with multiple sclerosis and the precursors of change. *Qual Health Res* 2009;19:181–93.
- McCabe M, You E, Tatangelo G. Hearing their voice: a systematic review of dementia family caregivers’ needs. *Gerontologist* 2016;56:e70–88.
- Giordano A, Uccelli MM, Pucci E, *et al*. The multiple sclerosis knowledge questionnaire: a self-administered instrument for recently diagnosed patients. *Mult Scler* 2010;16:100–11.
- Bessing B, Honan CA, van der Mei I, *et al*. Development and psychometric properties of the multiple sclerosis knowledge assessment scale: Rasch analysis of a novel tool for evaluating MS knowledge. *Mult Scler J* 2021;27:767–77.
- Messmer Uccelli M, Traversa S, Trojano M, *et al*. Lack of information about multiple sclerosis in children can impact parents’ sense of competency and satisfaction within the couple. *J Neurol Sci* 2013;324:100–5.
- Mishel MH. Methodological studies: instrument development. In: Brink, P., Wood, M. (Eds.), *Advanced Design in Nursing Research*, Sage, Newbury Park 1998;2:238–284.
- MFIS Website. n.d. Available: <https://www.msif.org/>
- AISM Website. n.d. Available: <https://www.aism.it/>
- Izard J. For Educational Planning II. Trial testing and item analysis in test construction. International Institute for Educational Planning/UNESCO; 2005. Available: <https://books.google.it/books?id=JbaeAQAACAAJ>
- Kline TJ. Classical test theory: assumptions, equations, limitations, and item analyses. In: *Psychol Test A Pract Approach to Des Eval*. 2005: 91.
- Ebel RL, Frisbie DA. *Essentials of educational measurement*. 1972.
- Zubairi AM, Kassim NLA. Classical and Rasch analyses of Dichotomously scored reading comprehension test items. *Malaysian J ELT Res* 2006;2:1–20. Available: <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.535.2955&rep=rep1&type=pdf>



- 28 Clark LA, Watson D. Constructing validity: new developments in creating objective measuring instruments. *Psychol Assess* 2019;31:1412–27.
- 29 Bowling A. *Research methods in health: investigating health and health services*. McGraw-hill education (UK), 2014.
- 30 McHorney CA, Tarlov AR. Individual-patient monitoring in clinical practice: are available health status surveys adequate?. *Qual Life Res* 1995;4:293–307.
- 31 Kobelt G, Berg J, Lindgren P, et al. Costs and quality of life of patients with multiple sclerosis in Europe. *J Neurol Neurosurg Psychiatry* 2006;77:918–26.
- 32 Rattray J, Jones MC. Essential elements of questionnaire design and development. *J Clin Nurs* 2007;16:234–43.
- 33 Iyer RS, Sunny AA, Jaranraj N, et al. Knowledge gap exists among caregivers of adults compared to caregivers of children with epilepsy: a comparative analysis from a low resource setting. *Epilepsy Behav Rep* 2022;18:100528.
- 34 Viswanath K, Finnegan JR. The knowledge gap hypothesis: twenty-five years later. *Ann Int Commun Assoc* 1996;19:187–228.
- 35 Jorge C, Cetó M, Arias A, et al. Level of understanding of Alzheimer disease among caregivers and the general population. *Neurologia (Engl Ed)* 2021;36:426–32.
- 36 Eshbaugh E, Stratton L. Knowledge of Alzheimer's disease among family caregivers. *J Comm Pub Health Nurs* 2016;02:2–7.
- 37 Hennell SL, Brownsell C, Dawson JK. Development, validation and use of a patient knowledge questionnaire (PKQ) for patients with early rheumatoid arthritis. *Rheumatology (Oxford)* 2004;43:467–71.
- 38 Youssef G, Ip EH, Magee M, et al. Validity and reliability of a (brief) diabetes "survival skills" knowledge test: KNOW diabetes. *Diabetes Educ* 2019;45:184–93.
- 39 Barlow JH, Cullen LA, Rowe IF. Comparison of knowledge and psychological well-being between patients with a short disease duration ( $\leq 1$  year) and patients with more established rheumatoid arthritis ( $\geq 10$  years duration). *Patient Educ Couns* 1999;38:195–203.
- 40 Barlow JH, Pennington DC, Bishop PE. Patient education leaflets for people with rheumatoid arthritis: a controlled study. *Psychol Heal Med* 1997;2:221–35.
- 41 Knowledge on diabetic retinopathy among diabetes mellitus patients attending the Colombo South teaching hospital, Sri Lanka. *UCMS* 2016;13.
- 42 AISM. Carta Dei Diritti delle Persone con sclerosi multipla e Patologie correlate, Loro Familiari E Caregiver. 2022. Available: [https://agenda.aism.it/2022/download/Carta\\_dei\\_diritti\\_2022.pdf](https://agenda.aism.it/2022/download/Carta_dei_diritti_2022.pdf)