PART A

1. Research project title

PREferences related to Quality Of Life attributes in Multiple Sclerosis: patient and health professionals' views [PREQOLIMS]

2. Duration (months)

24 months

3. Main ERC field

SH - Social Sciences and Humanities

4. Possible other ERC field

LS - Life Sciences

5. ERC subfields

1. SH4_3 Clinical and health psychology
2. SH7_4 Social aspects of health, ageing and society
3. LS5_11 Neurological and neurodegenerative disorders

6. Keywords

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<td>1.</td>
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2. multiple sclerosis
3. patient reported outcomes
4. decision making
5. health psychology

7. Principal Investigator

ROSATO  
Surname

ROSALBA  
Name

Professore Ordinario (L. 240/10)  
Qualification

OMISSIS  
Date of birth

OMISSIS  
Personal identification code

Università degli Studi di TORINO  
Organization

OMISSIS  
Phone number

OMISSIS  
E-mail address

PI - Certified E-mail (CEM)

OMISSIS

Age limits derogation

The PI and/or the substitute PI are over 40 and they don't intend to benefit from derogations to the age limits for the amount allocated to under 40 PI;

8. List of the Research Units

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<td>1</td>
<td>ROSATO Rosalba</td>
<td>Professore Ordinario (L. 240/10)</td>
<td>Università degli Studi di TORINO</td>
<td>Via Verdi, 8 - TORINO (TO)</td>
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<td>PATTI Francesco</td>
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9 - Substitute Principal Investigator *(To be identified among one of the associated investigators participating in the project).*

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10. Brief description of the proposal

Multiple sclerosis (MS) is a chronic disease bringing to a broad spectrum of physical, social and psychological effects. Previous studies showed that health related quality of life (HRQOL) dimensions are not all equally important for people with MS (PwMS). Information about HRQOL preferences allows physicians to better understand patient expectations about the possible changes during MS, and let them make appropriate clinical decisions.

The main aims of the study are: 1) To identify a set of attributes that define the HRQOL construct; 2) To measure what matters to patients in terms of utility preferences; 3) To assess the influence of socio-demographic, clinical and psychological characteristics with preference priorities; and 4) To ascertain health professionals (HPs)’ perception regarding their patients’ preference patterns. This is a prospective, multi-center, non-interventional study involving PwMS and HPs, consisting of two phases.

Phase 1 - Identification of a set of HRQOL attributes. A literature review will be followed by a one-day consensus meeting with PwMS, PwMS’s significant others, neurologists, and other HPs. At the end, a set of HRQOL attributes will be identified.

Phase 2 - Assessment of patients’ and HPs’ preferences. A minimum of 600 PwMS will be recruited from those attending the MS center for a scheduled visit. Consenting PwMS will fill out an ad hoc socio-demographic and clinical questionnaire, and seven inventories assessing HRQOL, personality, perceived social support, and self-efficacy and coping style. PwMS preferences for different HRQOL dimensions will be assessed using a Discrete Choice Experiment (DCE). The DCE will be made up of several scenarios in which two health profiles will be presented. For each scenario, respondents will answer which hypothetical person was, in their opinion, in the best health state. Using the same list of HRQOL attributes that describe the DCE health profiles, PwMS will rank the attributes of their own HRQOL in order of importance from the most important to the least important. A sample of at least 65 neurologists and 65 other MS HPs will be recruited. They will be invited to complete an online questionnaire including personal information, center’s features, and then, in order to evaluate their notion of patients’ preference patterns, they will be asked to do the same HRQOL attribute ranking as did for PwMS.

DCE data will be analyzed using a finite mixture logit model, while the ranking of HRQOL attributes given by PwMS and HPs will be analyzed through Z-tests and odds ratios. This study will help identify those HRQOL dimensions that are prioritized by PwMS, and to compare them with those prioritized by their HPs. These data will help clinicians to provide a care that is better aligned to PwMS needs and priorities.

11. Total cost of the research project identified by items

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N.B. The Item B and TOTAL columns will be filled in automatically

- item A.1: enhancement of months/person of permanent employees
- item A.2.1: cost of contracts of non-employees, specifically to recruit
- item B: overhead (flat rate equal to 60% of the total personnel cost, A.1+A.2.1, for each research unit)
- item C: cost of equipment, tools and software products
- item D: cost of consulting and similar services
- item E: other operating costs

PART B

B.1
1. State of the art

Multiple sclerosis (MS) is a chronic inflammatory disease of the central nervous system, and the most common disabling neurological disease in young adults [1,2]. MS is associated with diverse symptoms (such as fatigue, pain, depression, and cognitive dysfunction) which are difficult to quantify by health care providers but significantly interfere with the patient’s ability to work, and perform activities of daily living [3].

In recent years, clinical authorities and regulatory guidelines recommend that new drugs support labeling claims of benefits to patients using outcomes considered relevant to patients and expressed using the patient voice, by promoting the use of health-related quality of life (HRQOL) instruments. HRQOL instruments are intended to improve the detection of disease aspects that would otherwise go unrecognized, help clinicians identify patient priorities (particularly those related to treatment goals), facilitate physician-patient communication, and promote shared decision making [4].

HRQOL instruments allow the assessment of patient well-being including multiple dimensions, but do not take into account how much relevant is each of these dimensions for each individual patient. As stated by O’Boyle et al. [5], “[…] a valid measure of HRQOL should quantify the level of functioning of each individual in those areas of life that he/she believes to be most important” (p. 1088), however, this may be too cumbersome to achieve. Thus, increasing knowledge of what is most important for PwMS and how they differ in their HRQOL attribute relevance rankings may be further investigated.

Different approaches to the HRQOL assessment have been proposed [6]. Health profile questionnaires focus on mental and emotional status, physical and social functioning, and include a set of items measuring the impairment for each HRQOL domain. However, these questionnaires do not assess the patient priority on each HRQOL aspect. Preference measures, on the other hand, allow to estimate the importance placed to any specific HRQOL aspect, benefits or losses [7]. While many HRQOL key dimensions can be measured using the health profile questionnaires, the only way to balance gains in one area against losses in another is to use ‘utility theory’. According to the utility theory, when people make choices under condition of uncertainty, first of all they construct a representation of options, contingencies and outcomes that are relevant to the choice and afterwards, they assess the value of each option, and choose accordingly. Imagine a treatment for fatigue that leaves the patient with weak legs, unable to walk. Clearly, the “value” of reducing fatigue is not as high as the “value” of walking. Thus, patients would likely, if asked, prefer to walk than to reduce their fatigue. This utility value reflects the desirability or preference an individual has for a given HRQOL aspect, and can be equated to a measure of the strength of that preference [8].

Discrete Choice Experiments (DCEs) have been extensively used to estimate the relative importance (or ‘utility function’ in health economics), to value health care intervention and policies [9]. DCEs are also applied to understand preferences for HRQOL attributes given by respondents, but it is likely that individuals vary in which features of HRQOL matter to them most. In a previous pilot study [10], we found that three classes of PwMS exist: the first mainly worried about physical impairments, the second worried about pain/fatigue and emotional dimensions, while the third was worried by anxiety/depression. However, a possible relevant HRQOL dimension, such as the social domain, was not included in that study.

Previous studies highlighted also that patients’ rankings (i.e. preferences) vary according to patient mobility [11], age, type of MS diagnosis, and treatment [10]. However, it cannot be ruled out that other personal characteristics dealing with values, personality or beliefs could play a role, combined with demographics, and disease-related variables. Previous studies showed that several psychological factors predict individual differences in MS adjustment. Coping strategies used to manage illness-related demands, perceived self-efficacy regarding generic life situations and MS management, illness perception, social support perception, optimism and illness acceptance were found to be relevant in predicting MS adjustment [12]. These factors could also be related to individual differences in priority ranking.

Moreover, not only different patients can attach more or less importance to the different HRQOL aspects, but also their evaluation could differ from that of their HPs. When asked, physicians typically indicate the physical domain as the most important for PwMS [4,11,13], and undervalue psychological/mental dimensions, such as vitality [11,13], mental health [8] or emotional role limitation [4, 11,13].

2. Detailed description of the project: methodologies, objectives and results that the project aims to achieve and its interest for the advancement of knowledge, as well as methods of dissemination of the results achieved

The overall aim of the present study is to derive a map of patient priorities that will contribute to a more comprehensive understanding of which aspects of patients’ daily lives need to be most preserved, which characteristics are associated with these priorities, and how physicians are aware of these preferences by adopting a person-centered healthcare perspective. This information could help improve the use of HRQOL inventories as outcome measures, and improve shared decision-making process. This general aim may be detailed in the following specific milestones (M):

M1. To identify the set of attributes that define the HRQOL construct in PwMS, examining the existing MS-specific instruments and the results of studies investigating this topic. Potentially important HRQOL attributes will be identified by literature review. The provisional pool of HRQOL dimensions will be discussed using the nominal group technique (NGT) with PwMS, significant others, neurologists, and other health professionals (HP) with the aim to define the most important HRQOL dimensions for all participants.

M2. To measure what matters most to PwMS by conducting a DCE about the HRQOL dimensions affected by the disease. We hypothesized that there could be different PwMS sub-populations that vary in what aspects of HRQOL matter most to them. However, no specific hypotheses were formulated regarding the magnitude of differences or what particular attribute would be consistently more highly valued by PwMS. PwMS preferences will be also assessed asking them to rank the HRQOL attributes from the most important to the least important.
M3. To understand the variables mainly differentiating the PwMS sub-populations, and accounting for their preferences and group membership, we will assess the association between preferences scores with socio-demographic and clinical variables, such as age, gender, education, disease duration, medications, comorbidities, self-reported HRQOL and psychological factors. We hypothesize that psychological factors, such as perceived self-efficacy and coping strategies in facing illness-related conditions, locus of control beliefs, illness perception, perceived social support alongside personality traits may contribute to account for PwMS' priorities ranking.

M4. To ascertain the professionals' perception of their patients' preference patterns, and whether they are consistent with patients' actual preferences. Therefore, the primary research question is not what doctors and other HPs themselves think it is important, but what they believe is important from a patient's perspective.

The general management and coordination of the research activities [WP1] will be conceived to guarantee an optimal collaborating interchange among participating units. A project web site and a web application for data collection, storage, and an electronic Case Report Form (eCRF) will be developed. To comply with privacy regulations, an identification code will be generated for each participant without the possibility of tracing the real identity.

PHASE 1-IDENTIFICATION OF A SET OF HRQOL ATTRIBUTES [WP2-WP3]

The objective of this phase will be to identify MS-specific HRQOL instruments, and systematically assess the development process, the reliability and validity of such instruments.

[WP2] Literature review. We will systematically assess clinical trials, and observational studies concerned with HRQOL. Our database search will be applied to Medline and adapted for EMBASE, PsycINFO, CINAHL, and Google Scholar. Search terms will include “health-related quality of life”, “quality of life”, “health profiles”, “well-being”, and “multiple sclerosis”. Two researchers will check titles and abstracts identified by the search and decide independently which should be examined further. Findings will be qualitatively synthesized in a research template considering the HRQOL dimensions investigated, the questionnaires used [14], and their psychometric properties. A specific part of the review will deal with the evaluation of psychological aspects that may impact on HRQOL preference.

A provisional list of relevant HRQOL attributes in MS will be prepared to be used in the next WP.

[WP3] Nominal Group Technique meeting. The consensus meeting aims to select a maximum of 6/7 HRQOL dimensions, i.e. the most important for PwMS. A one-day consensus meeting with PwMS, significant others (SOs), neurologists, and other HPs will be held using the nominal group technique (NGT), which is a consensus method commonly adopted in health service research [15-16]. No fixed threshold number has been hypothesized to select attributes for inclusion, although recent reviews have reported that most DCEs used a number of attributes between 4 and 7 [17].

A sample of 20 participants will be recruited, including 10 PwMS from the different geographic areas, 5 PwMS SOs, 5 neurologists, and 5 other HPs caring for PwMS. Four group meetings will be conducted, one with neurologists and other HPs, one with SOs and two with PwMS. Written informed consent will be obtained for all the participants before the meeting. The NGT meeting will be held at the University of Turin, and it will consist of three steps.

1. Plenary session 1: after providing information about the study purpose (“to determine the most important attributes for HRQOL in MS from the patient perspective”), and giving a brief description of the NGT procedures, each HRQOL dimension will be presented.
2. Parallel group session: participants will be then split into homogeneous groups. Each group discusses the proposed HRQOL dimensions, guided by a facilitator, and each participant will be then asked to rank the list of dimensions in order of importance from 1 (the most important) to “n” (the least important) on a worksheet. The individual rankings will be summed across participants to derive the rank order at the group level.
3. Plenary session 2: a plenary session will follow, in which the priority ranking of the HRQOL dimensions (overall and at the group level) will be presented. Ideas and comments will be further discussed (and noted). The meeting results will be used to define the DCE contents (next study phase).

Data Analysis [WP6 Task 1].

Narratives will be analyzed thematically [18]. Specifically, two researchers will collate and order the data according to themes, in order to enable comparison of comments from participants. Then, the analyses will be jointly discussed by the Steering Committee. Meeting results will be submitted to participants (respondent validation). The reporting of the qualitative data will follow the Consolidated Criteria for Reporting Qualitative Studies [19].

Phase 2-ASSESSMENT OF PATIENTS’ AND HEALTH PROFESSIONALS’ PREFERENCES [WP4-WPS]

[WP4 task 1] Devising the DCE questionnaire

Based on attributes and levels, hypothetical alternatives are produced and grouped into choice questions to develop the DCE questionnaire. The DCEs present respondents with a sample of hypothetical scenarios (i.e. choice tasks) drawn a priori from all possible choice tasks according to statistical principles. The choice tasks comprise two health profiles (alternatives) which vary along several attributes, and respondents are asked to choose the alternative which indicates a best HRQOL. Health profiles will be described in terms of up to 6 or 7 HRQOL attributes (identified in the Phase 1 above), scored with 3 levels (e.g. severe, moderate, no impairment) that systematically vary across the choice tasks. In fact, a full factorial survey design would include all possible combinations of attributes and levels to generate all possible alternatives. For example, if we consider 6 HRQOL attributes with 3 levels each, the full factorial design consists of 36 =729 health profiles, and it would not be feasible. Hence, experimental design methods are used to create smaller and more manageable sets of alternatives to generate fractional factorial designs. To further reduce the number of combinations shown to each respondent, the design will be split into different blocks of respondents. Assuming a fractional design with 18 choice tasks, different groups of respondents are required to ensure that each PwMS fulfils up to 9 choice tasks, as suggested by the literature [10]. Blocking leads to an increase of the sample size, but reduces patients’ burden. According to Orme’s rule [20], with 9 tasks, six attributes scaled by three levels and two choice alternatives, the minimum sample
size is 250, per block, 500 considering 2 blocks. An additional 20% of participants will be included to compensate for possible exclusion of respondents after controlling for data quality (incomplete data or incoherent responses to the control choice tasks). Among the 9 choice tasks administered to each respondent, there will be two fixed choice tasks which will be used to check responses quality, and not for deriving preferences scores: one presenting the same choice twice, and the other presenting a dominated alternative. To prevent a potential bias based on order presentation, the choice tasks will be randomized.

(WP4 Task 2) Patient recruitment and cross sectional survey. This is a prospective, multi-center, non-interventional cross-sectional study involving a sample of at least 600 PwMS that will be recruited at Catania, Turin, and at MS Center of IRCCS S. Lucia Foundation centers.

Consenting PwMS will be consecutively recruited when they attend a regularly scheduled visit at MS center. At the end of the visit, neurologists provide a brief description of the study procedures, and patients will be asked if they will be interested to participate. Patients will be recruited provided that all the following criteria are satisfied: MS diagnosis [21] communicated from ≥ 6 months; age ≥ 18 years; no relapse in the previous month; no impairment precluding participation (i.e., patients cognitively preserved), and fluent in Italian. At each center, the Brief International Cognitive Assessment for MS (BICAMS) test will be administered. The BICAMS includes three neuropsychological tests: The Symbol Digit Modalities Test (SDMT), the California Verbal Learning Test-II (CVLT-II), and the Brief Visuospatial Memory Test-Revised (BVMTR) [22]. According to the Italian normative values, patients showing at least one altered BICAMS test will be classified as cognitive impaired, and excluded from the study.

Interested patients will then be asked to read and sign an informed consent form. In case the participants decide to complete the questionnaires at home, consent to be contacted by email will be requested.

PwMS provide demographic information (age, gender, completed education, work status, living conditions), and complete a battery of questionnaires (see below) which will be digitized to be self-administered on a tablet during the visit.

The patients are then provided with information on the DCE tasks. To introduce the DCE, respondents will be given a standard and accurate description of the selected HRQOL attributes and levels to ensure that participants are interpreting the task in the same manner. A research assistant will be available to help patients in questionnaire completion (he/she can help but not influence choices). Finally, patients will be asked to make a ranking of their HRQOL attributes in order of importance – from the most important to the least important.

The investigator records the following clinical information: level of disability (assessed with the Expanded Disease Severity Scale (EDSS) [23], MS course (relapsing remitting/primary progressive/secondary progressive) [24], presence of comorbidities (i.e. vascular/autoimmune/ musculoskeletal/ gastrointestinal/ visual/ cancers/ mental/ respiratory, adapted from Marrie et al. 2011) [25]; and medications (disease-modifying/ symptomatic/for co-morbidities).

(WP4 Task 3) Psychological assessment of patients’ preferences. In exploring the psychological correlates of patients’ preferences in terms of what features of HRQOL are most important, the theoretical framework of reference is the life span developmental approach. In this perspective, psychological development extends over the entire life span and illness experience is seen as a non-normative challenge that some people have to face in order to restore their psychological well-being. MS is indeed a huge challenge as it is a chronic disease and the way patients cope with it is the result of the interaction of many factors, either at individual or at environmental level. Thus, illness management and adjustment are subjective and depend on the psychological characteristics of each individual [26].

In line with this theoretical perspective, the following psychological factors were considered: perceived self-efficacy, that is the individual perception of being able to perform a specific task or to deal with a specific challenging situation; illness perception that is patient’s beliefs about its cause, consequences, emotional impact, timeline and treatment prospects; locus of control beliefs that refers to respondent beliefs about who is responsible for her health condition; coping strategies in facing stressful illness-related events; perceived social support and personality traits assessed within the Big Five model that considers five broad dimensions: Openness to experience, Conscientiousness, Extraversion, Agreeableness (i.e. how much friendly and cooperative a person is) and Neuroticism (emotional instability).

The set of psychological factors and their measurement instruments will be eventually revised in light of the literature review results. Respondents will complete the questionnaires reported below.

The MSQOL-29 [27] consists of 7 multi-item subscales: Physical function; Sexual function; Bodily pain, Emotional wellbeing, Energy, Cognitive function, and Health distress; and four single-item (Social function, Health perceptions, Overall quality of life, and Change in health) which form two composite scores (physical and mental quality of life). Cronbach’s alpha ranged from 0.88 to 0.90.

The SEMS (Self-Efficacy in Multiple Sclerosis scale) [28] is a 15-item bidimensional MS-specific instrument measuring perceived self-efficacy about goal setting (planning activities, asking for support and maintaining social life), and symptoms management (fatigue, physical disabilities, and negative emotions). Reliability was good for both subscales: 0.90 for goal setting scores, and 0.87 for symptom management.

The Italian version of the Brief-IPQ (Brief Illness Perception Questionnaire) [29] is composed of 8 items that assesses six illness-related cognitive dimensions: consequences (How much does your illness affect your life?); timeline (How long do you think your illness will continue?); control (How much control do you feel you have over your illness?); identity (How much do you experience symptoms from your illness?); emotions (How much does your illness affect you emotionally?), and comprehensibility (How well do you feel you understand your illness?).

The Italian version of the MHLCS (Multidimensional Health Locus of Control Scale, Form C) includes 18 items covering 4 LOC dimensions: Internal LOC, representing the belief on personal responsibility of the events; Doctors LOC, representing the belief that doctors can have the control of the patient health condition; Other people, consisting in the belief that other people, family or friends for example, have the control of the health condition; and Chance LOC, consisting in the belief that the luck has the control of the pathology.

Three subscales of the CMSS scale (Coping with Multiple Sclerosis Scale) [30] are considered: Problem solving (e.g. I think about how I might best solve the problem), Emotional release (e.g. I let my feelings out), and Avoidance (e.g. I go on as if nothing happened). Cronbach alpha was 0.71 for Problem solving, 0.69 for Emotional release, and 0.59 for Avoidance.
The Italian version of the MOS-SSS has 19 items and 4 subscales: Emotional-informational support, Tangible support, Positive social interactions, and Affectionate support. The MOS-SSS showed good to excellent internal consistency, for both the subscales (having Cronbach’s alpha ranging from 0.85 to 0.93), and for the total scale (Cronbach alpha=0.94) [31].

The I-TIP1-R is the Italian version of a brief measure of personality traits composed of 10 items and 5 subscales: Openness, Conscientiousness, Extraversion, Agreeableness and Neuroticism. It demonstrated good test-retest reliability (correlations ranged from 0.79 to 0.90).

Completion time for the WP4 tasks above about 20 minutes.

A pilot study involving 15 PwMS (same eligibility criteria as above) recruited at the Turin clinical center will be performed to check comprehensibility of all the questionnaires, particularly the DCE section.

Data Analysis [WP6 Task 2,3]. DCE data will be analyzed by using a finite mixture logit model. Preference variation is accommodated by identifying 2 or more latent classes that are internally homogeneous (i.e. grouping participants with similar preferences). The selection of the final model will be made according to several goodness of fit statistics and McFadden R2 will be used as an effect size measure.

To characterize patient groups derived by the previous analysis, multinomial logistic regression will be performed using demographic, clinical and psychological characteristics, as independent variables. The Chi square will be used to assess the congruence between the HRQOL attributes preferences estimated by the latent class model and those directly stated by PwMS. NLOGIT version 4.0 statistical software package [32] will be used for the estimation of the DCE.

[WP5 Task 1,2] Survey with health professionals. The assessment of neurologist and HP opinions on patients’ HRQOL preferences will involve at least 65 neurologists and 65 other HPs recruited through the involvement of the SIN and the SNO. Neurologists and HPs who have followed at least 5 PwMS in the year prior to enrolment will be eligible to participate in the survey.

Data will be collected using an online questionnaire. A first email will be sent to obtain the consent to participate, and a second email will provide the link to the questionnaire. In case of non-response, participants will be notified with a recall by email two weeks later. Participants will give some personal information (age, gender, years of specialty practice), and some information about the center’s features (i.e. geographical area, type of clinical setting, center volume, service organization and provision of services over time; adapted from Mattarozzi et al. 2017) [33].

HPs will be given the same descriptions of HRQOL attributes used in the patient survey, and asked to do the same ranking of HRQOL attributes as for the PwMS, i.e. to rank the attributes from the most important for the patient to the least important. In order to grasp the way of reasoning that leads participants to sort the attributes, a final question will ask how they arrived at their choice, offering them two alternatives: a) thinking about what is known in the literature about patients’ preferences; and b) thinking about what patients report during the visits. Completion time for the survey is about 5-10 minutes.

Data Analysis [WP6 Task 4]. For each HRQOL attribute, the sum of rank will be calculated and compared with the proportion obtained in the patients’ sample. Odds ratio and z-test will be used for the comparisons between patient and HP preferences. Cohen’s d will be used as an effect size measure.

Sample size estimate was based on previous research [11]. To assess the difference between the proportion of neurologists (75%) and patients (58%) who include the “physical function” attribute among the three most important aspect of HRQOL [13], the required sample size is 65 neurologists (α=0.05, 1- β=0.80). In case only 60 neurologists would be willing to participate, the power (1-β) is 0.78 and in the worst scenario in which only 55 neurologists will be available to be recruited, the power decreases to 0.71. To obtain two balanced samples of professionals, the same sample size will be used for the other HPs.

Dissemination [WP7]

Communication and dissemination plan is critical to achieve the study goal and, as such, is integrated with all other project activities. Dissemination will occur throughout the project to ensure information sharing and maximize project impact. Goals, activities, and key messages to be disseminated include: 1. Demonstrate how this project addresses current challenges of patient-centered care; 2. Engage potential beneficiaries/users of project outcomes, and disseminate our best practices in the management of other chronic diseases with high QOL and health system impact; 3. Engage with key stakeholders, pursue valorization of project activities and outcomes, and engage diverse stakeholders (patients, SOs, HP, and policy makers).

There are multiple dissemination channels that can be used: social media, websites, conferences, videos, promotional materials, and local closing events.

We plan to establish a dedicated website with all news, events (e.g. seminars, workshops), and preprints.

The website serves as the first point of contact for information about the project to a wide audience and presents its purpose, activities and progress. At the same time, it represents the main communication and dissemination channel, providing visibility and outreach, and regularly informing the public about the project’s activities, as well as relevant news, documents, and activities related to key PREQOLISM issues. Work on the website will continue throughout the project duration, with new sections and content being added as they become available. The website design is based on a user-friendly and attractive interface open to the public and various stakeholders - clear structure, easy navigation, evoking positive and encouraging emotions. Optimized for all types of mobile devices (phones, tablets for iOS and Android operating systems), and fully accessible to all users in compliance with the GDPR (consent to privacy for all forms, consent for cookies on first visit, etc.). There will be the possibility to share (social media), send (email), and print pages, as well as browse the website. The website structure should reflect the needs of the project, all WP packages and partners, while providing clear and intuitive navigation.

The use of social media should increase awareness among potential users, generate interest in the project, and encourage participation to project events. The various social media profiles will be selected to reach a broad and relevant audience. We will use the following social media platforms: Facebook, Twitter, and LinkedIn. Facebook is popular with citizens and local communities, while Twitter will help us reach and engage with European institutions, public authorities, industry, the media, the scientific community and EU-funded projects to maximize the dissemination of results, and increase the visibility of the project. Finally, LinkedIn is a social network for professionals, and allows the creation of specific communities and groups to discuss specific topics and disseminate.

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information to a wide audience of professionals. In this sense, a group is created and used to connect with key stakeholders and relevant projects and initiatives to create synergies and promote knowledge transfer. Selected articles, news and other communication contents will be also published on this platform.

The study results will be publicized and disseminated through publication on the project website, articles in scientific journals, social media, newsletters/brochures, and presentations at national and international conferences. A meeting with key stakeholders is planned and the study results will also be disseminated through the organization of workshops or seminars (online) in collaboration with the Italian Multiple Sclerosis Society (AISM), the Italian Society of Neurology and the Italian Multiple Sclerosis Study Group. The results will be presented at national and international conferences dedicated to QOL and MS, including the RIMS (Rehabilitation In Multiple Sclerosis), ISOQOL (International Society Of Quality Of Life), and EAN (European Academy of Neurology) annual conferences, in order to raise the scientific profile of the researchers at the international perspective. The project reports will also be reported on the pages of the UniTO website, dedicated to the communication and dissemination of applied research to unite research, economic system and citizens (http://www.agorascienza.it/index.php/it).

3. Project development, with identification of the role of each research unit, with regards to related modalities of integration and collaboration

The team consists of three research units, based at Turin, Aosta Valley, Catania universities. The investigators share a strong common background mainly in MS and QOL assessment. At the same time there are important exclusive expertise at each unit, and specific synergies among the units. More specifically we highlight that: the unit of the PI has contributed to several important recent progresses concerning the WP4.1-WP4.2 tasks, while WP4.3 task is mostly developed within the Aosta unit; qualitative studies in MS (WP2-WP3) were conducted and coordinated by the Turin unit and studies on HPs (WP5) perspectives were carried out by the Catania unit. We also emphasize that the units are already quite well integrated among them, with a good record of scientific collaboration on research papers. In conclusion, the whole team has the perfect blend of diversity and integration to successfully carry out the present project. Part of the funding will be used to hire three research fellows in order to give a further boost to the
The role of each unit with regards to the expected targets - The main efforts towards the Phase 1 targets will be done jointly by the investigators at Turin unit for what concerns the NGT consensus meeting and the literature review (WP2, WP3). Their efforts will also be supported by Dr. A. Solari (Fondazione IRCCS Istituto Neuroligico Carlo Besta, Milan), a leading expert in patient reported outcomes and shared decision making. The leading unit for the core of the patient survey (WP4.1-4.3) will be UniTO together with some pivotal contributions by Aosta unit. Catania unit will be also in charge of the patient recruitment (WP4.2). We forecast intense collaboration with Dr. MG. Grasso (IRCCS Santa Lucia Foundation, Rome), her unit will also contribute to the project by recruiting PwMS. For the same targets we also intend to keep a strict contact with some research groups working in the field (most likely E.W. de Bekker-Grob in The Netherlands; N. Mayo, McGill University, Canada) in order to discuss our results and identify interesting possible new directions within the above research. Concerning the psychological aspects of PwMS [WP4.3], we forecast collaborations with the Italian Multiple Sclerosis Study Group within the Italian Society of Neurology.

Modalities of integration and collaboration
The research units will actively contribute to the project implementation in compliance with a shared work-flow document (Figure 1), including deadlines and specific deliverables (formats and contents).

We plan to create a website dedicated to the project and including all the related news, events (seminars, workshops, visitors) and preprints. A web application for data collection, and an electronic Case Report Form (eCRF) will be developed. The collaboration suite will provide methods for exchanging requests and responses, web conferences for consults and sharing opinions in a monitored context.

There will be two levels of integration and collaboration among the research units.

A first level of integration will deal with the organization of a series of keynote lectures across the units on the detailed state of the art of the main project targets. These lectures will be delivered at the very beginning of the project by the leading scientists for each topic, and it is expected that the majority of the team members will attend them.

A second level of integration consists of a series of invitations of leading researchers related to the main targets of the project to discuss patient enrolment. We plan at least a workshop where each sub-group will illustrate results and discuss future steps. The workshop will maximize the attendance by the team members. Finally, at the end of the second year, an international event with a format in between a workshop and a conference will be realized.

Work packages
The project will be structured in 7 work packages assembling the different activities and objectives of the project.

WP1: Management and coordination. The WP1 regards the general management of the project and the coordination of the research activities, and it is conceived to guarantee an optimal collaborating interchange among units/work packages. Considering that each WP has a person in charge of coordinating activities and task execution, the project organization will include a Steering Committee (SC) made up of the representatives of each partner and led by UniTO. The SC work is devoted to ensure a smooth progress of the overall work plan, the timely achievement of project milestones as well as the administrative and financial management and reporting to the Ministry of University and Research (MUR). Alongside the SC, a dedicated board of professionals will assist the working team both “on demand” and systematically, in order to periodically supervise progress.

The WP1 is also designed to guarantee a data collection, analysis and reporting consistent with the EU GDPR 2016/679 and with the
EU guidelines for storage of the data in project-independent archives which preserve long-term accessibility.

Project management exclude any form of discrimination.

UniTO is in charge of the WP1 and of its four tasks:
1.1) Project Management & management support (work-flow plan)
1.2) Data Management Plan, rules and Ethics Committee approvals
1.3) Quality Control and Risk Management
1.4) Administrative and financial reporting

1.5) Development and maintenance of a web application. A triple protected (password, transport protocol, anonymity) web platform will be set up to perform the following function: data manager, link platform, document repository, and exchange platform.

WP2: Literature review. A systematic literature review will be performed to provide insight into the existing knowledge and evidence regarding HRQOL and its psychological determinants. This work package contains two tasks:
2.1) consulting bibliographic databases as PubMed (Medline), CINAHL, PsycINFO, Google Scholar and EMBASE identifying the relevant HRQOL dimensions for PwMS to produce a research template containing the HRQOL dimensions and the psychological factors.
2.2) data synthesis to produce a manuscript. If possible, meta-analyses will be carried out to quantify the influence of psychological factors on HRQOL.

Moreover, the results of the review will be included in the knowledge synthesis (see WP4.2). UniTO unit will carry out the literature review; the review will be submitted to the SC for approval. Other investigators will take part in the selection and data extraction of relevant publications.

WP3: NGT meeting. In light of WP2 achievements, the WP3 aims to select a list of a maximum of 6 or 7 HRQOL dimensions, i.e. the most important for PwMS. In preparation of this meeting, UniTO will provide a synthesis of the results obtained in WP2. NGT meetings will be held in Turin, but if it is not possible to arrange face-to-face meetings, it will be done online by using a bespoke web portal. WP3 consists of three tasks:
3.1) Planning and conducting the NGT consensus meeting
3.2) Knowledge synthesis and report
3.3) Qualitative research: manuscript draft and submission

WP4: Patient survey. This WP entails the following tasks:
4.1) Devising the DCE questionnaire
4.2) Patients recruitment and survey administration
4.3) Psychological assessment of patients’ preferences

WP5: HP survey. In this WP we will assess the HPs’ opinion on patients’ HRQOL preferences. We take care of two tasks:
5.1) Developing the online survey
5.2) HPs recruitment and survey administration. Neurologists will be recruited through the involvement of the Italian Society of Neurology and the Italian Multiple Sclerosis Study Group. The other HPs will be recruited through the involvement of the Italian Multiple Sclerosis Nurses Society (SISM), and other relevant HP societies.

WP6: Analyses. The WP contains four tasks:
6.1) Qualitative data analyses referred to WP3
6.2) DCE analysis using finite mixture logit models (WP 4.3)
6.3) Analysis of psychological correlates of patient’s preferences by multivariate regression models (WP 4.4)
6.4) Multivariate regression logistic model on professionals’ data (WP 5)

WP7: Dissemination. In this WP the study results will be made available to the stakeholders, and to a wider audience. The activities will be coordinated by the University of Turin, with support and input from the University of Catania. The established tasks are:
7.1) Dissemination plan: design and application
7.2) Project website design, implementation and updating
7.3) Project leaflet, informative documents and gadgets
7.4) Quantitative research: manuscripts draft and submission
The project is planned over a two-year time frame as illustrated in Figure 2

4. Possible application potentialities and scientific and/or technological and/or social and/or economic impact

This project provides information, raises awareness of, and improves knowledge about MS by involving people living with the disease, caregivers, and HPs to understand their needs and expectations. The impacts of the project are scientific, clinical and social.

4.1 Scientific impact
MS affects broader aspects of people’s lives, their relationships and social support, and ultimately their HRQOL. Working on patient preferences for HRQOL allows to assess the importance patients attach to the different HRQOL dimensions, and provides useful data for MS clinical practice and research.

From a scientific point of view, the project increases knowledge at national and international level by providing utility estimates derived from the re-prioritization of HRQOL dimensions performed in the Italian context. The NGT consensus meeting, the systematic review, and the assessment of patients’ and HPs’ preferences will provide the national and international scientific community with novel findings on what PwMS perceive should be preserved throughout their lives. Further, HRQOL preferences and psychological assessment of patients may reveal significant factors in shared decision making and provide an opportunity to improve treatment outcomes. The project allows to increase knowledge about HRQOL from the patient perspective, by determining a priority ranking on the aspects they would like to preserve longer.

Moreover, the possibility to identify PwMS subpopulations characterized by a different priority ranking will allow to develop a more personalized way of assessing HRQOL that takes into account what matter most to each PwMS subpopulation. A global HRQOL score could be calculated as a weighted mean of domains score, in which the weights would be specific for each PwMS subpopulation.

Existing instruments produce a global unweighted mean score in which all the domain scores have the same importance, such as the Multiple Sclerosis International Quality of Life Questionnaire [34], or in case of preference-based HRQOL measures, such as the EQ-5D, the same set of weights are used for the whole target population.

Based on the results of the present project, patient-tailored HRQOL instruments could be developed taking into account the heterogeneity in patients’ preferences. Moreover, international collaborations can be established with the aim to cross-culturally validate the results, and to develop an electronic tool for assigning patients to a subpopulation and derive their weighted total HRQOL score.

4.2 Clinical and social impact
This project has an impact not only on the scientific community, but also on the society at large, as it allows to focus on this complex...
disease within the framework of programs and policies on healthcare, inclusion, welfare, employment, civic participation, and research. This is possible because the knowledge of priorities of individuals and the ability to relate them to personal- and disease-related aspects, makes it possible to develop care models built on the needs of everyone. The MS onset is at a young age and presents a variety of symptoms, including disability of the upper and lower limbs, spasticity, fatigue, visual disturbances, balance and coordination problems, altered sensations, speech disorders, swallowing disorders, fatigue, bladder and bowel problems, sexual dysfunction and cognitive and emotional disorders. MS can substantially and adversely affect the individual HRQOL and is associated with high costs for PwMS, their families, and the society. There is an increasing need for integrating HRQOL into clinical assessment as a means of promoting patient-centered care [1]. Subjective evaluations of HRQOL and their determinants improve patient–provider communication, clinical outcomes, and quality of care, particularly in patients with chronic conditions [2]. In Europe, chronic diseases are the leading cause of illness and disability. It has become increasingly evident for health care organizations and institutions that knowing all relevant life domains of specific populations and using these assessments is key to promote effective and equitable care while keeping costs at bay.

There is a wide variety of organizations/agents who can be interested in HRQOL preferences collected within this study, which can be grouped into three main types:
1. Health care organizations, institutions, charities, and pharma companies. HRQOL data can be used in clinical practice and research. At the micro level, HRQOL data can be collected from patients and delivered to clinicians to be used during the consultation, to feed shared decision making, patient’s adherence/persistence, self-management, and empowerment. At the meso level, HRQOL preferences may fit with the requirements of the European Medicines Agency and other regulatory agencies given their growing interest in patient reported outcomes. Finally, at the macro level HRQOL can be used to inform and evaluate health policies, in line with the drive towards value-based (as opposed to volume-based) payments [35]. These three levels are not mutually exclusive but should interact efficiently: as an example, the integration of HRQOL data into the electronic health records and eHealth apps also allows its use at an aggregate (meso) level, and for system-wide quality improvement.
2. Policy making institutions and organizations. HRQOL is a broad concept which is concerned with the overall well-being of people in the society. As a result, customers at the local, national, and international government levels can use preference data to inform policies in education, community management, social work, public administration.
3. Academia, marketing firms and advertising agencies. In the perspective of a widespread use of the results of the study, the high-quality data gathered on profiled individuals will allow us to define more precisely what is considered important for the wellbeing of a significant part of the citizens, and targeted populations. The results can be also used by academic institutions and research organizations in the field of the social sciences, economics, and politics.

Increasing the patient’s involvement during the decision-making process of their treatment plan and improving their HRQOL by providing them with personalized care according to their psychological profile allows reducing the burden of the management of those patients both at personal and societal levels.

Since neurologist and patient beliefs about patient HRQOL are not always correlated, it may be difficult to fully understand patient illness perceptions, and act appropriately. Since personal beliefs, attitudes and values can provide important insights into consumer preferences, the results of this study can show HPs potential differences, and can enable them to tailor healthcare services for PwMS to their preferences.

To increase the social impact, we intend to involve the following stakeholders with which some investigators of the local units have already collaborated in previous studies:
- The Italian Multiple Sclerosis Society (AISM)
- The Italian Society of Neurology (SIN)
- The Italian Society of Hospital Neurologists Neurosurgeons and Neuroradiologists (SNO).

5. Financial aspects: costs and funding for each research unit

<table>
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<th>Total cost (euro)</th>
<th>Co-funding (item A.1) (euro)</th>
<th>MUR funding (other items) (euro)</th>
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<td>70.139</td>
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6. Bibliography


B.2

1. Scientific Curriculum of the Principal Investigator

Personal information
First name/Surname ROSALBA ROSATO
Nationality: omissis
Date of birth: omissis

Education and Employment
Dr. Rosato graduated cum laude in psychology from the University of Turin in 1997. She obtained her license to practice psychology at the same university in 1998 and her Ph.D. in applied statistics at the University of Florence in 2003.

From 2006 to 2018 she was Assistant Professor of Psychometrics (M-PSI/03); from 2018 to 02/2022 she was Associate Professor Psychometrics; currently, she is Full Professor of Psychometrics at the Department of Psychology of the University of Turin.

Since 2010 she has been a member of the Teaching Committee of the Ph.D. School of Psychological, Anthropological and Educational Sciences, University of Turin.

Since 1998, she has collaborated with the Cancer Epidemiology Department of the Azienda Ospedaliera Città della Salute e della Scienza in Turin and with the Centre for Cancer Prevention (CPO) in Piedmont, providing epidemiological-statistical consulting services.

Research activity and publications
Dr. Rosato is a researcher in health outcomes, health services, and population health and is interested in all aspects of measuring the construct of quality of life and disability in people with chronic diseases. She is currently conducting research projects on multiple sclerosis and cancer. In these areas, she focuses on health outcome measurement, the application of advanced statistical methods, and knowledge translation.

A noteworthy project in this research area deals with the study of the psychometric properties and the definition of a shortened version of the most widely used multiple sclerosis quality of life questionnaire, MSQOL-54. She is currently developing a computer adaptive test version (CAT) of the multiple sclerosis quality of life questionnaire MSQOL-54.

Rosalba is the PI of the following projects:
- Statistical methods for dealing with response shift and missing data in repeated assessments of the quality of life in clinical studies;
- Application of the discrete choice experiment in a cohort of colorectal cancer patients to understand their preferences for different characteristics of chemotherapy supply.
- Clinical and psychological factors associated with health-related quality of life and treatment choice at cancer diagnosis and during disease progression; and
- Development of a multidimensional computerized adaptive short form of the Multiple Sclerosis Quality of Life-54 (MSQOL-54-MCAT): an international collaborative project.

From a methodological perspective, she has contributed to the study of correlated data models and survival analysis methods, in particular by studying Aalen’s additive models in the presence of competing risks and repeated observations, and by applying IRT models to quality of life measures.

She is currently conducting her research at the Department of Psychology, University of Turin, and collaborating with: the Unit of Cancer Epidemiology, Azienda Ospedaliera Città della Salute e della Scienza, Turin, the Neuroepidemiology Unit Foundation IRCCS Neurological Institute C. Besta, Milan, and the Neuroepidemiology Unit, Centre for Epidemiology and Biostatistics, Melbourne School of Population and Global Health, University of Melbourne, Melbourne, Australia.

Leadership of and participation in research groups
Scientific coordinator of the workshop "Measuring quality of life: some methodological issues" in collaboration with the University of Turin and SPHERE, the Laboratory of Biostatistics, Pharmacoepidemiology and Subjective Measures in Health Sciences, University of Nantes, France; Turin, 18-11-2016.

- Participation in the research group "Measurement and Modelling of Psychological Constructs (MeMPsyC)", Department of Psychology, University of Turin. (http://www.dippsicologia.unito.it/do/gruppi.pl/Show?id=4f54).
- Participation in the research group "Neuropsychology of cognitive impairment and central nervous system degenerative diseases", Department of Psychology, University of Turin. (http://www.dippsicologia.unito.it/do/gruppi.pl/Show?id=3nwy).
- Participation in the multidisciplinary research group Unit of Cancer Epidemiology, Hospital "Città della Salute e della Scienza" - University of Turin and CPO Piemonte, Turin.
- Participation in PRIN Project 20107JZAF4_00411 - Unit of Turin: "Maternal and paternal perinatal depression as risk factors for the development of infantile affective regulation: assessment of impact and early intervention"; from 01-02-2013 to 01-02-2016.
Head of Methodology and Statistics of the regional project "Act on Ageing", PI S. Ciairano (research supported by the Piedmont Region - Competitive call for Human Sciences -2009-2012); from 01-01-2009 to 01-01-2012.

Research Grants
Fondazione Italiana Sclerosi Multipla (Italian Multiple Sclerosis Foundation) (FISM), "An abbreviated computerized version of the MSQOL-54: development and preliminary validation using Confirmatory Factor Analysis and Item Response Theory", 2013-2016;
Piedmont Region - Regional Health Authority, "Sclerosi multipla e qualità della vita: il punto di vista del medico" (Multiple sclerosis and quality of life: the physician's perspective), 2009-2011;
Piedmont Region - Regional Health Authority, "Quality of life utility functions in patients with multiple sclerosis. An application of the conjoint analysis" 2008-2010;
Piedmont Regional Health Authority, "Quali strumenti per valutare qualità della vita e depressione nei pazienti oncologici anziani" (What instruments to assess quality of life and depression in elderly cancer patients) 2008-2010;

Dr. Rosato is author/co-author of more than 100 full articles and scientific abstracts. About 90 of them have been published in English in peer-reviewed journals.
H-index 27 (03/14/2022 Source: SCOPUS Author ID: 7003601145 - ORCID ID: 0000-0002-4921-374X). Total number of citations: 2369 (03/14/2022 -SCOPUS Source).
She is also on the review panel of leading international journals on quality of life and epidemiology.
Ad hoc referee for the following journals: Quality of Life Research; Health Quality of Life Outcomes; Frontiers in Psychology; BMC Neurology; The Patient: Patient-Centred Outcomes Research; PM&R: The journal of injury, function and rehabilitation; Diabetes, Obesity and Metabolism; European Journal of Neurology; Patient Preference and Adherence; International Journal of Preventive Medicine; Journal of Diabetes Research; Epidemiology.

2. Scientific Curriculum of the associated investigators

1. PATTI Francesco
Omissis
Scholastic career
Il level education 1976
Degree Medicine and Surgery 1982 maximum cum laude
Post Degree Neurology, University of Catania, 1986
Post Degree Physiotherapy, University of Parma, 1990

Work activity
• 1987-1988 Regional fellowship as Junior Neurologist to study " Descriptive Neuroepidemiology of most frequent neurological diseases in Sicily", progetto Regionale 55/P, sponsored by WHO.
• 1987–1989 Assisting Professor of Neuroendocrinology and Neuroimmunology Scuola di Specializzazione in Neurologia, University of Catania
• 1991–2000 "CollaboratoreTecnico" Chair of Neurorheabilitation, Institute of Neurological Sciences, University of Catania.
• 2000–2002 "Tecnico Laureato" (Funzionario Tecnico) Department of Neurological Sciences
• November 2002 – October 2014 "Ricercatore Confermato" (Aggregate Professor) Clinical Researcher Department of Neurological Sciences, University of Catania.
• November 2014 - up till now Associate Professor of Neurology, Department of Medical and Surgical Sciences and Advanced Tecnologes G.F. Ingrassia, University of Catania
• Senior teacher of Neurology at University of Catania, Medicine School since 2014
• Senior teacher of Neurehabilitation at University of Catania, Physiotherapy degree, since 2002
• Senior teacher of Neurology at University of Catania, Nursing School since 2005
• Director of Magistral Degree Course Science of Rehabilitation of Health Professions 2016-current

Clinician profile and working activities
He is responsible of the tertiary centre of multiple sclerosis at the University of Catania (Italy). He is responsible for diagnostic process, place in therapy and switching therapy (when needed) of each patient. He also works as hub
centre in respect to a 3 satellite centers of the same region.
The centre follows more than 3000 patients suffering from Multiple Sclerosis and roughly 100 patients suffering from Devic Disease and Neuromyelitis Optica Spectrum Disorder diseases.
The centre follows also patients suffering from ALS (currently 100 patients) and other people with different forms of spasticity, offering them with a multidisciplinary approach every kind of assistance. More in details for both ALS patients and spasticity patients, he plans rehabilitation program and he is responsible of symptomatic therapies. In this field he realized an intrahospital network opened to territory with other health professionals anof different specializations to make easier living with disabilities of patients
Scientific activity
- Research Interests;
- Preclinical (1981-1988);
- Neurochemistry, Neuroendocrinology, Neuropsychopharmacology;
- Clinical: (1989-current);
- Neuroepidemiology;
- Clinical Immunology;
- Quality of Life;
- Neurorehabilitation;
- Multiple Sclerosis;
- Clinical Trials;
- Real world studies;
- Symptomatic therapies (i.e. Nabiximols, Levitiracetam, etc)
- Cognitive impairment in Multiple Sclerosis

Author of more than 400 peer reviewed scientific articles of neurochemistry and neuropharmacology, neurology, and more recently of multiple sclerosis (clinical, epidemiology, immunology, treatment, quality of life and rehabilitation). Author of several reviews on different topics in MS research (cognition, adherence, treatment, specific drugs). Scopus H Index score 50, over than 9000 citations, Total IF >1600, mean IF 4.76.
Author of a book “Il Trattamento multiintegrate sintomatico e riabilitativo della Sclerosi Multipla”.

Academic affiliations
- Advisor of Italian Neurological Society (Consigliere della SIN – Società Italiana di Neurologia);
- Advisor of Regional Committee for the PDTA (Percorso diagnostico terapeutico assistenziale) of MS since October 24, 2014;
- Chief of Italian Study Group of Multiple Sclerosis (2017-2021);
- Delegate of European Academy of Neurology, Section Demyelinating Diseases
- Advisor of ECTRIMS (current, since September 2020)
- Member of Italian Study Group of Quality of Life;
- Associate Member of American Academy of Neurology.

Collaborative Multicenter Studies
He is involved in clinical trials activities (phase II, III and observational) in Multiple Sclerosis, NMO and Amyotrophic Lateral Sclerosis in accordance with Good Clinical Practice (SA307JG, RADIANCE, CFTY720D2311, CFTY720D2306, CFTY720D2399, WANT, BREMSO, BEAT, BRAVE DREAMS, BEHAVIOR, VANTAGE, 205-MS-301, 205-MS-201, 205-MS-303, NOVA, LIBERTO, ENSEMBLE, CONSONANCE, Cladfit, Classic, LEMQoL, etc……).
He is national coordinator or NMO committee member of several national and international multicentre studies (Clad fit, ECU-NMO-301, BETAVAL, RELIEF, COGIMUS, BEACON, Cyclophosphamide, Italian use of Immunosuppressive agents, Golden, GAP, etc……).
He passed GCP course (last certified on 27 jan 2016).

He was funded by FISM for several epidemiological studies on Multiple Sclerosis:
1. Disphagia in MS;
2. Dymus questionnaire on disphagia;
3. Pain in MS;
4. Coexistence of illness and well-being;
5. Validation of short form MSQoL-54;
6. Validation of MS 12 walking test;
7. PENSAMI Phase II study on Palliative care for advanced MS patients.

He was funded by University of Catania, FIR project for the study of “Trace elements and Amyotrophic Lateral Sclerosis”.

He was inspected by FDA in July 2015 for the study 205-MS-301 (Daclizumab and Multiple Sclerosis): no Form 483 reported.

I authorize the use of my personal data in compliance with Legislative Decree 196/03, GDPR 679/2016/UE and subsequent modifications.

2. TESTA Silvia
Silvia Testa
Personal Information
Date of birth: omissis
Work Address: Department of Human and Social Sciences, University of Valle d’Aosta, Strada Cappuccini 2/A, 11100 Aosta
e.mail: omissis

Academic positions
2019 – Ongoing Associate professor in Psychometrics, Department of Human and Social Sciences, University of Valle d’Aosta, Aosta.
2002 – 2018 Assistant professor in Psychometrics, Department of Psychology, University of Torino, Torino.
1997 – 2000 Adjunct professor in Psychometrics, Department of Psychology, University of Torino, Torino.

Education and training
2001-2002 Research fellowship "Modelli matematico-statistici per la spiegazione del comportamento elettorale" (Mathematical and statistical models for explaining electoral behaviour), University of Torino, Social Science Department.
1995-1997 Post-graduated grant for teaching activities in the field of psycho-social research methodology, University of Torino, Faculty of Psychology.
1996 Qualified Psychologist.
1995 Graduated in Psychology from the University of Torino with 110/110 cum laude

Academic appointments
2020 – Ongoing Coordinator of the Bachelor’s Degree in Psychology, Department of Human and Social Sciences, University of Valle d’Aosta.
2019 – Ongoing Vice-Director of the Department of Human and Social Sciences, University of Valle d’Aosta.
2008-2018 Contact person at the Psychometrics and data analysis technical laboratory, Department of Psychology, University of Torino.
2013-2018 Member of the Joint Committee Psychologists Order/Psychology Department for post graduate professionalizing internships, University of Torino.

Teaching activity
Introductory and Advanced Statistical Methods in Psychology
Psychometrics and Test Theory
Research Methods in Psychology

Research interests
Development and validation of psychological tests
Latent variable modeling: Factor Analysis, Structural Equation Modeling, Irt Models
Psychology of emotions
Developmental psychology
Quality of life and well-being assessment in clinical and general populations

Membership in scientific societies and associations, editorial boards
Research projects participation and publications

2020-2023. Principal investigator in the dual PI research project “Successo accademico e didattica di qualità: fattori psicologici, pedagogico-didattici e organizzativi” [Academic success and quality teaching: psychological, pedagogical and organizational factors], funded by University of Valle d’Aosta, Progetti di Rilevante interesse di Ateneo (PRA).


2018-ongoing Member of the “Measurement and modelling of psychological constructs (MeMPsyC)” group, Department of Psychology, University of Torino. 2015-2018 Coordinator of the “Measurement and modelling of psychological constructs (MeMPsyC)” group, Department of Psychology, University of Torino.


2008-2011 Participant in the research project “Studio biennale per l’adattamento italiano del test K-ABC di Kaufman (forma II)” (Two-year study for the Italian adaptation of Kaufman’s K-ABC test (form II), funded by Compagnia di San Paolo, Turin.

2009-2011 Participant in the project “Sclerosi multipla e qualità della vita: il punto di vista del medico” (Multiple sclerosis and quality of life: the physician’s perspective) funded by Piedmont Region-Regional Health Authority.

2008-2010 Participant in the project “Quality of life utility functions in Multiple sclerosis patients. An application of the conjoint analysis” funded by Piedmont Region-Regional Health Authority.

H-index =11, citations = 317, documents 35 (25/3/22, scopus author id 24077576900 – orcid id 0000-0002-8732-4790)

3. Main Principal Investigator’s scientific publications (Max. 20)


4. Main scientific publications of the associated investigators (Max. 20, for each research unit)

1. **PATTI Francesco**


   2. Chisari, Clara G., Comi, Giancarlo, Filippi, Massimo, Paolicelli, Damiano, Iaffaldano, Pietro, Zaffaroni, Mauro, Brescia Morra, Vincenzo, Cocco, Eleonora, Marfia, Girolama Alessandra, Grimaldi, Luigi Maria... (2021). PML risk is the main factor driving the choice of discontinuing natalizumab in a large multiple sclerosis population: results from an Italian multicenter retrospective study. JOURNAL OF NEUROLOGY, ISSN: 0340-5354, doi: 10.1007/s00415-021-10676-6 - Articolo in rivista


   4. Amato, Maria Pia, Fonderia, Mattia, Portaccio, Emilio, Pasto, Luisa, Razzolini, Lorenzo, Prestipino, Elio, Bellinvia, Angelo, Tudisco, Laura, Fratangelo, Roberto, Comi, Giancarlo... (2020). Disease-modifying drugs can reduce disability progression in relapsing multiple sclerosis. BRAIN, ISSN: 0006-8950, doi: 10.1093/brain/awaa251 - Articolo in rivista


2. TESTA Silvia


Unit 1 - ROSATO Rosalba

Personnel of the research unit

<table>
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<tr>
<th>n°</th>
<th>Surname Name</th>
<th>Qualification</th>
<th>University/ Research Institution</th>
<th>e-mail address</th>
<th>Months/person expected</th>
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<td>1.</td>
<td>ROSATO Rosalba</td>
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Possible sub-unit

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Unit 2 - PATTI Francesco

Personnel of the research unit

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Unit 3 - TESTA Silvia

Personnel of the research unit

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6. *Information on the new contracts for personnel to be specifically recruited*

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7. *PI “Do No Significant Harm (DNSH)” declaration, in compliance with article n. 17, EU Regulation 852/2020.* (upload PDF)

"The data contained in the application for funding are processed exclusively for carrying out the institutional functions of MUR. The CINECA, Department of Services for MUR, is data controller. The consultation is also reserved to universities, research institutes and institutions (each for its respective competence), MUR - Directorate-General Research- Office III, CNVR, CdV, and the reviewers in charge of the evaluation peer review. MUR also has the right to the dissemination of the main economic and scientific data related to the funded projects."

Date 28/03/2022 ore 10:31
Codice progetto: 2022CA2FK8

Titolo: PREferences related to Quality Of LIfe attributes in Multiple Sclerosis: patient and health professionals' views [PREQOLIMS]

Coordinatore: ROSATO Rosalba

Contributo MIUR per Ricerca: 186.759
Cofinanziamento Ateneo/Ente: 57.514
Costo totale: 244.273

Suddivisione dei costi delle Unità

La suddivisione fondi è stata trasmessa il 27/06/2023

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