Study Protocol

Date: September 22, 2025

1. Title Page

Organization's Unique Protocol ID: 24-5.1T/1
Brief Title: Sexual Dysfunction in Women with Multiple Sclerosis (MS)
Acronym: MS
Official Title: Sexual Dysfunction Prevalence and Its Relationship with Various Factors in Women with Multiple Sclerosis
Protocol Version and Date: Version 1.0 – September 2025
Principal Investigator: Merve Dokumaci, Resident Doctor, Department of Physical Medicine and Rehabilitation
Institution: Ege University, Faculty of Medicine

2. Background and Rationale

Sexual dysfunction in women with multiple sclerosis (MS) is an important but often overlooked issue.
It significantly affects quality of life, relationships, and psychological well-being. Despite its impact, sexual dysfunction in MS remains under-researched and underdiagnosed.

The primary aim of this study is to determine the prevalence of sexual dysfunction among female patients with MS.
The secondary aim is to investigate the associations between sexual dysfunction and other clinical parameters such as cognitive dysfunction, fatigue, depression, anxiety, and overactive bladder symptoms.

3. Objectives

Primary Objective: To determine the prevalence of sexual dysfunction in female patients with MS.

Secondary Objectives: To evaluate the association between sexual dysfunction and:
- Cognitive dysfunction
- Fatigue
- Depression and anxiety
- Overactive bladder symptoms

4. Study Design

Study Type: Observational
Observational Model: Cohort
Time Perspective: Cross-sectional
Recruitment Status: Recruiting
Study Start Date: July 16, 2024 (Actual)
Primary Completion Date: October 2025 (Anticipated)
Study Completion Date: November 2025 (Anticipated)

5. Study Population and Eligibility

Sex: Female
Age Range: 25–50 years
Sampling Method: Non-probability sample

Inclusion Criteria:
- Female patients aged 25–50 years
- Literate and able to comprehend written and spoken instructions
- Diagnosed with relapsing-remitting form of MS
- Having a continuous/regular sexual partner
- Expanded Disability Status Scale (EDSS) score ≤ 5
- At least 3 months since the last relapse
- Sexually active within the past 3 months
- Spasticity level < grade 2 according to the Modified Ashworth Scale

Exclusion Criteria:
- Pregnancy
- Illiteracy or inability to understand instructions
- Absence of a continuous/regular sexual partner
- EDSS score > 5
- Not sexually active within the past 3 months
- Spasticity level ≥ grade 2 (Modified Ashworth Scale)

6. Sample Size and Statistical Considerations

To estimate prevalence of sexual dysfunction with a 95% confidence interval (±10% width) for expected frequencies of 70%, 75%, and 80%,
the required minimum sample sizes were calculated as 91, 82, and 72 patients, respectively.

For examining the association between sexual dysfunction and cognitive dysfunction, power analysis was performed using the Mann-Whitney U test for two independent groups. With a two-sided test at a significance level of 0.05 and a medium effect size (d=0.23), a total of 134 participants (67+67) are required to achieve 80% power.
Calculations were conducted using G*Power 3.1.9.4 software.

Based on these estimations, the planned enrollment is 140 patients to ensure adequate power for both prevalence and association analyses.

7. Study Procedures

All assessments will be conducted face-to-face at enrollment during a single study visit. The following validated instruments will be applied:
- Female Sexual Function Index (FSFI)
- Brief International Cognitive Assessment for MS (BICAMS)
- Hospital Anxiety and Depression Scale (HADS)
- Fatigue Severity Scale (FSS)

In addition, demographic data, clinical history, disease duration, and Expanded Disability Status Scale (EDSS) scores will be recorded.

8. Outcome Measures

Primary Outcome Measure:
- Outcome: Prevalence of sexual dysfunction in female patients with MS
- Time Frame: At enrollment (Baseline, cross-sectional assessment)

Secondary Outcome Measures:
- Outcome: Association between sexual dysfunction and cognitive dysfunction, fatigue, depression, anxiety, and overactive bladder symptoms
- Time Frame: At enrollment (Baseline, cross-sectional assessment)

9. Ethical Considerations

Ethics Committee Approval: Ege University Faculty of Medicine Clinical Research Ethics Committee
Approval Number: 2024-2411
Approval Status: Approved
Board Affiliation: Ege University Faculty of Medicine
Board Contact:
- Phone: +90 232 390 2134
- Email: egetaek@gmail.com
- Address: Ege University Faculty of Medicine

All participants will provide written informed consent before study entry.
Patient confidentiality and data protection standards will be ensured throughout the study.

10. Locations

Facility Name: Ege University Faculty of Medicine, Department of Neurology
City: Izmir, Bornova

Country: Turkey
Recruitment Status: Recruiting