PHARMACIST-LED OBSERVATIONAL STUDY ON QUALITY OF LIFE IN RELAPSING-REMITTING MULTIPLE SCLEROSIS: EVIDENCES FROM THE QOSMOS STUDY

V. DAMUZZO[1], D. MENGATO[2], F. MILANI[1], L. AGNOLETTO[3], N. FREDDI[4], R. RAMPAZZO, N. REALDON[1]

1 School Of Hospital Pharmacy, Department Of Pharmaceutical And Pharmacological Sciences- University Of Padua, Padua, Italy.
2 Bolzano General Hospital, Hospital Pharmacy, Bolzano, Italy.
3. Santa Maria Della Misericordia Hospital, Hospital Pharmacy, Rovigo, Italy.
4 Sant'Antonio Hospital - AULSS 6 Euganea, Department Of Neurology, Padua, Italy.
5 Health Department- Veneto Region, Coordinamento Settore Farmaceutica- Dispositivi E Protesica, Venice, Italy.

Background and Importance

Patient-reported outcomes (PRO) are increasingly used to evaluate effectiveness of treatments for Multiple Sclerosis (MS) and they often include an evaluation of health-related quality of life (QoL).

In 2017 the Italian Society of Clinical Pharmacy and Therapeutics (SIFaCT) and the National Association of Hospital Pharmacy Students (ReNaSFO) established a join action to update existing data on QoL and its correlation with use of disease-modifying drugs in Italian patients.

Results will be helpful as reference for future studies using PRO.

Aim and Objectives

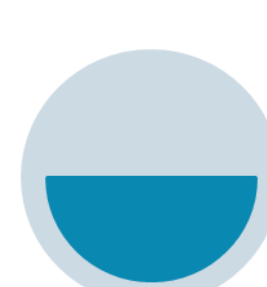✓ <u>Primary endpoint</u> was to measure QoL score in MS patients.

✓ <u>Secondary objectives</u> include correlation of QoL with pharmacological therapy and clinical characteristics of patients.
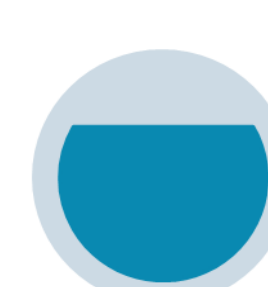
Materials and Methods

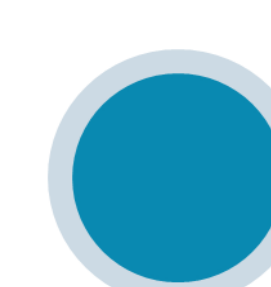**DESIGN**
Observational, cross-sectional, multicentered

CRF
MS-QOL54
Clinical characteristics: sex, age, MS type, Expanded Disability Status Scale (EDSS), history of pharmacological treatments
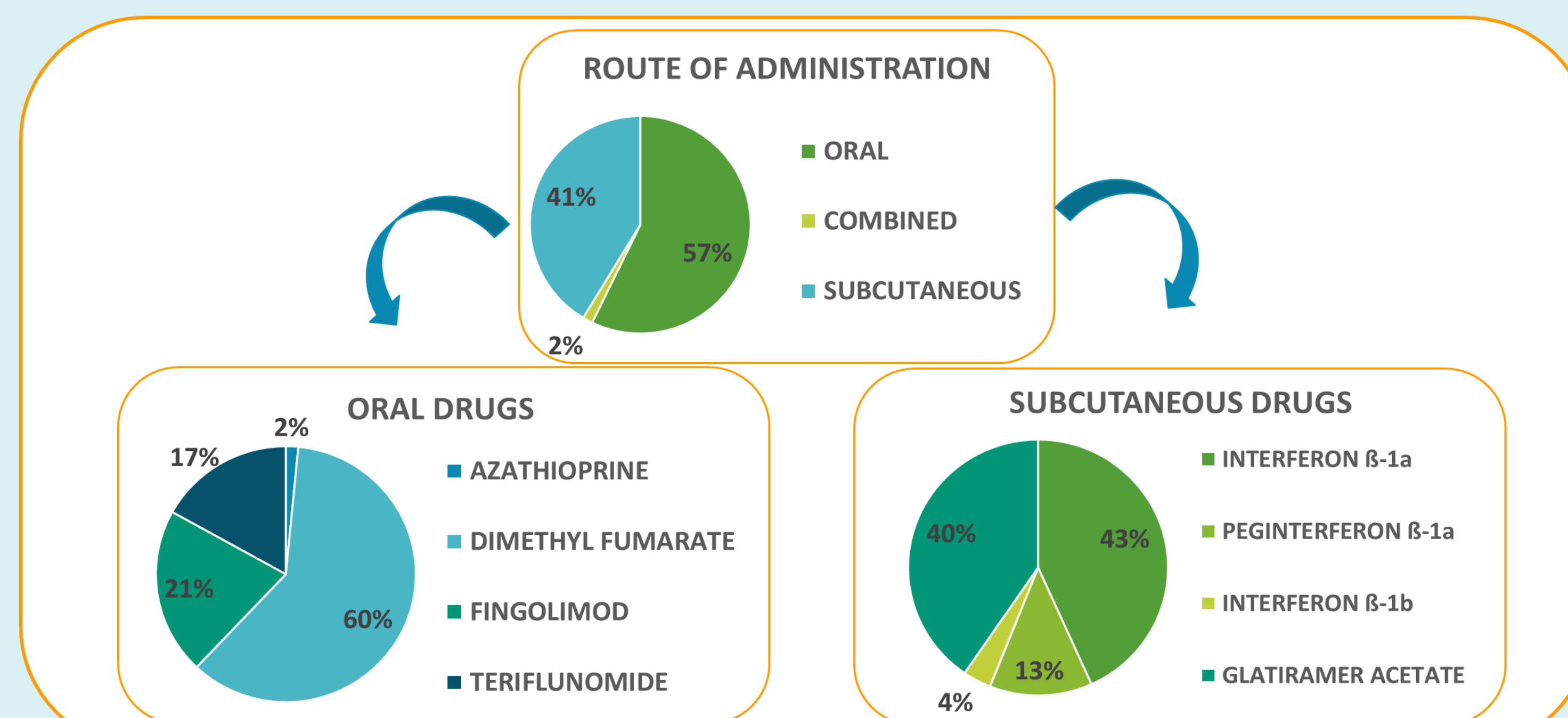
FEASIBILITY
Ethic approval
Centre specific activies managed by students of Hospital Pharmacy School
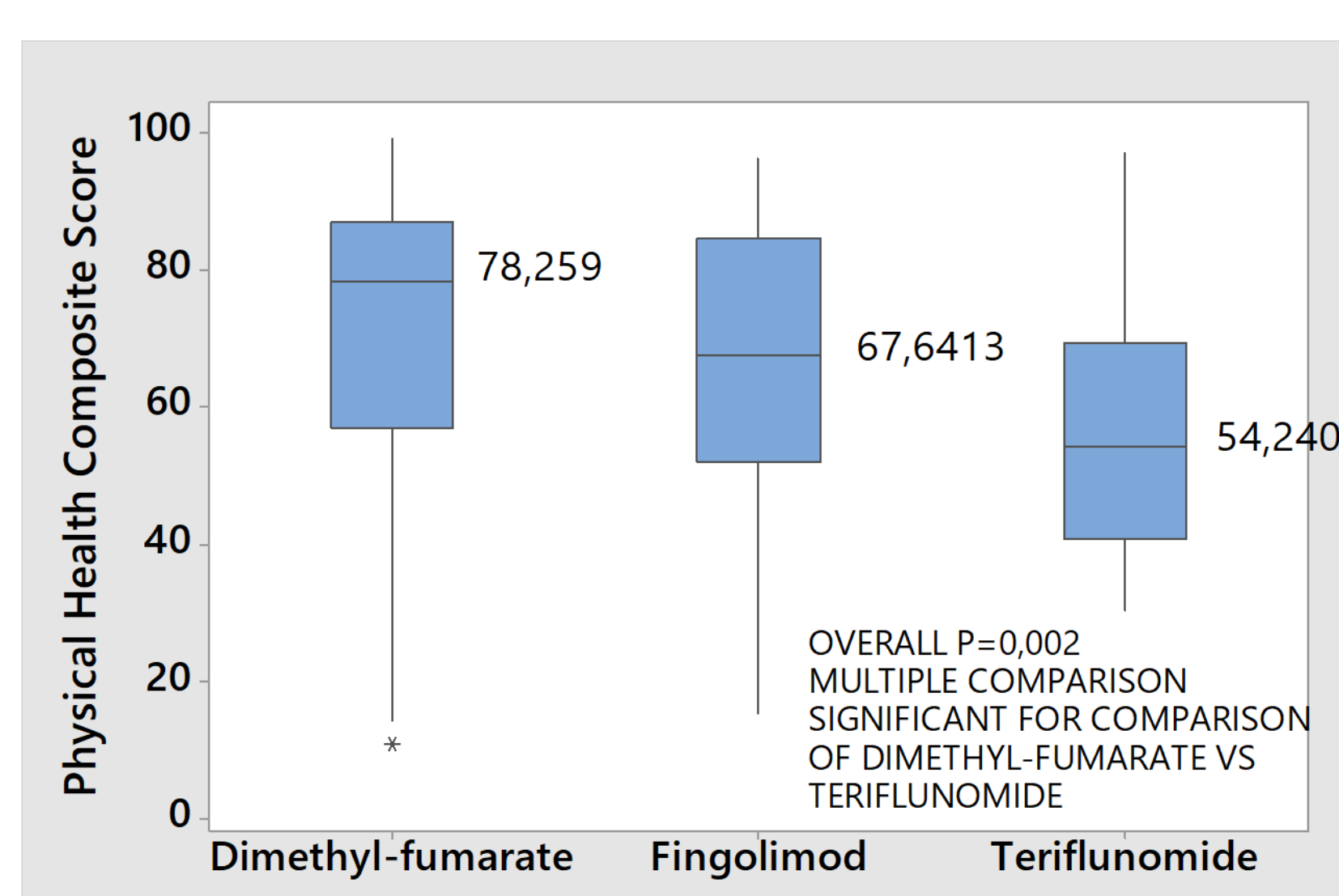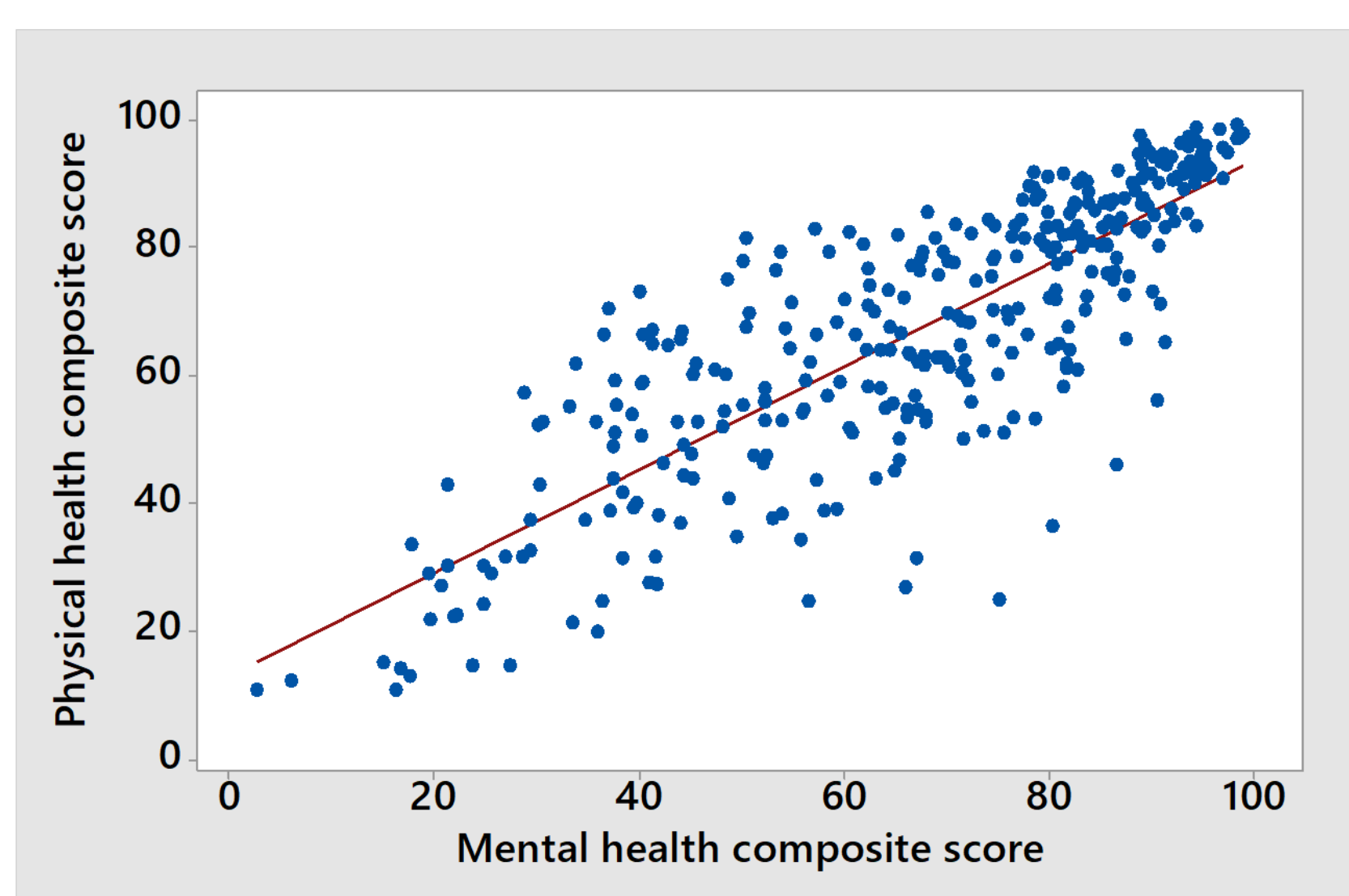Patient informed consent

STATISTICS
Spearman correlation test, Anova on ranks for multiple comparison and Mann-Withney test for simple comparison.

Results

		N (%)
N PATIENTS		341 (100%)
SEX	F	235 (68.9)
	M	106 (31.1)
ETHNIC GROUP	CAUCASIAN	339 (99.4)
	ARAB	1 (0.3)
	MIXED	1 (0.3)
Age (median [range])		44 [19, 75]
DIAGNOSIS	RR-MS (Relapsing- remitting)	319 (93.5)
	SP-MS (Secondary progressive)	11 (3.2)
	RP-MS (Progressive relapsing)	3 (0.9)
	PP-MS (Primary progressive)	1 (0.3)
	OTHER demyelinating disease	7 (2.1)
Score EDSS (median [range])		1.50 [0.00, 7.00]
Number of relapses in last two years (median [range])		0.00 [0.00, 6.00]
Time from diagnosis (median [range])		6.85 [0.30, 34.22]

ROUTE OF ADMINISTRATION
- ORAL 57%
- COMBINED 2%
- SUBCUTANEOUS 41%

ORAL DRUGS
- AZATHIOPRINE 2%
- DIMETHYL FUMARATE 60%
- FINGOLIMOD 21%
- TERIFLUNOMIDE 17%

SUBCUTANEOUS DRUGS
- INTERFERON ß-1a 43%
- PEGINTERFERON ß-1a 13%
- INTERFERON ß-1b 4%
- GLATIRAMER ACETATE 40%

✓ We enrolled 341 patients from 16 centres (median age44.1 years; 68.9% women) with relapsing–remitting MS from May 2018 to June 2019
✓ Physical and mental well being were correlated with each other (R=0.826; p<0.001) according to a direct proportionality
✓ Both indexes had an inverse correlation with the degree of EDSS disability (R=0.511, p<0.001 and R=0.344, p<0.001, respectively).
✓ Patients treated with teriflunomide had lower physical QoL scores compared with patients treated with other oral drugs

OVERALL P=0.002
MULTIPLE COMPARISON SIGNIFICANT FOR COMPARISON OF DIMETHYL-FUMARATE VS TERIFLUNOMIDE

78,259 / 67,6413 / 54,2407

A multiple linear regression analysis was calculated to predict QoL based on age, EDSS score and type of treatment.

Participant's Physical Health Composite Score decreased 7,36 points for each point of EDSS and 10,29 points in patients treated with teriflunomide (R^2=35,08, p<0,001)

Conclusion and Relevance

✓ The study achieved primary and secondary endpoints and indicated a relevant decrease in QoL related to physical health associated with teriflunomide, which deserves further investigations.

✓ We also demonstrated that joint action by a scientific society and a student association was a valuable method to perform a no profit, multicentre, observational study in real practice