ISRCTN78466206 https://doi.org/10.1186/ISRCTN78466206

# The quality of life of multiple sclerosis patients in Europe

**Submission date**
06/08/2019

**Recruitment status**
No longer recruiting

**Registration date**
13/08/2019

**Overall study status**
Completed

**Last Edited**
14/04/2021

**Condition category**
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

## Plain English summary of protocol

Background and study aims
The HORIZON 2020 (H2020) Optogenerapy project aims to develop a new medical implant for the controlled release of beta interferon (IFN-β) treatment into the body for treating Multiple Sclerosis (MS) patients. By replacing standard interferon delivery with this implant the aim is to improve treatment effectiveness with fewer side effects and lower healthcare costs, improving the quality of life of MS patients. The aim of this study is to measure the current quality of life and health status of MS patients.

Who can participate?
Patients aged 18 and over with MS

What does the study involve?
The survey asks questions about participants' disease, treatment, health status and quality of life. They only have to fill in the survey once and it takes about 15-20 minutes to fill out.

What are the possible benefits and risks of participating?
There are no physical, legal or economic risks associated with participation in this study. Participants do not have to answer questions that they do not wish to answer. Participation is voluntary and can stop at any time.

Where is the study run from?
Erasmus School of Health Policy & Management at the Erasmus University Rotterdam (Netherlands)

When is the study starting and how long is it expected to run for?
January 2019 to October (updated 19/08/2020, previously: December 2019)

Who is funding the study?
European Union Horizon 2020

Who is the main contact?
L.A.Visser
l.a.visser@eshpm.eur.nl

### Study website
https://optogenerapy.eu/ms-patients-survey

## Contact information

### Type(s)
Public

### Contact name
Mrs Laurenske Visser

### ORCID ID
http://orcid.org/0000-0002-1478-813X

### Contact details
Bayle Building
Burgemeester Oudlaan 50
Rotterdam
Netherlands
3062 PA
+31 (0)10 408 8648
l.a.visser@eshpm.eur.nl

## Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
MEC-2018-1636

## Study information

### Scientific Title
The quality of life of multiple sclerosis patients in Europe

### Acronym
QOLMSE

## Study objectives
The aim of this study is to asses the current quality of life and health status of multiple sclerosis patients in five European countries (including the United Kingdom, the Netherlands, France, Germany and Italy).

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 28/01/2019, The Erasmus MC Medical Ethics Review Committee (Postbus 2040, 3000 CA Rotterdam, Tel: +31 (0)10 7033625 extension nr 34428; Email: metc@erasmusmc.nl), ref: MEC-2018-1636

## Study design
Observational cross-sectional survey

## Primary study design
Observational

## Secondary study design
Cross sectional study

## Study setting(s)
Internet/virtual

## Study type(s)
Quality of life

## Participant information sheet
https://optogenerapy.eu/wp-content/uploads/2019/05/EN_InformedConsent_ENGLISH-1.pdf

## Health condition(s) or problem(s) studied
Multiple sclerosis

## Interventions
The online questionnaire consists of questions about patient demographics, clinical characteristics, quality of life measures (using the multiple sclerosis quality of life (MSQOL)-54), health state (using the EuroQol 5 Dimensions (EQ-5D-5L)). The questionnaire will be made available in five languages (Dutch, French, English, German and Italian). Official translations of the MSQOL-54 and EQ-5D-5L will be used and the remaining questions will be translated. Patients that choose to participate in the questionnaire will only have to fill it out once.

## Intervention Type
Other

## Primary outcome measure
1. Quality of life measured using MSQOL-54
2. Health status measured using EQ-5D-5L
Both outcomes measured at a single timepoint, when the participant fills out the questionnaire

## Secondary outcome measures

Clinical and treatment characteristics, measured by questionnaire at a single timepoint, when the participant fills out the questionnaire

### Overall study start date
07/01/2019

### Completion date
01/10/2019

## Eligibility

### Key inclusion criteria
1. Patients diagnosed with clinically definite multiple sclerosis (relapsing-remitting MS, secondary progressive MS, primary progressive MS)
2. Age 18 years or older
3. No restrictions whether patients are or are not using immunomodulatory therapy, or have used other therapies in the past
4. Participants have to have access to internet and the OPTOGENERAPY website to fill in the online questionnaire

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
250

### Total final enrolment
182

### Key exclusion criteria
Patients with a co-morbidity that negatively influences their cognition (for example dementia, stroke)

### Date of first enrolment
26/06/2019

### Date of final enrolment
31/12/2019

## Locations

### Countries of recruitment
France

Germany

Italy

Netherlands

United Kingdom

### Study participating centre
**Erasmus School of Health Policy & Management, Erasmus University Rotterdam**
Bayle Building
Burgermeester Oudlaan 50
Rotterdam
Netherlands
3062 PA

### Study participating centre
**CIC Neurosciences, Institut de Cerveau et de la Moelle epiniere ICM**
Hospital Petie-Salpetriere
47-83 bd de l'Hospital
Paris
France
75651 PARIS CEDEX 13

## Sponsor information

### Organisation
Erasmus School of Health Policy & Management

### Sponsor details
Bayle Building
Burgemeester Oudlaan 50
Rotterdam
Netherlands
3062 PA
+31 (0)10 408 8648
l.a.visser@eshpm.eur.nl

### Sponsor type
University/education

**ROR**
https://ror.org/057w15z03

# Funder(s)

**Funder type**
Government

**Funder Name**
Horizon 2020 grant agreement No 720694.

**Alternative Name(s)**
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**

# Results and Publications

**Publication and dissemination plan**
Publish the quality of life and health status results of the participants in 2020-2021.

**Intention to publish date**
01/10/2020

**Individual participant data (IPD) sharing plan**
The trial data will only be used by the researchers within the same research field at the Erasmus University Rotterdam for patient confidentiality reasons. The research data be made available (for example to check on scientific integrity) to a person outside the research group, only if truly necessary.

**IPD sharing plan summary**
Not expected to be made available

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 20/03/2021 | 14/04/2021 | Yes | No |