ISRCTN45742963 https://doi.org/10.1186/ISRCTN45742963

Physical activity and quality of life in people with multiple sclerosis in Tyrol, Austria

Submission date
07/12/2020

Recruitment status
Recruiting

Registration date
27/01/2021

Overall study status
Ongoing

Last Edited
04/08/2025

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims:
Multiple sclerosis (MS) is a disease of the human nervous system. Approximately 2.5 million people suffer from this disease worldwide. Increasing mobility impairment is a key symptom in people with MS. That leads to reduced social participation and quality of life in people concerned. These limitations appear early in the course of the disease and are often seen together with deconditioning and muscle weakness. Both factors are related with a reduction in physical activity in the MS population. People with MS are less physically active compared to adults from the general population and are at a higher risk of suffering from diseases like heart diseases. Physical activity and physical exercise can help people with MS to manage symptoms and optimize their quality of life. Therefore, it is very important to increase the amount of physical activity in the MS population and motivate them to spend more time exercising and being more physically active. The aim of this study is hence to learn about the amount of physical activity, quality of life and other influencing factors in the MS population in Tyrol. A second aim of the study is to develop a German language questionnaire, which assesses physical activity barriers and motivators in people with MS. The in-depth knowledge gained from our study will then help us developing targeted interventions for enhancing physical activity in people with MS.

Who can participate?
Adults aged 18 years and over who were diagnosed with MS, are fluent in German and live in the Austrian region of Tyrol.

What does the study involve?
This study will be conducted in four clinics in the Austrian region of Tyrol and consists of three study phases. We plan to include a total of 550 people with MS in this study. In Phase 1, 30 participants will be interviewed about aspects of their physical activity. Results from that will be utilized for developing a questionnaire on the barriers and motivators for physical activity in people with MS. In Phases 2 and 3, 460 people with MS with mild to moderate disability will be asked to complete 7 questionnaires to assess their amount, barriers and motivators for physical activity and quality of life. Another 60 people with MS with severe disability will be interviewed

about the comprehension of a physical activity questionnaire previously translated into German. In addition, these people will be asked to complete 5 of the above-mentioned questionnaires. An Actigraph GT3X-BT will be used to measure their physical activity.

What are the possible benefits and risks of participating?
There will be no immediate direct benefits to those taking part. We however expect an indirect benefit to people with MS over the longer term. This is due to our increased knowledge about the activity behaviour, barriers and motivational factors to physical activity the MS population, which enables us to develop new treatment strategies. Hence, we hope that our study findings will positively influence the rehabilitation process in people with MS. There will be no risks to the participants of this study.

Where is the study run from?
The study is run by the Karl Landsteiner Institute for Interdisciplinary Research at the Rehabilitation Center Muenster, Austria and will take place at four clinics in the Austrian region of Tyrol.

When is the study starting and how long is it expected to run for?
December 2020 to June 2026

Who is funding the study?
The present study is funded by Sanofi Genzyme GmbH (Austria)

Who is the main contact?
Dr. Christian Brenneis
Christian.Brenneis@reha-muenster.at

Study website
https://www.reha-muenster.at/multiple-sklerose.html

Contact information

Type(s)
Scientific

Contact name
Dr Barbara Seebacher

ORCID ID
https://orcid.org/0000-0001-5699-9077

Contact details
Gröben 700
Münster
Austria
6232
+43 5337200046205
Barbara.Seebacher@reha-muenster.at

Type(s)
Public

Contact name
Mr Andreas Wanitschek

ORCID ID
https://orcid.org/0009-0006-6077-4966

Contact details
Gröben 700
Münster
Austria
6232
+43 5337200046204
Andreas.Wanitschek@reha-muenster.at

Type(s)
Public

Contact name
Dr Rainer Ehling

ORCID ID
https://orcid.org/0000-0002-6291-9659

Contact details
Gröben 700
Muenster
Austria
6232
+43 5337200046336
Rainer.Ehling@reha-muenster.at

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1288/2020

Study information

Scientific Title
Activity behaviour and health related quality of life in people with multiple sclerosis in Tyrol, Austria: A cross-sectional study

Acronym
PAMS

Study objectives
1. The level of physical activity in people with multiple sclerosis in Tyrol does not meet the recommended values
2. There is a moderate positive correlation between the levels of physical activity and health-related quality of life in people with multiple sclerosis in Tyrol
3. There is a significant influence of disease-specific factors and self-efficacy on the physical activity behaviour in people with multiple sclerosis in Tyrol
4. Barriers and facilitating factors to physical activity can be identified in people with multiple sclerosis in Tyrol

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/11/2020, Ethics review committee Medical University of Innsbruck Austria (Innrain 43, A-6020 Innsbruck, Austria; +43 (0)50 504-25444; ethikkommission@i-med.ac.at), ref: 1288 /2020

Study design
Multicenter observational cross-sectional trial

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Observation of the activity behaviour and quality of life in people with multiple sclerosis in Tyrol

Interventions
The development of the BaFa-PAMS questionnaire consists of several study phases which are interconnected.

The qualitative interviews are necessary to define the construct of barriers and facilitators to physical activity in people with MS. This is followed by the development of an item pool where items will be created based on the literature research and the results from the qualitative

interviews. For initial validation of the item pool, the remaining questionnaires and actigraph measures are necessary to test for external validity. Currently, there is no validated German-language questionnaire which is why the translation of the PARA-Sci interview questionnaire is required. Currently the barriers and facilitators to physical activity for people with severe MS are not known, so it is important that they are included in the development study.

Study phase 1
People with MS meeting the inclusion criteria will be invited by the principal investigator to participate in an interview during their inpatient rehabilitation at the Rehabilitation Center Muenster/ Karl Landsteiner Institute for Interdisciplinary Research at the Rehabilitation Center Muenster. The duration of the interview will be approximately 30 min, and for each study participant, the study duration will be 1 day

Study phase 2
Participants with mild to moderate disability (Expanded Disability Status Scale (EDSS) score of 0 - 6.5):
Participants will be asked to complete 7 questionnaires. Completion of the 7 questionnaires will need approximately 60 min and for each study participant, the study duration will be 1 day

Participants with severe disability (EDSS score of >6.5):
People with MS meeting the inclusion criteria will be invited to participate in the study by the principal investigator of the respective study center. Participants will be asked to complete 5 questionnaires, take part in 1 interview and wear an actigraph. Completion of the 5 questionnaires will need approximately 45 min and the duration of the interview will be approximately 45 min. Participants will wear an actigraph for a period of 7 days. For each study participant, the study duration will be 8 days

Study phase 3
Participants with mild to moderate disability (EDSS score of 0 - 6.5):
People with MS meeting the inclusion criteria will be invited to participate in the study by the principal investigator of the respective study center. Participants will be asked to complete 6 questionnaires once. In addition, they will be asked to complete 1 questionnaire twice, within a period of 14 days. The duration for the participants to complete the 7 questionnaires (re-test included) will be approximately 70 min and for each study participant, the study duration will be 14 days.

Participants with severe disability (EDSS score of >6.5):
Participants who are meeting the inclusion criteria are asked to join the study by the principal investigator of the respective study center. Participants are going to complete 5 questionnaires, 1 interview and they are going to wear an actigraph. One of the 5 questionnaires is going to have a re-test 14 days after the initial testing. The duration for the participants to complete the 5 questionnaires (re-test included) will be approximately 55 min. The duration for the participants to complete 1 interview will be approximately 45 min. Participants are going to wear the actigraph for 7 days and will be included in the study for the duration of 21 days

Intervention Type
Other

Primary outcome measure
1. Physical Activity measured by the International Physical Activity Questionnaire (IPAQ), Godin Leisure Time Exercise Questionnaire (GLTEQ) at baseline
2. Physical Activity measured by the Physical Activity Recall Assessment for People with Spinal

Cord Injury (PARA-SCI) over 3 days
3. Physical Activity measured by the Actigraph GT3X-BT (ActiGraph) for 7 days
4. Health-related quality of life is measured by the Multiple Sclerosis International Quality of Life questionnaire (MusiQol) at baseline
5. Disease-specific factors are collected from the patient records at baseline

Secondary outcome measures
1. Fatigue is measured by the Würzburger Erschöpfungsinventar (WEIMUS) at baseline
2. Depression is measured by the Hospital Anxiety and Depression Scale (HADS-D) at baseline
3. Self-efficacy is measured by the Unidimensional Self-Efficacy Scale for MS (USE-MS-G) at baseline
4. Mobility is measured by the Multiple Sclerosis Walking Scale-12 (MSWS-12) at baseline

Overall study start date
01/01/2019

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Diagnosed with multiple sclerosis according to revised McDonald criteria (Thompson et al., 2018), independent of disease phenotype or ethnicity
2. Age ≥18 years
3. Principal residence in Tyrol
4. Excellent knowledge of the German language
5. EDSS-Score from 0 to 9.0 (Kurtzke 1983)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
550

Key exclusion criteria
1. Recent relapse from MS (within 90 days prior to the study start)
2. Pregnancy
3. Comorbidity (malignant disease, dementia, other neurological or psychiatric diseases)

Date of first enrolment

01/02/2021

Date of final enrolment
16/06/2026

Locations

Countries of recruitment
Austria

Study participating centre
Rehabilitation Center Muenster/ Karl Landsteiner Institute for Interdisciplinary Research at the Rehabilitation Center Muenster
Gröben 700
Muenster
Austria
6232

Study participating centre
Clinical Department of Neurology, Medical University of Innsbruck
Anichstraße 35
Innsbruck
Austria
6020

Study participating centre
Clinical Department of Neurology, State Hospital in Austria, Hochzirl-Natters
Hochzirl 1
Zirl
Austria
6170

Study participating centre
Clinical Department of Neurology, District Hospital Kufstein
Endach 27
Kufstein
Austria
6330

Sponsor information

Organisation
Karl Landsteiner Institute for Interdisciplinary Research at the Rehabilitation Center Muenster

Sponsor details
Gröben 700
Muenster
Austria
6232
+43 5337200046326
christian.brenneis@reha-muenster.at

Sponsor type
Research organisation

Website
https://www.reha-muenster.at/

ROR
https://ror.org/05r0e4p82

Funder(s)

Funder type
Industry

Funder Name
Sanofi Genzyme

Alternative Name(s)
Genzyme Corporation, Genzyme Corp.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication of results and protocol in a peer-reviewed journal.

Intention to publish date
31/12/2027

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication