

Improved involvement of multiple sclerosis patients in discussions about treatment

Submission date 23/06/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 24/06/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/10/2022	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Multiple sclerosis (MS) is one of the most common diseases of the central nervous system (brain and spinal cord). Healthy nerves are coated in a fatty casing (myelin sheath) which helps messages to travel quickly and smoothly along nerves. When a person is suffering from MS, the immune system, which normally helps to protect against infection, attacks the myelin sheath, stripping it from the nerves (demyelination). This demyelination means that messages cannot travel along the nerves effectively, causing a range of problems including loss of vision, problems with balance and coordination as well as fatigue (extreme tiredness), stress and mental health difficulties such as depression. Patients with MS often face difficult decisions about their choice of treatment. The reasons for this are several: the natural course of the disease is unpredictable but potentially serious, there are several new drugs available with different effects, side effects, and risks, and because of the drugs' novelty long-term effects are not well-known, while the disease itself is life-long usually spanning decades. It is hard, even for a doctor, to keep track of all the information available, and even experts will admit uncertainty about choice of treatment. Patient involvement in these situations is a difficult task. Patient involvement in decision-making requires information too be provided during medical encounters. Several studies indicate that doctors do not provide sufficiently structured, precise information and it is often characterized by use of jargon, and not adjusted to the patient's needs. This study aims to try out whether a rather simple training session for doctors leads to an improvement in these respects, in a way that helps patients to better recall the information they received.

Who can participate?

Adults with MS who are currently on their first drug treatment and doctors working in the Neurological department of Akershus University Hospital who regularly meet MS patients.

What does the study involve?

All participating doctors receive a three hour training session in groups of 5-8. The training session involves a brief introduction followed by learning about how best to provide patients with information. The rest of the session involves role playing, reflecting on the content of the session and providing feedback, before a brief summary at the end. Patients are randomly allocated to one of two groups. Those in the first group meet with the doctor for a consultation

before they have attended the training session and those in the second group meet with the doctor after they have attended the training session. For both groups, the consultations are videotaped so that they can be reviewed by the research team to assess the information provided in the session. Patients are also interviewed before and immediately after the consultation in order to find out how much information the doctor gave them they are able to remember.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Akershus University Hospital (Norway)

When is the study starting and how long is it expected to run for?

April 2014 to December 2019

Who is funding the study?

Norwegian Foundation for Health and Rehabilitation, ExtraStiftelsen (Norway)

Who is the main contact?

Professor Pål Gulbrandsen

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2015/FO7408

Study information

Scientific Title

Enabling shared decision-making about treatment with multiple sclerosis patients: A preclinical intervention study

Study objectives

A three hour course in how to provide information will improve MS patients' ability to recall information given by doctors.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Regional Committee for Medical and Health Research Ethics (Southeast Norway) decided that as this experiment is not medical or health research and therefore exempted from review. 24/03/2015, ref: 2015/161

Study design

Preclinical randomised parallel study

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Available in Norwegian by contacting the principal investigator: pal.gulbrandsen@medisin.uio.no

Health condition(s) or problem(s) studied

Multiple sclerosis

Interventions

Participating patients are randomly allocated to meet a doctor before or after the doctor has been trained. One researcher observes the doctor-patient interaction and notes all information that is provided. The researcher interviews the patient directly after, first using open questions to elicit understanding and recall, followed by prompted, but not leading questions about information the doctor provided to elicit as accurate recall as possible. Both doctor-patient interaction and post-visit interview are videotaped, and independent coders that will not know if the interaction is pre or post intervention identify and decide whether patient recall of each information the doctor has given is sufficiently precise to represent the information given. Following these procedures the percentage of given information that is recalled, and whether there is a significant difference between patients in the pre-course and post-course arms of the

study is calculated. In addition, a battery of questionnaires (MAPPIN'SDM, Collaborate, Four Habits Patient Questionnaire) will be used to map the patients' evaluation of communication, information provision, and involvement in decision-making.

The training session for doctors is led by an experienced teacher in clinical communication and lasts 3 hours and is run for groups of 5-8 doctors at a time. The training session involves being given a brief introduction about the 6 main steps of information provision:

1. Inducing a trusting atmosphere
2. Finding out what the patient knows
3. Prioritising which information to convey
4. Portioning information using micropauses
5. Rationing information when sensing that the patient feels unsafe
6. Checking what the patient has understood.

The rest of the session consists of role-plays, reflections, and feedback, and there is a brief summary round at the end.

Intervention Type

Behavioural

Primary outcome measure

The amount of information provided by the doctors that is recalled by the patients is measured using patient interviews immediately after the consultation.

Secondary outcome measures

1. Patient involvement is measured using:
 - 1.1. Control preference scale (Degner et al), before and after consultation (patients and doctors)
 - 1.2. MAPPIN' SDM (Kasper et al.) after the consultation (patients and doctors)
 - 1.3. Collaborate (Elwyn et al.) after the consultation (patients only)
2. Communication and information quality is measured using the Four Habits Patient Questionnaire (patients)
3. Doctor communication self-efficacy is measured using Parle et al.'s self-efficacy questionnaire before and after the consultation and three months later
4. Adherence to information principles is measured through reviewing the video recordings of the sessions using the Four Habits Coding Scheme

Overall study start date

01/04/2014

Completion date

31/12/2019

Eligibility

Key inclusion criteria

Patients:

1. Patients with relapsing remitting MS
2. Currently use a first line drug
3. Not previously been exposed to the decision to begin with a second line drug
4. Aged 18 years and over

Doctors:

1. All doctors working in the Neurological department of Akershus University Hospital
2. Regularly meet multiple sclerosis patients

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Patients: 32 Doctors: 16

Total final enrolment

51

Key exclusion criteria

No exclusion criteria.

Date of first enrolment

01/05/2016

Date of final enrolment

31/05/2016

Locations**Countries of recruitment**

Norway

Study participating centre

Akershus University Hospital

Post office box 1000

Lørenskog

Norway

1478

Sponsor information

Organisation

Akershus University Hospital

Sponsor details

Sykehusveien 25
Lørenskog
Norway
1478

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/0331wat71>

Funder(s)**Funder type**

Government

Funder Name

Norwegian Foundation for Health and Rehabilitation, EkstraStiftelsen (EkstraStiftelsen Helse og Rehabilitering)

Alternative Name(s)

Norwegian Foundation for Health and Rehabilitation, EkstraStiftelsen Helse og Rehabilitering, EkstraStiftelsen, Stiftelsen Dam & Dam Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Norway

Results and Publications**Publication and dissemination plan**

Current publication and dissemination plan as of 29/12/2021:

Planned publication of papers in scientific journals:

1. The effect of the training on patient recall
2. The effect of the training on patient evaluation of communication, information, and involvement

3. The effect of the training on doctor adherence to principles of information provision

Previous publication and dissemination plan as of 15/01/2021:

Planned publication of papers in scientific journals:

The effect of the training on patient recall (soon to be submitted)

The effect of the training on patient evaluation of communication, information, and involvement (soon to be submitted)

The effect of the training on doctor adherence to principles of information provision (soon to be submitted)

Previous publication and dissemination plan:

Planned publication of several papers in scientific journals:

The effect of the training on patient recall

2. The effect of the training on patient evaluation of communication, information, and involvement

3. The effect of the training on doctor adherence to principles of information provision

4. Several other papers using qualitative methods, not about effects of the trial, but rather about how training affects the interaction in other ways

Intention to publish date

30/06/2022

Individual participant data (IPD) sharing plan

As soon as the results article is published, an anonymized version of reported data will be made available as an SPSS file by request from the principal investigator Prof Pål Gulbrandsen (pal.gulbrandsen@medisin.uio.no).

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Assessment of physician adherence to intervention	13/10/2021	29/12/2021	Yes	No
Results article		15/03/2022	18/03/2022	Yes	No
Protocol file	in Norwegian	21/05/2014	18/10/2022	No	No