ISRCTN42739508 https://doi.org/10.1186/ISRCTN42739508

Improved involvement of multiple sclerosis patients in discussions about treatment

Submission date
23/06/2016

Recruitment status
No longer recruiting

Registration date
24/06/2016

Overall study status
Completed

Last Edited
18/10/2022

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
pal.gulbrandsen@medisin.uio.no

Contact information

Type(s)
Scientific

Contact name
Prof Pål Gulbrandsen

Contact details
HØKH Research Centre
Akershus University Hospital
Lørenskog
Norway
1475
95827288
pal.gulbrandsen@medisin.uio.no

Additional identifiers

Protocol serial number
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

Study type(s)
Other

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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

ROR
https://ror.org/0331wat71

Funder(s)

Funder type
Government

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

Alternative Name(s)

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

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Norway

Results and Publications

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?
Results article		15/03/2022	18/03/2022	Yes	No
Other publications	Assessment of physician adherence to intervention	13/10/2021	29/12/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	in Norwegian	21/05/2014	18/10/2022	No	No