ISRCTN78940214 https://doi.org/10.1186/ISRCTN78940214

Implementation of the Sapere Migliora Information aid for newly diagnosed multiple sclerosis (MS) patients in routine clinical Practice (SIMS-Practice)

Submission date
03/07/2012

Recruitment status
No longer recruiting

Registration date
04/09/2012

Overall study status
Completed

Last Edited
13/09/2016

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
Multiple sclerosis (MS) is a condition which affects the brain and spinal cord, causing problems with vision, arm or leg movement, sensation and balance. Information aids are increasing being used to improve patients' understanding of their illness, prognosis and treatment, and help them participate more actively in decision-making. The educational materials available for people with MS include booklets, websites and videos, but few have been tested for their value in educating their target audience. A recent study demonstrated the effectiveness, in terms of higher MS knowledge and care satisfaction, of the Sapere Migliora information aid, which consists of a website-assisted personal interview with a doctor, and a take-home booklet. The aims of this study are to evaluate the use of the updated and revised Sapere Migliora information aid in everyday practice, and to assess its acceptability and effectiveness compared to the take-home booklet/website consultation alone. The focus will be on the short-term results (about one month after MS diagnosis) because this is an especially taxing period for people with MS.

Who can participate?
Patients aged 18 and over who have received an MS diagnosis in the last 2 weeks

What does the study involve?
This study has two parts: Survey A and Survey B. Survey A participants receive the updated Sapere Migliora information aid. This consists of a personal interview with a health professional with MS expertise which takes place within 2 weeks of their MS diagnosis. At the end of the interview, participants receive the take-home Sapere Migliora booklet and a website password, together with four study questionnaires (assessing MS knowledge, satisfaction with care, anxiety and depressive symptoms, sociodemographic information and satisfaction with the information aid). Participants are asked to complete and send the questionnaires to the study center within 6 weeks using a return-paid envelope. Survey B is conducted in 19 MS centers, randomly selected from the 220 Italian MS centers. After receiving their MS diagnosis,

participants are given the take-home Sapere Migliora booklet/website password and the four study questionnaires described above. The effectiveness of the updated Sapere Migliora information aid (Survey A) is compared to the take-home booklet/website consultation alone (Survey B)

What are the possible benefits and risks of participating?
The previous study found that people with MS who received the information aid were more knowledgeable and satisfied with care compared to those who received standard care. Anxiety symptoms are common around MS diagnosis. However, the information provided with the Sapere Migliora information aid did not increase anxiety. Anxiety and mood symptoms are assessed in the two surveys.

Where is the study run from?
A total of 24 Italian MS centres take part in this study. The lead centre is the Foundation IRCCS Neurological Institute C. Besta, Milan.

When is the study starting and how long is it expected to run for?
May to November 2012

Who is funding the study?
Italian MS Society [Fondazione Italiana Sclerosi Multipla (FISM)]

Who is the main contact?
Dr Alessandra Solari
solari@istituto-besta.it

Contact information

Type(s)
Scientific

Contact name
Dr Alessandra Solari

Contact details
Foundation of the Carlo Besta Neurological Institute
Unit of Neuroepidemiology
Via Celoria, 11
Milan
Italy
20133
+39 (0)2 2394 2391
solari@istituto-besta.it

Additional identifiers

Protocol serial number
2010/S/1

Study information

Scientific Title
Implementation of the Sapere Migliora Information aid for newly diagnosed multiple sclerosis (MS) patients in routine clinical Practice (SIMS-Practice): a phase IV open-label trial

Acronym
SIMS-Practice

Study objectives
Increasing interest in patient-physician communication is evinced by the proliferation of aids to facilitate patients' understanding of their illness, prognosis and treatment, and make it easier for them to participate more actively in decision-making. The educational materials available for PwMS include booklets, web sites and videos, but few have been rigorously evaluated for their value in educating their target audience. Accordingly, the National Institute for Clinical Excellence "grade A" recommendation for an information pack specific for newly diagnosed PwMS was mainly based on evidence from stroke and cancer patients.

The Sapere Migliora information aid (IA) demonstrated its effectiveness in improving disease knowledge and care satisfaction compared to standard care in newly-diagnosed MS patients (ISRCTN81072971; Solari 2010a; Borreani 2011). The SIMS-Practice is a multicenter, open-label, phase IV study that will evaluate:
1. The effectiveness of the IA (Survey A) compared to the take-home booklet/website consultation alone (Survey B)
2. The implementation of the IA in routine practice, using more liberal requirements.
We will focus on short term results (about one month after MS diagnosis communication) because this is an especially taxing period, whereas, over time, both disease knowledge and care satisfaction tend to increase.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board and Foundation of the Carlo Besta Neurological Institute Ethics Committee, March 2011, ref: 13/2011

Primary study design
Interventional

Study design
Multicenter open-label phase IV study

Study type(s)
Treatment

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

Interventions
The Sapere Migliora IA used in the SIMS-Trial (ISRCTN81072971) consisted of a personal interview with a navigable CD, and a take-home booklet which was given to the patient at the end of the interview. The personal interview was scheduled 1-15 days after the patient received

the diagnosis of MS, with a trained physician. A patient's significant other could be present if requested by the patient. The path through the CD during the session was tracked electronically, and the time spent on each topic recorded. The materials were developed in Italian by a multidisciplinary expert group through an iterative process of review and revision in collaboration with MS patients, using information derived from focus groups with patients and clinicians, and a comprehensive literature review.

Prior to the initiation of the SIMS-Practice, the IA was updated (based on relevant advances in the field of MS) and revised (based on the results of the SIMS-Trial and SIMS-Qual studies). The CD was replaced by a website.

Two surveys - Participants and procedures
Survey A is conducted in the 5 centers that participated in the SIMS-Trial. The intervention is the updated Sapere Migliora IA (personal interview assisted by a website and take home booklet /website consultation). Participants to the personal interview are the PwMS, a health professional with MS expertise (physician, psychologist or nurse) and (if requested by the PwMS) his/her significant other. The personal interview takes place within 2 weeks following the communication of the MS diagnosis. At the end of the interview, the patient receives the take-home Sapere Migliora booklet and a web-site password, together with study questionnaires (MSKQ, COSM-R, HADS) and a socio-demographic/satisfaction with the information aid questionnaire) to be completed and sent to the coordinating center within 6 weeks, using a return-paid envelope.

Survey B is conducted in 19 MS centers in Italy. Thirty centers from the 220 Italian MS centers (stratified randomization - 10 centers from each geographic area) were invited to participate, provided >= 3 new MS diagnoses had been made at the center in the previous year. Of these, one center did not fulfil the inclusion criterion, 10 did not express interest in the study, 19 agreed to participate and obtained Institutional Review Board approval. After MS diagnosis disclosure, participants to Survey B receive the take-home Sapere Migliora booklet, the website password, and the 4 study questionnaires reported above.

Sample size and data analysis
The primary study endpoint is a score in the highest tertile of possible scores for both the MSKQ (score >17) and COSM-R section 2 (score >40).
Estimated sample size was based on the SIMS-Trial findings (ISRCTN8107297): The primary outcome was achieved by 30/60 (50%) patients assigned to the information aid vs. 8/60 (13%) patients assigned to standard care, with a possible effect attributable to the study intervention of 37%. This value was used as expected value for H0 (Survey A = Survey B).
There are no data available on the effect of the booklet only (Survey B), and we hypothesize an effect of 14% vs. standard care (H1). Our power analysis was based on 80% power and an alpha error of 5% (two-tailed test). The group sample sizes of 61 in Survey A and 61 in Survey B detects a difference between the group proportions of 23%. Assuming 20% missing items plus drop-outs, 152 patients will be required.
Comparisons of proportions will be performed using Pearson's chi-square test or Fisher's exact test. Unadjusted odds ratios (ORs) will be compared with ORs produced by logistic regression models adjusted for the following covariates: patient's age, gender, education, HADS scores, geographic area and time since disease onset.
Continuous variables will be compared between groups using the Student t or Wilcoxon rank-sum test. All p-values will be derived from two-tailed tests and unadjusted for multiple testing. The analyses will be performed using Stata 10.

Intervention Type

Other

Phase
Phase IV

Primary outcome(s)
1. The MSKQ is a self-administered general MS knowledge questionnaire consisting of 25 multiple-choice items; it is available in two versions (A and B) differing in order of item presentation; version A will be used in the present study. Total score is the number of correct responses (range 0-25). A French for France version of the MSKQ has been recently produced by the Mapi Institute.
2. The COSM-R (Comunicazione medico-paziente nella Sclerosi Multipla-revised version) is a self-administered multiple-choice questionnaire assessing satisfaction regarding the moment of MS diagnosis communication (section 1, 5 items; not an endpoint of the present study) and the ensuing period (section 2, 15 items). Five additional items do not contribute to the score but record diagnosis disclosure date, who communicated it, and whether additional information and second opinions were sought.
3. Measures taken to minimize/avoid bias (Surveys A and B): Two weeks after the expected return date, patients who do not send back the postal questionnaires will be sent a reminder (and new questionnaire, if required) by the coordinating unit. General characteristics of non-responders will be compared with those of responders.

Key secondary outcome(s)
1. The HADS is a self-assessed questionnaire consisting of 14 multiple-choice (0-3 Likert scale) items probing symptoms of anxiety (7 items) and depression (7 items). HADS anxiety (HADS-A) and depression (HADS-D) scores range from 0 (no symptoms) to 21 (most severe symptoms)
2. Patient's socio-demographic data, and his/her satisfaction with the information aid will be recorded on Questionnaire 4
3. Clinical information will be obtained from the case report form

Completion date
30/11/2012

Eligibility

Key inclusion criteria
1. MS diagnosis (Polman 2011 criteria)
2. MS diagnosis disclosed <= 2 weeks
3. Age >=18 years
4. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Primary progressive MS course

Date of first enrolment
03/05/2012

Date of final enrolment
30/11/2012

Locations

Countries of recruitment
Italy

Study participating centre
Foundation of the Carlo Besta Neurological Institute
Milan
Italy
20133

Sponsor information

Organisation
Foundation of the Carlo Besta Neurological Institute (Italy)

ROR
https://ror.org/05rbx8m02

Funder(s)

Funder type
Research organisation

Funder Name
Fondazione Italiana Sclerosi Multipla ref: 2010/S/1

Alternative Name(s)
Italian Multiple Sclerosis Foundation, Italian MS Foundation, FISM

Funding Body Type
Government organisation

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

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2014		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes