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Effectiveness of a Structured Information interview in people with newly-diagnosed Multiple Sclerosis

Submission date	Recruitment status	[_] Prospectively registered
31/03/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/04/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/10/2014	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2007/R/19

Study information

Scientific Title

Acronym
SIMS-Trial

Study objectives
To assess the effectiveness, in terms of patient knowledge and satisfaction with the information received, of a structured add-on information interview, given within 15 days of communicating a diagnosis of multiple sclerosis (MS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Neurological Institute "C. Besta" Foundation IRCCS Ethics Committee, 18/12/2007, ref: 9/2007

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Interventions
At least 120 patients will be recruited from eight Italian centres and randomly assigned to receive the study intervention (add-on information aids, n = 60) or control (no add-on information aids, n = 60).

The add-on interview is conducted by trained neurologists (approximately one hour in length), during which information about MS is presented with the aid of a specifically designed compact

disc (CD). The information is tailored to individual needs; the patient is also given a booklet containing all the information provided.

The "Sapere Migliora" CD:
"Sapere Migliora" can be approximately rendered as "knowledge helps"; it works in Italian because the initials of the condition are SM sclerosi multipla. The CD contains an introduction followed by a menu of the headings:
1. MS insights:
1.1. Central nervous system
1.2. The myelin and the axon
1.3. Myelin and axon's damage
1.4. Mechanisms of damage
2. The diagnosis:
2.1. Relapses
2.2. Most common symptoms at disease onset
2.3. Clinical examination
2.4. Laboratory examinations
3. What happens after diagnosis:
3.1. MS course
3.2. Scheduled visits
4. Therapies:
4.1. Research at basis of therapies
4.2. Treatment for relapses
4.3. Disease-modifying drugs
5. Emotions:
5.1. Common emotional reactions
5.2. Reactions due to neurological damage
5.3. Depression
6. Having a child:
6.1. Motherhood
6.2. Fatherhood
7. Frequently asked questions (FAQs):
7.1. General questions
7.2. Questions on pregnancy
8. Glossary

Animations and intuitively-obvious aids are used extensively throughout the CD. A voice in the background illustrates the entire presentation. Emotions are also presented as a movie lasting eight minutes.

At the beginning of the interview, the "Sapere Migliora" CD is started and an opening menu appears. The patient indicates to the "informing neurologist" at which point on the program he /she wants to start. The "informing neurologist" navigates through the program guided by the patient's preferences, spending as much time as needed on each topic, skipping parts that the patient shows little interest in; opportunity is provided to repeat the exposition of topics and discuss them. Links to the glossary are present from all pertinent points on the program. Patients are encouraged to ask questions. The path through the CD during the session is traced electronically, and time spent on each topic is recorded, for subsequent analysis. At the end of the interview the patient is given the take-home booklet.

At each centre there will be an "informing neurologist" trained to conduct the add-on interview. It is desirable that the referring neurologist is always the same for each patient; however, in

large centres working in a team a single patient can be followed by more than one referring physician.

The "Sapere Migliora" Booklet:
The "Sapere Migliora" take-home booklet (A5 148 x 210 mm notepad format) has eight chapters (90 pages), a glossary (36 pages), and a section for the patient's notes. The first seven chapters match the CD topics in title and information provided. Chapter eight (Communicating the MS diagnosis: experiences of patients and health professionals) reports findings from our preliminary study. At the end of each chapter a small number of references/links are given, selected from the most comprehensive and up-to-date material available, many in Italian but some in English.

Total duration of follow-up: six months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Primary endpoints, assessed one and six months after diagnosis disclosure, are knowledge and satisfaction with diagnosis communication as determined by the MS Knowledge Questionnaire (MSKQ) and the instrument "Comunicazione medico-paziente nella Sclerosi Multipla" (revised) (CoSM-R):
1. MSKQ: no widely-accepted measure of patient knowledge on MS is currently available. The MSKQ, specifically devised for this study, consists of 25 multiple-choice items, is self-administered, and designed to be applicable to a wide range of people with MS. The total score is the number of correct responses (range 0 - 25).
2. CoSM-R: this MS-specific scale was recently devised for this study. CoSM-R is self-administered and consists of multiple-choice questions about the moment of MS diagnosis communication (9 items), and about the period immediately following diagnosis communication (16 items).

Secondary outcome measures
Secondary endpoints are changes at one and six months in:
1. The Hospital Anxiety and Depression Scale (HADS)
2. The Control Preference Scale (CPS). The CPS was translated and cross-culturally adapted into Italian from the original English version.

Other endpoints measured over the study period:
3. Attrition
4. Number of consultations
5. Number of visits to the MS centre

Overall study start date
18/03/2008

Completion date
31/03/2010

Eligibility

Key inclusion criteria
Subjects are eligible for recruitment if all the following criteria are satisfied:
1. Diagnostic workup to confirm/exclude MS diagnosis
2. Age 18 years and above, either sex
3. Signed informed consent (pre-diagnostically)

Consenting subjects will be randomised at the end of the diagnostic workup, provided that all the following criteria apply:
1. Diagnosis of MS confirmed
2. Interval between informed consent and MS diagnosis within seven months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
At least 120 patients (intervention n = 60 or control n = 60)

Key exclusion criteria
Subjects will be excluded from the study if one or more of the following criteria apply:
1. Previous MS diagnosis
2. Presence of definite cognitive compromise, psychiatric disease, or substance abuse

Date of first enrolment
18/03/2008

Date of final enrolment
31/03/2010

Locations

Countries of recruitment
Italy

Study participating centre
Unit of Neuroepidemiology
Milan
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Sponsor information

Organisation
Neurological Institute "C. Besta" Foundation IRCCS (Italy)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.istituto-besta.it

ROR
https://ror.org/05rbx8m02

Funder(s)

Funder type
Research organisation

Funder Name
The Italian Multiple Sclerosis Society (Italy)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	01/11/2010		Yes	No
Results article	results	15/08/2011		Yes	No
Results article	qualitative study results	01/02/2014		Yes	No
Results article	results	01/02/2014		Yes	No