Developing and testing the *"Sapere Migliora"* information aid for newly-diagnosed MS patients

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ISTITUTO NEUROLOGICO CARLO BESTA

Sistema Sanitario Regione Lombardia

MRC FRAMEWORK (from Craig 2008)

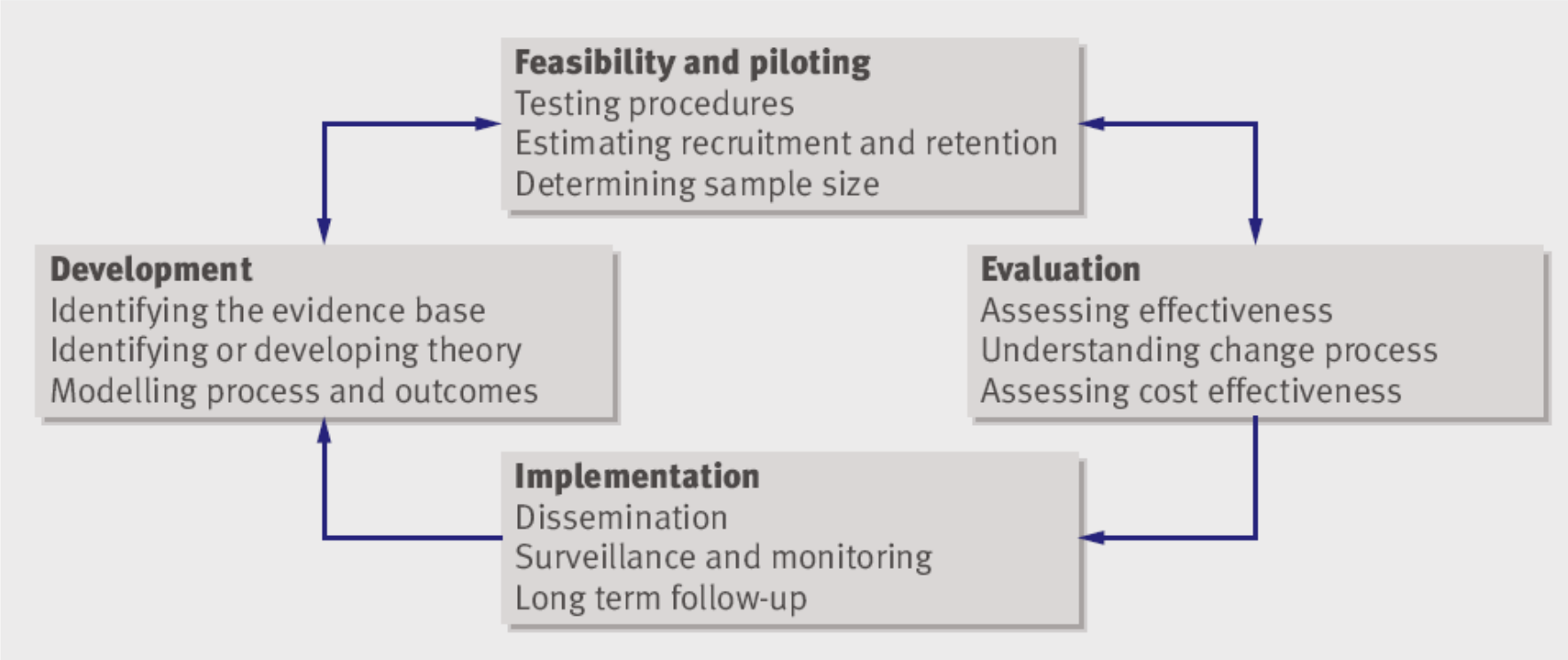
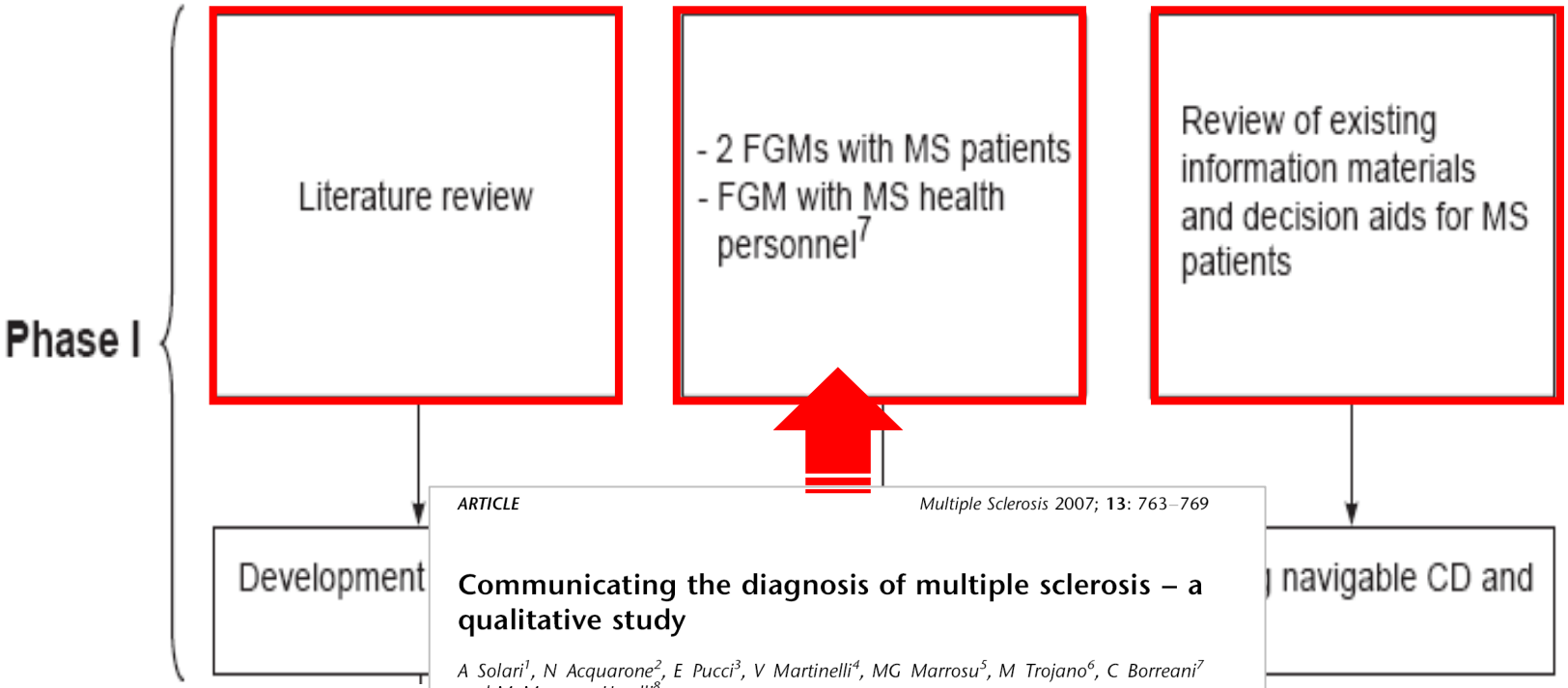


Fig 1 | Key elements of the development and evaluation process

PHASE 1: DEVELOPMENT



ARTICLE *Multiple Sclerosis* 2007; **13**: 763–769

Communicating the diagnosis of multiple sclerosis – a qualitative study

A Solari[1], N Acquarone[2], E Pucci[3], V Martinelli[4], MG Marrosu[5], M Trojano[6], C Borreani[7] and M Messmer Uccelli[8]

Studies on communicating the diagnosis of multiple sclerosis (MS) are few, and all reveal communication and information deficits. We explored the personal experience of diagnosis communication of people with MS and health professionals, using a qualitative methodology. Data were obtained from two sets of focus group meetings (FGM) with people with MS (total 23; 16 females; age range: 23–70) and one FGMs with health professionals (four neurologists, three psychologists, two nurses). The methods of framework analysis were applied to meeting transcripts to identify key topics and categories. The experience of communicating/receiving an MS diagnosis was highly varied; all patients reported the moment as powerfully evocative and unforgettable. Very poor levels of support and information were sometimes given. Although diagnosis communication had improved in more recent experience, all felt it should be further improved with appropriate setting (privacy, no interruptions, sufficient time), information tailored to the individual, and continuity of care. Such improvements imply a more meaningful patient–neurologist relationship, and also structural and organisational changes. *Multiple Sclerosis* 2007; **13**: 763–769. http://msj.sagepub.com

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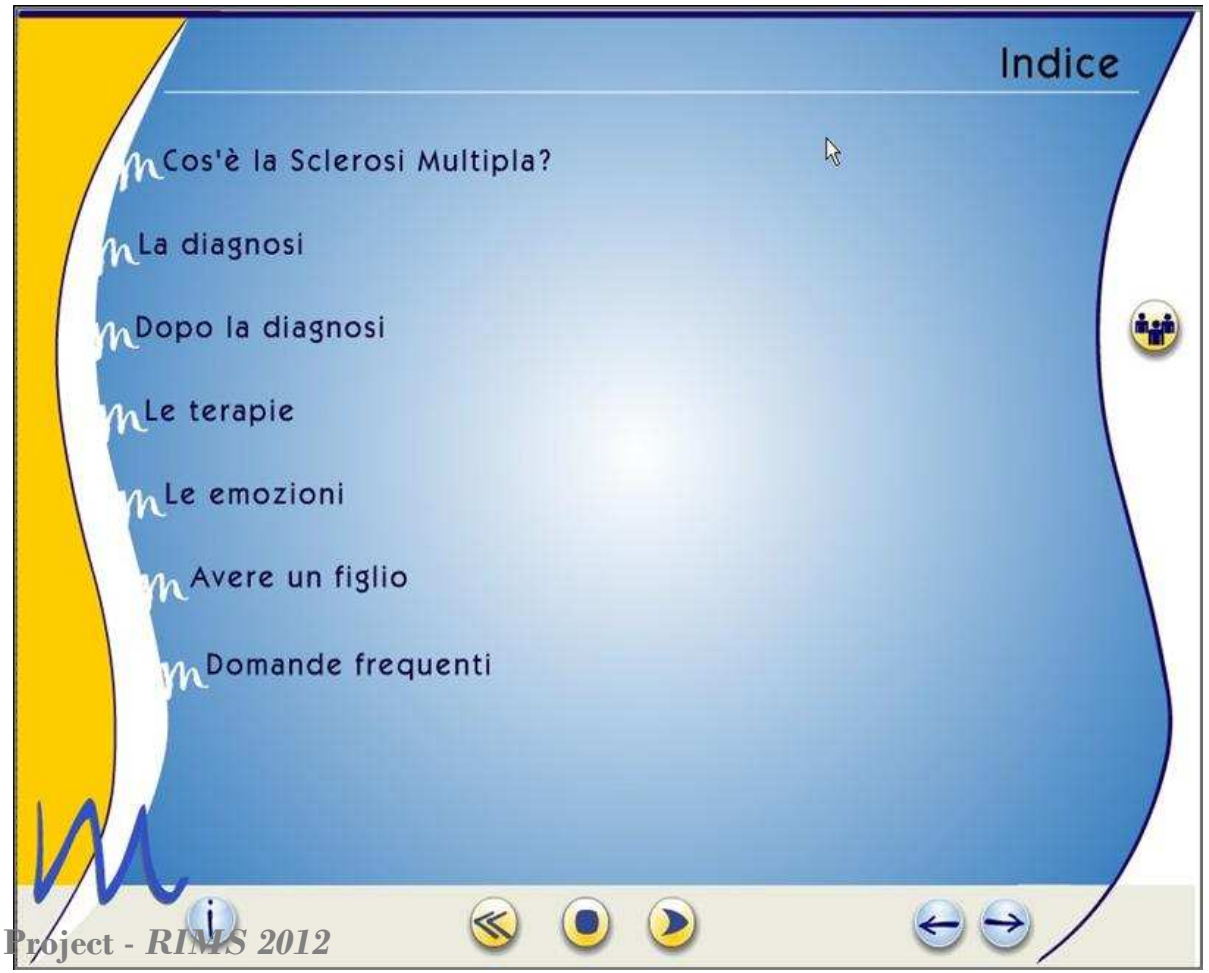
PHASE 1: DEVELOPMENT

Personal interview with "Sapere Migliora" CD



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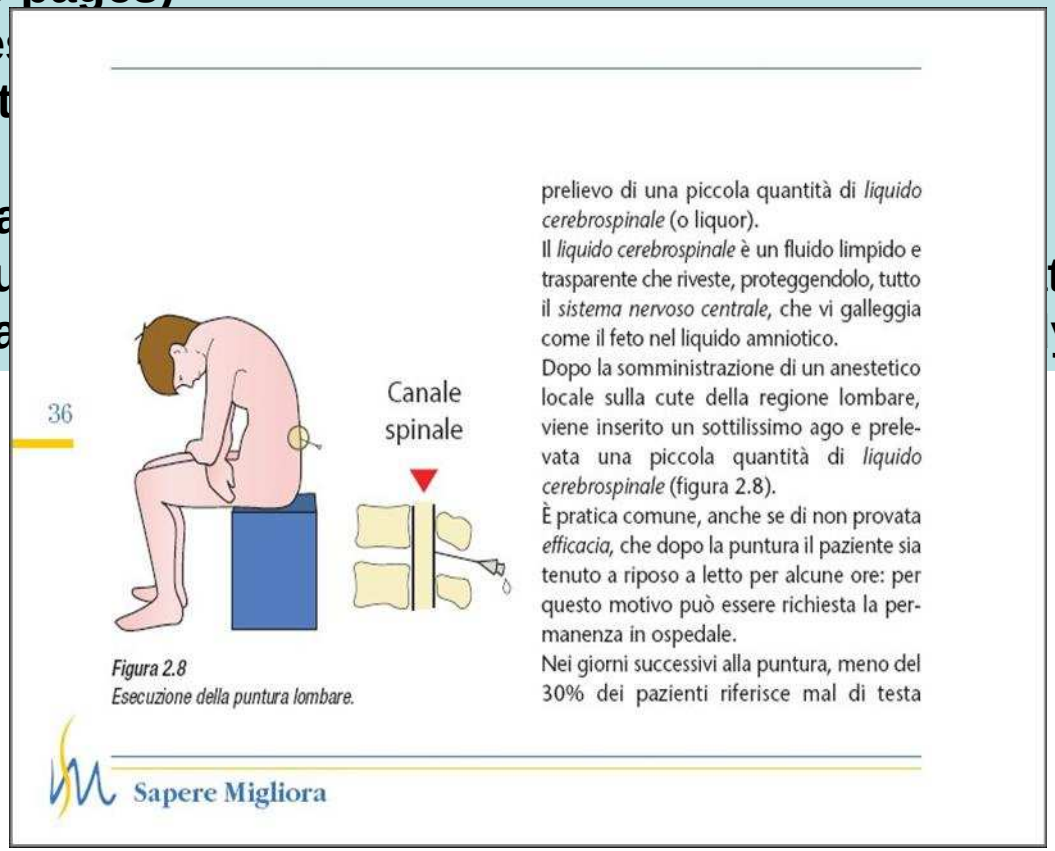
PHASE 1: DEVELOPMENT

"Sapere Migliora" Booklet

A5 148 × 210 mm notepad format
Eight chapters (90 pages)
Glossary (36 page
Section for patient

Chapters 1 to 7 ma
Chapter 8 (Commu **tients and**
health professiona **y**



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Canale spinale

Figura 2.8
Esecuzione della puntura lombare.

prelievo di una piccola quantità di *liquido cerebrospinale* (o liquor).
Il *liquido cerebrospinale* è un fluido limpido e trasparente che riveste, proteggendolo, tutto il *sistema nervoso centrale*, che vi galleggia come il feto nel liquido amniotico.
Dopo la somministrazione di un anestetico locale sulla cute della regione lombare, viene inserito un sottilissimo ago e prelevata una piccola quantità di *liquido cerebrospinale* (figura 2.8).
È pratica comune, anche se di non provata *efficacia*, che dopo la puntura il paziente sia tenuto a riposo a letto per alcune ore: per questo motivo può essere richiesta la permanenza in ospedale.
Nei giorni successivi alla puntura, meno del 30% dei pazienti riferisce mal di testa

Sapere Migliora

PHASE 1: DEVELOPMENT

PRIMARY OUTCOMES

Research Paper

Multiple Sclerosis

Multiple Sclerosis
16(1) 100–111
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DOI: 10.1177/1352458509352865
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The Multiple Sclerosis Knowledge Questionnaire: a self-administered

Research Paper

Multiple Sclerosis

Multiple Sclerosis
16(10) 1237–1247
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DOI: 10.1177/1352458510376178
msj.sagepub.com
SAGE

Development and validation of a patient self-assessed questionnaire on satisfaction with communication of the multiple sclerosis diagnosis

A Solari[1], K Mattarozzi[2], L Vignatelli[3], A Giordano[1], PM Russo[2], M Messmer Uccelli[4], R D'Alessandro[5], on behalf of the SIMS-Trial group[6] and of the GERONIMUS group[7]

Abstract

Background: We describe the development and clinical validation of a patient self-administered tool assessing the quality of multiple sclerosis diagnosis disclosure.

Method: A multiple sclerosis expert panel generated questionnaire items from the Doctor's Interpersonal Skills Questionnaire, literature review, and interviews with neurology inpatients. The resulting 19-item Comunicazione medico-paziente nella Sclerosi Multipla (COSM) was pilot tested/debriefed on seven patients with multiple sclerosis and administered to 80 patients newly diagnosed with multiple sclerosis. The resulting revised 20-item version (COSM-R) was debriefed on five patients with multiple sclerosis, field tested/debriefed on multiple sclerosis patients, and field tested on 105 patients newly diagnosed with multiple sclerosis participating in a clinical trial on an information aid. The hypothesized monofactorial structure of COSM-R section 2 was tested on the latter two groups.

Results: The questionnaire was well accepted. Scaling assumptions were satisfactory in terms of score distributions, item–total correlations and internal consistency. Factor analysis confirmed section 2's monofactorial structure, which was also test–retest reliable (intraclass correlation coefficient [ICC] 0.73; 95% CI 0.54–0.85). Section 1 had only fair test–retest reliability (ICC 0.45; 95% CI 0.12–0.69), and three items had 8–21% missed responses.

Conclusions: COSM-R is a brief, easy-to-interpret MS-specific questionnaire for use as a health care indicator.

onlу two published questionnaires.
estionnaire (MSKQ), a self-assessed
nceived to test MS knowledge, were
; in an intermediate 26-item version.
alidity (validation sample I). The final
mation aid to newly diagnosed MS
· intervention (validation sample II)
vely, 18 (range 9–23) and 17 (range
and content validity were good.
ident predictors of MS knowledge.
negative association). In conclusion,
vention. We propose the MSKQ as

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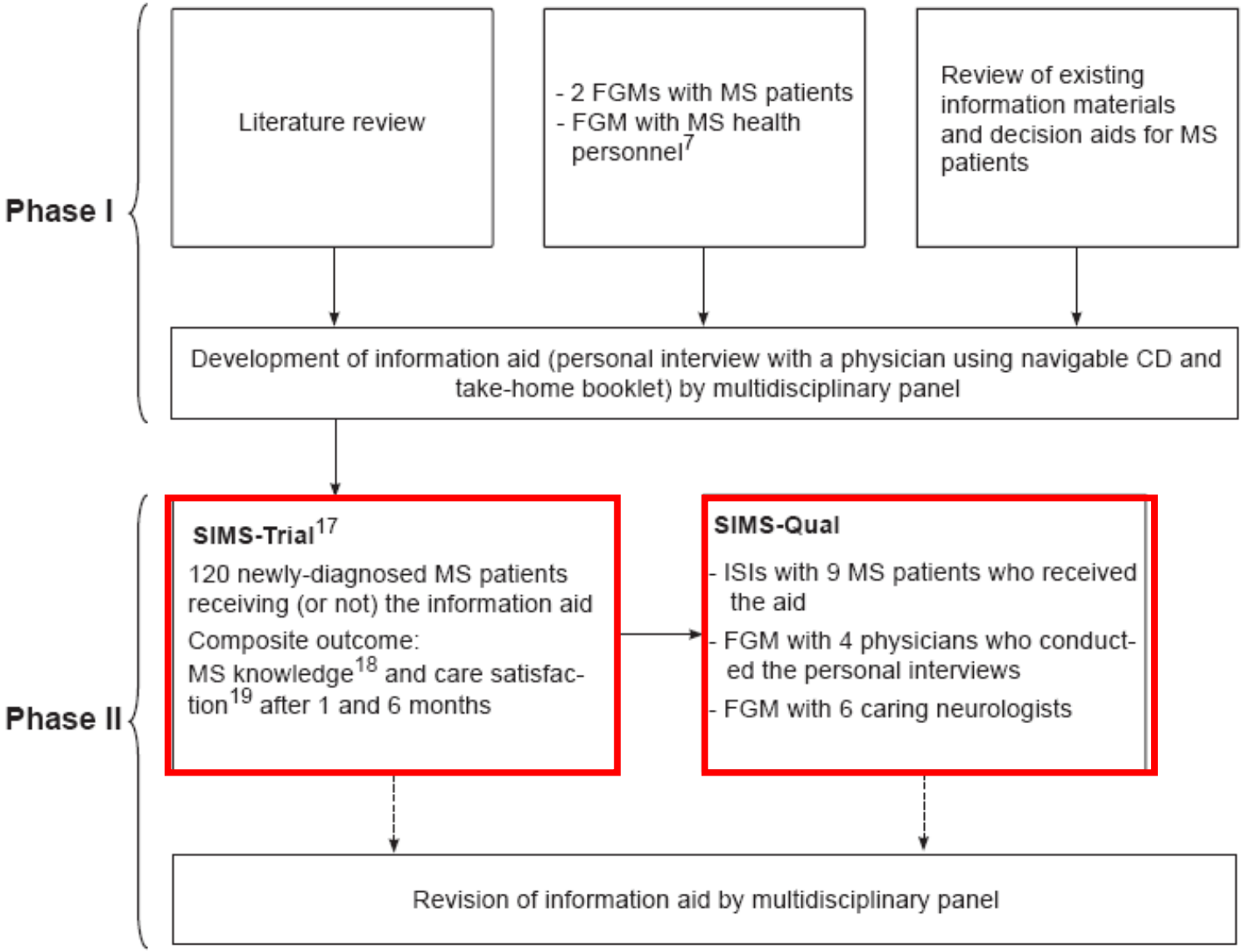
Phase I
Literature review
- 2 FGMs with MS patients
- FGM with MS health personnel[7]
Review of existing information materials and decision aids for MS patients
Development of information aid (personal interview with a physician using navigable CD and take-home booklet) by multidisciplinary panel
Phase II
SIMS-Trial[17]
120 newly-diagnosed MS patients receiving (or not) the information aid
Composite outcome:
MS knowledge[18] and care satisfaction[19] after 1 and 6 months
SIMS-Qual
- ISIs with 9 MS patients who received the aid
- FGM with 4 physicians who conducted the personal interviews
- FGM with 6 caring neurologists
Revision of information aid by multidisciplinary panel

PHASE 2: EVALUATION

SIMS-Trial

Effectiveness of a Structured Information Interview in People with Newly-Diagnosed MS

Protocol no: 2007/R/19

ISRCTN81072971

Multicenter Phase III Prospective RCT
Grant: FISM (2007/R/19)
ICH GCP

PHASE 2: EVALUATION

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Research Paper

Multiple Sclerosis

Multiple Sclerosis
16(11) 1393–1405
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An information aid for newly diagnosed multiple sclerosis patients improves disease knowledge and satisfaction with care

A Solari[1], V Martinelli[2], M Trojano[3], A Lugaresi[4], F Granella[5], A Giordano[1], M Messmer Uccelli[6], R D'Alessandro[7], E Pucci[8], P Confalonieri[9] and C Borreani[10] on behalf of the SIMS-Trial group*

Journal of the Neurological Sciences 307 (2011) 86–91

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Contents lists available at ScienceDirect

Journal of the Neurological Sciences

journal homepage: www.elsevier.com/locate/jns

Anxiety and depression in multiple sclerosis patients around diagnosis

Andrea Giordano [a], Franco Granella [b], Alessandra Lugaresi [c], Vittorio Martinelli [d], Maria Trojano [e], Paolo Confalonieri [f], Davide Radice [g], Alessandra Solari [a,*] and on behalf of the SIMS-Trial group [1]

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Key Points

The *"Sapere Migliora"* information aid was **well received and safe** in 120 newly-diagnosed patients from 5 Italian Centers (no SAE, drop-outs 8%)

It was effective: At one month, 30/60 intervention and 8/60 control patients achieved the primary endpoint (**OR 6.5, 95% CI 2.6–16.0; p<0.001; NNT 3**). Figures at six months were 26/60 intervention and 11/60 control patients (**OR 3.4, 95% CI 1.5–7.8; p=0.04; NNT=4**)

<20% of controls (well below 45% hypothesized) achieved the combined endpoint, indicating **need to improve standards of care in the crucial peri-diagnostic period**

SIMS-Qual

Participants' perspective on information aid for newly-diagnosed MS patients: a qualitative study within the SIMS-Trial

Protocol no: 2009 SIMS 02

Grant: FISM (2009/R/4)

SIMS-Qual

Participants' perspective on information aid for newly-diagnosed MS patients: a qualitative study within the SIMS-Trial

Protocol no: 2009 SIMS 02

Grant: FISM (2009/R/4)

PHASE 2: EVALUATION

SIMS-Qual

Participants' perspective on information aid for newly-diagnosed MS patients: a qualitative study within the SIMS-Trial

doi: 10.1111/j.1369-7625.2011.00736.x

Experience of an information aid for newly diagnosed multiple sclerosis patients: a qualitative study on the SIMS-Trial

WILEY-BLACKWELL
Health Expectations An International Journal of Public Participation in Health Care and Health Policy

Claudia Borreani MSc,* Andrea Giordano MSc,† Monica Falautano MSc,‡ Alessandra Lugaresi MD,§ Vittorio Martinelli MD,¶ Franco Granella MD,** Carla Tortorella MD,†† Imma Plasmati MD,†† Marta Radaelli MD,¶ Deborah Farina MD,§ Eleonora Dalla Bella MD,** Elisabetta Bianchi MSc,* Nicola Acquarone MSc,‡‡ Guido Miccinesi MD§§ and Alessandra Solari MD† on behalf of the SIMS-Trial group[1]

*Psychology Unit, National Cancer Institute Foundation, Milan, †Unit of Neuroepidemiology, Foundation IRCCS Neurological Institute C. Besta, Milan, ‡Deparment of Neurology, Psychology Unit, Scientific Institute Hospital San Raffaele, Milan, §Department of Neuroscience and Imaging, University "G. d'Annunzio" of Chieti-Pescara, Chieti, ¶Department of Neurology, Scientific Institute Hospital San Raffaele, Milan, **Department of Neurosciences, Neurology Unit, University of Parma, Parma, ††Departments of Neurological and Psychiatric Sciences, University of Bari, Bari, ‡‡Department of Personnel and Innovation, Province of Genoa, Genoa and §§Epidemiology Unit, Cancer Prevention and Research Institute (ISPO), Florence, Italy

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Key Points

Positive

The aid improved **information delivery**, **patient understanding** & **communication** with MS team & significant others, as well as **attitude to disease**

All components of the aid were considered necessary

Negative

Aid unsuitable for patients with **primary progressive MS**

Difficult to integrate personal interview within working practice of MS centers (particularly high-volume ones) for structural and personnel limitations

HOME | MONITORA PAZIENTI | SURVEY A | SURVEY B | DOMANDE FREQUENTI

Sapere Migliora

Ciao, Medico1 Uscita

Introduzione

Questo ausilio informativo è parte di un progetto che ha lo scopo di migliorare la conoscenza della SM (da cui il titolo, Sapere Migliora) nelle persone che hanno da poco ricevuto la diagnosi di Sclerosi Multipla. I suoi contenuti sono una sintesi delle conoscenze sulla malattia messa a punto da neurologi, psicologi e altri ricercatori che da anni vi si dedicano.

Lo sviluppo dell'ausilio informativo è iniziato nel 2005 con uno studio, che ha visto la diretta partecipazione delle persone con SM e del personale sanitario dedicato. La prima edizione (2007), ad uso "sperimentale", è stata impiegata in uno studio clinico cui hanno partecipato cinque Centri SM. I risultati di queste fasi della ricerca sono stati pubblicati tra il 2007 e il 2011 in riviste internazionali.

L'attuale edizione, aggiornata nei contenuti e rivista in base al risultato della fase "sperimentale", è ora resa disponibile a tutti i Centri SM italiani per le persone neo-diagnosticate. In circa 30 Centri la ricerca continua impiegando "Sapere Migliora" anche in versione web.

Oltre a fornire informazioni generali sulla SM e chiarimenti ai dubbi che inevitabilmente sorgono, strumenti come questo servono anche per fare scaturire nuovi spunti e, non da ultimo, per consolidare il rapporto di scambio e conoscenza con il proprio medico.

L'ausilio informativo non sostituisce la relazione medico-paziente, ma è uno strumento per migliorarla e arricchirla.

PHASE 3: IMPLEMENTATION

SIMS-Practice

Objective:

To assess the effectiveness of the new information aid **in every-day practice**

Methods:

- **Survey A**: 76 MS patients from the 5 SIMS-Trial centers receiving the revised information aid
- **Survey B**: 76 MS patients from 19 Italian MS centers receiving the revised booklet/website only

Eligibility: Same as SIMS-Trial but primary progressive MS excluded

Outcomes: Same as SIMS-Trial (MSKQ COSM-R HADS)

MRC FRAMEWORK (from Craig 2008)

Our path (and timing)

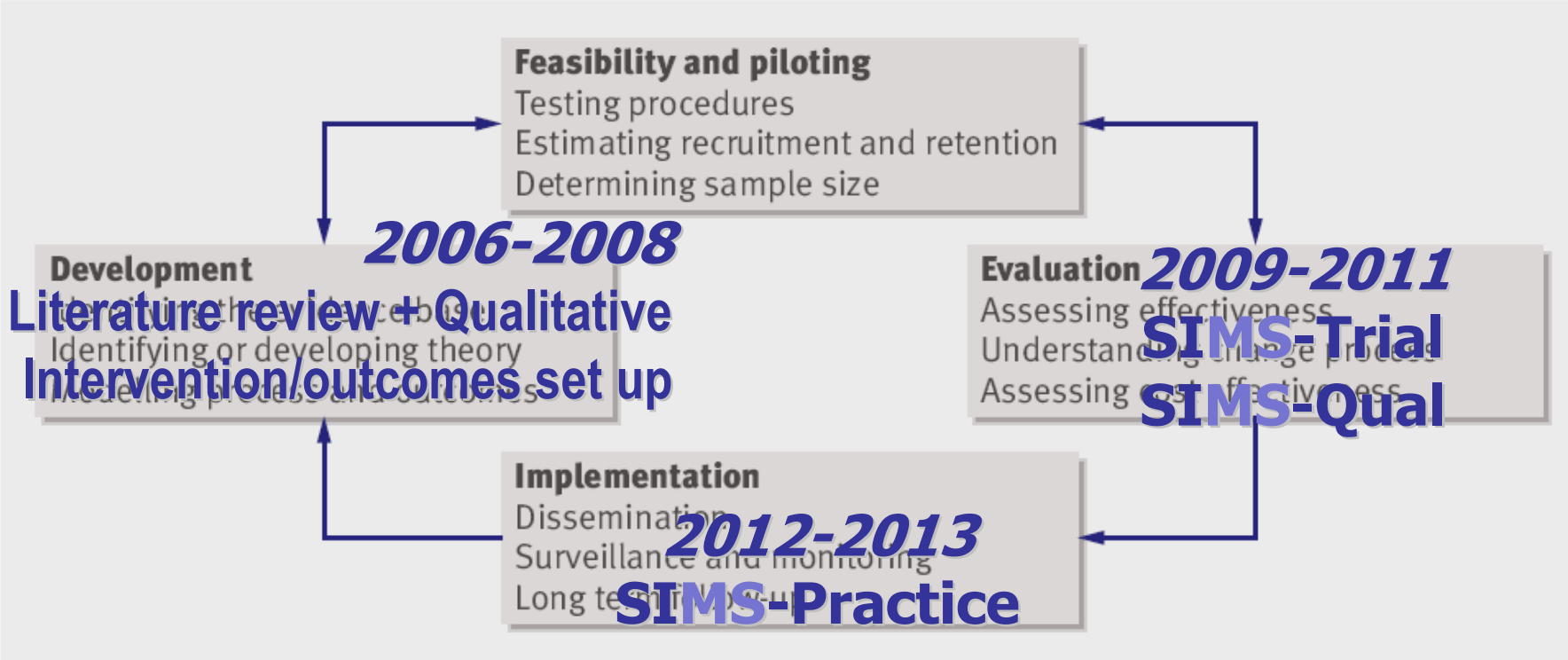

Fig 1 | Key elements of the development and evaluation process

Verona University Hospital – *MD Benedetti*
Mirano Hospital (Venice) – *C Ziuliani*
Ospedali Riuniti di Bergamo – *MR Rottoli*
S Giovanni Battista Hospital, Torino – *P Cavalla*
C. Besta Neurological Institute, Milan – *A Giordano, P Confalonieri, A Solari*
Scientific Institute Hospital San Raffaele, Milan – *V Martinelli, M Radaelli*
Melegnano Hospital (Milan) – *F Sasanelli*
Piacenza Hospital – *P Immovilli*
Parma University Hospital – *F Granella*

Livorno Hospital – *G Meucci*
INRCA, Ancona – *O Scarpino*
L'Aquila University Hospital – *R Totaro*
G D'Annunzio Chieti-Pescara University – *A Lugaresi, E Pietrolongo*
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S Filippo Neri Hospital, Rome – *G Di Battista*
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Federico II University Hospital, Naples – V *Brescia Morra*
Istituto Mediterraneo di Neuroscienze, Pozzilli (IS) – *R Fantozzi*
Bari University Hospital – *M Trojano, C Tortorella*
Magna Grecia University Hospital, Catanzaro – *A Quattrone, P Valentino*
Ospedali Riuniti BMM, Reggio Calabria – *U Aguglia*
Policlinico "G. Martino", Messina – G Vita
Villa Sofia Hospital, Palermo – *S Cottone*

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