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Evaluation of the effectiveness of professionally guided self care for consumers

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/08/2014	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

Protocol serial number
PCD/A2/27

Study information

Scientific Title

Study objectives
The overall aim of the project was to design and evaluate a consumer focused professionally guided self-care programme for a community sample of people with Multiple Sclerosis (MS). The project had 3 stages, each with a different objective.
Stage 1: To obtain the views and priorities of people with MS to inform the design of the self-care programme.
Stage 2: To assess the efficacy of the self-care programme.
Stage 3: To obtain participant feedback in order to inform the refinement of the programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Other

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

Interventions
Stage 2: (Single blind randomised controlled trial). The self-care programme primarily comprised discussion with a health care professional (physiotherapist) of self-care strategies, supported by an information booklet developed for the study and based on priorities identified in Stage 1. The discussion focused on individual's needs rather than on covering all the information in the booklet. Participants were encouraged to change some aspect of their self-care routine, following discussion, although they were not required to do so. The discussion was conducted on 2 occasions, either one-to-one or in a group setting. Sessions lasted between 1 and 2 hours and were organised at times and places which were convenient to each individual.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. The results from the Delphi survey were the outcome measures in stage 1.
2. The outcome measures in stage 2 included the Barthel Index, Functional Mobility Assessment Scale, Cope Scale, SF-36, Standard Day Dependency Record, and the Inventory of Avoidable Complications in MS.
3. The outcome measure in stage 3 was the feedback questionnaire.

Key secondary outcome(s))

Not provided at time of registration

Completion date
30/04/1999

Eligibility

Key inclusion criteria
Participants were recruited through MS voluntary organisations. The only selection criterion was that the MS diagnosis was confirmed by GPs. In stage 1 the panel comprised 200 volunteers, living throughout the UK, of whom 136 responded to the survey (68%). In stage 2 the panel comprised 278 volunteers, living in and around London, of whom 183 were randomised and 169 (92%) completed the study. In stage 3, 73 people from the intervention group in stage 2 provided feedback.
The randomised controlled trial was conducted at the Centre for Research in Rehabilitation at Brunel University in London.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/09/1995

Date of final enrolment
30/04/1999

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Health Studies
Middlesex

United Kingdom
TW7 5DU

Sponsor information

Organisation
Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
NHS National Physical and Complex Disabilities Programme (UK)

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	01/02/2000		Yes	No
Results article	results	01/03/2002		Yes	No