

Intermittent self catheterisation in people with multiple sclerosis

Submission date 26/01/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 03/05/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 15/11/2017	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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
N/A

Study information

Scientific Title

A prospective exploration of the experiences and factors affecting the continuity of use of intermittent self-catheterisation in people with multiple sclerosis

Acronym

ISiMS

Study objectives

People with multiple sclerosis (MS) may be advised to undertake intermittent self-catheterisation (ISC) to help manage their bladder. However, research shows that although the use of ISC is supported both by clinicians and MS population in general, many do not find it acceptable and discontinue use after a while. Research indicates that there are gaps within current knowledge relating to the experiences of and the factors affecting ISC within this population. Therefore, in order to better understand the factors that impact ISC use and continuation, the Multiple Sclerosis Society has funded a study in which we will recruit 250 people with MS who are learning to use ISC and follow them for 12 months to investigate how patients experience ISC and the issues which impact its use.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

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

Health condition(s) or problem(s) studied

Multiple sclerosis

Interventions

Data will be collected at four different points: baseline, 4, 8 and 12 months and in three ways:

1. Assessment log, recording (among other things) patient demographics, medical history, bladder symptoms, socio-economic status
2. Telephone-based questionnaires measuring quality of life including clinical data collection booklet - to be completed by the clinician
3. In addition to clinical data, semi-structured qualitative interviews will be conducted with a purposively selected sample of 12 - 20 patients at 4 and 12 months. These will enable us to have an in-depth understanding of the issues, dynamics and impact of ISC including the factors which lead to its discontinuation.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Completed at 4, 8 and 12 months:

1. Bladder diary
2. Qualiveen Questionnaire
3. International Consultation on Incontinence Modular Questionnaire (ICIQ) - Female Lower Urinary Tract Symptoms (FLUTS) and Male Lower Urinary Tract Symptoms (MLUTS)

Secondary outcome measures

Completed at 4, 8 and 12 months:

1. Assessment Log
2. Clinical Data Collection Booklet
3. Semi-structured interviews

Overall study start date

01/05/2011

Completion date

01/05/2012

Eligibility

Key inclusion criteria

1. People with MS
2. Aged 18 - 80 years, either sex
3. Have agreed with their clinician to be taught ISC
4. Willing to take part in the study

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

250

Key exclusion criteria

1. Unable to give informed consent
2. Unable to follow the study process

Date of first enrolment

01/05/2011

Date of final enrolment

01/05/2012

Locations**Countries of recruitment**

Scotland

United Kingdom

Study participating centre

Glasgow Caledonian University

Glasgow

United Kingdom

G4 0BA

Sponsor information**Organisation**

Glasgow Caledonian University (UK)

Sponsor details

c/o Professor Mike Smith

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Sponsor type
University/education

Website
<http://www.gcu.ac.uk/>

ROR
<https://ror.org/03dvm1235>

Funder(s)

Funder type
Charity

Funder Name
Multiple Sclerosis Society (UK) (ref: 932/10)

Alternative Name(s)
Multiple Sclerosis Society of Great Britain and Northern Ireland, The MS Society, MS Society UK, Multiple Sclerosis Society UK, MS Society

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

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