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Intermittent self catheterisation in people with multiple sclerosis

Submission date 26/01/2011	**Recruitment status** No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 03/05/2011	**Overall study status** Completed	☐ Statistical analysis plan ☐ Results
Last Edited 15/11/2017	**Condition category** Nervous System Diseases	☐ Individual participant data ☐ 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

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

Study type(s)
Quality of life

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(s)
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)

Key secondary outcome(s)
Completed at 4, 8 and 12 months:
1. Assessment Log
2. Clinical Data Collection Booklet
3. Semi-structured interviews

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

Scotland

Study participating centre
Glasgow Caledonian University
Glasgow
United Kingdom
G4 0BA

Sponsor information

Organisation
Glasgow Caledonian University (UK)

ROR
https://ror.org/03dvm1235

Funder(s)

Funder type
Charity

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

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

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration