

A randomised controlled trial investigating the clinical and cost-effectiveness of a patient self-management programme (SMP) for basic footcare in the elderly

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/11/2007	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

rctc94 441772

Study information

Scientific Title

Study objectives

To design and implement a new patient self-management programme for elderly patients seeking podiatry for basic foot problems. Access to NHS chiropody is often gained on "entitlement" rather than clinical need and in the elderly routine follow up is becoming a costly problem. The Department of Health has called on the profession to tackle this issue within the constraints of current funding levels. We have identified successful use of patient self-management programmes (SMP) for chronic low-grade conditions in other clinical fields and our key objective in this study is to develop a relevant programme for basic footcare in the elderly. We aim to test this, in terms of its clinical and cost-effectiveness, against conventional care in a (as yet unfunded) randomised controlled trial. The SMP will contain elements of information, giving training and education and telephone helpline support involving patients, relatives, carers, voluntary sector workers and podiatry services. We are currently validating a foot health disability measure as the primary outcome measure alongside measures of foot morbidity, patient satisfaction, quality of life and foot health knowledge.

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Basic foot care

Interventions

Patient self-management programme versus standard care.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

EuroQol, foot disability index - to be validated, foot morbidity Index, foot health knowledge questionnaire - based on SMP, patient satisfaction questionnaire.

Secondary outcome measures

Not provided at time of registration

Overall study start date

02/01/1999

Completion date

04/01/2001

Eligibility

Key inclusion criteria

Feasibility study - sample of 50 subjects, mostly new referrals to the NHS podiatry service in Calderdale.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

153

Key exclusion criteria

Diabetes mellitis, circulatory disorders.

Date of first enrolment

02/01/1999

Date of final enrolment

04/01/2001

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Leeds

Leeds

United Kingdom

LS2 9NZ

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

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SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive Northern and Yorkshire (UK)

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		01/11/2003		Yes	No