

# 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

☐ Prospectively registered

☐ Protocol

**Registration date**

23/01/2004

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

07/11/2007

**Condition category**

Musculoskeletal Diseases

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Philip Helliwell

**Contact details**

University of Leeds

Rheumatology & Rehabilitation Research Unit

36 Clarendon Road

Leeds

United Kingdom

LS2 9NZ

+44 (0)113 233 4952

p.helliwell@leeds.ac.uk

## 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

Richmond House

79 Whitehall

London

United Kingdom

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?
<a href="#">Results article</a>		01/11/2003		Yes	No