

Evaluation of a model of integrated care for the identification and clinical management of high risk diabetic foot

Submission date

23/01/2004

Recruitment status

No longer recruiting

Registration date

23/01/2004

Overall study status

Completed

Last Edited

29/01/2010

Condition category

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ 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

Protocol serial number

D/05/11.96/Tooke

Study information

Scientific Title

Study objectives

Diabetic foot ulceration and lower limb amputation remain major health problems and the government is committed to the reduction of amputation rates by 50%. Centralised, hospital based specialist foot services have demonstrated that it is possible to reduce amputation rate through patient education and expert medical and chiropodial care. However increasingly routine diabetic care is devolved to general practice and if foot health in the majority of people with diabetes is to be improved care arrangements need to reflect this shift. We propose to evaluate a new model of diabetic foot care, centred on the general practice based diabetic annual review. Five practices will be randomised to receive the new model of care, and associated educational input, with five matched practices continuing with current care arrangements. The success or otherwise of the initiative will be-determined by assessing

1. Patients' understanding of footcare and their attitudes to the footcare service;
2. The knowledge base of the healthcare professionals involved in diabetic footcare, and
3. The appropriateness of patients referred to subserving chiropody units and the specialist foot clinic.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Diabetes

Interventions

A practice visit by the specialist diabetic footcare team to deliver an educational programme; provision of, and instruction in the use of, an objective means of neuropathy assessment (Semmes-Weinstein monofilament); provision of referral guidelines and patient educational material.

Control: current standard care.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Patients' attitudes regarding the value and importance of footcare
2. Patients' footcare knowledge
3. Healthcare professionals' footcare knowledge
4. Pattern of service utilisation

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/1998

Eligibility

Key inclusion criteria

One thousand nine hundred and thirty nine people with diabetes aged over 18 years.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/05/1997

Date of final enrolment

31/12/1998

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Royal Devon and Exeter Healthcare NHS Trust
Exeter
United Kingdom
EX2 5AW

Sponsor information

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

Funder(s)

Funder type
Government

Funder Name
NHS Executive South West (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	01/08/2000		Yes	No