

Enhancing self-care in leg ulcer patients: tandem practices as a model for interdisciplinary care

Submission date 03/07/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 28/07/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 07/01/2010	Condition category Circulatory System	☐ 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
01GL0507

Study information

Scientific Title

Acronym

TANDEM study

Study objectives

Does an additional nurse-led education programme improve wound healing, Health Related Quality of Life (HRQoL), and recurrence rates in patients suffering from venous leg ulcers treated by general practitioners?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics committee of the University of Witten/Herdecke (reference number: 21/2005), date of approval: 17/05/2005 (first amendment: 28/10/2005, second amendment: 22/06/2006).

Primary study design

Interventional

Study design

Open, multicentre randomised controlled trial (randomisation on the level of general practitioners' practices)

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Venous leg ulcers

Interventions

Nurses offer an education programme to patients receiving usual care by their general practitioner (GP). In addition, the nurse specialist offers support to the medical doctor himself. The content of the nurse-led education programme was based on an evidence-based self-care activity catalogue which was derived from national and international clinical guidelines. The teaching of the nurse specialists was based on the theory of self-care competence. The control group received usual care from their GP, but not the nurse led education programme.

Both groups, the medical doctors in the intervention and in the control group, received written information on the "state-of-the-art"-therapy of patients with venous leg ulcers (short and comprehensive version of the actual official guideline).

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

At 12 weeks (+/- two weeks)(t2):

1. Wound healing (proportion of healed leg ulcers)

2. Reduction of wound area (measured by digital planimetry)
3. Health-related quality of life (Freiburg Life Quality Assessment (FLQA), scale 1: physical complaints)

Key secondary outcome(s)

At six weeks (+/- one week)(t1), 12 weeks (+/- two weeks)(t2), 24 weeks (+/- four weeks)(t3) and 52 weeks (+/- four weeks)(t4) secondary outcomes:

1. Characteristics of healing (using the Leg Ulcer Measurement Tool [LUMT])
2. Health-related quality of life using the FLQA
3. Self-care competence
4. Health economic evaluation (use of resources)
5. Costs of the intervention
6. Satisfaction and personal opinion of all concerned subjects (patients, medical doctors and their teams, relatives, nurses)

Completion date

31/03/2007

Eligibility**Key inclusion criteria**

1. Patients suffering from venous leg ulcers (stadium C6 according to CEAP classification)
2. Patients receiving treatment in a study practice
3. Patients have an ability of self-care (or the control of dependent care e.g. by relatives)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Exclusion criteria (before the study i.e.: no inclusion):

1. Other stadium of chronic venous insufficiency
2. Other etiology of the leg ulcer (e.g. arterial insufficiency, ulcus mixtum, diabetic foot)
3. Cognitive impairment (hindering self-care)
4. Insufficient competence of the German language
5. Inability to read
6. Parallel participation in another clinical trial

Exclusion criteria (during the study):

1. Change of the general practitioner during the first six months after inclusion in the study

2. Ending of the study participation of the general practitioner
3. In-patient treatment (at least for 14 days)
4. Newly developed severe illness (hindering self-care)

Date of first enrolment

01/12/2005

Date of final enrolment

31/03/2007

Locations

Countries of recruitment

Germany

Study participating centre

University of Witten / Herdecke, Alfred-Herrhausen-Str. 50

Witten

Germany

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Sponsor information

Organisation

Federal Ministry of Education and Research (Bundesministerium fuer Bildung und Forschung) (BMBF) / German Aerospace Center (DLR)

ROR

<https://ror.org/04pz7b180>

Funder(s)

Funder type

Government

Funder Name

Main Sponsor:

Funder Name

Federal Ministry of Education and Research (BMBF)/German Aerospace Center (DLR) (ref. number: 01GL0507)

Funder Name

Additional funding:

Funder Name

B. Braun foundation (Melsungen, Germany)

Funder Name

Bauerfeind AG (Zeulenroda, Germany)

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	14/08/2009		Yes	No