

# Evaluation of a leadership intervention for implementing recommendations for nursing care for people with diabetes and foot ulcers in community nursing practice

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<b>Registration date</b> 12/09/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/09/2008	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Ms Wendy Gifford

**Contact details**  
1258 Portland Avenue  
Ottawa  
Canada  
K1V 6E9  
+1 613 260 8334  
wgifford@rogers.com

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## Study information

### Scientific Title

The impact of a tailored leadership intervention on the nursing assessments and management of foot ulcers for people with diabetes in community nursing practice

### Study objectives

H1: Nurses working in centres that receive the intervention will obtain significantly higher scores for practicing in accordance with guideline recommendations than the control group.

H0: No change in group means will occur following the intervention.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

The University of Ottawa Health Sciences and Science Research Ethics Board on the 9th May 2007 (ref: H-03-07-09)

### Study design

A two phase mixed method design with matched pair cluster randomised controlled trial and qualitative methods

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied

Diabetes/foot ulcers/knowledge translation

### Interventions

In addition to usual implementation strategy, a 12 week strategy will be offered to managers, supervisors, resource nurses, and two preceptor staff from each centre consisting of:

1. Mailed package of printed materials: study purpose; summary of recommendations, models of leadership and planned change; literature article; four questions related to assessing barriers to practice change. Review time: approx 15 - 30 minutes.
2. Interactive workshop (7.5 hours) at SEHC Corporate Office. Content and structure will be

tailored to results of phase one, tentatively planned to include:

- 2.1. Evidence and theory on leadership and implementing practice change
  - 2.2. Focus group discussions about barriers to implementing change based on recommendations
  - 2.3. Case study discussions
  - 2.4. Role playing exercises
  - 2.5. Games
  - 2.6. Development of implementation plan for each centre tailored to identified barriers.
- Workshop will be facilitated by Co-PI (WG); SEHC senior administrator (NL); and administrative /clinical staff from SEHC to be determined.
3. Post-workshop teleconferences: (2, 6, and 10 weeks after workshop) to provide a forum for questions, discussions and networking amongst participants

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

Nursing Assessments of Client Risk Factors Scores (NACRF), a composite score of 8 items based on recommendations from the Diabetes/Foot Ulcer guidelines.

Timepoints for primary and secondary outcomes: 12 weeks following completion of the intervention, chart audits will be conducted on all patients being treated for diabetic foot ulcers. To understand the leadership and management behaviours that influenced nursing practice, semi structured qualitative interviews will be conducted 12 weeks following intervention strategy with managers, supervisors, resource nurses and staff nurses at control and experimental centres.

## **Secondary outcome measures**

1. Proportion of people with healed ulcers at 12 weeks (defined as complete wound closure)
2. Healing time, in number of weeks
3. Types of treatments used (e.g., hydrogel dressings, sharp debridement, offloading devices)
4. Referral rates to specialists services
5. Documented patient education
6. Proportion clients assessed for all items in the NACRF scale (all-or-none measure)
7. Nursing participant satisfaction and perceived utility of elements of the intervention

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## **Overall study start date**

01/09/2007

## **Completion date**

01/12/2008

# Eligibility

## Key inclusion criteria

1. Service delivery centres with minimum number of clients with diabetes being treated for foot ulcers to satisfy sample size calculations
2. Chart audit: all adult clients (18 years or older) diagnosed with type 1 or type 2 diabetes that have been treated for a first or recurring foot ulcer(s) in the previous 6 months
3. Intervention: managers, supervisors, resource nurses and two staff nurses from each intervention site

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Sex

Both

## Target number of participants

4 centres/60 clients

## Key exclusion criteria

1. Service delivery centres that did not have the minimum number of clients on service for diabetic foot ulcers to meet sample size calculations (i.e. 15 clients per centre in 6 months)
2. Clients that do not meet inclusion criteria:
  - 2.1. Under 18 years of age
  - 2.2. Do not have type 1 or type 2 diabetes
  - 2.3. Not receiving home care service for a diabetic foot ulcer

## Date of first enrolment

01/09/2007

## Date of final enrolment

01/12/2008

# Locations

## Countries of recruitment

Canada

## Study participating centre

**1258 Portland Avenue**  
Ottawa  
Canada  
K1V 6E9

## **Sponsor information**

### **Organisation**

Canadian Nurses Foundation (Canada) - Nursing Care Partnership Fund

### **Sponsor details**

50 Driveway  
Ottawa  
Canada  
K2P 1E2  
+1 613 237 2159  
jsolis@cna-aiic.ca

### **Sponsor type**

Research organisation

### **Website**

<http://www.cnf-fiic.ca/Home/tabid/36/language/en-US/Default.aspx>

### **ROR**

<https://ror.org/04j4csk75>

## **Funder(s)**

### **Funder type**

Research organisation

### **Funder Name**

Canadian Nurses Foundation (Canada) - September 2006

## **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