

Reviewer	Name (year), Country	Full ref Vancouver (HTA style)
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VERIFICATION OF ELIGIBILITY FOR INCLUSION

✓ as appropriate

	YES	NO	UNCLEAR
P: Adults or children with diabetes (type or type 11)			
I:			
Education			
Footwear			
Insoles			
Self-care			
Foot care			
Screening			
Other			
C:			
O: Primary outcome: Foot Ulceration (Patients must be free of ulceration at the point of recruitment, exclude prevalent ulcers)			
O: Secondary outcome:			
Amputation			
Compliance/adherence			
Knowledge			
Behaviour			
Mortality			
Hospital admission			
Other:			
S: RCT			

Notes: Other measures were unexpected Visits, Missed Visits, Tinea and Hyperkeratosis at study entry and end of study.

DECISION

Include	Exclude	Discuss	Contact authors

Comments: (Record reason for exclusion/contacting authors, date authors contacted and outcome; pilot or on-going study, duplicate/multiple publication et

STUDY CHARACTERISTICS
PICOS

Trials Aim <ul style="list-style-type: none"> • 				
Objectives <ul style="list-style-type: none"> • 				
Rationale: <ul style="list-style-type: none"> • • • 				
Inclusion criteria: <ul style="list-style-type: none"> • • • • 				
Exclusion criteria: <ul style="list-style-type: none"> • • • 				
Intervention: <ul style="list-style-type: none"> • • 				
Control:				
Standard Care:				
Outcome of interest: (primary or secondary/incident or prevalent)				
Study design of RCT <ul style="list-style-type: none"> • Parallel • Cross over • Factorial design • Cluster 				
Study Setting:				
Health care providers:				
Funders:				
Contact:				
	Intervention 1	Intervention 2	Control	Overall
N= at randomisation				
N= who completed				
N= lost to FU				
Male:	n (%)	n (%)	n (%)	n (%)

Female:	n (%)	n (%)	n (%)	n (%)
Mean age				
T2 DM (%)				
Duration of diabetes				
HbA1c				
Previous ulcers (%)				
Diabetic foot risk classification <ul style="list-style-type: none"> • 1 • 2 • 3 				
History of amputation				
Length of follow-up From randomisation or end of trial				
Ulcer risk classification	L	M	H	NS
Ulcer definition				

DATA (Binary):

Outcome	Intervention		Control	
Outcome	Total pop	Total pop with outcome	Total pop	Total pop with outcome

Outcome	Intervention		Control	
Outcome	Total pop	Total pop with outcome	Total pop	Total pop with outcome

DATA (continuous)

Outcome	Intervention			Control		
	N=	Mean	SD	N=	Mean	SD

Outcome	Intervention			Control		
	N=	Mean	SD	N=	Mean	SD

Quality assessment

Explanation of items	Yes	No	Unclear
Sequence generation State the method: (e.g. computer generated):			
Allocation concealment			
Blinding <ul style="list-style-type: none"> • Participant • Provider • Outcome assessor 			
Incomplete outcome data			