

# **Research Q2 Evidence Profile (Quantitative)**

Recommendation question 2: Should guided self-screening for DFU risk assessment be recommended for persons at risk of or living with DFUs and their care partners?

Recommendation 2.0: The expert panel suggests that persons and/or care partners perform guided self-screening to prevent and manage diabetic foot ulcers.

Population: People at risk of a diabetic foot ulcer (DFU) and their care partners Intervention: Guided self-screening performed by patients or care partners to prevent DFU Comparison: No guided self-screening by patient or care partners to prevent DFU; Standard/usual care Outcomes: Screening rates (critical), patient satisfaction (critical) [not measured], diabetic foot ulcer occurrence/recurrence (important), neuropathy screening (important) [not measured], amputation rate (important) [not measured]

Setting: All health-care settings, including but not limited to: community care, outpatient care, and acute care

Quality assessment							No. of participants					
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control	Effect	Certainty	Reference	
Diabetic foot ulcer occurrence/recurrence (measured using an infrared thermometer device, observation)												
1 Screening	Systematic Review of 5 RCTs rates (measu	Not seriousª rred using Dia	Not serious betic Foot Evaluation F	Not serious <sup>b</sup>	Serious reported questionna	Undetected aire) 9 months follow-up	N=383 <sup>d</sup> Total events = 72 <i>time</i>	N=389 <sup>d</sup> Total events = 120	The studies in this systematic review reported that the use of foot temperature self-monitoring may prevent DFU occurrence/recurrence. For every 100 people who use an infrared thermometer for daily foot temperature monitoring, 15 less people will have a DFU reoccurrence (ranges from 21 less to 5 less).	⊕⊕⊖⊖ Low	(1)	
1	RCT	Very serious <sup>e</sup>	Not serious	Not serious	Very serious <sup>r</sup>	Undetected	N= 45	N=43	The study showed that the screening rate was higher in the experimental group 1 than in other two groups when the 9 <sup>th</sup> month data were examined among groups. Foot checking behavior was similar in all 3 groups at the beginning of the study (X <sup>2</sup> =0.002), and increased at the 9th month (X <sup>2</sup> =17.475). Rate of daily foot checking was higher in experimental group 1 than the other 2 groups (X <sup>2</sup> =41.138 at 9 months)	⊕⊖⊖⊖ Very low	(2)	

Table 1 – Quality details



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Quality assessment						No. of participants					
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control	Effect	Certainty	Reference
									Rate of monthly foot checking frequency was higher in experimental group 1 vs. the other 2 groups (Kruskal-Wallis test (KW) = 2.523 at beginning vs. KW 52.534 at 9 months)		
Neuropathy Screening [not measured]											
N/A											
Patient Satisfaction [not measured]											
N/A											
Amputation rate [not measured]											
N/A											



# Table 2 – Individual Study Details

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias					
Diabetic foot ulcer occurrence/recurrence (measured using an infrared thermometer device, observation)											
(1)	Systematic Review of 5 RCTs	Norway (n=1) & USA (n=4)	Interventions in the studies (5) included the use of an infrared thermometer for daily foot temperature monitoring <sup>9</sup> . Participants were told to check their foot temperature at least twice a day. Two studies reported that if participants noted a difference in skin temperature of >2.0 degrees Celsius to contact a health provider and reduce physical activity. N= 383 Total events = 72	Standard/usual care or standard care plus instructions to perform daily foot inspection. N= 389 Total events = 120	The controlled studies in this systematic review reported that the use of foot temperature self- monitoring may prevent DFU occurrence /recurrence. RR of 0.51 (95% CI: 0.31–0.84) (I <sup>2</sup> : 49%) Infrared thermometer: For every 100 people who use an infrared thermometer for daily foot temperature monitoring, 15 less people will have a DFU reoccurrence (ranges from 21 less to 5 less).	LOW					
Screening rates (me	asured using Diabetic Foot E	valuation Form, Par	ticipant self-reported questionnaire)								
(2)	RCT	Turkey	Experimental Group 1: reminder diabetic foot mirror (alarm set at most appropriate time of day), one-to-one training on the use of the mirror. Experimental Group 2: diabetic foot mirror without a reminder, patients familiarized with mirror and its features. N=45 Foot checking at beginning (group 1): 17/45= 37.8%; (group 2): 21/45 = 46.7% Foot checking at 9 months (group 1): 44/45=97.8%; (group2): 37/45=82.2%	Participants were not given a diabetic foot mirror or a reminder diabetic foot mirror. N=43 Foot checking at beginning: 16/43 = 37%.2 Foot checking at 9 months (control): 27/43=62.8%	The study showed that the screening rate was higher in the experimental group 1 than in other two groups when the 9 <sup>th</sup> month data were examined among groups. Foot checking behavior was similar in all 3 groups at the beginning of the study (X <sup>2</sup> =0.002), and increased at 9th month (X <sup>2</sup> =17.475). Rate of daily foot checking was higher in experimental group 1 than other 2 groups (X <sup>2</sup> =41.138 at 9 months) Rate of monthly foot checking frequency was higher in experimental group 1 vs. other 2_groups (Kruskal-Wallis test (KW) = 2.523 at beginning vs. KW 52.534 at 9 months)	VERY SERIOUS					

Acronyms Cl: Confidence Interval

DFU: Diabetic Foot Ulcer

ITT: Intention To Treat

KW: Kruskal-Wallis test

RCT: Randomized Control Trial

ROB: Risk Of Bias

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### RR: Risk Ratio

#### N/A: not applicable

#### vs: versus

## References

- 1. Van Netten JJ, Raspovic A, Lavery LA, Monteiro-Soares M, Paton J, Rasmussen A, et al. Prevention of foot ulcers in persons with diabetes at risk of ulceration: A systematic review and meta-analysis. Diabetes Metabolism Res. 2024 Mar;40(3):e3652.
- 2. Akça Doğan D, Enç N. The effect of using a reminder diabetic foot mirror on foot checking frequency and development of diabetic foot in people with diabetes. Int J Diabetes Dev Ctries. 2022 Apr;42(2):321–30.

## Explanations

- e Based on the quality appraisal using the ROB 2.0 tool for RCTs, the study had critical risk of bias due to having some concerns about the randomization process, high deviations from intended interventions. We downgraded by 2.
- <sup>f</sup> The total number of participants was far less than the optimal number of 800 (n = 108). We downgraded by 2

<sup>&</sup>lt;sup>a</sup> The review was assessed using the ROBIS tool for systematic reviews, and had low risk of bias (ROB). Studies included in the review were assessed the authors using the Cochrane ROB tool for RCTs; 4 studies had a low or very low ROB, 1 study had a high ROB. We downgraded by 0.5.

<sup>&</sup>lt;sup>b</sup> Majority of studies showed a positive direction of effect, however there was a slight variation in intervention carried out in one small study. We downgraded by 0.5.

<sup>°</sup> The total number of events was far less than the optimal number of 300 (n=192). We downgraded by 1.

<sup>&</sup>lt;sup>d</sup> This number signifies the total number of participants in the study. Authors for 1 of the RCT did not report on the number of participants per group. Data taken from the supplementary document.

<sup>&</sup>lt;sup>9</sup> The authors of the systematic review included different self-management questions to answer their research question (such as m-health, nail lacquer and smart insoles). The BPG's expert panel decided to only include the studies that reviewed athome foot temperature monitoring for the purposes of the BPG's recommendation question.