

Research Q1 Evidence Profile (Quantitative)

Recommendation question 1: Should person engagement strategies be recommended or not for health providers delivering self-management support for diabetic foot care (e.g., motivational interviewing, cognitive behavioral therapy or other psychosocial interventions)?

Recommendation 1.0: When delivering self-management support, the expert panel suggests that health providers use person engagement strategies. These engagement strategies are tailored to the person and their care partners.

Population: People at risk of or living with a diabetic foot ulcer (DFU)

Intervention: Person engagement strategies (e.g., motivational interviewing, cognitive behavioral therapy or other psychosocial interventions)

Comparison: Usual DFU care or no person-engagement strategies

Outcomes: Person satisfaction (critical), self-efficacy (critical), person adherence (critical), DFU occurrence/recurrence (important), amputation rates (important) [not measured]

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

Table 1 – Quality details

Quality assessment							No. of participants		Effect	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
Person satisfaction (measured using an unspecified tool)											
1	Non-RCT	Very serious ^a	Not serious	Not serious	Very serious ^b	Undetected	N = 49	N = 49	The study reported the patients in the one-to-one education group had a higher level of nursing care satisfaction than did those in the basic nursing group.	⊕○○○ Very low	(1)
Self-efficacy (measured using a variety of self-reported self-efficacy or confidence scales)											
4	RCT	Serious ^c	Serious ^d	Not serious	Very serious ^e	Undetected	N=128	N=115	3 of the 4 RCTs reported improved self-efficacy in the intervention groups compared to the control groups when person engagement strategies were used to deliver self-management education. In 1 of the 4 RCTs, self-confidence scores were higher for those who received the intervention; however, this difference was only seen among participants with secondary or tertiary levels of education.	⊕○○○ Very low	(2-5)
3	Non-RCT	Very serious ^f	Not serious ^g	Not serious	Serious ^h	Undetected	N=160	N=251	Overall, all 3 non-RCTs studies reported an increase in self- efficacy post- intervention.	⊕○○○ Very low	(1,6,7)

Quality assessment							No. of participants		Effect	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
1	Non-randomized single arm study	Serious ⁱ	Not serious	Not serious	Very serious ⁱ	Undetected	N=33	N/A	This study reported that the intervention had a large positive effect on improving foot care self-efficacy.	⊕○○○ Very low	(8)
Person adherence (measured using compliance behaviour scores and percentage of steps taken while wearing orthopedic shoes)											
1	RCT	Serious ^k	Not serious	Not serious	Very serious ^l	Undetected	N=53	N=68	This study reported that a higher number of participants in the control group wore their orthopedic shoes compared to the intervention group after 3 months. <u>Intervention:</u> Adherence at 3 months to wearing orthopedic shoes: 15.1% <u>Control:</u> Adherence at 3 months: 30.9%	⊕○○○ Very low	(9)
1	Non-RCT	Very serious ^m	Not serious	Not serious	Very serious ⁿ	Undetected	N = 49	N = 49	The scores of compliance behavior in the one-to-one education group were higher than those in the basic nursing group. <u>Intervention:</u> Foot bathing mean score ± SD = 8.63 ± 1.01 Exercise health care mean score ± SD = 8.51 ± 0.97 Shoes and socks selection mean score ± SD = 9.04 ± 1.24 <u>Control:</u> Foot bathing mean score ± SD = 6.87 ± 0.81 Exercise health care mean score ± SD = 6.94 ± 0.83 Shoes and socks selection mean score ± SD = 8.05 ± 1.01	⊕○○○ Very low	(1)
DFU occurrence/recurrence (measured using a Foot Assessment Form and observation methods)											

Evidence Profile Recommendation 1 - Diabetic Foot Ulcers: Prevention, Assessment and Management

Quality assessment							No. of participants		Effect	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
1	RCT	Not serious ^o	Not serious	Not serious	Very serious ^p	Undetected	N=53 18 of the 53 participants developed 22 ulcers.	N=68 19 of the 68 participants developed 21 ulcers.	Between intervention and control groups, there were no important differences in regards to the proportion of participants who developed one or more ulcers during the 1 - year follow-up period (respectively 34% and 28%).	⊕○○○ Very low	(9)
2	Non-RCTs	Serious ^a	Not serious ^r	Not serious ^s	Serious ^t	Undetected	N=140	N=232	Overall, both studies demonstrated a positive direction of effect. One study showed a decreased percentage of foot risk factors for ulceration, and one study reported a decreased incidence of lesions and average time to new lesion.	⊕○○○ Very low	(6,10)
Amputation rates [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
Person satisfaction (measured using an unspecified tool)						
(1)	Non-RCT	China	Participants in the intervention group received one-to-one education from a senior nurse. Education was tailored to their education level, personality characteristics and severity of illness at the time to admission N = 49	The control group was provided general education, through the distribution of knowledge manuals, oral presentations and other ways to explain daily life matters needing attention. N = 49	The study reported the patients in the one-to-one education group gained more knowledge and had a higher level of nursing care satisfaction than those in the control group. Intervention: People very satisfied with nurses (%): n=33 (67.35) People basically satisfied with nurses (%): n=16 (32.65) People unsatisfied with nurses (%): n=0 (0.00) People's overall nursing satisfaction degree (%): n=49 (100.00) Control:	CRITICAL

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias
					People very satisfied with nurses (%): n=24 (48.98) People basically satisfied with nurses (%): n=14 (28.57) People unsatisfied with nurses (%): n=11 (22.45) People's overall nursing satisfaction degree (%): n=38 (77.55)	
Self-efficacy (measured using a variety of self-reported self-efficacy or confidence scales [e.g., Diabetic Foot Care Self-Efficacy Scale or Self-care Capacity Scale])						
(2)	RCT	Singapore	Collaborative patient education –Study team members developed a patient education approach which involves: a) collaboration with the patient; b) respecting that patients are experts of their own lives; and c) drawing out patients' intrinsic self-motivation and know-hows to work towards co-creating a treatment plan. The collaborative approach was delivered alongside standard diabetes wound care treatment such as wound cleansing/dressing, scalpel debridement, offloading through paddings, orthotics, or boot as appropriate. Podiatrists delivered the intervention. N (completed) = 28	The control group received standard diabetes wound care and education which was delivered in the traditional didactic style. Standard diabetes wound care treatment covered areas such as wound cleansing and dressing, scalpel debridement, offloading through paddings, orthotics or boot, as appropriate. N (completed) = 14	Participants with primary level of education in the intervention group experienced no difference in confidence score. The greatest increase in confidence score was experienced by participants in the control group with primary level of education. Participants with secondary or above education in the intervention group experienced an increase in confidence scores. Participants with secondary or tertiary levels of education in the control group reported a decrease in confidence score with respect to self-management of small wounds. Intervention (Results expressed in mean score ± SD – maximum score is 3): <u>Primary education level:</u> Post-study score: 2.67 ± 0.58 Pre-study score: 2.67 ± 0.58 Mean difference (95% CI): 0.00±1.00 (-2.48, 2.48) <u>Secondary education level:</u> Post-study score: 2.27 ± 0.80 Pre-study score: 2.20 ± 0.56 Mean difference (95% CI): 0.07± 0.70(-0.32, 0.46) <u>Tertiary education level:</u> Post-study score: 2.40 ± 0.70 Pre-study score: 2.30 ± 0.68 Mean difference (95% CI): 0.10±0.88 (-0.53, 0.73) Control (Results expressed in mean score ± SD – maximum score is 3): <u>Primary education level:</u> Post-study score: 2.75 ± 0.50 Pre-study score: 2.50 ± 1.00	SOME CONCERNS

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias
					<p>Mean difference (95% CI): 0.25±1.26 (-1.75, 2.25)</p> <p><u>Secondary education level:</u> Post-study score: 2.71 ± 0.49 Pre-study score: 2.86 ± 0.38 Mean difference (95% CI): -0.14±0.38 (-0.50, 0.21)</p> <p><u>Tertiary education level:</u> Post-study score: 1.67 ± 1.53 Pre-study score: 2.00 ± 1.00 Mean difference (95% CI): -0.33±0.58 (-1.77, 1.10)</p>	
(3)	RCT	Iran	<p>The educational intervention was based on Pender's health promotion model which included responsibility for health, stress management, interpersonal support and self-actualization.</p> <p>Education was performed through lectures, individual and group discussion, question and answer, and an educational booklet containing: (1) nutrition, (2) exercise, (3) responsibility for health, (4) stress management, (5) interpersonal support, and (6) self-actualization.</p> <p>Educational content collected 1: investigating the feelings and beliefs of patients with diabetic foot ulcers related to disease; 2: asking clients to determine their information about foot ulcers; 3: explain to diabetes mellitus and its complications; 4: risk factors for foot ulcers; 5: screening, and diagnostic criteria, 5: diet management 6: healthy lifestyle behaviors, 7: stress management, 8: physical activity, 9: evaluation of training, knowledge management, and then evaluated based on forms related to diabetic foot ulcers after training. N=37</p>	<p>Usual education from clinic staff before discharge. N=37</p>	<p>Positive effect on self-efficacy (SE) scores after completion of the intervention. Intervention group: After 50 days of intervention, there was an increase in SE mean scores. Before mean score± SD: 33±12/50 After mean ± SD: 60/70±9/50</p> <p>Control: no difference in SE mean scores before and 50 days after the intervention. Before mean score± SD: 45/783±21/107 After mean score± SD: 46/162±15/912</p>	HIGH
(4)	RCT	Malaysia	<p>The health education program's materials consisted of a questionnaire, a 20–30-minute Power Point presentation (PPT) and a pamphlet (for participants), and a checklist reminder (for the local healthcare provider). As a measure to improve participant retention, a foot kit (containing a pamphlet on foot care,</p>	<p>Standard care was routine or usual health-care service for persons with diabetes received from the local health provider in the elderly care facility. N= 38</p>	<p>Foot care self-efficacy (efficacy expectation), improved in the intervention group compared to the control group after 12 weeks of program implementation.</p> <p><u>Intervention:</u> Baseline mean ± SD score: 34.32±5.32 Week 4 mean ± SD score: 40.76 ±5.55</p>	SOME CONCERNS

Evidence Profile Recommendation 1 - Diabetic Foot Ulcers: Prevention, Assessment and Management

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias
			nail-clipper, moisturizing lotion, small towel) was given to the participants. The information distributed included awareness of risk factors and its complications, hygiene and inspection, skin and nail care, appropriate footwear, injury prevention, and when to seek a healthcare professional. During each follow-up, experience sharing, feedback on goals as well as an assessment of obstacles and problematic situations were conducted. The health education program had components for enhancing self-efficacy level such as performance accomplishment, vicarious experience, physical and emotional states, and verbal persuasion. N= 38		Week 12 mean \pm SD score: 40.89 \pm 4.91 <u>Control:</u> Baseline score mean \pm SD: 34.00 \pm 5.31 Week 4 mean \pm SD score: 34.39 \pm 5.09 Week 12 mean \pm SD score: 34.37 \pm 4.69 95%CI: (2.27, 4.68)	
(5)	RCT	Turkey	A transtheoretical model-based foot care program consisted of training, follow-up, and motivational interviewing-based counseling during a 6-month period. Participants received training intervention in the endocrinology outpatient unit. The training focused on foot self-examination, foot and toenail care, sock and shoe choice, high-risk condition prevention, and foot exercise. For the follow-up session, participants were divided into five subgroups according to their current stage of change. Each subgroup had different goals, and interventions for each subgroup were conducted separately. Motivational interviewing-based counseling occurred bimonthly via video calls. N= 25	Participants in the control group received only the same training as the intervention group and continued to receive usual diabetes care which was including diagnostic tests and medical treatment. N= 26	After intervention, the intervention group's diabetic foot care self-efficacy scale scores increased at 3 and 6 months, compared with the control group. <u>Intervention (mean \pm SD score):</u> Baseline: 54.48 \pm 13.59 3 months: 59.88 \pm 10.21 6 months: 67.00 \pm 10.13 <u>Control (mean \pm SD score):</u> Baseline: 50.50 \pm 11.96 3 months: 52.46 \pm 14.50 6 months: 56.53 \pm 14.49	SOME CONCERNS
(1)	Non-RCT	China	One to one education group (1) A comprehensive assessment of the patient's education level, personality characteristics and severity of the illness at the time of admission to provide basic guidance for the formulation of subsequent individualized health education programs; and (2) One-to-one education. N = 49	The control group was provided general education, through the distribution of knowledge manuals, oral presentations and other ways to explain daily life matters needing attention. N = 49	The self-care capacity scores of the one-to-one education group were higher than those of the basic nursing group. <u>Intervention:</u> Self-care capacity scale (ESCA) self-care skills score (mean \pm SD): 35.98 \pm 3.65 ESCA self-concept score (mean \pm SD): 26.19 \pm 2.57 ESCA self-care responsibility score (mean \pm SD): 27.94 \pm 3.11 ESCA self-care knowledge score (mean \pm SD): 44.89 \pm 4.01 <u>Control:</u> ESCA self-care skills score (mean \pm SD): 26.87 \pm 3.16	CRITICAL

Evidence Profile Recommendation 1 - Diabetic Foot Ulcers: Prevention, Assessment and Management

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias
					ESCA self-concept score (mean ± SD): 20.13 ± 3.02 ESCA self-care responsibility score (mean ± SD): 21.06 ± 2.09 ESCA self-care knowledge score (mean ± SD): 35.16 ± 3.16	
(6)	Non-RCT	Italy	<p>Psychoeducational protocol included:</p> <ol style="list-style-type: none"> 1) General pre-sensation, basal questionnaire on foot care competence, motivation to change; 2) Diabetes care, the importance of prevention; 3) Healthy behaviors. Select appropriate instruments for foot care; 4) Shoes and snickers; 5) Discrepancy, self-efficacy, barriers to change. 6) Wrap-up. Q&A <p>The communicative style of each session was collaborative and aimed at strengthening motivation and commitment of change, in keeping with the principles of motivational interviewing. N = 81</p>	Standard care – not defined N = 172	<p>This study reported an increase in self-efficacy in psychoeducational group compared to standard care.</p> <p><u>Intervention:</u> Visual analogic score (VAS): median 80% 5 to 95% CI: 50-100%</p> <p><u>Control:</u> VAS: median 70% 5 to 95% CI: 40-90%</p>	
(7)	Non-RCT	Iran	<p>In this training session, how to care the diabetic foot and preventing the development and the formation of new ulcers were taught to patients by focusing on seven important items of the Diabetes Foot Self-care Behaviour Scale (DFSBS) (checking the extremities and checking between the fingers, washing between the fingers, drying between the fingers after washing, the use of lotions and checking inside shoes). Also, trainings in relation to diet and intake of food groups, sport activities and weight control, the way and time of measuring blood sugar, the proper way of insulin injections and emergency procedures in the disease were presented. Transfer method of training materials was via the lecture, using slides, videos as well as viewing practical skills of trainer and individual's experience during the participation in training process After practical training to patients, they were also given a training pamphlet on how to perform the care. Moreover, they were asked to do the health-care daily. N=30</p>	No training N=30	<p>This study reported that the educational intervention resulted in higher mean SE scores in the intervention groups compared to the control groups three months after intervention.</p> <p><u>Intervention:</u> Pre-test mean score ± SD: 81.65±3.1 Post-test mean score ± SD: 182.25±1.4</p> <p><u>Control:</u> Pre-test mean score ± SD: 87.95±2.1 Post-test mean score ± SD: 93.56±2.1</p>	CRITICAL

Evidence Profile Recommendation 1 - Diabetic Foot Ulcers: Prevention, Assessment and Management

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias
(8)	Non-randomized single arm study	Turkey	Educational intervention based on Bandura's self-efficacy theory. The research team prepared the educational intervention using literature and theory. Each patient received a one-on-one training (one session for 1 hour) session including assessment of foot, skincare of foot, nail cutting and care, modifying daily life activities, and selecting socks and footwear. N=33	N/A	This study reported that the educational intervention had a large positive effect on improving foot care self-efficacy. Before mean score \pm SD: 50.18 \pm 20.88 After mean score \pm SD: 72.67 \pm 20.74	CRITICAL
Person adherence (measured using compliance behaviour scores and percentage of steps taken while wearing orthopedic shoes)						
(9)	Cluster RCT	Netherlands	The intervention consisted of usual care plus motivational interviewing (MI). A certified MI trainer trained the podiatrists assigned to the MI-group in the principles of MI during a 3-day basic training. During the MI-consultations, the podiatrist focused on improving acceptance of and adherence to orthopedic shoes. N=53	Usual care consisted of: (a) foot screening and professional foot care by a podiatrist once every 1–12 months, depending on the International Working Group on the Diabetic Foot risk classification; (b) structured education about appropriate foot self-care for preventing a foot ulcer; (c) orthopedic shoes fitted by a pedorthist, if indicated based on foot condition and ulcer risk. N=68	This study reported that a higher number of participants in the control group wore their orthopedic shoes compared to the intervention group after 3 months. <u>Intervention:</u> Adherence at 3 months to wearing orthopedic shoes: 15.1% <u>Control:</u> Adherence at 3 months: 30.9%	SOME CONCERNS
(1)	Non-RCT	China	One to one education group (1) A comprehensive assessment of the patient's education level, personality characteristics and severity of the illness at the time of admission to provide basic guidance for the formulation of subsequent individualized health education programs; and (2) One-to-one education. N = 49	Basic nursing group was provided general education, through the distribution of knowledge manuals, oral presentations and other ways to explain daily life matters needing attention. N = 49	The scores of compliance behavior in the one-to-one education group were higher than those in the basic nursing group. <u>Intervention:</u> Foot bathing mean score \pm SD = 8.63 \pm 1.01 Exercise health care mean score \pm SD = 8.51 \pm 0.97 Shoes and socks selection mean score \pm SD = 9.04 \pm 1.24 <u>Control:</u> Foot bathing mean score \pm SD = 6.87 \pm 0.81 Exercise health care mean score \pm SD = 6.94 \pm 0.83 Shoes and socks selection mean score \pm SD = 8.05 \pm 1.01	CRITICAL
DFU occurrence/recurrence (measured using a Foot Assessment Form and observation methods)						
(9)	Cluster RCT	Netherlands	The intervention consisted of usual care plus motivational interviewing (MI). A certified MI trainer trained the podiatrists assigned to the MI-group in the principles of MI during a 3-day basic training. During the MI-consultations the podiatrist focused on improving acceptance of and adherence to orthopedic shoes. N=53	Usual care consisted of: (a) foot screening and professional foot care by a podiatrist once every 1–12 months, depending on the International Working Group on the Diabetic Foot risk classification; (b) structured education about appropriate foot self-care for	Between intervention and control groups, there were no important differences in regards to the proportion of participants who developed one or more ulcers during the 1 -year follow-up period (respectively 34% and 28%). <u>Intervention:</u> 18 of the 53 participants developed 22 ulcers.	SOME CONCERNS

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias
				preventing a foot ulcer; (c) orthopedic shoes fitted by a pedorthist, if indicated based on foot condition and ulcer risk. N=68	<u>Control:</u> 19 of the 68 participants developed 21 ulcers.	
(10)	Non-RCT	Vietnam	All four principal sources of information of self-efficacy: performance accomplishments, vicarious experiences, verbal persuasion, and physiological states were utilised in intervention strategies. Included: Small group multifaceted education and hands-on skills session; - foot care written materials, a foot care kit; and - three regular booster follow-up phone calls over six months Intervention group also received usual care: (1) anthropometric measurements (height, weight, BMI, waist circumference, body fat percentage, body fat distribution); (2) regular biochemistry test; (3) consultations and treatment by medical doctors specialised in diabetes and chronic disease and; (4) professional diet and exercise consultation (if required) by dietitian or medical staff. N: 59	In addition to usual care, participants in the control group received a foot care brochure. At the end of the study, each of the participants in this arm was offered foot care written materials (a booklet and A3-steps guide waterproof tip sheet), a foot care kit and a foot care education session. N: 60	At the sixth month point, the percentage of the foot risk factors of dry skin, cracked skin, corn/callus (DCC) for ulceration was lower in the intervention group compared to those in the control group. The ratio of the odds of having DCC at 6-month relative to the baseline in the intervention group compared to those in the control group was 0.045 (95% CI: 0.014 – 0.141). In other words, the odds of having DCC in the intervention group were 22.22 times (i.e. 1/0.045) lower than the odds of having DCC in the control group over six months. Unadjusted model OR – Group x Time (95% CI): 0.054 (0.019-0.157) Adjusted model (primary income sources and baseline foot care self-efficacy Group x Time (95% CI): 0.045 (0.014-0.141)	MODERATE
(6)	Non-RCT	Italy	The psychoeducational protocol was jointly delivered by a trained podiatrist and a psychologist expert in motivational interviewing during five weekly sessions. The program included: 1) General presentation, basal questionnaire on foot care competence, motivation to change; 2) Diabetes care, the importance of prevention; 3) Healthy behaviors. Select appropriate instruments for foot care; 4) Shoes and snickers; 5) Discrepancy, self-efficacy, barriers to change. A logbook to register daily practices; 6) Wrap-up. Q&A N: 81	Standard care – not defined N: 172	The incidence of new lesions was lower in the psychoeducational group compared to standard care group. The average time to new lesions were increased in the psychoeducational group compared to standard care group. <u>Psychoeducational group:</u> Average time to occurrence of new lesions: 30.4 ± 11.2 months <u>Standard care:</u> Average time to occurrence of new lesions: 24.8 ± 14.5 months Risk of diabetic foot lesion occurrence/recurrence in relation to participation on the psychoeducational program vs. standard care (Data represented as hazard ratio, 95% confidence interval). Model 1: unadjusted 0.53, 0.30-0.95 Model 2: adjusted for age and duration of diabetes 0.49, 0.26-0.91	CRITICAL

Evidence Profile Recommendation 1 - Diabetic Foot Ulcers: Prevention, Assessment and Management

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias
					Model 3: additional adjustment for baseline skin lesions and foot risk score 0.34,0.18-0.66	

Acronyms

- CI = confidence interval
- DCC = dry skin, cracked skin, corn/callus
- DFSBS = Diabetes Foot Self-care Behaviour Scale
- DFU = diabetic foot ulcer
- ESCA = self-care capacity scale
- GDM = guideline development methodologist
- HCP = health-care provider
- HPM = health promotion model
- MI = motivational interviewing
- OR = odds ratio
- RCT = randomized control trial
- SD = standard deviation
- SE = self-efficacy
- SR = systematic review
- VAS = visual analogic score

References

1. Fu XJ, Hu SD, Peng YF, Zhou LY, Shu T, Song DD. Observation of the effect of one-to-one education on high-risk cases of diabetic foot. *World Journal of Clinical Cases*. 2021;9(14):3265.
2. Heng ML, Kwan YH, Ilya N, Ishak IA, Jin PH, Hogan D, et al. A collaborative approach in patient education for diabetes foot and wound care: A pragmatic randomised controlled trial. *International Wound Journal*. 2020 Dec;17(6):1678–86.
3. Vakilian P, Mahmoudi M, Oskouie F, Firouzian AA, Khachian A. Investigating the effect of educational intervention based on the Pender's health promotion model on lifestyle and self-efficacy of the patients with diabetic foot ulcer: A clinical trial. *Journal of education and health promotion [Internet]*. 2021 [cited 2023 Oct 11];10. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8826777/>
4. Ahmad Sharoni SK, Abdul Rahman H, Minhat HS, Shariff-Ghazali S, Azman Ong MH. The effects of self-efficacy enhancing program on foot self-care behaviour of older adults with diabetes: A randomised controlled trial in elderly care facility, Peninsular Malaysia. *PloS one*. 2018;13(3):e0192417.
5. Kes D, Sahin F, Ertinmaz Ozkan A, Erem Basmaz S. Effectiveness of a Transtheoretical Model-Based Foot Care Program in Improving Foot Care Behaviors and Self-Efficacy in Adults With Type 2 Diabetes: An Assessor-Blinded Randomized Controlled Trial. *Res Theory Nurs Pract*. 2022 Feb 1;36(1):3–19.
6. Baccolini L, Centis E, Malaguti A, Forlani G, Marchesini G, Petroni ML. A psycho-educational intervention for the prevention of foot lesions in people with diabetes: Report of a clinical audit. *Nutrition, Metabolism and Cardiovascular Diseases*. 2022;32(9):2264–72.
7. Bahador RS, Afrazandeh SS, Ghanbarzei N, Ebrahimi M. The impact of three-month training programme on foot care and self-efficacy of patients with diabetic foot ulcers. *Journal of Clinical and Diagnostic Research: JCDR*. 2017;11(7):IC01.
8. Toygar I., Hancerlioglu S., Utku T., Simsir I.Y., Cetinkalp S. Effect of an Educational Intervention Based on Bandura's Theory on Foot Care Self-Efficacy in Diabetes: A Prospective Quasi-Experimental Study. *Int J Lower Extremity Wounds*. 2020;((Toygar, Hancerlioglu, Utku, Simsir, Cetinkalp) Ege University, Izmir, Turkey):1534734620948327.
9. Jongbloed-Westra M, Exterkate SH, Van Netten JJ, Kappert KDR, Koffijberg H, Bode C, et al. The effectiveness of motivational interviewing on adherence to wearing orthopedic shoes in people with diabetes at low-to-high risk of foot ulceration: A multicenter cluster-randomized controlled trial. *Diabetes Research and Clinical Practice*. 2023 Oct;204:110903.

Evidence Profile Recommendation 1 - *Diabetic Foot Ulcers: Prevention, Assessment and Management*

10. Nguyen TPL, Edwards H, Do TND, Finlayson K. Effectiveness of a theory-based foot care education program (3STEPFUN) in improving foot self-care behaviours and foot risk factors for ulceration in people with type 2 diabetes. *Diabetes research and clinical practice*. 2019;152:29–38.

Explanations:

-
- ^a Based on quality appraisal using the ROBINS-I tool, the study had critical risk of bias due to lack of control for confounding variables, deviations from intended interventions, and measurement of outcomes. We downgraded by 2.
- ^b The total number of participants was far less than the optimal number of 800 (n= 98). We downgraded by 2.
- ^c Based on the risk-of-bias-tool for randomized trials (RoB 2), three studies had some concerns and one study with critical risk-of-bias due to deviations from intended interventions, missing data and measurements of outcomes. We downgraded by 1.5.
- ^d There was variability in the direction of effect shown in the studies; most studies demonstrated a positive direction of effect, but one study had no difference in SE score at primary level of education. There was variation in tools used to measure outcomes. We downgraded by 1.
- ^e Across the four studies, the total number of participants was far less than the optimal number of 800 (n=243). We downgraded by 2.
- ^f Based on the quality appraisal using the ROBINS-I tool, all studies had critical risk-of-bias due to lack of control for confounding variables. 1 study had critical risk-of-bias due to measurement of outcomes. All studies had some serious concerns with classification of interventions, deviations from intended interventions, missing data, and/or measurement of outcomes. We downgraded by 2.
- ^g All 3 studies showed a positive direction of effect, however there were slight variations in the tools used. We downgraded by 0.5.
- ^h Across the three studies, the total number of participants was much less than the optimal number of 800 (n=411). We downgraded by 1.
- ⁱ Based on quality appraisal using the ROBINS-I tool, the study had critical risk of bias due to lack of control for confounding variables. We downgraded by 1.
- ^j The total number of participants was far less than the optimal number of 800 (n=33). We downgraded by 2.
- ^k Based on the risk-of-bias-tool for cluster-randomized trials (RoB 2 CRT), the study had serious risk of bias due to some concerns for deviations from intended interventions and measurement of outcomes. We downgraded by 1.
- ^l The total number of participants was far less than the optimal number of 800 (n=121). We downgraded by 2.
- ^m Based on quality appraisal using the ROBINS-I tool, the study had critical risk of bias due to lack of control for confounding variables, and measurement of outcomes. We downgraded by 2.
- ⁿ The total number of participants was far less than the optimal number of 800 (n=90). We downgraded by 2.
- ^o Based on the risk-of-bias-tool for cluster-randomized trials (RoB 2 CRT), although the study had no serious risk of bias we downgraded by 0.5 due to some concerns for deviations from intended interventions. We downgraded by 0.5.
- ^p The total number of events was far less than the optimal number of 300 (n=43). We downgraded by 2.
- ^q Based on quality appraisal using the ROBINS-I tool, both studies had critical risk of bias due to lack of control for confounding variables. We downgraded by 1.5.
- ^r Both studies showed a positive direction of effect, however there were slight variations in the tools used. We downgraded by 0.5.
- ^s The outcome of "dry skin, cracked skin, corn/ callus" was different from the original outcome of interest (DFU occurrence/recurrence). We downgraded by 0.5.
- ^t The total number of participants was far less than the optimal number of 800 (n= 372). We downgrade by 1.