Research Q4 Evidence Profile (Quantitative)

Recommendation question: Should virtual care (e.g., telemedicine, telehealth, social media) be recommended or not to support/supplement (in conjunction with in-person service) the delivery of diabetic foot care services?

Recommendation 4.0: The expert panel suggests that health providers use virtual care platforms in-conjunction with in-person services to supplement the provision of diabetic foot care services.

Population: Adults at risk of or living with diabetic foot ulcer (DFU)
Intervention: Use of virtual technology (e.g., telemedicine, telehealth, social media) to support/supplement in-person DFU prevention or management strategies
Comparison: No use of virtual technology in DFU care delivery
Outcomes: Self-efficacy (critical), screening rates (critical), provider satisfaction (critical) [not measured], patient satisfaction (critical) [not measured], diabetic foot ulcer occurrence/recurrence (important), neuropathy screening (important) [not measured]

Setting: Across any settings (community [home, clinic, primary care], acute hospital care [in-patient, out-patient], congregate care [long-term care (LTC), retirement homes (RH)], rehab etc.)

Table 1 – Quality details

Quality assessment							No. of participants		Effect	Certainty	Reference
№ of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Intervention**	**Control**			
Self-efficacy *(measured using Diabetic Foot Care Self-Efficacy Scale (DFCSES)*											
1	RCT	Very serious[a]	Not serious	Not serious	Very serious[b]	Undetected	N= 65 participants	N=65 participants	The intervention group scored 11 points higher on the final assessment of self-efficacy on the DFCSE scale compared to control group.	⊕◯◯◯ Very low	(1)
Screening rates *(measured using Diabetes Self-Management Questionnaire)*											
1	RCT	Very serious[c]	Not serious	Not serious	Very serious[d]	Undetected	N=30 participants	N=30 participants	The intervention group scored 4.37 points higher on the final assessment of self-screening rates on the Diabetes Self-Management Questionnaire compared to the control group.	⊕◯◯◯ Very low	(2)
Diabetic Foot Ulcer occurrence/recurrence *(measured using observation, i.e., trained nurse blinded to the intervention evaluating the patient, or electronic health records and medical claims)*											
2	RCT	Serious[e]	Very serious[f]	Not serious	Very serious[g]	Undetected	N= 28 events	N= 30 events	One study[h] demonstrated no change in the incidence of DFUs with the addition of mHealth to foot thermometry after 18 months of follow up. The other study demonstrated that the intervention group who received risk assessment with	⊕◯◯◯ Very low	(3,4)

Quality assessment							No. of participants		Effect	Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
									smartphone thermography evaluation had a lower DFU recurrence rate compared to the control group.		
1	Non-randomized single-arm study	Very serious[i]	Not serious	Not serious	Very serious[j]	Detected[k]	N= 55 events	No control groups.	Participants in the study had lower rates of DFU recurrence in the pre-post analysis (RRR=0.37). During the program, there were larger reductions of moderate and severe foot ulcers (RRR=0.91) and all foot ulcers (RRR=0.46).	⊕◯◯◯ Very low	(5)
Provider satisfaction [not measured]											
N/A											
Patient satisfaction [not measured]											
N/A											
Neuropathy screening [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
Self-efficacy *(measured using Diabetic Foot Care Self-Efficacy Scale (DFCSES)*						
(1)	RCT	Turkey	All participants received diabetes foot care education through the app at home. Participants received reminder notifications bi-weekly using visual cartoon images to continue using the app. N= 65 participants	Participants in the control group received usual diabetic foot care education in line with the clinical guidelines at the hospital. N=65 participants	Individuals in the experimental group who received animation-supported M-DFCE had higher self-efficacy than the control group 1 month after education. The intervention group scored 11 points higher on the final assessment of self-efficacy on the DFCSE scale compared to control group.	VERY SERIOUS
Screening rates *(measured using Diabetes Self-Management Questionnaire)*						
(2)	RCT	Indonesia	The smartphone application of diabetes coaching program. N=30 participants	Routine services were continuously provided by community health centers during the same period N=30 participants	After implementation, the self-management behaviors among the experimental groups were improved compared to the control group in terms of screening of complications. There was a mean difference of 4.150 (95% CI 3.52 – 4.78) between the intervention and control groups.	VERY SERIOUS
Diabetic Foot Ulcer occurrence/recurrence *(measured using observation, i.e., trained nurse blinded to the intervention evaluating the patient, or electronic health records and medical claims)*						
(3)	RCT	Peru	All participants received education about foot care practices, early signs of ulceration; and instructions for the use of the TempStat™ device. Participants were asked to contact fieldworkers if one of the alarm signs appeared in the pads of the TempStat™. Participants received mHealth (mobile health) reminder messages and foot care promotion messages. N= 86 participants	Participants in the control group received only foot thermometry and followed up at 18 months. N= 86 participants	The study demonstrated no change in the incidence of diabetic foot ulcers (DFUs) with the addition of mHealth to foot thermometry after 18 months of follow up.	SERIOUS
(4)	RCT	Indonesia	Baseline risk assessment including smartphone thermography evaluation was performed. Personalized foot care and education were conducted monthly for participants whose thermographs showed increased foot lesion temperature at baseline risk assessment. The captured infrared thermal images were reviewed to detect early signs of inflammation near or on pre-ulcerative lesions. N= 60 participants	The control group underwent a thorough foot inspection to assess the overall condition of their feet, calluses were shaved using surgical blades, and participants received basic education regarding diabetes and its complications using an educational leaflet. Throughout the six-month follow-up period, the control group participants received monthly home visits. During these visits, specialists in wound care management captured images of the participants' feet to confirm the presence or recurrence of foot ulcers N= 60 participants	The study demonstrated that the intervention group who received risk assessment with smartphone thermography evaluation had a lower DFU recurrence rate compared to the control group (15% versus 35%). The intervention group also had a reduced risk of a DFU recurrence by 59% (HR 0.41 95% CI 0.18-0.96).	SERIOUS

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias
(5)	Non-randomized single-arm study	USA	Participants used the foot temperature monitoring mat to monitor abnormal temperatures indicative of foot inflammation. In-home once-daily foot temperature monitoring, care management to support participants in engagement with the program, and periodic podiatric exams prompted by abnormal foot temperature readings (differences in temperature exceeding 2.2° C over two consecutive uses). N= 80 participants	There was no control group, and the authors aimed to compare results before, during, and after intervention.	Participants in the study had lower rates of DFU recurrence in the pre-post analysis (RRR=0.37). During the program, there were larger reductions of moderate and severe foot ulcers (RRR=0.91) and all foot ulcers (RRR=0.46).	VERY SERIOUS

Acronyms

aHR = Adjusted Hazard Ratio
ARR = Absolute Risk Reduction
CI = confidence interval
DFU = Diabetic Foot Ulcer
HER = Electronic Health Record
HR = Hazard ratio
M-DFCE = Mobile Diabetic Foot Care Education
N/A = Not Applicable
OTN = Ontario Telemedicine Network
RCT = Randomized Clinical Trial
RRR = Relative Risk Reduction
SD = Standard Deviation
SMS = Short Message Service

References

1. Dincer B, Bahçecik N. The effect of a mobile application on the foot care of individuals with type 2 diabetes: A randomised controlled study. Health Education Journal. 2021 Jun;80(4):425–37.

2. Pamungkas RA, Usman AM, Chamroonsawasdi K. A smartphone application of diabetes coaching intervention to prevent the onset of complications and to improve diabetes self-management: A randomized control trial. Diabetes & Metabolic Syndrome: Clinical Research & Reviews. 2022;16(7):102537.

3. Lazo-Porras M, Bernabe-Ortiz A, Taype-Rondan A, Gilman RH, Malaga G, Manrique H, et al. Foot thermometry with mHeath-based supplementation to prevent diabetic foot ulcers: a randomized controlled trial. Wellcome open research [Internet]. 2020 [cited 2023 Oct 11];5. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7463300/

4. Qin Q, Oe M, Nakagami G, Kashiwabara K, Sugama J, Sanada H, et al. The effectiveness of a thermography-driven preventive foot care protocol on the recurrence of diabetic foot ulcers in low-medical resource settings: An open-labeled randomized controlled trial. International Journal of Nursing Studies. 2023 Oct;146:104571.

5. Isaac AL, Swartz TD, Miller ML, Short DJ, Wilson EA, Chaffo JL, et al. Lower resource utilization for patients with healed diabetic foot ulcers during participation in a prevention program with foot temperature monitoring. BMJ Open Diabetes Research and Care. 2020;8(1):e001440.

Explanations

[a] Based on the quality appraisal using the ROB 2.0 tool for RCTs, the study had a very serious risk of bias due to some concerns in the randomization process, deviations from intended interventions, and measurements of outcomes. We downgraded by 2.
[b] The total number of participants was far less than the optimal number of 800 (n=130). We downgraded by 2.
[c] Based on the quality appraisal using the ROB 2.0 tool for RCTs, the study had a very serious risk of bias due to concerns with the randomization process, deviations from intended interventions, and measurements of outcomes. We downgraded by 2.
[d] The total number of participants was far less than the optimal number of 800 (n=60). We downgraded by 2.
[e] Based on the quality appraisal using the ROB 2.0 tool for RCTs, the study had a serious risk of bias due to some concerns about deviations from intended interventions and missing data. We downgraded by 1.
[f] The two studies demonstrated different direction of effects. One study reported no change in DFU incidence while the other reported a lower DFU reoccurrence in the intervention group compared to the control group. We downgraded by 2.
[g] The total number of events was far less than the optimal number of 300 (n=58). We downgraded by 2.
[h] The aHR provides an explanation to the increase in DFU incidence in intervention group in comparison to the control group. Factors including insufficient information on previous ulceration status, site of DFU occurrence influenced this result.
[i] Based on the quality appraisal using the ROBINS-I tool, the study had critical risk of bias due to serious concerns with confounding variables and missing data, and critical concerns with classification of interventions. We downgraded by 2.
[j] The total number of events was less than the optimal number of 300 (n= 55). We downgraded by 2.
[k] The reviewers noted in the authors' report that the research was funded and supported by Podimetrics Inc. and Kaiser Permanente Mid-Atlantic States. Podimetrics Inc. funded study analysis whilst Kaiser Permanente Mid-Atlantic States provided resources for the clinical management of the study. The study device was manufactured by Podimetrics Inc, where a third of authors (5/15) are employees and shareholders. We downgraded by 0.5.