Remote Patient Pedal Monitoring for Foot Ulcer Prevention

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PREFACE

The VA Evidence Synthesis Program (ESP) was established in 2007 to conduct timely, rigorous, and independent systematic reviews to support VA clinicians, program leadership, and policymakers improve the health of Veterans. ESP reviews have been used to develop evidence-informed clinical policies, practice guidelines, and performance measures; to guide implementation of programs and services that improve Veterans' health and well-being; and to set the direction of research to close important evidence gaps. Four ESP Centers are located across the US. Centers are led by recognized experts in evidence synthesis, often with roles as practicing VA clinicians. The Coordinating Center, located in Portland, Oregon, manages program operations, ensures methodological consistency and quality of products, engages with stakeholders, and addresses urgent evidence synthesis needs.

Nominations of review topics are solicited several times each year and submitted via the ESP website. Topics are selected based on the availability of relevant evidence and the likelihood that a review on the topic would be feasible and have broad utility across the VA system. If selected, topics are refined with input from Operational Partners (below), ESP staff, and additional subject matter experts. Draft ESP reviews undergo external peer review to ensure they are methodologically sound, unbiased, and include all important evidence on the topic. Peer reviewers must disclose any relevant financial or non-financial conflicts of interest. In seeking broad expertise and perspectives during review development, conflicting viewpoints are common and often result in productive scientific discourse that improves the relevance and rigor of the review. The ESP works to balance divergent views and to manage or mitigate potential conflicts of interest.

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Operational Partners

Operational partners are system-level stakeholders who help ensure relevance of the review topic to the VA, contribute to the development of and approve final project scope and timeframe for completion, provide feedback on the draft report, and provide consultation on strategies for dissemination of the report to the field and relevant groups.

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Technical Expert Panel

To ensure robust, scientifically relevant work, the technical expert panel (TEP) guides topic refinement; provides input on key questions and eligibility criteria, advising on substantive issues or

possibly overlooked areas of research; assures VA relevance; and provides feedback on work in progress. TEP members included:

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DISCLOSURES

This report was prepared by the ESP Center located at the **Durham VA Medical Center**, directed by Jennifer M. Gierisch, PhD, MPH, and Karen M. Goldstein, MD, MSPH and funded by the Department of Veterans Affairs, Veterans Health Administration, Health Systems Research.

The findings and conclusions in this document are those of the author(s) who are responsible for its contents and do not necessarily represent the views of the Department of Veterans Affairs or the United States government. Therefore, no statement in this article should be construed as an official position of the Department of Veterans Affairs. The final research questions, methodology, and/or conclusions may not necessarily represent the views of contributing operational and content experts. No investigators have affiliations or financial involvement (eg, employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties) that conflict with material presented in the report.

Main Report

Evidence Synthesis Program

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ABBREVIATIONS TABLE

Abbreviation	Definition
aHR	Adjusted hazard ratio
AHRQ	Agency for Healthcare Research and Quality
aRR	Adjusted risk ratio
COE	Certainty of evidence
GRADE	Grading of Recommendations Assessment, Development and Evaluation
ICD	International Classification of Diseases
IWGDF	International Working Group on the Diabetic Foot
LEA	Lower extremity amputation
MeSH	Medical subject headings
NNT	Number needed to treat
OR	Odds ratio
PAVE	Prevention of Amputations for Veterans Everywhere
PI	Prediction interval
PRESS	Peer Review of Electronic Search Strategies
QoL	Quality of life
RCT	Randomized controlled trial
RD	Rate difference
ROB	Risk of bias
ROBINS-I	Risk Of Bias In Non-randomized Studies – of Interventions
RR	Risk ratio
RRR	Relative risk reduction
TEP	Technical expert panel

BACKGROUND

Foot ulcers, defined as a physical deterioration of skin that results in an open wound on the plantar, interdigital, medial, or lateral aspects of the foot, remain a growing problem in the US, with an incidence rate of approximately 1.6 million cases annually.[1] Foot ulcers typically occur due to the pathophysiological impact of neuropathy, foot deformities, and decreased perfusion that increases the tissues susceptibility to damage and ulcer formation.[1] Due to the associated loss of protective sensation, ulcer development often progresses with minimal or no symptoms, as common early warning signs of tissue damage such as pain may be significantly diminished or absent due to concurrent neuropathy.[2] Frequent monitoring and close inspection is thus critical for early detection of tissue damage and prevention of ulcer development.

Foot ulcer rates are highest among individuals with diabetes, with a lifetime incidence of 19%–34% and an average recurrence rate of 40% at 1 year and 65% within 3 years.[3] Several other comorbidities, however, are also associated with an increased risk of ulcer formation including vascular disease, kidney disease (stage 4 or 5), and peripheral neuropathy. Foot ulcers are also associated with a range of serious complications including infection, lower extremity amputation (LEA), and decreased quality of life (QoL).[4] Furthermore, foot ulcers may exacerbate long-term adverse outcomes among certain patients, such as those with peripheral arterial disease, among whom a 40% mortality rate has been shown within 5 years after ulcer development.[4]

Current management practices for diabetes and peripheral arterial disease are centered upon preventive foot self-care strategies including daily skin inspection, appropriate or prescription footwear and orthotics, skin care, and periodic foot examination for signs of tissue injury.[2,4] Although an effective tool for ulcer prevention, these self-care approaches are often limited by suboptimal adherence rates due to lack of patient education, improper technique, or physical and visual limitations.[5] Previous guidelines have recommended the use of at-home foot skin temperature self-monitoring, which has shown some benefit for ulcer prevention, although this strategy may also be limited by adherence.[6] Recent advancements in technology have sought to address this problem through the development of in-home or wearable telemedicine devices including mats, smart socks, and smart insoles that allow for remote patient pedal monitoring of pressure and/or temperature with asynchronous transmission of data to clinical providers. These devices hold promise for their ability to identify early warning signs of ulcer development, while also potentially improving usability and adherence.[7]

Among Veterans who receive care at the VA, almost 25% (1.6 million individuals) are diagnosed with type 2 diabetes and over 3,400 undergo a diabetes-related LEA annually.[8,9] The Prevention of Amputations for Veterans Everywhere (PAVE) Program was established by the VA to provide specialized care for Veterans at risk for foot ulcer and related complications.[10] Historically, however, low compliance with PAVE clinical guidelines has been demonstrated, with almost one-third of patients in 2010 failing to receive annual specialist foot care, as recommended for all high-risk Veterans.[11]Alternative or additional preventive approaches among this population are therefore urgently needed. Emerging telemedicine devices may provide a timely and effective method for bridging this gap in clinical care for at-risk Veterans, ensuring delivery of appropriate preventive foot care. Findings from this review will inform the development of clinical guidance regarding use of remote patient pedal monitoring devices for prevention of foot ulcers within VA.

METHODS

REGISTRATION AND REVIEW

A pre-registered protocol for this review can be found on the PROSPERO international prospective register of systematic reviews (CRD420251071267). A draft version of this report was reviewed by external peer reviewers; their comments and author responses are provided in the Supplementary Materials.

KEY QUESTIONS AND ELIGIBILITY CRITERIA

The following key questions were the focus of this review:

- *Key Question 1a (KQ1a)*: Among at-risk adults, what is the efficacy and safety of remote patient pedal monitoring devices for the prevention of foot ulcers?
- *Key Question 1b (KQ1b)*: Does the efficacy and safety of remote patient pedal monitoring devices for the prevention of foot ulcers vary based on patient demographics, the presence of chronic kidney disease, patient device adherence, or physical activity level?
- *Key Question 1c (KQ1c)*: Does the efficacy and safety of remote patient pedal monitoring devices for the prevention of foot ulcers vary based on the type of monitoring device, frequency of monitoring, or methods of monitoring feedback to patients?

Study eligibility criteria are shown in the table below.

Domain	Eligibility Criteria: Inclusion	Eligibility Criteria: Exclusion
Population	Ambulatory adults who are at risk for foot ulcer based on the presence of 1 or more of the following: • Diabetes (type 1 or 2) • Stage 4 or 5 chronic kidney disease • Peripheral arterial disease • History of foot ulcer on plantar, interdigital, medial, or lateral aspect of foot (or history of foot ulcer with location not specified) • LEA • Peripheral neuropathy including Charcot foot (neuropathic arthropathy) • Otherwise described as at risk for foot ulcers	Unhealed plantar ulcer Non-ambulatory adults < 18 years old Traumatic LEA or ulcers

Domain	Eligibility Criteria: Inclusion	Eligibility Criteria: Exclusion
Intervention	Remote patient pedal monitoring of pressure, temperature, and/or visual monitoring technology intended to identify physiological changes responsive to off-loading to prevent foot ulcer formation • At-home monitoring without concurrent direct clinical assessment • Device company can respond to alerts and interact with the patient before connecting to clinical provider or not transmit data • Patient can use monitoring device from a sitting position if they are otherwise ambulatory	In-clinic monitoring technology to identify at-risk persons or conditions Treatments for physiological changes that require off-loading without associated monitoring devices
Comparator	In-clinic monitoring such as direct visualization without assistive technology Different remote patient pedal monitoring device types	No comparator
Outcomes	LEA Hospitalization Mortality Ulcer incidence Time to ulceration Ulcer recurrence Adherence (*eg,* average device use; patient discontinuation) Satisfaction/ease of use Adverse events (*eg*, falls, electrical shortage) QoL Patient engagement/involvement in care Process outcomes (*eg*, episodes of device alerting)	Pressure ulcers for immobile or non-ambulatory individuals Tissue injury or inflammation with unbroken skin (*eg*, inflamed callus, stage 1)
Timing	Any	None
Setting	Outpatient Institutional settings if ambulatory and able to self-monitor	In-hospital
Study Design	Comparative studies including randomized trials and comparative observational studies	Non-comparative studies (*eg,* cohort studies without a comparator/unexposed group, qualitative or ethnography studies, descriptive studies, systematic reviews)
Language	Any	NA

Domain	Eligibility Criteria: Inclusion	Eligibility Criteria: Exclusion
Publication Types	Full publication in a peer-reviewed journal	Letters, opinion pieces, editorials, narrative reviews, dissertations, qualitative studies, systematic reviews, meeting abstracts, non-peer-reviewed studies, and case studies

Notes. Remote patient pedal monitoring did not require transmission of data to a third party (*eg,* clinical provider or device company). Ulcer was defined as physical breakdown of skin on plantar, interdigital, medial, or lateral aspect of foot. We only evaluated adherence as an outcome in the context of a comparative study design.
Abbreviations. LEA=lower extremity amputation; NA=not applicable.

SEARCHING AND SCREENING

We conducted a primary search from inception to May 5, 2025, of MEDLINE (via Ovid), CINAHL (via EBSCO), Scopus (via Elsevier), and Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Trials (via Wiley). We used a combination of medical subject headings (MeSH) keywords and selected free-text terms to search titles and abstracts. (see Appendix for complete search strategies). To ensure completeness, search strategies were developed in consultation with an expert medical librarian and peer reviewed in accordance with PRESS guidance.[12] We also hand-searched previous related systematic reviews. An additional citation was identified by searching for subsequent results papers corresponding to relevant protocol registries. English-language titles, abstracts, and full-text articles were independently reviewed by 2 investigators, and disagreements were resolved by consensus.

DATA ABSTRACTION AND RISK OF BIAS ASSESSMENT

Study characteristics from included reports were abstracted into Covidence by 1 reviewer and over-read by a second reviewer. Disagreements were resolved by consensus or by obtaining a third reviewer's opinion when agreement could not be reached between the first and second reviewers. Key study characteristics abstracted included remote patient pedal monitoring device information (*eg,* type of monitoring device, frequency of monitoring, or methods of providing feedback to patient and/or clinical team), patient characteristics (*eg*, presence of chronic kidney disease, patient device adherence, or physical activity level), comparator details, and outcome measures. Multiple reports from a single study were treated as a single data point, prioritizing results based on the most complete and appropriately analyzed data. When critical data were missing or unclear, we requested additional data from the study authors.[13,14]

We used an adapted Cochrane ROBINS-I tool to assess risk of bias (ROB) for non-randomized studies that compare health effects of 2 or more interventions. ROBINS-I includes domains for (1) confounding; (2) participant selection; (3) intervention classification; (4) deviations from intended interventions; (5) missing data; (6) outcome measurement; and (7) selective outcome reporting. Overall, ROB judgments included low ROB, moderate ROB, serious ROB, critical ROB, and insufficient information. For RCTs, we adapted the Cochrane ROB-2 tool. This tool includes the following domains: (1) bias arising from the randomization process; (2) bias due to deviations from intended interventions; (3) bias due to missing outcome data; (4) bias in measurement of the outcome; (5) bias in selection of the reported result and has overall ROB as low, some concerns, or high ROB.

ROB was assessed by 2 reviewers independently and disagreements resolved as described above for data abstraction.

SYNTHESIS

We summarized the primary literature using relevant data abstracted from eligible studies. Summary characteristics of the primary studies were reviewed including study design, patient demographics, and intervention and comparator details. Similarly, we reviewed the relevant protocols and trial registrations of ongoing studies for key elements. We then determined the feasibility of completing a quantitative synthesis (*ie*, meta-analysis) to estimate summary effects. For meta-analyses, feasibility depended on the volume of relevant literature, conceptual study homogeneity, and completeness of results reporting.

We aggregated outcomes when there were at least 3 studies with the same outcome, based on the rationale that 1 or 2 studies do not provide adequate evidence for summary effects. We grouped outcomes into conceptually similar interventions (*eg*, temperature-sensing devices, pressure-sensing insoles).

When quantitative synthesis was possible, dichotomous outcomes were combined using rate difference and random-effects models as appropriate. Due to the small number of included studies ($k < 20$), we used the Knapp-Hartung approach to adjust the standard errors of the estimated coefficients. We evaluated statistical heterogeneity using visual inspection and use of 95% prediction intervals (PI).

When quantitative synthesis was not feasible, we analyzed the data narratively. We emphasized the evidence from higher quality studies with more precise estimates of effect. Our narrative synthesis focused on documenting and identifying patterns in intervention efficacy and safety across conditions and outcome categories. We analyzed potential reasons for inconsistency in treatment effects across studies by evaluating differences in the study population, intervention, comparator, and outcome definitions.

When meta-analyses were feasible, we considered subgroup analysis to explore quantitative or qualitative interactions of pre-specified potential effect modifiers such as monitoring device type, monitoring frequency, or methods of providing feedback (see KQ1c). Regarding patient-level characteristics of interest (*ie*, ulcer type, patient demographics, comorbidities, rurality, or activity level), we identified analyses conducted within the primary literature that sought to identify effect modification (*eg*, subgroup analyses, regression model explanatory variables). When we were unable to conduct meaningful quantitative analysis of effect modification across characteristics of interest, we narratively considered the representation of subgroups within identified studies in comparison to the VA population. We also considered subgroup analyses for similar device types (*eg*, hand-held thermometry devices).

Of note, we report the brand name of evaluated devices when describing individually, but when summarizing across studies we describe the physiological parameter measured and physical type of device.

Strength of Evidence

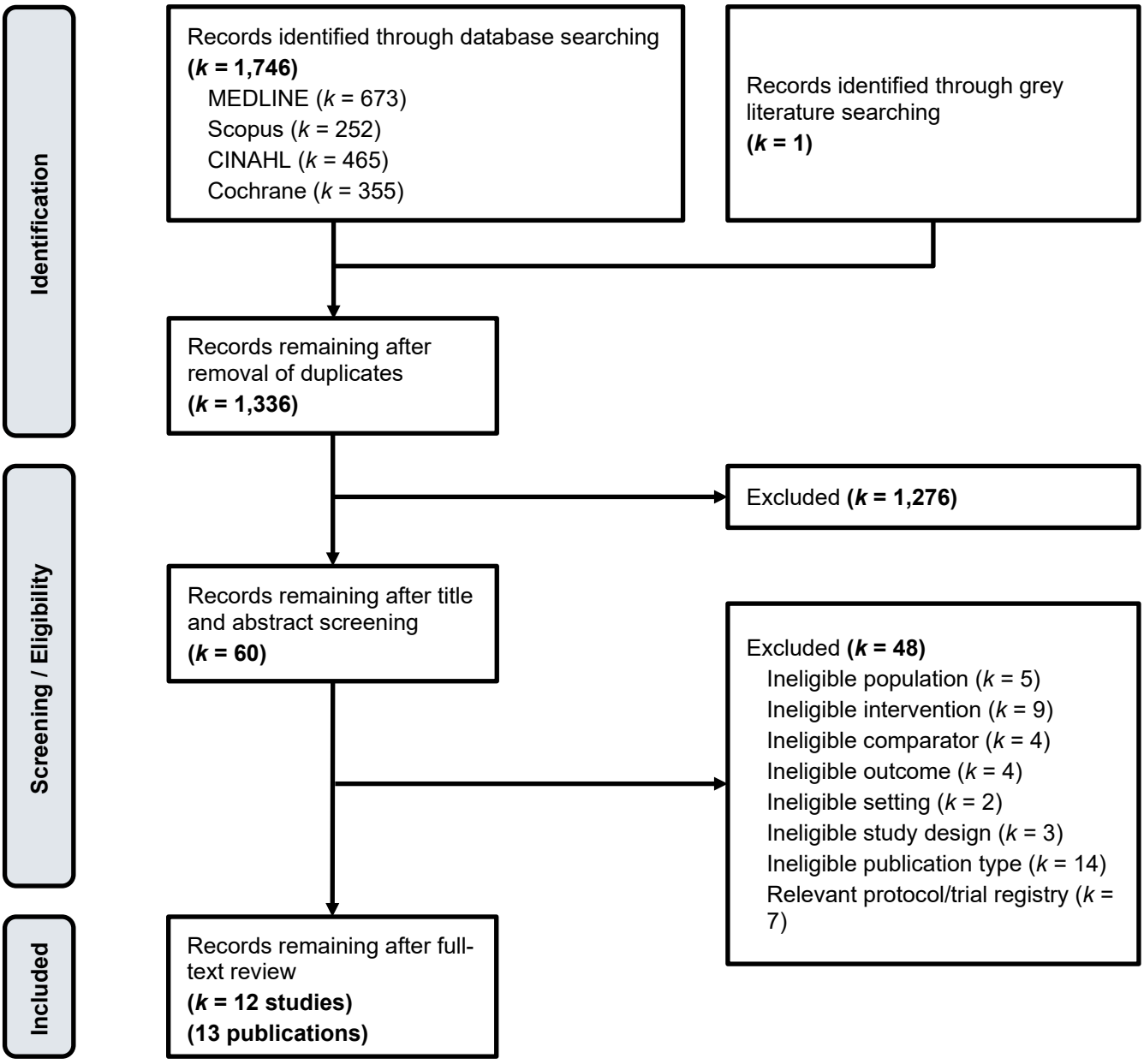
The strength of evidence was assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. We limited GRADE ratings to outcomes identified

through discussion with the stakeholder and TEP as critical to decision-making: LEA, hospitalization, mortality, ulcer incidence or recurrence. Briefly, GRADE requires assessment of 4 domains: ROB (*eg*, ROB ratings of individual studies taken holistically), consistency (*eg*, extent to which studies found similar directions of effect), directness (*eg*, extent to which included literature reflects the desired population, intervention, comparator, and outcomes of interest), and precision (*eg*, how narrow or exact the 95% CIs for the effect estimate[s]). Additional domains to be used when appropriate are coherence, dose-response association, impact of plausible residual confounders, strength of association (magnitude of effect), and publication bias. We considered each domain qualitatively and assigned a summary rating after discussion by 4 investigators (KMG, KRB, AMG, RC) as high, moderate, low, or very low strength of evidence. In some cases, high, moderate, or low ratings were impossible or imprudent to make. In these situations, a grade of insufficient was assigned.

RESULTS

LITERATURE FLOW DIAGRAM

The literature flow diagram summarizes the results of the study selection process. A full list of excluded studies is provided in the Supplementary Materials.



OVERVIEW OF INCLUDED STUDIES

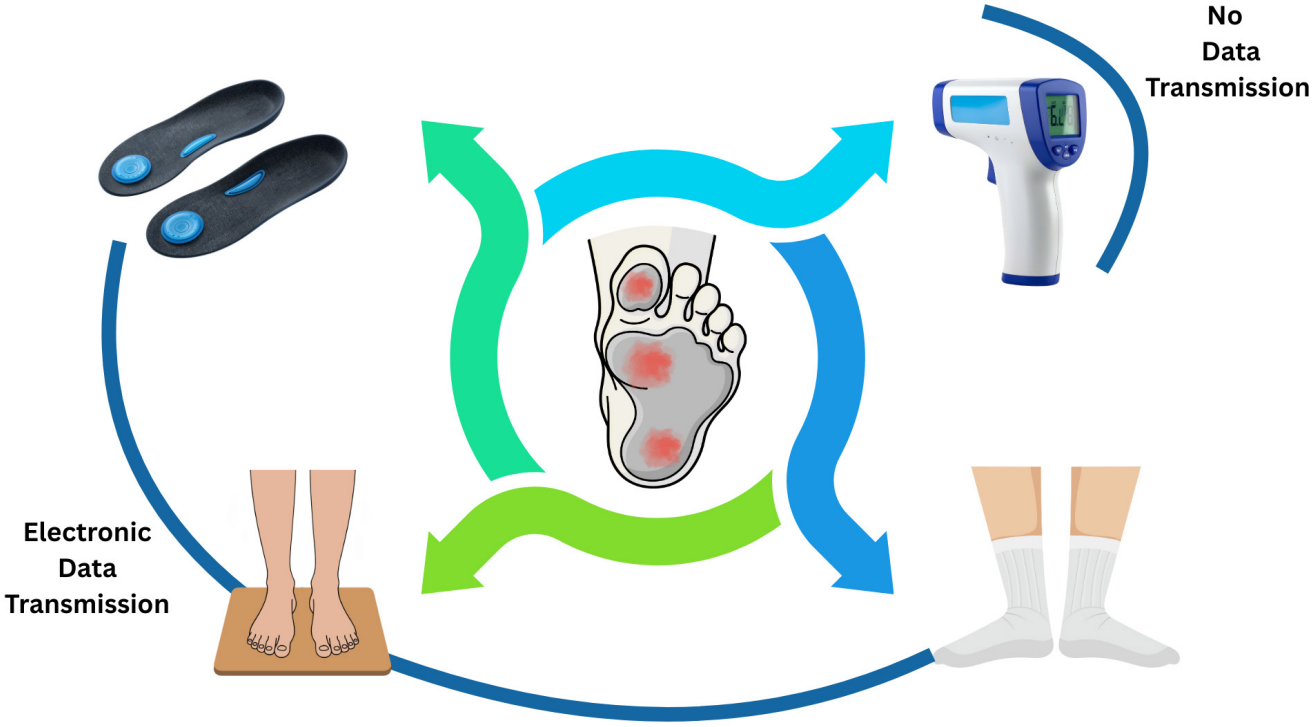
Our search identified 43 potentially relevant articles after deduplication and title and abstract screening. Of these, 12 primary studies (in 13 publications) were eligible and consisted of 9 RCTs, 1 interrupted time series, 1 controlled before-and-after study, and 1 comparative cohort study (Table 1). The included studies evaluated 7 different manufactured products: SurroSens by Orphyx, TempTouch thermometers, Podimetrics SmartMat, TempStat foot thermometry pad, Thorsis Technologies sensor-equipped insoles, Siren Socks, and commercially available infrared thermometers (Figure 1). TempTouch thermometer, a hand-held temperature measuring device, was the most evaluated product. Hand-held thermometers did not incorporate remote transmission of monitoring data either directly to a clinical provider or to a monitoring device company. All other devices incorporated remote data transmission except for 1.[15] Four studies reported variations in the effect of digital foot self-monitoring by adherence, patient demographics, or physical activity (KQ1b). None of the included studies reported variation by device type, monitoring frequency, or method of feedback (KQ1c). Across KQ1a, KQ1b, and KQ1c, studies were conducted in the US, the UK, the Netherlands, Canada, Norway, Germany, and Peru. We identified 2 studies (1 RCT and 1 comparative cohort) that were conducted by VA with Veteran patients. Detailed characteristics of included studies are shown in the Supplementary Materials. We identified 7 relevant protocols including 4 studies currently underway.

Table 1. Evidence Profile of Included Studies

Study Characteristic	Category (Number of Relevant Studies)
Number of studies	12 (13 publications)
Study designs	RCT (*k* = 9), interrupted time series (*k* = 1), controlled before-and-after (*k* = 1), comparative cohort (*k* = 1)
Publication year range	2004–2024
Total N by design	RCT (*N* = 1,403), interrupted time series (*N* = 77), controlled before-and-after (*N* = 122), comparative cohort (*N* = 3,681)
Countries	US (*k* = 6), UK (*k* = 1), Netherlands (*k* = 1), Peru (*k* = 1), Germany (*k* = 1), Norway (*k* = 1), Canada (*k* = 1)
Devices without transmission of data	Hand-held thermometers (*k* = 6), temperature measuring mat (*k* = 1)
Devices with transmission of data	Temperature measuring mats (*k* = 2), temperature measuring insoles (*k* = 1), temperature measuring socks (*k* = 1), pressure insoles (*k* = 1)
Outcomes assessed	Ulceration (*k* = 11), LEA (*k* = 4), utilization (*k* = 4), mortality (*k* = 3), adherence (*k* = 7), alarm frequency (*k* = 2), adverse events (*k* = 4), QoL (*k* = 3)
Participant condition, *N* (%)	
Diabetes	4,007 (75.8)
Prior foot ulcer	3,778 (71.5)
Stage 4 or 5 kidney disease	1,474 (27.9)
LEA	1,256 (23.8)
Peripheral neuropathy	752 (14.2)
Peripheral arterial disease	322 (6.1)

Abbreviations. LEA=lower extremity amputation; QoL=quality of life.

Figure 1. Remote Patient Pedal Monitoring Devices for the Prevention of Foot Ulcers



KQ1A: WHAT IS THE EFFICACY AND SAFETY OF REMOTE PATIENT PEDAL MONITORING DEVICES?

Ulceration

Summary of Findings

We identified 10 studies,[13-22] including 8 RCTs, that measured at least daily pedal temperature monitoring using digital devices.[13-15,17,18,20-22] Among the 6 RCTs (N = 832) examining hand-held thermometer devices without remote data transmission, there was a small beneficial effect on ulcer occurrence with a rate difference of -0.09 (95% CI [-0.18, -0.01]; see Figure 2);[13,17,18,20-22] this rate difference was equivalent to a risk ratio of 0.54 (95% CI [0.30, 0.97]). To contextualize this finding, we found that 11 patients would need to use a hand-held thermometer at least daily to prevent 1 ulcer (number need to treat [NNT] = 10.61). This finding was associated with moderate heterogeneity, indicated by a rate difference 95% PI of -0.28 to 0.09, which indicates that future similar studies could include a null effect.

Two RCTs evaluated other methods of temperature monitoring (N = 428; see Figure 2*)*. One trial compared a temperature-sensing mat with and without receipt of adherence reminders and found a small reduction in ulcers for patients who did not receive reminders. The other trial compared temperature-sensing insoles to standard of care and found no statistically significant benefit. Only 1 small trial[23] (N = 58) with high ROB evaluated plantar pressure monitoring and found conflicting results depending on analytical approach.

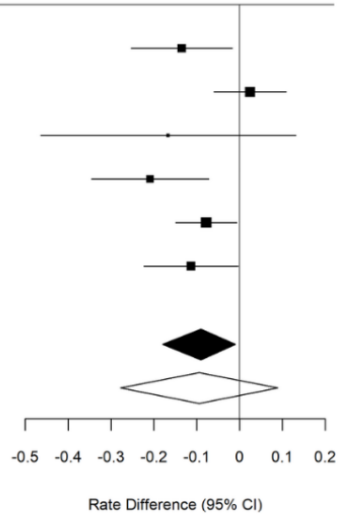
Included studies used variable definitions of being at risk for ulcers and duration of follow-up. Overall, these studies were small, with a median size of 115 participants (range = 41–304). There were 2 low ROB studies,[14,18] 5 some concerns,[13,15,20-22] 1 moderate ROB,[19] 2 high ROB,[17,23] and 1 serious ROB study.[16] Common causes of ROB across these studies included concerns about the randomization process, missing outcome data, selection of results, deviations from intended interventions, and confounding.

Figure 2. Meta-Analysis of Foot Temperature Monitoring and Ulceration

Handheld Thermometers:

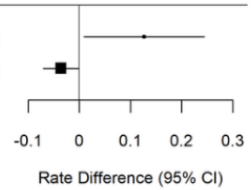
Author (Year)	Intervention Description	Intervention Ulcers	Intervention Total	Comparison Description	Comparison Ulcers	Comparison Total	Assessment Point	IV, Random, 95% CI
Lavery (2004)	Handheld TempTouch™	1	41	Standard of care	7	44	6 months	-0.13 [-0.25, -0.02]
Stevens (2023)	Handheld thermometer	1	34	Standard of care	0	26	6 months	0.02 [-0.06, 0.11]
Skafjeld (2015)	TempTouch™ + counselling	7	21	Standard of care	10	20	12 months	-0.17 [-0.46, 0.13]
Lavery (2007)	Handheld TempTouch™	5	59	Standard of care	17	58	15 months	-0.21 [-0.35, -0.07]
Armstrong (2007)	Handheld TempTouch™	5	111	Standard of care	14	114	18 months	-0.08 [-0.15, -0.01]
Bus (2021)	Handheld TempTouch™	54	151	Standard of care	72	153	18 months	-0.11 [-0.22, -0.00]
Total (95% CI)								**-0.09 [-0.18, -0.01]**
95% Prediction Interval								**[-0.28, 0.09]**

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 10.77$, df = 5 (P = 0.06); $I^2 = 0\%$



Non-Handheld Thermometers:

Author (Year)	Intervention Description	Intervention Ulcers	Intervention Total	Comparison Description	Comparison Ulcers	Comparison Total	Assessment Point	IV, Random, 95% CI
Lazo-Porras (2020)	TempStat™ mat + reminders	19	79	TempStat™ mat only	9	79	18 months	0.13 [0.01, 0.24]
Ming (2024)	Temperature insole	0	133	Standard of care	5	137	24 months	-0.04 [-0.07, -0.00]



Detailed Findings

Eleven studies reported the occurrence of foot ulcers in patients using a remote patient pedal monitoring device, including 9 RCTs,[13-15,17,18,20-23] 1 controlled before-and-after,[16] and 1 interrupted time series.[19] One study[23] measured pressure using a pressure insole, while the remaining 10 measured temperature using either a hand-held thermometer ($k = 6$),[13,17,18,20-22] socks ($k = 1$),[16] insoles ($k = 1$),[14] or a mat ($k = 2$).[15,19] Study timeframes ranged from 6 months to 24 months. Six studies[15,17-21] used daily temperature measurements, 3 studies[13,14,22] used twice daily temperature measurements, and 2 studies used either continuous pressure[23] or temperature monitoring.[16] The inclusion criteria for all 11 studies included individuals at high risk for foot ulcer development, with variable definitions. Studies either included patients consistent with International Working Group on the Diabetic Foot (IWGDF) category 3 (*ie*, neuropathy and history of ulcer and/or LEA) ($k = 5$),[18-21,23] categories 2 (*ie*, neuropathy and deformity) or 3 ($k = 5$),[13-15,17,22] or based on provider discretion of medical necessity ($k = 1$).[16] Identification of ulcer development was based on different definitions (*eg*, foot ulcer, International Classification of Diseases [ICD] codes, Wagner Grading Scale), with 6 studies[13,15-17,19,22] reporting ulcer incidence, 4 studies[18,20,21,23] reporting ulcer recurrence, and 4 studies[13,14,20,21] evaluating time to ulcer development. Seven of the trials[13,14,17,18,20-22] had a comparator group of "standard/usual care," although this definition varied, with the most common elements including education, daily foot inspections, therapeutic footwear, use of a daily logbook, and structured foot examinations with a medical provider during the study. Two remaining studies[15,23] had comparator groups that used the device (insole or hand-held thermometer) without associated reminders or alerts. The final 2 studies[16,19] compared a device intervention group with pre-implementation data.

Results of trials evaluating ulcer occurrence are described above in Summary of Findings. In addition, 2 observational studies that examined the effect of remote temperature monitoring and 1 RCT that evaluated the effect of pressure monitoring were not included above.[16,19,23] One before-and-after study[16] ($N = 115$) with serious ROB concerns used post-market registry data to evaluate continuous temperature monitoring through smart sock use and reported a 68% relative risk reduction (RRR = 0.68, 95% CI [0.52, 0.79]). A small interrupted time series study[19] ($N = 77$) with moderate ROB used medical claims and electronic health record data and a found substantial reductions in both overall ulcer rates (adjusted RRR [aRRR] = 0.46, 95% CI [0.21, 0.66]) and severe ulcers (aRRR = 0.91, 95% CI [0.56, 0.99]) with temperature-monitoring smart mats. The single small trial[23] with high ROB that evaluated continuous plantar pressure monitoring demonstrated no significant difference in time to ulceration (hazard ratio [HR] = 0.51, 95% CI [0.15, 1.83]), but a 71% reduction in ulceration risk using count-based analysis (incidence rate ratio [IRR] = 0.29, 95% CI [0.09, 0.93]). This study had notably high attrition, with only 23 of 58 participants completing 18 months of follow-up.

Lower Extremity Amputation

Summary of Findings

Four studies[16,19,22,24] evaluated the effect of digital temperature self-monitoring devices on LEA during 6 months to 3 years of follow-up with mixed results, including no effect in a large VA-based cohort. One RCT[22] ($N = 85$) with some ROB used a hand-held thermometry device for twice-daily temperature measurements without remote transmission of monitoring data, while 3 studies used remote monitoring devices. Specifically, 2 studies[19,24] used SmartMat for once-daily temperature monitoring, and 1 study[16] investigated continuous remote temperature-monitoring socks. Of these 3, 1 study using a before-and-after study design and 1 with a matched retrospective longitudinal cohort

design were rated as serious ROB,[16,24] and 1 study[19] ($N = 77$) employing interrupted time series was rated as moderate ROB.

Detailed Findings

The only RCT[22] to report LEA found no LEAs in the hand-held thermometry group ($N = 41$) and 2 in the comparison group ($N = 44$). No comparative analysis was reported, and LEA level was not defined.

Only the VA cohort study[24] ($N = 3,681$) enrolled in a continuous remote temperature-monitoring program using SmartMat ($N = 924$) matched to non-enrolled patients ($N = 2,757$) clearly defined LEA as a primary outcome and identified LEAs at any level. This study concluded that use of the SmartMat was not associated with LEA incidence (aHR = 0.92, 95% CI [0.62, 1.37]), a finding supported by sensitivity analyses conducted among adherent patients.[24] The other 2 observational studies observed a significant reduction in LEAs; specifically the before-and-after study[16] of temperature-measuring socks at serious ROB (RRR = 0.83, 95% CI [0.39, 0.95]; NNT = 41.7) and the interrupted time series study[19] of the SmartMat at moderate ROB (RRR = 0.71, 95% CI [0.22, 0.9]; NNT = 6.4). Neither provided clear definitions of LEA level. Studies reporting LEAs were noted to have heterogeneity in baseline patient characteristics (*eg,* prevalence of diabetes, pre-existing LEA, prior ulcers).

Utilization

Summary of Findings

Four studies[16,18,19,24] ($N = 4,178$) evaluated the relationship between digital temperature self-monitoring devices and rates of hospitalization or emergency department visits and found mixed results, including no effect in the 1 RCT[18] which evaluated a hand-held thermometer. Two studies[19,24] evaluated the SmartMat and 1 study[16] evaluated the Siren Socks. Non-RCT study designs included interrupted time series,[19] controlled before-and-after,[16] and comparative cohort analyses.[24] No studies evaluated the effect of pressure-monitoring devices on utilization.

Detailed Findings

The 1 RCT[18] ($N = 304$) was a low ROB multicenter trial (DIATEMP) which evaluated whether at-home foot temperature monitoring using a hand-held-thermometer could reduce acute care utilization among participants with diabetes, neuropathy, and a history of foot ulceration, across 7 hospitals and 4 podiatry practices. Hospitalizations decreased in the intervention group by 24.5% versus 18.3% in usual care, although this was not statistically significant ($p = 0.187$).

In the VA retrospective cohort study[24] ($N = 924$), the incidence rate of all-cause hospitalization was similar between the mat-based temperature-monitoring intervention and matched control groups (35.6 vs 34.1 per 100 person-years), with no significant association between monitoring enrollment and hospitalization risk (aHR = 0.97, 95% CI [0.82, 1.14]). Although emergency department or urgent-care visits were measured 2 years prior to baseline and included as covariates (73.8% in monitored patients vs 69.0% in controls), emergency department utilization was not analyzed as an independent outcome.

An interrupted time series study[19] with moderate ROB evaluated a 1-year diabetic foot ulcer prevention program that provided once-daily SmartMat temperature monitoring to 77 patients with recently healed ulcers. Compared with the 2 years before enrollment, hospitalization rates declined by roughly 50% (0.28 vs 0.58 per patient-year), corresponding to a 52% relative risk reduction (RRR =

0.52; NNT = 3.4; $p < 0.002$). Emergency department visits similarly decreased by 40% (0.23 vs 0.46 per patient-year; NNT = 5.1), while outpatient visits declined by 26% (aRR = 3.5 per patient-year). Of note, patients were excluded for conditions which "rendered the patient unsuitable or unreliable," though it is not reported how many were excluded for this reason.

Finally, a multicenter retrospective before-and-after registry-based analysis[16] ($N = 115$) with serious ROB, which included high-risk diabetic patients across 15 podiatry practices, evaluated a continuous remote temperature-monitoring program using sensor-embedded socks and active nursing surveillance. Compared with the pre-enrollment period, hospitalization rates fell from 0.28 to 0.10 per patient-year, representing a 63% relative risk reduction (RRR = 0.628, 95% CI [0.33, 0.80]; NNT = 5.7; $p < 0.002$), with an absolute risk reduction of 0.18. Outpatient podiatry visits also reduced by 69% (RRR = 0.31, 95% CI [0.24, 0.37]; NNT = 0.46; $p < 0.001$) relative to the pre-enrollment period.[16]

Mortality

Summary of Findings

Two trials[18,21] found no effect of hand-held thermometer use on mortality and 1 cohort study found a reduced mortality rate with temperature-monitoring mat use.[18,21,24]

Detailed Findings

Both RCTs[18,21] evaluated the TempTouch hand-held digital infrared thermometer compared to standard of care and followed patients for 15–18 months. One RCT[18] ($N = 305$) with low ROB reported 8 deaths: 5 (3.3%) in hand-held temperature-monitoring arm and 3 (2%) in control arms ($p = 0.46$). The other RCT[21] with some concerns for ROB reported 2 (3.4%) deaths in the standard therapy group and 1 (1.7%) death in the intervention arm. The VA-based cohort study[24] defined mortality as having a recorded date of death and examined it as a secondary outcome among 924 patients who were issued a temperature-monitoring mat.[24] This study reported mortality rates reduced in the remote monitoring group (89/924, 9.6%) compared to the matched control group (378/2,757, 13.7%) (aHR = 0.63, 95% CI [0.49, 0.82]). The per-protocol sensitivity analysis revealed a reduced HR for mortality in compliant time-at-risk (HR = 0.29, 95% CI [0.18, 0.47]) but not in non-compliant time-at-risk (HR = 1.05, 95% CI [0.75, 1.42]).

Adherence

Summary of Findings

Overall, rates of adherence to remote patient pedal monitoring devices ranged from 50% to 91.5% across 7 studies (6 RCTs[14,15,17,20,23,25] and 1 interrupted time series[19]), though definitions of adherence varied (*eg*, categorically by the number of hours, total wear time, mean days with self-assessment recorded). In addition, the majority measured adherence via participant self-report, while only 3 studies[14,19,23] measured adherence objectively via monitoring device. Three studies included feedback to participants about adherence to monitoring devices via general cues to use the device,[15] nurse calls reminding them to use the device when non-adherence was detected,[19] or discussion of adherence at monthly study visits.[23] The 2 studies[15,23] in which both study arms used remote patient pedal monitoring devices found the addition of automated reminders did not increase adherence,[15] with 1 study[23] reporting greater use of the monitoring device among participants who did not receive feedback regarding when to offload, based on abnormal pressure distribution. Three studies[17,20,25] reported adherence to daily use of hand-held temperature monitors.

Detailed Findings

Two studies[15,19] evaluated adherence to daily use of temperature-monitoring mats. One trial[15] (*N* = 172) with some concerns for ROB compared the use of remote temperature monitoring alone to monitoring plus regular mHealth messages. Daily messages reminding participants to use the device were first sent for 2 weeks via SMS or voice messaging, then twice weekly, and alternated between reminders and foot care messages. At 18 months, the added reminders showed no effect on adherence, defined as ≥ 80% of daily temperatures self-reported in a logbook (adjusted odds ratio [OR] = 0.43, 95% CI [0.13, 1.40]), though the CI included both clinically meaningful increases and decreases in adherence. Of note, crude rates of meeting this adherence threshold were 91.5% in the monitoring-only arm versus 83.1% in the monitoring plus reminders arm (OR = 0.45, 95% CI [0.15, 1.42]), but only 69% of randomized participants returned a logbook from which to evaluate adherence. The second study[19] was an interrupted time series with moderate ROB using real-world data from 4 large integrated health care system ulcer recurrence prevention programs (*N* = 77). This study found patients used a temperature-monitoring mat a mean of 4.1 (SD = 1.6) times per week, using objective measures translating to 61% of participants (47/77) using the mat at least 3 days per week. Non-adherence for 4 or more consecutive days led to a nurse call to prompt re-engagement, which occurred 5.1 (SD = 4.6) days per participant-year; 75.3% of participants required more than 1 re-engagement call.

Three studies[17,20,25] reported adherence to daily use of hand-held temperature monitors. One trial[20] (*N* = 41) with low ROB found a similar percentage of self-reported daily foot observations in those monitoring via visual inspection only (14/20; 70%) versus visual and temperature inspection (14/21, 67%). No association was found between adherence to self-monitoring and ulcer occurrence. The second trial[17] (*N* = 62) with high ROB found that while more patients in the hand-held thermometer group self-reported any foot assessment compared to the education-only arm (150.98 days vs 119.84 days, $p = 0.02$), there was no significant difference in proportion of participants completing ≥ 80% days of logbook documentation of self-monitoring (75% vs 50%, $p = 0.061$). When controlling for years since diagnosis of diabetes, the temperature-monitoring arm had higher odds of completing foot assessment for ≥ 80% days of logbook documentation than the education-only arm (OR = 3.54, 95% CI [1.11, 11.29]). The DIATEMP study[25] (*N* = 305) with low ROB reported adherence to entering both the recorded temperature values in the logbook and offloading after identification of a hot spot.[25] This study defined adherence as ≥ 70% days of recording temperature. Of the 151 patients in the hand-held thermometer arm, 94 met the adherence threshold (62.3%), although the study reports that adherence rates were significantly different ($p < 0.001$) over the first 3 months (78.1%) compared to months 4 through 18 (57.4%). Adherence to offloading, defined as a 50% reduction in activity per day until hot spot resolution, was reported in 24 of 83 participants (28.9%).

Finally, 2 studies[14,23] examined adherence to insole-based devices. One trial[14] (*N* = 283) with low ROB reported that 70% of potential observation days had an objectively measured temperature recorded among 133 participants randomized to temperature monitoring twice daily. A second trial[23] (*N* = 90) with high ROB reported objectively measured adherence to use of pressure-sensing insoles in the intervention arm that received feedback from insoles via automated smart watch messages and the control arm which did not receive feedback.[23] Participants in the control arm wore the insoles for longer than the intervention arm (median 763.4 hours, IQR [188.4, 1461] vs median 539.0 hours; IQR [190.0, 1488.5]).

Alarm Frequency

Summary of Findings

Two trials[14,15] reported frequency of alarms during use of monitoring devices.

Detailed Findings

An RCT[14] with low ROB comparing a temperature-sensing insole to daily self-inspections reported alarm frequency as a secondary outcome. Among those randomized to the insole arm, authors measured the frequency of a > 1.5 ºC asymmetry of a patient's feet for > 32 hours, which triggered an alarm received by the physician. A total of 75 verified alarms were reported among 133 patients over 24 months, where physicians instructed patients to offload for 5 days. Although the exact number was not reported, several alarms were also triggered due to missing or faulty sensors, incomplete contact between the foot and the sensor, and temperature decrease due to intermittent limb ischemia. A second trial[15] found that among the 118 participants (74%) who returned their logbook across both arms that received a temperature monitoring mat, 41% recorded an alarm sign.

Adverse Events

Summary of Findings

Four studies[14,19,21,23] reported adverse events in the context of use of remote patient pedal monitoring devices to prevent foot ulceration.[14,19,21,23] Only 1[19] of these 4 studies specified adverse events related to the direct use of a patient pedal monitoring device (temperature mat), of which none were observed or reported.

Detailed Findings

Of the 3 studies that did not specify a relationship between adverse effects and patient pedal monitoring devices, 1[14] reported no difference in adverse events generally and 1[21] showed no meaningful differences in reasons for withdrawal in the intervention versus control (*eg*, foot trauma in setting hand-held thermometer). The third study[23] evaluated insoles for pressure measuring and reported 29 adverse events among 26 control group participants versus 22 events among 32 intervention group participants (including pain in lower back, falls, toenail infection).

Quality of Life

Summary Findings

There was no clear benefit of patient pedal remote monitoring devices on quality of life (QoL) across 3 RCTs ($N = 430$).[14,17,22]

Detailed Findings

Two trials evaluating hand-held thermometers each noted no difference in QoL between arms but differed in how the outcomes were measured. The first study[22] ($N = 85$) utilized SF-36 scores to compare daily temperature monitoring plus an educational component to an education-only control arm over 6 months. No statistical differences were found in the SF-36 scores (total or subcategory scores) either between groups (unpaired t test) or, in the pre- and post-study evaluations, within groups (paired t test). The second trial[17] ($N = 62$) with high ROB used a QoL Enjoyment and Satisfaction Short Form to compare the twice-daily use of a hand-held thermometer alongside an educational

intervention to the education-only control arm over 6 months. No difference was reported between or within the 2 study groups across time points (*ie*, baseline, 3, and 6 months), though corresponding data were not included in this publication.

A third study[14] tested a temperature-sensing insole paired with a mobile application and listed QoL as a planned outcome but did not present data accessible with the publication, nor were we able to obtain data by request. This low ROB trial ($N = 283$) measured QoL with the World Health Organization-5 Well-Being Index. While both the intervention and control group saw improvements in QoL, the intervention group demonstrated higher QoL after 24 months. We could not access the supplemental information which may have reported the exact proportion of patients in the intervention group that had an increased QoL and any tests for significant differences.

Certainty of Evidence

We conducted certainty of evidence (COE) ratings for the KQ1a outcomes prioritized by the operational partners (Table 2). Overall, our COE for prioritized outcomes across the included studies was very low. Six of the included RCTs reported ulcer incidence or recurrence among patients using hand-held thermometers. Certainty in the reduction of ulcers as demonstrated by these 6 RCTs is limited by serious imprecision, serious ROB, as well as indirectness. Two RCTs evaluated digital temperature devices and the incidence or recurrence of ulcers. The COE of these studies were very low due to serious inconsistency, serious imprecision, serious indirectness, and suspected publication bias. One other RCT evaluated a pressure-sensing device. Similarly, we found low COE that digital foot self-monitoring reduces ulceration across 2 observational studies, due to serious ROB and imprecision. As we only identified 1 RCT that reported LEAs, we graded this category as insufficient. We graded the 3 observational studies that reported LEAs; however, given the serious imprecision, serious inconsistency, and very serious ROB, we had very low COE that digital foot self-monitoring reduced LEAs. As we only identified 1 RCT that reported hospitalization, we also graded this category as insufficient. The 3 observational studies that reported hospitalization as an outcome were very seriously imprecise, seriously inconsistent, and had very serious ROB; thus we found low COE that digital self-monitoring reduced subsequent hospitalization. Two RCTs reported mortality rates across both hand-held thermometry and usual care arms. We determined that there was very low COE that digital self-monitoring reduced mortality given the serious imprecision, serious ROB, as well as indirectness due to the lack of non-hand-held thermometer studies and suspected publication bias. Only 1 observational study reported mortality outcomes and was graded as insufficient.

Table 2. Summary of Available Evidence

Outcome	Studies (Participants)	Summary of Findings	Consistency	Precision	Risk of Bias	Directness	Other Consider-ations	Certainty of Evidence
Ulcer incidence/ recurrence	6 RCTs[13,17,18,20-22] (832)	Hand-held thermometer: RD -0.09, 95% CI [-0.18, -0.01]	Not seriously inconsistent	Serious imprecision	Serious ROB	Seriously indirect for hand-held thermometry	None	Very low for reduction in ulceration
	2 RCTs[14,15] (439)	Digital temperature: RD 0.13 95% CI [0.01, 0.24] RD -0.04 95% CI [-0.07, -0.00]	Serious inconsistency	Serious imprecision	No serious ROB	Seriously indirect for comparator	Suspected publication bias	Very low for reduction in ulceration
	1 RCT[23] (58)	Pressure: HR 0.51, 95% CI [0.03, 1.83]						Insufficient
	2 Observational studies[16,19] (192)	RRR 0.46, 95% CI [0.21, 0.66] RRR 0.68, 95% CI [0.52, 0.79]	Consistent	Serious imprecision	Serious ROB	Not seriously indirect		Very low for reduction in ulceration
LEA	1 RCT[22] (85)	Hand-held thermometry arm: 0/41 Standard of care arm: 2/44						Insufficient
	3 Observational studies[16,19,24] (3,874)	RRR 0.71, 95% CI [0.22, 0.96] RRR 0.83, 95% CI [0.39, 0.95] aHR 0.92, 95% CI [0.62, 1.37]	Serious inconsistency	Very serious imprecision	Very serious ROB	Not seriously indirect		Very low for reduction in LEAs
Hospitalization	1 RCT[18] (304)	Hand-held thermometry arm: 37/151 Standard of care arm: 18/153 *p* = 0.187						Insufficient
	3 Observational studies[16,19,24] (3,874)	RRR = 0.52, 95% CI [0.14, 0.89] RRR = 0.63, 95% CI [0.33, 0.80] aHR = 0.97, 95% CI [0.82, 1.14]	Serious inconsistency	Very serious imprecision	Very serious ROB	Not seriously indirect		Very low for reduction in hospital utilization

Outcome	Studies (Participants)	Summary of Findings	Consistency	Precision	Risk of Bias	Directness	Other Consider-ations	Certainty of Evidence
Mortality	2 RCTs (477)[18,21]	Hand-held thermometry: 1/59 Standard of care: 2/58 Hand-held thermometry: 5/151 Standard of care: 3/153 *p* = 0.46	Consistent	Very serious imprecision	Serious ROB	Seriously indirect for hand-held thermometry only; suspected publication bias		Very low for reduction in mortality
	1 Observational study (3,683)[24]	aHR 0.63, 95% CI [0.49, 0.82]						Insufficient

Abbreviations. aHR=adjusted hazard ratio; HR=hazard ration; RD=rate difference; ROB=risk of bias; RRR=relative risk reduction.

KQ1B: DOES THE EFFICACY AND SAFETY VARY BASED ON PATIENT DEMOGRAPHICS, THE PRESENCE OF CHRONIC KIDNEY DISEASE, PATIENT DEVICE ADHERENCE, OR PHYSICAL ACTIVITY LEVEL?

Few studies examined differences in remote monitoring efficacy by patient-level characteristics.

Four studies[18,20,21,24] reported the impact of remote patient pedal monitoring device adherence on ulceration, LEA, and hospitalization and found no consistent effect benefiting those with greater adherence. Three studies[18,20,21] reported on the impact of adherence to hand-held thermometry on ulceration rates. One trial[18] ($N = 304$) with low ROB found that among the 93 intervention-arm participants who completed ≥ 70% of daily temperature monitoring with a hand-held thermometer, there was no difference in ulceration compared to usual care arm (RR = 0.91, 95% CI [0.65, 1.30]). One trial[21] ($N = 173$) with some concerns of ROB reported that the 59 patients using a hand-held foot thermometer who self-reported foot temperature ≥ 50% of the time were less likely to develop an ulcer at 15 months (OR = 50.0, $p < 0.001$), though the proportion of participants who met this criteria was not provided.

In a study[20] ($N = 21$) with some concerns for ROB, individuals with diabetic neuropathy and prior foot ulcer were randomized to monitor their feet daily with a hand-held thermometer. No difference was found in ulceration between those who used the thermometer ≥ 80% versus < 80% of the time.[20] Patients in the VA cohort study[24] who used temperature-sensing mats ($N = 924$) and identified as compliant (54% at least twice weekly) did not experience lower LEA rates nor significantly lower rates of hospitalization.

Only the VA cohort study[24] examined the effect of chronic kidney disease on key outcomes. This study found no statistically significant difference in LEA risk in sensitivity analyses excluding patients with chronic kidney disease.

No studies reported differences in efficacy or safety by baseline physical activity level.

KQ1C: DOES THE EFFICACY AND SAFETY VARY BASED ON THE TYPE OF MONITORING DEVICE, FREQUENCY OF MONITORING, OR METHODS OF MONITORING FEEDBACK TO PATIENTS?

We found no literature comparing the effect of different remote patient pedal devices directly, nor did we identify any studies evaluating different frequency of device use on key outcomes. As noted above, there was 1 study[15] that examined the effect of mHealth-based reminders in supplement to mat-based daily thermometry compared to mat use alone which found no difference in ulceration.

TRIAL REGISTRIES AND ONGOING STUDIES

This review identified 7 protocols[26-32] that matched our eligibility criteria without an available outcomes' publication (see Supplementary Materials). The most frequent primary outcome of the included protocols was the incidence or recurrence of ulceration ($k = 6$, 85%).[26,27,29-32] Adherence to wearing the prescribed footwear with a smart insole was also identified as a primary outcome in 1 study.[28] Secondary outcomes included adherence or engagement ($k = 2$),[27,32] QoL ($k = 2$),[29,30] utilization ($k = 2$),[29,32] foot temperature or pressure ($k = 2$),[30,31] patient satisfaction ($k = 1$),[27] cost effectiveness ($k = 1$),[27] adverse events ($k = 1$),[27] response rates to alerts ($k = 1$),[28] LEA ($k = 1$),[29]

satisfaction ($k = 1$),[29] foot or ankle symptoms or impairment ($k = 1$),[30] and reduction in ulcer severity ($k = 1$).[32] The interventions described in these protocols included measuring foot temperature ($N = 3$, 42%),[29,31,32] pressure ($N = 2$, 30%),[27,28] or temperature and pressure ($N = 2$, 30%).[26,30] The study site locations included North America ($N = 5$, 71%)[27-29,31,32] or Asia.[30] One protocol[26] did not report the site location.

The 6 protocols reviewed were RCTs.[26-29,31,32] One study[30] did not specify that they planned to use a random assignment method between arms. These protocols introduce alternative approaches to remote monitoring for the risk of recurrent ulcers in high-risk patients. Two protocols[28,30] presented mobile phone integration that supports temperature and pressure monitoring. For example, 1 protocol[30] proposed the application of an artificial intelligence-assisted infrared thermometer for plantar temperature monitoring, incorporating a pressure image recognition system through a mobile application. One protocol[26] described an insole that measures plantar pressure, temperature, motion, and adherence remotely. Other approaches to remote monitoring for occurrence of ulcers included using a step-on thermometer,[31] remote temperature monitoring using the Podimetrics "smart" mat[29] evaluated previously,[19,24] and the Bluedrop Monitoring system which uses the Delta foot scanner mat to monitor temperature.[32]

We found the status of 1 included protocol to be unknown[31] and another was terminated early due to low enrollment.[32] One protocol[27] was marked as complete, though we did not identify a subsequent publication of results. One protocol[29] is still recruiting with potential publication of results by 2031,[29] and 2 protocols have not yet started recruiting but anticipate publication by 2026[28] and 2028.[26] Of note, 1 of the ongoing trials is set in VA and aims to randomize at least 406 Veterans to the use of a temperature-sensing mat compared to usual care with a primary outcome of rate of foot ulceration.

DISCUSSION

We found that older hand-held temperature monitoring devices designed to identify early signs of foot ulcers show reduced ulcer incidence, though there is little trial-based data for newer temperature-sensing devices that incorporate remote transmission of data. Across 9 RCTs and 3 observational studies, the most studied remote patient pedal monitoring device was a hand-held temperature device designed for once or twice daily use at 6 points on each foot. Other less commonly studied devices were temperature-sensing mats designed for once-daily use, insoles designed for twice-daily use, and insoles or socks designed for continuously monitoring pressure or temperature. Length of follow-up, eligibility criteria, definition of being at risk for a foot ulcer, and outcome measures varied across studies. Additionally, remote patient pedal monitoring devices were typically compared to standard of care, which is likely more stringent than the usual care received in most settings.

Our work adds to prior systematic reviews of remote patient pedal monitoring devices. Specifically, we identified 3 prior systematic reviews on hand-held thermometer-based monitoring only, all of which reported a similar summary estimate for hand-held thermometer studies and ulceration (OR and RR = 0.51, 95% CI [0.31, 0.84]). Our subgroup analysis restricted to hand-held thermometer devices only had a similar finding (RR = 0.54, 95% CI [0.30, 0.97]; RD = - 0.09) (see Supplementary Materials for a comparison table)[5,33,34] Our review includes 5 studies[13,18,20-22] found in prior reviews and adds data from another RCT of 60 individuals, with 34 new participants using hand-held thermometers.[17] With the addition of this newer study, we found a persistent benefit equivalent to a NNT of 10.61. One prior systematic review[5] identified a pilot RCT evaluating pressure-sensing insoles[23] and a temperature mat with mobile health text reminders,[15] both of which we also included. Our review included 4 additional studies evaluating non-hand-held remote foot monitoring technologies, most of which were not RCTs (*eg*, interrupted time series, controlled before-and-after).[14,16,19,24] Among studies of newer remote monitoring devices, observational studies generally reported a beneficial effect on ulcer prevention that was not found in randomized trials. Forthcoming data from 4 ongoing trials studying newer, non-hand-held devices may shed light on the potential benefit of newer monitoring device strategies.[26,28-30] Particularly relevant to the VA is a trial that plans to evaluate the reduction of ulcerations among 406 Veterans at risk for foot ulcers, randomized to use a temperature-monitoring mat versus usual care.[29] This plan also includes evaluating facilitators and barriers to implementation within the VA, via qualitative interviews with Veterans and providers. Trial registration indicates that it will be completed in 2026 and published by 2031.

Like most medical interventions, remote patient pedal monitoring devices require significant patient-level adherence to both the device itself and any recommended actions to achieve full potential benefit. One intent of newer devices is to facilitate adherence through passive monitoring, the provision of continuous rather than point-in-time measurements, and remote monitoring data transmission to clinical providers. While adherence measurement approaches varied across the included studies, the overall estimates ranged from 50% to 91.5% within a trial setting. Real-world adherence in a VA observational cohort study[35] was 54%, and others have reported adherence to often be lower.[35] Importantly, regular monitoring at recommended frequencies may be burdensome to patients and may balance out benefits of device use.[36] We found little data demonstrating how to increase device adherence. Specifically, we identified only 1 trial that evaluated a method of boosting adherence through the addition of text message reminders to use a mat, which found no benefit.[15] If currently marketed devices are found to be effective under controlled trial conditions, it will be key to figure out how to boost adherence in typical care settings among patients who would benefit most. Evidence from

real-world settings, such as the VA, show that the initial uptake of remote patient pedal monitoring devices is not equitably distributed, with lower rates among Black Veterans, those with low income, and those living far from specialty care.[37]

CLINICAL AND POLICY CONTEXT

Remote monitoring technology for foot ulcer prevention has been identified and adopted as a key foot ulcer prevention technique by international clinical practice guidelines and large health care systems, including the Agency for Healthcare Research and Quality (AHRQ),[38] VA,[10] and the IWGDF.[2] VA in particular has a strong commitment to foot ulcer prevention. The national PAVE Program, originally called the Preservation-Amputation Care and Treatment Program, was established in 1993 and continues to provide a model of care to delay or prevent LEA. The program includes regular screening reminders in primary care, access to durable medical equipment such as diabetic shoes and insoles, and access to facility-level specialists including endocrinology, podiatry, and diabetes educators. Given the large number of Veterans at risk for foot ulcer development and subsequent LEA, there is great potential impact of an acceptable, effective remote monitoring program in VA. The impact may be particularly pertinent in certain Veteran populations including those residing in rural areas who may have reduced opportunities for in-person specialty care, or older adults with physical or visual limitation who may have difficulty performing daily foot inspections. Among rural patients, remote monitoring could bridge gaps in access to podiatry and wound care specialists, while potentially reducing travel burden and associated costs.

Existing interest in remote patient pedal monitoring devices is clear given the 207 VA sites with over 11,000 Veterans currently participating in a VA-based remote temperature-monitoring program.[39] As noted, the ongoing VA-based trial will also provide additional evidence on the potential effectiveness of the Podimetrics SmartMat for foot ulcer prevention in the VA setting.[29] The potential benefit of this non-invasive and low-risk intervention may justify its continued use in clinical practice, considering the current lack of evidence supporting newer, more expensive devices. In the meantime, VA providers should ensure that all high-risk patients are identified and receive standard of care for foot ulcer prevention, including performing regular manual self-monitoring.

LIMITATIONS

Our review should be considered in light of its limitations. First, we are limited by the available data in the published literature. Second, the included articles had notable variability across population demographics, monitoring device type, outcome definitions, and length of follow-up. In particular, only 8 studies evaluated adherence to a remote patient pedal monitoring device; approaches to evaluate adherence varied, including self-report via daily logbook entries and via direct data transmission from the device to the provider. Third, patient populations at risk for ulceration differed across studies with 7 enrolling patients with prior ulcers as well as peripheral neuropathy and 5 enrolling only those with prior ulcers. For example, across the 4 studies evaluating LEA, most participants had diabetes, but 2 of the 4 studies excluded participants with peripheral vascular disease[22,19] while the other 2 did not.[24,16] There were also differences between these 4 studies based on presence of pre-existing LEAs: The VA cohort study[24] excluded participants with bilateral LEAs and included those with minor and major LEAs, resulting in pre-existing LEAs in approximately 30% of the cohort. Lastly, 6 studies measured ulcer recurrence defined as ulcer recurrence anywhere on the foot after a prior ulcer, while a minority of studies defined recurrence only in the specific place on the foot where the first occurred.

FUTURE RESEARCH

Future research could address limitations of existing literature. For example, we do not know in which patient populations these devices may be most appropriate. Although all studies evaluated high-risk individuals for foot ulcer development, the definition of high risk varied across studies. Standardized definitions of at-risk populations would support future research to determine if specific populations may most benefit from remote monitoring (*eg*, comorbidities, disease severity, demographics). Furthermore, methodological and outcome measurement variation across studies made inferring the most beneficial practice difficult. Future research could address key gaps including optimal monitoring frequency, temperature thresholds for intervention, and comparative effectiveness between different device types. Future studies should also report on important secondary outcomes such as hospitalization and LEA rates.

The disconnect between guideline recommendations and available evidence presents challenges for health systems, including VA. Continued use of standardized protocols for device use and clinical response may be needed while more definitive evidence is generated.[10] Cost-effectiveness data comparing different monitoring approaches would also inform device selection, particularly when considering potential downstream benefits such as hospitalizations and LEAs. Finally, longitudinal studies of ≥ 12 months would be helpful for evaluating long-term adherence and efficacy. Recommendations for future research on remote patient pedal monitoring devices for foot ulcer prevention are provided in Table 3.

Table 3. Recommendations for Future Research Design Considerations

Domain	Study Design Targets for Future Research
Population	Clearly defined patient population to determine if there is a group of patients that these devices would be effective for, including: • Individuals with difficulty performing foot exams due to physical limitations • Individuals with higher risk due to multiple comorbidities (*eg*, more severe diabetes/neuropathy, history of previous foot ulcer, chronic kidney disease, *etc*) • Individuals who live alone vs those who live with family or a caregiver • Individuals with peripheral vascular disease (due to a potential inability to mount an inflammatory response recognizable by monitoring devices) • Sufficiently powered subgroup analysis by key patient populations including patient demographics/characteristics (*eg*, age, skin tone), end stage renal disease, vascular disease, and physical activity level
Intervention	Newer devices including pressure sensing and temperature sensing Adherence boosting components Maintenance Monitoring frequency (*eg,* is there a benefit from twice a day versus once a day) vs continuous monitoring
Comparator	Clearly defined standard of care
Outcomes	Consistent definition of LEA Adherence Time from alert to clinical action Qualitative data on experience of user including ease of use, device burden, alarm frequency, and impact of device Cost effectiveness

Domain	Study Design Targets for Future Research
Timing	Longitudinal studies (*ie*, at least 12 months) to determine long-term effects and adherence

Abbreviations. LEA=lower extremity amputation.

CONCLUSIONS

There is a lack of evidence for the benefit of newer remote monitoring devices on the prevention of foot ulcers among at-risk individuals, though older model hand-held thermometry devices show consistent relative reduction in ulcer incidence. The current evidence also does not demonstrate consistent reductions in LEA, hospitalization, or mortality. Ongoing trials may provide needed guidance on the clinical value of remote patient pedal monitoring technology to improve outcomes for Veterans.

REFERENCES

1. Armstrong DG, Tan TW, Boulton AJM, et al. Diabetic Foot Ulcers: A Review. *JAMA*. 2023;330(1):62-75.
2. Bus SA, Sacco ICN, Monteiro-Soares M, et al. Guidelines on the prevention of foot ulcers in persons with diabetes (IWGDF 2023 update). *Diabetes Metab Res Rev*. 2024;40(3):e3651.
3. Armstrong DG, Boulton AJM, Bus SA. Diabetic Foot Ulcers and Their Recurrence. *N Engl J Med*. 2017;376(24):2367-2375.
4. Writing Committee M, Gornik HL, Aronow HD, et al. 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS Guideline for the Management of Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2024;83(24):2497-2604.
5. van Netten JJ, Raspovic A, Lavery LA, et al. Prevention of foot ulcers in persons with diabetes at risk of ulceration: A systematic review and meta-analysis. *Diabetes Metab Res Rev*. 2024;40(3):e3652.
6. Jones PJ, Lavery L, Davies MJ, et al. Hotspots: Adherence in home foot temperature monitoring interventions for at-risk feet with diabetes-A narrative review. *Diabet Med*. 2023;40(10):e15189.
7. Srass H, Ead JK, Armstrong DG. Adherence and the Diabetic Foot: High Tech Meets High Touch? *Sensors (Basel)*. 2023;23(15).
8. Liu Y, Sayam S, Shao X, et al. Prevalence of and Trends in Diabetes Among Veterans, United States, 2005-2014. *Prev Chronic Dis*. 2017;14:E135.
9. Franklin H, Rajan M, Tseng CL, et al. Cost of lower-limb amputation in U.S. veterans with diabetes using health services data in fiscal years 2004 and 2010. *J Rehabil Res Dev*. 2014;51(8):1325-30.
10. Rothenberg GM, Page J, Stuck R, et al. Remote Temperature Monitoring of the Diabetic Foot: From Research to Practice. *Fed Pract*. 2020;37(3):114-124.
11. US Department of Veterans Affairs O. Healthcare inspection: Foot care for patients with diabetes and additional risk factors for amputation. Veterans Affairs Office of Inspector General (OIG); 2013.
12. McGowan J, Sampson M, Salzwedel DM, et al. PRESS Peer Review of Electronic Search Strategies: 2015 Guideline Statement. *Journal of Clinical Epidemiology*. 2016;75:40-46.
13. Armstrong DG, Holtz-Neiderer K, Wendel C, et al. Skin temperature monitoring reduces the risk for diabetic foot ulceration in high-risk patients. *The American journal of medicine*. 2007;120(12):1042-6.
14. Ming A, Alhajjar A, Walter I, et al. Telemedical Monitoring of Plantar Temperature in Diabetic Patients at Risk of Foot Ulcers. *Deutsches Arzteblatt international*. 2024;121(1):9-16.
15. Lazo-Porras M, Bernabe-Ortiz A, Taype-Rondan A, et al. Foot thermometry with mHeath-based supplementation to prevent diabetic foot ulcers: A randomized controlled trial. *Wellcome Open Res*. 2020;5:23.
16. Shih C-D, Scholten HJ, Ripp G, et al. Effectiveness of a Continuous Remote Temperature Monitoring Program to Reduce Foot Ulcers and Amputations: Multicenter Postmarket Registry Study. *JMIR diabetes*. 2024;9(101719410):e46096.
17. Stevens K, Moralejo D, Ersser S, et al. Effectiveness of a foot self-management intervention that utilized commercially available infrared thermometers: Mixed methods research incorporating a pilot RCT. *Journal of tissue viability*. 2023;32(1):33-38.

18. Bus SA, Aan de Stegge WB, van Baal JG, et al. Effectiveness of at-home skin temperature monitoring in reducing the incidence of foot ulcer recurrence in people with diabetes: a multicenter randomized controlled trial (DIATEMP). *BMJ open diabetes research & care*. 2021;9(1).
19. Isaac AL, Swartz TD, Miller ML, 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 & care*. 2020;8(1).
20. Skafjeld A, Iversen MM, Holme I, et al. A pilot study testing the feasibility of skin temperature monitoring to reduce recurrent foot ulcers in patients with diabetes--a randomized controlled trial. *BMC endocrine disorders*. 2015;15(101088676):55.
21. Lavery LA, Higgins KR, Lanctot DR, et al. Preventing diabetic foot ulcer recurrence in high-risk patients: use of temperature monitoring as a self-assessment tool. *Diabetes care*. 2007;30(1):14-20.
22. Lavery LA, Higgins KR, Lanctot DR, et al. Home monitoring of foot skin temperatures to prevent ulceration. *Diabetes care*. 2004;27(11):2642-7.
23. Abbott CA, Chatwin KE, Foden P, et al. Innovative intelligent insole system reduces diabetic foot ulcer recurrence at plantar sites: a prospective, randomised, proof-of-concept study. *The Lancet. Digital health*. 2019;1(6):e308-e318.
24. Littman AJ, Timmons AK, Korpak A, et al. Evaluation of the Effectiveness of Remote Foot Temperature Monitoring for Prevention of Amputation in a Large Integrated Health Care System. *Diabetes care*. 2023;46(8):1464-1468.
25. Rovers FJ, Van Netten JJ, Busch-Westbroek TE, et al. Adherence to at-Home Monitoring of Foot Temperatures in People with Diabetes at High Risk of Ulceration. *The international journal of lower extremity wounds*. 2022(101128359):15347346221114565.
26. Bray E. WIREDUP: wearable Insoles for Recurrent Diabetic Ulcer Prevention. 2023.
27. Nct. Diabetes Foot Care Clinical Pathway - Orpyx Medical Technologies. 2016.
28. Mbue NN, Bijan Benefits of Insoles With Real-Time Alert and Foot Self-Care Education. 2021.
29. Littman AJ. Effectiveness of Remote Foot Temperature Monitoring. 2023.
30. Shi H. A study for the prevention of diabetic foot ulcers. 2024.
31. Higgins KR. Novel Home Care Device for High-Risk Diabetic Patients. 2007.
32. Green J. Remote Monitoring of the Diabetic Foot to Prevent Re-Ulceration. 2023.
33. Alahakoon C, Fernando M, Galappaththy C, et al. Meta-analyses of randomized controlled trials reporting the effect of home foot temperature monitoring, patient education or offloading footwear on the incidence of diabetes-related foot ulcers. *Diabet Med*. 2020;37(8):1266-1279.
34. Golledge J, Fernando ME, Alahakoon C, et al. Efficacy of at home monitoring of foot temperature for risk reduction of diabetes-related foot ulcer: A meta-analysis. *Diabetes Metab Res Rev*. 2022;38(6):e3549.
35. Littman AJ, Timmons AK, Korpak A, et al. Remote Foot Temperature Monitoring Among Veterans: Large Observational Study of Noncompliance and Its Correlates. *JMIR Diabetes*. 2024;9:e53083.
36. Van Netten JJ, Aan De Stegge WB, Dijkgraaf MGW, et al. Cost-effectiveness of temperature monitoring to help prevent foot ulcer recurrence in people with diabetes: A multicenter randomized controlled trial. *Diabetes Metab Res Rev*. 2024;40(4):e3805.
37. Littman AJ, Timmons AK, Jones KT, et al. Assessing equity in the uptake of remote foot temperature monitoring in a large integrated US healthcare system. *PLoS One*. 2024;19(4):e0301260.

38. Dy SM, Bennett WL, Sharma R, et al. AHRQ Comparative Effectiveness Reviews. *Preventing* Complications *and Treating Symptoms of Diabetic Peripheral Neuropathy*. Rockville (MD): Agency for Healthcare Research and Quality (US); 2017.
39. Masadeh SN, K. Remote Monitoring for Diabetic Foot Ulceration and Amputation Prevention. 2024:dvagov.sharepoint.com.