

CLINICAL RESEARCH ARTICLE

Type 2 diabetes–related foot care knowledge and foot self-care practice interventions in the United States: a systematic review of the literature

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Introduction: The purpose of this systematic literature review is to review published studies on foot care knowledge and foot care practice interventions as part of diabetic foot care self-management interventions.

Methods: Medline, CINAHL, CENTRAL, and Cochrane Central Register of Controlled Trials databases were searched. References from the included studies were reviewed to identify any missing studies that could be included. Only foot care knowledge and foot care practice intervention studies that focused on the person living with type 2 diabetes were included in this review. Author, study design, sample, intervention, and results were extracted.

Results: Thirty studies met the inclusion criteria and were classified according to randomized controlled trial ($n = 9$), survey design ($n = 13$), cohort studies ($n = 4$), cross-sectional studies ($n = 2$), qualitative studies ($n = 2$), and case series ($n = 1$). Improving lower extremity complications associated with type 2 diabetes can be done through effective foot care interventions that include foot care knowledge and foot care practices.

Conclusion: Preventing these complications, understanding the risk factors, and having the ability to manage complications outside of the clinical encounter is an important part of a diabetes foot self-care management program. Interventions and research studies that aim to reduce lower extremity complications are still lacking. Further research is needed to test foot care interventions across multiple populations and geographic locations.

Keywords: *diabetes; foot care; foot care knowledge; diabetic foot disease; self-care management*

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With an impact of over 300 million people worldwide, diabetes has become the fastest developing chronic disease (1). Despite cases of unreported causes of death in the United States, diabetes (T2DM) was still noted as the seventh leading cause of death in 2006 (2). Lifestyle behavior changes are required for management of this condition, including physical activity, dietary changes, monitoring blood glucose levels, and adherence to medication (3). The quality of life of someone living with T2DM can be greatly improved with the implementation of self-management education to help them manage the condition (2). Similar to how continuing education is essential for healthcare providers, there must also be continuous education for the person that is battling T2DM (4). According to the American Association of Diabetes Educators 7 Self-Care Behaviors framework,

people with T2DM should be skilled in self-care behaviors that improve their quality of life while reducing associated complications of this condition (5). The skills needed to accomplish this include the following: monitoring of blood glucose levels; monitoring of blood pressure; eliminating smoking; foot self-checks; and routine eye, foot, and dental exams (5). Self-care management has the capacity to reduce the gap between patient needs and available health care services to meet those needs (6). Health care providers must equip patients with the tools needed to effectively monitor their blood glucose levels, maintain any dietary restrictions, and be active participants in their individual self-care to control their disease (7).

Uncontrolled T2DM has serious health implications other than chronic hyperglycemia, such as heart disease, stroke, retinopathy, neuropathy, and nephropathy (2).

The complications do not end there; lower extremity amputations comprise over 60% of non-traumatic amputations in the United States (8). These T2DM-related lower extremity amputations cause critical implications for individuals, family members, and caretakers in terms of psychosocial, physical, functional, and financial implications (9). T2DM-related complications account for a death risk that is two times higher than that of someone that does not have T2DM (10). However the development of such complications can be prevented and reduced through the implementation of comprehensive programs focused on foot care, which have been shown to greatly reduce amputation rates (8).

T2DM foot complications, which more often affect older adults, have the capacity to diminish a person's quality of life (1). Foot self-care behaviors, including daily inspection of feet, professional treatment, hygiene, and proper shoe gear help minimize the risk of foot complications (1). T2DM is multifaceted and requires a multidisciplinary approach to the treatment of the condition and prevention of associated complications (11). McCook-Martinez et al. (1979) found that when patients were properly informed about foot care, disease-associated morbidity, hospitalization, and amputation rates were lower than for those that did not have foot care information (12). Lavery et al. (13) noted a reduction in hospitalizations and amputations in their study, which developed a lower extremity disease management program that included lower limb screening and treatment protocols for the at-risk foot within a health care facility (12). Despite evidence of the success of multidisciplinary approaches to T2DM care, this approach to care has yet to be fully implemented as part of the standard of care (14). The purpose of this systematic literature review was to compile and evaluate published evidence for increasing foot care knowledge and self-care practices as part of a targeted T2DM foot care intervention.

Methods

Data sources

This systematic review contains research studies of foot care knowledge and foot care practices interventions. The inclusion criteria were limited to studies that evaluated T2DM-related foot care knowledge and foot self-care interventions. We excluded studies that were not peer reviewed, did not discuss T2DM, contained no element of T2DM-related lower extremity complication, were not in English, and were not conducted within the United States.

Medline (OVID), CINAHL (Ebsco), CENTRAL (Wiley Cochrane), and Cochrane Central Register of Controlled Trials databases were searched using the following combinations of search terms: 1) diabetes mellitus, type 2 diabetes, type II diabetes, non-insulin dependent diabetes,

diabetic foot, or diabetes complications; 2) foot care, self-management, self-care, self-care knowledge, health knowledge, health activities, health practice, preventive care, preventive health, or preventive health services; and 3) foot, feet, toes, podiatry, or diabetic foot. The Medline search was modified for the other databases. The reference lists of the studies included in the evaluation were also searched systematically for any eligible studies that may have been overlooked, but were not included.

Study selection

Two investigators (TJB and ESL), independently reviewed publications by title and abstract according to the above mentioned criteria by rating the studies with a *yes* or *no*. A full-text review was then conducted on those studies that were designated as *yes*. The methodologies and findings of the included articles were then reviewed by one investigator (TJB) for validity assessment, which included determining whether the studies were described in sufficient enough detail to include in the current review. The Strength of Recommendation Classification Scheme (15) was one of the quality assessment tools utilized for this review (Table 1). This classification scheme uses a hierarchy to rank the strength and validity of evidence from each study included in this systematic review. This scheme allowed the investigators to rank the strength of not only randomized controlled trials, but also the strength of observational studies, cohorts, case-control studies, case series, and case reports, many of which have also been included in this systematic review. The included studies were also appraised using the Strength of Reporting Observational Studies in Epidemiology (STROBE) tool (Table 2) (16). This tool was also used because it addresses cohort, case-control, and cross-sectional studies, which have been included in this review (16). The tool consists of 22 items, but the last item, funding, was omitted from the checklist, which brings the tool to 21 items (1).

Table 1. The strength of recommendations classification scheme

IA	Evidence for meta-analysis of randomized, controlled trials
IB	Evidence from at least one randomized, controlled trial
IIA	Evidence from at least one controlled study without randomization
IIB	Evidence from at least one other type of quasi-experimental study (nonrandomized)
III	Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies, and case-controlled studies
IV	Evidence from expert committee reports or opinions or clinical experience of respected authorities

Adapted from Shekelle et al. (15).

Table 2. Strength of reporting observational studies in epidemiology

	Item	Recommendation
<i>Title and abstract</i>	1	(1) Indicate the study's design with a commonly used term in the title and abstract. (2) Provide in the abstract an informative and balanced summary of what was done and what was found.
<i>Introduction</i>		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported.
Objectives	3	State specific objectives, including any prespecified hypotheses.
<i>Methods</i>		
Study design	4	Present key elements of study design early in the paper.
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection.
Participants	6	(1) Cohort study – give the eligibility criteria and the sources and methods of selection of participants Describe methods of follow-up. Case-control study – give the eligibility criteria and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls. Cross-sectional study – give the eligibility criteria and the sources and methods of selection of participants. (2) Cohort study – for matched studies, give matching criteria and number of exposed and unexposed. Case-control study – for matched studies, give matching criteria and the number of controls per case.
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.
Data sources/ measurement	8	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group.
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why.
Statistical/methods	12	(1) Describe all statistical methods, including those used to control for confounding. (2) Describe any methods used to examine subgroups and interactions. (3) Explain how missing data were addressed. (4) Cohort study – if applicable, explain how loss to follow-up was addressed. Case-control study – if applicable, explain how matching of cases and controls was addressed. Cross-sectional study – if applicable, describe analytical methods taking account of sampling strategy.
<i>Results</i>		
Participants	13	(1) Report number of individuals at each stage of study – e.g. number potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed. (2) Give reasons for non-participation at each stage. (3) Consider use of a flow diagram.
Descriptive data	14	(1) Give characteristics of study participants (e.g. demographic, clinical, social) and information on exposures and potential confounders. (2) Indicate number of participants with missing data for each variable of interest. (3) Cohort study – summarize follow-up time (e.g. average and total amount).
Outcome data	15	Cohort study – report numbers of outcome events or summary measures over time. Case-control study – report numbers in each exposure category, or summary measures of exposure. Cross-sectional study – report numbers of outcome events or summary measures.
Main results	16	(1) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g. 95% confidence interval). Make clear which confounders were adjusted for and why they were included. (2) Report category boundaries when continuous variables were categorized. (3) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period.
Other analyses	17	Report other analyses done – e.g. analyses of subgroups and interactions, and sensitivity analyses.
<i>Discussion</i>		
Key results	18	Summarize key results with reference to study objectives.

Table 2 (Continued)

	Item	Recommendation
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.
Generalizability	21	Discuss the generalizability (external validity) of the study results.

Adapted from Vandembroucke et al. (16).

An explanation and elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the following websites: PLoS Medicine at www.plosmedicine.org/; Annals of Internal Medicine at www.annals.org/; and Epidemiology at www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Data extraction

Data abstraction was conducted by one investigator (TJB) using the procedures in Garrard's method of literature review (17). The information extracted from the included studies was then entered into tables including 1) author/year, 2) rank/score, 3) sample (size, ethnicity, and mean age), 4) intervention, and 5) results. The selected abstracts were then reviewed by another investigator (ESL). The second investigator (ESL) independently reviewed and extracted data from 18 of the 31 articles that were selected for the review. Any discrepancies between the two investigators' scores were then resolved through a second review of the abstracts, discussion of discrepancies, and a finalized consensus.

Results

The literature search identified 1,443 articles. The number of articles that were excluded at each stage of the selection process is presented in Fig. 1. Articles were excluded after not meeting the following inclusion criteria: 1) peer reviewed, 2) T2DM-related, 3) lower extremity disease component as the basis of the study, 4) study conducted in the United States, and 5) foot care education or foot care practices intervention only in participants that were living with T2DM. As a result, 30 studies were included in this review.

Study characteristics

The journals that have reported studies are from foot and ankle journals ($n = 2$), diabetes journals ($n = 12$), nursing journals ($n = 7$), rehabilitation journals ($n = 4$), and medical journals ($n = 6$). The sample size of the studies ranged from 3 to 772, with a median of 198.7. Two studies examined type 1 diabetics along with the type 2 diabetics. There were 18 studies that included female participants, 21 studies that included male participants, and nine studies that did not report the gender of the participants. One study included Filipino participants, 17 included African-American participants, five studies included Hispanic participants, two studies included Native Americans,

and 10 studies did not include participants' racial or ethnic information.

Study quality

This systematic review is composed of studies ranging from randomized controlled trials ($n = 9$), surveys ($n = 13$), cohort studies ($n = 4$), cross-sectional studies ($n = 2$), qualitative studies ($n = 2$), and case series ($n = 1$) (Supplementary Table 1). The Strength of Recommendation Classification Scheme (15) was used to rank all the studies based on strength and validity of the studies (18). Of the nine randomized control trials, seven of the nine studies received a 1B. The randomized controlled trials that did not receive a 1B received a 1C due to not describing the control group, not providing analysis for the intervention group, and not providing between-group analysis. Of the 13 survey studies included, all received a rank of IIA. The cohort studies, case series, cross-sectional studies, and qualitative inquiries were assigned a rank of III. A modified version of the STROBE tool was used to appraise the included studies. The scores varied between 13 and 18 (out of 21). The majority of the included studies failed to report how the study size was calculated or any source of bias. Most of the studies also acknowledged that there were limitations to the generalizability of the results.

Data synthesis

Thirty-one studies were represented within this review. The interventions included in the studies were general T2DM education (19), exercise sessions (19), counseling sessions (19), referrals to a foot care specialist (20), therapeutic foot gear (20, 21), professional foot assessments (19, 21–23), foot care education (8, 9, 12, 21, 24–27), foot care skills (12, 22, 24, 25, 28), questionnaires (29, 30), semi-structured interviews (31–33), videos and pamphlets (2, 26, 34), and physician reminders (35).

Learning outcomes

The learning outcomes of the studies were measured by general T2DM knowledge scores (36), self-care scores (30, 37–40), foot care knowledge scores (8, 29, 33, 41, 42, 43),

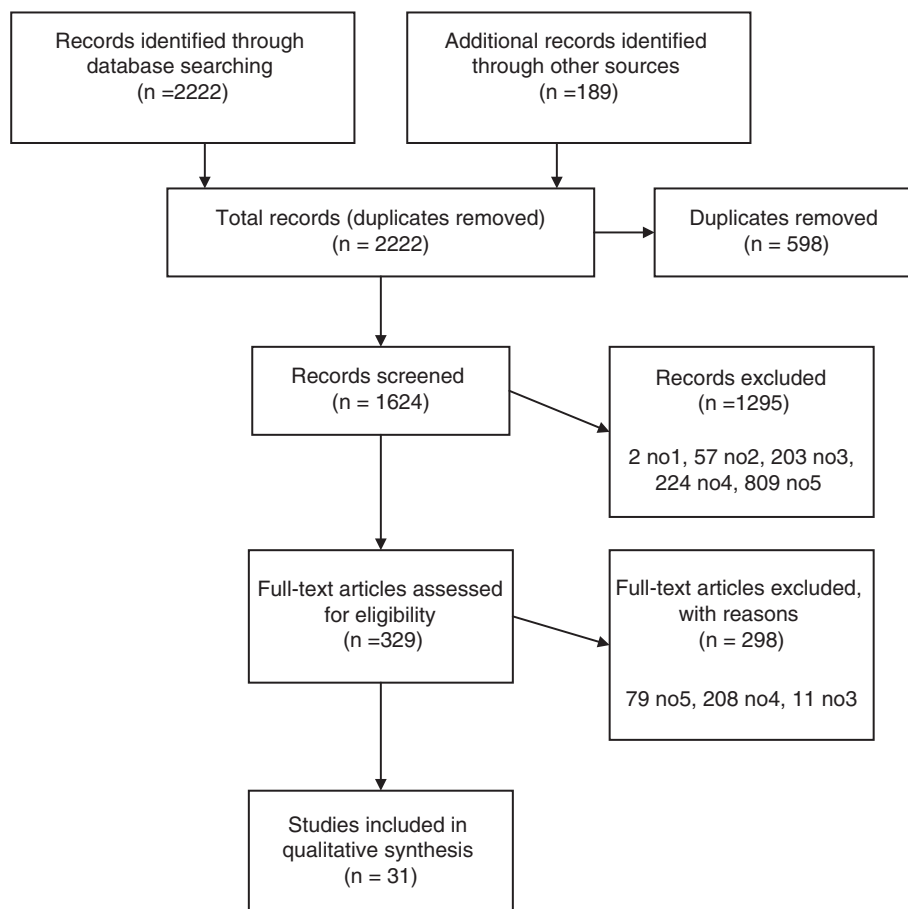


Fig. 1. Systematic review flow diagram on diabetes-related foot care knowledge and foot care skills interventions in US studies.

self-efficacy scores (30, 31, 37), and physician prevention survey scores (44). All of the studies that measured foot care knowledge saw an improvement in health outcomes based on receipt of foot care education. The post-test scores of the control groups were also poorer than the post-test scores of the intervention groups, revealing the need for foot care-specific education. All the studies that assessed foot care practices noticed an improvement in foot care practices, but not in lower extremity complications. There was one study (22) that noted that improvement of practices coupled with foot care education did not reduce the incidence of lower extremity complications in the study participants.

The behavioral outcomes that were assessed in the studies included foot self-exams (22, 24, 36, 45); daily foot inspection (9, 20, 29, 36); proper footwear (25, 36); foot washing (22, 24); visits to a podiatrist (35); applying moisturizer to dry skin on feet (25, 36); reporting foot problems to a health care professional (25, 36); wearing socks with shoes (25, 36); avoiding soaking feet (36); inspecting footwear for foreign objects (25, 36) like nail points (36), torn lining, or rough areas (36); gently filing calluses on feet (25, 36); drying between toes after wash-

ing (25, 29); cutting toenails straight across (25, 36); inspecting feet daily for blisters, cuts, and scratches (36); and testing water temperature with hand before immersing feet (25, 36). Many of the behaviors demonstrating significant improvements were those surrounding daily foot checks (20, 22, 45) and proper foot self-exams (24).

The clinical outcomes that were assessed in the studies included hospitalizations (23), ulcerations (23, 32, 42), ER visits (23), antibiotic treatments (23), foot operations (23), lower extremity amputations (23, 26), missed work days (23), presence of vascular disease (32), foot trauma (32), comorbid complications (32), foot lesions (25, 36), calluses (9), peripheral vascular disease (9), bunions (9), hammertoes (9), glucose levels (9), dorsalis pedis pulses (25), posterior tibial pulses (25), femoral pulses (25), peripheral neuropathy (25), dry or cracked skin (25), ingrown nails (25), fungal nail infections (25), fungal skin infections (25), and interdigital macerations (25). Many of the clinical outcomes that showed significant improvement in the studies included foot-related ulcer days (23), hospitalizations (23), hospital days (23), ER visits (23), antibiotic prescriptions (23), foot surgery (23), lower extremity amputations (23, 26), missed work days (23),

ulcerations (26), foot lesions (25, 36), cracked skin (25), ingrown nails (25), fungal nails (25), macerated web spaces (25), and incidence of neuropathy (35).

Discussion

In this systematic review, foot care interventions were analyzed between 1989 and 2012. Thirty-one studies investigated various foot care interventions that mostly utilized foot care education, professional foot assessments, and foot care skills, although the interventions varied between studies. The learning outcomes assessed in the studies utilized self-care scores, foot care knowledge scores, and self-efficacy scores as they related to foot care. The major behavioral outcomes assessed in the studies were daily foot checks and foot self-exams. The clinical outcomes assessed in the studies varied greatly across the studies, but the most common outcome assessed was presence of ulceration, risk of amputation, or presence of a foot lesion. In the randomized controlled trials, there were no studies that reported improved outcomes in the control group as opposed to the intervention group. Although there were many interventions and health outcomes assessed in the included articles, consistency in the type of intervention was lacking collectively throughout the studies.

Importance of foot care practices on health outcomes

Proper foot self-care behaviors can reduce the risk of injury, infection, and amputation in someone with an at-risk foot (37). Ideal foot self-care behaviors include daily foot and shoe gear checks, proper daily foot hygiene, not walking barefoot, wearing appropriate shoe gear, trimming toenails, avoiding using anything abrasive on the feet, early professional care for open wounds and lesions on the foot, and routine foot exams by a professional trained to identify diabetic foot complications (29). T2DM health care providers strongly encourage patients to implement these foot self-care practices (1). Previous studies have found an increase in foot ulcers and amputations in those patients that do not adopt these practices (45).

Importance of foot care education interventions on health outcomes

Foot injuries and ulceration have been associated with poor T2DM-related foot care knowledge and foot self-care skills (29). This lack of knowledge has been recognized as a contributing factor to why people with T2DM do not undertake foot self-care practices (46). It is widely accepted that additional education will lead to improved knowledge, self-care behaviors, and reduction of foot complications (1). Funnell et al. (47) noted that this additional education should be tailored to the individual needs and beliefs of the person with T2DM. There are studies that have shown a clear reduction in amputation rates

following a foot care intervention (48). Litzelman et al. (25) found that along with the implementation of a self-care contract, there was a sizable improvement in foot self-care behaviors as compared to standard care.

Importance of overall self-care management on health outcomes

Diabetes Self Management Education (DSME) has been shown to be the foundation of care for anyone with T2DM wanting to improve disease-related health outcomes (49). DSME is an essential component in the prevention of T2DM-related complications, but it also provides disease prevention for those with pre-T2DM (50). Patients that are not offered DSME have a fourfold risk of developing T2DM-related complications compared with those that have had some form of DSME (51). Studies have shown that these educational interventions have the ability to lower rates of lower extremity amputations by up to 85% (52). DSME is effective at controlling illness and improving health, and it is accepted as a cost-effective strategy (53). Ollendorf et al. (52) noted that educational interventions aimed at foot self-care behavior and skills may offer the highest economic benefit in the reduction of lower extremity amputation rates.

Strengths and limitations

This systematic literature review is a comprehensive examination of foot self-care knowledge and practice interventions conducted within the United States, solely on individuals with T2DM. This review provides an important insight into an area of T2DM management and care that has been ignored by research studies and interventions. The studies included within this systematic literature review provide evidence of improved health outcomes, learning outcomes, and behavioral outcomes and how those outcomes ultimately improve the quality of life for those with T2DM. The limitations of this review are that it only analyzed studies within the United States and only those studies that examined foot care knowledge and foot care practices in the actual population that lives with T2DM. The systematic review also did not include studies that examined the foot care knowledge and foot care practices of caregivers or health care providers.

Conclusion and future implications

The literature has shown that T2DM self-care management programs have a positive impact on self-care behaviors, as well as health outcomes, even with a lack of consensus on the best approach. Standardization of these programs is needed in T2DM, but the inclusion of self-care for associated comorbidities and complications also needs deeper examination by program developers. Future research should examine the effects of a standardized foot self-care program across multiple populations and intervention sites that focuses on the reduction of

complications associated with a T2DM diagnosis. This potential intervention has the ability to expand the scope of DSME to not only include foot care, but also other complications associated with this condition.

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Conflict of interest and funding

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