Article Highlights

- Temperature monitoring of plantar foot temperature with an expensive medical-grade thermometer has been identified as a promising strategy to help patients identify early inflammation that could lead to a diabetic foot ulcer (DFU) and take action to address the inflammation by resting or seeing their healthcare provider.
- We wanted to ask whether daily temperature self-monitoring with a low-cost commercially available infrared thermometer (CAIT) supports foot-self management.
- We found that the strategy engaged patients, improved foot assessment, and prompted action to address foot concerns.
- The CAIT is a tool that could support foot self-management and prevent DFUs.

Abstract

Objective: To evaluate the effectiveness of a foot self-management strategy that utilized a commercially-available infrared thermometer (CAIT) for prevention of diabetic foot ulcers.

Research Design and Methods: In this six-month pilot randomized controlled trial, Phase 2 of a three-phase mixed methods research study, 62 participants were randomized to a thermometer and education group (n=34) and an education-only group (n=26). Both groups received foot care education and were assessed by a certified orthotist. All participants recorded their number of steps and recorded a foot assessment in a logbook daily. The thermometer and education group also recorded their daily temperature assessment. A temperature difference of > 4 degrees Fahrenheit (F) between the two feet prompted participants to rest their feet. Participants were directed to see their healthcare provider if the temperature difference did not decrease to below 4 degrees F in two days. Phase 3 of the study explored the Phase 2 results to understand the findings further.

Results: The strategy improved foot assessment and action: the thermometer and education group had significantly more days with any assessment completed than the education-only group

(150.98/180 vs. 119.84/180, p =.02). Phase 3 findings showed that the thermometer engaged participants, prompted action, and offered reassurance regarding foot health.

Conclusions: A CAIT is a tool that could support foot self-management and may offer several benefits, such as promoting and providing structure for a foot assessment and direction for action.

Clinical trial reg no. NCT0306776 clinicaltrials.gov

Key words: infrared thermometry, foot health, diabetes, self-management

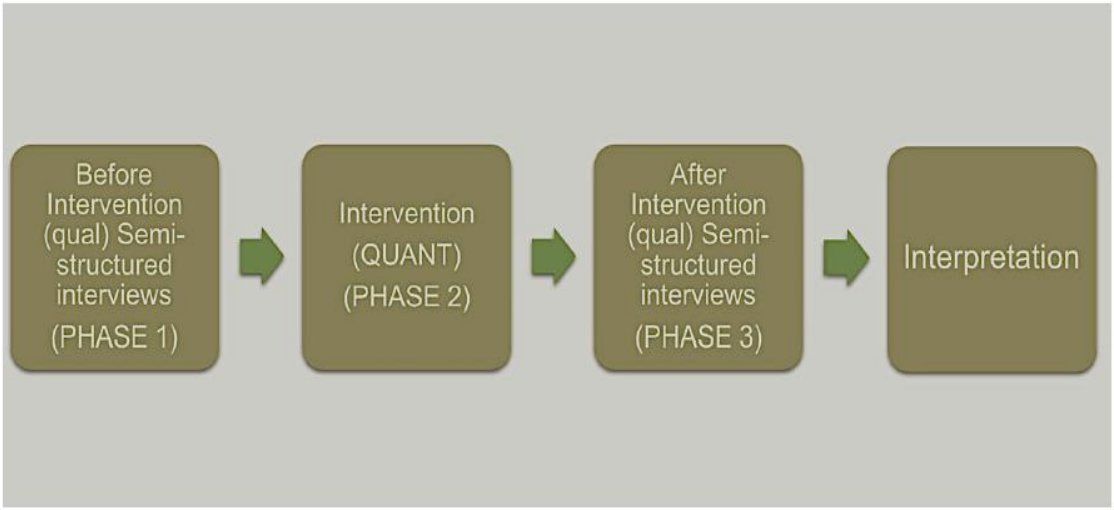
Lower limb complications related to diabetes are a significant and preventable cause of the global disease burden and are costly to the healthcare system (1, 2). The International Diabetes Federation has argued that more focus needs to be on preventing DFUs (3). DFUs often take a long time to heal and may lead to re-ulceration, amputation, and death. Having a DFU is a personal crisis for that person and their family with implications for quality of life (QoL) (4,5,6). With the number of people with diabetes increasing, complications can be expected to rise unless preventative actions are taken. Several factors contribute to developing a diabetic foot ulcer (DFU), with pressure and trauma being the most important causes of inflammation leading to skin breakdown. Patients must identify this inflammation early and take action to reduce the risk of skin breakdown.

A recent systematic review and meta-analysis, which contained five randomized controlled trials (RCTs), indicated that the use of personal temperature monitoring with a medical-grade infrared thermometer was an effective way to identify plantar inflammation and prevent DFUs (7); however, these thermometers are expensive, costing approximately $700 (USD). A commercially-available infrared thermometer (CAIT), which costs $30-100, has been validated against the medical-grade thermometer. This device could be used to detect a plantar temperature increase associated with inflammation before skin breakdown occurs (8,9). Once the increase in temperature is identified, the individual can address the underlying source of inflammation by relieving pressure until the temperature normalizes and inflammation decreases (7). If the temperature does not normalize in two days, an HCP should be consulted.

This three-phase study employed a mixed-methods research (MMR) approach using an exploratory and explanatory model, as shown in Figure 3.1 and aimed to test the effectiveness of

a six-month foot self-management intervention that utilized a CAIT. In Phase 1 (P1) (exploratory), self-management was explored using qualitative methods with patients, linked support persons, and HCPs, and what was learned informed the intervention (N=24 participants). Results from P1 are reported elsewhere (10). This report focuses on Phases 2 and 3 (P2 and P3).

Figure 1: Mixed methods exploratory and explanatory model



Research Design and Methods

In P2, the RCT tested the intervention's effectiveness with 62 patients randomly assigned to an education and thermometer group or an education-only group. In P3 (explanatory), participants were interviewed regarding their experiences to gain further clarity regarding P2 results.

Setting and Sample

The timeframe for recruitment for P2 was from August 2017 until October 2018. Data collection ended in August 2019, and P3 was conducted in October 2019. The study was registered at clinicaltrials.gov, NCT0306776. Ethical approval was obtained from the Health Research Ethics Authority, and all participants provided written informed consent.

Participants were recruited from clinics and geographical areas served by Eastern Health in Newfoundland and Labrador (NL). Inclusion criteria were: 18 years of age or older; history fit with International Diabetic Foot Risk Classification System category 2 (decreased sensation on four areas of the foot, decreased blood supply, or foot deformity) or category 3 (previous ulcer or amputation). Exclusion criteria were severe peripheral arterial disease as evidenced by an ankle brachial index (ABI) < 0.8. As the response rate for recruitment was low in the initial six months of the study, the inclusion and exclusion criteria were adjusted and approved by the ethics board. Inclusion and exclusion criteria are listed in Supplementary Table 1.

The sample size was calculated using an alpha of .05 and a beta of .80 and assuming the NL population had similar ulceration rates as a previous study that used a similar intervention: 8.5% in the intervention group and 29.3% in the control group (11). To allow for a possible 10% loss of participants, 71 individuals were to be enrolled in each group to ensure 64 participants per group completed the study. Due to difficulties with recruitment, the target sample size was not achieved. P2 was declared a pilot study with the goal of obtaining preliminary results and testing the methods.

Intervention

Participants in both groups received education, completed an orthotic assessment, and had a foot assessment completed by an advanced foot care nurse at baseline, three, and six months. An orthotic assessment (i.e., biomechanical assessment) was completed by a certified pedorthist. In Canada, a certified pedorthist focuses on the assessment of the lower limb and are specialists in footwear, and postural, musculoskeletal, and joint analysis (12). The orthotic assessment included assessing the patient history, activity level, and current injuries. An examination was also completed to assess for postural imbalances, muscle bulk similarities, positional deformities,

muscle tightness, tenderness, range of motion, arch height, and gait. The pedorthist made recommendations to address any identified issues (e.g., footwear).

See Supplemental information for an outline of the education session and CAIT teaching points. Participants were directed to record their assessment and foot temperature in a logbook. If there was a temperature difference of > 4 degrees F between the two feet, participants were directed to rest their feet and recheck it the next day (See Supplemental information for sample logbook page). If the temperature was still elevated in 48 hours, the participants were directed to see their HCP.

Measurement

The primary outcome of the presence or absence of a DFU was assessed using the 60 Second Foot Screen (13) and self-report. The secondary outcomes that will be reported here were completion of a visual foot assessment, temperature assessment, any assessment (either visual or a temperature assessment), action taken in response to foot assessment, and QoL. Completing any assessment was calculated as the percentage of days out of the total potential days in the study (180 days) that a participant recorded either a temperature assessment, visual assessment, or both. Taking action, which was defined as doing something (e.g., resting, changing shoes, and/or seeing an HCP) to address a concern was measured using logbook data and the exit interview results. A foot concern was defined as an elevated temperature, unexplained pain, and any issue identified during the visual assessment. The QoL Enjoyment and Satisfaction Short Form was used at baseline, three, and six months (14). The results of additional measures related to confidence, general health, and readiness are not discussed in this article. An exit interview was completed with each participant at the end of P2. The measures used and the data collection schedule are summarized in Supplementary Table 2.

Potential confounders were measured and identified based on studies that found these variables to be confounders. Factors that were potential confounders were: pedometer readings, HbA1C, orthotic assessment, temperature, depression symptoms, and information collected in the participant profile. The purpose of the pedometer reading was to assess activity before and after a temperature increase and/or ulceration. The findings related to the pedometer readings will be reported in future articles.

Statistical Analysis

Participants' characteristics were summarized using descriptive statistics. We used t-tests to evaluate differences in means for some variables. Chi-square and Fisher's exact test were used for differences in proportion. An alpha of 0.05 and 95% confidence interval (CI) were used for all analyses. Logistic regression was utilized to determine variables that contributed to foot assessment. All the analyses were conducted using the intent to treat approach. Stata 14.2 was used to analyze the data (15).

P3 Methods

At the end of P2, participants who indicated during the exit interview that they were open to being contacted were recruited for P3. Following analysis of P1 and P2 findings, the P3 interview guide was developed and focused on areas that required further explanation. Considering which participants could best answer the questions, participants were recruited using purposive convenience sampling. Participants were contacted by telephone or email. After obtaining verbal consent, semi-structured 30-60 minute interviews were conducted with 9 RCT participants. Transcriptions of the audiotaped interviews were used to supplement interview notes. The data were analyzed using Interpretive Description.

Results

Sample Characteristics. Supplementary material Fig. 1 presents the flow of participants through the study. Table 1 summarizes the characteristics of the participants. There were no statistically significant differences between the groups at baseline except for insulin use; more participants in the thermometer and education group were using insulin. Concerning foot characteristics, over 30% of each group were at moderate to high risk for foot ulceration, according to the International Working Group on the Diabetic Foot Risk Stratification (16). Two participants had a history of ulceration in the thermometer and education group and three in the education-only group. Nine participants were interviewed in P3, six participants from the thermometer and education group and three from the education-only group.

DFUs. At the end of six months, there were no differences between the two groups for DFUs, with only one person in the intervention group re-ulcerating and withdrawing from the study at month two.

Improved foot assessment. As shown in Table 2, P2 results showed that the thermometer and education group had more days than the education-only group where any foot assessment was completed (150.98 vs. 119.84, p =.02). Any assessment was defined as either completing a visual assessment and/or the temperature assessment. Skin temperature monitoring was divided into 80% or more of the days and less than 80% of the days. The goal of 80% was chosen for several reasons. Even though the best-practice recommendation is for people with diabetes to check their feet daily (16), no literature supported that this was the optimal frequency, which is unknown. The clinicians on the research team decided that using 80% as the cut-off would be appropriate as 100% compliance would be difficult to achieve considering the amount of time people with diabetes invest daily in self-management (17) and that foot assessment is often not incorporated (10; 18). In their study reporting temperature monitoring and DFUs,

Skafjeld et al. (19) reported their outcome in terms of greater then and equal to 80% of days; using the same cut-off allowed for the comparison of study results.

A greater proportion of patients in the thermometer and education group (73.5%) completed the logbook on 80% or more of the days compared to patients in the education-only group (50%), but the difference was not statistically significant ($p = .061$). Logistic regression was conducted to assess the effect of the following variables on completing an assessment on 80% or more vs. less than 80% of the days: group (thermometer and education and education-only group); age; gender; marital status; education; income; occupation; type of diabetes; the number of years with diabetes; taking insulin; history of a foot ulcer; neuropathy; foot risk classification; stage of change; depression (at baseline); and comorbidities. Although there was a significant difference in insulin use between the two groups at baseline, only the variable for group was a significant predictor in the final model, with the number of years with diabetes as an important confounder. When years with diabetes was controlled for, group significantly predicted whether an exam was completed more than 80% of the time (OR: 3.54; 95% CI: 1.11 – 11.29; $p = 0.032$). Overall, however, the model explained less than 10% of the variation ($R^2 = 0.0989$).

Analysis of the logbooks showed that participants often completed the temperature reading without indicating that they assessed their feet. The average days of temperature assessment was 150.97, and the average days of visual assessment was 114.8 (See Table 2). It was unclear what was happening; therefore, this finding was explored further with participants in P3. Results showed that participants also looked at their feet when they took their temperature, either prior to or after taking the temperature. One participant described the temperature and visual check as going "hand in hand."

Improved actions based on foot assessment. Both the logbook data and the exit interview results, summarized in Tables 2 and 3, showed that the CAIT had the potential to provide patients with direction for identifying a concern and taking action to address the concern. For the thermometer and education group, 27 (81.82%) participants identified a concern on 0-30 days compared to 19 participants (73.08%) in the education-only group. Concerning taking action, for the thermometer and education group, 16 (59.26 %) participants took action on 0-30 days compared to 12 participants (48%) in the education-only group (See Table 3). During the exit interviews, 22.22% of participants in the thermometer-education group indicated that they changed what they planned to do when they checked the temperature in their feet, such as choosing appropriate activities, resting, re-assessment, and seeing their HCP. These results were explored further in P3. Participants shared that a temperature reading of < 4 degrees F reassured participants that their feet were fine. In contrast, a temperature of > 4 degrees F heightened concern and prompted action such as: resting, rechecking, and going to see an HCP.

Patient's perception of usefulness. The exit interview results supported that participants viewed the thermometer as valuable and easy to use. The results showed that 96.8% of participants indicated they would continue to use the CAIT, and 37.9% indicated that they would only use it sometimes or rarely (see Table 3). Participants in P2 stated they would use the thermometer to: identify inflammation and any issues; have a baseline assessment; and monitor for hot spots. In P3, these findings were explored further to clarify whether or not the thermometer was helpful. Participants in P3 shared that taking their temperature was a prompt to look at their feet, prompted a more thorough foot check, raised their awareness of their feet, made them feel more involved in their assessment; and improved the structure of the assessment.

In P2 there were no differences between the two groups or within groups for the QoL scores. When asked in P3 about the addition of self-management activities, a participant who used the thermometer said there was a time commitment to incorporate the thermometer and assessment into her schedule. However, she did not see this negatively, and she adjusted her schedule as needed.

During P2, the researcher noted some minor issues with how participants used the thermometer. During the exit interview, 48% of participants used it correctly, and 48% completed some aspects incorrectly (See Table 3). Issues were noted related to: logistics; understanding thermometer purpose; interpretation of results; and taking action based on the assessment.

Conclusions

A multi-modal intervention was delivered in this study with demonstrated benefits for foot self-management concerning assessment and taking action to prevent complications. The CAIT may provide information that would help a person make the best decisions for their foot health. Other research using thermometry showed that participants were less likely to have a DFU if they recorded their foot temperature at least 50% of the time (OR 50.0, $p = 0.001$) (11). Although ulceration was a primary outcome, only one participant in the thermometer and education group had an ulcer. As this was a re-ulceration of a wound that had recently healed prior to enrollment, it was not a good indicator of the impact of the intervention on ulceration. With a six-month intervention, as used in this study, the length of follow-up was not enough to assess the impact of the intervention on the incidence of foot ulceration.

One of the most important benefits of the intervention was promoting assessment and engagement in foot self-management without being a burden. The results showed more

assessment days being completed in the thermometer education group than in the education-only group. The findings also showed that the intervention engaged participants in their foot self-management. Participants reported feeling more involved in their assessment and reassured about their foot health when they measured a temperature difference of < 4 degrees F. Another benefit identified from using the CAIT was the potential to provide direction for taking appropriate action. Participants reported that when they obtained a temperature difference > 4 degrees F, they performed such actions as resting, re-assessing their feet, and seeing their HCP. Likewise, Lavery et al. (20) concluded that the use of the thermometer provided patients with "actionable information" (p.2646).

It is essential to highlight that although participants did not perform the temperature assessment daily, they still benefited. These findings lead to the question of the optimal schedule to complete a foot assessment. It may be that this schedule needs to be individualized for patients based on their foot assessment. Currently, it is recommended that patients assess their feet daily to pick up on any changes. Until the efficacy of having individualized scheduling of foot assessment and temperature measurement is established, HCPs should continue to reinforce the importance and rationale for the daily assessment. Optimal scheduling of temperature assessment could be a focus of future research.

The CAIT did not seem to be a burden for participants concerning additional self-management activities. The high adherence rate in the thermometer education group may also reflect that the intervention did not add too much burden to daily self-management. This finding is in keeping with Skajfeld et al. (19), who reported that participants using the thermometer had a high adherence rate. Similar to this study, these authors reported that 67% of participants recorded the temperature assessment 80% or more of the time. P3 interviews showed that since

completing the study, participants did not use the thermometer every day but used it periodically and planned to continue. This may show that a thermometer is a tool that can be incorporated into long-term foot self-management.

Even with providing teaching and completing two return demonstrations, by the end of the six months, only half of the participants followed the directions correctly. Sometimes a participant's physical challenges made it difficult to complete the temperature assessment. These challenges were minimal for participants who had a support person to complete the assessment. These findings have implications for patient education and the importance of regular follow-up. HCPs should reinforce with patients the purpose of the thermometer assessment and regularly evaluate how patients are using the thermometer.

There were several strengths of this study. This is the first study to report using a CAIT as part of a multi-modal intervention. All participants had a foot assessment completed by an advanced foot care nurse at baseline, three and six months. Furthermore, intervention integrity was maintained through one researcher completing the education with participants. Also, an MMR approach allowed for testing of an intervention that was developed based on patients' experiences in a local context and for a greater understanding of the delivery and impact of the intervention. Finally, by utilizing logistic regression, confounding variables were controlled in the analysis. The study also had limitations. First, the study had low power to assess the outcome of DFUs. Secondly, the length of the intervention was only six months. A longer intervention would have permitted an assessment of the long-term impacts. Finally, as most variables measured were self-report, the potential for social desirability bias may have been an issue.

In summary, this study contributes to refining the work on using infrared thermometry and preventing foot complications and suggests that a CAIT is an available tool that could

support foot self-management for people with diabetes. Using a CAIT may offer several benefits, such as promoting and providing structure for a foot assessment and direction for action. We look forward to more intervention research that builds on this research and tests the use of the CAIT with a larger sample size and utilizing a longer intervention.

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Declarations of interest: none

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Prior Presentation. The findings of this research have been presented at several conferences: Nursing Research Day, Centre for Nursing Studies, St. John's, NL (November 2021); 11th ICN Nurse Practitioner/Advanced Practice Nurse Network Conference. https://api.ltb.io/show/ABDMB (August 2021); Canadian Association of Footcare Nurses Annual Conference (May 2021); and Share Summit (Science, Health and Research Education Summit), St. John's, NL (November, 2020). The findings of this research can also be found in the unpublished doctoral dissertation http://research.library.mun.ca/id/eprint/14389 and in a non-peer reviewed publication https://qualityofcarenl.ca/wp-content/uploads/2021/02/Practice_Points_Vol7_web_interactive.pdf

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