

Benefits And Challenges Of Using A Commercially Available Infrared Thermometer For Foot Self-Management For Patients With Diabetes: Findings Of A Mixed Methods Study

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Daily foot assessment, with appropriate action, is recommended for patients with diabetes to prevent diabetic foot ulceration (DFU). A daily foot assessment includes looking between the toes and at the bottoms of the feet and assessing for any changes since the last self-assessment. Symptoms such as inflammation (e.g., redness, pain, swelling, loss of function and temperature increase), broken, peeling and/or dry skin and callusing should be noted. If the person identifies any areas of concern or unexplained pain, they

should make an appointment to see their health-care provider (HCP).¹

However, many patients do not assess their feet daily. Authors of a recent scoping review analyzed 44 studies on foot inspection and reported that 0–91% of participants regularly assessed their feet (median 41%; IQR 33–56%).² For those that do regularly assess their feet, detecting the signs and symptoms of skin inflammation may be challenging. For patients with neuropathy, identifying foot inflammation is especially difficult as they



may not experience pain or loss of function associated with inflammation.³ Additional tools are needed to support foot assessment and provide patients with the information to prevent complications such as DFU and amputation.

Self-monitoring skin temperature using an infrared thermometer is a promising tool for supporting daily assessment, detecting early inflammation and preventing skin breakdown on the plantar aspects of the feet. One of the earliest signs of DFU is inflammation; a temperature increase associated with inflammation can be subtle and is difficult for individuals to detect by palpation.⁴ Patients who cannot rely on cues such as pain need to change their understanding that signs of inflammation may constitute symptoms of DFU or potential DFU.⁵ Self-management tools that identify early signs of inflammation may help

effectively prevent skin breakdown by giving patients the information they need to address the identified concern.

In three randomized controlled trials (RCTs),^{3, 6, 7} and a pilot RCT,⁸ patients assessed their foot temperature daily for inflammation. Inflammation was determined by a difference of greater than (>) 4 degrees F (> 2.2 degrees C) between the two feet. If inflammation was detected patients were directed to rest that day. If the temperature was still elevated in 48 hours, patients were directed to see their health-care professional.^{3, 6, 7, 8} The researchers found that using temperature monitoring with a \$700 *medical-grade* infrared thermometer was an effective way to predict and thus prevent DFUs. A 2015 study compared a low-cost, *commercially available* infrared thermometer (CAIT) to medical-grade thermometers

and found them to be a reliable measure of skin temperature. However, they did not use the CAIT as part of foot self-management for patients with diabetes.⁹

None of the studies that tested the use of the thermometer captured the patients' perspective. What needs to be discovered is the patients' opinion and their viewpoint on incorporating this tool into their daily foot self-management. Understanding the benefits will strengthen the evidence and rationale for using a thermometer for foot self-management. Understanding the challenges and usability is also essential so HCPs can provide education and support to patients that address challenges. This study evaluated the impact on assessment and the patient perspective of using a \$30 CAIT. This research is part of a more extensive study that assessed the effectiveness of a foot self-management intervention that utilized a CAIT. This paper focuses on the patients' experience of using the CAIT.

Research Design And Methodology

This paper focuses on the explanatory sequence (Phases 2 and 3) of a more complex Mixed Methods Model research design (see Figure 1). In Phase 2, a 6-month pilot randomized controlled trial (RCT) was conducted to test the effectiveness of a thermometer and education intervention developed for the study and informed by the

Phase 1 qualitative data (N=24). The Phase 1 and Phase 2 (i.e., intervention) results are reported elsewhere.^{10,11,12} In the RCT, participants were randomized to the thermometer and education group (n = 34) and education-only group (n = 26). In Phase 3, interviews were conducted with participants regarding their experiences with the intervention (n = 9) (i.e., explanatory sequence). Integration of all phases occurred at the end of the explanatory sequence. The study was registered at clinicaltrials.gov, NCT0306776.

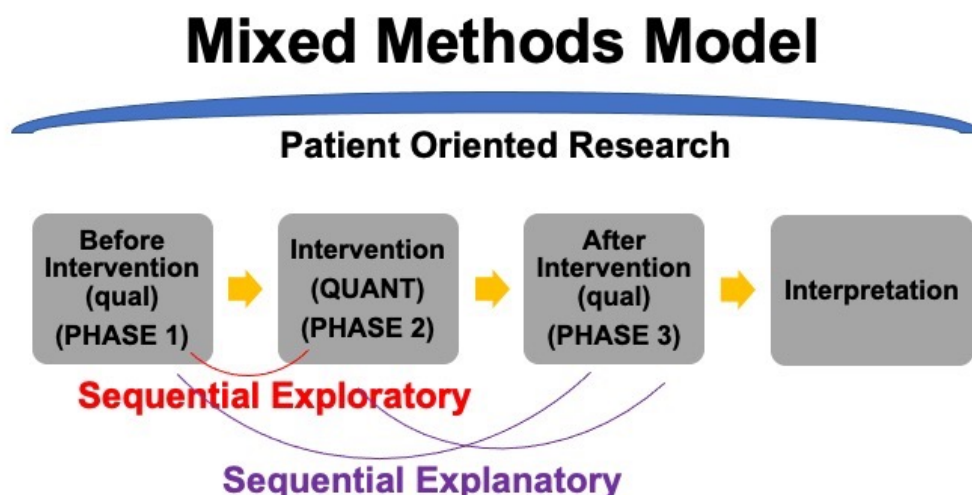
Research questions:

1. What are the benefits and challenges of using a CAIT as part of foot self-management?
2. Would participants continue to use the CAIT, and why?

Setting And Sample

Participants were recruited from health clinics and communities in Newfoundland and Labrador's Eastern Health Authority zone. Recruitment for Phase 2 occurred from August 2017 until October 2018, with data collection ending in August 2019. Key inclusion criteria were 18 years of age or older and foot assessment fit with International Diabetic Foot Risk Classification category 2 or 3. A key exclusion criterion was peripheral arterial disease with an ankle brachial index (ABI) less than (<) 0.8. As recruitment was slow, this exclusion criterion was adjusted to an ABI <0.7. Phase

Figure 1. Mixed Methods Model



3 was conducted in October 2019. All participants provided informed consent and ethical approval was obtained from the Health Research Ethics Authority.

Data Collection Methods

The data collection methods for this study are described in detail elsewhere.^{10,11,12} The methods relevant to this paper are the following Phase 2 measures: the foot assessment, self-report logbook data, quality of life (QoL) measure and an exit interview. The foot assessment was completed by an advanced foot care nurse at baseline, three and six months using the validated Simplified 60-Second Foot Screen.¹³ For the logbooks, all participants daily recorded their visual foot inspection and recorded their number of steps using a pedometer. The participants in the thermometer-education group also recorded their daily temperature. The return demonstration data, logbook data and exit interview results were used to determine the usability of the CAIT. To measure QoL, the Quality of Life Enjoyment and Satisfaction Short Form (Q-LES-SF) was administered at baseline, three and six months.¹⁴ After the intervention, an exit interview that included a return demonstration was completed with the Phase 2 participants.

Statistical Analysis

Descriptive statistics, t-test and Chi-square were used to summarize participants' characteristics and evaluate differences between variables. Any assessment was determined by calculating how many days a participant measured and recorded in the logbooks, either a visual inspection, temperature monitoring, or both, out of the 180 days. To determine the variables that contributed to foot assessment, logistic regression was utilized. Intent to treat approach was used for all analysis, which was conducted using Stata 14.2.

Phase 3 Methods

Phase 3 recruitment began after analyzing the Phases 1 and 2 findings. Phase 2 participants

who indicated they would be interested in a follow-up interview were contacted to participate. The decision regarding who to contact was made considering who could best answer the questions related to the Phase 2 findings that needed further explanation. For example, to gain more understanding regarding how the thermometer helped direct action, participants who took action were contacted for an interview. Nine participants completed a 30-60 minute semi-structured interview. Notes were taken during the interviews, with transcriptions of the audiotaped interviews supplementing the notes. Interpretive Description was used to analyze the data. Interpretive Description aims to address real-world clinical practice issues.¹⁵ A joint display was used to analyze the data and support data integration.

Results

Patient Characteristics: There were slightly more males than females in both groups. The average age of the participants in both groups was similar: for the thermometer and education group, the average age was 66.2 years and for the education-only group, it was 65.7 years. There was a wide age range of 38-86 across both groups. The average number of years with diabetes was similar: the mean for the thermometer and education group was 13.9 years and the education-only group was 17.9 years. There was also a wide range for the duration of diabetes, <1-54 years across both groups. There was no statistically significant difference between the groups, except for the use of insulin; 65.4% of participants in the education-only group used insulin compared to 29.4% in the thermometer and education group ($p = 0.009$). Other characteristics, such as co-morbidities, foot-risk classification and previous DFU, were comparable between the two groups (see Table 1).

Benefits of Using the CAIT: Analysis of the data showed that there were benefits to using the CAIT. One of the primary benefits was foot assessment, which was defined as either a temperature check, visual check, or both. The intervention group had more days where an assess-

Table 1. Patient Characteristics

Characteristic	Thermometer and Education % (n)*	Education-only % (n)*
Gender	Male 52.84 (18) Female 47.06 (16)	Male 57.69 (15) Female 42.31 (11)
Age in years (mean)	66.2 (range 38-80)	65.69 (range 49-86)
Marital Status	Single 8.82 (3) Married 67.65 (23) Widowed 11.76 (4) Divorced 11.76 (4)	Single 15.38 (4) Married 80.77 (21) Widowed 3.85 (1) Divorced 0
Income		
< \$20000	9.68 (3)	20 (5)
\$20,000-100,000	80.65 (25)	60 (15)
>\$100,000	9.68 (3)	20 (5)
Education (highest level completed)		
Elementary	2.94 (1)	0
High School	35.29 (12)	11.54 (3)
Post-Secondary	35.29 (12)	50 (13)
Some University	2.94 (1)	0
Degree	23.53 (8)	38.46 (10)
Comorbidities	No 11.76 (4) Yes 88.24 (30)	No 0 Yes 100 (28)
Type of Diabetes	Type 1 5.88 (2) Type 2 94.12 (32)	Type 1 15.38 (4) Type 2 84.62 (22)
Had Previous Foot Ulcer	5.88 (2)	11.54 (3)
Neuropathy	38.24 (13)	46.15 (12)
Foot Risk Classification**		
Very low	61.76 (21)	53.85 (14)
Low	2.94 (1)	11.54 (3)
Moderate	29.41 (10)	26.92 (7)
High	5.88 (2)	7.69 (2)

* % (n) is the proportion and number of participants in the thermometer and education group (n = 34) and the education-only group (n =26) who had the identified characteristics.

** Foot risk classification was based on International Diabetic Foot Risk Classification System

ment was completed (150.98 vs 119.84, $p = .02$). As shown in Figure 2, 67.7% (23) of participants in the thermometer and education group completed an assessment > 80% of the days compared to 50% (13) in the education-only group. When years with diabetes were controlled for, those in the intervention group were significantly more likely to have completed an exam >80% of the time, compared to the control group (OR: 3.54; 95% CI: 1.11 – 11.29; $p = 0.032$) $R^2 = 0.0989$. A

benefit that could be related to the increased frequency of assessment is that the CAIT prompted participants to check their feet. In Phase 3 interviews, participants shared that taking their temperature prompted a thorough visual check, raised awareness of their feet and made them feel more involved in their foot assessment. One participant discussed how recording the temperature increased the structure of her assessment. Another participant stated that it gave her more

of an acute awareness of the surface of her foot.

The Phase 2 logbook data showed that both groups took action to address foot concerns such as applying cream, wearing appropriate footwear, choosing appropriate activities, re-assessment and seeing an HCP. In the exit interviews, participants were asked whether they changed what they planned to do based on their temperature assessment. Six (22.22%) participants indicated that they rested, rechecked later in the day, went to bed earlier and decreased walking. These results were explored further in Phase 3 to understand the CAIT readings' interpretation better and how the temperature readings guided action.

Participants in Phase 3 shared that a temperature reading of < 4 degrees F provided reassurance that their feet were fine. One participant said that when the reading was < 4 degrees F, she felt she was, "good to go" and to do whatever activity she had planned, such as dancing. In contrast, a temperature of > 4 degrees F heightened concern and prompted action such as: resting, further investigating, rechecking, looking and going to see a health-care professional. For example, one

participant said that if it was > 4 degrees F, he would cancel going for a walk that day.

Another benefit was decreased callusing, which was measured by presence or absence of callusing using the Simplified 60-Second Foot Screen.¹³ The data showed that participants in both groups had reduced callusing when comparing baseline and three months. At baseline, 17.6% of the intervention group had no calluses on their left foot; this increased to 43.8% at three months, a difference of 26.2 percentage points. In the control group, the difference was 21 percentage points (from 15.4% to 36.4%). These differences were not statistically significant but were clinically meaningful (See Figure 3). The improvement was not sustained, but more participants had no calluses at six months compared to baseline.

Another benefit is that the CAIT facilitated discussion about foot health with health-care professionals. Participants were given a letter to provide to their primary health-care professional explaining the intervention and use of the CAIT. In the exit interview, 67.86% of the participants indicated that they gave their health-care profes-

Figure 2.

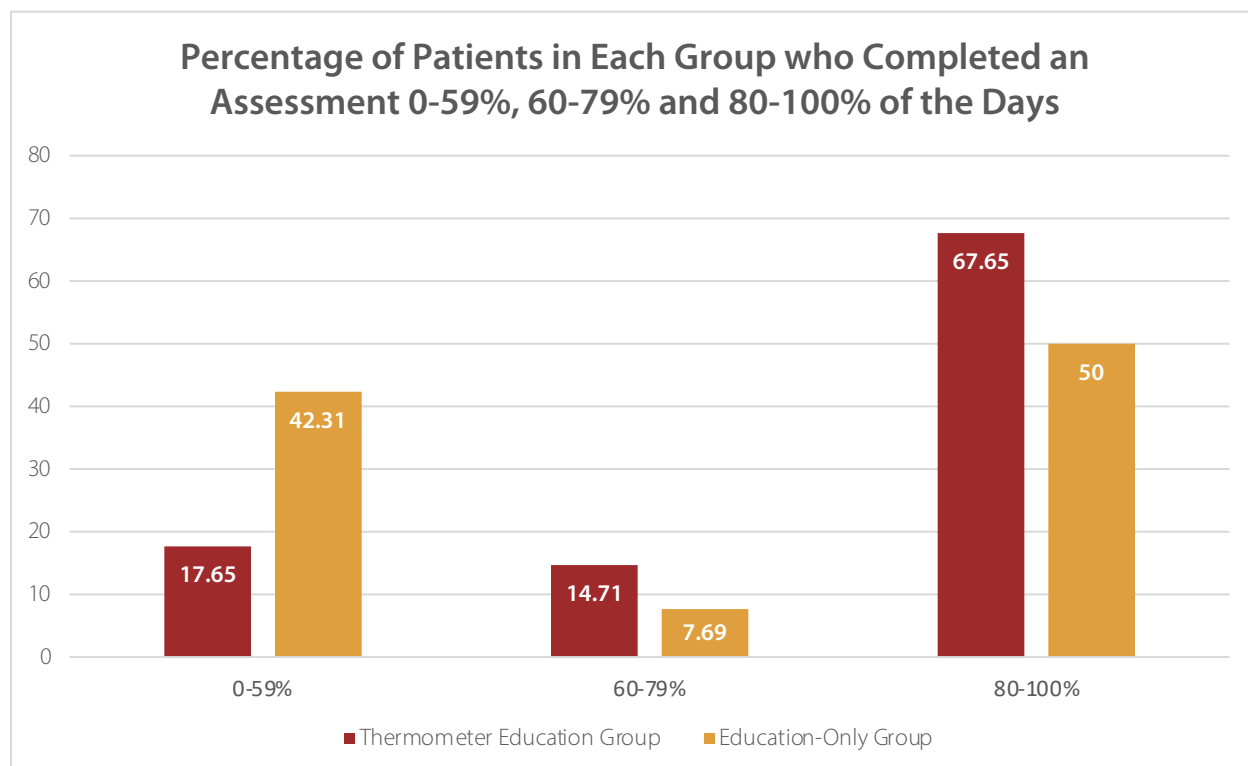
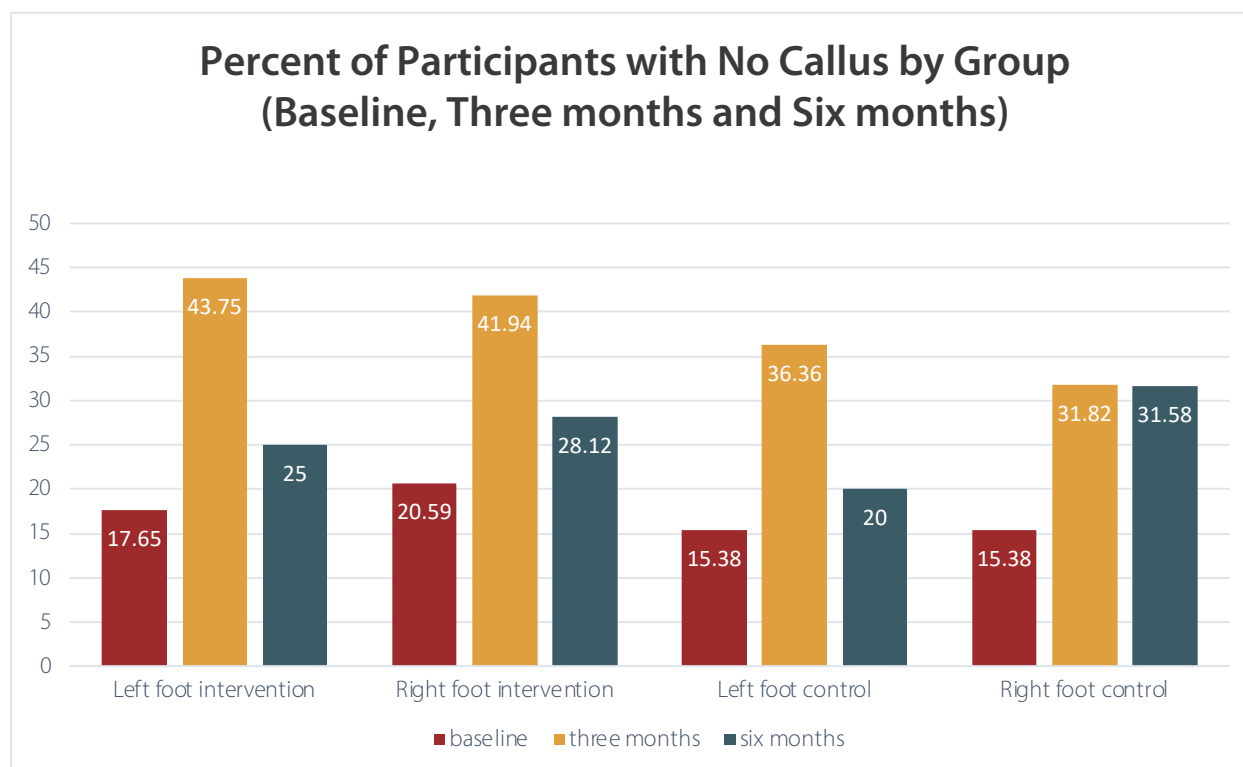


Figure 3.



sional the letter, with two stating that they did not provide the letter but told their health-care professional about the study. During the study, six participants visited their physician about their feet for various reasons (e.g., assessment, activity level, issue found during self-assessment). One of the participants shared that they went to the doctor because they were having redness and swelling, but the temperature readings were consistent (e.g., no difference in temperature).

Challenges of Using the CAIT: There were also challenges identified with using the CAIT. During Phase 2, challenges with using the CAIT were identified by the researcher and participants related to: lack of clarity regarding the purpose of the thermometer; misunderstanding of what to consider a concern and when to take action; interpreting the findings and taking action based on the assessment and the logistics of using the CAIT. Based on these findings, participants' understanding was further explored in Phase 3. When asked what information the CAIT provided, some participants in Phase 3 were clear that the CAIT helped identify inflammation or infection.

However, other answers were more vague, with one participant stating that a temperature difference would tell him he needed to rest his feet. One participant who never identified a temperature difference noted that the CAIT provided no information.

There were also issues identified in Phase 2 with participants understanding the temperature readings and taking appropriate action. Why participants did not change their activity level when measuring a temperature difference > 4 degrees F was explored in Phase 3. One participant stated that when he got a temperature difference, he would look for other reasons why his temperature would be increased, such as the room temperature. Another participant considered that he might have done something wrong when checking the temperature, resulting in an inaccurate reading. Another reason was that the foot issue was a concern but insufficient to take action: they would 'watch it'. The issue of not taking action was also related to a lack of clarity regarding what should be considered a foot concern that needed to be addressed. From all three phases

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of the study, it was found that participants were only sometimes clear on what would be a foot concern and when they should take action to see their health-care professional.

During the Phase 2 teaching sessions and the return demonstrations, the researcher noted issues related to the logistics of using the CAIT. Some participants had difficulty completing the temperature reading because of physical challenges such as flexibility, arthritis and vision loss. Using the CAIT and obtaining an accurate temperature reading required participants to complete several steps. A return demonstration during the Phase 2 exit interview showed that half the participants were using the thermometer correctly, and the remaining participants were completing only aspects of the assessment correctly (e.g., having the thermometer too far or close to the foot; incorrect settings; incorrect recording and not scanning the whole foot).

A Phase 3 participant highlighted the complexity of completing a CAIT reading when he stated:

"There were four or five things that I had to do to make sure I was taking it right. It had to be a certain distance from the foot, it had to stay on the foot. They might have been one little step that I didn't do correctly so this might be the reason it might not be giving me the correct temperature reading."
(Participant)

It was observed that several participants in the thermometer group had help from their linked support person in completing the temperature checks. This assistance may have minimized issues related to logistics and physical challenges. Participants in the intervention group with multiple sources of support did complete more days of assessment (M: 165 days) vs. spousal support alone (M:146) or family support (M:102). Similar trends were seen in the control group for multiple sources of support (M:134.2) vs. other sources (M: 89.2-121). However, no conclusion regarding causality can be drawn between the support provided and the use of the thermometer.

One potential challenge was the time

commitment to using the CAIT, as identified by one participant in Phase 3. However, she saw the CAIT as favourable and adjusted her schedule. Because we wondered if adding the thermometer to foot self-management would negatively impact QoL, we utilized the Q-LES-SF to measure QoL. There were no differences between the two groups or within groups for the QoL scores. This finding indicated that additional self-management activities did not impact the QoL of participants and thus would not be expected to discourage the use of the thermometer.

Continued Use of the Thermometer: The Phase 2 exit interview results showed that everyone in the intervention group found the CAIT easy to use. The vast majority (96.8%) indicated they would continue to use the CAIT, but 37.9% indicated that they would only use it sometimes or rarely. Furthermore, 93.1% said they would recommend the CAIT to a person with diabetes (See Table 2). Participants in Phase 2 stated they would use the thermometer to: see if there was inflammation; keep a record and have a baseline assessment; help monitor for hot spots; identify any issues and find out the difference. They also indicated they would use it because it was practical and part of their regime. Those who said they would use it sometimes indicated that they would do it to, "keep an eye on things," to see if anything was wrong, such as an infection, or if they noticed any redness or pain.

These findings were explored further in Phase

Table 2. Exit Interview Results for Thermometer Group

Question	Result % (n)*
Was it easy to use the thermometer?	Yes 100 (25)
Will you continue to use the thermometer?	No 3.45 (1) Yes 58.62 (17) Sometimes 31.03 (9) Rarely 6.90 (2)
Would you recommend a thermometer to another person who had diabetes?	No 6.90 (2) Yes 93.10 (27)

* % (n) is the proportion and number of participants in the thermometer and education group (n = 29)

- Findings suggest that the use of a CAIT is an available low-cost tool that could support foot self-management for people with diabetes.
- Using a CAIT may offer several benefits, such as promoting foot assessment and direction for action.
- Understanding possible challenges with using the CAIT and involving, as appropriate, support persons with foot self-assessment can help health-care providers strengthen patient education and foot self-management.
- Future research is needed to determine the optimal schedule and technique for CAIT assessment and to better understand decision making related to foot self-management (e.g., why patients take action or do not take action).



3 to clarify whether the CAIT was a helpful technology for participants. Five of the six participants from the thermometer and education group interviewed in Phase 3 used the CAIT since completing Phase 2. The reasons provided by participants for using the CAIT were curiosity, habit, another step in the inspection process and concern after completing the visual foot assessment. One participant said it gave her confidence in determining whether the issue she identified was serious. Two participants shared that they had a schedule for using the thermometer; one used it weekly, and another stored it with his blood pressure kit and checked it every couple of weeks. Other participants used it more sporadically, such as when they identified a concern with visual inspection.

Conclusions: It is clear from the findings that the intervention that combined education and using a CAIT supported foot self-management and offered several benefits to patients without being a burden concerning time. Participants shared that they felt more involved in their assessment and felt reassured about their foot health feet when the temperature difference was < 4 degrees F between their feet. Participants that used the thermometer were more likely to have a regular daily approach to their assessment that did not include only measuring their foot temperature but also a visual inspection of their feet; they checked their feet more frequently and identified more concerns compared to those in the control group. Considering most patients with diabetes do not regularly assess their feet,² providing a tool that supports assessment is very useful.

For a person with diabetes at risk for foot complications, taking appropriate action based on foot assessment findings is crucial. Another important benefit of using the CAIT is that it may provide information to help a person with diabetes make the best decisions for their foot health. Completing an assessment for inflammation with the thermometer and a regular visual inspection of their feet would allow patients to identify any changes that may have occurred and may prompt them to action. Although both groups took action, participants in the therm-

ometer group had more information to guide action in relation to resting. Reduced callusing was seen in both groups, suggesting that education is an important element for promoting foot self-management. There was a greater improvement in the thermometer and education group, however, which may reflect an additive benefit of using the thermometer. Lavery et al. (2004) concluded that the use of the thermometer provided patients with, "actionable information".³ (p.2646) It was suggested by Lavery et al. (2007) that using an infrared thermometer would allow patients to decide their safe activity level, similar to how a glucometer reading enables a patient to determine the correct insulin dose.⁷

Another noteworthy benefit is that the thermometer facilitated discussion with health-care professionals. Participants gave the letter about the research to their health-care professional, and some participants indicated that they saw their practitioner about their feet based on their self-assessment. Research supports that foot self-management is complex in interactions with health-care professionals. The communication between patients and the professional was identified in two studies to be an enabler and barrier. Clear communication had a positive impact on foot health practices. However, if patients had a negative experience with an health-care professional, they were more likely not to participate in positive foot health behaviours.¹⁶ It was noted that health-care professionals often did not provide information on foot care which contributed to the lack of knowledge and the perception that foot care was not critical.¹⁷ Therefore, the use of a tool like the CAIT may be an enabler and support discussions about foot health between patients and health-care professionals.

Although it was clear that the CAIT potentially offered benefits, there were several issues related to using the CAIT, such as: a lack of clarity regarding the purpose of the CAIT; the findings; not taking action based on the assessment and the logistics of CAIT use. Some participants needed clarification regarding the thermometer purpose and that a temperature difference > 4 degrees F identified inflammation that could lead to skin

breakdown. Sometimes, when participants had a temperature difference, rather than considering that there could be an issue with their feet, they looked for other reasons for the temperature increase. This reasoning may be linked to a need for more clarity regarding the purpose of the assessment.

There were also several challenges identified with the process of taking action to address the foot assessment findings. First, interpreting the visual inspection was an issue. It was apparent that some participants needed clarification about what assessment findings would be considered a concern. Most participants identified that a break in the skin was a concern that required attention. However, some participants did not view findings such as bruising and pain as a concern requiring attention and were comfortable waiting to see if these settled back to normal and whether the symptoms were transient or persistent. The decision to wait and see if a concern settled back to normal and not take action may be related to the challenge of getting a health-care professional appointment. Participants in Phase 3 highlighted this challenge. It could take a week or more for a patient to see their health-care professional. This limited access would make it difficult for patients to follow what they were directed to do: get their feet checked immediately if there was a concern. It also may be related to risk perception, a highly variable concept. The variability of the answers may reflect that people perceive risk concerning their foot health differently. Decision-making related to taking action should be explored in future research, considering behaviour modification. Furthermore, structural equation modeling should be used in future research to determine the contribution of multiple components to taking action.

The logistics of using the CAIT also presented challenges. Participants had a lot to remember when completing the temperature assessment. There were several steps to complete: having the foot up, waiting five minutes after removing the socks, having the thermometer the correct distance from the foot, ensuring the laser stays on the foot and using the correct settings. Taking the

temperature reading was more difficult for participants with physical issues such as a sore shoulder or knee. Some participants had a support person who would take their foot temperature, enabling the completion of the assessment. Participants received two return demonstrations at baseline and one-week post-enrollment in the study. However, even with this teaching, only half of the participants completed the temperature check correctly at the end of the study. These findings have implications for health-care professionals; understanding the possible challenges with using the thermometer is essential for providing effective patient education, involving support persons and regular follow-up to ensure patients complete the temperature assessment correctly.

These findings also have implications for patient education and policy. Health-care professionals should reinforce with patients what assessment findings would be a foot concern and what would be the appropriate action, whether it be waiting and watching their feet closely or seeing the relevant practitioner. Health-care professionals should stress to patients with neuropathy who cannot rely on cues such as pain that signs of inflammation may be symptoms of DFU or potential DFU.⁵ As well, the concept of teach-back should also be considered to help identify a knowledge gap. Teach-back is a technique that can be utilized to see if the health-care provider was clear in their explanation and if patients have understood all the concepts that were conveyed. This strategy has been shown to be effective in chronic disease management.¹⁸ Incorporated into this approach could be two key messages: what are foot concerns and when should a patient see their health-care professional. Concerning the thermometer, if patients use the CAIT as an assessment tool, their process of completing the measurement should be evaluated regularly by a health-care professional to ensure it is being performed correctly and to explore options for addressing any challenges.

The CAIT may be a tool that could be used on a long-term basis for foot self-management as participants reported that it was easy to use, they would recommend the thermometer to

other patients with diabetes and they would continue to use the thermometer. Although many participants said they would continue using the CAIT, it would not be daily. Although patients would not use it daily, they still benefited from using the CAIT as it supported completing a visual assessment. More research is needed on the optimal schedule for a foot assessment, including temperature monitoring and the role of the support persons in supporting use of this tool as part of self-management. Until this gap is filled, health-care professionals should continue recommending and supporting daily foot assessments.

A strength of this MMR research is that it is the first study to assess using a CAIT from the patients' perspective concerning usability, challenges and benefits. Another strength relates to intervention integrity. All Phase 2 participants had their feet assessed by an advanced foot care nurse and one researcher provided the education. Using sophisticated data analysis was also a strength, as logistic regression allowed for the control of confounding variables. A limitation of this study relates to using a six-month intervention. The long-term impacts of the intervention may have been better understood with a 12- or 18-month intervention. As well, the daily logbook data was a limitation as some participants did not always fill in the information. Another limitation was the small sample size in the RCT. Although, differences were not statistically significant they may be clinically meaningful.

To prevent foot complications, it is recommended that patients with diabetes complete a daily visual inspection of their feet to identify a concern and take action to address the issue. However, often patients do not complete this inspection regularly and due to nerve damage, many patients cannot identify the signs of inflammation. Findings from this study indicate that the CAIT is a promising low-cost tool that offers several benefits related to completing and prompting a regular assessment and direction for action, improving the condition of the skin and facilitating a discussion about foot health with health-care professionals. There were challenges identified with use of the CAIT, such as

lack of clarity regarding the purpose of the tool, taking appropriate action based on the temperature reading, logistics with using the CAIT and the time commitment. Even with the additional time commitment, we did not find there was an impact on the QoL of participants. Overall, our findings show that a CAIT is an available and affordable tool that supports foot self-management. Understanding the patient perspective in relation to benefits, challenges and usability has implications for patient education and follow-up by health-care professionals. 📱

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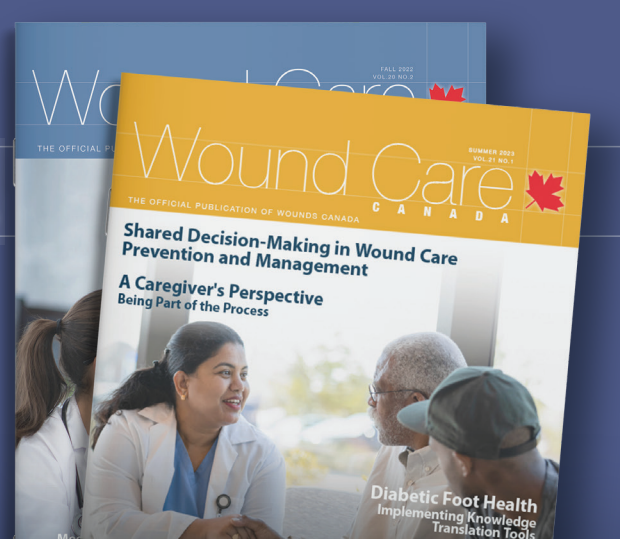
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