

The Pairing Of Patient-Oriented Research And Mixed Methods Research For Prevention Of Foot Complications Related To Diabetes: An Exemplar

Kathleen Stevens RN PhD, **Donna Moralejo** RN PhD, **Steven Ersser** RN PhD
and **Cathy MacLean** MD

Abstract: With increasing prevalence of diabetes and diabetic foot ulcers worldwide, practical interventions that are patient-centred are needed to prevent foot complications. In this article, we describe how we used patient-oriented and mixed methods research, using an exploratory and explanatory mixed methods sequence, to develop and test an education and infrared thermometer-based intervention to prevent foot complications for patients with diabetes. We argue that instead of employing a randomized controlled trial alone, the pairing of these methodological approaches offered more. We learned not only that, but also how the thermometer supports foot self-management. Pairing patient-oriented and mixed-methods research offers many benefits for developing and testing effective and practical interventions and can provide pertinent information to clinicians and policymakers for practice and policy.

Key words: *diabetic foot complications, prevention, thermometer-based intervention, patient-oriented research, mixed methods research.*

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Background And Purpose

The incidence and prevalence of diabetes is increasing worldwide, resulting in an increase in the number of people who are experiencing foot complications that can lead to diabetic foot ulcers (DFUs) and amputation.¹ With these increases, the global burden is high and impacts both individuals and health-care systems. Prevention of foot complications is critical, as stressed in the recently released *2023 International Working Group on the Diabetic Foot (IWGDF) Guidelines*. Research evidence is needed to develop and test practical interventions that meet patients' needs, thus guiding policy and practice regarding the most cost-effective interventions to prevent DFUs and amputation.² A randomized controlled trial (RCT) is an appropriate design to test how well an intervention

works, and attention is paid to methodological rigour. However, more is needed because an RCT may not capture why the intervention is working or why it is not working. Therefore, researchers need to know more about patient circumstances and the local context to help explain results. In our experience, patient-oriented research (POR) and mixed methods research (MMR) are methodological approaches that will help fulfill this research mandate.

Designing patient-oriented interventions would allow researchers to identify potential issues and address these as part of the intervention to ensure research is relevant to patient needs. POR is, "a continuum of research that engages patients as partners, focusses on patient-identified priorities and improves patient outcomes."³ The patient

is defined as a person, family member, or friend who has experience with the health issue.³ Funding agencies in several countries promote POR, including the Canadian Institute of Health Research's Strategy for Patient Oriented Research in Canada, the Patient-Centered Outcome Research Institute in the United States and the National Institute for Health Research's INVOLVE in the United Kingdom.

MMR is an approach that can help operationalize POR and ensure that practical interventions are developed and tested. In MMR, quantitative and qualitative data are collected and integrated; the qualitative data might inform an intervention or a quantitative evaluation or might explain results obtained in the quantitative phase. Integrating both sets of data provides more comprehensive evidence and a better understanding of the research problem than could be obtained from qualitative or quantitative data alone.⁴

In this article, we will discuss the results of an MMR study to illustrate how using MMR and POR to develop and test an intervention provided benefits that would not have been gained through only one approach or an RCT alone. We will show how pairing these two approaches offers substantial

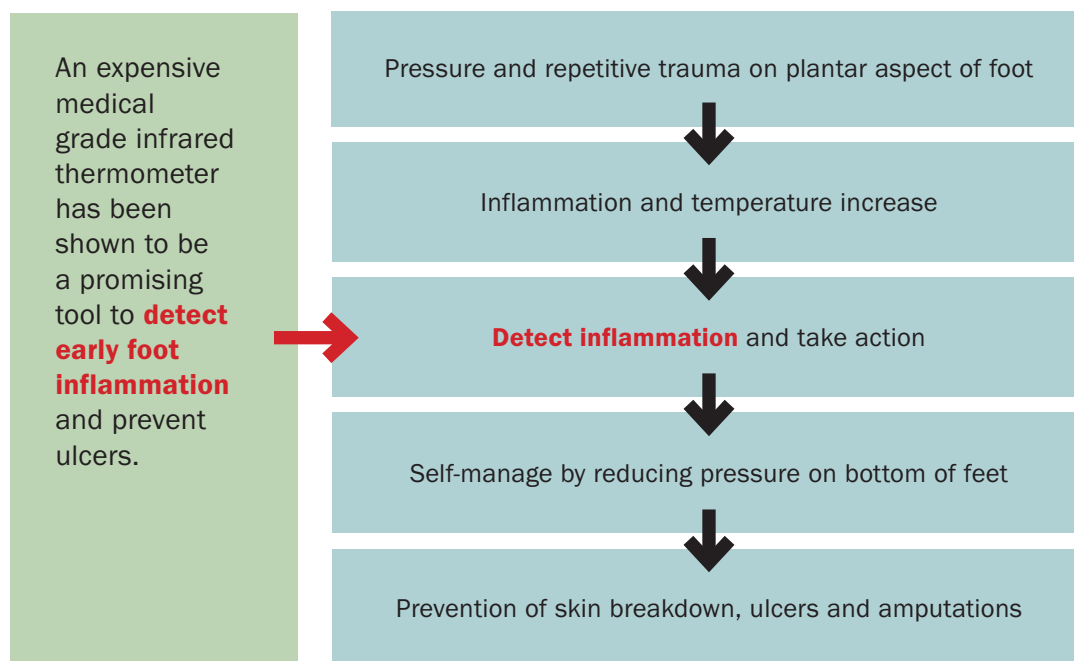
benefits for testing practical and patient-centred interventions. First, we will provide a brief overview of the exemplar study background and method. Next, we will give specific examples showing the benefits of using MMR and POR.

Overview Of The Exemplar Study

The exemplar study is an MMR and POR study that we conducted focused on developing and testing a foot self-management intervention for patients with diabetes. Self-management is defined as, "the ability of individuals and or their caregivers to engage in the daily tasks required to maintain health and well-being or to manage the physical, psychological, behavioural and emotional sequelae of a chronic disease based on the knowledge of the condition, its consequences, and the plan of care co-developed with their health-care team."⁵

To help prevent DFUs and amputation, as health-care providers (HCPs), we need to promote self-management strategies with our patients that both prevent skin breakdown and detect early signs of skin breakdown, so actions can be taken to prevent deterioration. Skin breakdown is caused by pressure and repetitive stress on the bottom of the foot, leading to inflammation. If patients do not detect the inflammation, and thus do not take action, skin breakdown can result.⁶ A temperature difference greater than 4 degrees Fahrenheit (F) or higher between the left and right foot indicates inflammation.⁷ If patients know they have inflammation, they can rest or remove sources of pressure

Figure 1: Prevention of Plantar Skin Breakdown and the Infrared Thermometer. This figure illustrates the process of plantar skin breakdown and how the thermometer can detect inflammation.



until the inflammation decreases. As shown in Figure 1, using an expensive \$700 infrared thermometer is a promising self-management strategy that patients can use to detect early foot inflammation and prevent ulcers.^{8,9,10} A commercially-available infrared thermometer that costs between \$30 and \$100 was validated against the medical-grade thermometer but had yet to be widely tested in practice.¹¹ [Editor's note: all costs in CDN dollars.]

Based on the research literature available at the time of the study, it would have been appropriate for us to conduct an RCT and evaluate the commercially-available infrared thermometer in practice. An RCT would have told us about the effectiveness of the thermometer. However, we know that foot-self management is complex and impacted by many factors, such as knowledge of diabetes and foot health self-management, as well as physical abilities.^{12,13} The addition of daily thermometer readings needed to be understood in the wider and local context and was best explored using POR strategies and qualitative and quantitative data that could be collected using an MMR design. Therefore, we designed and conducted an MMR and POR study and received ethics approval from the Newfoundland and Labrador Health Research Ethics Authority. Further details about the methods and results of the study are described elsewhere.^{14,15,16}

The research questions we addressed were:

1. What are the issues related to self-management of feet?
2. Does a foot health intervention that utilizes a commercially-available infrared thermometer improve foot outcomes?
3. What are the participants' experiences with foot health self-management and the intervention?

To best answer these questions, we designed an MMR study to support developing and testing an intervention that attempted to address the multiple factors impacting self-management and foot health. The MMR study had three phases with exploratory and explanatory sequences. Sequential designs intend to build one stage on the other.⁴ In Phase 1, self-management was explored and

semi-structured interviews were completed with 12 patients, nine health-care providers and four support persons. The interviews were analyzed using Interpretive Description. The exploratory sequence involved using Phase 1 results to inform the development of a multi-modal intervention; this was the first point of integration in the study. The intervention was then tested using an RCT (Phase 2).

In the RCT, the intervention group (n = 34) received foot education and a thermometer to assess foot temperature, while the control group (n = 26) received foot education only. Participants monitored their feet and completed daily logbooks for 180 days. Phase 2 exit interviews were conducted with all participants, then, following completion of the RCT, Phase 3 semi-structured qualitative interviews were conducted with some Phase 2 participants (N = 9). The interviews focused on Phases 1 or 2 findings that we determined required further explanation. The explanatory sequence involved the integration of results from all phases (i.e., the second point of integration).

POR Methods And Value

The MMR was also patient oriented. We invited a support person for a patient with diabetes and a patient with neuropathy to join the research team. These patient representatives contributed in several important ways. They reviewed the findings of Phase 1 and provided feedback that ensured we were capturing the themes. This feedback also helped inform the intervention and both patient representatives participated in a pilot education session before the start of Phase 2. Their feedback was very valuable. For example, they provided feedback on whether the PowerPoint presentation was clear and covered all the information that would be helpful to patients. Several revisions were made to the content and slides based on their suggestions. Another meaningful way that the patient representatives contributed to the study was by providing advice regarding locations for recruitment and recruitment materials such as the poster and pamphlet used in Phase 2. Finally, the representatives reviewed a draft of the research report

and provided feedback that was incorporated into the final version.

Illustrations Of The Value Of MMR

Examples from the Exploratory Sequence

Several examples from the exploratory sequence illustrate the value of MMR. The findings from Phase 1 reinforced what we knew from the literature regarding how complex self-management and foot health are for patients. Specifically, Phase 1 findings identified the personal challenges patients experienced and the system barriers they encountered concerning foot self-management. We also learned about their educational needs and what resources patients considered to be a support. These findings and the feedback from the patient representatives helped us understand the factors impacting self-management and informed the intervention, which we tested in Phase 2. In Table 1, we summarize the results from the first point of integration, i.e., how the findings from Phase 1 impacted the intervention and RCT (Phase 2). We will explore these examples in the following paragraphs, including validation of the additions based on the Phase 2 and Phase 3 interviews.

Addition of a Comprehensive Education

Component: In the initial planning of the study, we decided that an educational component would be incorporated into the intervention that focused on caring for feet with a diagnosis of diabetes. The findings from Phase 1 reinforced our decision but also highlighted that patients had a limited understanding of the prevalence of diabetes, how diabetes impacted feet, what a diabetic foot

ulcer was, and how they occurred. As a result, we incorporated this content into the education component that was delivered to both groups. The education component was piloted with the patient representatives and we further refined it based on their feedback. Notably, in the Phase 2 exit interviews, most participants thought the education they received was one of the best components of the intervention.

Addition of a Mirror: Another critical Phase 1 finding that stood out was that patients had difficulty reaching and examining the bottom of their feet due to co-morbidities such as arthritis. To address this problem, we provided participants in both the intervention and control groups with an inexpensive long-handled mirror purchased at a hardware store and used for visualizing engines. The mirror could be angled to help visualize different parts of the foot and had a telescopic handle. The participants also had the option of turning on a small light built into the mirror to aid in examining their feet. In the Phase 2 exit interviews, some participants shared that the mirror was one of the best parts of the intervention. We noted during Phase 3 that this was a tool some participants continued to use.

Critical Role of Support Persons: Phase 1 results reinforced the critical role of the linked support person in supporting self-management for some patients. Based on this, we invited and encouraged support persons to attend the education session and assist the participants with their assessments and data collection. As the study progressed, we noted the important role of support persons in encouraging foot self-management and

Table 1: Exploratory Sequence: The Impact of Phase 1 Findings on the Intervention and Randomized Controlled Trial Method (Phase 2)

Findings from Phase 1	Integration of findings and impact on intervention and Randomized Controlled Trial method (Phase 2)
1. Patients had limited knowledge of diabetes and foot health and care of feet.	1. A comprehensive education component was included as part of the intervention.
2. Patients had difficulty assessing the bottoms of their feet.	2. A mirror was provided to each participant.
3. Support persons played an important role in self-management.	3. Support persons were encouraged to attend the education session.
4. Patients had varying degrees of readiness to make changes and self-manage.	4. A questionnaire was incorporated into data collection to measure readiness for change.

completing the daily foot assessments for some participants.

Measure of Readiness: Finally, the analysis of the interviews from Phase 1 showed us that, in general, patients had varying degrees of readiness to make changes related to diabetes self-management. Based on this finding, we recognized that this was a potential factor influencing self-management of foot health; therefore, we decided to add a measurement of readiness to baseline Phase 2 data collection. Although validity and reliability were not established, this tool was based on the Transtheoretical Model. It was used successfully in a research study related to diabetes education to categorize patients into a stage of change.¹⁷ Results related to this measure are discussed in a later section.

Examples from the Explanatory Sequence

Interviews were conducted in Phase 3 to help us further understand the findings from Phases 1 and 2. Findings from all three phases were analyzed in relation to one another and the data was assessed for three possible outcomes: *confirmation*, *expansion* and *discordance*. *Confirmation* occurs when the findings from one phase confirm the findings from another phase. This similar conclusion provides greater credibility to the results. *Discordance* occurs if the qualitative and quantitative findings are inconsistent or disagree with each other. Finally, *expansion* occurs when the findings from the phases diverge and expand the understanding of the concepts of interest.¹⁸ We did not identify any occurrences of discordance when considering Phase 1 and Phase 2 findings. Any instances of confirmation between Phase 1 and Phase 2 were not explored further in Phase 3. In Phase 3, we focused on expansion because several findings were identified that we wanted to know more about. Table 2 shows a selection of Phase 1 and 2 findings that we explored further in Phase 3 and the data collection results. We will discuss these findings further below.

Thermometer and Foot Assessment:

Participants in Phase 1 interviews felt that the thermometer could be helpful. Analysis of the data from Phase 2 showed us that there was a significant difference between participants in the

intervention and the control group regarding the completion of any foot assessment. However, we noted mismatched reporting in the logbooks, with participants in the intervention group recording completion of the temperature reading an average of 150 out of 180 days and only recording completion of the visual assessment an average of 114 out of 180 days. It was unclear to us whether participants were only completing the thermometer assessment on some days or whether the thermometer and visual assessment were completed together and this was an issue of recording. We learned in Phase 3 that the thermometer and visual assessments went ‘hand in hand’ and participants were looking at their feet when they completed the temperature assessment, even though they did not record it. Along with this explanation, we gained greater clarity into the participants’ experience with the thermometer. We learned that using the thermometer prompted a visual assessment, provided structure to the foot assessment, made the participant feel more involved in their foot self-management and provided reassurance or increased vigilance related to their foot health, depending on if the temperature difference was greater or less than 4 degrees F.

Understanding a Foot Concern and Taking

Action: It was apparent from the Phase 1 interviews that participants lacked understanding related to what a foot concern was and what the appropriate action would be. As a result, we included various foot concerns and the appropriate action in the Phase 2 teaching session. An analysis of the logbooks in Phase 2 showed that participants would record a concern but did not indicate that they took action to address the concern. As well, we noted discrepancies regarding what was considered an action. For example, some participants considered putting cream on their feet as taking action, while others used cream and did not record this as an action. Phase 3 findings showed that participants clearly understood that a break in the skin was a concern and were able to identify some other assessment findings that would constitute a concern. Concerning action, a break in the skin was a concern that would prompt them to see their HCP. However, with other concerns, such as

Table 2: Explanatory Sequence: Examples of Integration Across the Three Phases

Phase 1 findings (N=24)	Phase 2 findings (N=62)	Goal of Phase 3	Phase 3 findings (N=9)
1. Participants thought that the thermometer would be a useful tool.	Number of days with any foot assessment: intervention vs. control group (150.98 vs. 119.84, p = .02). For intervention group: Temperature reading completed out of 180 days (M = 150, SD = 43) Foot assessment completed out of 180 days (M = 114 days, SD = 64).	To explain the connection between the thermometer and visual foot assessment.	Participants indicated the thermometer: • prompted looking at feet • provided more structure • made them feel more involved • provided reassurance when the temperature difference was < 4 °F and heightened vigilance when it was > 4 °F.
2. Participants were unsure about what would be considered a concern.	Mismatched reporting in relation to the foot assessment. For example, number of days with a concern often did not equal the number of days of action; discrepancy about what was viewed as an action.	To explain participants' understanding of a concern and why they did or did not take action.	Breaks in the skin were a concern that participants would have assessed right away by an HCP. Participants would wait to see if 'things settled back' for findings such as pain, tenderness, colour change, and bruising. A temperature difference > 4 °F was considered a concern for only some participants in the intervention group.
3. There was a continuum related to patient readiness to not only manage foot health, but to self-manage diabetes in general.	Stages of change • Precontemplation: 1.67% (1) • Contemplation: 5% (3) • Preparation: 16.67% (10) • Action: 36.67% (22) • Maintenance: 40% (24). Changes made to diabetes management during study: Intervention group: 58% Control group: 50%.	To explain more about readiness and foot self-management.	Participants from the preparation, action, and maintenance stages were interviewed. All were interested in finding out more about diabetes management regardless of stage of change.

pain and tenderness, they were willing to wait and see if these issues settled back to normal.

Readiness to Manage Foot Health: As discussed previously, we found in Phase 1 that there was a continuum of readiness to self-manage diabetes

and we added a measurement of readiness to the Phase 2 data collection. As shown in Table 2, we found in Phase 2 that most participants were in the action and maintenance stage, and over half of the participants made changes to their dia-

What is already known about this topic?

- The number of people with diabetes is increasing and health-care providers need effective interventions that prevent diabetic foot ulcers and amputations and guide policy and practice.
- Consequently, researchers need to focus on developing and testing practical interventions that meet patients' needs.
- To ensure research is relevant to patient needs, several large research funding agencies are promoting patient-oriented research.

What does the paper add to the literature?

- We argue that researchers can use mixed methods research to operationalize patient-oriented research and develop and test patient-centred interventions to address the prevention of diabetic foot ulcers and amputation.
- To illustrate this argument, we share our experience of pairing patient-oriented and mixed methods research and how this resulted in developing and testing a patient-centred foot self-management intervention for patients with diabetes.
- The pairing of these two approaches provided benefits that would not have been gained through using only one approach or a randomized controlled trial alone.

betes management during the six-month pilot RCT. Based on this analysis, we decided that the concept of readiness to self-manage foot health required further explanation. Therefore, in Phase 3, we interviewed participants from the preparation, action and maintenance stages. The findings showed that regardless of the stage of change, participants were interested in learning about managing diabetes and were open to making changes.

Discussion

When we reflected on pairing these methodological approaches, the benefit gained from utilizing POR and MMR was clear. With the exploratory sequence, we were pleased that we added to the intervention, as data collected during the exit interviews for the RCT (Phase 2) and Phase 3 confirmed that these changes strengthened the intervention. For example, in the exit interview for Phase 2, most participants indicated that the education provided and the awareness they developed about their foot health were the best parts of the strategy, while other participants identified the mirror as one of the best parts of the intervention. Some Phase 3 participants indicated they were still using a mirror. Several spouses attended the Phase 2 education session and were involved in helping the participants throughout the study.

Overall, the pairing of MMR and POR adds to the literature in several areas and these advances would not have been achieved through employing only an RCT. We gained a new understanding of the importance, for many participants, of comprehensive education and the fact that patients may still need help to identify and take appropriate action for foot concerns even with education. We also learned how using a mirror and including a support person were important for some participants. Although these strategies may not be considered novel, these findings expand our understanding of the potential positive impact on patients when used as part of a foot self-management intervention. The clinical implications of these findings are that it is important to discuss foot health needs with patients, individualize plans of care and reinforce foot assessment education.

Completing the explanatory sequence (Phase 3) was valuable because it helped us understand and gain further clarity about the results of Phases 1 and 2. The findings also expand knowledge related to the use of the thermometer. Prior studies that used an RCT found a decrease in DFUs but did not explore patients' experiences using infrared thermometry.^{8,9,10} Through exploring these experiences, we learned not only that, but also how, the thermometer supports foot self-management. However, because we conducted Phase 3, we now

better understand the extent of the value of using the commercially available infrared thermometer. Specifically, we have learned that participants felt it prompted foot assessment, provided reassurance about the assessment results and directed action. Further, POR and MMR research is needed with longer follow-up (i.e., > six months) to validate these findings and assess the optimal scheduling for taking temperature measurements and the long-term use of the thermometer.¹⁶

Another area these findings contribute to is readiness to self-manage foot health in patients with diabetes. A lack of research has caused readiness to change to be considered a predictor of diabetes foot self-management. The results of this study suggest that the stage of change may not indicate whether patients consider new information and explore making changes to their self-management. Regardless of the stage of readiness, participants were still interested in exploring changes to improve their diabetes management. As they do need to manage their diabetes and foot health, they need knowledge and skills to do so, even though the learning curve is steep. Further research about readiness and self-management is warranted.

We did experience some common challenges with taking an MMR approach: skills and time.⁴ Researchers need knowledge and skills of patient-oriented research, quantitative methods, qualitative methods and how to integrate the findings. Individual researchers do not need all skills; instead, they should establish a research team whose members contribute the relevant skills to the collaborative whole. Also, the time it takes to conduct a study such as this can be challenging for all team members. With MMR, time is required to collect and analyze two different types of data and then integrate this data.⁴ The use of POR prolongs the time required for the study to enable the involvement of the patient representatives.

Conclusion

In this paper we discussed the development and testing of an intervention informed by POR and MMR and the associated clinical and research implications. This discussion extends knowledge

about the value of pairing these methodologies and contributes to knowledge related to diabetes and foot self-management. Research that is patient-oriented is vital to ensure that interventions that are real-world and practical are developed and tested. MMR provides an effective methodological structure for POR. We encourage all HCPs, when reviewing POR and MMR studies, to recognize and appreciate the value and insight gained when these two methodologies are used. Considering the benefits highlighted with our study, we also encourage researchers to consider the pairing of MMR and POR as it offers many benefits for developing and testing all types of interventions for different populations. The findings of this research can provide pertinent information to HCPs and policymakers for practice and policy. ■

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Declaration of Conflicting Interest

The authors declare that there is no conflict of interest.

Kathleen Stevens* RN PhD is an advanced foot care nurse and Assistant Professor at Memorial University Faculty of Nursing, St. John's NL, Canada.

Donna Moralejo RN PhD is a Professor at Memorial University Faculty of Nursing, St. John's NL, Canada.

Steven Ersner RN PhD is a Professor of Nursing and Dermatology at Bournemouth University, Poole, United Kingdom.

Cathy MacLean MD is a Professor and Director of Faculty Development for the College of Medicine at the University of Saskatchewan, Saskatoon SK, Canada.

*Correspondence should be directed to kathleen.stevens@mun.ca

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