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RESEARCH

# Plan for Scale Out: Adapting a Diabetes Prevention Program for Implementation in Rural and Remote British Columbia

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## Abstract

**Background** Rural and remote communities in Canada face a higher incidence and risk of developing type 2 diabetes (T2D) compared to urban populations (Government of Canada SC, 2022). *Small Steps for Big Changes* is an evidence-based diabetes prevention program designed to support individuals at risk of T2D in adopting and maintaining sustainable changes to their diet and exercise through the application of behavior change techniques. To expand the reach of *Small Steps for Big Changes* and address the significant gap in T2D prevention resources in rural and remote communities, the program was scaled out to rural and remote community organizations across British Columbia. The aim of this study was to describe the process used to scale out *Small Steps for Big Changes* and to identify the program and implementation strategy (IS) adaptations made during the pre-implementation phase to support delivery.

**Method** Adoption rates were analyzed and reported according to the adoption dimension of the RE-AIM (*Reach, Effectiveness, Adoption, Implementation, Maintenance*) framework (Glasgow et al., *Am J Public Health* 89(9):1322–1327, 1999 Sep) to describe the proportion of settings willing to deliver *Small Steps for Big Changes*. Data on adaptations were extracted from meeting notes and email correspondence. Adaptations to IS were identified by comparing these data to IS used in a previous *Small Steps for Big Changes* implementation project. All adaptations were deductively coded by two independent coders using the *Framework for Reporting Adaptations and Modifications to Evidence-Based Interventions* (S, Wiltsey Stirman et al., *Implement Sci* 14(1):58, 2019 Jun 6) and the *Framework for Reporting Adaptations and Modifications to Implementation Strategies* (CJ Miller et al., *Implement Sci* 16(1):36, 2021 Apr 7).

**Results** Three organizations in the Interior and two in the Northern region of British Columbia adopted *Small Steps for Big Changes*, representing adoption rates of 23% and 22%, respectively. Twenty-seven program adaptations were made with a primary goal of improving program oversight and quality improvement. 15 implementation strategy adaptations were identified and an additional 15 implementation strategies were added to support scale-out in attempts to improve reach, adoption, acceptability, or fidelity of the program.

**Conclusion** These findings can inform targeted implementation efforts and guide decisions about scaling diabetes prevention programs, such as S*mall Steps for Big Changes*, into diverse community settings.

**Keywords** Prediabetic state · Diabetes mellitus · Type 2 / prevention & control · Health plan implementation · Evidence-based practice · Community health services · Health promotion

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## Introduction

Type 2 diabetes (T2D) is a serious chronic health condition characterized by impaired insulin function and elevated blood glucose levels [1]. Its incidence continues to rise globally [1], despite strong evidence that it is preventable [2, 3]. In Canada, diabetes affects approximately 5.7 million people and is associated with annual healthcare costs of approximately $29 billion [4]. An additional 6 million Canadians are living with prediabetes [4], with up to 70% expected to progress to T2D within 10 years without intervention or changes to health behaviors [5]. Together, these trends underscore the urgent need for effective prevention programs.

The burden of T2D is disproportionately higher in rural and remote communities in Canada compared to urban populations [6]. This elevated risk is largely driven by health disparities, including overlapping social, environmental, and healthcare access challenges [7, 8]. In British Columbia, residents of rural and remote areas face significant barriers to accessing diabetes prevention support [9]. In recognition of these inequities, the *Framework for Diabetes in Canada* emphasized strengthening diabetes care capacity in rural and remote communities through tailored practices and accessible tools [10].

*Small Steps for Big Changes* is an evidence-based diabetes prevention program designed to support individuals at risk of T2D in adopting and maintaining sustainable changes to their diet and exercise through the application of behavior change techniques [11]. *Small Steps for Big Changes*was initially implemented in three urban community settings beginning in 2017. In these settings, SSBC participation was associated with weight reduction and improved glycemic outcomes, with 42% of participants reporting normoglycemia at 12 months post program [11].

To address the gaps in access to diabetes prevention services, *Small Steps for Big Changes* was scaled out to rural and remote community organizations across British Columbia. In implementation science, "Scale out" refers to the process of expanding an evidence-based intervention (EBI) to a new population, setting, or delivery system distinct from previous implementations [12]. While scaling out is critical for reaching underserved populations and achieving population-level impact [12], interventions developed in urban contexts often require intentional adaptation to ensure feasibility, acceptability, and effectiveness in rural and remote settings, which differ in population density, healthcare access, infrastructure, and sociocultural context [13].

Successful scale-out of an EBI requires a structured process that considers the needs of the target population, the delivery setting, and implementation infrastructure, while preserving the intervention's essential functions [12, 14]. This process requires engagement from the community organization to truly understand local needs and improve the salience of modifications [15, 16]. While it is important to carefully consider adaptations across all implementation phases, adaptations to intervention components and implementation strategies (IS) should begin to be addressed during the pre-implementation planning phase. [12, 17]. Pre-implementation refers to a critical initial stage of implementation that examines and addresses the contextual conditions necessary for successful delivery of an EBI [18, 19]. This phase relies on input and engagement from multiple partners and involves consideration of factors such as fit, resources, needs, and capacity to implement [19].

Systematically documenting adaptations to EBIs is critical for understanding how implementation processes and strategies contribute to intervention effectiveness [14] and sustainability [20]. However, such reporting of EBI and IS modifications has historically been limited in scale-out research [21]. To address this gap, the *Framework for Reporting Adaptations and Modifications to Evidence-Based Interventions* (FRAME) [14] and *Framework for Reporting Adaptations and Modifications to Implementation Strategies* (FRAME-IS) [22] were developed to provide structured approaches to characterize what was modified, why modifications were made, who was involved in decision-making, and how the changes relate to fidelity of the intervention and its core functions [14, 22]. To ensure that *Small Steps for Big Changes* was tailored to the local context of these rural communities, where diabetes prevention resources are limited, adaptations were made to both the program, and it's IS during the pre-implementation planning phase of the project. The FRAME and FRAME-IS were used to characterize these modifications. This study aimed to describe the process used to scale out the EBI *Small Steps for Big Changes* program and to identify the program and IS adaptations made during pre-implementation to support delivery in five rural and remote communities in *British Columbia*.

## Methods

### Positionality

As researchers, we recognize our role as collaborators working alongside the rural and remote communities where *Small Steps for Big Changes* was implemented. This positionality influenced how we engaged with site leaders, interpreted adaptations to the program and its IS, and reflected on contextual factors shaping both adoption and pre-implementation efforts. Grounded in a pragmatic research paradigm, our approach emphasized practical relevance, responsiveness to

community needs, and the co-existence of multiple forms of knowledge, including community and research perspectives. We acknowledge that this research was conducted on the traditional, ancestral, and unceded territory of the Syilx, Lheidli T'enneh, Sinixt, and Saik'uz Nations.

## Small Steps for Big Changes

*Small Steps for Big Changes* is an evidence-based program that supports individuals at risk of T2D in making and sustaining changes to their diet and physical activity using a client-centered approach and established behavior change techniques [11]. The program is brief, consisting of six one-hour, one-on-one sessions over one month with a trained coach. Sessions include discussions on diet and physical activity and goal setting, followed by supervised exercise. The program has demonstrated success on health-related outcomes [23–26] and has been described previously (see [11] for full details). *Small Steps for Big Changes* was implemented in urban community settings in British Columbia beginning in 2017, where it was delivered by trained YMCA staff without prior specialized education or healthcare experience [27]. A 1-year pre-implementation phase was conducted with the YMCA of Southern Interior British Columbia to support translation of the program into community implementation settings resulting in the development of IS. These strategies were in alignment with organizational priorities and emerged from areas identified for successful implementation, including program fidelity, training, ongoing support and consistent communication between the research and delivery teams. IS were defined and documented in accordance with Expert Recommendations for Implementing Change (ERIC) framework [28] and have been previously published [29].

## Identifying Partners

Research assistants conducted a community scan of the Northern and Southern Interior regions of British Columbia to identify rural and remote communities as potential *Small Steps for Big Changes* implementation sites. Communities were classified as remote and rural using criteria from BC's Rural Practice Subsidiary Agreement and Health System Strategy [30]. This scan gathered information on population size, the presence of blood requisition clinics for possible referrals, the availability of community liaisons (e.g., nurse practitioners or diabetes educators), and potential host facilities, including infrastructure and staff contact information. These details were not eligibility criteria but allowed the research team to get a better understanding of the community context before initiating implementation.

Following the scan, initial meetings between the research team (the Principal Investigator and Project Coordinator) and community facility contacts were held via Zoom. During these meetings, the research team provided an overview of the S*mall Steps for Big Changes* program, available grant funding, and the general implementation steps and timeline. Sites interested in adopting the program signed a service agreement and were asked to designate a "Site Lead" to champion the program and participate in regular meetings with the research team throughout the implementation phases. Each community organization designated staff to be trained as *Small Steps for Big Changes* coaches to deliver the program to clients. These staff were given access to the online coach training modules and their progress through the asynchronous modules were monitored through a tracking spreadsheet by the research team.

## Data Collection

The pre-implementation phase included two one-hour meetings per month over a minimum of three months, equating to six planning sessions with community partners. The primary aim of these meetings was to review, discuss, and adapt program content and IS in collaboration with the site lead and/or senior leadership staff from each community facility. Adaptations were defined as "a thoughtful and deliberate alteration to the design or delivery of an intervention, or an implementation strategy with the goal of improving its fit or effectiveness in a given context" [14, 22]. Proposed adaptations were reviewed weekly in internal research team meetings and strategies were developed for implementing the suggested changes. During each of these meetings, detailed notes were taken by a research team member documenting all proposed modifications and decisions. Emails including these details between research team members and partners were also retained for analysis. Adaptations to program content made during pre-implementation were extracted from meeting notes and saved email correspondence and transferred to an Excel spreadsheet by KB that was then used for coding.

Several actors were involved in the implementation and scale-out of *Small Steps for Big Changes* with distinct but complementary roles. The *research team* was responsible for securing grant funding and leading implementation of the program in collaboration with community partners. The *research team* comprised the Principal Investigator (PI) who provided overall project oversight; research assistants, who supported various pre-implementation activities; a designated project coordinator who led the pre-implementation process and served as the primary point of contact between the research team and community partners; and a data manager who provided direct technical support during pre-implementation and oversaw data collection.

*Community organizations*, also referred to as the *delivery team*, adopted and delivered the program and were a key part of the pre-implementation team collaborating to adapt *Small*

*Steps for Big Changes* to their local contexts. The *delivery team* included *Small Steps for Big Changes* coaches who were trained to deliver the program to clients; a Site Lead who oversaw program delivery at the local site and served as the primary point of contact for the research team; and Senior Leaders who provided organizational oversight and made executive-level decisions related to program implementation. Collectively, the research team and delivery team were referred to as the pre-implementation team during this implementation phase.

### Analysis

Setting adoption was assessed and defined as a site's formal commitment to deliver *Small Steps for Big Changes*, indicated by signing a service agreement. Adoption rates were analyzed and reported according to the adoption dimension of the Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework [31] to describe the proportion of settings willing to deliver *Small Steps for Big Changes* within this scale-out initiative from those approached.

To identify adaptations to IS made during the pre-implementation phase, a predefined list of IS from the prior urban Kelowna community implementation project was used as the reference point (see Table 1; [29]). KB conducted a retrospective comparison of pre-implementation activities against this list to identify modifications to existing strategies and the addition of new IS. Meeting notes and email records were used by KB to identify both modifications to existing strategies and the addition of new strategies. The ERIC [28] definitions for IS were utilized and further operationalized to fit the context of *Small Steps for Big Changes*. The list of added strategies, documented modifications, and corresponding rationales were independently reviewed by NG prior to coding. Both KB and NG were research members of the pre-implementation team and contributed contextual knowledge not fully captured in the written documentation.

All adaptations were deductively coded by two independent coders (KB and SP) to each domain of the FRAME and FRAME-IS. Prior to coding, three meetings were held between the two independent coders (KB and SP) to develop coding rules. Constructs originally framed for clinical populations were adapted to a community context: for example, "Clinical Judgement" was modified to "Judgement" (defined as decisions based on individual client needs), and the term "patient" was replaced with "client" throughout both frameworks. Four consensus meetings were held to resolve discrepancies throughout the coding process. Any unresolved discrepancies were discussed with a third reviewer (MJ) to achieve final consensus. Interrater reliability was assessed using Cohen's kappa and the prevalence-adjusted bias-adjusted kappa (PABAK) statistics.

This work is part of the larger, ongoing scale-out project funded by Diabetes Canada (#020337) and the Canadian Institutes of Health Research (#020438) and was approved by the University of British Columbia Clinical Research Ethics Board (#H22-00486).

## Results

### Adoption

The community scan identified 21 rural and remote communities in the Interior and 17 in Northern regions of *British Columbia* with fitness or recreation centers. Based on criteria such as available amenities, and population size, 13 community organizations in the Interior, and nine in the Northern region were contacted. Of these, six organizations in the Interior and four in the Northern region responded and participated in a meeting to discuss potential program adoption. Three organizations in the Interior (Partner A, Partner B, and Partner C) and two in the Northern region (Partner D, Partner E) adopted *Small Steps for Big Changes* and signed service agreements, representing adoption rates of 23% and 22% respectively. Reasons for adoption included operational capacity and program alignment with organizational goals. Organizations that declined adoption cited limited staff capacity to champion and deliver the program, lasting effects of the COVID-19 pandemic on recreational services, and ongoing organizational transitions and turnover that hindered their ability to commit to *Small Steps for Big Changes* delivery. Table 2 summarizes setting-level adoption.

### Pre-implementation Process

The pre-implementation phase ranged from three to 24 months across sites, with an average duration of 12 months prior to program delivery at each site. The structure of this phase varied across organizations: some met with the research team every two weeks, while others met monthly. Most meetings were conducted virtually; however, Partner A adopted a hybrid format as the first implementing site, with researchers attending several meetings in person. Other sites completed the pre-implementation phase completely virtually, other than a single full-day visit from the research team, which included training and support for local recruitment ahead of the launch. Delays in the pre-implementation phase were attributed to factors such as the COVID-19 pandemic (n = 1), a local flood at the YMCA (n = 1), postponed coach training (n = 3), staff turnover (n = 3), transitioning to a new data management system (n = 3), and recruitment challenges (n = 1). These descriptives are summarized in Table 3.

**Table 1** Adaptations to Kelowna implementation strategies categorized by components of the Framework for Reporting Adaptations and Modifications to Implementation Strategies [22]

| Implementation strategy | Project definition | Adaptation | Why adaptation is needed for rural context? | What is being modified? | Nature of modification | Goal |
|---|---|---|---|---|---|---|
| **Strategies modified from the original community implementation** | | | | | | |
| Centralize technical assistance | A project coordinator dedicated to assisting the implementation efforts. All staff, site leads, and site managers had the contact information for the project coordinator | Addition of a data manager to provide technical assistance for implementation and data collection | To manage the data across a larger project with multiple geographically distinct communities | Context: Personnel | Adding elements | Increase the acceptability, appropriateness, or feasibility of the implementation effort |
| Create a learning collaborative | Project coordinator planned and led monthly team meetings with staff involved in the project. Project coordinator provided a skeleton framework of support and encouraged staff to seek support from each other beyond site meetings | Site Leads assumed greater responsibility for supporting coaches with less involvement from research staff | Increased leadership from the facility staff to support delivery within each geographically distinct community | Content | Drift from the IS without returning | Increase the acceptability, appropriateness, or feasibility of the implementation effort |
| Build a coalition | During the planning process an implementation team formed. This team consisted of three stakeholders from the organization and three stakeholders from the research team committed to the project. The team met monthly | Pre-implementation team expanded to include additional organizational and research team members. The meeting schedule was extended to provide additional support during this phase | Increased support and time needed for more adaptations | Context: Personnel (Pre-implementation team)<br>Context: Format (Meeting Schedule) | Tailoring/tweaking/refining | Increase the acceptability, appropriateness, or feasibility of the implementation effort |

**Table 1** (continued)

| Implementation strategy | Project definition | Adaptation | Why adaptation is needed for rural context? | What is being modified? | Nature of modification | Goal |
|---|---|---|---|---|---|---|
| Use advisory boards and workgroups | Monthly implementation team meetings discussed implementation progress, solved challenges that arose, developed marketing and communication plans and continued to plan future scale-up strategies. A client advisory committee provided feedback on intervention content and tools (e.g., recruitment letter, client workbook) A stakeholder advisory committee provided feedback on program promotion, recruitment, and marketing | Stakeholder and client advisory committees were not established during pre-implementation | Stakeholders were not identified early in the project to establish advisory committees | Context: Population | Removing/skipping elements | Increase the acceptability, appropriateness, or feasibility of the implementation effort |
| Conduct educational meetings | Two local community events were held with multiple stakeholder groups attending (e.g., physicians, local health authority staff, university staff, community members, organization staff). Goals of these meetings were to provide updates to the community on study progress, distribute results, share success stories, and inform the community on the overall initiative to support stakeholder involvement, recruitment and support | No planned meetings to with multiple stakeholders to provide updates to the community<br>Creation of workshop for member services staff | No meetings with stakeholders: To improve feasibility of pre-implementation meetings<br>Workshop: To promote awareness to member services staff | Content, Training | No meetings with stakeholders: Removing/skipping elements,<br>Workshop: Adding elements | Increase the acceptability, appropriateness, or feasibility of the implementation effort<br>Increase the adoption of the EBP<br>Increase the reach of the EBP |

**Table 1** (continued)

| Implementation strategy | Project definition | Adaptation | Why adaptation is needed for rural context? | What is being modified? | Nature of modification | Goal |
|---|---|---|---|---|---|---|
| Develop academic partnerships | In 2017, the research team partnered with the organization. In 2019, an official memorandum of understanding was signed to signify long-term commitment to the partnership | Partners used a service agreement rather than a memorandum of understanding to formalize their commitment | To establish a formal partnership structure that aligned with the needs and context of the new facility, implementation process, and grant | Content | Tailoring/tweaking/refining | Increase the acceptability, appropriateness, or feasibility of the implementation effort |
| Develop educational materials | Developed a staff manual with details on the communication style (motivational interviewing), the program content (prediabetes, diabetes, diet and exercise), and additional supplementary information to support implementation (e.g., frequently asked questions section). Developed educational videos on program content, how-to videos and videos of senior research staff facilitating the program to clients to supplement the in-person training. All staff have ongoing access to videos on an online training platform | The research team moved the coach training to an online platform (no staff manual, new online modules, and videos created with actors rather than researchers) | To facilitate training from a distance and improve accessibility of resources | Training | Tailoring/tweaking/refining (Structure of training and resources)<br>Changes in packaging or materials (Online platform) | Improve sustainability of the EBP<br>Decrease the costs of the implementation effort<br>Increase the adoption of the EBP |
| Distribute educational materials | Each staff was provided a hard-copy program manual in addition to access to an online training platform with additional educational, how-to, and senior research staff facilitating the program videos | The research team provided coach training electronically to the delivery team. The research team visited in person to deliver supporting resources (workbooks, SOPs) | To reduce cost of physical training resources and multiple shipments for supporting resources | Training | Substituting | Decrease the costs of the implementation effort |

**Table 1** (continued)

| Implementation strategy | Project definition | Adaptation | Why adaptation is needed for rural context? | What is being modified? | Nature of modification | Goal |
|---|---|---|---|---|---|---|
| Make training dynamic | In-person training was delivered with a variety of tasks such as PowerPoint slides, role-play, videos, discussion, and hands-on learning, practicing, and skill demonstration. In addition, ongoing access was provided to an online training platform with additional videos (shadowing, educational, and how-to videos) | The research team shifted coach training from in person to online delivery | To facilitate training from a distance and improve accessibility of resources | Training | Changes in packaging or material, Substituting | Increase the adoption of the EBP, Improve sustainability of the EBP Decrease the costs of the implementation effort |
| Obtain and use patients/consumers and family feedback | All clients in the program were offered to participate in an optional interview at the end of the program. In addition, all clients were provided with surveys that collect program outcomes and program feedback at multiple time-points | The research team did not plan client interviews to obtain and use consumer feedback | Different grant objectives | Content | Removing/skipping elements | Increase the acceptability, appropriateness, or feasibility of the implementation effort |

**Table 1** (continued)

| Implementation strategy | Project definition | Adaptation | Why adaptation is needed for rural context? | What is being modified? | Nature of modification | Goal |
|---|---|---|---|---|---|---|
| Shadow other experts | Videos were created with a senior research staff facilitating the program to a client. As part of the mandatory training, all staff viewed segments of the videos demonstrating delivery of core program content. Full length videos were also added, and staff were encouraged to watch the full-length videos of a counseling session to understand session flow. As part of the mandatory training, all new staff had a senior research staff shadow them while they facilitated their first client through the program (expert shadows new staff) | The research team had videos created with actors and removed the requirement of coach shadowing before delivering to a client | To facilitate training from a distance and improve accessibility of resources | Training, Content | Tailoring/tweaking/refining, Substituting, Removing/skipping elements | Increase the acceptibility, approprioateness, or feasibility of the implementation effort<br>Decrease the costs of the implementation effort<br>Improve sustainability of the EBP |
| Stage implementation scale-up | During the planning process two local sites were selected for the first stage. Building on the success and lessons learned from the first sites, a third local site would launch. The project would continue to scale-up in a such a staged process, continually building on lessons learned | The research team used a more flexible sequence and pace for preparing rural sites | To accommodate differences in site readiness and implementation timelines across geographically distinct rural communities | Context: Setting | Other | Increase the acceptability, appropriateness, or feasibility of the implementation effort<br>Increase the adoption of the EBP |
| **New implementation strategies introduced during scale-out** | | | | | | |
| Access new funding | The Principal Investigator secured grants to fund the scale-out of up to 10 rural or remote sites in British Columbia | Added strategy | To fund implementation across the new sites | Content | Adding elements | Increase the adoption of the EBP, Increase the reach of the EBP |

**Table 1** (continued)

| Implementation strategy | Project definition | Adaptation | Why adaptation is needed for rural context? | What is being modified? | Nature of modification | Goal |
|---|---|---|---|---|---|---|
| Alter incentive/allowance structures | The research team provides awarded funding to the sites. Funding will be provided to pay delivery staff to complete the coach training and deliver client sessions as part of the formal service agreement | Added strategy | To promote adoption of the program in rural communities | Content | Adding elements | Increase health equity or decrease disparities in EBP delivery<br>Increase the adoption of the EBP |
| Alter patient/consumer fees | The community organization agreed to offer a membership in kind to participants. Therefore, there is no cost for clients who participate in the program. The 6 program sessions are free of charge and are comparable to the equivalent of 6 personal training sessions at organization locations, therefore clients are paying less for a program that is more specific to their T2D risk and health needs | Added strategy | To improve accessibility to the program and increase the likelihood of member retention in the community facility | Content | Adding elements | Increase health equity or decrease disparities in EBP delivery<br>Increase the reach of the EBP |
| Change physical structure and equipment | The pre-implementation team discussed changes regarding the physical structure and necessary equipment at various sites during meetings to best accommodate program delivery at each specific site. The research team sent necessary resources to each site | Added strategy | To adapt to the various facility's infrastructures | Context: Other | Adding elements | Increase the acceptability, appropriateness, or feasibility of the implementation effort |

**Table 1** (continued)

| Implementation strategy | Project definition | Adaptation | Why adaptation is needed for rural context? | What is being modified? | Nature of modification | Goal |
|---|---|---|---|---|---|---|
| Create new clinical teams | The research team does not require any educational pre-requisites to become a coach. This allows for a variety of community lay personnel to become coaches. The process of certification is the same for each coach | Added strategy | To train more individuals to deliver the program | Context: Population | Adding elements | Increase the acceptability, appropriateness, or feasibility of the implementation effort |
| Create or change credentialing and/or licensure standards | The research team awarded certification to those who successfully completed the coach training program. Only certified coaches will be eligible to deliver the program to clients in the community | Added strategy | To establish intervention fidelity | Training | Adding elements | Improve fidelity to the EBP |
| Develop resource sharing agreements | The research team established partnerships with sites that had the interest and resources needed to implement the program and uphold its core components. Service agreements were signed by each location and the research team to provide a shared understanding of the partnership and transparency of expected roles, timelines, responsibilities and available resources | Added strategy | To establish partnerships with implementation sites | Content | Adding elements | Increase the adoption of the EBP |

**Table 1** (continued)

| Implementation strategy | Project definition | Adaptation | Why adaptation is needed for rural context? | What is being modified? | Nature of modification | Goal |
|---|---|---|---|---|---|---|
| Involve patients/consumers and family members | The delivery and research team will invite program alumni to be coaches if they are interested in assisting in the delivery of the program. The research team will collect feedback from clients through acceptability and satisfaction surveys | Added strategy | To train more individuals to deliver the program | Context: Personnel | Adding elements | Increase the adoption of the EBP |
| Model and simulate change | The research team applied lessons learned across the community project and earlier rural pre-implementation activities to anticipate potential challenges and refine implementation processes as the rural project progressed | Added strategy | Research team applied lessons learned from previous implementation experiences to anticipate challenges and refine processes before and during subsequent rural implementation | Context: Setting | Adding elements | Increase the acceptability, appropriateness, or feasibility of the implementation effort |
| Prepare patients/consumers to be active participants | The delivery team will provide clients with program workbooks during session one. Coaches will deliver sessions using an MI-informed counselling style to ensure the program is client-centered and encourages their autonomy and likelihood they will take an active role in their health | Added strategy | Process not included in previous Kelowna project | Content | Adding elements | Increase the clinical effectiveness of the EBP |

**Table 1** (continued)

| Implementation strategy | Project definition | Adaptation | Why adaptation is needed for rural context? | What is being modified? | Nature of modification | Goal |
|---|---|---|---|---|---|---|
| Provide clinical supervision | Site leads who oversee the delivery of the program at their organization location will be supported by the Project Coordinator through all stages of the implementation process. Site leads will be provided with a standard operating procedures document to assist with their supervision role. The site lead will be the main point of contact for each site | Added strategy | To provide support to delivery staff | Context: Personnel | Adding elements | Improve fidelity to the EBP<br>Increase the acceptability, appropriateness, or feasibility of the implementation effort |
| Remind clinicians | Coaches will be prompted to deliver the program as intended through the use of REDCap session checklists and data collection reminders | Added strategy | To support fidelity of the intervention | Content | Adding elements | Improve fidelity to the EBP |
| Use data warehousing techniques | A data manager will oversee data collection. A survey platform known as REDCap will used to collect all quantitative data across the project for all sites | Added strategy | To support management of the data collected | Content | Adding elements | Other—program evaluation/data management |
| Use mass media | The research team developed social media accounts to advertise the program and engage with eligible audiences. The research team also developed media template documents provided to sites | Added strategy | To increase awareness of the program to individuals that may be eligible. A strategy that can be employer from a geographically separate location | Content | Adding elements | Increase the reach of the EBP |

**Table 1** (continued)

| Implementation strategy | Project definition | Adaptation | Why adaptation is needed for rural context? | What is being modified? | Nature of modification | Goal |
|---|---|---|---|---|---|---|
| Intervene with patients/consumers to enhance uptake and adherence | The delivery team will host health assessment days in the community to enhance uptake of the program and increase knowledge of T2D risk | Added strategy | To provide opportunities for registration within the rural communities for participants that might be eligible | Content | Adding elements | Increase the reach of the EBP |

**Table 2** Setting-level adoption

| | Interior *British Columbia* | Northern *British Columbia* |
|---|---|---|
| Identified rural community organizations | 21 | 17 |
| Communities approached to participate | 13 | 9 |
| Communities expressing interest | 6 | 4 |
| Communities that adopted *Small Steps for Big Changes* | 3 | 2 |
| Adoption rate | 23% | 22% |

Adoption rate = (Number of communities that adopted the program ÷ Number of communities approached) × 100

## Program Adaptations

This paper reports exclusively on the pre-implementation of the project and as a result all adaptations to the program and IS (100%) were coded as planned and part of this phase. Percentages within some domains of both the FRAME and FRAME-IS exceed 100% because individual adaptations were assigned multiple codes. Cohen's kappa and PABAK were calculated following independent coding by KB and SP. Results indicated substantial to outstanding interrater reliability [32] for program content adaptations ($\kappa = 0.72$, PABAK = 0.85) and for IS adaptations and additions ($\kappa = 0.70$, PABAK = 0.85).

Across adopting sites, 27 program adaptations were identified. Table 4 describes each of these adaptations linking them to the nature and goal of each modification. Appendix A describes how these adaptations aligned with the FRAME and presents the frequency and percentage of each construct in the five community settings; illustrative examples are listed below. Of these adaptations, 56% (n = 15) were ultimately decided by the *researchers* and 44% (n = 12) by the *delivery team*. Partner E required the greatest degree of program adaptation, with modifications driven largely by the *delivery team* (100%; n = 15) rather than the *research team*. This likely reflects the unique challenges of implementing the program in a setting without a gym and within a distinct cultural context.

Modifications were made to several domains including *implementation scale-up activities* (n = 9; 33%), *context* (n = 8; 30%), *content* (n = 5; 19%), and *training and evaluation* (n = 5; 19%). An adaptation made to *implementation and scale-up activities* across all sites was the development of an online eligibility survey to streamline the onboarding process and increase accessibility across these geographically distinct and remote communities; a role previously carried out by the *research team* prior to scale-out. The survey allowed clients to self-enroll in the program by confirming their eligibility and providing consent, thereby reducing the burden on each site to screen participants. In Vanderhoof, Partner E did not have gym equipment, leading to a *contextual* adaptation in which the exercise protocol was delivered

**Table 3** Descriptives of sites that adopted Small Steps for Big Changesand their pre-implementation phases and corresponding number of program adaptations

| Community Organization | Pre-implementation length | Pre-implementation team | Community population (2021 census) | Factors attributing to delays in pre-implementation phase | Number of program adaptations |
|---|---|---|---|---|---|
| Partner A: *Oliver* Parks and Recreation (Interior Region) | March 2021-March 2023 (24 months) | Director of Recreation, Recreation Coordinator *Small Steps for Big Changes* Coach Research Coordinator 5 Research Assistants Principal Investigator | 5094 | COVID-19 pandemic, postponed coach training, transitioning to a new data management system | 13 |
| Partner D: *Prince* George Family YMCA (Northern Region) | June 2022-June 2023 (12 months) | Director of Health, Fitness and Aquatics General Manager Fitness Supervisor Research Coordinator 4 Research Assistants Principal Investigator | 76,708 | Postponed coach training, transitioning to a new data management system | 11 |
| Partner E: Vanderhoof Aquatic Center (Northern Region) | June 2022-Novemeber 2023 (17 months) | Director of Health, Fitness and Aquatics, Fitness Supervisor Research Coordinator 4 Research Assistants Principal Investigator | 4346 | Local flood, recruitment challenges, transitioning to a new data management system | 15 |
| Partner B: *Grand Forks* and District Recreation (Southern Interior) | March 2023-May 2023 (3 months) | Director of Recreation Research Coordinator 2 Research Assistants | 4112 | | 12 |
| Partner C: *Summerland* Aquatic and Fitness Center (Southern Interior) | July 2023-November 2023 (5 months) | Director of Recreation Research Coordinator | 12,042 | Postponed coach training | 12 |

in the pool for participants to complete the exercise component of the program. An example of a *content* adaptation was the inclusion of location-specific activity suggestions in the client workbook for the Northern communities, such as skating on frozen lakes, snowshoeing, and curling. An adaptation to *training and evaluation* across all sites was the integration of hemoglobin A1c (HbA1c) testing using the Point of Care machine. Because this was not included in the online coach training, researchers visited each site to deliver the equipment, manual, and training log, and to demonstrate use of the machine to at least one representative, who could then train additional staff as they were onboarded as *Small Steps for Big Changes* coaches.

The primary goal of the modifications was often to *improve feasibility* (n = 20; 74%). Partner C had limited staff availability and capacity to complete the training and deliver *Small Steps for Big Changes* to clients. However, the center had an established relationship with Partner A, who had already launched *Small Steps for Big Changes*. Senior leadership at the two facilities agreed that *Small Steps for Big Changes* coaches from Partner A would travel to deliver the program at Partner C while local coach capacity was being developed. Most adaptations were related to *program oversight* (n = 21; 78%), an example of this was an adaptation made in Partner B, where the program was offered only on certain days of the week to accommodate the single coach's work schedule and the site's programming schedule.

## Implementation Strategies

Fifteen adaptations to IS were identified, and 15 strategies from ERIC were added during pre-implementation. Table 1 provides a detailed list of strategies distinguishing between the two projects and describing adaptations and additions of strategies, along with their respective actors and actions. Appendix B provides frequencies for the adaptations and additions of IS in alignment with the FRAME-IS across all five community settings. IS adaptations and additions were informed by 3 different groups: *researchers*, *the delivery team*, and *funders*. *Researchers* (n = 15; 100%) and *Small Steps for Big Changes delivery team* (n = 1; 7%) participated in the decision to modify strategies, while *researchers* (n = 15, 100%) and *funders* (n = 1; 7%) informed the addition of strategies. Of the adapted IS, the ultimate decision was made by *researchers* (n = 15; 100%). In contrast, the ultimate

**Table 4** Adaptations to the Small Steps for Big Changes categorized by components of the Framework for Reporting Adaptations and Modifications to Evidence-Based Interventions [14]

| Specific adaptation | FRAME: What was modified? | FRAME: Goal of modification | Why adaptation was needed for the rural context | How was it implemented? | Locations affected? |
|---|---|---|---|---|---|
| Eligibility survey: Development of an online survey to determine if a client is eligible for the program that subsequently links to the consent form rather than staff calling to screen | Implementation and scale-up activity | Increase reach or engagement, improve feasibility | Reduces the burden on research and delivery teams of screening each client. It also improves accessibility for the general public to sign up for the program | Developed by the research team and promoted locally for public access | Across all sites |
| Onboarding log: To share lists of registrants with the delivery sites rather than through a research developed online booking system | Implementation and scale-up activity | Improve feasibility | A method to communicate client's registration and consent in the program to delivery staff that allowed delivery staff to use internal scheduling processes | Developed by the research team and shared with the implementation sites' delivery teams | Across all sites |
| REDCap training session added to SSBC coach training process | Training and Evaluation | Improve feasibility | To train delivery staff on the new data collection system | 1 h zoom call where a research team member explains how to use REDCap in sessions with clients. The call is synchronous with a requirement of any new client to watch the asynchronous recording or do the same call with a member of the research team | Across all sites |
| Modifications to the Site Lead Standard Operating Procedure | Training and Evaluation | Improve feasibility | To provide information about the new implementation tools and strategies | Information added to the SOP by the research team and shared with the delivery team | Across all sites |
| Addition of healthcare calendar in client workbook | Content: Adding elements or modules | Increase reach or engagement | To assist clients in tracking their healthcare data to report in surveys | Added to the existing workbooks and printed for delivery team by the research team | Across all sites |
| Addition of a Site Visit: research team members to travel to the implementation site | Implementation and scale-up activity | Increase reach or engagement | A way to deliver all necessary equipment, engage with delivery staff, and advertise the program in the community | A planned visit by the research team to the rural or remote implementation site | Across all sites |
| Rural Research Coordinator SOP | Implementation and scale-up activity | Improve feasibility | To provide guidelines to research management and oversight of the rural scale-out project | Created by research team for the research coordinator in charge of the rural project | Across all sites |
| Communication System for Replenishing Affinion Point of Care Supplies | Implementation and scale-up activity | Improve feasibility | A communication method for delivery teams to notify the research teams when they need supplies replenished | Log book developed by the research team and given to the delivery teams | Across all sites |

**Table 4** (continued)

| Specific adaptation | FRAME: What was modified? | FRAME: Goal of modification | Why adaptation was needed for the rural context | How was it implemented? | Locations affected? |
|---|---|---|---|---|---|
| Self-referred clients: Clients that signed up for the program despite being screened were screened by the research team | Context: Format | Improve feasibility | Delays in the developing a screening tool for the rural context, three individuals interested in the program were screened by the research team | The research team called these individual and did the eligibility survey over the phone. Eligible clients were shared with the delivery staff for initiating participation in the program | Parter A |
| Recruitment in neighboring communities | Implementation and scale-up activity | Increase reach or engagement | To improve awareness, increase reach to those that travel to Oliver for other services | The suggestion came from delivery staff, and recruitment strategies were co-created and co-implemented | Parter A |
| In person Qualtrics training | Training and evaluation | Improve feasibility | Before switching to REDCap, the research team orientated the delivery team to the current data management platform so that they could input client data while delivering sessions | The research team led training in person with delivery staff | Parter A |
| Virtual Mock Sessions for Coach Training | Training and evaluation | Reduce cost | To facilitate coach training in the virtual environment | The research team conducted mock sessions with staff in training over Zoom | Parter A |
| Hybrid pre-implementation meetings | Implementation and scale-up activities | Improve feasibility | To facilitate collaborative meetings between the research team and delivery teams at a distance | Meetings were hosted over Zoom, and in person (research team would travel to the community) | Parter A |
| Scheduling process | Implementation and scale-up activity | Improve feasibility | To ensure scheduling processes aligns with local facility operations, the responsibility to schedule was changed from the research team, to the community Site Lead | The Site Lead books sessions and rooms for coaches and clients | Partner C |
| Oliver coaches contracted to deliver SSBC in Summerland | Context: Personnel | Improve feasibility | Due to inadequate coach capacity | Coaches trained in Oliver were contracted to deliver sessions in Summerland | Partner C |
| Program inquiries directed to member services rather than the research team or Site Lead | Context: Format | Improve feasibility | To ensure communication flow aligns with local facility operations | Material was adapted to provide contact information for the member services team | Partner C |
| Coaches in training shadowing an experienced coach before delivering sessions themselves | Training and evaluation | Improve effectiveness/outcomes | To improve confidence of coaches in training | New coaches were given the opportunity to shadow an experienced coach if they client in the session consented | Partner C |

**Table 4** (continued)

| Specific adaptation | FRAME: What was modified? | FRAME: Goal of modification | Why adaptation was needed for the rural context | How was it implemented? | Locations affected? |
|---|---|---|---|---|---|
| Setting and schedule for session delivery | Context: Setting | Improve feasibility | Due to limited room availability for session delivery | The setting and schedule was adapted to allow for session delivery in the pool lobby while it was closed to the public | Partner B |
| Scheduling system | Context: Format | Improve feasibility | To ensure scheduling processes aligns with local facility operations | Scheduling for the program was integrated into the already established online booking system in Grand Forks | Partner B |
| Restricted session delivery times | Context: Personnel | Improve feasibility | Due to limited staff resources at the facility, only one part time staff delivered the program | Session times were offered on select days and times | Partner B |
| Delivery team | Context: Personnel | Improve feasibility | Due to limited staff resources at the facility | One staff assumed the role of Site Lead and coach | Partner B |
| Activity additions to the client workbook and coach script | Content: Tailoring/ tweaking/ refining | Improve fit with recipients, Address cultural factors | To align with the community context | The client workbook and coach scripts were adapted to include activities specific to the community | Partner D and Partner E |
| Food adaptations to the client workbook | Content: Tailoring/ tweaking/ refining | Improve fit with recipients, Address cultural factors | To align with the community context | The client workbook and coach scripts were adapted to include foods that could be available in the community | Partner D and Partner E |
| Location specific promotional content | Content: Tailoring/ tweaking/ refining | Improve fit with recipients, Increase reach or engagement | To align with the community context | Location specific pictures were added to promotional material | Partner D and Partner E |
| Aquatic exercise protocol | Context: Setting | Improve feasibility | The facility did not have a gym space or equipment, only a pool | The research team co-developed an aquatic protocol with instructors that aligned with the exercise protocol in the program | Partner E |
| Scheduling addition to client workbook | Content: Tailoring/tweaking/ refining | Increase reach or engagement | To promote other facility programs to clients | A link to the pool schedule was added to client workbooks | Partner E |
| Alternate location for session delivery | Context: Setting | Improve feasibility | Due to limited space for session delivery | Another space owned by the organization planned to be an alternate spot for session delivery | Partner E |
| Incentive structure | Implementation and scale-up activities | Improve feasibility, Increase satisfaction | To incentivize individuals to join the program | A 45 day membership included in participation rather than standard 30 days | Partner E |

decision to add strategies was often shared by *researchers* (n = 12; 80%) and the *delivery team* (n = 7; 47%).

Adaptations were primarily made to *context* (n = 7; 47%), for example, a strategy previously employed in Kelowna locations was "Build a coalition" in which an implementation team was formed during the planning process. For scale-out, the strategy was adapted by increasing the number of individuals on the implementation team and modifying the frequency of meetings. Added strategies were often related to *content* (n = 10; 67%), for example, an added implementation strategy was "Reminding clinicians" (operationalized for coaches), in which it was planned that delivery staff would be prompted to deliver the program as intended through the use of REDCap session checklists and data collection reminders.

Multiple goals were identified, with the most frequent goal for adapted strategies being to *increase acceptability, appropriateness, or feasibility* (n = 10; 67%). During the Kelowna urban implementation, the strategy "Create a learning collaborative" involved the project coordinator planning and leading monthly team meetings with staff. For scale-out to rural communities, greater distance made in-person meetings challenging, so community organizations appointed a Site Lead to meet with the delivery team and serve as a liaison between the project coordinator and the organization.

Added strategies were often to *increase the reach* (n = 4; 27%) or *adoption* (n = 4; 27%) of *Small Steps for Big Changes*. For example, to *increase the reach*, "Use mass media" was a strategy added in which social media and template materials were created to promote the program and support local media engagement. To *increase adoption*, the strategy "Involve consumers and family members" was utilized by planning to invite interested alumni of the program to take the online training and become a *Small Steps for Big Changes* coach at their local facilities.

## Discussion

This study examined the adoption of *Small Steps for Big Changes* in rural and remote communities and documented adaptations to both the program and IS to support delivery in these contexts. Using the adoption dimension of the RE-AIM framework [31] allowed for systematic assessment of setting-level adoption, providing critical insight into the contextual factors that influenced uptake. Overall, adoption of *Small Steps for Big Changes* at the setting level was lower than anticipated across participating communities. Barriers were primarily related to limited staff capacity and ongoing organizational transitions. These challenges are consistent with previous research demonstrating that staffing constraints such as staff shortages can impact adoption of both primary care [33] and physical activity interventions [34] in rural communities. In this study, these barriers may have been exacerbated by the residual effects of the COVID-19 pandemic on rural and remote recreation facilities. Given that staff capacity is a persistent challenge in rural contexts, future scale-out efforts should consider allocating dedicated resources and time to support workforce capacity and readiness prior to adoption.

Once a site chose to adopt *Small Steps for Big Changes* the duration and structure of the pre-implementation phase varied across community organizations. For example, the longest pre-implementation phase was at Partner A due to the COVID-19 pandemic, delaying the launch of the program by a year, while Partner B and Partner C moved more quickly through this phase compared to the other three communities. The shorter timelines may be explained by small organizational size and fewer administrative layers, which can facilitate more efficient decision-making. The QUERI Roadmap for Implementation and Quality Improvement explains that large organizations and complex systems often experience bureaucratic inertia, implying that smaller organizations may be able to navigate the planning process and decision-making more quickly, especially if the EBI is in alignment with the organizational mission and values [18]. However, this finding also highlights a tension in implementation research, where larger organizations are often prioritized for recruitment due to their greater reach, yet smaller organizations may be better positioned to rapidly adopt and implement interventions. Partner B and Partner C also had the advantage of initiating implementation later and drawing on established processes and insights from earlier sites like Partner A. Previous literature indicates that creating standardized intervention packages or "playbooks" during pre-implementation can support future scale-up by enabling rapid dissemination into additional sites and shorter pre-implementation phases [18, 35]. At the same time, a longer pre-implementation phase offered opportunities to build stronger relationships between researchers and community partners, which may in turn support stronger maintenance and sustainment of those partnerships over time. This is especially important in rural and remote communities, where trust, collaboration, and sustained partnerships are critical to successful and equitable implementation [13].

The use of the FRAME and FRAME-IS enabled the systematic documentation of adaptations to both the intervention and its IS. These frameworks helped identify not only what was modified, but also why and how those decisions were made. Program adaptations were jointly decided upon by researchers and community organization partners, while adaptations to existing implementation strategies were more often research-led. In contrast, newly introduced implementation strategies were frequently co-developed. This pattern likely reflects the structure of pre-implementation meetings,

which focused on program adaptations in collaboration with community organizations, often prompting ideas for additional strategies, while refinements to existing implementation strategies were typically addressed internally by the research team. This finding underscores the importance of engaging community partners in shaping implementation strategies from the outset. As reported in previous research, relying on pre-determined implementation strategies, rather than identifying preferences of community partners, can inadvertently create barriers rather than bridges [17]. Co-developing new IS with community organizations fosters collaboration and leverages existing practices to improve alignment [17], suggesting that future scale-out efforts should prioritize early and meaningful partner engagement in implementation strategy design to produce context-responsive strategies.

Findings also revealed differences among sites in decision-making of program adaptations. At earlier sites such as Partner A, decisions were more often led by the research team, whereas later sites such as Partner B demonstrated greater partner-led decision-making. This shift likely reflects both the availability of established implementation templates and the research team's growing confidence in adopting a more flexible, context-responsive approach over time. This evolution is consistent with the broader implementation science literature, which emphasizes that the implementation process, much like interventions themselves, evolve over time through iterative cycles of implementation [20].

Most of the program adaptations related to oversight and quality improvement emphasizing the need for strong administrative support and close supervision of program delivery with scale-out. As this was the first planned scale-out of *Small Steps for Big Changes* beyond its original setting, several adaptations were made to facilitate delivery by local teams operating with limited on-site support from the research team. This highlights a common challenge in implementing programs in geographically distant rural communities, where physical separation from the central support team can make it harder to provide real-time support and sustain collaborative relationships [36]. Such challenges align with the proximity paradox, where research in underserved rural communities is strongly recommended yet difficult to execute because geographic distance hinders the development and maintenance of relationships essential for successful implementation [37]. These results may shape future scale-up efforts by encouraging early prioritization of strategies to improve program coordination and operational support to ultimately preserve process fidelity and sustain relationships with delivery organizations.

When comparing the five communities, addressing cultural factors was a goal for program adaptations only in the Northern communities. Another notable difference was that most of the content modifications occurred in the Northern region, whereas other types of modifications were more evenly distributed across all communities. This may reflect the demographic composition of the region as Northern British Columbia has a substantially higher proportion of individuals who identify as Indigenous compared to the Interior [38] necessitating adaptations to program content to ensure cultural relevance and acceptability. Modifications made for the target intervention group were only made with Partner E likely due to the difference in infrastructure in this community, where there was no formal gym equipment, only a pool to complete the exercise portion of the program. This may have implications for future implementation of DPPs in Northern British Columbia underscoring the importance of designing interventions that are flexible and responsive to culture and resource limitations to improve feasibility and acceptability.

While the Northern context highlights specific resource and cultural considerations, the most commonly highlighted goal of adapting IS was to *increase acceptability, appropriateness, or feasibility of the implementation effort* across all five rural and remote sites. This reflects the priority of advancing the fit of *Small Steps for Big Changes* to the community organization and tailoring to the needs of the community before delivery. This is in alignment with existing literature encouraging that tailoring IS to the needs of diverse contexts could promote implementation outcomes such as adoption, reach and fidelity [17]. This finding is unsurprising given the well-documented challenges and need for tailoring implementation strategies in similar contexts. If rural and remote realities are not deliberately accounted for, implementation efforts may become not just inefficient but ineffective, ultimately risking the amplification of the inequities they are intended to reduce [13]. It is important to note that tailoring an EBI does not conclude at the pre-implementation stage. It is an iterative process that will continue through implementation and sustainability phases as the community organization trials and gains experience with delivery.

## Strengths and Limitations

This work extends prior research, reinforcing the need for documenting adaptations to EBIs and their strategies in the pre-implementation stage. This thorough process requires regular engagement with community partners who are given the autonomy to inform adaptations to the program and implementation strategies. A strength of this work is the integration of both the FRAME and FRAME-IS, providing a more complete and rigorous approach, as most existing literature reports on only one framework, failing to consider adaptations to both the EBI itself and its IS. Using both frameworks allows for a comprehensive understanding of adaptations made not only to the intervention but also to the strategies necessary for successful implementation, which

enhances the generalizability of the results and their utility for future research. The cross-project analysis allowed for interpretation of adaptations across the five different community settings and highlighted the unique realities of each context. This study is not without limitations, as it reports on adaptations made during the pre-implementation phase and does not assess the implementation outcomes associated with these adaptations. This gap reflects a broader trend in rural implementation research: a scoping review found that studies often indicate use of theories and frameworks in their protocols or planning stages but rarely link these early activities to outcomes [15]. Future research could examine how these early adaptations influence later outcomes such as reach, fidelity, and sustainability.

## Conclusion

This paper describes the thorough scale-out process of the EBI *Small Steps for Big Changes* program in five distinct rural and remote community settings. It highlights the proportion of sites that adopted *Small Steps for Big Changes*, and adaptations made to the program and strategies during the pre-implementation phase. These findings can inform targeted implementation efforts and guide decisions about scaling diabetes prevention programs into diverse community settings.

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**Data Availability** The data supporting the findings of this study are available from the corresponding author upon reasonable request.

### Declarations

This work was conducted as an implementation project and did not constitute human subjects research; therefore, informed consent was not required.
This work was approved by the University of British Columbia Clinical Research Ethics Board (#H22-00486).
This article does not contain any studies with animals performed by any of the authors.

**Competing interests** The authors declare no competing interests.

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