BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2024-091934
Article Type:	Original research
Date Submitted by the Author:	01-Aug-2024
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Keywords:	HIV & AIDS < INFECTIOUS DISEASES, Digital Technology, Implementation Science, Randomized Controlled Trial

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Finding the balance between rigor and relevance: Implementing adaptations to the implementation of a pragmatic randomized controlled trial of a two-way texting intervention for voluntary medical male circumcision in South Africa

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Word count: 4147

Abstract

Background: Adaptation and fidelity are major components in implementation science (IS) research. Pragmatic randomized controlled trials (pRCTs) are implemented to assess the benefits and detriments of interventions in real-world settings, aiming for more practical or actionable results. While pRCTs must be implemented with fidelity, some adaptations are necessary to contextualize the evidence-based intervention.

Objective: To document adaptations that were made to the implementation of the Two-Way Texting (2wT) intervention for Voluntary Male Medical Circumcision (VMMC) in South Africa and to provide a nuanced discussion on the differences between adaptations and fidelity in this context.

Methods: We conducted a qualitative study using the Framework for Reporting Adaptations and Modifications in Evidence-based Implementation Strategies (FRAME-IS) to examine 2wT adaptations. We reported adaptations to the 2wT intervention using two steps. First, we categorized adaptations in a shared study-specific Google Doc that documented participant engagement with the 2wT system, tracked daily RCT implementation notes, reported software bugs, and noted reminder emails about adaptations for the research team. Second, we conducted a qualitative assessment of the influence of adaptations on project outcomes via 10 periodic reflection meetings with VMMC implementers. Reflection documentation included notes from field observations, meeting minutes, and informal partners check-ins to complete adaptation documentation. Using the FRAME-IS as a codebook, adaptations were categorized.

Results: Between June 2021 and February 2022, 13 adaptations were identified in three phases during the implementation of the 2wT pRCT. The first phase of adaptations aimed to augment study recruitment, including: conducting weekend VMMC recruitment camps; using mobile outreach services in the rural site; adding two urban sites to increase recruitment; using weekly WhatsApp calls for updates with all implementing teams; using virtual meetings to implement the 2wT strategy remotely during COVID-19 restrictions; and allocating one clinician to work outside of normal working hours. The second phase of adaptations further enhanced enrollments, including adding two local language translations in the usability survey for 2wT men and contributing a portion towards the salary of the implementing staff by the research partner. The third phase included: the exclusion of two rural clinics as recruitment sites due to inconsistent mobile phone networks; adding another layer of data quality checks to ensure data quality; training non-clinical counselors to help with enrolling clients; retraining of staff in the

rural site with high staff turnover; and using both primary and alternative phone numbers for enrollment to reduce loss to follow up.

Conclusions: This study made adaptations to the 2wT pRCT without compromising the fidelity of the study. The 2wT pRCT balances rigor (fidelity) and relevance (adaptation). Adaptations should not be confined by rigor but should also not go unchallenged or unverified. We conclude that fidelity can be maintained with adaptations that are implemented to close the gap between research in the laboratory and practice.

Trial Registration: The trial from which this study was conducted, "Expanding and Scaling Two-way Texting to Reduce Unnecessary Follow-Up and Improve Adverse Event Identification Among Voluntary Medical Male Circumcision (VMMC) Participants in the Republic of South Africa," was registered at ClinicalTrials.gov (ID: NCT04327271) on March 31, 2020.

Keywords: adaptations; pragmatic randomized controlled trial; rigor; relevance; two-way testing; voluntary medical male circumcision.

Contributions to the literature

- Adaptations made to the 2wT pRCT improved the implementation of post-operative follow-up for men who had undergone voluntary medical male circumcision (VMMC).
- These adaptations enabled the 2wT intervention to be compatible to the post-operative follow-up program of VMMC clients in rural and urban contexts.
- Adaptations to the 2wT pRCT strengthened the implementation of the VMMC follow-up program.
- Overall, adaptations that were made to the 2wT pRCT improved the quality of post-operative follow-up for VMMC in South Africa. Adaptations can be made to an intervention without compromising the fidelity of the study.

Background

Implementation science (IS) involves finding ways to maximize the adoption and uptake of known and tested evidence-based interventions (EBIs) in practice (1). To aid in the adoption of EBIs, researchers, and implementers may make use of implementation strategies, which cover the 'how to' part of delivering the EBIs (2). These strategies may include methods of provider training, use of tool kits, checklists, guidelines, and user manuals (3).

In acknowledging the difference in settings and environments in which EBIs are implemented, it is imperative that these implementation strategies be tailored for each specific setting for the efficient delivery of the EBI (3). Adaptation to IS strategies can be defined as altering the delivery of an EBI considerately and deliberately to improve its fit or effectiveness in a particular context (4). Adaptations, themselves, reflect diverse processes of change that can be internally or externally motivated, proactive, or responsive to unanticipated challenges that arise during a particular period or context (5). Adaptations are required to meet better the needs of the community where the EBI is implemented and to fit the program, budget, timelines, and staffing needs in a different environment (6). In addition, adaptations may also be needed at the policy or health system levels to facilitate EBI implementation and sustainability (7). When adaptations are made to the implementation strategies, the original design of the EBI is usually left unaltered, thereby maintaining fidelity. Fidelity is staying true to the original EBI design by implementing the intervention as its developers intended (8).

Adaptations and fidelity are concepts that are carefully negotiated in randomized controlled trials (RCTs). RCTs require implementers to remain consistent with the core elements of EBI through the rationale, process, and outcome of the intervention– maintain fidelity. RCTs implemented in real-world, routine, or community settings may require implementation scientists to adapt even well-planned studies due to evolving changes in the population characteristics, research and implementing agencies, and/or community contexts (9). The term, *pragmatic* RCT (pRCT), is defined as an RCT that aims to evaluate the effectiveness of an intervention in real-world settings rigorously, not strictly research settings, to understand better and bridge the divide between research and routine contexts (10). Adaptations of implementation strategies are tools that are used to achieve this.

We conducted a pRCT in South Africa between 2021 and 2022, applying the process of planned or purposeful adaptations to the content and delivery of the intervention (11) in response to emerging and evolving COVID-19 constraints and opportunities (11-13). The pRCT aimed to

determine if a mobile health (mHealth) innovation, two-way texting (2wT) can safely reduce post-operative follow-up after voluntary medical male circumcision (VMMC) while reducing provider workload. For the pRCT, 1093 men were randomized 1:1 across 2 arms and divided equally across urban and rural districts, with 553 men assigned to the 2wT intervention arm (see Consort diagram) (11). Males ages 18+ were followed up for 14 days by either routine, post-operative, in-person visits on days 2 and 7 (control) or 2wT daily messaging with a VMMC nurse in lieu of clinical reviews (intervention). All participants returned for a study-specific review on postoperative day 14 to ascertain healing and document adverse events (AEs). 2wT aimed to support patients in independently monitor their wound-healing while empowering them to opt-in for physical follow-up visits at their local VMMC clinic only if needed or desired. 2wT visits and AE outcomes were compared between groups. Study recruitment started on June 7, 2021, and follow-up concluded on February 21, 2022.

In this paper, we describe adaptations to the delivery of a mHealth-focused pRCT in response to the volatile environment during the COVID-19 lockdown period in South Africa.

Methods

Study design and framework

We conducted a qualitative study using the Framework for Reporting Adaptations and Modifications in Evidence-based Implementation Strategies (FRAME-IS) summarized in Figure 1. We documented adaptations to the strategies that were employed in implementing the 2wT EBI using four modules of FRAME-IS to describe: (1) the 2wT EBI, the implementation strategies employed, and the adaptations done; (2) what was adapted; (3) the nature of the content adapted; and (4) the goal and the level of the rationale for the adaptation (14). We also assessed rigor and relevance in documenting adaptations.

Figure 1: The FRAME-IS for documenting adaptations to implementation of interventions

Insert Figure 1

Source: Miller, Barnett, Baumann (15)

Using the FRAME-IS as a codebook, adaptations were described and categorized. We documented adaptations to the implementation strategies using two steps: (1) we used qualitative data from Google Sheets to identify, categorize, and describe adaptations; (2) qualitatively assessed the impact of adaptations on project outcomes via a review of program reflection documentation (field observations, meeting minutes, informal check-ins, etc.) (Table 1) (7).

Table 1: Summary of data collection techniques, and what was documented for each objective

Objective	Data collection method	What was documented
Adaptations to the implementation strategy of the 2WT intervention.	Conducted 10 monthly reflections and observations of real-time adaptations with a tracking database using a Google Sheets daily spreadsheet.	Reach of 2wT, acceptability, appropriateness, and feasibility of implementation of the 2wT intervention.
Whether the adaptations improved the fit (compatibility) of the 2WT intervention.	Reviewed men's engagement with the 2wT system, tracked the database for daily RCT notes and bugs, and reviewed reminder emails about adaptations to research team and partners.	Men's engagement with the 2wT system, feasibility of implementation and increase in equity and decrease in disparities in delivery of 2wT
The effectiveness of implementation of 2wT intervention.	Reviewed field notes, meeting minutes, informal check-in with partners and did member-checking	Costs, sustainability, clinical outcomes, adoption, and fidelity of 2wT

Data collection methods and documentation

We used various data collection methods to document the implementation strategies for the delivery of pRCT, as summarized in Table 1.

Step 1) Google Sheets and other secondary data sources: Daily progress notes and other operational data were recorded on Google Sheets as part of routine study monitoring. Adaptations to the implementation strategies were extracted and coded from Google Sheets.

Other secondary data sources included participant observations, training workshop notes, site visit reports, emails, and communication through the study team's WhatsApp. We used a data extraction sheet to document data on adaptations that were made to the implementation strategies, reviewing and coding content in Google Sheets related to adaptations made to the strategy, fit and effectiveness.

Step 2) Periodic reflections: As part of informal or routine partner and stakeholder review meetings, we conducted ten (10) periodic reflections with implementers of the 2wT pRCT in the rural and urban sites to answer the following IS optimization questions:

1. *What* component or part of the implementation strategies to deliver the 2wT intervention was changed in this adaptation; in other words, what was the nature of the change?
2. *Who* was responsible for first suggesting or initiating this change? Was this the person or persons who implemented the change? If not, who implemented the adaptation?
3. *When* during the 2wT intervention was this adaptation first made?
4. *Why* was this adaptation made? Was this done to get more people to participate, to make the program attractive to more settings, to increase its effectiveness, to make it easier to deliver, to make it easier to maintain or reduce costs, etc.? (10)

The research manager conducted *periodic reflections* and *observations* in the form of 15–60-minute meetings, at least once a month. These were lightly guided discussions by telephone, Zoom or site visit conducted with individuals (such as nurses, clinical associates, team leaders, data managers, recruiters, etc), small teams (such as the surgical, data management, or recruitment teams) or site teams (rural or urban teams) to observe, discuss and document real-time adaptations. The periodic reflections were audio-recorded and transcribed.

Outcome Measures

Adaptation

To explore adaptations in the pRCT, we reviewed participants' engagement with the 2wT system, tracked the database for daily operational notes, and reviewed reminder emails about adaptations to the research team and partners. We documented implementation choices, constraints, and challenges of the 2wT intervention via a shared Google Doc that was accessible to all pRCT study staff and updated each weekday as per study protocol. At the completion of the pRCT, we qualitatively and descriptively reviewed and considered the adaptations to the

various implementation strategies. We documented changes made to improve men's engagement with the 2wT system, reviewed choices that improved implementation feasibility and updates to implementation strategy that aimed to increase equity (e.g., language, operation hours) of 2wT delivery in both rural and urban environments. The Google Sheet was consistently reviewed by principal investigators (PIs) to reduce missing adaptations and ensure accuracy. We documented adaptations that impacted costs as well.

Fidelity

We employed two distinct sources of fidelity data: firstly, through direct observations during periodic reflections with implementers, leveraging their expertise and objectivity; secondly, by analyzing clients' engagement with the 2wT system, benefitting from real-time reporting. This dual-source approach allowed for comprehensive comparisons between fidelity information derived from implementers and clients. The weekly collection of detailed client data in the system facilitated a nuanced analysis of fidelity patterns over time, supplying valuable information to the principal investigators and adaptation team (16).

Data analysis

Using the FRAME-IS coding manual, two researchers categorized the adaptations to the 2wT project using the categories within each FRAME-IS construct (15). We used the Google Doc and periodic reflections to identify, categorize and describe adaptations. Then, we qualitatively assessed the influence adaptations had on project outcomes. To assess influence, we examined the categories for each adaptation within the project in relation to the construct of perceived short-term impact, including impacts to reach, adoption, and implementation, and whether the adaptation preserved or altered the intervention's core elements or functions. The researchers used their depth of knowledge about the intervention to determine whether the adaptation had influence or impact on outcomes (17).

Thematic content analysis was used to analyze the data from periodic reflections and source documents. We created a spreadsheet of key themes derived from FRAME-IS model, described the adaptation and answered the four categories of IS questions (what, who, when, why). Codes were compared between analysts and discussed to reach a consensus for documenting adaptations.

Ethics

This qualitative study was embedded in an RCT, "Expanding and Scaling Two-way Texting to

Reduce Unnecessary Follow-Up and Improve Adverse Event Identification Among Voluntary Medical Male Circumcision (VMMC) Participants in the Republic of South Africa," that is registered at ClinicalTrials.gov (ID: NCT04327271). The overall study, including this sub-study, was approved by the Internal Review Board of the University of Washington (Study 00009703, PI: Feldacker) and the University of the Witwatersrand, Human Research Ethics Committee (Ethics Reference No: 200204, PI: Setswe). Participants in periodic reflections received comprehensive information regarding their voluntary participation in the study and signed a written informed consent form prior to study enrollment.

Results

The EBI being implemented was 2wT, a text-based follow-up method for VMMC tested through a pRCT in rural and urban settings in South Africa. The consort flow diagram (attached as an additional file) provides the flow of enrolment, allocation, follow-up and data analysis for the 2wT RCT. Table 2 dissects adaptations made to various implementation strategies employed to deliver the EBI. For each adaptation, we described the adaptation, indicated when the adaptation was made, who made it, at what level, and the goal of the adaptation as shown in Table 2.

Between June 2021 and February 2022, thirteen adaptations in three phases were made across 7 rural and urban sites where the 2wT pRCT was implemented. These adaptations (Table 2) included tailoring, tweaking, or refining some elements, changes in the packaging of materials, and removing elements.

Table 2: Adaptations made to implementation strategies to deliver 2wT for VMMC, adopted from FRAME-IS

Description of the adaptation	Goal of the adaptation	When was the adaptation done?	What was adapted?	Who?	Level of adaptation
Phase 1					
To recruit more VMMC clients, the team decided to conduct camps on selected weekends to recruit and perform MCs at the same time	Increase the reach of 2wT (the number of patients receiving 2wT)	Implementation	Context	VMMC team	Implementer level
During COVID-19 lockdowns, the rural VMMC team conducted circumcision as a mobile outreach service visiting patients in their communities	Improve feasibility of implementation in rural areas	Implementation (COVID-19 lockdown)	Context	Department Health	Organizational level
Two urban sites were added to increase the recruitment of VMMC clients	Improve urban, engagement, and implementation	Implementation	Context, local setting	ncipal estigator (PI)	Implementer level
The use of WhatsApp, check-in calls three times a week, weekly project update calls with all implementing teams (PI, technical and VMMC teams) to improve communication between implementation and research teams	Increase reach, engagement, or implementation	Implementation	Communication	Research Manager	Implementer level
During COVID-19 lockdowns, the team used virtual meetings and digital technology to implement 2wT remotely	Improve acceptability, appropriateness and feasibility, engagement, and implementation of the 2wT	Pilot and implementation	Context	Project manager, and VMMC team	Organizational level
The clinical team drew a duty roster to allocate one clinician to be available to communicate with clients on weekends and public holidays	Improve feasibility, engagement, and implementation of the 2wT	Pilot	Context, personnel implementing 2wT	Project Manager and VMMC team leaders	Clinician or researcher level
Phase 2					
Adding local language translations (Setswana and isiZulu) in the usability survey	Increase engagement and feasibility of 2wT and to improve the fit between the implementation effort	Pilot	Context, and format of 2wT	Research Manager	Clinician or researcher level

	and the needs of those receiving 2wT				
To fit the 2wT intervention into routine care, the research partner contributed a portion towards the salary of the implementing staff.	To increase equity and decrease disparities in the delivery of 2wT and routine care.	Implementation	Context	Project manager, and VMMC team	Organizational and implementer levels
Phase 3					
Two rural clinics were purposively excluded as recruitment sites to reduce costs and improve the effectiveness of the 2wT of the 2wT strategy.	Decrease costs of the implementation effort	Implementation	Context, local setting		Organizational and implementer levels
The PIs implemented additional data quality checks to ensure the validity of the data.	Improve the sustainability of 2wT and increase the chances that 2wT remains in practice	Implementation	Context, and format of the intervention	Research team	Organizational level
Non-clinical counsellors were trained to help enroll clients and capture them on the Medic system.	Increase the effectiveness of the clinical outcomes of the patients receiving 2wT.	Implementation	Training and evaluation	Research manager and VMMC team	Organizational and implementer levels
Retraining of staff members on recruitment, recording and follow-ups in the rural site with high staff turnover	Increase adoption or number of clinicians recommending and patients using 2wT.	Pilot and Implementation	Training and evaluation	Research Manager	Organizational and implementer levels
Enabling the system to accommodate enrollment of VMMC clients to the 2wT platform using both primary and alternative phone numbers	Improve fidelity or the extent to which 2wT is delivered as intended.	Implementation	Context	Technical and Research team	Organizational and implementer levels

Sources: Adapted from Miller, Barnett, Baumann (2021) (15) and Kirk, Nilsen, Andersen, et al., (2021) (18).

Phase 1

The first phase of adaptations aimed to augment study recruitment, including: conducting weekend VMMC recruitment camps; using mobile outreach services in the rural site; adding two urban sites to increase recruitment; using weekly WhatsApp calls for updates with all implementing teams; using virtual meetings to implement the 2wT strategy remotely during COVID-19 restrictions; and allocating one clinician to work outside of normal working hours.

During the week, participants were working or attending school. To address this and other contextual factors, such as high unemployment rates and precarious employment opportunities, we adapted the 2wT strategy. We conducted camps on selected weekends, reaching men without disrupting their work or school schedules and significantly boosting study recruitment.

Recognizing the slow enrolment in the urban area, we identified the need for additional sites. During the implementation stage, we proactively added two more sites to address the time constraints associated with the pRCT target recruitment numbers. These sites were selected based on the implementing partner's already existing setup within public clinics, ensuring a smooth and efficient process.

South African COVID-19 level 4 restrictions required the decongestion of health facilities. At the rural site, we used mobile outreach facilities to reach clients in their community. This adaptation addressed geographic distances in rural areas, allowing for more men to be reached.

The team used virtual meetings and digital technology to implement and refine 2wT remotely to compensate for international and local COVID-19 travel bans, which restricted the possibilities of physical meetings. To address communication challenges arising from COVID-19 restrictions, the challenges of working across countries and provinces, and working in network-poor locations, various platforms—such as WhatsApp and virtual calls—allowed the teams to provide updates on progress, deal with challenges as they arose, and adapt implementation accordingly.

Clients would contact clinicians after hours, on public holidays, and weekends. One adaptation made was a roster for clinicians to attend to clients after hours to distribute the additional workload. Before the roster, all the extra hours would fall on one or two clinicians, creating unequal workloads.

Phase 2

The second phase of adaptations further enhanced enrollments, including adding two local language translations in the usability survey for 2wT men and contributing a portion towards the salary of the implementing staff by the research partner. During the pilot, the team ascertained that the usability study needed to be translated into local languages (i.e., Setswana and isiZulu) to reach participants who were not fluent in English. Implementing staff initially viewed 2wT as a separate intervention from routine follow-up for VMMC, resulting in a reluctance to attend to clients after hours and additional time burdens for documentation of pRCT processes. To address this, a portion of the implementing staff's salary was allocated from the 2wT budget.

Phase 3

The third phase included: the exclusion of two rural clinics as recruitment sites due to inconsistent mobile phone networks; adding another layer of data quality checks to ensure data quality; training non-clinical counselors to help with enrolling clients; retraining of staff in the rural site with high staff turnover; and using both primary and alternative phone numbers for enrollment to reduce loss to follow up.

Two facilities in the rural area were excluded because these sites had no mobile phone network coverage during load-shedding[1], and enrolments could not be done. While offline enrollments in the Medic system were not possible at the time of the pRCT, developing future offline functionality could further adapt the intervention to network-poor contexts. These sites were also very far from the rural team hub, and routine client follow-ups were impractical.

The VMMC team had data quality monitors, but continuous monitoring revealed quality assurance gaps. To address this, the PIs added another layer to review the quality of the data collected. The research team also conducted in-person data reviews to catch data quality issues.

During the busy winter season, clinicians were occupied attending to MCs and could not administer informed consent and capture client details on the Medic system. To address this, non-clinical counselors were recruited to assist with client enrollment and capture them on the Medic system. Each intern was provided with a device and sufficient data to recruit, educate about the 2wT approach, and enroll clients in the Medic system. This adaptation reduced clinicians' workload while increasing the intervention's reach.

[1] Due to South Africa's energy crisis, periodic scheduled electricity cuts, referred to as load shedding, were implemented nationally to reduce the burden on the electricity grid.

Staff turnover became very high in the rural site during the early part of the intervention. New staff had to be trained in onboarding, and existing staff were retrained as needed. To accommodate high staff turnover rates, a robust training approach that is effective for quickly onboarding new staff is required.

On a few occasions, participants would change or lose their primary phones, which led to their being lost to follow-up. The team adapted the enrollment process to include collecting additional contact details to assist with tracing.

Discussion

Fidelity and adaptations

Conducting research under pragmatic settings enabled both researchers and implementers to better understand how the EBI performed in diverse populations and settings. The FRAME-IS helped explore and explain the influence of adaptation to ensure, not reduce, fidelity. There are merits to emphasize both intervention fidelity for internal validity and encouraging acceptance of adaptations that boost external validity for diverse intervention contexts (17). We present three IS-related takeaways from our adaptation exploration.

First, fidelity and adaptation may not be opposing concepts; instead, there should be an exploration of how to achieve a balance between intervention fidelity and adaptation within EBIs, allowing for *adaptive interventions* (16). Chambers & Norton (2016) challenge the assumption that the common trajectory of moving with fidelity from RCT to routine practice is best. Rather, they call for flexibility to consider the positive effect of adaptations made during intervention implementation, an openness for new data that could drive intervention efficiency gains, and recognition that intervention momentum may drive implementation fit even before the evidence base is solidified (19). They continue by proposing the *Adaptome* with a more fluid concept of where, when, and how evidence is gathered in support an intervention's evolving positive impact, allowing for considerations of adaptations to optimize the intervention and its implementation over time (19). In line with Chambers, adaptations to 2wT implementation were considered throughout the RCT, responding to needs to improve fit at clinician, clinic, and organizational levels, showing awareness of, and openness to, opportunities for improving 2wT implementation over time and context. Indeed, responding to needs as they arose allowed us to stay attuned to contextual sensitivities, limitations and opportunities and (re)shape 2wT implementation to be an equitable, reliable and quality health

solution. Recognition that fidelity and adaptation can be concurrent, and not oppositional, forces along the pathway from research to practice is also promoted by the Value Equation developed by von Thiele Schwarz et al (20). In growing recognition that adaptation is necessary to optimize fit, a simplified summary of von Thiele Schwarz's model suggests that the optimal intervention value (V) for multiple stakeholders is a combined product of an evolving intervention (IN) that reflects its broad context (C), and adaptive implementation strategies (IS) that drive intervention fit. Overall, the Value Equation suggests that implementers consider a broad view of intervention value, using adaptive implementation strategies to align EBIs with their contexts, and be transparent in the processes to guide both internal and external considerations for intervention expansion.

Second, 2wT adaptations appear acceptable and in line with enhanced fidelity. The nature and content of the adaptations in this study, as supported by O'Connor, Small and Cooney, (2007) are acceptable adaptations (17). For adaptation of the 2wT intervention, there was no deviation from the established implementation strategy, characterized by a lack of loosening in structure or departure ("drift") within the implementation. Likewise, there was no instance of drifting from the implementation strategy without subsequent return, such as ceasing to offer consultation or halting post-operative follow-ups (18). The adaptations also aimed to reduce the number of patients who were lost to follow up, improving fidelity or the extent to which 2wT is delivered as intended. Pérez, Van der Stuyft, Zabala, *et al*., (2015) support the idea that fidelity and adaptation co-exist and that adaptations can impact the effectiveness of the intervention either positively or negatively (16). They further suggest that it is essential to look systematically at the aspects of an intervention that are being adapted and that implementation research should answer the question of how an adequate fidelity-adaptation balance can be reached.

Third, adaptation was necessary in the context of COVID-19 to enhance effectiveness in this real-world setting. The 2wT implementation adaptations largely responded to the changing landscape of COVID-19 restrictions, changes in policy for in-person reviews, and reflected waves of client concerns in accessing healthcare services – especially voluntary ones like VMMC. Adapting the strategy to reach more patients with routine VMMC services, and therefore increase the likelihood of 2wT recruitment, was a near-contact challenge during this period. Moreover, 2wT adoption was likely enhanced during this period when healthcare workers and programs sought methods or options to reduce clinician/patient contact.

Furthermore, although clearly not in response to the global pandemic, the timeliness of the 2wT intervention cannot be understated. COVID-19 likely improved the fit between the implementation effort and the needs of those delivering 2wT. Rapid adoption of other virtual follow-up and tacit approvals for telehealth over potential for increased transmission also helped improve fidelity of the intervention. Growing understanding of the underlying cost advantages (less travel), improved equity (more language options for client communication, reduced client transport costs) and improved safety using 2wT likely created an enabling environment for adaptations and their acceptance.

Overall, adaptations occurred at four levels. At socio-political level, the adaptations were done to address existing national VMMC follow-up mandates such as reducing the number of physical visits to health facilities and replacing them with 2wT. At organizational level, adaptations were implemented to address available staffing or materials. For example, counsellors were trained to enroll and consent clients to relieve the load from clinicians so they can have more time to conduct circumcisions. The implementer level (program and clinical teams) was for those charged with leading the implementation effort. The team leader of the implementation team could make adaptations or decisions on who does circumcisions or follow-ups or enrolments daily. The patient or recipient level was for the circumcised men who were benefitting as intended from the 2wT intervention. They could enroll in a language that was familiar to them and receive follow-up support via 2wT instead of in-person reviews.

Limitations of the study

We attempted to capture adaptations in real time, rather than through interviews as is often the case with studies on adaptations. This process may have identified more or different adaptations than if we had waited until the end of the study period. We also experienced variability in opportunities to identify adaptations for direct communication between researchers and implementation teams. Transferability of the adaptation findings may be limited as these adaptations were tied to the times and the contexts in which they were found. For example, key adaptations were implemented to accommodate the COVID-19 pandemic. While clearly unplanned, the COVID-19 pandemic influenced both updates and adaptations in the 2wT approach to reflect the clinical and contextual realities of the tumultuous time. While the adaptations made to the 2wT project may not be generalizable, the process developed to capture and make sense of adaptations could be utilized by researchers in other settings (21).

The COVID-19 crisis spurred these adaptations, and 2wT became the right mHealth tool at the right time.

Developing equitable, reliable and quality health solutions to understand and address health needs in resource-constrained settings is shaped by a particular set of opportunities and challenges that impact the planning and conducting of research (22-25). IS is designed to improve routine healthcare, but the capacity to carry out IS research in resource-constrained settings is limited by inequality, poverty, human resources capacity, overburdened healthcare clinics and so forth (26). This was felt particularly in the implementation of 2wT. Contextual realities shape possibilities of how IS can(not) be done in resource-constrained settings. In doing an IS pRCT within both the emergency context of COVID-19 and longstanding contextual constraints embedded in the South African healthcare system, it became difficult to command and control the routine setting to the minute detail. For example, while men were supposed to be enrolled in the system when they were first seen at the clinic, clinicians sometimes enrolled them in the 2wT system at night to make up for network downtime and busy clinics. Real-time adaptations slipped into the implementation without broader discussion to manage real-world challenges as they arose. While the research team conducted a pRCT, the clinical teams did their everyday jobs. The implication is that not all adaptations could be meticulously documented as they were embedded within everyday practice. Therefore, adapting the approach to account for local constraints also requires right sizing our rigour.

Conclusions

The adaptations made to the 2wT pRCT in South Africa and the justifications provided, support the idea that adaptations are common and inevitable to account for the needs of specific contexts. The results reflect that the reality of implementing mHealth interventions is a highly dynamic and adaptive process in which adaptations contribute to optimization for maximum impact. There are merits to arguments for both fidelity and adaptation. We used the FRAME-IS model to reconcile the debate on fidelity and adaptation. Although the model is meant to be a flexible, practical tool for documenting adaptations to the implementation of EBI, its use may help illuminate the pivotal processes and mechanisms by which implementation strategies exert their effects. We suggest that the FRAME-IS be used to help IS move toward a better understanding of the roles of fidelity and adaptation in the implementation process. Adaptations helped the study balance research rigor and relevance to the rural and urban environments

where the intervention was implemented. Fidelity and rigor should not be the enemy of adaptation and relevance in closing the gap between research in the laboratory and practice.

Declarations

Ethics approval and consent to participate.

This Multiple Principal Investigators (MPI) study was approved by the Internal Review Boards of the University of Washington (00009703, PI: Feldacker) and the University of the Witwatersrand, Human Research Ethics Committee (Ethics Reference No: 200204, PI: Setswe). Consent to participate in the study was obtained from all eligible clients.

Consent for publication

The authors give consent to Implementation Science and its publishers to publish this manuscript.

Availability of data and materials

All relevant data from this study are within the manuscript and its Supporting Information files. The data sets generated during or analyzed during this study are available from the corresponding author upon reasonable request. Our complete transcripts contain data that is sensitive or includes identifying information. We would like the confidentiality of the participants protected in accordance with the consent agreement. Due to these concerns, we are unable to make the full transcripts available to a wider audience. We will make the transcripts easily available to fellow researchers or reviewers who complete a data sharing agreement.

Competing interests

None declared.

Funding

Research reported in this publication was supported by the National Institute of Nursing Research of the National Institutes of Health under award number 5R01NR019229, “Expanding and Scaling Two-Way Texting to Reduce Unnecessary Follow-up and Improve Adverse Event Identification Among Voluntary Medical Male Circumcision Clients in the Republic of South Africa” (principal investigators: CF and GS).

Authors' contributions

GS and CF conceptualized the study.

CF, GS and JP acquired funding and provided the resources for the 2wT RCT and this study.

GS and CF supervised this study as Principal Investigators and ensured adherence to the protocol.

GS, CF, and JP conducted the 2wT trial from which this study was created.

GS, CF, FN, and JP deliberated and agreed on the FRAME-IS as a methodology to guide the study.

GS and FN collected data on adaptations into the google doc, project meeting records and from interviews with field teams and conducted formal analysis of the data.

GS, CF, FN, JP, VN, SD and IS contributed to the writing, review and editing of the manuscript.

Acknowledgements

The authors would like to thank the Departments of Health of the Gauteng and North West provinces; implementing partner, Right to Care, for enabling the participation of the clinical teams; and the CHAPS study implementation team for their dedication and skills in study recruitment, data management, and data capture. The authors would also like to thank the Medic Research team for their support of the 2wT study implementation and adaptation process.

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Responsibility: Dr Day is Senior Research Officer at the University of Cape Town. She served as the Research Manager at CHAPS during the RCT, and was involved in research activities in the study.

Abbreviations

2wT: two-way texting

AE: adverse event

CHAPS: Center for HIV-AIDS Prevention Studies

EBI: evidence-based intervention

FRAME-IS: framework for reporting adaptations and modifications in evidence-based implementation strategies.

HCW: health care worker

IS: implementation science

KII: key informant interview

MC: male circumcision

M&E: monitoring and evaluation

mHealth: mobile health

NDoH: national department of health

pRCT: pragmatic randomized controlled trial

RCT: randomized controlled trial

RTC: right to care

VMMC: voluntary medical male circumcision

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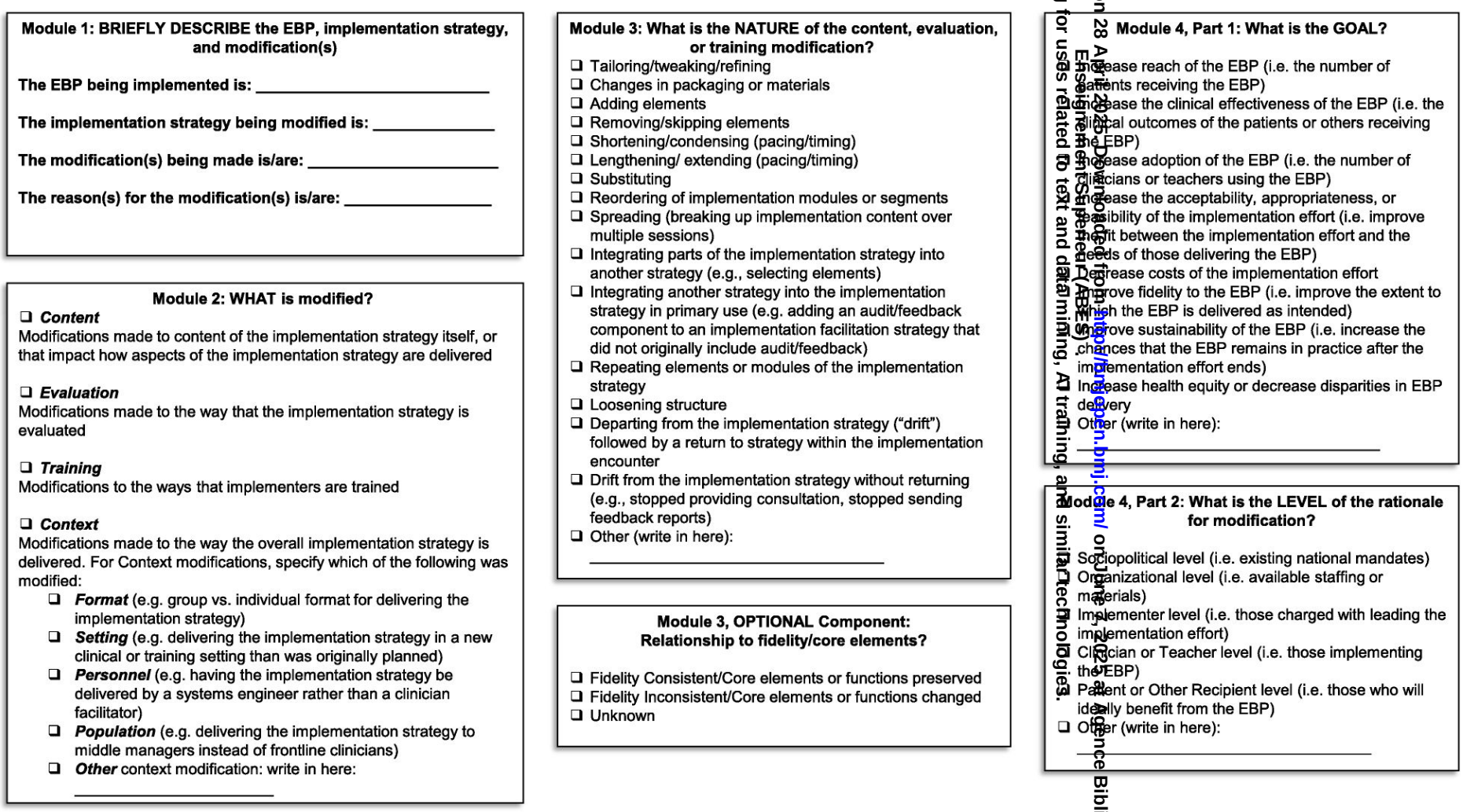
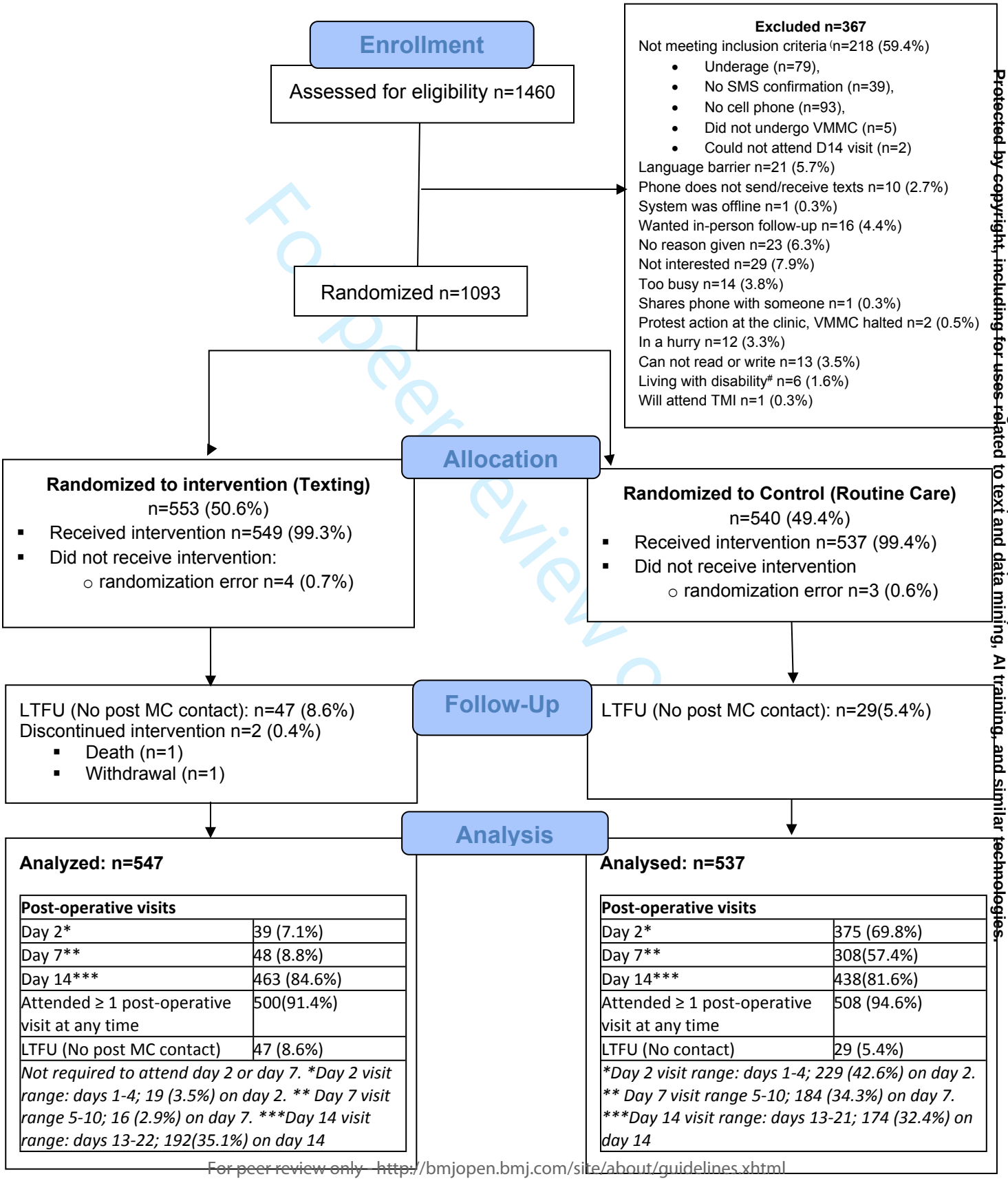
Figure 1: The FRAME-IS for documenting adaptations to implementation of interventions.



Source: Miller, Barnett, Baumann [15]

CONSORT 2010 Flow Diagram



Living with disability; deaf n=2, blind n=2, mentally handicapped n=2

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Finding the balance between rigor and relevance: Implementing adaptations to the implementation of a pragmatic randomized controlled trial of a two-way texting intervention for voluntary medical male circumcision in South Africa

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2024-091934.R1
Article Type:	Original research
Date Submitted by the Author:	05-Mar-2025
Complete List of Authors:	Setswe, Geoffrey; Aurum Institute; University of South Africa, Department of Health Studies Day, Sarah; University of Cape Town; Centre for HIV-AIDS Prevention Studies (CHAPS) Ndebele, Felex; Aurum Institute Pienaar, Jacqueline; Aurum Institute; Centre for HIV-AIDS Prevention Studies (CHAPS) Ncube, Vuyolwethu; Aurum Institute Feldacker, Caryl; University of Washington School of Public Health, Global Health; International Training and Education Center for Health,
Primary Subject Heading:	Public health
Secondary Subject Heading:	HIV/AIDS
Keywords:	HIV & AIDS < INFECTIOUS DISEASES, Digital Technology, Implementation Science, Randomized Controlled Trial

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Finding the balance between rigor and relevance: Implementing adaptations to the implementation of a pragmatic randomized controlled trial of a two-way texting intervention for voluntary medical male circumcision in South Africa

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Abstract

Objectives: To document adaptations that were made to the implementation of the Two-Way Texting (2wT) randomised controlled trial for Voluntary Male Medical Circumcision (VMMC) in South Africa and to provide a nuanced discussion on the differences between adaptations and fidelity in this context.

Design: We conducted a qualitative study using the Framework for Reporting Adaptations and Modifications in Evidence-based Implementation Strategies (FRAME-IS) to examine 2wT adaptations. We reported adaptations to the 2wT intervention using two steps. First, we categorized adaptations in a shared study-specific Google Doc that documented participant engagement with the 2wT system, tracked daily RCT implementation notes, reported software bugs, and noted reminder emails about adaptations for the research team. Second, we conducted a qualitative assessment of the influence of adaptations on project outcomes via 10 periodic reflection meetings with VMMC implementers. Reflection documentation included notes from field observations, meeting minutes, and informal partners check-ins to complete adaptation documentation. Using the FRAME-IS as a codebook, adaptations were categorized.

Setting: The RCT was conducted in a rural and urban VMMC clinics in the North West and Gauteng districts of South Africa

Participants: Implementation scientists and VMMC implementers who implemented the 2wT pRCT were participants for the adaptation study.

Primary and secondary outcome measures: The primary outcome measure was the adaptations that were made during the implementation of the 2wT pRCT. The secondary outcome measures were fidelity and rigor of implementing adaptations to the 2wT pRCT.

Results: Between June 2021 and February 2022, 13 adaptations were identified in three phases during the implementation of the 2wT pRCT. The first phase of adaptations aimed to augment study recruitment, including: conducting weekend VMMC recruitment camps; using mobile outreach services in the rural site; adding two urban sites to increase recruitment; using weekly WhatsApp calls for updates with all implementing teams; using virtual meetings to implement the 2wT strategy remotely during COVID-19 restrictions; and allocating one clinician to work outside of normal working hours. The second phase of adaptations further enhanced enrollments, including adding two local language translations in the usability survey for 2wT men and contributing a portion towards the salary of the implementing staff by the research

partner. The third phase included: the exclusion of two rural clinics as recruitment sites due to inconsistent mobile phone networks; adding another layer of data quality checks to ensure data quality; training non-clinical counselors to help with enrolling clients; retraining of staff in the rural site with high staff turnover; and using both primary and alternative phone numbers for enrollment to reduce loss to follow up.

Conclusions: This study made adaptations to the 2wT pRCT without compromising the fidelity of the study. The 2wT pRCT balances rigor (fidelity) and relevance (adaptation). Adaptations should not be confined by rigor but should also not go unchallenged or unverified. We conclude that fidelity can be maintained with adaptations that are implemented to close the gap between research in the laboratory and practice.

Trial Registration: The trial from which this study was conducted, "Expanding and Scaling Two-way Texting to Reduce Unnecessary Follow-Up and Improve Adverse Event Identification Among Voluntary Medical Male Circumcision (VMMC) Participants in the Republic of South Africa," was registered at ClinicalTrials.gov (ID: NCT04327271) on March 31, 2020.

Keywords: adaptations; pragmatic randomized controlled trial; rigor; relevance; two-way testing; voluntary medical male circumcision.

Strengths and limitations of this study

- In capturing adaptations in real time, rather than through interviews as is often the case with studies on adaptations, we have identified more and different adaptations than if we had waited until the end of the trial period.
- Although the adaptations were implemented to accommodate the COVID-19 pandemic, the pandemic in turn spurred these adaptations, and 2wT became the right mHealth tool at the right time.
- Implementation Science is designed to improve routine healthcare, but the capacity to carry out an IS adaptation study of a 2wt pRCT in resource-constrained settings was limited by inequality, poverty, human resources capacity, overburdened healthcare clinics and so forth [1].
- In conducting an IS pRCT within both the emergency context of COVID-19 and longstanding contextual constraints embedded in the South African healthcare system, it became difficult to command and control the routine setting to the minute detail to achieve the rigor demanded by an RCT.

- While the research team conducted a pRCT and the clinical teams did their everyday jobs to ensure relevance, adapting the approach to account for local constraints also required balancing between rigour and relevance.

Background

Implementation science (IS) involves finding ways to maximize the adoption and uptake of known and tested evidence-based interventions (EBIs) in practice [2]. To aid in the adoption of EBIs, researchers, and implementers may make use of implementation strategies, which cover the 'how to' part of delivering the EBIs [3]. These strategies may include methods of provider training, use of tool kits, checklists, guidelines, and user manuals [4].

In acknowledging the difference in settings and environments in which EBIs are implemented, it is imperative that these implementation strategies be tailored for each specific setting for the efficient delivery of the EBI [4]. In this study, an adaptation was defined as altering the delivery of the pragmatic randomized controlled trial (pRCT) considerately and deliberately to improve its fit or effectiveness in the rural and urban contexts [5]. The adaptations we made, reflected diverse processes of change that were responsive to unanticipated challenges that arise during implementation of the pRCT [6]. These adaptations were required to fit the pRCT, its budget, timelines, and staffing needs in the rural and urban environments [7]. When adaptations were made to the pRCT, the original design of the intervention was left unaltered, thereby maintaining fidelity. We defined fidelity as staying true to the original design of the pRCT by implementing the 2wT intervention as we intended as developers [8].

Adaptations and fidelity are concepts that are carefully negotiated in randomized controlled trials (RCTs). RCTs require implementers to remain consistent with the core elements of EBI through the rationale, process, and outcome of the intervention– maintain fidelity. Our pRCT, implemented in real-world, routine, rural and urban community settings required implementation scientists to make adaptions due to evolving changes in the population characteristics, research and implementing agencies, and/or community contexts [9]. Our *pragmatic* RCT (pRCT), aimed to evaluate the effectiveness of a 2wT intervention in real-world settings rigorously, not strictly research settings, to understand better and bridge the divide between research and routine contexts [10]. We used adaptations as tools to achieve this.

We conducted a pRCT in South Africa between 2021 and 2022, applying the process of planned or purposeful adaptations to the content and delivery of the intervention [11] in response to emerging and evolving COVID-19 constraints and opportunities [11-13]. The pRCT aimed to determine if a mobile health (mHealth) innovation, two-way texting (2wT) can safely reduce post-operative follow-up after voluntary medical male circumcision (VMMC) while reducing provider workload.

In this paper, we describe adaptations to the delivery of a mHealth-focused pRCT in response to the volatile environment during the COVID-19 lockdown period in South Africa.

Methods

The 2wT intervention

The 2wT messaging platform was built using Medic's open-source Community Health Toolkit. The intervention was described in detail previously [11-14]. In brief, the 2wT system comprises 4 core components at the provider and patient levels: (1) hybrid automated and interactive patient-to-provider messaging over the first 13 days of post-VMMC follow-up; (2) SMS text messaging–based triaging of clients by nurses (e.g. for reassurance, referrals to care, follow-up in case of no contact); (3) daily client monitoring via SMS text messaging; and (4) longitudinal patient records (potential AEs, AE follow-up, and referral confirmation) and reporting (e.g. client response rates). These features of 2wT were designed to support a streamlined workflow, reinforce high-quality VMMC services, and generate data to monitor the program delivery [11-14].

For the pRCT, 1093 men were randomized 1:1 across 2 arms and divided equally across urban and rural districts, with 553 men assigned to the 2wT intervention arm [11]. Recruitment for the study commenced on June 7, 2021, and follow-up was completed on February 21, 2022. Males ages 18+ were followed up for 14 days by either routine, post-operative, in-person visits on days 2 and 7 (control) or 2wT daily messaging with a VMMC nurse in lieu of clinical reviews (intervention). All participants returned for a study-specific review on postoperative day 14 to determine healing status and record adverse events (AEs). 2wT aimed to support patients to monitor wound-healing on their own and to empower them to opt-in for physical follow-up visits only if necessary. 2wT visits and AE outcomes were compared between groups.

Study design and framework

We conducted a qualitative study using the Framework for Reporting Adaptations and Modifications in Evidence-based Implementation Strategies (FRAME-IS) summarized in Figure 1. We documented adaptations to the strategies that were employed in implementing the 2wT EBI using four modules of FRAME-IS to describe: (1) the 2wT intervention, the implementation strategies employed, and the adaptations done; (2) what was adapted; (3) the

nature of the content adapted; and (4) the goal and the level of the rationale for the adaptation [15]. We also assessed rigor and relevance in documenting adaptations.

Insert Figure 1

Using the FRAME-IS as a codebook, adaptations were described and categorized. We documented adaptations to the implementation of the 2wT study using two steps: (1) we used qualitative data from Google Sheets to identify, categorize, and describe adaptations; (2) qualitatively assessed the impact of adaptations on project outcomes via a review of program reflection documentation (field observations, meeting minutes, informal check-ins, etc.) [16].

Patient and public involvement

A Community Advisory Board (CAB) that was consulted during the conduct and design of the study and acted as community gatekeeper. The results of the study were disseminated to study participants and community stakeholders at two district health research conferences in 2023 and 2024. Dissemination to other stakeholders is planned through the local and international conferences and publications.

Ethical approvals

The study obtained ethics approval from the University of Witwatersrand Health Research Ethics Committee (HREC) and the provincial research ethics committees in the two provinces where the study was conducted. The Data Safety Monitoring Board (DSMB) for the 2wT study reviewed interim safety at periodic intervals and upon completion of the recruitment of 1093 men in the study

Data collection methods and documentation

We used various data collection methods to document the implementation for the delivery of pRCT, as summarized in Table 1.

Step 1) Google Sheets and other primary data sources:

Daily progress notes and other operational data were recorded on Google Sheets as part of routine study monitoring.

Google sheets is a web-based spreadsheet that allowed the research team to create, update, modify and share the data online which we accessed through our Google accounts. The study nurse and the data capturer completed the Google doc daily. This process documentation for the study showed enrolments per site, per arm, and daily interactions with the participants. It was also used to triangulate data and was shared in real-time.

Table 1: Google Sheet for the 2wT Arm

Column (Day 2/ Day 7)	F /J	G/K	H/L	I/M
	Day 2/7 spontaneous text response yes/no	**Day 2/7 text reminder yes/no**	**Day 2/7 call yes/no**	**Day 2/7 tracing referral made yes/no**
Instructions	Did the participant respond to the automated texts? Go under reports and look for No AE Reported or Suspected AE Reported reports. If there are no reports, check under messaged if the client did not initiate a conversation or did not send messages. If none of this is present, answer with a No. Otherwise enter **Yes** and leave columns G, H & I.	I f column F is answered a No, the nurse is expected to have sent a reminder text. Did the participant respond to the reminder text? Id not, answer this column with a No. **Otherwise enter Yes and leave column H & I blank.**	If the participant did not respond to the reminder text, the nurse is expected to have called the participant. Did the nurse get hold of the participant via phone call? If not, then answer this column with a No. Otherwise enter **Yes** and leave column I blank.	Was contact made during a home visit? If not, then answer this column with a No and then we note that no contact was made with the participant for their Day 2 / Day 7 milestone.

For the two-way texting arm, columns F through I were completed between Day 1 and Day 3 for the Day 2 visit, and columns J through M were entered between Day 6 and Day 8 for the Day 7 visit. This section recorded whether we made contact with the participant between Day 1 and Day 3 and is equivalent to the Day 2 Visit for routine care and between Day 6 and 8 for the Day 7 visit. Only one of these columns in each section (Columns F – I and Columns J – M) could be answered with Yes to indicate the type of contact that was first documented. If the participant did not respond to automated texts, text reminders, and phone calls, then all fields could be answered with a No.

Other primary data sources included participant observations, training workshop notes, site visit reports, emails, and communication through the study team's WhatsApp. We used a data

extraction sheet to document data on adaptations that were made to the implementation strategies, reviewing and coding content in Google Sheets related to adaptations made to the strategy, fit and effectiveness. Adaptations to the implementation of the 2wT study were extracted and coded from Google Sheets.*Step 2) Periodic reflections*: As part of informal or routine partner and stakeholder review meetings, we conducted ten (10) periodic reflections with implementers of the 2wT pRCT in the rural and urban sites to answer the following IS optimization questions:

1. *What* component or part of the implementation to deliver the 2wT intervention was changed in this adaptation; in other words, what was the nature of the change?
2. *Who* was responsible for first suggesting or initiating this change? Was this the person or persons who implemented the change? If not, who implemented the adaptation?
3. *When* during the 2wT intervention was this adaptation first made?
4. *Why* was this adaptation made? Was this done to get more people to participate, to make the program attractive to more settings, to increase its effectiveness, to make it easier to deliver, to make it easier to maintain or reduce costs, etc.? [10]

The research manager conducted *periodic reflections* and *observations* in the form of 15–60-minute meetings, at least once a month. These were lightly guided discussions by telephone, Zoom or site visit conducted with individuals (such as nurses, clinical associates, team leaders, data managers, recruiters, etc), small teams (such as the surgical, data management, or recruitment teams) or site teams (rural or urban teams) to observe, discuss and document real-time adaptations. The periodic reflections were audio-recorded and transcribed.

Data analysis

To explore adaptations in the pRCT, we reviewed participants' engagement with the 2wT system, tracked the database for daily operational notes, and reviewed reminder emails about adaptations to the research team and partners. We documented implementation choices, constraints, and challenges of the 2wT intervention via a shared Google Doc that was accessible to all pRCT study staff and updated each weekday as per study protocol. At the completion of the pRCT, we qualitatively and descriptively reviewed and considered the adaptations to the various implementation strategies. We documented changes made to improve men's engagement with the 2wT system, reviewed choices that improved implementation feasibility and updates to implementation strategy that aimed to increase equity (e.g., language, operation hours) of 2wT delivery in both rural and urban environments. The Google Sheet was

consistently reviewed by principal investigators (PIs) to reduce missing adaptations and ensure accuracy. We documented adaptations that impacted on costs as well.

We employed two distinct sources of fidelity data: firstly, through direct observations during periodic reflections with implementers, leveraging their expertise and objectivity; secondly, by analyzing clients' engagement with the 2wT system, benefiting from real-time reporting. This dual-source approach allowed for comprehensive comparisons between fidelity information derived from implementers and clients. The weekly collection of detailed client data in the system facilitated a nuanced analysis of fidelity patterns over time, supplying valuable information to the principal investigators and adaptation team [17].

Using the FRAME-IS coding manual, two researchers categorized the adaptations to the 2wT project using the categories within each FRAME-IS construct [18]. We used the Google Doc and periodic reflections to identify, categorize and describe adaptations. Then, we qualitatively assessed the influence adaptations had on project outcomes. To assess influence, we examined the categories for each adaptation within the project in relation to the construct of perceived short-term impact, including impacts to reach, adoption, and implementation, and whether the adaptation preserved or altered the intervention's core elements or functions. The researchers used their depth of knowledge about the intervention to determine whether the adaptation had influence or impact on outcomes [19].

Thematic content analysis was used to analyze the data from periodic reflections and source documents (18). We created a spreadsheet of key themes derived from FRAME-IS model, described the adaptation and answered the four categories of IS questions (what, who, when, why). Codes were compared between analysts and discussed to reach a consensus for documenting adaptations.

Ethics

This qualitative study was embedded in an RCT, “Expanding and Scaling Two-way Texting to Reduce Unnecessary Follow-Up and Improve Adverse Event Identification Among Voluntary Medical Male Circumcision (VMMC) Participants in the Republic of South Africa,” that is registered at ClinicalTrials.gov (ID: NCT04327271). The overall study, including this sub-study, was approved by the Internal Review Board of the University of Washington (Study 00009703, PI: Feldacker) and the University of the Witwatersrand, Human Research Ethics Committee (Ethics Reference No: 200204, PI: Setswe). Participants in periodic reflections received comprehensive information regarding their voluntary participation in the study and

signed a written informed consent form prior to study enrollment.

Results

The EBI being implemented was 2wT, a text-based follow-up method for VMMC tested through a pRCT in rural and urban settings in South Africa. The consort flow diagram (attached as an additional file) provides the flow of enrolment, allocation, follow-up and data analysis for the 2wT RCT. Table 2 dissects adaptations made to various implementation strategies employed to deliver the EBI. For each adaptation, we described the adaptation, indicated when the adaptation was made, who made it, at what level, and the goal of the adaptation as shown in Table 2.

Between June 2021 and February 2022, thirteen adaptations were made across 7 rural and urban sites where the 2wT pRCT was implemented. These adaptations (Table 2) included tailoring, tweaking, or refining some elements, changes in the packaging of materials, and removing elements. Two sets of adaptations were made to ensure rigor/fidelity or relevance. In Table 2 under Goal of the adaptation, we label each of the adaptations either as an adaptation to 1) ensure *rigor or fidelity* in implementing the 2wT as it was designed or 2) ensure *relevance* of the study to the context and environment that prevailed. Of the thirteen (13) adaptations made to the 2wT study, 6 were adaptations to ensure rigor or fidelity and 7 were adaptations to ensure relevance of the study.

276 **Table 2: Adaptations made to implementation strategies to deliver 2wT for VMMC, adopted from FRAME-IS**

Description of the adaptation	Goal of the adaptation	When was the adaptation done?	What was adapted?	Who?	Level of adaptation
To recruit more VMMC clients, the team decided to conduct camps on selected weekends to recruit and perform MCs at the same time	Increase the reach of 2wT (the number of patients receiving 2wT) [Rigor/Fidelity]	Implementation	Context	VMMC team	Implementer level
During COVID-19 lockdowns, the rural VMMC team conducted circumcision as a mobile outreach service visiting patients in their communities	Improve feasibility of implementation in rural areas. [Relevance/Adaptation]	Implementation (COVID-19 lockdown)	Context	le Department of Health	Organizational level
Two urban sites were added to increase the recruitment of VMMC clients	Improve urban engagement, and implementation [Relevance/Adaptation]	Implementation	Context, local setting	ncipal vestigator (PI)	Implementer level
The use of WhatsApp, check-in calls three times a week, weekly project update calls with all implementing teams (PI, technical and VMMC teams) to improve communication between implementation and research teams	Increase reach, engagement, or implementation. [Rigor/Fidelity]	Implementation	Communication	Research Manager	Implementer level
During COVID-19 lockdowns, the team used virtual meetings and digital technology to implement 2wT remotely	Improve acceptability, appropriateness and feasibility, engagement, and implementation of the 2wT [Rigor/Fidelity]	Pilot and implementation	Context	Project manager, and VMMC team	Organizational level
The clinical team drew a duty roster to allocate one clinician to be available to communicate with clients on weekends and public holidays	Improve feasibility, engagement, and implementation of the 2wT [Relevance/Adaptation]	Pilot	Context, personnel implementing 2wT	Project Manager and VMMC team leaders	Clinician or researcher level
Adding local language translations (Setswana and isiZulu) in the usability survey	Increase engagement and feasibility of 2wT and to improve the fit between the implementation effort	Pilot	Context, and format of 2wT	Research Manager	Clinician or researcher level

	and the needs of those receiving 2wT. [Rigor/Fidelity]				
To fit the 2wT intervention into routine care, the research partner contributed a portion towards the salary of the implementing staff.	To increase equity and decrease disparities in the delivery of 2wT and routine care. [Relevance/Adaptation]	Implementation	Context	Project manager, and VMMC team	Organizational and implementer levels
Two rural clinics were purposively excluded as recruitment sites to reduce costs and improve the effectiveness of the 2wT of the 2wT strategy.	Decrease costs of the implementation effort [Relevance/Adaptation]	Implementation	Context, local setting		Organizational and implementer levels
The PIs implemented additional data quality checks to ensure the validity of the data.	Improve the sustainability of 2wT and increase the chances that 2wT remains in practice [Rigor/Fidelity]	Implementation	Context, and format of the intervention	Research team	Organizational level
Non-clinical counsellors were trained to help enroll clients and capture them on the Medic system.	Increase the effectiveness of the clinical outcomes of the patients receiving 2wT. [Relevance/Adaptation]	Implementation	Training and evaluation	Research manager and VMMC team	Organizational and implementer levels
Retraining of staff members on recruitment, recording and follow-ups in the rural site with high staff turnover	Increase adoption or number of clinicians recommending and patients using 2wT. [Rigor/Fidelity]	Pilot and Implementation	Training and evaluation	Research Manager	Organizational and implementer levels
Enabling the system to accommodate enrollment of VMMC clients to the 2wT platform using both primary and alternative phone numbers	Improve fidelity or the extent to which 2wT is delivered as intended. [Relevance/Adaptation]	Implementation	Context	Technical and Research team	Organizational and implementer levels

Sources: Adapted from Miller, Barnett, Baumann (2021) [18] and Kirk, Nilsen, Andersen, et al., (2021) [20].

Adaptations to ensure Rigor or Fidelity

Six of the thirteen adaptations aimed to ensure rigor and fidelity of the study. These adaptations were to 1) increase the reach of 2wT or the number of patients receiving 2wT through weekend VMMC recruitment camps, 2) increase recruitment using weekly WhatsApp calls for updates with all implementing teams; 3) improve acceptability, appropriateness and feasibility, engagement, and implementation of the 2wT by using check-in calls three times a week, weekly project update calls with all implementing teams, 4) increase engagement and feasibility of 2wT and to improve the fit between the implementation effort and the needs of those receiving 2wT by adding two local language translations in the usability survey, 5) improve the sustainability of 2wT and increase the chances that 2wT remains in practice by implementing additional data quality checks, and 6) increase adoption or number of clinicians recommending and patients using 2wT by retraining of staff members on recruitment, recording and follow-ups.

During the week, participants were working or attending school. To address this and other contextual factors, such as high unemployment rates and precarious employment opportunities, we adapted the 2wT strategy. We conducted camps on selected weekends, reaching men without disrupting their work or school schedules and significantly boosting study recruitment.

During COVID-19 lockdowns, the team used virtual meetings and digital technology to implement 2wT remotely to ensure rigor and fidelity.

Adaptations to enhance enrollments and ensure compliance to study protocols included adding two local language translations in the usability survey for 2wT men and contributing a portion towards the salary of the implementing staff by the research partner. During the pilot, the team ascertained that the usability study needed to be translated into local languages (i.e., Setswana and isiZulu) to reach participants who were not fluent in English.

The team used virtual meetings and digital technology to implement and refine 2wT remotely to compensate for international and local COVID-19 travel bans, which restricted the possibilities of physical meetings. To address communication challenges arising from COVID-19 restrictions, the challenges of working across countries and provinces, and working in network-poor locations, various platforms—such as WhatsApp and virtual calls—allowed the teams to provide updates on progress, deal with challenges as they arose, and adapt implementation accordingly.

The VMMC team had data quality monitors, but continuous monitoring revealed quality assurance gaps. To address this, the PIs added another layer to review the quality of the data collected. The research team also conducted in-person data reviews to deal with data quality issues.

Staff turnover became very high in the rural site during the early part of the intervention. New staff had to be trained and onboarded, and existing staff were retrained as needed. To accommodate high staff turnover rates, a robust training approach that is effective for quickly onboarding new staff is required.

Adaptations to ensure Relevance

Seven of the thirteen adaptations were to ensure that the study is relevant to the context and environment in which it was implemented.

South African COVID-19 level 4 restrictions required the decongestion of health facilities. At the rural site, we used mobile outreach facilities to reach clients in their community. This adaptation addressed geographic distances in rural areas, allowing for more men to be reached.

Recognizing the slow enrolment in the urban area, the research team identified the need for additional sites. During the implementation stage, we proactively added two more sites to address the time constraints associated with the pRCT target recruitment numbers. These sites were selected based on the implementing partner's already existing setup within public clinics, ensuring a smooth and efficient process (2).

Implementing staff initially viewed 2wT as a separate intervention from routine follow-up for VMMC, resulting in a reluctance to attend to clients after hours and additional time burdens for documentation of pRCT processes. To address this, a portion of the implementing staff's salary was allocated from the 2wT budget.

Clients would contact clinicians after hours, on public holidays, and weekends. One adaptation made was a roster for clinicians to attend to clients after hours to distribute the additional workload. Before the roster, all the extra hours would fall on one or two clinicians, creating unequal workloads.

The exclusion of two rural clinics as recruitment sites due to inconsistent mobile phone networks; adding another layer of data quality checks to ensure data quality; training non-clinical counselors to help with enrolling clients; retraining of staff in the rural site with high

staff turnover; and using both primary and alternative phone numbers for enrollment to reduce loss to follow up.

Two facilities in the rural area were excluded because these sites had no mobile phone network coverage during periodic scheduled electricity cuts called load-shedding, and enrolments could not be done. While offline enrollments in the Medic system were not possible at the time of the pRCT, developing future offline functionality could further adapt the intervention to network-poor contexts. These sites were also very far from the rural team hub, and routine client follow-ups were impractical.

During the busy winter season, clinicians were occupied attending to MCs and could not administer informed consent and capture client details on the Medic system. To address this, non-clinical counselors were recruited to assist with client enrollment and capture them on the Medic system. Each intern was provided with a device and sufficient data to recruit, educate about the 2wT approach, and enroll clients in the Medic system. This adaptation reduced clinicians' workload while increasing the intervention's reach.

On a few occasions, participants would change or lose their primary phones, which led to their being lost to follow-up. The team adapted the enrollment process to include collecting additional contact details to assist with tracing.

Discussion

Fidelity and adaptations

The researchers made 13 adaptations to the 2wT study, 6 were adaptations to ensure rigor or fidelity and 7 were adaptations to ensure relevance of the study. Conducting research under pragmatic settings enabled both researchers and implementers to better understand how the 2wT intervention performed in diverse populations and settings. The FRAME-IS helped explore and explain the influence of adaptation to ensure, not reduce, fidelity. There are merits to emphasize both intervention fidelity for internal validity and encouraging acceptance of adaptations that boost external validity for diverse intervention contexts [19]. We present three implementation science-related takeaways from our adaptation exploration.

First, fidelity and adaptation may not be opposing concepts; instead, there should be an exploration of how to achieve a balance between intervention fidelity and adaptation within interventions, allowing for adaptive interventions [17]. Chambers & Norton (2016) challenge

the assumption that the common trajectory of moving with fidelity from RCT to routine practice is best. Rather, they call for flexibility to consider the positive effect of adaptations made during intervention implementation, an openness for new data that could drive intervention efficiency gains, and recognition that intervention momentum may drive implementation fit even before the evidence base is solidified [21]. They continue by proposing the *adaptome* with a more fluid concept of where, when, and how evidence is gathered in support an intervention's evolving positive impact, allowing for considerations of adaptations to optimize the intervention and its implementation over time [21]. In line with Chambers, adaptations to 2wT implementation were considered throughout the 2wT RCT, responding to needs to improve fit at clinician, clinic, and organizational levels, showing awareness of, and openness to, opportunities for improving 2wT implementation over time and context. Indeed, responding to needs as they arose allowed the research team to stay attuned to contextual sensitivities, limitations and opportunities and (re)shape 2wT implementation to be an equitable, reliable and quality health solution.

Second, recognition that fidelity and adaptation can be concurrent, and not oppositional, forces along the pathway from research to practice is also promoted by the Value Equation developed by von Thiele Schwarz et al [22]. In growing recognition that adaptation is necessary to optimize fit, a simplified summary of von Thiele Schwarz's model suggests that the optimal intervention value (V) for multiple stakeholders is a combined product of an evolving intervention (IN) that reflects its broad context (C), and adaptive implementation strategies (IS) that drive intervention fit. Overall, the Value Equation suggests that implementers consider a broad view of intervention value, using adaptive implementation strategies to align EBIs with their contexts, and be transparent in the processes to guide both internal and external considerations for intervention expansion.

Third, 2wT adaptations appear acceptable and in line with enhanced fidelity. The nature and content of the adaptations in this study, as supported by O'Connor, Small and Cooney, (2007) are acceptable adaptations [19]. For adaptation of the 2wT intervention, there was no deviation from the established implementation strategy, characterized by a lack of loosening in structure or departure ("drift") within the implementation. Likewise, there was no instance of drifting from the implementation strategy without subsequent return, such as ceasing to offer consultation or halting post-operative follow-ups [20]. The adaptations also aimed to reduce the number of patients who were lost to follow up, improving fidelity or the extent to which

2wT is delivered as intended. Pérez, Van der Stuyft, Zabala, *et al*., (2015) support the idea that fidelity and adaptation co-exist and that adaptations can impact the effectiveness of the intervention either positively or negatively [17]. They further suggest that it is essential to look systematically at the aspects of an intervention that are being adapted and that implementation research should answer the question of how an adequate fidelity-adaptation balance can be reached.

Fourth, adaptation was necessary in the context of COVID-19 to enhance effectiveness in this real-world setting. The 2wT implementation adaptations largely responded to the changing landscape of COVID-19 restrictions, changes in policy for in-person reviews, and reflected waves of client concerns in accessing healthcare services – especially voluntary ones like VMMC. Adapting the strategy to reach more patients with routine VMMC services, and therefore increase the likelihood of 2wT recruitment, was a near-contact challenge during this period. Moreover, 2wT adoption was likely enhanced during this period when healthcare workers and programs sought methods or options to reduce clinician/patient contact. Furthermore, although clearly not in response to the global pandemic, the timeliness of the 2wT intervention cannot be understated. COVID-19 likely improved the fit between the implementation effort and the needs of those delivering 2wT. Rapid adoption of other virtual follow-up and tacit approvals for telehealth over potential for increased transmission also helped improve fidelity of the intervention. Growing understanding of the underlying cost advantages (less travel), improved equity (more language options for client communication, reduced client transport costs) and improved safety using 2wT likely created an enabling environment for adaptations and their acceptance.

Overall, adaptations to the 2wT intervention occurred at four levels. At socio-political level, the adaptations were done to address existing national VMMC follow-up mandates such as reducing the number of physical visits to health facilities and replacing them with 2wT. At organizational level, adaptations were implemented to address available staffing or materials. For example, counsellors were trained to enroll and consent clients to relieve the load from clinicians so they can have more time to conduct circumcisions. The implementer level (program and clinical teams) was for those charged with leading the implementation effort. The team leader of the implementation team could make adaptations or decisions on who does circumcisions or follow-ups or enrolments daily. The patient or recipient level was for the circumcised men who were benefitting as intended from the 2wT intervention. They could

enroll in a language that was familiar to them and receive follow-up support via 2wT instead of in-person reviews (8).

Conclusions

The adaptations made to the 2wT pRCT in South Africa and the justifications provided, support the idea that adaptations are common and inevitable to account for the needs of specific contexts. The results reflect that the reality of implementing mHealth interventions is a highly dynamic and adaptive process in which adaptations contribute to optimization for maximum impact. There are merits to arguments for both fidelity and adaptation. We used the FRAME-IS model to reconcile the debate on fidelity and adaptation. Although the model is meant to be a flexible, practical tool for documenting adaptations to the implementation of evidence-based interventions, its use has helped to illuminate the pivotal processes and mechanisms by which implementation strategies exert their effects. We suggest that the FRAME-IS be used to help IS move toward a better understanding of the roles of fidelity and adaptation in the implementation process. Adaptations helped the study balance research rigor and relevance to the rural and urban environments where the intervention was implemented. Fidelity and rigor should not be the enemy of adaptation and relevance in closing the gap between research in the laboratory and practice.

Declarations

Ethics approval and consent to participate.

This Multiple Principal Investigators (MPI) study was approved by the Internal Review Boards of the University of Washington (00009703, PI: Feldacker) and the University of the Witwatersrand, Human Research Ethics Committee (Ethics Reference No: 200204, PI: Setswe). Consent to participate in the study was obtained from all eligible clients.

Consent for publication

The authors give consent to Implementation Science and its publishers to publish this manuscript.

Availability of data and materials

All relevant data from this study are within the manuscript and its Supporting Information files. The data sets generated during or analyzed during this study are available from the corresponding author upon reasonable request. Our complete transcripts contain data that is sensitive or includes identifying information. We would like the confidentiality of the participants protected in accordance with the consent agreement. Due to these concerns, we are

unable to make the full transcripts available to a wider audience. We will make the transcripts easily available to fellow researchers or reviewers who complete a data sharing agreement.

Competing interests

None declared.

Funding

Research reported in this publication was supported by the National Institute of Nursing Research of the National Institutes of Health under award number 5R01NR019229, "Expanding and Scaling Two-Way Texting to Reduce Unnecessary Follow-up and Improve Adverse Event Identification Among Voluntary Medical Male Circumcision Clients in the Republic of South Africa" (principal investigators: CF and GS).

Authors' contributions

CF is the guarantor of the study.

GS and CF conceptualized the study.

CF, GS and JP acquired funding and provided the resources for the 2wT RCT and this study.

GS and CF supervised this study as Principal Investigators and ensured adherence to the protocol.

GS, CF, and JP conducted the 2wT trial from which this study was created.

GS, CF, FN, and JP deliberated and agreed on the FRAME-IS as a methodology to guide the study.

GS and FN collected data on adaptations into the google doc, project meeting records and from interviews with field teams and conducted formal analysis of the data.

GS, CF, FN, JP, VN, SD and IS contributed to the writing, review and editing of the manuscript.

Acknowledgements

The authors would like to thank the Departments of Health of the Gauteng and North West provinces; implementing partner, Right to Care, for enabling the participation of the clinical teams; and the CHAPS study implementation team for their dedication and skills in study recruitment, data management, and data capture. The authors would also like to thank the Medic Research team for their support of the 2wT study implementation and adaptation process.

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Responsibility: Dr Feldacker carries the end-responsibility of the project from the I-TECH, University of Washington side, including the development and implementation of the study protocol, data collection and analysis, and reporting of results.

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Responsibility: Ms Ncube was involved in the research activities and write-up of the study.

Abbreviations

2wT: two-way texting

AE: adverse event

CHAPS: Center for HIV-AIDS Prevention Studies

EBI: evidence-based intervention

FRAME-IS: framework for reporting adaptations and modifications in evidence-based implementation strategies.

HCW: health care worker

IS: implementation science

KII: key informant interview

MC: male circumcision

M&E: monitoring and evaluation

mHealth: mobile health

NDoH: national department of health

pRCT: pragmatic randomized controlled trial

RCT: randomized controlled trial

RTC: right to care

VMMC: voluntary medical male circumcision

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Figure Legend

Figure 1: The FRAME-IS for documenting adaptations to implementation of interventions

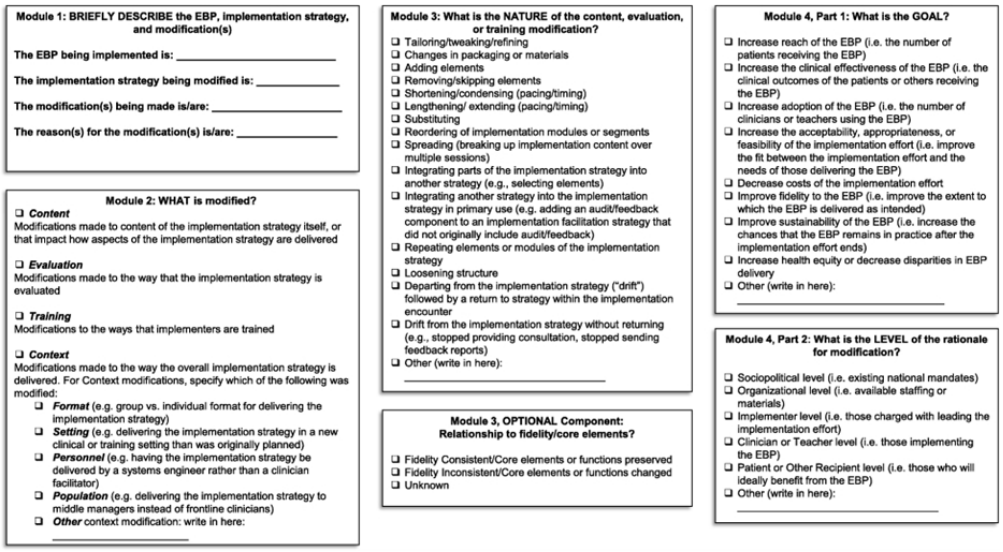

Figure 1: The FRAME-IS for documenting adaptations to implementation of interventions

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