Finding balance between rigor and relevance: Implementing adaptations to a pragmatic randomized controlled trial (pRCT) of a two-way texting study for voluntary medical male circumcision in South Africa using the Framework for Reporting Adaptations and Modifications in Evidence-based Implementation Strategies (FRAME-IS)

Geoffrey Setswe (gsetswe@auruminstitute.org)
The Aurum Institute

Felex Ndebele
The Aurum Institute

Jacqueline Pienaar
The Aurum Institute

Beatrice Wasunna
Medic Mobile

Vuyolwethu Ncube
The Aurum Institute

Lactricia Maja
The Aurum Institute

Kenneth Sherr
University of Washington Department of Global Health

Scott Barnhart
University of Washington Department of Global Health

Caryl Feldacker
University of Washington Department of Global Health

Research Article

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

Posted Date: August 17th, 2023

DOI: https://doi.org/10.21203/rs.3.rs-2731828/v1

License: This work is licensed under a Creative Commons Attribution 4.0 International License. Read Full License
Abstract

Background

One of the major debates in implementation research is around fidelity and adaptation. The growing interest in obtaining evidence on the relative benefits and harms of interventions in real-world settings led to the use of pragmatic randomised controlled trials (pRCTs). While pRCTs must be implemented with fidelity, adaptation challenges the basic assumption that its core components must be implemented with fidelity.

Objective

To document adaptations that were made to the implementation strategy, the fit and effectiveness of the Two-Way Texting (2wT) intervention in South Africa and to provide a nuanced and generalizable difference between adaptations and fidelity.

Methods

We conducted a qualitative study using the Framework for Reporting Adaptations and Modifications in Evidence-based Implementation Strategies (FRAME-IS) to document adaptations to the 2wT intervention. Using the FRAME-IS as a codebook, adaptations were described and categorized. We documented adaptations to the 2wT intervention using two-steps: (1) used the Google doc to identify, categorize and describe adaptations made; (2) qualitatively assessed the impact of adaptations on project goals, and outcomes. We conducted ten (10) periodic reflections with VMMC implementers, and observations of real-time adaptation. For the fit, we reviewed participant engagement with the 2wT system, tracked the database containing daily RCT notes and bugs, and reminder emails about adaptations to research team and partners. For effectiveness, we used field notes, meeting minutes, did informal check-in with partners and member-checking for missing adaptations.

Results

Between June 2021 and February 2022, 13 adaptations were identified in the 2wT pRCT; 6 to the implementation strategy, 2 to improve the fit and 5 to strengthen the effectiveness of the 2wT system. Adaptations to the strategy were to conduct weekend camps to recruit and perform MCs at the same time, using mobile outreach services in the rural site, addition of two urban sites to increase recruitment, use of weekly WhatsApp calls for updates with all implementing teams, use of virtual meetings to implement the 2wT strategy remotely during COVID-19 restrictions, and allocating one clinician to be available to communicate with clients after normal working hours. Adaptations to the fit included adding two local language translations in the usability survey for 2wT men, and the contribution of a portion towards the salary of the implementing staff by the research partner. Adaptations to effectiveness were the exclusion of two rural clinics as recruitment sites because of constant phone network disruptions, adding another layer of data quality checks to ensure validity of the data, training non-clinical counsellors to help with enrolling clients and capturing them on the system, retraining of staff in the rural site with high staff turnover, and enabling the 2wT system to accommodate enrolment of at-risk VMMC clients using both primary and alternative phone numbers.

Conclusions

This study made adaptations to the 2wT pRCT without compromising the fidelity of the study. The 2wT pRCT provided a balance between rigor (fidelity) and relevance (adaptation). Adaptations should not be confined by rigor but should also not go unchallenged or unverified. We conclude that fidelity should not be the enemy of adaptation in closing the gap between research in the laboratory and in practice.

Trial Registration:

This 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.

Contributions to the literature

- Adaptations, changes and modifications 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 fit (or be compatible) to the post-operative follow-up program of VMMC clients in rural and urban contexts.
- Adaptations to the 2wT pRCT strengthened the effectiveness of implementation of the VMMC follow-up program.
• Overall, adaptations that were made to the 2wT pRCT improved the quality of post-operative follow-up after VMMC in South Africa. Adaptations can be made to an intervention without compromising the fidelity of the study because fidelity should not be the enemy of adaptation in closing the gap between clinical and implementation research.

**Background**

Adaptation is an implementation science (IS) process of altering the design or delivery of an intervention thoughtfully and deliberately, with the goal of improving its fit or effectiveness in a particular context [1]. 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 [2]. Interventions are often adapted from their original design when they are implemented in a new community by new staff or a new organization. Adaptations are required to better meet the needs of the community where the intervention is implemented, to fit the program, budget, timelines, and staffing needs in a different environment [3]. Adaptations to interventions usually influence outcomes [4]. When an intervention is adapted and not delivered as planned in the protocol, it is considered to have low fidelity [3, 4]. Fidelity is staying true to the original intervention design by implementing the intervention as its developers intended [5].

Unfortunately, true fidelity is not easily achieved in practice. Practitioners often change or adapt evidence-based interventions (EBIs) as they implement them, whether intentionally or not [3]. In the literature, modifications may be presented as a distinct concept from adaptations. Adaptations are planned or ad hoc with a set of systematic changes that involve stakeholder input and have a more rigorous program planning process [6–9]. In contrast, modifications are reactive changes that may be implemented haphazardly for convenience or in response to time or resource constraints [4], marking them as more accidental in nature. Adaptations are often made to EBIs by various role players during the implementation process. The degree to which core elements of an EBI can be maintained while allowing for local adaptation is unclear. In addition, adaptations may also be needed at the policy, or health system levels to facilitate EBI implementation and sustainability [22]. The degree to which core elements of an EBI can be maintained while allowing for local adaptation is unclear.

The rationale, process, and outcomes of adaptations and modifications in randomized control trials (RCTs) are poorly understood, resulting in little evidence of their influence on the targeted intervention [10]. Yet, 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. The term, pragmatic RCT (pRCT), is defined as an RCT that aims to rigorously evaluate the effectiveness of an intervention in real-world settings, not strictly research settings, to better understand and bridge the divide between research and routine contexts [10].

The issue of fidelity and adaptation has been controversial for many years due to the longstanding tensions between achieving internal and external validity. The debate centers around scholars who emphasize the importance of drawing valid conclusions about the effects of an intervention, thereby prioritizing internal validity, versus those who highlight the need for interventions to fit the daily operations of different systems and organizations, thus highlighting the virtue of external validity. von Thiele Schwarz, et al (2019) cite several efforts to improve the reporting of fidelity and adaptation, but says to date, neither adaptations nor fidelity, are sufficiently described or documented in effectiveness trials. This leaves a gap in understanding the full scope of the fidelity and adaptation dilemma earlier in the research-to-practice pathway [20]. The current debate is finding a balance between fidelity or rigor in attaining intended results versus adaptation or relevance in attaining improved implementation. The long debate about the balance between fidelity to EBIs and the need for adaptation for specific contexts is relevant to implementation research for VMMC follow-up. von Thiele Schwarz, et al (2019) synthesized arguments from both fidelity and adaptation perspectives to provide a comprehensive understanding of the challenges involved [20].

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 [4] in response to emerging and evolving COVID-19 constraints and opportunities [12–14]. The pRCT aimed to determine the impact of a mobile health (mHealth) innovation, two-way texting (2wT), on the quality of post-operative follow-up after voluntary medical male circumcision (VMMC). For the pRCT, 1121 men were randomized 1:1 across 2 arms and divided equally across urban and rural districts, with 563 men assigned to 2wT. 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 post-operative day 14 to ascertain healing and document adverse events (AEs). 2wT aimed to support patients to 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 June 7, 2021, and follow-up concluded February 21, 2022. In total, 1084 men were enrolled with 547 randomized to 2wT and 537 to routine care with near equal proportions of rural and urban participants across groups (see Consort diagram) [12].

In this paper, we describe adaptations to a mobile health-focused pRCT that challenge the basic assumption that core components of an intervention must be implemented with fidelity to achieve intended effectiveness and expected outcomes [5]. We used the FRAME-IS model to document adaptations that were made to the implementation strategy, the fit or compatibility, and effectiveness of the 2wT pRCT and provide a nuanced and generalizable difference between adaptations and fidelity.

**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 Fig. 1, for implementing adaptations to the 2wT intervention using four modules of FRAME-IS to describe: (1) the intervention; (2) what was adapted; (3) the nature of the content adapted; and (4) the goal and the level of the rationale for the adaptation. We also assessed rigor and relevance in documenting adaptations.

Using the FRAME-IS as a codebook, adaptations were described and categorized. We documented adaptations to the 2wT intervention using two-steps: (1) we used the periodic reflections and data from Google sheets to identify, categorize and describe adaptations made; (2) qualitatively assessed the impact of adaptations on project goals and outcomes [12].

Data collection strategies and documentation

We used various data collection strategies to document the strategy, fit and effectiveness of the pRCT, as summarized in Table 1.

<table>
<thead>
<tr>
<th>Objective</th>
<th>Data collection method</th>
<th>What was documented</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adaptations to the implementation strategy of the 2wT intervention.</td>
<td>Conducted 10 monthly reflections and observations of real-time adaptations with a tracking database using a Google Sheets daily spreadsheet.</td>
<td>Reach of 2wT, acceptability, appropriateness, and feasibility of implementation of the 2wT intervention.</td>
</tr>
<tr>
<td>Whether the adaptations improved the fit (compatibility) of the 2wT intervention.</td>
<td>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.</td>
<td>Men’s engagement with the 2wT system, feasibility of implementation and increase in equity and decrease in disparities in delivery of 2wT</td>
</tr>
<tr>
<td>The effectiveness of implementation of 2wT intervention.</td>
<td>Reviewed field notes, meeting minutes, informal check-in with partners and did member-checking</td>
<td>Costs, sustainability, clinical outcomes, adoption, and fidelity of 2wT</td>
</tr>
</tbody>
</table>

Periodic reflections

We conducted ten (10) periodic reflections with implementers of the 2wT pRCT in the rural and urban sites answer the following questions

- What component or part of the 2wT intervention was changed in this adaptation; in other words, what was the nature of the change? For example, was it a change to program content, format, delivery mode, staff delivering it, patients eligible, where, when or how it was delivered, or what?
- Who was responsible for first suggesting or initiating this change? Was this the person or persons the ones who implemented the change? If not, who implemented the adaptation?
- When during the 2wT intervention was this adaptation first made?
- 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.? [16]

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, 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.

Google sheets and other secondary data sources

To document data on adaptations that were made to the implementation strategy, the primary data was recorded in our real-time tracking database using Google process documentation on Google sheets daily spreadsheet. Other secondary data sources included participant observations, training workshop notes, emails, and the study team’s WhatsApp group to document adaptations to this pragmatic RCT and for tracking results and improvements to ensure fidelity. We used a data extraction sheet to document data on adaptations that were made to the implementation strategy, reviewing and coding content in Google Sheets related to the reach, acceptability, appropriateness, and feasibility of implementation of the 2wT system.

Measures

Adaptation

To determine whether the adaptations improved the fit (or compatibility) of the 2wT pRCT in the rural and urban contexts, we reviewed participants’ 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. For this objective, we documented implementation progress, 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. The research coordinator was the primary person responsible for updating content. At the completion of the pRCT, we qualitatively and descriptively reviewed and considered the adaptations of the 2wT pRCT implementation. We documented men’s engagement with the 2wT system, feasibility of implementation and increase in equity and decrease in disparities in delivery of 2wT in both rural and urban environments.
To determine the effectiveness of implementation of the 2wT pRCT, the research team reviewed field notes, meeting minutes, informal check-in with partners and did member-checking for missing adaptations and to check for accuracy. When the research teams visited the sites, they kept field notes about adaptations made and how effective they are. The minutes of the weekly project meetings were reviewed to assess the effectiveness of adaptations made.

**Fidelity**

We used two sources of fidelity data: direct observations during periodic reflections with implementers, and clients’ engagement with the 2wT system. The former has the advantage of expertise and objectivity, and the latter has the advantage of real-time reporting. The dual source measures provided the opportunity for detailed comparisons between fidelity information gathered from implementers and from clients. The more detailed client-report data gathered on a weekly basis provide opportunities to examine patterns of change in fidelity over time and provide data to the principal investigators and adaptation team [22].

Member checking, also known as participant or respondent validation, is a technique for exploring the credibility of results where data or results are returned to participants to check for accuracy and resonance with their experiences [17]. The Google Sheet was consistently reviewed by PIs to reduce missing adaptations and ensure accuracy. We documented adaptations to the costs, sustainability, clinical outcomes, adoption, and fidelity of the 2wT system.

**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. Our analysis process consisted of two steps: Step 1, we used the Google doc and periodic reflections to identify, categorize and describe adaptations made. Step 2, we qualitatively assessed the impact adaptations had on project goals, and outcomes. To assess impact, 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 any short-term impact or impact on goals and outcomes [18].

We conducted a rapid qualitative analysis of source documents to compile and review the adaptations made to the strategy, fit and effectiveness of the 2wT system. Thematic content analysis was used to analyze the data from periodic reflections and source documents. We firstly created a spreadsheet of key themes, namely implementation strategy, fit (compatibility) and effectiveness. We then identified sub-themes under each of the 3 major themes. 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**

**Rigor and relevance in documenting adaptations**

Periodic reflections: 10 structured reflections were completed during an 18-month period spanning pre-implementation (Jan-May 2021), implementation (June 2021-February 2022), and early phase scale-up activities (March – June 2022). These reflections provided detailed, real-time information on the RCT’s implementation strategy, fit or compatibility and effectiveness. Reflections also provided an opportunity for implementation teams to engage in recurring reflection and problem-solving [19]. We also used data from Google sheets and other secondary data sources such as training workshop notes, emails, and the study team’s WhatsApp group to document adaptations made and for tracking results.

We describe what was discarded, added or adapted from the original protocol into the implementation strategy, the fit to the routine VMMC settings, and whether the adaptations impacted the effectiveness of implementation.

**Description of the intervention (module 1 of FRAME-IS)**

The evidence-based project (EBP) being implemented was the 2wT intervention for VMMC follow-ups in rural and urban settings in South Africa. This study was conceptualized as an RCT, but was implemented as a pragmatic RCT. The consort flow diagram (attached as additional file) provides the flow of enrolment, allocation, follow-up and analysis of data for the 2wT RCT. The implementation strategy being adapted was the pRCT to determine the impact of a mobile health (mHealth) innovation, two-way texting (2wT), on the quality of post-operative follow-up following a VMMC. The adaptations being made were to the design, delivery, or implementation of the 2wT pRCT in South Africa. The reasons for the adaptations to the 2wT intervention were to provide quality interactive care to strengthen VMMC post-operative follow-up in rural and urban sites in South Africa, to empower men to seek in-person follow-up care only when needed or desired and to decrease the burden for both health care workers (HCWs) and patients.
Adaptations made to the 2wT trial (module 2 of FRAME-IS)

Between June 2021 and February 2022, thirteen (13) adaptations were made across 7 rural and urban sites where the 2wT pRCT was implemented: six to the implementation strategy; two to improve fit (compatibility); and five to the effectiveness of implementation.

Elements that were adapted include content and context in which the 2wT intervention was implemented. Elements of the context that were adapted include the format, setting, personnel or population [15]. Table 2 uses the FRAME-IS to summarize adaptations made to the implementation strategy, the fit and effectiveness of the 2wT RCT.
Table 2

<table>
<thead>
<tr>
<th>Description of the adaptation</th>
<th>When was the adaptation done?</th>
<th>What was adapted?</th>
<th>Who?</th>
<th>level of adaptation</th>
<th>Nature of the adaptation</th>
<th>goal of the adaptation</th>
<th>Reasons for the adaptation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adaptations to the STRATEGY</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>To recruit more VMMC clients, the team decided to conduct weekend camps to recruit and perform MCs at the same time.</td>
<td>Implementation</td>
<td>Context</td>
<td>VMMC team</td>
<td>Implementer level</td>
<td>Conduct client recruitment and circumcision over selected weekends</td>
<td>Increase reach of 2wT (the number of patients receiving 2wT)</td>
<td>Participants were working or at school during weekdays but were available over weekends to be circumcised without disrupting their work or school schedule.</td>
</tr>
<tr>
<td>During COVID-19 lockdowns, the rural VMMC team conducted MCs as mobile outreach service visiting patients in their communities.</td>
<td>Implementation</td>
<td>Context</td>
<td>The DoH</td>
<td>Organizational level</td>
<td>Refining and tailoring the intervention for local settings and environmental conditions</td>
<td>Improve feasibility of implementation in rural areas</td>
<td>Legislation: South African COVID-19 level 4 restrictions required decongesting health facilities</td>
</tr>
<tr>
<td>Two urban sites were added to increase recruitment of VMMC clients.</td>
<td>Implementation</td>
<td>Context, local setting</td>
<td>PI</td>
<td>Implementer level</td>
<td>Adding additional site</td>
<td>Improve urban reach, engagement, and implementation</td>
<td>Available resources and time constraints: urban enrolment was slow and two additional sites had to be added.</td>
</tr>
<tr>
<td>The use of WhatsApp, check-in calls three times a week, weekly project update calls with all implementing teams (PI, technical and VMMC teams)</td>
<td>Implementation</td>
<td>Communication</td>
<td>PI, Research Manager</td>
<td>Implementer level</td>
<td>Improve communication between implementation and research teams</td>
<td>Increase reach, engagement, or implementation</td>
<td>Implementation and research teams communicated at frequent intervals to update on progress and to deal with problems on the spot.</td>
</tr>
<tr>
<td>During COVID-19 lockdowns, the team used virtual meetings and digital technology to implement the 2Wt strategy remotely.</td>
<td>Pilot and implementation</td>
<td>Context</td>
<td>PI, Project manager, and VMMC team</td>
<td>Organizational level</td>
<td>Refining and tailoring the intervention for local settings and environmental conditions</td>
<td>Improve acceptability, appropriateness and feasibility, engagement, and implementation of the 2wT</td>
<td>Legislation: Due to the COVID-19 lockdown in South Africa international and local travel was banned, and physical meetings were restricted.</td>
</tr>
<tr>
<td>The clinical team drew a duty roster to allocate one clinician to be available to communicate with clients on weekends and public holidays.</td>
<td>Pilot</td>
<td>Context, personnel implementing 2wT</td>
<td>Project Manager and VMMC team leaders</td>
<td>Clinician or researcher level</td>
<td>Extending the time - a clinician is available to communicate with clients via text message</td>
<td>Improve feasibility, engagement, and implementation of the 2wT</td>
<td>Clients were sending text messages even outside routine work hours.</td>
</tr>
</tbody>
</table>

Adaptations to the FIT

Sources: Adapted from Miller, Barnett, Baumann (2021) and Kirk, Nilsen, Andersen, et al., (2021) [4, 15].
## Adapts to the STRATEGY

<table>
<thead>
<tr>
<th>Description of the adaptation</th>
<th>When was the adaptation done?</th>
<th>What was adapted?</th>
<th>Who?</th>
<th>level of adaptation</th>
<th>Nature of the adaptation</th>
<th>goal of the adaptation</th>
<th>Reasons for the adaptation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adding local language translations (Setswana and isiZulu) in the usability survey were implemented</td>
<td>Pilot</td>
<td>Context, and format of 2wT</td>
<td>PI, Research Manager</td>
<td>Clinician or researcher level</td>
<td>Refining and tailoring the 2WT intervention survey for local settings</td>
<td>Increase engagement and feasibility of 2WT and to improve the fit between the implementation effort and the needs of those receiving 2wt</td>
<td>Spoken languages: Some clients indicated that they did not fully understand the English survey</td>
</tr>
<tr>
<td>In order to fit the 2WT intervention into routine care, the research partner contributed a portion towards the salary of the implementing staff</td>
<td>Implementation</td>
<td>Context</td>
<td>PI, Project manager, and VMMC team</td>
<td>Organizational and implementer levels</td>
<td>Tailoring and tweaking by paying a portion of staff salary to integrate 2WT into the follow-up care</td>
<td>To increase equity and decrease disparities in delivery of 2WT and routine care.</td>
<td>Implementing staff initially viewed 2WT as a separate intervention from routine follow-up for VMMC</td>
</tr>
</tbody>
</table>

## Adapts to the EFFECTIVENESS

<table>
<thead>
<tr>
<th>Description of the adaptation</th>
<th>When was the adaptation done?</th>
<th>What was adapted?</th>
<th>Who?</th>
<th>level of adaptation</th>
<th>Nature of the adaptation</th>
<th>goal of the adaptation</th>
<th>Reasons for the adaptation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two rural clinics were purposively excluded as recruitment sites to reduce costs and improve effectiveness of the 2WT of the 2WT strategy</td>
<td>Implementation</td>
<td>Context, local setting</td>
<td>PI</td>
<td>Organizational and implementer levels</td>
<td>Refining and tailoring the 2WT intervention for local settings</td>
<td>Decrease costs of the implementation effort</td>
<td>Location/accessibility: These sites had no mobile phone network coverage during load shedding periods, and enrolments could not be done. These sites were also very far from the rural team hub and follow-ups for routine clients were not practical</td>
</tr>
<tr>
<td>An additional layer of data quality checks was implemented by Principal Investigators to ensure validity of the data</td>
<td>Implementation</td>
<td>Context, and format of the intervention</td>
<td>PI, Research team</td>
<td>Organizational level</td>
<td>Adding a quality control measure</td>
<td>Improve sustainability of 2WT and increase the chances that 2WT remains in practice</td>
<td>The VMMC team had data quality monitors but there were gaps in their work so there was a need to add another layer to review the quality of the data collected.</td>
</tr>
<tr>
<td>Non-clinical counsellors were trained to help with enrolling clients and capture them on the Medic system</td>
<td>Implementation</td>
<td>Training and evaluation</td>
<td>Research manager and VMMC team</td>
<td>Organizational and implementer levels</td>
<td>Refining and tailoring the EBI for local settings</td>
<td>Increase the effectiveness or the clinical outcomes of the patients receiving 2wT.</td>
<td>Available human resources: During the busy winter season, clinicians were occupied attending to MCs and could not administer informed consent as well as capture clients on the Medic system.</td>
</tr>
<tr>
<td>Retraining of staff members on recruitment, recording and follow-ups in the rural site with high staff turnover</td>
<td>Pilot and Implementation</td>
<td>Training and evaluation</td>
<td>Research Manager</td>
<td>Organizational and implementer levels</td>
<td>Refining and tailoring 2WT for local settings and environmental conditions</td>
<td>Increase adoption or number of clinicians recommending and patients using 2wT.</td>
<td>During the early part of the intervention, staff turnover became very high in the rural site. New staff had to be trained upon onboarding and retraining for existing staff was conducted as needed.</td>
</tr>
</tbody>
</table>

Sources: Adapted from Miller, Barnett, Baumann (2021) and Kirk, Nilsen, Andersen, et al., (2021) [4, 15].
Adaptations to the implementation strategy

Six adaptations were made to the implementation strategy (Table 2). To increase the reach of 2wT and recruit more VMMC clients, the team decided to conduct weekend camps to recruit and perform MCs at the same time. This was because participants were working or were at school during weekdays but were available over weekends to be circumcised without disrupting their work or school schedule.

To improve the feasibility of implementation of 2wT in rural areas while ensuring compliance with level 4 COVID-19 restrictions implemented in South Africa at the time of the study, the rural VMMC team conducted MCs as mobile outreach services recruiting, circumcising and following up on clients in their communities. When urban enrolment started slowing down, two additional urban sites were approved to increase urban reach of 2wT where there are limited resources and time constraints to reach recruitment targets.

The use of WhatsApp check-in calls three times a week, weekly project update calls with all implementing teams (Principal Investigators, technical and VMMC teams) was introduced to improve communication between implementation and research teams and to respond to challenges in a timely manner.

During COVID-19 lockdowns, the team used virtual meetings to implement the 2wT strategy remotely to improve communication between implementation and research teams.

When clients started sending 2wT messages outside normal working hours, the clinical team drew a duty roster to allocate one clinician to be available to communicate with clients on weekends and public holidays. This was to ensure that clients were attended to promptly when they had queries or potential adverse events (AEs). The 2wT pRCT was implemented in the middle the COVID-19 pandemic. This was a unique experience for the research and implementation teams as COVID-19 restrictions affected all aspects of the delivery of the intervention, leading to an enormous amount of rapid innovation and adaptation. The unique context of the pandemic provided an opportunity to examine adaptations across multiple elements of the delivery of the project [18].

Adaptations to improve the fit

Two adaptations were made to improve fit or compatibility of 2wT intervention with the population where the intervention was implemented. The research team added translations to two local languages commonly spoken in the research sites (Setswana and isiZulu) to the usability survey. The aim was to increase the acceptability, appropriateness, and feasibility of 2wT and to improve the fit between the implementation effort and the needs of those receiving 2wT intervention.

Day 14 reviews, which are a part of expected routine care compliance with visits to healthcare facilities, were compulsory to all participants to offset perceptions that once 2WT clients are circumcised they are lost to the routine care. This ensured that visits were conducted on schedule but also improved implementation of the pRCT within the routine context. To avoid implementing staff from viewing 2wT as separate intervention from routine care and to increase health equity and decrease disparities in delivery of 2wT and routine care, project leaders introduced a salary split where the research partner contributed a portion towards the salary of the implementing staff. of the 2WT RCT in the rural and urban South African contexts?

Adaptations to strengthen the effectiveness of 2wT

To decrease costs and to increase effectiveness of implementation effort, two rural clinics were purposively excluded as recruitment sites of the 2wT strategy. These sites had no mobile phone network coverage during load shedding periods, and enrolments could not be completed. These sites were also very far from the rural team hub and follow-ups for routine clients were not practical.

The RCT obtained good quality data and answered key questions about AE ascertainment, reduced workload, and costs. The VMMC team had data quality monitors but there were gaps in their work so there was a need to add another layer to review the quality of the data collected. To improve sustainability of 2wT and increase the chances that it remains in practice, the research team leaders added another layer of data quality assurance (DQA). This additional layer of data quality checks was implemented to ensure validity of the data.
During the busy circumcision season, clinicians were occupied attending to MCs and could not get time to administer informed consent as well as capture clients on the Medic system. Non-clinical counsellors were trained to help enroll clients and to capture them on the Medic system. The aim here was to increase the effectiveness or clinical outcomes of patients receiving 2wT.

During the early part of implementing the intervention, staff turnover became very high in the rural site. New staff had to be trained upon onboarding and re-training of existing staff was conducted as needed. Retraining of staff on recruitment, implementation and follow-up was aimed at increasing adoption or number of clinicians recommending and patients accepting to use 2wT.

On a few occasions, participants would change or lose their primary phones which led to them being lost to follow-up. Additional contact details assisted with tracing these participants. When this happened, the technical and research teams would enable the system to accommodate the enrolment of VMMC clients to the 2wT platform using both primary and alternative phone numbers.

**Discussion**

**Fidelity and adaptations**

As the team documented and implemented adaptations, it was essential to consider the fidelity of the intervention. The thirteen (13) adaptations made to the 2wT pRCT helped the team to implement the pRCT with fidelity. These adaptations helped to improve the implementation strategy, fit and effectiveness of the intervention. There are merits and convincing arguments in support of both fidelity and adaptations representing points of view of intervention developers and internal validity on the one hand and users and external validity on the other. Instead of characterizing fidelity and adaptation as mutually exclusive, von Thiele Schwarz, et al (2019) propose that fidelity and adaptation should better be conceptualized as complimentary, synergistic perspectives that can increase the relevance of research, and provide a practical way to approach the goal of optimizing client outcomes [20]. They proposed, the “Value Equation,” method for reconciling the fidelity and adaptation debate by putting it in relation to the value (V) that is produced. The equation involves intervention (IN), context (C), and implementation strategies (IS). According to this model, fidelity and adaptation determine how these terms are balanced and, in turn, the value it produces for patients, providers, organizations, and systems. The Value Equation summarizes three key propositions: 1) The product of implementation efforts should emphasize overall value rather than only the intervention effects, 2) implementation strategies can be thought of as a method to create fit between interventions and context, and 3) transparency is vital; not only for the intervention but for all of the four terms of the equation [20].

While this study made two adaptations to improve fit or compatibility of 2wT intervention, Chambers & Norton (2016) argued for the development of strategies to advance the science of adaptation in the context of implementation that would more comprehensively describe the fit between interventions and their settings and embrace opportunities for ongoing learning about optimal intervention delivery over time [21].

**The impact of adaptations on goals and outcomes of the 2wT trial**

During analysis, we found that the FRAME-IS modules that provided the most explanatory details as to why an adaptation was rated as having an impact or not on the project were: 1) the nature of the content adaptations, 2) the goal of adaptation, 3) reasons for the adaptation, and 4) levels of the rationale for the adaptation.

**The nature of the content of the adaptations (module 3 of FRAME-IS)**

The nature and content of the adaptations in this study included some tailoring, tweaking, or refining of some elements, changes in packaging of materials, removing elements such as two rural clinics located in an area with poor network reception, shortening or reducing the number of physical clinic visits by circumcised men postoperatively, reordering of implementation such as connecting with clients through two-way texting instead of physical visits to clinics, integrating weekend camps into the implementation strategy, adding a quality improvement component to an implementation strategy that did not originally include quality assurance (QA) by research leaders, and repeating training of staff, when it was required, for the implementation of the strategy. These are described by O’Connor, Small and Cooney, (2007) as acceptable adaptations [3]. If the adaptations had included reducing the number or length of follow-up contacts, lowering the level of participant engagement, eliminating key messages during post-operative care, removing topics like bandage removal, using staff who are not adequately trained or qualified or using fewer staff than recommended, then O’Connor, Small and Cooney (2007) would describe them as risky or unacceptable adaptations [3].

For adaptation of the 2wT intervention, there was no loosening of structure or departing from the implementation strategy (“drift”) followed by a return to strategy within the implementation encounter or drift from the implementation strategy without returning (e.g., stopping to provide consultation, stopping to conduct post-operative follow-ups [13].

The Hawthorne effect may have lessened the effectiveness of implementation of the intervention when the implementing teams perceived their actions were being watched by study personnel. Due to the Hawthorne effect, routine teams provided better support and follow-up to clients and were able to identify and follow up more clients with adverse events (AEs). This was seen as a concern in a pragmatic trial that does not have routine setting - it is implemented in the real world and certain controls and influences cannot be avoided. Through this adaptation, we wanted to contribute to the debate about what defines and characterizes a pragmatic RCT is - how to adapt it and make it flexible to match COVID-19 restrictions and the context. We also wanted to know how we can make the RCT methods work for the pragmatic setting and contribute to the internal external validity discussion.
Reducing the number of patients who are lost to follow up would, in effect, improve 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 [5]. 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.

**Goals of adaptations (module 4a of FRAME-IS)**

The adaptations covered several goals such as increasing the reach or number of patients receiving 2wT, increasing the effectiveness or clinical outcomes of the patients or others receiving 2wT, increasing adoption or the number of clinicians using 2wT, and increasing the acceptability, appropriateness or feasibility of the implementation effort which involved improving the fit between the implementation effort and the needs of those delivering 2wT. Other goals include decreasing costs of the implementation effort, improving fidelity or the extent to which 2wT is delivered as intended, improving sustainability or the chances that 2wT remains in practice, and increasing health equity or decreasing disparities in 2wT delivery [15].

**The levels of the rationale for adaptation (module 4b of FRAME-IS)**

There were four levels where adaptations in this study were taking place. 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 was for those charged with leading the implementation effort. The team leader to the implementation team could make adaptations or decisions on who does circumcisions or follow-ups or enrolments daily. The clinician or researcher level pertains to decisions or changes made by those implementing 2wT. The patient or other recipient level was for the circumcised men who were benefitting as intended from the 2wT intervention [15].

**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 adaptations than if we had waited until the end of the study period. We also experienced variability in opportunities to identify adaptations related to the direct communication between researchers and implementation teams [18].

Another limitation of this study is the transferability of the findings to any other study or intervention. This is difficult to achieve as the adaptations to this study 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 which may not happen again in the intensity it did. The researchers provided thick descriptions of the context in the analysis, to provide a possibility to transfer the findings to other contexts [4]. 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 [18].

**Conclusions**

As many as 13 adaptations were made to the implementation strategy, to improve the fit and effectiveness of implementation of the 2wT pragmatic RCT. Some adaptations were systematically planned, whereas others occurred unplanned or forced by the situation, but all contributed to refining the implementation of the intervention. We conclude that rigor should not be the enemy of adaptation.

The adaptations that were made to the 2wT pragmatic RCT 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 key elements that make the 2wT intervention effective, were identified and not changed or adapted. Without these, effectiveness of a pRCT may decrease if they compromise the core elements and underlying logic of the intervention. The adaptations helped the study achieve a balance between research rigor and relevance to the rural and urban environments where the intervention was implemented.

The results from this study show that implementing mHealth interventions is a highly dynamic and adaptive process in which adaptations were made to both the 2wT intervention and its implementation plan. 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 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 in helping implementation science move toward a better understanding of the roles of fidelity and adaptation in the implementation process, Adaptations should not be confined by rigor but should also not go unchallenged or verified. In short, fidelity and rigor should not be the enemy of adaptation and relevance in closing the gap between research in the laboratory and in practice.

**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

**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, JP, BW, VN, LM conducted the 2wT trial from which this study was created.

GS, CF, KS, SB, BW, FN, 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, KS, SB, BW, FN, JP, VN and LM 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, including Femi Oni, Adnan Alhassan, and Maryanne Mureithi, and Raymond Mugwanya.

Authors' information (optional)

1. Professor Geoffrey Setswe, DrPH, MPH
   Affiliation: Implementation Research Division, The Aurum Institute, Johannesburg
   Role: Principal Investigator
   Responsibility: Prof Setswe carries the overall end-responsibility of the project, including oversight for the protocol development, implementation, and assurance for the timely reporting and dissemination of study results.

2. Dr Caryl Feldacker, PhD, MPH
   Affiliation: I-TECH, University of Washington.
   Role: Principal Investigator
   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.

3. Felex Ndebele, BPharm, MSc (Implementation Science)
   Affiliation: Implementation Research Division, The Aurum Institute, South Africa
   Role: Project Manager
   Responsibility: Mr Ndebele oversaw and managed all aspects of local implementation and participated in the collection of data for this substudy.

4. Professor Scott Barnhart, MD
   Affiliation: I-TECH, University of Washington.
   Role: Co-Investigator
   Responsibility: Prof. Barnhart will help lead the development and implementation of the study protocol and contribute to reporting of results.

5. Ms. Jacqueline Pienaar, MPH, MSc
   Affiliation: The Aurum Institute, South Africa
   Role: Co-Investigator
   Responsibility: Ms. Pienaar is the Technical Director for HIV prevention and program lead for VMMC and key populations at the Aurum Institute. She served as Chief Executive Officer for the implementing partner, CHAPS during the RCT so she is involved with the implementation of the study and functions as the liaison with participating stakeholders.

References


**Module 1: BRIEFLY DESCRIBE the EBP, implementation strategy, and modification(s)**

The EBP being implemented is: 
The implementation strategy being modified is: 
The modification(s) being made is/are: 
The reason(s) for the modification(s) is/are: 

**Module 2: WHAT is modified?**
- **Content**
  Modifications made to content of the implementation strategy itself, or that impact how aspects of the implementation strategy are delivered
- **Evaluation**
  Modifications made to the way that the implementation strategy is evaluated
- **Training**
  Modifications to the ways that implementers are trained
- **Context**
  Modifications made to the way the overall implementation strategy is delivered. For Context modifications, specify which of the following was modified:
  - **Format** (e.g., group vs. individual format for delivering the implementation strategy)
  - **Setting** (e.g., delivering the implementation strategy in a new clinical or training setting than was originally planned)
  - **Personnel** (e.g., having the implementation strategy be delivered by a systems engineer rather than a clinician facilitator)
  - **Population** (e.g., delivering the implementation strategy to middle managers instead of frontline clinicians)
  - **Other context modification: write in here:**

**Module 3: OPTIONAL Component: Relationship to fidelity/core elements?**
- Fidelity Consistent/Core elements or functions preserved
- Fidelity Inconsistent/Core elements or functions changed
- Unknown

**Module 4, Part 1: What is the GOAL?**
- Increase reach of the EBP (i.e. the number of patients receiving the EBP)
- Increase the clinical effectiveness of the EBP (i.e. the clinical outcomes of the patients or others receiving the EBP)
- Increase adoption of the EBP (i.e. the number of clinicians or teachers using the EBP)
- Increase the acceptability, appropriateness, or feasibility of the implementation effort (i.e. improve the fit between the implementation effort and the needs of those delivering the EBP)
- Decrease costs of the implementation effort
- Improve fidelity to the EBP (i.e. improve the extent to which the EBP is delivered as intended)
- Improve sustainability of the EBP (i.e. increase the chances that the EBP remains in practice after the implementation effort ends)
- Increase health equity or decrease disparities in EBP delivery
- Other (write in here):

**Module 4, Part 2: What is the LEVEL of the rationale for modification?**
- Sociopolitical level (i.e. existing national mandates)
- Organizational level (i.e. available staffing or materials)
- Implementor level (i.e. those charged with leading the implementation effort)
- Clinician or Teacher level (i.e. those implementing the EBP)
- Patient or Other Recipient level (i.e. those who will ideally benefit from the EBP)
- Other (write in here):

Source: Miller, Barnett, Baumann [15]

**Figure 1**

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

**Supplementary Files**

This is a list of supplementary files associated with this preprint. Click to download.

- 2wTCONSORT2010FlowDiagramChecklist.docx