What Matters When Exploring Fidelity in Interventions Using Health It to Reduce Disparities in Language-diverse Populations?”

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Abstract

Background: Evidence-based interventions often develop strategies to engage diverse populations while also attempting to maintain external validity. When using health IT tools to deliver patient-centered health messages, systems-level requirements are often at odds with ‘on-the ground’ tailoring approaches employed in patient-centered care, particularly regarding ensuring equity is achieved linguistically diverse populations.

Methods: STAR MAMA, is a 5-month bilingual (English and Spanish) intervention adapted from the Diabetes Prevention Program, examined in a pilot RCT conducted among 181 post-partum women with recent gestational diabetes. Fidelity to pre-determined ‘core’ intervention components (e.g. systems integration) as well as important ‘modifiable’ components focused on population equity (e.g. health coaching responsiveness, and variation in outcomes by language), were assessed, using an adapted implementation fidelity framework. Evaluation data included participant-level surveys, systems-level databases of message delivery, call completion, and health coaching notes.

Results: Participant mean age was 31.5 years, 96.6% of participants are Latina and 80.9% were born outside the US. Among those receiving the STAR MAMA calls 55 received the calls in Spanish (61%) and 35 English (39%). Of those in the call arm, 81 women (90%) completed all 20 weeks of the program. There were many more systems errors in the beginning of the program, than over time. Health coaching triggers were also more widespread in the first several weeks of the STAR MAMA intervention, notably among Spanish-speakers. Although Spanish speakers had more triggers than English-speakers, the difference was not statistically significant. Of the calls that triggered a health coach follow-up, a call-back attempt was made for 85.4% (n=152) of the English call triggers and for 80.0% (n=279) of the Spanish call triggers (NS). Of those with attempted calls, health coaching calls were complete for 55.6% (n=85) of English-language call triggers and for 56.6% of Spanish-language call triggers (NS). Some differences in acceptability were noted by language, with Spanish-speakers reporting higher satisfaction with prevention content ($p<0.01$) and English-speakers reporting health coaches were less considerate of their time ($p=0.03$).

Conclusions: Implementation fidelity for health IT interventions involving health coaching should address moderating factors, such as language, as well as systems level factors.

Trial Registration: National Clinical Trials registration number: CT02240420 Registered September 15, 2014 . ClinicalTrials.gov

Contributions To The Literature

- Evidence-based interventions (EBIs) must reconcile fidelity with adaptations in order to reach diverse populations
- Multi-lingual Health IT EBIs are often not evaluated for fidelity or for equity in program delivery

- This article contributes to the literature examining fidelity, by examining core intervention components as well as essential moderators, including language equity, for an EBI directed to reduce the risk of type 2 diabetes among primarily Spanish-speaking women

Introduction

To improve evidence-based practice, practice-based interventions must balance adaptations to local circumstances with attempts to maintain external validity. It is implied but not always explicitly described that for an intervention or evidence-based practice (EBI) to be considered evidence-based, findings need to be replicated with fidelity, even while adaptations occur [1]. According to Carroll et al., fidelity refers to “the degree to which an intervention is delivered as intended” and is how you determine to what extent an intervention has been adequately ‘replicated’[2]. Monitoring and assuring fidelity are critical for planning to replicate an intervention in a variety of settings and populations, and thus is seen as instrumental to determining factors associated with implementation success and failure, one of the cornerstones of implementation science [3]. Fidelity most often involves attention to content, dose and duration, which can be thought of as general measures of protocol adherence [4, 5].

Increasingly, there is more attention to *context* in discussions of fidelity [6], and to adaptations of interventions so as to be responsive to local conditions. To further understand the relationship between context and fidelity, investigators have called for a more comprehensive approach to clarify the concept of fidelity and the function of factors *moderating* fidelity, including context, participant responsiveness, intervention complexity, among others [6, 7, 8]. Increasing attention to the conceptualization, measurement and documentation of adaptations means that there is more information about the relationship between fidelity, adaptations and outcomes [7, 8]. As well, recent theoretical work in this area [8], has proposed reviewing both fidelity and adaptation in the context of a ‘value equation’ which focuses more on the final desired outcomes beyond intervention effects, linking three concepts: 1) The end product should emphasize overall value rather than only the intervention effects, 2) implementation strategies are a means to method to create ‘fit’ between EBIs and context, and 3) transparency is required. As many factors operate as potential moderators of the relationship between intervention implementation and intended outcomes, it is essential to determine how to understand moderators, even if to do so does not completely resolve the tension between fidelity and adaptation.

When using health IT tools as an implementation strategy, as with interventions focused on self-management support or prevention, systems-level technology requirements are often at odds with ‘on-the-ground’ approaches that employ patient-centered adaptations to individual circumstances [2, 9] and thus are an important place to explore the adaptation and fidelity relationship. As well, with a focus on ensuring that health equity is improved not worsened when applying health IT to vulnerable populations[10, 11], such as those with limited English proficiency and poor access to healthcare, attention to fidelity and adaptation in this context is important.

In the United States, patients with limited health literacy and limited English proficiency disproportionality experience suboptimal diabetes care and poor health outcomes, including a higher prevalence of type 2

diabetes [12, 13]. Language-concordant care, delivered through patient counselling or health coaching, is a critical predictor of improved diabetes self-management outcomes[14, 15, 16]. Technology-assisted diabetes self-management and prevention programs, including those that provide patient-centered supports, have expanded significantly in the last decade with a myriad of approaches including: web-based programs[17, 18], SMART phone applications or apps [19, 20], telephone-based automated call programs, (often referred to as Automated Telephonic Self-Management Support, or 'ATSM' or Interactive Voice Response) which blend narratives content with queries that require patients to respond via touch tone with the information going to a central location for review [21, 22, 23, 24, 25]. Each of these program archetypes provides an efficient platform to deliver multi-lingual content, content tailored to local context, and a range of additional modular features. However, studies have noted that language-concordant availability is often limited [26]. Recent literature has called attention to the importance of evaluating Health IT interventions in ways to ensure the digital divide, is not exacerbated for low-income populations, for those with limited English proficiency, and ethnic minority groups. In the context of expanding implementation for health IT delivered diabetes care/diabetes prevention support [27, 28], it is important to understand how an expanded view of moderators of implementation fidelity, such as language of delivery, interact with specified core components, such as intervention dose, consistency or timing, when considering program sustainability, dissemination, and equity.

In this paper we explore implementation outcomes and moderating factors for a health IT enabled health coaching program focusing on diabetes prevention behaviors called STAR MAMA (**Support via Telephone Advice and Resources Sistema Telefonico de Apoyo y Recursos**) [29, 30, 31]. We build on the value outcome concept described above in relationship to fidelity, in that the end product maps back to the goals, using an equity lens to interpret the value equation for STAR MAMA evaluation. By focusing attention to equity as well as to patient-centered outcomes, we explore moderators of implementation fidelity focusing on understanding variability, participant responsiveness, acceptability, quality of delivery, and cultural or language-concordant tailoring (as well as other equity-focused moderators).

Methods

Study Summary

STAR MAMA is an ATSM-based program which combines automated 3–5 minute weekly calls including queries and narratives with 'live' follow-up calls from a language-concordant health coach (plus opt-in text messages) to encourage diabetes prevention behaviors among post-partum women with recent gestational diabetes (Fig. 1). We apply an established implementation framework for fidelity evaluation[6, 7, 9] and a range of data sources in order to explore the reach and engagement of intervention content to linguistically diverse populations.

The STAR MAMA program pilot tested a 20 week bilingual (English and Spanish) ATSM diabetes prevention program, and evaluated for impact on 9–12 month outcomes, using a type 1 hybrid implementation effectiveness study and a randomized clinical trial design [32]. Women were individually

randomized during a baseline visit at the end of their pregnancies to either STAR MAMA calls or to an education only arm. Health outcomes were evaluated for effectiveness at 9–12 months post-partum using structured interviews and medical records review, and included: weight loss (BMI reduction), breast-feeding duration and the percentage of women actively engaged in chronic disease risk reduction behaviors (such as increased physical activity and decreased consumption of sugar sweetened beverages and program acceptability for those in the intervention arm). The trial enrolled 181 post-partum women receiving health care in safety net settings in the San Francisco Bay Area, between 2014 and 2018. Study sites included Zuckerberg San Francisco General Hospital (ZSFGH), SF-Women Infant Child Programs, and Sonoma County- Women Infant Child Programs and a Federally Qualified Health Center. Women were enrolled during prenatal visits and had a clinician-confirmed gestational diabetes diagnosis at 32 weeks of pregnancy. All study procedures were approved by the University of California, San Francisco Committee on Human Research. Participants were given gift cards valued at \$135 total as reimbursement for their participation in baseline and follow-up interviews.

STAR MAMA was developed using a theory-informed approach, applying the Capability Opportunity and Motivation (COM-B) model and related Behavior Change Wheel [33], as well as Social Cognitive Theory alongside a stakeholder engagement process to improve the relevance and reach of the intervention content for the linguistically diverse populations receiving it [29, 30]. The bilingual program adapted from the Diabetes Prevention Program (DPP) content [34]. Based on stakeholder input, STAR MAMA included content focusing on health at the individual level (participant), but included content for infant care as well as about socio-ecological drivers affecting health behavior, such as food insecurity and social support/social isolation (Appendix). The content includes a mix of narrative storytelling showcasing supportive messaging about challenges often encountered in post-partum period (e.g. stress, mood, fussy babies), questions that ask about behaviors for the coaches to review responses to (e.g. *“Are you having trouble breastfeeding?, press 1 if yes and 0 if no”*), and tips, in the form of recipes, text links to videos for exercise and community resources. Topics focused on behaviors related to diabetes prevention (weight loss, healthy eating, physical activity, glucose screening, breast feeding, stress and mental health) and on key areas of infant health in the first 6 months (vaccination timing, breastfeeding, fussiness, sleep, introduction of food). The intervention was delivered weekly beginning at 6 weeks post-partum at a day and time selected by the participant, and lasting 20 weeks, after which a follow-up interview was completed over the phone or in-person.

The structure of STAR MAMA includes both a “push” of diabetes prevention messages directed at improving adherence to diabetes prevention related behaviors to women, and a “pull” of engaging participants with health coaching call backs, based on participant responses to behavioral questions (e.g. *“how many sugar sweetened drinks did you have in the last 7 days? enter the number of drinks”*) and pre-determined trigger thresholds for health coaching call backs (e.g. reporting more than 1 day drinking sugar sweetened beverages, or ‘yes’ to difficulty with breastfeeding). Primary health outcomes from the study will be reported elsewhere regarding weight loss, physical activity, breast feeding and diabetes-relevant behaviors.

Fidelity Analysis- Overview of Fidelity-Related Outcomes

The goals of the fidelity analysis are to determine to what extent the STAR MAMA program was delivered as intended, for **core intervention components** related to: (1) System Integration: *completeness and correct timing* of the STAR MAMA delivery system such that women first received their calls as intended beginning 6 weeks post-partum, at their preferred day and time; (2) Intervention Delivery: *correct sequencing* of the weekly calls, the “push” of the intervention; and (3) Call Consistency: for calls over the intervention period; and (4) Health Coach Responsiveness: for attempted call backs for call triggers generated by the STAR MAMA system. (Table 1; Fig. 2). All measures were evaluated for variation by language as a potential equity moderator of fidelity.

Table 1
Core STAR MAMA Intervention Components and Moderating Factors Evaluated

Domain	What is required for high fidelity	Fidelity Assessment Questions	Specific Outcome	[Data Source]
Core Fidelity Component Assessment				
1. System Integration <i>(Combining participant registry with intervention delivery platform)</i>	a) Complete registration and uploading of GDM patient details to ATSM system (after baseline enrolment/randomization) b) Activation of the ATSM system to initiate intervention delivery (timed to 6 weeks post-partum)	a) Was the participant-level data integrated into the ATSM system prior to 6 weeks post-partum? b) Was the STAR MAMA start correctly implemented for the first call to be delivered 6 weeks post-partum?	a) % of enrolled women in trial at each clinical site, with data uploaded to the ATSM delivery platform. b) % of intervention starts correctly linked to delivery date	[System-generated weekly report]
2. Intervention Delivery	Correct ATSM 'push' of weekly intervention content to each participant, at a pre-specified time and day, based on participant preferences	Did the ATSM system correctly deliver weekly call content to participants? a) All the calls were sent as planned b) Delivery of all intervention weeks (completeness) c) Delivery of correct sequencing of intervention (alignment with intervention logic for post-partum period/infant development)	a) % of calls correctly delivered b) % of participants delivered/not delivered all 20 weeks of calls c) % of participants with delivered weeks in the correct sequence for all 20 weeks	[System-generated weekly and daily reports]

Domain	What is required for high fidelity	Fidelity Assessment Questions	Specific Outcome	[Data Source]
<i>3. Consistency of intervention delivery over time</i>	Consistency of ATSM 'push' of weekly intervention content across the study intervention period	Did the ATSM system result in error clustering? Or were errors spread out over time across weeks and over the study period?	% of participants with an early (weeks 1–5) vs later ($\geq$ week 6) missed week delivery	[System-generated weekly and daily reports]
<i>4. Health Coach Responsiveness to participant 'triggers'</i>	Responsiveness of health coaches to participant triggers generated by touch tone responses to calls	Did health coaches call back participants whose daily reports indicated a trigger warranted further follow up?	% of women with at least one documented trigger who subsequently received a health coach initiated call attempt	[System-generated weekly and daily reports] and [Health Coach Database]
Moderating Factors				
<i>Health coach consistency of outreach over time</i>	Level of fluctuation in call-back attempts over time by health coaches	Did health coaches make call-back attempts consistently over the study intervention period?	% of triggers over time that received an attempted call back	[System-generated weekly and daily reports] and [Health Coach Database]
<i>Language Equity: Health coach consistency of outreach for participant language and enrolment site</i>	Level of fluctuation in call-back attempts by language or site	Did health coaches make call-back attempts similarly for Spanish and English speaking participants and for enrolment sites?	% of triggers by language, over time, that received an attempted call back	[System-generated weekly and daily reports] and [Health Coach Database]
<i>Language Equity: Acceptability of the STAR MAMA calls and health coaching package</i>	N/A	How acceptable was the intervention to enrolled women? Would they do it again or refer others?	Levels of acceptability reported at follow-up after the program was over.	[Interview data]

As we were interested specifically in potential moderators, we also explored the impact of moderators, such as health coaching call consistency over time, and language, on fidelity outcomes (Fig. 2).

Acceptability was also included in the fidelity assessment for women in the STAR MAMA intervention arm as a moderator—the rationale being that participant engagement in the intervention could affect the health coaches responses, and it would be important to understand which program aspects had higher and lower acceptability, and variation by language.

Integration of the participant enrollment registry with the STAR MAMA delivery system was estimated as the percent of enrolled women who were subsequently uploaded to the Health IT intervention delivery platform prior to the target start date of the women's calls, beginning 6 weeks post-partum. This time-sensitive activity involved site-level identification of the eligible women with GDM (with confirmation at 30 weeks gestation) through review of weekly clinic trackers and WIC databases, contacting women post-partum to determine their preferences for call dates and times, uploading preferences, and activating the STAR MAMA call initiation.

System delivery of the STAR MAMA call content was measured by counting the number of calls with the correct content (vs. "incorrect"), delivered in the correct sequence (vs. "skipped"), and in the correct language for the patient based on weekly system generated reports. We also measured the consistency of call delivery over time, evaluating whether all 20 weeks of STAR MAMA calls were delivered, and whether any errors were consistently appearing over the 20 weeks (such as missed weeks), and variation by language.

Fidelity Analysis- Moderators

We explored potential moderators of the quality of delivery including: health coach consistency of attempted call backs over time and health coach consistency regarding attempted call backs by participant language and enrollment site (i.e.: consistency over real time and program week, minutes on each trigger type, and call back rates by language). For participant responsiveness, the proportion of the target group that engaged with the intervention, and variation by language were examined. We calculated the counts of calls picked-up, calls completed, and whether the health coach made the protocol-driven follow-up call. Acceptability measures were derived from 9–12 month semi-structured follow up interviews, and included: overall acceptability with the STAR MAMA program; acceptability of different aspects of the pushed content, acceptability of health coaches; level of involvement of other close friends/family in program activities; and indication of intention to do another program like STAR MAMA again.

Fidelity Analysis- Data Analysis

Data sources for the fidelity analysis include: (1) an automatic system report (call attempts, week of the message, call duration, triggers indicated); (2) project-driven information (health coach notes, database of daily reports); and (3) interview data. Engagement measures for the fidelity analysis included: delivery of ATSM calls, ATSM call responses by participants, and health coaching (HC) summary notes, including topics discussed, resources referred, action plans made and length of call.

Relevant reporting guidelines based on the StaRI checklist, Standards for Reporting Implementation Studies, were completed for this study. See Additional Files for more information.

Results

Of the 181 women who were recruited 90 were randomized to the STAR MAMA ATSM calls and 91 to the education only arm (see CONSORT diagram Fig. 3). Participant mean age was 31.5 years, 96.6% of participants are Latina and 80.9% were born outside the US. Among those receiving the ATSM calls 55 received the calls in Spanish (61%) and 35 English (39%). Of those in the ATSM arm, 81 women (90%) completed all 20 weeks of the program. Five participants withdrew (3 English-speaking and 2 Spanish-speaking, total of 6% of enrolled population) and 4 were lost to follow-up. Sixty-one women in the intervention arm who completed follow-up interviews are included in the acceptability assessment.

Overall STAR MAMA Call Completion: Program Adherence

Overall STAR MAMA engagement was moderately high, with a mean of 11.8 weeks (standard deviation (SD) = 7.0) completed out of 20 total weeks in the program (Fig. 4). Seventy (86.4%) of the 90 women randomized to calls completed at least the first week of the program. Fifty-four (66.7%) women completed at least half (10+) of the weeks in the program and forty (50%) women completed at least 70% (14 weeks) of the program. Spanish speaking participants had higher levels of call completion than did English-speaking participants (those completing 10 or more calls), but the result was not statistically significant. The mean number of calls completed was 12.4 (SD 6.6) for Spanish speakers and 10.7 (SD 7.5) for English speakers.

Delivery of the STAR MAMA program: System Integration

There were no errors in the system integration components evaluated with all participants correctly uploaded to the platform, and for the activation of calls to begin at 6 weeks after the confirmed delivery date.

Delivery of the STAR MAMA program: Intervention Delivery Completeness

We separate out program call completion assessments into two categories: system-driven and participant-driven. Of the 81 participants who completed some or all of the 20 weeks, there were a total of 1,620 total calls programmed to be pushed by the ATSM system. At the system-level, there were 31 (1.9%) missed calls, 5 (0.3%) incorrect calls, 29 (2.2%) skipped calls, and 73 (4.5%) error messages. The number of unique patients affected was 21 (25.9%) for missed calls, 5 (6.2%) for incorrect calls, 23 (28.4%) for skipped calls, and 30 (37%) for error messages. There were 666 (41.1%) partially completed calls, in which the participant did not complete the entirety of the call response prompts but did some of them. There were 9 (11.1%) participants who did not complete the call in at least one of the weeks.

Delivery of the STAR MAMA program: Intervention Delivery Sequencing

A sequencing issue (“skipped” week) occurs when the wrong week’s content was delivered in a certain week. There were a total of 29 calls sent that contained the incorrect week of content. This affected 23 unique patients (28% of participants who completed the STAR MAMA calls); the majority ($n = 20$) experiencing one skipped week.

Delivery of the STAR MAMA program: Consistency over time

Participants who started when the program was first implemented experienced more call issues, as the program was working out the technical issues. For example, the first 17 participants experienced 56% of all the problems with the STAR MAMA call delivery and sequencing, and the first 25 participants experienced 70% of all the call issues. The patients who experienced the most call issues experienced 3–4 missed calls over the course of their 20-week program; these patients were within the first 17 participants to start the program. Looking at total errors, a significant proportion were experienced in the first 5 weeks (41.1% of all errors) of the 20 weeks total program duration. These system-level errors for delivery completeness, sequencing and consistency over time did not disproportionately affect either language group (data not shown).

Health Coaching Triggers and Participant Call-Backs

The mean number of weeks where a health coaching call back was triggered was 6.5 ($SD = 4.1$, median = 7), representing about one-third of the calls that could have triggered a health coaching call-backs ($n = 18$ weeks). The mean number of weeks with a completed health coaching call-backs was 3.2 ($SD = 3.01$, median = 2). The total duration of the health coaching calls for each patient varied considerably, with a mean of 41.8 minutes ($SD = 38.9$, median = 29). By week five of the program, 43% of all triggers had occurred. Seventy-four percent of all triggers indicated occurred in the first 11 weeks of the program.

Of all 1,620 possible calls, English speakers ($n = 31$, 38% of participants) should have received 620 calls, and Spanish speakers ($n = 50$, 62% of participants) should have received 1,000 calls (see Fig. 5). Of the calls in English, 29% ($n = 178$) triggered a health coach follow-up, while of the calls in Spanish, 35% ($n = 349$) triggered a health coach follow-up. There were many more triggers in the first several weeks of the STAR MAMA intervention than later on in the program, especially among Spanish-speakers. Although Spanish speakers had more triggers than did English-speakers, the difference was not statistically significant. Of the calls that triggered a health coach follow-up, a call-back attempt was made for 85.4% ($n = 152$) of the English call triggers and for 80.0% ($n = 279$) of the Spanish call triggers. Of those with attempted calls, health coaching calls were complete for 55.6% ($n = 85$) of English-language call triggers and for 56.6% of Spanish-language call triggers. Again, there were no differences by language in attempted or completed health coaching call-backs. Additionally, attempted call backs were consistent over time and by language of call trigger (Fig. 6).

Acceptability

Overall acceptability was high for STAR MAMA calls (Table 2) and in general did not differ by language, with a few notable exceptions including agreement that the program provided “useful information on diabetes prevention and baby care” (Spanish speakers reporting higher agreement, $p < 0.01$), and English speakers were less likely to report the health coaches were considerate of their time ($p = 0.03$). Ninety percent of women interviewed reported they would do the program again. Over half (55.6%) had shared the program ideas with friends and 75.8% had engaged a partner in some of the STAR MAMA content. Two-thirds reported that the number of weeks was ‘fine’, with a third indicating the program was “too long”.

Table 2
Acceptability Indicators Among STAR MAMA Call Participants Completing Follow-Up (n = 61)

	Combined (N = 61)		English-Speaking participants		Spanish speaking participants		P-value
Technical Indicators - Acceptability	% agree program worked fine/no call problems	% agree there were 1 or more call problems	% agree program worked fine/no call problems	% agree there were 1 or more call problems	% agree program worked fine/no call problems	% agree there were 1 or more call problems	
Quality of sequencing of calls	82.8%	17.2%	90.5%	9.5%	78.4%	21.6%	0.30
Call length	88.5%	11.5%	91.5%	8.5%	81.8%	18.2%	0.06
Audio quality	91.6%	8.3%	90.9%	9.1%	92.1%	7.9%	1.00
Clarity of call	98.3%	1.7%	100%	0%	97.4%	2.6%	1.00
Text 'opt in' quality*	67.2%	32.8%	66.7%	33.3%	67.6%	32.4%	1.00
Call Content Indicators-Acceptability	% Agree	% Disagree, or neither agree or disagree					
Information useful for diabetes prevention	86.0%	14.0%	63.5%	36.5%	97.0%	3.0%	0.003
Information useful for baby care	91.8%	8.2%	73.3%	26.7%	100%	0%	0.006
Information useful for losing weight	88.4%	11.6%	94.1%	5.9%	85.7%	14.2%	0.65
Information useful for increasing physical activity	94.2%	5.8%	94.1%	5.9%	94.2%	5.7%	1.00
Information useful for eating healthy/nutrition	98.0%	2.0%	100%	0%	97.2%	2.8%	1.00

*n = 41 women opting in to text messages

	Combined (N = 61)		English-Speaking participants		Spanish speaking participants		P-value
Information useful for reducing intake of sugars	98.0%	2.0%	94.1%	5.9%	100%	0%	0.32
Call Content Indicators-Social Support	% Agree	% Disagree, or neither agree or disagree					
Supported my feelings as a new mom	93.3%	6.7%	86.4%	13.6%	97.4%	2.6%	0.14
Gave me ideas to find other people in my life to support me in diabetes prevention	76.7%	23.2%	63.6%	36.3%	84.2%	15.8%	0.11
Health Coaching Acceptability Indicators**	% Agree	% Disagree, or neither agree or disagree					
Health Coaches helped me for diabetes prevention	78.4%	21.6%	75%	25%	80%	20%	0.72
Health Coaches helped me for baby care	92.3%	7.7%	94.1%	5.9%	91.4%	8.5%	1.00
Health Coaches helped me feel supported as a new mom	92.3%	7.7%	88.3%	11.7%	94.3%	5.7%	0.58
Health Coaches were considerate of my time	96.1%	3.9%	83.3%	16.7%	100%	0%	0.03
*n = 41 women opting in to text messages							

Discussion

In this paper we report that core fidelity metrics for the STAR MAMA study, the relationship of language and other moderators to fidelity outcomes assessed and describe several inconsistencies over time at the

systems level. Although there were few effects of a language differential in the evaluation, there were some trends in differences by language in systems-level problems as well as in health coaching interactions. We believe that it is critical to determine to what extent efforts to increase diverse populations in health IT interventions are well adapted to the local context and to this end, it is important to evaluate the errors inherent in any automated processes designed to reach a wider range of participants.

Technology can be a great enabler of care delivery, but if left unchecked, can also cause fidelity failure. Some authors support the view that To explore this topic we evaluate language as a moderator across a wide range of fidelity outcomes—for systems delivery and in-person touches. Based on these findings, we recommend consideration of language equity should be included as a moderator in multi-lingual Health IT interventions, as it concerns whether an intervention is delivered equally across all populations (in our case between Spanish-speaking and English-speaking participants) over time. This work builds on existing implementation research to study how technology is implemented, to explore the impact on multi-lingual populations [35]. This study also highlights an approach to make more concrete existing fidelity frameworks with a step-wise approach outlined in the conceptual model. We hope this work can guide exploration of fidelity for health IT interventions, and in particular, those that include an automated ‘push’ along with a ‘personalized’ follow-up by a health coach or other health professional.

For low-income populations such as the women enrolled in this study, the underlying contributions of social determinants and structural barriers (such as limited economic resources, language barriers, or limited healthcare access), may impede engagement with health coaching programs if participants are not able to prioritize addressing their prevention-focused health needs in real time in addition to the other demands they face. It is critical to explore to what extent offering adapted multi-lingual interventions, especially those with health coaching components, are acceptable and to what extent modifiers may impact core fidelity measures. Some authors indicate that adaptation is needed in order to achieve users’ involvement and ownership for successful implementation [36], which was one of the intervention development steps involved in adapting STAR MAMA and may have contributed to the high levels of engagement and acceptability. That we identified greater engagement and acceptability with the non-English speaking group is consistent with other work we and others have done regarding language and health coaching engagement. for each group [37, 38, 39].

There are several limitations to this study. As mentioned above, information on high and low adopters, by language would have provided critical insights into necessary modifications. We did find high acceptability across language groups but drivers of dissatisfaction, are less specified in the quantitative descriptive analysis. Additionally, conducting modeling to explore the relationship between fidelity and health outcomes was out of scope for this study, since it was a pilot, with a relatively small intervention arm sample size. Also, it is possible that there are complex relationships between moderators, as suggested by Carroll 2007 [2]. Similar to how more facilitation strategies does not necessarily mean better implementation (because of the level of complexity), more “equitable” delivery does not necessarily mean better implementation. Understanding each population’s variability, through exploration of high and low adopters for example, with in-depth interviews, can move towards an assessment of social determinants,

and suggest recommendations for intervention adjustments that do not violate core components, but can address the context of the needs of each particular group.

Conclusion

Implementation fidelity for health IT interventions should address moderating factors, such as language, as well as systems level factors. A modified fidelity framework that explicitly considers equity-based moderators can help ensure there is equitable delivery of interventions.

Abbreviations

STAR MAMA

Support via Telephone Advice and Resources Sistema Telefonico de Apoyo y Recursos

Health IT

Health Information Technology

ATSM

Automated Telephonic Self-Management Support

Declarations

Declarations: We have no conflicts of interest or other declarations to report.

Ethics approval and consent to participate: Research ethics approval was sent to the Research Ethics Committee of the University of California, San Francisco [INSERT IRB#10-02524]

Consent for publication: not applicable

Availability of data and materials: The datasets that support the findings of this study are not publicly available due to information that could compromise research participant consent and privacy but can be made available from the corresponding author (MH) with appropriate precautions and upon reasonable request.

Competing interests: The authors declare that they have no competing interests.

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Authors' contributions: MH conceived of the study and conducted the analytic framing and writing. JL and CW conducted data analysis. AN conducted data collection and health coaching note review. DV conducted data collection and health coaching note review. PA conducted data collection and writing of the paper.

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Figures

Figure 1

STAR MAMA Program. (1) The woman is enrolled in the program 6 weeks post-partum. (2). The system “pushes” weekly calls using touch tone responses, which a health coach reviews (3) in a weekly report and then engages the patient in follow-up health coaching telephone calls, based on pre-determined ‘triggers’ for weekly responses. (4) Health coaches provide linkages to clinic and community resources.

Figure 2

Conceptual Framework for Fidelity Evaluation: STAR MAMA

Figure 3

STAR MAMA CONSORT Flow Diagram

Figure 4. STAR MAMA Completed Calls by Week and Language

Legend: Dashed Line=Spanish.
Dotted Line=Combined.
Solid Line=English

Figure 4

STAR MAMA Completed Calls by Week and Language

Health Coach Triggers by Language over time

Figure 5

Health Coach Triggers for STAR MAMA: By Language and Over Time

Figure 6

Health coach Attempts (%) by Language over time

Supplementary Files

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- [APPXSTARMAMAWEEKLYCONTENT.docx](#)
- [StaRlchecklistforauthorcompletion10302020.docx](#)