Bungoma County Woman's Study: A Pilot Randomized Evaluation to Estimate the Impact of a Screening and Referral Service on Contraceptive Use

by

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Thesis submitted in partial fulfillment of
the requirements for the degree of Master of Science in the Duke Global Health Institute
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ABSTRACT

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Abstract

Background: An estimated 225 million women globally have an unmet family planning need, three-quarters of whom live in low and middle-income countries. Addressing this need requires new and innovative approaches, such as digital health solutions. We examined the impact of a new phone-based screening and referral service on the take-up of family planning as part of a pilot study to prepare for a full trial of the intervention.

Methods: This pilot study tested the procedures for a randomized encouragement trial. We recruited 112 women with an unmet need for family planning from local markets in Western Kenya, conducted an eligibility screening, and randomized half of the women to receive an encouragement to try the investigational intervention. Four months after sending an encouraging to the treatment group, we attempted to conduct a follow-up survey with all enrolled participants.

Results: The encouragement sent via text message to the treatment group led to differential rates of intervention uptake between the treatment and control groups, but take-up among the group was lower than anticipated (33.9% vs 1.8% in the control group). Study attrition was also substantial. We obtained follow-up data from 44.6% of enrolled participants. Among those in the treatment group who tried the intervention, however, the instrumental variables estimate of the Local Average Treatment Effect was an increase of 41 percentage points in the probability of contraceptive take-up.

Conclusion: This randomized encouragement design and study protocol is feasible but requires modifications to the encouragement and follow-up data collection procedures. The investigational intervention appears to have a positive impact on contraceptive take-up among women with an unmet need despite a number of contextual challenges.

Dedication

To Mathai, Molly, and Ashley, thank you for your unwavering encouragement and support throughout my journey. I am grateful to have you all as my family.

Contents

List of Tables

List of Figures

Acknowledgements

I would like to thank my thesis committee, Drs. Eric Green, Megan Huchko, and Larry Park, for their expertise, feedback, and support. This thesis would not have been possible without their mentorship. An additional acknowledgement goes to Dr. Violet Naanyu, the co-investigator from Moi University in Eldoret, Kenya who provided valuable feedback during the execution of this study.

I would also like to thank Joseph Kipkoech and George Ambani from Dr. Wendy O'Meara's Enact Dx team who offered encouragement and hospitability during my time in Kenya. Additional thanks go to my friends in Durham, especially Nolan Kurtz, Matthew Nelson, and Yucheng Bai for their camaraderie and support.

I am indebted to Mercy Muringi, Nancy Wairimu, Maximilla Chivini, and Purity Nyangweso for their work during the enrollment phase of the Bungoma County Women's Health Study. Additional gratitude goes to Leonard Ng'eno for his help with Swahili translations.

Finally, I would like to thank Anna-Karin Hess and Lulla Kiwinda. Without your patience and hard work, none of the fieldwork components of the Bungoma County Women's Health study would have succeeded.

1. Introduction

Family planning is one of the most effective public health interventions. By reducing unintended and high-risk pregnancies and unsafe abortions, increased access to family planning has reduced maternal deaths in developing countries by 40 percentage points and lowered overall fertility rates over a 20 year span (1982-2012) [1]. Additionally, increased access to family planning is associated with improved outcomes for newborns, including greater childhood survival and better cognitive development [2, 3]. The effects of these improved outcomes extend throughout the lifecourse, leading to better educational attainment and earnings during adulthood [3].

In spite of a documented increase in the use of family planning methods globally, the number of women in LMICs (Low and Middle-Income Countries) with an unmet family planning need remains high. In 2014, an estimated 225 million women had an unmet family need, three-quarters of whom lived in LMICs [4]. Seeking to address the lack of institutional (macro-level) support for family planning, the Family Planning 2020 initiative was launched at the 2012 London Summit on Family Planning. More than 40 nations pledged to address the policy, financing, delivery, and socio-cultural barriers that women face accessing family planning information and services. Though 38.8 million additional women and girls have obtained access to modern family planning methods since the initiative began, the current pace of uptake is not meeting expectations [5].

At the micro-level, there are several individual and community level barriers for women that prevent uptake and sustained use of family planning methods. One of these barriers is limited access to comprehensive sex education from parents, health providers, and other institutions [4]. Though the majority of women of reproductive age have awareness of modern contraceptive methods, this educational disparity results in women having inaccurate perceptions of their pregnancy risk and limited knowledge of the proper use of family planning methods. Subsequently, many women discontinue or resist using contraceptive methods due to perceived side effects such as infertility [6].

The Demographic Health Survey program defines a woman to have an unmet planning family need if she is not currently using a family planning method, but expresses a desire to either space or postpone her next birth (i.e., "spacing") or stop having children all together (i.e., "limiting") [9]. In Kenya, 18% of married women have an unmet need for family planning. This need is higher among those with lower educational levels; 28% of married women with no formal education have an unmet need [7]. This is within a setting where 2 out of 5 pregnancies are unplanned [8].

In addition to the high need for family planning in Kenya, a large information gap exists among currents users of family planning methods. All family planning users should be informed about the potential side effects of the method that they are using, what to do should they experience side effects, and what alternative methods are available for them. In Kenya, only 52% of current users are aware about what to do should they experience side effects from a method. Adding to this gap, 40% of users

report that their healthcare providers did not inform them of potential side effects during their first visit to initiate a family planning method [7].

Kenya has taken steps to address its high need for family planning. Since its pledge at the 2012 London Summit on Family Planning, the Kenyan government has established 70 youth empowerment centers across the country. These centers provide transparent information to youth on family planning methods. Additionally, the government has worked to integrate family planning services with HIV care and increase the availability of long-acting methods in public health facilities across the country [10, 11].

In spite of these efforts, human resource shortages still hinder engagement with marginalized communities in Kenya. As a result, women living in these communities with an unmet need may not be referred in a timely manner to the appropriate health provider. Overcoming this human resource shortage will be difficult as the government has slashed its yearly support for family planning. Though it committed $6.6 million US dollars (USD) in 2012, its current allocation for family planning is now $500,000 USD [10, 11].

Continuing to address the unmet need for family planning in Kenya will require new and innovative solutions. Digital health solutions, specifically mobile health (mHealth) innovations, offer promise in this realm. When integrated appropriately into existing health systems in low and middle-income settings, mHealth solutions can provide opportunities to overcome human resource shortages, improve patient

education, and provide both transparent data collection and reporting for key health indicators. In many cases, only simple phone functions (e.g., SMS text messages) are required to deliver a mHealth solution [12]. With the rapid growth and expansion of wireless telecommunication networks across Sub-Saharan Africa (SSA)—Kenya in particular—mobile messaging has become a widely used medium of communication. Currently, there are more mobile phone subscriptions in SSA than in the United States or the European Union [13]. In Kenya, 90.4% of the population—nearly 41 million Kenyans—were mobile phone subscribers by the end of 2017 [14].

In this study, we examined the impact of a new phone-based screening and referral service called Nivi [https://www.nivi.io/] on the uptake of family planning as part of a pilot study to prepare for a full trial of the intervention. The objectives of this pilot study were to generate a preliminary estimate of efficacy while developing and testing the recruitment, screening, and follow-up procedures.

2. Methods

2.1 Design

The study design employed in this pilot evaluation is a randomized encouragement trial, a variant of the traditional, parallel-randomized control trial. This approach was chosen, as the investigated service was publicly available within Bungoma County, Kenya, the setting for this pilot study. Under this condition, it was impossible to randomly assign access to the service at the individual level. Though cluster-level designs are often used to address this constraint, it was not financially nor logistically feasible during this pilot study to randomize access at a higher level such as a county. Under this constraint, an intent-to-treat estimate would have significant bias due to the two-sided non-compliance that would occur due to all study participants having public access to the service.

In this situation, a randomized encouragement trial design can be employed to obtain an unbiased causal estimate. Under this design, participants are randomized to receive an encouragement or invitation to take up the intervention while participants randomized to the control arm do not receive the encouragement. As long as the encouragement or invitation enables differential uptake of the intervention between the two arms, a causal estimate (Local Average Treatment Effect or "LATE") can be determined [13]. This estimate is the causal effect of the intervention for participants whose decision to use the intervention was due to having received an encouragement.

2.2 Study Setting

The setting for this study in Bungoma County, the fifth most populous county in Kenya. Bungoma County is situated in what was the former Western Province. In 2010, a new constitution of Kenya was passed that dissolved the former provinces and transferred local governance to 47 newly created county governments. This constitution became enacted in 2013.

Predominantly rural, Bungoma County is one of these new counties and has nearly 1.4 million residents. Estimates place 47% of residents to be living in poverty [16].

2.3 Participants

Women were eligible to be enrolled in this pilot study if they were between the ages of 18 and 35, had an unmet need for family planning, and were residing in Bungoma County, Kenya at the time of recruitment. In addition, these women must not have been using a family planning method, pregnant, or four months post-partum. To ensure that they could be contacted for follow-up, these women needed to have also demonstrated primary phone ownership and were willing to be contacted for follow-up. Finally, as the baseline survey was administered using a tablet computer, eligible participants had to successfully answer a series of example questions to demonstrate understanding of how to use the tablet.

We determined an eligible woman to have an unmet need if she had a desire to postpone her next birth for at least two years ("spacing") or stop having children altogether ("limiting"), but was not using a family planning method [7]. The DHS

algorithm used to characterize unmet need is traditionally applied to married women, but we extended it to include women single women who reported being sexually active in the past month [9].

Recruitment for the pilot study happened between July and August 2017 during set marketplace days in six peri-urban locations within Bungoma County, Kenya. Within each location, the study team rented a marketplace spot and had signage advertising the study.

2.4 Intervention

The investigational intervention offers screening and referral services for family planning. Women interested in learning more about family planning can send a free SMS to begin an automated family planning session. Based off her individual family planning preferences, an algorithm will recommend family planning methods that fit the client's goals. The woman is then given a list of local family planning providers offering these methods along with a referral code via SMS. This referral code/voucher can be redeemed at any of the referred local facilities.

2.5 Procedures

Women who passed the initial eligibility screen could choose to self-administer the baseline survey on a tablet or take the survey with assistance from a Kenyan enumerator. Women who opted to self-administer the survey were provided with headphones to listen to listen to each survey item and its response options. The baseline

survey was built using the Open Data Kit platform (https://opendatakit.org/), an open-source survey authoring solution.

If a potential participant was ultimately found to be eligible to enroll into the study, the enumerator explained the study and obtained informed consent and registered the woman's name and contact information in the study registry. No identifying information was collected from any woman found not to be eligible or who declined to participate in the study. Each participant signed a written consent form and was given a copy to keep.

Each woman who completed the baseline survey received 200 Ksh (~ $2 USD) mobile airtime. This honorarium was provided regardless of whether or not a woman was found to have a family planning need or consented to participate in the study if found to have a need.

At the end of the recruitment period, enrolled participants were randomized into the treatment arm or control arm. A randomized block design was used to ensure balance between arms on four baseline covariates: a participant's age, educational status (post-secondary education or not), previous use of a family planning method, and marital status (currently married/co-habiting or not).

Participants randomized to the treatment arm of the study received an encouragement to try the intervention via a series of text messages in either English or Swahili, depending on their stated language preference at the time of recruitment. In

addition to receiving these text messages, participants in the treatment arm also received a 200 Ksh airtime credit.

Participants randomized to the control arm received a different set of messages. These messages did not include any reference to the intervention. Instead, these messages thanked them for their participation in the study.

Approximately four months after the recruitment period ended, we invited all participants to complete a follow-up survey via SMS text messages. If a participant did not respond back to SMS survey, had issues completing the survey, or preferred to complete the survey through phone call, an enumerator called the participant and administered the survey over the phone, recording the participant's answers on a version of the survey built using Open Data Kit. The enumerator was blinded to participants' assignment to treatment until the end of the survey. Each participant who completed the follow-up survey received a 200 Ksh honorarium.

2.6 Outcome

The primary outcome in this study was uptake of a modern family planning method since the enrollment survey [15]. During follow-up, each participant self-reported if they had taken up a method since enrollment and which method it was. This included women who started using a method since the enrollment period but later discontinued use.

2.7 Analysis

Given the expected two-sided non-compliance, the intent-to-treat estimate of the impact of assignment to the intervention on modern family planning uptake will be biased. However, it is possible to obtain an unbiased Local Average Treatment Effect (LATE) for compilers. Compliers represented study participants in the treatment arm who used the intervention because they were encouraged to, but who would not have done otherwise had they not received the encouragement. In other words, the LATE describes the treatment effect for women who used the intervention due to having received an encouragement [15].

To determine the LATE, a 2-Stage OLS (ordinary least squares) regression approach was implemented. An instrumental variable, Z, indicated whether participants were randomly assigned to receive an encouragement to try the intervention. The dummy variable, X, indicated whether a participant used the intervention. We obtained this indicator by checking for the participants' phone numbers in the intervention logs; a woman was classified as having tried the service if her phone number appeared in the logs. Lastly, a dummy variable, Y, indicated that a participant adopted a modern family planning method.

For the first stage, an OLS regression was fitted between X and Z, the instrumental variable. To derive the LATE estimate, the predicted values from the first stage regression were then used to fit the second stage OLS regression between Y and X. We assume with the second stage that there is heteroskedasticity (unequal variability)

among the residuals for the predicted outcome values. The reported standard errors would be smaller than they should be due to the heteroskedasticity. To correct this, robust standard errors (Huber-White) were used for the second stage model.All statistical analyses were conducted in R (R Version 3.4.3), a free statistical computing software (https://cran.r-project.org). The following R packages were used in analyses: tidyverse, ivpack, and stargazer.

2.8 Ethical Considerations

The study was reviewed and approved by the Institutional Review Board at Duke University and the Institutional Research and Ethics Committee of Moi University in Eldoret, Kenya. Written informed consent was obtained from all of the participants.

3. Results

3.1 Enrollment Summary

During the enrollment period (July to August 2017), a total of 772 women completed the baseline survey. Of the women screened during enrollment, 112 women were ultimately found to be eligible and consented to be enrolled. The remaining 660 women were found ineligible to participate in the study. Additionally, 440 women did not pass the initial screening criteria (e.g., residence, primary phone ownership, etc), and218 women were found not to have an unmet family planning need. There was one woman who did not consent to participate, and another participant was determined not to have complete baseline data prior to randomization.

All 112 eligible participants were randomized to either the treatment or control arms. All members of the treatment arm received the allocated encouragement to try the investigation. Figure 1 below provides the flow diagram for this study, including the final number of participants analyzed per arm.

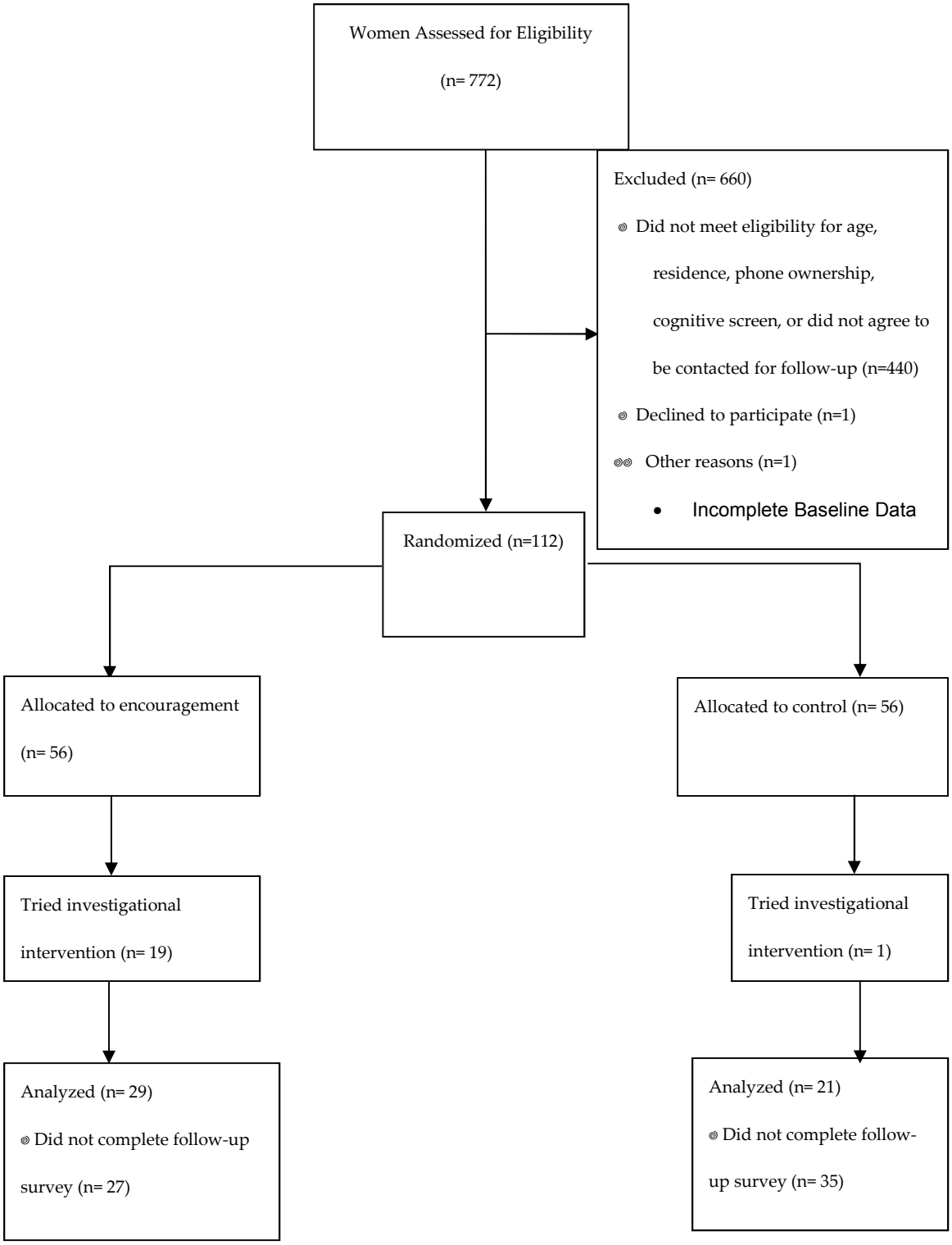

Figure 1: Consort Flow Diagram for Study

3.2 Sociodemographic Characteristics of Enrolled Participants (By Arm)

Table 1: Enrolled Participant Characteristics By Arm

Participant Characteristics (%)	Control Arm Participants (n=56)	Treatment Arm Participants (n=56)	Kenya DHS 2014 Reference Value	Kenya DHS 2014 Reference Group
Mean Age (SD)	24.9 (4.6)	24.6 (5.0)		
Married Or Co-Habiting, %	55.4	60.7	59.7	All women, national, 15-49
Christian, %	96.4	94.6	91.4	All women, national, 15-49
Luhya, Tribe %	75.0	78.6	15.0	All women, national, 15-49
Attended post-secondary education, %	19.6	17.9	7.2	All women, Bungoma, 15-49
No schooling, %	3.6	0	0.9	All women, Bungoma, 15-49
Nulligravida, %	30.4	33.9	35.3	All women, national, 20-24
Mean number of children born (SD)	1.7 (1.6)	1.5 (1.6)	1.1	All women, national, 20-24
Mean number of desired children (SD)	3.7 (1.4)	3.4 (1.1)	3.6	All women, national, 15-49
Unmet Need for Spacing, %	78.6	82.1	90.5	All married women with an unmet family planning need, national, 20-24
Past Use of Family Planning, %	75	67.9	30.5	All women[1], national, 15-49
Mean number methods known (SD)[2]	9.7 (1.9)	9.4 (2.5)	8.7	All women, national, 15-49
Not exposed to family planning messages, %[3]	21.4	17.9	18.9	All women, Western, 15-49

Notes: [1]Women who started an episode of contraceptive use within the last 5 years preceding the survey and discontinued within 12 months. [2] Asked about awareness of 12 common family planning methods. [3] Did not hear or see hear, read, or see a family planning message on radio, TV, or in a newspaper or magazine in the last 12 months prior to study enrollment.

Table 1 presents sociodemographic information for eligible participants by arm assignment. As a comparison, references values are provided using the results of the 2014 Kenya Demographic Health Survey. To summarize, the distributions of sociodemographic characteristics were relatively the same across the two arms. The mean ages of enrolled participants in the pilot study by arm were less than 26.5, the midpoint of the eligibility range for the study. Most participants were married or co-habituated with a partner. However, there were large percentages of participants in both study arms who self-defined themselves as single, but sexually active.

The majority of enrolled participants had an unmet family planning need due to spacing, previous used a family planning method, and were predominately Christian from the Luhya tribe. In addition, most participants had also been exposed to family planning messages through a popular media outlet (i.e., TV, Newspaper, Magazines, or Radio).

3.3 Uptake of Investigational Intervention

Table 2: Uptake of Intervention Among Participants (by Arm)

Investigational Intervention	Treatment Arm (n=56)	Control Arm (n=56)	*p*-Value
Uptake of Intervention, %	33.9%	1.8%	<0.001

*Two proportion z-test of differences in proportions was used.

One of the conditions to estimate a Local Average Treatment Effect (LATE) is differential uptake of the investigational intervention by study arm due to the randomization of the encouragement. This condition was satisfied as demonstrated by Table 2. There was a difference of 32.1 percentage points in the probability of uptake of the intervention between treatment and control arm participants.

3.4 Estimation of Treatment Effects

Table 3: Impact on Uptake of A Modern Family Planning Method

	First Stage	Addressing Unmet Family Planning Need
	Use of Intervention	Uptake of Modern Family Planning Method
Panel A. ITT Estimation		
Encouragement	0.31***	0.13*
	(0.18, 0.44)	(-0.01, 0.26)
Controls	Yes	Yes
Observations	112	112
Panel B. Instrumental Variable Estimation (2-Stage OLS): "Use of Intervention" Instrumented with "Encouragement"		
Use of Intervention		0.41*
		(-0.03, 0.85)[1]
Controls		Yes
Observations		112

Notes: 95% Confidence Intervals in Parentheses. Controls included indicator variables for method of follow-up (phone vs. SMS workflow) and several baseline characteristics: educational status (post-secondary education or not), previous use of a family planning method, marital status (currently married/co-habiting or not), nulligravida, age, and number of children born.

[1] Corrected with Robust (Huber-White) Standard Errors.

*p<0.1; **p<0.05; ***p<0.01

From the 2-Stage OLS Approach (Instrumental Variable Estimator), a LATE (Local Average Treatment Effect) estimate of .41 was obtained (Table 3), indicating the investigational intervention increased the probability of family planning uptake by 41 percentage points among compilers versus other the study participants.

Given the high attrition of participants during follow-up (55.4% of all participants), controls were included into the 2-Stage estimation procedure to adjust for selection bias. These controls were the original covariates that were blocked on during the randomization: educational status (post-secondary education or not), previous use of a family planning method, marital status (currently married/co-habiting or not), and participant's age. Method of follow-up (Phone vs. SMS Workflow) was also included as a control as there was differential response rates from participants by follow-up method.

To handle missing outcome data from participants lost to follow-up, we used the "Last Observation Carried Forward" (LOCF) imputation method, which calls for the last observed value to be used for a missing outcome. In this situation, since all participants at baseline were not using a contraceptive method, we set their outcome value to be 0, indicating that we assume these missing individuals to have not taken-up a family planning method.

Another approach to understanding the Local Average Treatment estimate is shown in Figure 2. We can conceptualize the LATE as a scaling of the Intention to Treat Estimate (ITT Estimate) between treatment assignment and family planning uptake. The LATE is the point estimate that comes from dividing the ITT Estimate by the differential

uptake of the investigational intervention between participants in the two arms (First Stage). The LATE estimate will always be larger than the ITT estimate due to the issue of two-sided noncompliance. Participants in both the treatment and control arms had access to the investigational intervention.

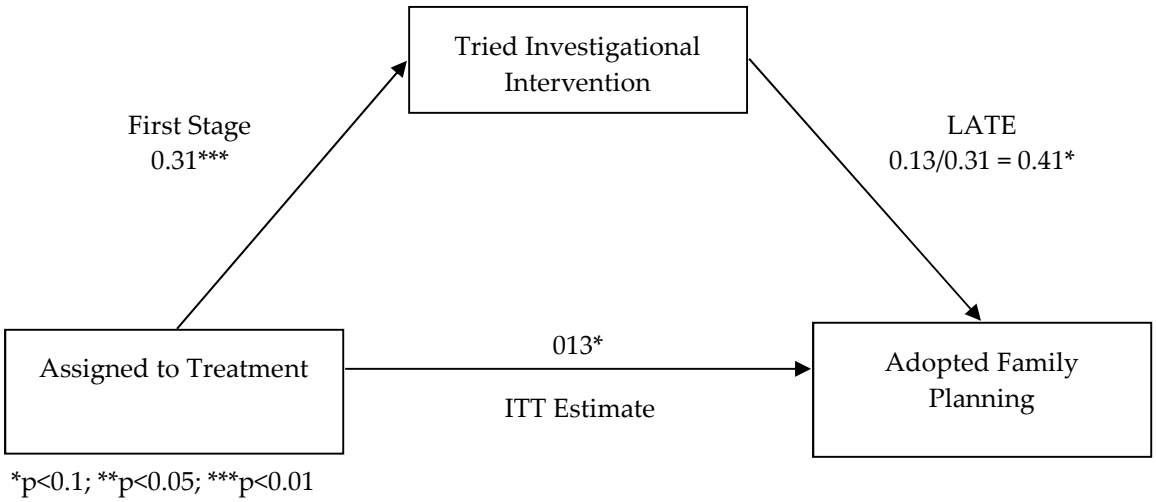

Figure 2: Estimation of Treatment Effects (Conceptual Diagram)

3.5 Baseline Characteristics of Participants by Follow-Up Status

Table 4: Baseline Characteristics of Participants by Follow-Up

Participant Characteristic	Found (n=50)	Lost (n=62)	*p*-Value
Assigned to Treatment, %	58.0	43.5	0.183
Mean Age (SD)	24.4 (4.6)	25.0 (5.0)	0.535
Married Or Co-Habiting, %	52.2	62.9	0.332
Christian, %	98.0	93.5	0.500
Attended post-secondary education, %	28.0	11.3	0.045**
No schooling, %	0	3.2	0.573
Nulligravida, %	42.0	24.2	0.071*
Mean number of children born (SD)	1.2 (1.3)	1.8 (1.7)	0.041**
Mean number of desired children (SD)	3.4 (1.1)	3.7 (1.4)	0.132
Unmet Need for Spacing, %	86.0	75.8	0.267
Past Use of Family Planning, %	68.0	74.2	0.609
Mean number of methods known (SD)[1]	9.8 (2.1)	9.4 (2.3)	0.307
Not exposed to family planning messages, %[2]	16.0	22.6	0.527

Notes: Two-sample t-tests of mean differences and two-proportion z-tests of differences in proportions are used. [1] Asked about awareness of 12 common family planning methods. [2] Did not hear or see hear, read, or see a family planning message on radio, TV, or in a newspaper or magazine in the 12 months prior to study enrollment.
*p<0.1; **p<0.05; ***p<0.01

Next, sociodemographic characteristics collected at baseline were tabulated for participants found during follow-up versus participants lost to follow-up. This was done to explore how the results might be impacted by the high attrition present within this pilot study. Differences in characteristics were compared using two-sample t-tests of mean difference for continuous outcomes and two-proportion z-tests of differences for categorical outcomes. Three baseline characteristics had statistically significant differences (p<0.01): Attended post-secondary education, nulligravida, and mean

number of children born. As such, these characteristics were included as controls in the estimation of treatment effects (Table 3).

4. Discussion

We examined the impact of a new phone-based screening and referral service on the take-up of family planning in Kenya as part of a pilot study. The results from our pilot study suggest that the randomized encouragement design and study protocol are feasible, but modifications to the study protocol are required in preparation for a full trial of the intervention.

To begin, there are opportunities to be more efficient with the recruitment protocol. The recruitment phase for this pilot study only yielded a 14.5% success rate. Around two-thirds of ineligible women were screened out due to basic criteria while a third of women were screened out for not having an unmet need. The full trial will require many more participants. To be more efficient in identifying eligible participants, recruitment should be extended to other locations such as post-secondary institutions and postnatal clinics in the full trial. Within post-secondary institutions, there is likely to be a high percentage of single, sexually active women with an unmet need. Within postnatal clinics, there is likely to be a high percentage of postpartum amenorrheic mothers who also have an unmet need.

The encouragement to use the investigational intervention was successful in that there was differential uptake of the intervention between the two treatment arms; however, this differential uptake was lower than anticipated at 32.1 percentage points. The expected value was 70 percentage points. This consideration is important in thinking about the appropriate sample size required to power the full trial. When

employing a randomized encouragement design, we are need to divide the sample size estimate obtained for a traditional parallel trial by the differential uptake of the intervention. As the anticipated differential uptake becomes smaller, the required sample size becomes bigger [17].

For the full trial, a redesign of the encouragement will be necessary to address the lower than expected differential uptake. One possible redesign for the encouragement would be in-person visits for those participants assigned to receive the encouragement. During these visits, promotional material explaining the investigational intervention could be given to the participant. This type of encouragement has been used before in other full scale evaluations [18].

One significant limitation was the high attrition experienced in this study. Only 44.6% of participants were found during follow-up. This attrition was significantly associated with certain baseline characteristics. However, this attrition was not significantly associated with treatment assignment in the study.

It was noted that participants found during follow-up had higher educational levels than those lost to follow-up. It is possible that primary phone ownership was not maintained in the four months between enrollment and follow-up. The phone and its associated number may have been transferred to someone else. It was noted that participants found during the follow-up had higher educational levels than those lost to follow-up. Though household wealth was not directly measured for each participant, higher educational levels are likely correlated with greater household wealth. It may be

then that there is a correlation between maintenance of primary phone ownership and household wealth.

Other mHealth studies have experienced similar issues with attrition, especially with the use of SMS for follow-up with participants [19]. For the full trial, a new follow-up protocol will be required to prevent the high attrition experienced in this pilot study. One approach would be physical follow-up in which a team of enumerators visits each participant in to determine outcomes. To implement this approach, during enrollment, each participant must also agree to provide her household address for follow-up.

To our knowledge, this is the first study employing a randomized encouragement design to evaluate the effectiveness of a mHealth intervention on contraceptive uptake. Overall, our analyses suggest that the intervention may have a positive effect. Given both the high attrition in this pilot study and the low sample size, we have high uncertainty around the treatment effect. This is reflected in the associated confidence interval for the LATE estimate, which crosses the null value.

The effect size found in this pilot study is relatively large compared to those in other published mHealth studies around reproductive health [19, 20, 21]. Given this consideration and the uncertainty around the effect estimate, a more conservative treatment estimate should be used in determining the sample size for the full trial.

Other limitations for this pilot study include self-reported data. Though this is the standard for trials such as this examining behavior change, there could be bias in the reporting. This study was also conducted during a time of political uncertainty in

Kenya. Between the enrollment and follow-up phases of this study, there were two presidential elections that took place in Kenya. Results from the first election that took place on August 8, 2017 were overturned by the Kenyan Supreme Court, and a second election took place in October [22]. Additionally, there was restricted access to family planning services for a period of time during the pilot study. There was a national nurses's strike that pulled many family planning providers away from health facilities [23].

In spite of these limitations though, results from this pilot study add to a growing evidence base supporting the use of mHealth solutions for improving reproductive health, especially within low resource settings. These limitations can be addressed in preparation for a full trial of the investigational intervention.

5. Conclusion

Based in a low-resource setting, this pilot study employed a randomized encouragement study design. Results from this pilot study suggests that there may be a positive treatment effect for the impact of digital screening and referral service on contraceptive uptake among women with an unmet family planning need. The study design and procedures are feasible, but modifications will need to be made for the full trial. This pilot study adds to a broader evidence base supporting the use of mHealth interventions in addressing challenges in reproductive health.

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