**CONSORT checklist of items for reporting pragmatic trials**

| Section | Item | Standard CONSORT description | Extension for pragmatic trials |
|---|---|---|---|
| Title and abstract | 1 | How participants were allocated to interventions (e.g., “random allocation,” “randomised,” or “randomly assigned”) | 1-2 |
| **Introduction** | | | |
| Background | 2 | Scientific background and explanation of rationale | 4-5 |
| **Methods** | | | |
| Participants | 3 | Eligibility criteria for participants; settings and locations where the data were collected | 5-6 |
| Interventions | 4 | Precise details of the interventions intended for each group and how and when they were actually administered | 6-7 |
| Objectives | 5 | Specific objectives and hypotheses | 5 |
| Outcomes | 6 | Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors) | 7-8 |
| Sample size | 7 | How sample size was determined; explanation of any interim analyses and stopping rules when applicable | 8-9 |
| Randomisation—sequence generation | 8 | Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification) | 6 |
| Randomisation—allocation concealment | 9 | Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned | 6 |
| Randomisation—implementation | 10 | Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups | 6 |
| Blinding (masking) | 11 | Whether participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment | 6 |
| Statistical methods | 12 | Statistical methods used to compare groups for primary outcomes; methods for additional analyses, such as subgroup analyses and adjusted analyses | 9 |
| **Results** | | | |
| Participant flow | 13 | Flow of participants through each stage (a diagram is strongly recommended)—specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analysed for the primary outcome; describe deviations from planned study | 10 |

| Section | Item | Standard CONSORT description | Extension for pragmatic trials |
|---|---|---|---|
| | | protocol, together with reasons | |
| Recruitment | 14 | Dates defining the periods of recruitment and follow-up | 6 |
| Baseline data | 15 | Baseline demographic and clinical characteristics of each group | 11 |
| Numbers analysed | 16 | Number of participants (denominator) in each group included in each analysis and whether analysis was by “intention-to-treat”; state the results in absolute numbers when feasible (e.g., 10/20, not 50%) | 11 |
| Outcomes and estimation | 17 | For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (e.g., 95% CI) | 12-13 |
| Ancillary analyses | 18 | Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating which are prespecified and which are exploratory | 13-15 |
| Adverse events | 19 | All important adverse events or side effects in each intervention group | Nil |
| **Discussion** | | | |
| Interpretation | 20 | Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes | 15-17 |
| Generalisability | 21 | Generalisability (external validity) of the trial findings | 15-17 |
| Overall evidence | 22 | General interpretation of the results in the context of current evidence | 3 and 15-17 |

**Statistical Analysis Plan**

**A cluster randomized controlled trial of innovative demand creation strategies to increase voluntary medical male circumcision uptake in Zimbabwe**

Final version 1.9, 14 January 2019, with addendum 15 May 2019

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**Update memo, 15 May 2019 (original SAP follows)**

This memo serves to update the final analysis plan with additional analysis details and proposed changes to the analysis of rate outcomes (i.e., primary outcome and secondary outcomes 2-5). The analysis and 6-8 (self-testing outcomes) will not change from the analysis plan dated 14 January 2019. The analysis of secondary outcome 1 (conversion proportion) will continue to be assessed at IPC-level, but the method of age-adjustment may change. As with the original plan, we suggested primary analyses be factorial analyses comparing arms with and without the two interventions of interest.

There are five topics covered in this memo:

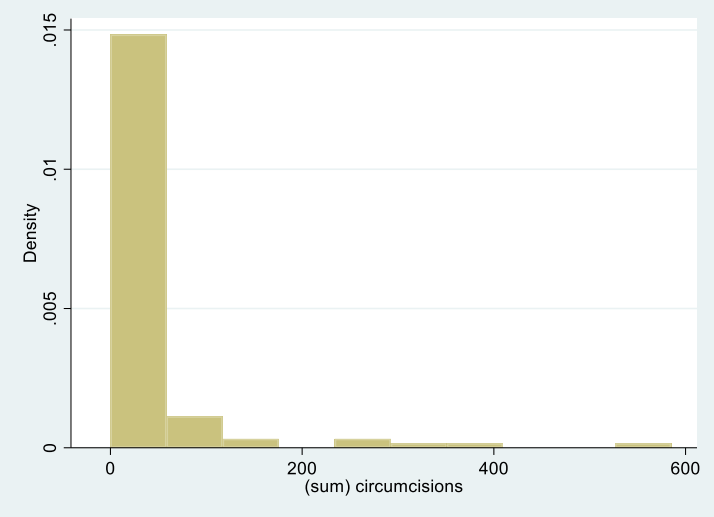
1. Overview of data and description of over dispersion
2. Problems with random effect model and suggestions for modelling strategy moving forward
3. Problems with age-adjustment in initial SAP and suggestions for modelling strategy moving forward
4. As treated v. ITT analysis as primary analysis for discussion

**1. Overview of data and description of over dispersion**

The primary outcome variable, whether defined at the IPC-level or the IPC-month level, was over dispersed, or more highly variable than expected assuming the Poisson distribution. C*ountfit* tests in Stata both suggest that negative binomial regression fits the outcome distribution better than Poisson, zero-inflated Poisson, or zero-inflated negative binomial models. Data summaries below show the distribution of circumcisions per IPC over the full follow-up period in tabular and graphical format, then the same information by arm for HCD-informed v. not.

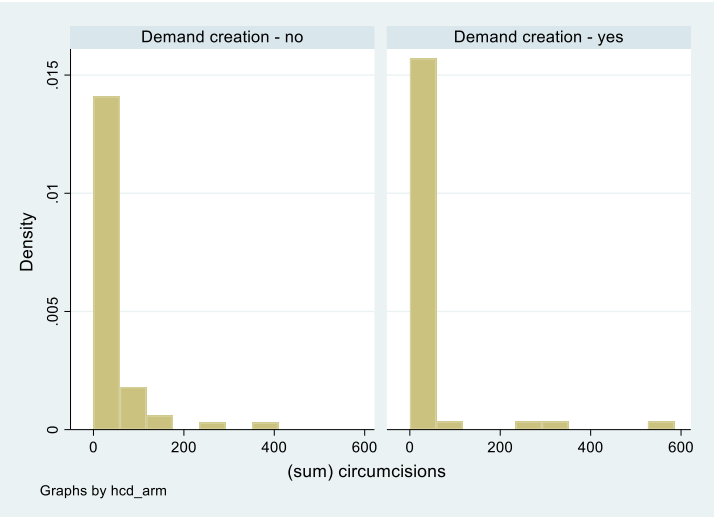
**Summary of total circumcisions/IPC across follow-up, as-treated analysis set (n=106), with histogram**

```
                    (sum) circumcisions
-------------------------------------------------------------
      Percentiles      Smallest
 1%             0             0
 5%             0             0
10%             0             0       Obs                 106
25%             0             0       Sum of Wgt.         106

50%           2.5                     Mean           29.88679
                        Largest       Std. Dev.      84.05637
75%            10           281
90%            79           343       Variance       7065.473
95%           136           358       Skewness       4.343688
99%           358           585       Kurtosis       23.92946
```




### By arm

```
. table hcd_arm, c(mean circumcisions sd circumcisions count circumcisions)

------------------------------------------------------------------------
              hcd_arm | mean(circum~s)    sd(circum~s)     N(circum~s)
----------------------+-------------------------------------------------
 Demand creation - no |       29.42105        64.94997              57
Demand creation - yes |       30.42857        102.6332              49
------------------------------------------------------------------------
```




## 2. Problems with random effects model and suggestions for modelling strategy moving forward

The final SAP called for a random effect of IPC to be used to adjust for IPC-level differences in circumcision rates, and for Stata's *xtnbreg* command to be used. *Xtnbreg* uses a beta distribution to account for both the over dispersion parameter and the higher-level random effect (*dispersion ~ beta(r, s)*). However, upon inspection the *xtnbreg* results have been difficult to interpret, and results of the model do not fit with description summaries of the data. First, the beta distribution parameters are both <1, and so standard measures used to check model fit (i.e., predicted values and deviance residuals) cannot be calculated. Second, the results vary widely if the random effect is parameterized differently (i.e., by using a mixed effect model with a dispersion parameter and a normally distributed random effect of IPC). Together, these suggest that the random-effects model is a poor fit to these data.

The poor fit of models with a random effect capturing IPC-level is likely because the bulk of the variability in the data can be found within IPCs rather than between. For example, ID Buhera-A03 had monthly totals ranging from 1-104, and A04 from 0-50 (see output). This is different from the usual pattern of variability in cluster randomized trials, with increased correlation within clusters.

**Circumcisions by month for three IPCs**

| clusterid | month | circum~s |
|---|---|---|
| Buhera-A01 | 5 | 0 |
| Buhera-A01 | 6 | 3 |
| Buhera-A01 | 9 | 0 |
| Buhera-A01 | 10 | 0 |
| Buhera-A03 | 5 | 96 |
| Buhera-A03 | 6 | 92 |
| Buhera-A03 | 7 | 104 |
| Buhera-A03 | 8 | 61 |
| Buhera-A03 | 9 | 1 |
| Buhera-A03 | 10 | 1 |
| Buhera-A03 | 11 | 3 |
| Buhera-A04 | 5 | 0 |
| Buhera-A04 | 6 | 50 |
| Buhera-A04 | 7 | 25 |

We believe that the most robust solution is to conduct all analyses on aggregated cluster-level data, i.e. at IPC-level, using standard negative binomial regression. This is a standard method often used in the analyses of cluster-randomized trials (see Hayes and Moulton), and will make minimal assumptions about the distribution of circumcisions by month within IPCs. Thus, rate based models will be of the general form:

$$circumcisions_i = \beta_0 + \beta_1 arm_i$$

Where circumcisions are measured over *i* IPCs as the sum over the full follow-up period, and are assumed to have a negative binomial distribution with variance $\mu+\alpha\mu^2$ (NB2). No random effect will be used. The as-treated analysis will also include an offset term with the logged number of months of follow-up included in the model with coefficient constrained to 1.

### 3. Problems with age-adjustment in initial SAP and suggestions for modelling strategy moving forward

Across arms, IPCs were believed to use standard group recruiting for young men, and this group recruiting was likely to result in large numbers of circumcisions per month across all arms. For this reason, the original SAP called for including an age-adjusted result, not to

adjust for baseline imbalance by age, but to add a fixed parameter to capture the variability in the outcome by client age. In the final SAP (dated 14 January 2019), age was adjusted at client level. However, based on discussions with the team it seems increasingly likely that age of client recruited was not a nuisance variable, but was substantially affected by the interventions themselves.

For this reason, we suggest that unadjusted rate ratios be the primary analysis, and to drop age-adjustment and to only present unadjusted rate ratios, as was suggested in earlier versions of the SAP. Differences in the impact of the outcome would be identified by analysing age-specific subgroups, including the pre-specified subgroups of 15-19 years, 20-29 years, 30+ years, and an additional post-hoc analysis of 18-19 years. These subgroup analyses will take the following form:

$$circumcisions\ of\ 15-17\ year\ old\ clients_i = \beta_0 + \beta_1 arm_i$$

They will have similar assumptions to the main model – i.e., the outcome will be the sum of all circumcisions in the follow-up period among this age group, and the outcome has a negative binomial distribution. Post-hoc subgroup analyses assessing impact among in-school v. out of school persons using similar models.

Additional post-hoc analyses could seek to explore differences in effectiveness over the follow-up period, by separately estimating impact earlier and later in the intervention. Specific dates of interest would have to be decided with input from PSI and CeSHHAR.

However, if there is a strong desire to adjust for age, the method for doing so should be at the level of the IPC not the level of the client, with the interpretation being that some IPCs were more likely to target younger clients. (This is the same method used to adjust for client age in the analysis of secondary outcome 2 (IPC conversion proportion, measured at IPC-level) as specified in the final SAP

The approximate model would then be:

*Rate outcome$_i$ = f(allocation$_i$, proportion clients circumcised by IPC who were 18-19 years$_i$, proportion 20-29 years$_i$, proportion 30+$_i$).*

Where *i* IPCs are measured across the follow-up period. The predicted exponentiated parameter on allocation is thus the rate ratio comparing the intervention and comparison among IPCs who circumcised only clients in the 15-17 year age group (i.e., with all other age groups = 0). This is a methodological improvement but still a very cumbersome interpretation, especially as we are aware that one of the effects of the intervention seemed to be to affect the age of clients reached

**4. As treated v. ITT analysis as primary analysis for discussion**

During the TAG meeting, there was some concern about using the as-treated analysis as the primary analysis for reporting. However, we believe that this is appropriate, given the pragmatic nature of this trial and the fact that ITT results will be reported simultaneously. It is particularly important to report ITT results given that IPCs were added to the trial after randomization. While we believe these added “at random” from a practical perspective, the work of these IPCs cannot be included in an ITT analysis because they were not randomized by the research statistician. However, we also believe that the information contributed by these IPCs is important and will be useful for understanding the impact of the interventions.

**SAP text dated 14 January 2019**

## 1. INTRODUCTION

Voluntary medical male circumcision (VMMC) has been recommended by the World Health Organization as a strategy for preventing HIV transmission in high-prevalence countries. VMMC clients are recommended to test for HIV pre-operatively, making VMMC services an opportunity for men to receive HIV testing services (HTS). Studies on VMMC uptake have identified several key barriers inhibiting men from taking up VMMC; these include fear of pain and complications, pre-operative testing, and lack of awareness of HIV risk.

This study evaluates a community-based VMMC demand creation tool designed to address concerns around VMMC and focused VMMC demand creation among high risk populations. This tool was developed by PSI and the Zimbabwe Ministry of Health and Child Care (MOHCC) based on robust market research data provided by IPSOS Healthcare. This research is funded by the Bill and Melinda Gates Foundation through PSI. The study also evaluates the effectiveness of distributing HIV self-testing for use as a pre-operative HIV test on VMMC uptake, and evaluates whether there is a synergistic effect of combining the VMMC demand creation tool with ST distribution on VMMC uptake. HIV self-testing is supported by the UNITAID/PSI STAR (Self-Testing Africa) Initiative.

## 2. TRIAL OVERVIEW

### 2.1. PRINCIPAL RESEARCH OBJECTIVE

The aim of this trial is to assess the effectiveness of two new community-based demand creation models (a demand creation tool and HIVST, respectively), in motivating men to take up VMMC.

### 2.2. TRIAL DESIGN

The study is a four-arm parallel-arm cluster-randomized trial of two interventions to promote VMMC – a community-based demand creation model and HIV self-test distribution. This design allows for estimation of a synergistic (greater than multiplicative) effect of combined behaviour change communication and self-testing on VMMC uptake.

However, we will additionally analyse this trial as a factorial trial, estimating the independent impact of ST intervention and the demand creation intervention on the primary and secondary outcomes. More detail on this is in **section 2.3** (trial arms, randomization, and blinding) and **section 4.3** (data analysis). (Please also see **appendix A**, which summarizes the post-hoc power calculation conducted in September 2018, and recommends a factorial analysis be conducted on these data due to power concerns.)

### 2.3. TRIAL ARMS, RANDOMIZATION, AND BLINDING

***Trial arms.*** Interpersonal communication agents (IPCs) were randomized using restricted randomization to four arms at a ratio of 1:1:1:1. The four arms include:

- **Arm 1:** To undertake standard community based demand creation for VMMC.
- **Arm 2:** To undertake standard community based demand creation for VMMC with the ability to offer HIV self-test kits to potential VMMC clients.

- **Arm 3:** To undertake community based demand creation using the new IPC demand creation approach (informed by human-centred design (HCD) and the market research)
- **Arm 4:** To undertake community-based demand creation using the new IPC demand creation approach with the ability to provide HIV self-test kits to potential VMMC clients.

Analyses will be completed using programme or survey data. Analyses will use principles for analysis of clustered RCTs with a large number of clusters (>20) per arm (1).

For the analysis as parallel arm trial, the following comparisons will be undertaken for the primary outcome and 3 secondary outcomes on VMMC uptake (Specific outcomes are listed in **section 3**):

- Effect of ST kits v. SOC (Arm 2/Arm 1)
- Effect of new IPC demand creation approach v. SOC (Arm 3/Arm 1)
- Effect of new IPC demand creation plus ST v. SOC (Arm 4/Arm1)
- Effect of new IPC demand creation plus ST v. ST kits only (Arm 4/Arm 2)

For the analysis as factorial trial, the following comparisons will be undertaken:

- Effect of ST kits (Arm 2 and arm 4 v. arm 1 and arm 3);
- Effect of IPC demand creation approach (Arm 3 and arm 4 v. arm 1 and arm 2).

Three outcomes related to the uptake of HIVST will be evaluated by comparing arms 4 and 2 only.

***Randomization.*** 143 IPCs were in the original sample, with 3 removed at random to allow for equal numbers of IPCs per arm. There were 140 IPCs assigned 1:1:1:1 to four arms of 35 IPCs each. Randomization was restricted by age and sex of IPC agent, and mobilization experience.

- **Age.** The mean age in the sample was 35.27 years (SD: 11.37). We restricted such that the mean age in each arm is within +/-5 years of the sample mean (i.e. between 30.27 and 40.27 years).
- **Gender.** There are 80 male IPCs (56%) in the sample. We restricted such that the proportion of male IPCs per arm is within +/- 15 percentage points of the total, so arms will have between 40.9-70.9% male IPCs.
- **Experience level.** 28.7% of IPCs had at least 12 months of experience. We restricted such that the proportion with ≥12months experience is between 18.7-38.7% in each arm.

The randomization was completed on 25 January 2018 by MN.

***Blinding.*** Due to the nature of the intervention, neither the IPCs nor the clients can be blinded to allocation. The statistician conducting the primary analysis (GM) will be blinded to allocation. Analyses of uptake of VMMC (primary outcome and secondary outcomes 2-5) will be completed first and using a dataset that does not include any self-testing data. A second dataset blinded to IPC demand creation tool allocation but including all self-testing arms will be prepared for analysis of the self-testing outcomes.

### 2.4. DURATION OF INTERVENTIONS

Both interventions will be implemented for 6 months. The initial timeline for the trial included a trial data collection from 20 February – 31 August 2018, with data collected on uptake of circumcision until 30 September 2018. After review of early process evaluation data which indicated that it was taking longer than expected for IPCs to become comfortable with the new IPC demand creation tool, the study team and TAG decided to add a run-in period from 20 February-30 April 2018, and shift the trial start date to 1 May 2018 and end date to 31 October 2018, with data collected on uptake of circumcision until 30 November 2018.

### 2.5. STUDY POPULATION AND INFORMED CONSENT

This trial was designed as a pragmatic trial of the effectiveness of two VMMC mobilization tools under usual programme conditions in the field. For this reason, there were no age restrictions for clients in this study beyond those usually used in programmatic conditions. However, both the demand creation tool and the HIV self-test are likely to appeal to older adolescents and adults. The demand creation tool was designed for use with men ages 15 years and older, and HIV self-testing distribution is limited to men ages 16 years and older. For this reason, we will conduct the factorial and parallel arm analyses on the population 15 years and older for the primary analysis of VMMC outcomes (primary and secondary outcomes 1-5), and 16 years and older for ST outcomes (secondary outcomes 6-8).

Because the interventions are being evaluated under field conditions and in a routine programmatic context, and because the interventions pose minimal risk to IPC agents or clients, written informed consent has not been obtained from men contacted by IPC agents.

Ethical approval for the study has been obtained from the London School of Hygiene and Tropical Medicine (ID: 14460, approved on 14 February 2018); the Liverpool School of Tropical Medicine (ID: 17-067, approved on 15 December 2017); and the Medical Research Council of Zimbabwe (ID 2231, approved on 29 November 2017).The trial is registered with the Pan-African Clinical Trials Registry as PACTR201804003064160.

## 3. PRIMARY OUTCOME AND SAMPLE SIZE CALCULATION

The primary outcome is the number of men circumcised per IPC-month of follow-up. Analysis will be by intention-to-treat (ITT) and per-protocol. There was substantial attrition among IPCs, including between randomization and initial training, the “as-treated” analysis will

In the ITT analysis, IPCs randomized to each arm assumed to contribute 6 full months of follow-up to the analysis. An “as-treated”-analysis of VMMC outcomes will also be conducted – this will account for the actual number of months of follow-up time contributed by IPCs. For the as-treated analysis, an IPC will be assumed to be active in a given calendar month if s/he has recorded reaching at least one client during that calendar month.

The study sample size was calculated to detect differences across arms in the primary outcome. To account for multiple comparisons across arms, the sample size was calculated to $\alpha=0.05/4$ (2)

This study requires 35 IPCs per arm, 140 IPCs across 4 arms to have 80% power to detect a 30% proportionate difference in VMMC uptake between any two arms even if variability between IPCs is high ($k=0.3$). It would also provide 90% power to detect a proportionate

30% difference in VMMC uptake between arms if variability between IPCs is less (k=0.25) and over 90% power to detect a 40% proportionate difference between arms if variability between IPC agents is higher (k=0.3).

**Sample size and potential power of the trial**

| 1-type I | power | z_a | z_b | | rate_0 | % | rate_1 | # of | cluster | person | k | # clusters |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | increase | | months | size | months | | per arm |
| **0.9875** | **0.8** | 2.497705 | 0.841621 | 11.1511 | **12** | **30%** | 15.6 | **6** | **1** | 6 | **0.25** | 25.79 |
| **0.9875** | **0.8** | 2.497705 | 0.841621 | 11.1511 | **12** | **40%** | 16.8 | **6** | **1** | 6 | **0.25** | 16.22 |
| **0.9875** | **0.8** | 2.497705 | 0.841621 | 11.1511 | **12** | **50%** | 18 | **6** | **1** | 6 | **0.25** | 11.61 |
| | | | | | | | | | | | | |
| **0.9875** | **0.8** | 2.497705 | 0.841621 | 11.1511 | **12** | **30%** | 15.6 | **6** | **1** | 6 | **0.3** | 34.95 |
| **0.9875** | **0.8** | 2.497705 | 0.841621 | 11.1511 | **12** | **40%** | 16.8 | **6** | **1** | 6 | **0.3** | 21.89 |
| **0.9875** | **0.8** | 2.497705 | 0.841621 | 11.1511 | **12** | **50%** | 18 | **6** | **1** | 6 | **0.3** | 15.60 |
| | | | | | | | | | | | | |
| **0.9875** | **0.9** | 2.497705 | 1.281552 | 14.28278 | **12** | **30%** | 15.6 | **6** | **1** | 6 | **0.25** | 32.75 |
| **0.9875** | **0.9** | 2.497705 | 1.281552 | 14.28278 | **12** | **40%** | 16.8 | **6** | **1** | 6 | **0.25** | 20.49 |
| **0.9875** | **0.9** | 2.497705 | 1.281552 | 14.28278 | **12** | **50%** | 18 | **6** | **1** | 6 | **0.25** | 14.59 |
| | | | | | | | | | | | | |
| **0.9875** | **0.9** | 2.497705 | 1.281552 | 14.28278 | **12** | **30%** | 15.6 | **6** | **1** | 6 | **0.3** | 44.49 |
| **0.9875** | **0.9** | 2.497705 | 1.281552 | 14.28278 | **12** | **40%** | 16.8 | **6** | **1** | 6 | **0.3** | 27.76 |
| **0.9875** | **0.9** | 2.497705 | 1.281552 | 14.28278 | **12** | **50%** | 18 | **6** | **1** | 6 | **0.3** | 19.69 |

| |
|---|
| 1-type 1 = 1 - (0.05/4) to account for multiple comparisons |
| Power = 0.8 or 0.9 (varied as requested by PSI/Gates in an earlier round) |
| Rate 0 = average of output per IPC agent per month in SOC (see data from PSI sheet) |
| % increases as requested by PSI |
| # months - 6 month trial |
| cluster size = 1 because rate is per IPC time, and there is 1 IPC/cluster |
| k = 0.25 or 0.3 (varied as requested by PSI/Gates in an earlier round) |

### 3.1. SECONDARY OUTCOMES

- ***Secondary outcome 1.*** The mean conversion proportion by trial arm (conversion proportion defined as number of men who are circumcised divided by the number of men reached by IPC agent per month).
- ***Secondary outcome 2.*** The number of men spoken to by IPC agents (not included in final analysis plan because data were not collected.)
- ***Secondary outcome 3.*** The number of men reached per IPC-month. A potential VMMC client is considered "reached" once they have been enrolled and have completed an individual-level demand creation session with an IPC agent.
- ***Secondary outcome 4.*** The number of men booked for VMMC per IPC-month.
- ***Secondary outcome 5.*** The number of men who present for VMMC per IPC-month.
- ***Secondary outcome 6***. Proportion of men offered HIV self-test kits who accepted the test. (Self-testing arms only [arm 4/arm 2]).
- ***Secondary outcome 7***. Proportion of men who obtain HIV self-test kits and go on to self-test. (Self-testing arms only [arm 4/arm 2]).
- ***Secondary outcome 8***. Proportion of men with a reactive HIV self-test result who link to post-test services (Self-testing arms only [arm 4/arm 2]).

## 4. OUTCOME EVALUATION AND DATA DESCRIPTION

The primary outcome and secondary outcomes 1-5 will be measured using programme data collected by PSI Zimbabwe. Data on the number of men reached and followed up by IPCs will be collected using electronic data capture and uploaded to the DHIS2 server.

Each IPC agent will conduct community mobilization and collect client data using an allocated tablet. Client data collected will include (at most) the information below depending on the arm:

1. Personal details that will include
    a. Name, surname, date of birth
    b. Other demographic characteristics such as level of education, marital status, employment status and religion
2. Contact numbers
3. Geographical location; Urban, Rural or Peri Urban
4. State whether group or one-on-one session
5. Record whether client opted to take a self-test kit or not. **(Note: Those men who are given self-test kits should be asked to bring the used self-test kit when they take up services at VMMC centres)**
6. Reasons for refusing to take self-test kit
    a. Tested recently/already tested (ask where, what type of test)
    b. Not interested
    c. Scared of known risk behaviour
    d. Prefer testing at health centre or VMMC site
    e. Other specify
7. Client segment/Colour code of the client
8. Agreed date for circumcision
9. Client referral card number/Unique identifier number
10. Date for follow up visit
11. Client follow-up details where applicable (number of times contacted after reach)
    a. 1st follow up visit
    b. 2nd follow up visit
    c. 3rd follow up visit
12. Date of circumcision

District Field Officers (DFO) and District Field Assistants (DFA) will supervise the IPC agents during implementation and will be responsible for checking consistency and completeness of data collected and ensure that it is uploaded to the DHIS2 server. The DFO will accompany the IPC agent in the field once a month to evaluate the IPC agent's effectiveness based on session adequacy of content, articulation of key VMMC benefits, ability to address questions with regards to VMMC, facilitation skills, use of segmentation tool, pain-o-meter and key messages, HIVST offer (for relevant arms) and ability to identify the barriers to MC from the client and to subsequently address them.

Secondary outcomes 6-8 will be measured using a follow-up survey administered by CeSHHAR researchers to clients reached by PSI 4 weeks after the clients were reached. The follow-up survey will be administered by telephone.

Data captured in the survey data include:

- Prior HIV testing
- Whether IPC offered ST kit and whether kit was used
- Confirmatory testing and treatment uptake for respondents with reactive HIVST
- VMMC uptake

**STATISTICAL METHODS**

All analyses will use methods appropriate for CRTs randomized at the community level with a large number of clusters (1). Reporting will conform to the 2010 Consort statement as applicable to cluster randomized trials (3).

### 4.1 RECRUITMENT AND REPRESENTATIVENESS OF SAMPLE

The trial flow chart will follow principles of CONSORT guidelines for CRTs, and will show the process of recruitment of clients (**figure 1**).

### 4.2 COMPARABILITY OF ARMS

We will first summarize client data by arm and IPC to detect imbalances by the following characteristics.

- Client age in years and in 5-year age bands
- Client in or out of school
- Client past HIV testing history for self-testing arms only using survey data

The study team will identify substantial differences between arms in terms of the above factors. This assessment will not be completed using statistical tests, and p-values will not be shown, as any difference will be due to chance if the randomisation was correctly performed. **Table 1** presents a sample analysis of comparability across arms.

### 4.3 ANALYSIS

Sample analysis tables are presented in **table 2a** (VMMC outcomes - parallel arm), **table 2b** (VMMC outcomes - factorial), and **table 3** (self-testing outcomes).

***Primary outcome – parallel arm analysis.*** The primary outcome is comparison of the number of men circumcised per IPC-month of follow-up by trial arm. The numerator is the number of clients circumcised per IPC-month.

Using programme data, the variables *eventdate and agent_code* will be used to identify the months each IPC agent was active for the as-treated analysis. *Client_circum* will be used to count the number of circumcisions, and *service_date* used to measure the date of circumcision. *Study_arm* will be used to allocate IPCs by study arm. Note that, for the last month of the trial, outcome measures will continue to be collected, and these outcomes will be included in the analysis as part of the last month of implementation.

The primary outcome will be modelled as a circumcision rate per IPC month using negative binomial regression, and will use a random effect of IPC to account for clustering of outcomes by IPC.

**Unadjusted**: $\log(Circ_{it}) = \beta_0 + \beta_1 arm2_i + \beta_2 arm3_i + \beta_3 arm4_i + log(person\ time_{it}) + u_i$

**Age-adjusted**: $\log(Circ_{it}) = \beta_0 + \beta_1 arm2_i + \beta_2 arm3_i + \beta_3 arm4_i + \Sigma B\ ageband_i + log(person\ time_{it}) + u_i$

In the above equation, $circ_{it}$ represents a circumcision associated with IPC agent *i* during month *t*. This equation calculates estimates of effect comparing arms 2, 3, and 4 to arm 1. To calculate the estimate of effect of arm 4 compared with arm 2, we will rerun the same equation using arm 2 as the reference category.

As a sensitivity analysis, we will also calculate p-values for the primary outcome comparisons using a permutation test accounting for the restrictions used in randomization (1). We will adjust p-values for multiple comparisons in the main (non-exploratory) analysis using this Benjamini-Hochberg procedure for controlling the false discovery rate (4).

***Primary outcome – factorial analysis.*** The definition of the primary outcome is the same in the factorial analysis.

The primary outcome will be modelled as a circumcision rate per IPC month using negative binomial regression, and will use a random effect of IPC to account for clustering of outcomes by IPC:

Comparison of self-testing arms (arms 2/4 v. arms 1/3)

**Unadjusted:** $\log(Circ_{it}) = \beta_0 + \beta_1 STarm_i + log(person\ time_{it}) + u_i$

**Age-adjusted:** $\log(Circ_{it}) = \beta_0 + \beta_1 STarm_i + \Sigma B\ ageband_i + log(person\ time_{it}) + u_i$

Comparison of IPC demand creation arms (arms 3/4 v. arms 1/2)

**Unadjusted:** $\log(Circ_{it}) = \beta_0 + \beta_1 DCarm_i + log(person\ time_{it}) + u_i$

**Age-adjusted:** $\log(Circ_{it}) = \beta_0 + \beta_1 DCarm_i + \Sigma B\ ageband_i + log(person\ time_{it}) + u_i$

***Secondary outcome 1 – parallel arms analysis.*** The mean conversion proportion by trial arm (conversion proportion defined as number of men who are circumcised divided by the number of men reached by IPC agent per month). Men are reached if they have completed the IPC session.

The numerator is the total number of circumcisions associated with an IPC over the total follow-up period.

The denominator is the total number of clients reached by an IPC over the total follow-up period.

*Cilent_circum* will be used to measure the numerator for this outcome, and the count of client records entered for each IPC will be used to generate the number of clients reached by each IPC.

This will be analysed at the IPC level using logistic regression analysis:

The parallel arm analysis will be completed as follows:

**Unadjusted:** $log\ odds\left(\frac{Circ_i}{Reached_i}\right) = \beta_0 + \beta_1 arm2_i + \beta_2 arm3_i + \beta_3 arm4_i$

**Age-adjusted:** $log\ odds\left(\frac{Circ_i}{Reached_i}\right) = \beta_0 + \beta_1 arm2_i + \beta_2 arm3_i + \beta_3 arm4_i + \Sigma B\ ageband_i$

This equation calculates estimates of effect comparing arms 2, 3, and 4 to arm 1. To calculate the estimate of effect of arm 4 compared with arm 2, we will rerun the same equation using arm 2 as the reference category. Odds ratios will be converted to risk (proportion) ratios and 95% confidence intervals using the *margins* post-estimation command in Stata 15.1.

***Secondary outcome 1 – factorial analysis.*** The definition of secondary outcomes will be the same in the factorial analysis. This outcome will be analysed at the IPC level using logistic regression analysis.

Comparison of self-testing arms (arms 2/4 v. arms 1/3)

**Unadjusted:** $log\ odds\left(\frac{Circ_i}{Reached_i}\right) = \beta_0 + \beta_1 STarm_i$

**Age-adjusted:** $log\ odds\left(\frac{Circ_i}{Reached_i}\right) = \beta_0 + \beta_1 STarm_i + \Sigma B\ ageband_i$

Comparison of IPC demand creation arms (arms 3/4 v. arms 1/2)

**Unadjusted:** $log\ odds\left(\frac{Circ_i}{Reached_i}\right) = \beta_0 + \beta_1 DCarm_i$

**Unadjusted:** $log\ odds\left(\frac{Circ_i}{Reached_i}\right) = \beta_0 + \beta_1 DCarm_i + \Sigma B\ ageband_i$

***Secondary outcome 2*** will not be analysed as these data have not been collected. (See **section 4** for details).

***Secondary outcome 3 – parallel arm and factorial analysis.*** The number of men reached per IPC-month. The count of client records entered for each IPC will be used to generate the number of clients reached by each IPC, and the *event_date* (or earliest *event_date* for each client if more than one event associated with this client) will be used to determine the date of the event.

The method of analysis will be similar to the primary outcome.

***Secondary outcome 4 – parallel arm and factorial analysis.*** The number of men booked for VMMC per IPC-month. The variable *client_booked* will be used to indicate whether or not a client was booked for VMMC. Clients are considered booked if they have agreed to VMMC and set an appointment for the procedure.

The method of analysis will be similar to the primary outcome.

***Secondary outcome 5 – parallel arm and factorial analysis.*** The number of men who present for VMMC per IPC-month. The variable *has_client_turned_up* will be used to indicate whether or not a client was present for VMMC.

The method of analysis will be similar to the primary outcome.

**Additional outcomes for self-testing arm comparisons only (arm 4/arm 2)**

These analyses use responses from the HIVST follow-up questionnaire administered by CeSHHAR.

***Secondary outcome 6***. Proportion of men offered HIV self-test kits who accepted the test.

- Numerator: ST taken (2a = yes)
- Denominator: ST offered (2 = yes)

This will be analysed using logistic regression of data at the client level. A random effect of IPC will be used to adjust for study design. Clients will be identified using PSI data, and the IPC and arm associated with each client will be allocated based on PSI data.

***Secondary outcome 7***. Proportion of men who obtain HIV self-test kits and go on to self-test.

- Numerator: (2b = yes)
- Denominator: ST taken (2a = yes), among respondents offered a test.

***Secondary outcome 8***. Proportion of men with a reactive HIV self-test result who link to post-test services

- Numerator: Respondents confirming reactive result (4 = yes)
- Denominator: Respondents with reactive result on HIVST (3 = positive/reactive, among respondents testing with ST [2b = yes]. Exclude respondents who had a previous HIV diagnosis [4d = no].)

### 4.4 ADJUSTED ANALYSES

Both unadjusted and age-adjusted analyses will be conducted for all outcomes. Age-adjusted analyses will include parameters for age, grouped into 5 levels: under 15 years, 15-17 years, 18-19 years, 20-29 years, and 30 years and older. Before conducting the final analyses, the statistician will confirm that there are sufficient numbers in the each age band to complete the analysis, and will adjust the number of age bands if needed.

The primary analysis for presentation will be the age-adjusted as-treated analysis using the factorial design.

### 4.5 PRESPECIFIED SUBGROUP ANALYSES

**Subgroup analysis by age:** In addition to the analyses described above, we will also conduct subgroup analyses estimating the impact of the ST distribution and the impact of the demand creation interventions on the primary outcome (VMMC conversions/IPC-month), secondary outcome 1 (conversion proportion), and secondary outcome 3 (number of men reached/IPC-month) among men 15-19 years, 20-29 years and 30 years and older. These will be conducted using the factorial analysis only, and will include both ITT and as-treated analyses. We will test for effect modification between age and each of the two interventions by fitting a model including parameters estimating the interaction effect of age and each intervention and testing the significance of these using likelihood ratio tests. **Table 4** presents subgroup analyses by age.

### 4.6 EXPLORATORY ANALYSIS

In addition to the main analysis conducted on the population 15 years and older, we will conduct exploratory analyses of VMMC outcomes (primary and secondary outcomes 1-5; see section 3.1) for all clients (regardless of age) entered into the VMMC client database will be compared by arm. This analysis will estimate the effectiveness of the two VMMC mobilization tools in increasing VMMC uptake among all men

### 4.7 METHODS FOR ADDRESSING MISSING DATA

Missing data will be examined for each variable and for each individual participant. A systematic assessment of missingness will be conducted to ascertain the reason and possible mechanism for missing data by identifying the quantity of missing data and patterns

within the data. Missingness will be particularly examined by IPC and between randomised arms to assess for systematic biases.

In cases where a client's circumcision date is missing, we will conduct a sensitivity analysis substituting the most recent event date for the client in the dataset for the date of circumcision.

### 4.8 PROCESS EVALUATION

A mixed methods process evaluation was conducted within the trial to provide an understanding of if, why and how the interventions were impacting VMMC uptake. We analysed programme data and conducted two rounds of monitoring visits at different time points, during which we observed 100 IPC agents (n=25 per arm) conducting VMMC mobilisation sessions. We held 24 in-depth interviews (IDIs) and four focus group discussions (FGDs) with purposively selected IPC agents (n=36) and IDIs with PSI's District Field Officers (n=5; 1 from each trial district). We conducted eight FGDs with men mobilised for VMMC (n= 40 who took up VMMC; n=40 who did not). Iterative qualitative data collection and analysis informed a grounded thematic analytical approach.

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**Figure 1. CONSORT flow diagram for full population analysis.**
(Additional row added to bottom of diagram will present numbers included in 15 years and older analysis by arm and numbers excluded).

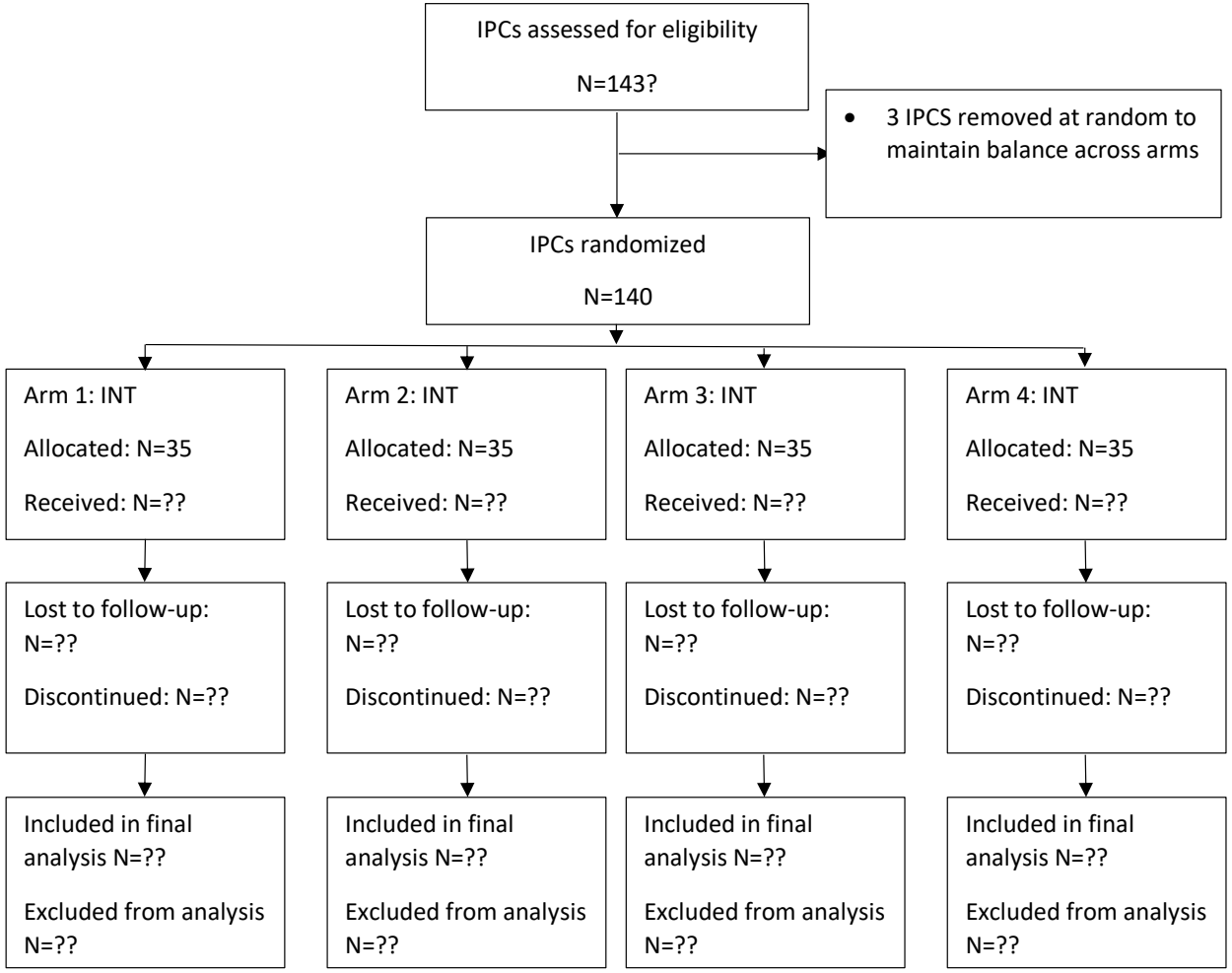


**Table 1. Characteristics of clients by arm – parallel arm and factorial analysis**
(Note: complete for both full population and 15 years and older analyses separately)

| | **Standard of care** | | **Demand creation only** | | **Self-test only** | | **Demand creation and self-test** | | **Total** | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Freq. | Pct. | Freq. | Pct. | Freq. | Pct. | Freq. | Pct. | Freq. | Pct. |
| IPCs (no.) | # | | # | | # | | # | | # | |
| Total IPC-months | # | | # | | # | | # | | # | |
| Male IPCs (% IPCs) | # | % | # | % | # | % | # | % | # | % |
| **Reached client characteristics** | | | | | | | | | | |
| Total | # | 100 | # | 100 | # | 100 | # | 100 | # | 100 |
| Age in years (% total) | | | | | | | | | | |
| <15 | # | % | # | % | # | % | # | % | # | % |
| 15-19 | # | % | # | % | # | % | # | % | # | % |
| 20-24 | # | % | # | % | # | % | # | % | # | % |
| 25-29 | # | % | # | % | # | % | # | % | # | % |
| 30-34 | # | % | # | % | # | % | # | % | # | % |
| 35-39 | # | % | # | % | # | % | # | % | # | % |
| 40-44 | # | % | # | % | # | % | # | % | # | % |
| 45-49 | # | % | # | % | # | % | # | % | # | % |
| 50+ | # | % | # | % | # | % | # | % | # | % |
| Education completed? | | | | | | | | | | |
| School-going | # | % | # | % | # | % | # | % | # | % |
| Out of school | # | % | # | % | # | % | # | % | # | % |
| Type of location of recruitment | # | % | # | % | # | % | # | % | # | % |
| Rural | # | % | # | % | # | % | # | % | # | % |
| Peri-urban | # | % | # | % | # | % | # | % | # | % |
| Urban | # | % | # | % | # | % | # | % | # | % |

**Table 2a. Effect of demand creation and HIV self-testing interventions on primary and secondary outcomes – parallel arm analysis**
(Note: complete for both full population and 15 years and older analyses separately)

| | **SOC** | | **Demand creation only** | | **ST only** | | **Demand creation and ST** | | **Effect of demand creation (v. SOC)** | | **Effect of ST (v. SOC)** | | **Effect of demand creation + ST v. SOC** | | **Effect of demand creation + ST v. ST only** | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | n/N | Rate or % | n/N | Rate or % | n/N | Rate or % | n/N | Rate or % | Rate/risk ratio (95% CI) | p-value | Rate/risk ratio (95% CI) | p-value | Rate/risk ratio (95% CI) | p-value | Rate/risk ratio (95% CI) | p-value |
| **Primary outcome**: VMMC uptake per IPC-month | **##/##** | **#.##** | **##/##** | **#.##** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** | **#.## (#.##,#.##)** | **#.###** | **#.## (#.##,#.##)** | **#.###** | **#.## (#.##,#.##)** | **#.###** |
| **Primary outcome as-treated**: VMMC uptake per active IPC-month | **##/##** | **#.##** | **##/##** | **#.##** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** | **#.## (#.##,#.##)** | **#.###** | **#.## (#.##,#.##)** | **#.###** | **#.## (#.##,#.##)** | **#.###** |
| **Secondary outcomes** | | | | | | | | | | | | | | | | |
| Conversion | **##/##** | **##.#%** | **##/##** | **##.#%** | **##/##** | **##.#%** | **##/##** | **##.#%** | **#.##** | **#.###** | **#.##** | **#.###** | **#.##** | **#.###** | **#.##** | **#.###** |

| | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| proportion | | | | | | | | | | (#.##,#.##) | | | | (#.##,#.##) | | | | (#.##,#.##) | | | |
| Men reached per IPC-month | ##/## | #.## | | ##/## | #.## | | ##/## | #.## | | ##/## | #.## | #.## (#.##,#.##) | #.### | #.## (#.##,#.##) | #.### | #.## (#.##,#.##) | #.### | #.## (#.##,#.##) | #.### |
| Men booked per IPC-month | ##/## | #.## | | ##/## | #.## | | ##/## | #.## | | ##/## | #.## | #.## (#.##,#.##) | #.### | #.## (#.##,#.##) | #.### | #.## (#.##,#.##) | #.### | #.## (#.##,#.##) | #.### |
| Men presenting for VMMC per IPC-month | ##/## | #.## | | ##/## | #.## | | ##/## | #.## | | ##/## | #.## | #.## (#.##,#.##) | #.### | #.## (#.##,#.##) | #.### | #.## (#.##,#.##) | #.### | #.## (#.##,#.##) | #.### |

**Table 2b. Effect of demand creation and HIV self-testing interventions on primary and secondary outcomes – factorial analysis**
(Note: complete for both full population and 15 years and older analyses separately)

| | **ST - yes** | | **ST - no** | | **Effect of ST** | | **Demand creation – yes** | | **Demand creation – no** | | **Effect of demand creation** | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | n/N | Rate or % | n/N | Rate or % | Rate/risk ratio (95% CI) | p-value | n/N | Rate or % | n/N | Rate or % | Rate/risk ratio (95% CI) | p-value |
| **Primary outcome**: VMMC uptake per IPC-month | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** |
| **Primary outcome as-treated**: VMMC uptake per active IPC-month | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** |
| **Secondary outcomes** Conversion proportion | **##/##** | **##.#%** | **##/##** | **##.#%** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **##.#%** | **##/##** | **##.#%** | **#.## (#.##,#.##)** | **#.###** |
| Men reached per IPC-month | **##/##** | **#.## #.##** | **##/##** | **#.## #.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.## #.##** | **##/##** | **#.## #.##** | **#.## (#.##,#.##)** | **#.###** |
| Men booked per IPC-month | **##/##** | **#.## #.##** | **##/##** | **#.## #.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.## #.##** | **##/##** | **#.## #.##** | **#.## (#.##,#.##)** | **#.###** |
| Men presenting for VMMC per IPC-month | **##/##** | **#.## #.##** | **##/##** | **#.## #.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.## #.##** | **##/##** | **#.## #.##** | **#.## (#.##,#.##)** | **#.###** |

**Table 3. HIVST secondary outcomes among clients ages 16 years and older**

| | **ST only** | | **Demand creation and ST** | | **Effect of demand creation + ST v. ST only** | |
|---|---|---|---|---|---|---|
| | n/N | % | n/N | % | Risk ratio (95% CI) | p-value |
| Men accepting HIVST | **##/##** | **##.#%** | **##/##** | **##.#%** | **#.## (#.##, #.##)** | **#.###** |
| Men using HIVST | **##/##** | **##.#%** | **##/##** | **##.#%** | **#.## (#.##, #.##)** | **#.###** |
| Men with reactive tests linked to HIV care | **##/##** | **##.#%** | **##/##** | **##.#%** | **#.## (#.##, #.##)** | **#.###** |

**Table 4. Planned subgroup analyses by age**

(Note: include all age [including men under 15 years])

| | **ST - yes** | | **ST - no** | | **Effect of ST** | | **Demand creation – yes** | | **Demand creation – no** | | **Effect of demand creation** | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | n/N | Rate or % | n/N | Rate or % | Rate/risk ratio (95% CI) | p-value | n/N | Rate or % | n/N | Rate or % | Rate/risk ratio (95% CI) | p-value |
| **Primary outcome**: VMMC uptake per IPC-month | | | | | | | | | | | | |
| **Under 15 years** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** |
| **15-17 years** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** |
| **18-19 years** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** |
| **20-29 years** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** |
| **30+ years** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** |
| **Primary outcome as-treated**: VMMC uptake per IPC-month | | | | | | | | | | | | |
| **Under 15 years** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** |
| **15-17 years** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** |

| | ST - yes | | ST - no | | Effect of ST | | Demand creation – yes | | Demand creation – no | | Effect of demand creation | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | n/N | Rate or % | n/N | Rate or % | Rate/risk ratio (95% CI) | p-value | n/N | Rate or % | n/N | Rate or % | Rate/risk ratio (95% CI) | p-value |
| **18-19 years** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** |
| **20-29 years** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** |
| **30+ years** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** |
| **Secondary outcome:** Conversion proportion | | | | | | | | | | | | |
| **Under 15 years** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** |
| **15-17 years** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** |
| **18-19 years** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** |
| **20-29 years** | **##/##** | **##.#%** | **##/##** | **##.#%** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **##.#%** | **##/##** | **##.#%** | **#.## (#.##,#.##)** | **#.###** |
| **30+ years** | **##/##** | **##.#%** | **##/##** | **##.#%** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **##.#%** | **##/##** | **##.#%** | **#.## (#.##,#.##)** | **#.###** |

| | **ST - yes** | | **ST - no** | | **Effect of ST** | | **Demand creation – yes** | | **Demand creation – no** | | **Effect of demand creation** | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | n/N | Rate or % | n/N | Rate or % | Rate/risk ratio (95% CI) | p-value | n/N | Rate or % | n/N | Rate or % | Rate/risk ratio (95% CI) | p-value |
| **Secondary outcome:** Men reached per IPC-month | | | | | | | | | | | | |
| **Under 15 years** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** |
| **15-17 years** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** |
| **18-19 years** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** |
| **20-29 years** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** |
| **30+ years** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** | **##/##** | **#.##** | **##/##** | **#.##** | **#.## (#.##,#.##)** | **#.###** |

**Appendix A: Summary of sub analysis for VMMC trial, 1 October 2018**

**(Prepared by HW and MN)**

**Design:**

4 armed trial comparing SoC, SoC plus HIVST, SoC plus HCD, SoC plus HCD and HIVST

Original sample size calculations assumed SoC arm would circumcise **12 men/month/IPC agent with 6 month follow up**

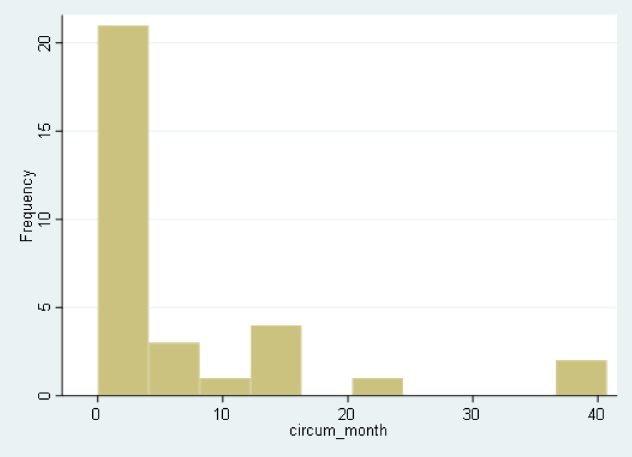
80% power to observe an increase of 30% per arm with 35 IPCs per arm with k=0.3

**Number of IPC agents randomized 140.** Number of IPC agents active 121

**Rationale:** Process evaluation suggested variability between how quickly IPC agents in different arms became proficient in delivering intervention assigned to that arm. SoC arm were proficient straight away but other arms appeared to take 2-3 months to become proficient. Suggestion was to increase run in (training) period, but to maintain 6 month follow up period so that IPC agents in all arms were assessed at similar levels of proficiency.

Sub-analysis conducted to explore power of trial if we shifted follow up from Feb to Sep to May to Dec.

**Results:** Examining data in SoC arm reveals a highly skewed distribution and hence a large degree of variability between IPC agents – overall monthly circumcision rate is 10.5 but varies between 0-239 (Figure) – such that k= 1.2 (instead of 0.3)




This maybe in part be explained because VMMC are being attributed to IPC agents in some settings differently than others – e.g. attribution during campaigns may be done differently or IPC agents in some settings operate very different. So we need to examine the reason for the variability.

If we take out extreme outliers, k falls to 0.88. (and the average rate falls to 5.4 VMMC/month/IPC agent)

Importantly there is no indication that k in the SoC arm is greater during the run-in period (Feb to May). While this may not be case for the other arms, the k included in analysis will be an average of k from SoC and other arms and so any reduction in k in the intervention arms will be influenced by the large k in SoC.

With this unanticipated variability in k, the power of the trial is diminished (and this cannot be overcome by extending length of trial – size of k swamps any benefit from increasing duration).

With 10.5 VMMC/month/IPC agent we have 80% power to detect a 160% increase (i.e. to 27.3 VMMC/month/IPC agent) by arm at 6 months (assuming k=1 i.e. slightly smaller than in the SoC due to smaller k in the intervention arms) – can show interactively in the spreadsheet at the meeting.

In practice we can legitimately analyse as a factorial design by combining intervention arms (will not have power to detect interaction between arm) giving us 65 IPC agents per arm.

**Summary: With 65 IPC agents per arm we have 80% power to detect between 90% increase in VMMC per intervention (e.g. 10.5 to 20).** (See table 5).

Table 5. Revised power calculations, 1 October 2018.

| 1-type I | power | z_a | z_b | | rate_0 | % increase | rate_1 | # of months | cluster size | person months | k | # clusters per arm |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **0.9875** | **0.8** | 2.497705 | 0.841621 | 11.1511 | **10.5** | **30%** | 13.65 | **6** | **1** | 6 | **1** | 338.82 |
| **0.9875** | **0.8** | 2.497705 | 0.841621 | 11.1511 | **10.5** | **40%** | 14.7 | **6** | **1** | 6 | **1** | 209.95 |
| **0.9875** | **0.8** | 2.497705 | 0.841621 | 11.1511 | **10.5** | **50%** | 15.75 | **6** | **1** | 6 | **1** | 147.73 |
| | | | | | | | | | | | | |
| **0.9875** | **0.8** | 2.497705 | 0.841621 | 11.1511 | **12** | **30%** | 15.6 | **6** | **1** | 6 | **0.3** | 34.95 |
| **0.9875** | **0.8** | 2.497705 | 0.841621 | 11.1511 | **12** | **40%** | 16.8 | **6** | **1** | 6 | **1** | 209.62 |
| **0.9875** | **0.8** | 2.497705 | 0.841621 | 11.1511 | **12** | **50%** | 18 | **6** | **1** | 6 | **1** | 147.51 |
| | | | | | | | | | | | | |
| **0.9875** | **0.8** | 2.497705 | 0.841621 | 11.1511 | **10.5** | **160%** | 27.3 | **6** | **1** | 6 | **1** | 35.05 |
| **0.9875** | **0.8** | 2.497705 | 0.841621 | 11.1511 | **10.5** | **90%** | 19.95 | **6** | **1** | 6 | **1** | 65.10 |
| **0.9875** | **0.9** | 2.497705 | 1.281552 | 14.28278 | **10.5** | **50%** | 15.75 | **6** | **1** | 6 | **1** | 188.94 |
| | | | | | | | | | | | | |
| **0.9875** | **0.9** | 2.497705 | 1.281552 | 14.28278 | **12** | **30%** | 15.6 | **6** | **1** | 6 | **1** | 432.97 |
| **0.9875** | **0.9** | 2.497705 | 1.281552 | 14.28278 | **12** | **40%** | 16.8 | **6** | **1** | 6 | **1** | 268.21 |
| **0.9875** | **0.9** | 2.497705 | 1.281552 | 14.28278 | **12** | **50%** | 18 | **6** | **1** | 6 | **1** | 188.66 |
| | | | | | | | | | | | | |

**5. Six segments of men and their characteristics**

| Segment Name* | Segment Color* | Characteristics |
|---|---|---|
| VMMC Enthusiasts | Orange | Large potential (21% of uncircumcised men) and high commitment already; need to overcome some dissonance issues |
| VMMC Champions | Purple | Low potential (6% of uncircumcised men), but easy conversion to action and highly likely to act as advocates for other men after VMMC |
| VMMC Neophytes | Yellow | Large potential (19% of uncircumcised men), but lack of knowledge is key to informing their commitment – addressing knowledge gap is relatively easy |
| Embarrassed Rejecters | Gray | Moderate potential (16% of uncircumcised men) but commitment is rather low and knowledge, embarrassment and fears are high – need a lot of support |
| Scared Rejecters | Brown | Moderate potential (17% of uncircumcised men) but commitment is very low and fears / dissonance are strong barriers |
| Highly Resistant | Maroon | Large potential (21% of uncircumcised men), but hard to crack; knowledgeable and little fear about VMMC; but do not recognize the need; commitment very low |

** These were names assigned by the market researchers for each of the segments identified through the quantitative approach. They were later reassigned as colours for use in the field.*

Based on the market research, VMMC program implementers decided to prioritize particular segments to target with an initial set of interventions. PSI prioritized three segments of men to target with demand creation interventions developed using human-centred design (HCD) methods. The three segments representing 56% of uncircumcised males 15-29 years are: VMMC *Enthusiasts (*orange), *Neophytes* (yellow), and *Embarrassed Rejecters* (grey). This decision was based on the following factors:

5. Size of the segment (21%, 19% & 16% of uncircumcised men, respectively for each of the segments)
6. High level of commitment to get circumcised in the future
7. High risk sexual behaviour and risk perception
8. Potential for advocating for VMMC among other men post circumcision

## 6. Human centred design (HCD)-informed approach tools

### 6.1 Segmentation typing tool

The segmentation tool helps IPC agents identify the segment within which each potential VMMC client falls in order to improve targeting and to ensure appropriate and specific segment messages are delivered. IPC agents ask the client a series of questions to which he responds by choosing his response from seven Likert scale options. The tool is designed in such a way that a sequence of responses will determine a client's segment (See Figure 1). In order for a client to be appropriately segmented, both the IPC agent and the client need to have a clear understanding of the questions and their response options. Otherwise, a client will be wrongly segmented.

**Figure 1: Copy of paper-based segmentation tool**


To facilitate user-friendliness, each of the segmentation tool's six segments is represented by a unique colour (Table 6).

**Table 6: VMMC segments and their corresponding colours**

| Segment | Color | |
|---|---|---|
| VMMC enthusiasts | Orange | |
| VMMC champions | Purple | |
| VMMC neophytes | Yellow | |
| Scared rejecters | Brown | |
| Embarrassed rejecters | Gray | |
| Highly resistant | Maroon | |

Initially, the segmentation tool was paper-based but it is now in an electronic form and has been uploaded onto a tablet.

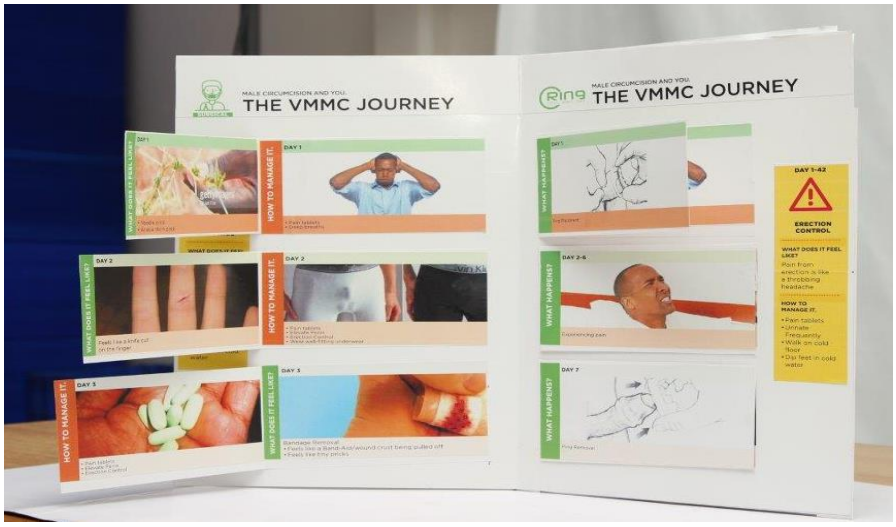
### 6.2 Targeted messaging to an individual

IPC agents have been trained to deliver tailored messages to men based on which segment they fall into and that segment's perceived information needs (as highlighted by the IPSOS research). If a client prefers a specific message instead of all messages in a catalogue of messages relevant to their segment, the IPC agent proceeds to provide the message and refer the client without having to deliver all messages. The segment for each client is recorded by the IPC agent. The client also gives the IPC agent his contact details during that session to allow the IPC agent to follow him up and encourage linkage to VMMC services.

### 6.3 Pain-o-meter

IPC agents have been trained to use a pain-o-meter - a job aid that was developed using Human-centred design (HCD) in response to IPSOS research findings indicating that men want honest communication on pain and procedure. The tool outlines the healing process (days 1 to 3 for surgical, days 1 to 7 for PrePex procedure) together with an analogy of the pain as well as the pain management techniques available in the VMMC program (based on experiences of circumcised men e.g. surgical VMMC pain on days 1 and 2 is likened to a thorn prick and knife cut on finger, respectively) (Figure 2). The tool is designed to help IPC agents communicate honestly about pain during IPC to prepare men to anticipate the MC pain better, thereby improving clients' overall VMMC experience.

**Figure 2: Copy of pain-o-meter illustrating pain of surgical and PrePex VMMC**



## 7. Changes to the trial protocol after trial commencement

***Change of timeline to allow for additional run-in period***. The initial timeline for the trial was 20 February-31 August 2018, with data collected on uptake of circumcision until 30 September 2018. After review of early process evaluation data, which indicated that it was taking longer than expected for IPC agents to become comfortable with the HCD-informed approach, a run-in period from 20 February-30 April 2018 was added, and the trial dates shifted to 1 May-31 October 2018. Data were collected on uptake of circumcision until 30 November 2018.

***Change in primary analysis from parallel-arm to factorial***. The trial was originally conceived as a parallel-arm design to identify synergistic effects between the two interventions under consideration. However, an analysis of blinded data in September 2018 indicated that the clustering of outcomes as measured by the cluster coefficient of variation was much greater than the assumptions used in the power calculation, leading to reduced power to detect differences between four parallel arms. Consequently, the primary analysis was changed from a parallel-arm to a 2x2 factorial analysis comparing arms with and without each of the two interventions. The parallel-arm analysis was conducted as a secondary analysis (see appendix A).

***Outcome measures used.*** The protocol specified that the primary outcome - completed circumcisions - and secondary outcomes, be measured as the number of events per month of IPC agent activity and analysed as Poisson-distributed clustered data with months of work nested within IPC agents. This assumed that IPC agents would have varying activity throughout the evaluation period, but that their outcomes would be similar and correlated across months. However, the preliminary review of data in September 2018 found that there was extremely high variability both between and within IPC agents making it difficult to estimate and interpret mixed effect models as planned. We therefore changed the analysis strategy to combine outcomes across IPC agents into a cluster-level analysis, a robust approach to departures from distributional assumptions.(5) We also used a negative binomial model to account for greater than expected variability. Separately, the number of men spoken to by IPC agents was included in the protocol, but programme data were not collected on this outcome and it was not included in the final analysis.

## 8. Intervention components

### 8.1 Arm 1: Standard demand creation mobilisation

IPC agents randomised to the standard demand creation arm received basic training on how to promote VMMC, including identifying barriers, clarifying myths and misconceptions, and summarising key benefits. Thereafter, they mobilised men and boys for VMMC either as individuals or in groups. Those men expressing willingness to undergo VMMC had appointments booked. Subsequently, these VMMC referees either went to VMMC sites on their own or were taken there in a PSI vehicle.

### 8.2 Arm 2: Standard demand creation plus offer of HIVST

In addition to standard demand creation, IPC agents in Arm 2 offered men they mobilised access to an oral-fluid-based HIVST kit. These IPC agents were trained to demonstrate use of the kit and demonstrated HIVST kit use if required. IPC agents recorded whether or not VMMC referees opted to take a kit.

### 8.3 Arm 3: HCD-informed demand creation approach

IPC agents randomised to this arm received basic training and were also trained to use the segmentation typing tool to identify the segment within which each potential VMMC client fell. They would then deliver messages tailored to that 'segment' addressing the specific information needs identified by the market research. If a client appeared to be interested in one specific message rather than hearing about all messages relevant to their segment, the IPC agent concentrated on that message. For each potential client mobilised, the segment was recorded. For this arm, IPC agents were specifically required to address any pain-related concerns using a visual aid (pain-o-meter) to outline the VMMC procedure, healing process (together with an analogy of the degree of pain that might be experienced at each stage of the VMMC process up to wound healing), as well as possible pain management techniques.

If a client was willing to be circumcised at the start of the discussion, IPC agents did not segment or deliver targeted messages. They allocated these men to a default 'segment' (green), which was not one of those included in the market research but which was added subsequently when IPC agents reported there were men who did not require more intensive demand creation approaches. Clients mobilised in groups at schools were also allocated to the 'green' segment.

### 8.4 Arm 4: HCD-informed demand creation approach plus offer of HIVST

In this arm, in addition to the HCD-informed demand creation approach, IPC agents offered the men they mobilised a HIVST kit and if they accepted it, they demonstrated how to use the kit.

## 9. Tables of results: parallel arm and factorial analyses

### Table S1: Factorial analysis

| | | Circumcisions/IPC | | | | | Circumcisions/IPC | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | HCD-informed | Not HCD-informed | IRR | (95% CI) | p-value | ST | No ST | IRR | (95% CI) | p-value |
| **Primary trial outcome: VMMC uptake per IPC** | | | | | | | | | | | |
| | Mean | 27 | 28.46 | 0.87 | (0.38.2.02) | 0.75 | 19.84 | 34.73 | 0.65 | (0.28.1.50) | 0.313 |
| | Std deviation | 92.5 | 63.3 | | | | 44.91 | 98.03 | | | |
| | | | | | | | | | | | |
| **Secondary trial outcomes** | | | | | | | | | | | |
| Conversion rate (circumcisions per men reached, not adj | | | | RR | | | | | RR | | |
| | Mean | 0.18 | 0.23 | 0.75 | (0.41.1.38) | 0.36 | 0.22 | 0.2 | 1.11 | (0.61.2.02) | 0.71 |
| | Std deviation | 0.32 | 0.32 | | | | 0.34 | 0.3 | | | |
| | | | | | | | | | | | |
| Men reached per IPC-month | | | | IRR | | | | | IRR | | |
| | Mean | 78.53 | 86.77 | 0.89 | (0.62.1.26) | 0.498 | 67.27 | 96.62 | 0.75 | (0.53.1.07) | 0.115 |
| | Std deviation | 106.45 | 93.97 | | | | 65.33 | 120.91 | | | |
| | | | | | | | | | | | |
| Men booked per IPC-month | | | | | | | | | | | |
| | Mean | 43.29 | 43.48 | 1.00 | (0.62.1.60) | 0.987 | 34.57 | 51.11 | 0.8 | (0.50.1.29) | 0.362 |
| | Std deviation | 91.97 | 70.97 | | | | 47.31 | 101.66 | | | |
| | | | | | | | | | | | |
| Men presenting for VMMC per IPC-month | | | | | | | | | | | |
| | Mean | 36.51 | 35.09 | 1.00 | (0.48.2.06) | 0.985 | 28.73 | 41.89 | 0.84 | (0.40.1.73) | 0.632 |
| | Std deviation | 101.37 | 65.61 | | | | 48.26 | 105.64 | | | |

### Table S2: Parallel arm ITT analysis

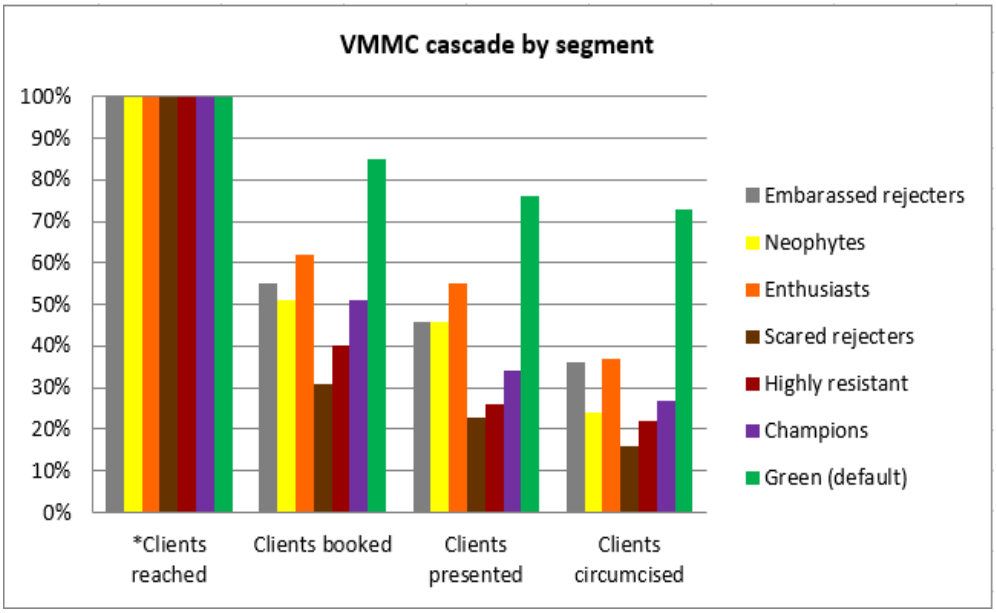
| | | SOC | ST | HCD | HCD+ST | Effect of ST vs SOC | | | Effect of HCD vs SOC | | | Effect of ST+HCD vs SOC | | | Effect of ST+HCD vs ST | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | IRR | (95% CI) | p-value | IRR | (95% CI) | p-value | IRR | (95% CI) | p-value | IRR | (95% CI) | p-value |
| **Primary trial outcome: VMMC uptake per IPC-month** | | | | | | | | | | | | | | | | | |
| | Mean | 27,74 | 13,77 | 26,94 | 10,29 | 0,61 | (0.16,2.40) | 0,484 | 1,20 | (0.31,4.69) | 0,791 | 0,57 | (0.133,2.41) | 0,443 | 0,92 | (0.20,4.20) | 0,917 |
| | Std deviation | 74,11 | 33,3 | 102,44 | 42,14 | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | |
| **Secondary trial outcomes** | | | | | | | | | | | | | | | | | |
| Conversion proportion* | | | | | | RR | | | RR | | | RR | | | RR | | |
| | Mean | 0,22 | 0,21 | 0,19 | 0,14 | 0,96 | (0.44,2.11) | 0,937 | 0,88 | (0.37,2.07) | 0,767 | 0,66 | (0.24,1.79) | 0,413 | 0,62 | (0.17,2.25) | 0,473 |
| | Std deviation | 0,28 | 0,31 | 0,33 | 0,27 | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | |
| Men reached per IPC-month | | | | | | IRR | | | IRR | | | IRR | | | IRR | | |
| | Mean | 81,42 | 38,26 | 54,17 | 38,11 | 0,58 | (0.30,1.13) | 0,11 | 0,82 | (0.42,1.60) | 0,567 | 0,72 | (0.35,1.45) | 0,354 | 1,23 | (0.59,2.58) | 0,582 |
| | Std deviation | 113,1 | 56,73 | 118,15 | 65,41 | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | |
| Men booked per IPC-month | | | | | | | | | | | | | | | | | |
| | Mean | 41,31 | 20,14 | 35,09 | 19,40 | 0,60 | (0.26,1.40) | 0,238 | 1,05 | (0.46,2.43) | 0,906 | 0,72 | (0.29,1.75) | 0,466 | 1,19 | (0.47,3.02) | 0,715 |
| | Std deviation | 83,28 | 39,67 | 103,64 | 45,26 | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | |
| Men presenting for VMMC per IPC-month | | | | | | | | | | | | | | | | | |
| | Mean | 29,83 | 18,51 | 33,60 | 16,17 | 0,77 | (0.23,2.55) | 0,667 | 1,39 | (0.42,4.62) | 0,586 | 0,83 | (0.23,2.96) | 0,773 | 1,08 | (0.28,4.09) | 0,911 |
| | Std deviation | 74,98 | 37,78 | 113,51 | 45,78 | | | | | | | | | | | | |

**Table S3: Parallel arm – as-treated analysis**

| | SOC | ST | HCD | HCD+ST | Effect of ST vs SOC | | | Effect of HCD vs SOC | | | Effect of ST+HCD vs SOC | | | Effect of ST+HCD vs ST | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | IRR | (95% CI) | p-value | IRR | (95% CI) | p-value | IRR | (95% CI) | p-value | IRR | (95% CI) | p-value |
| **Primary trial outcome: VMMC uptake per IPC-month** | | | | | | | | | | | | | | | | |
| Mean | 34.14 | 22.37 | 35.37 | 16.73 | 0.76 | (0.24.2.37) | 0.634 | 0.98 | (0.32.3.07) | 0.979 | 0.51 | (0.15.1.69) | 0.271 | 0.67 | (0.20.2.28) | 0.523 |
| Std deviation | 80.18 | 38.45 | 115.78 | 52.54 | | | | | | | | | | | | |
| **Secondary trial outcomes** | | | | | | | | | | | | | | | | |
| Conversion proportion (circumicisions per man reached) | | | | | Odds ratio | | | Odds ratio | | | Odds ratio | | | Odds ratio | | |
| Mean | 0.2 | 0.27 | 0.19 | 0.16 | 0.64 | (0.20.2.05) | 0.448 | 0.25 | (0.08.0.80) | 0.019 | 0.46 | (0.14.1.53) | 0.205 | 0.72 | (0.22.2.32) | 0.585 |
| Std deviation | 0.27 | 0.36 | 0.34 | 0.31 | | | | | | | | | | | | |
| Men reached per IPC-month | | | | | IRR | | | IRR | | | IRR | | | IRR | | |
| Mean | 107.07 | 64.96 | 85.41 | 70.09 | 0.69 | (0.43.1.12) | 0.135 | 0.82 | (0.51.1.32) | 0.405 | 0.68 | (0.41.1.13) | 0.133 | 0.98 | (0.59.1.64) | 0.933 |
| Std deviation | 113.05 | 62.95 | 130.02 | 69.52 | | | | | | | | | | | | |
| Men booked per IPC-month | | | | | | | | | | | | | | | | |
| Mean | 53.55 | 32.67 | 48.48 | 36.91 | 0.75 | (0.40.1.44) | 0.393 | 0.94 | (0.49.1.78) | 0.843 | 0.81 | (0.41.1.60) | 0.537 | 1.07 | (0.53.2.14) | 0.85 |
| Std deviation | 88.87 | 43.74 | 115.51 | 52.31 | | | | | | | | | | | | |
| Men presenting for VMMC per IPC-month | | | | | | | | | | | | | | | | |
| Mean | 39.9 | 29.93 | 44.04 | 27.27 | 0.91 | (0.34.2.46) | 0.857 | 1.07 | (0.40.2.88) | 0.896 | 0.81 | (0.28.2.31) | 0.689 | 0.88 | (0.30.2.57) | 0.822 |
| Std deviation | 82,00 | 42.57 | 127.89 | 55.45 | | | | | | | | | | | | |

### 10. VMMC cascade results

Men in the prioritised segments (embarrassed rejecters, neophytes, enthusiasts) were more likely to be circumcised that those in the non-prioritised segments. Overall however, men in the green (default) segment were much more likely than any other segment to undergo circumcision (>70%) (Figure S 1).




*Embarrassed rejecters (n=969:25.4%), Neophytes (n=849:22.3%), Enthusiasts (n=600:15.7%), Scared rejecters (n=282:7.4%), Highly resistant (n=410:10.8%, Champions (n=222:5.8%), Green (n=480:12.6%)

**Figure S1: VMMC cascade by segment**

### 11. IPC agents characteristics and uptake of VMMC

In the univariable model, gender, age, education and district were significantly associated with VMMC uptake while in the adjusted model age and district remained significantly associated with VMMC uptake (Table S4).

**Table S4: IPC agents characteristics and uptake of VMMC**

| Factor | N (%) N=105 | IRR (univariable) (95% CI) | p-value | IRR (Adjusted) (95% CI) | p-value |
|---|---|---|---|---|---|
| **IPC gender** | | | 0.002 | | 0.221 |
| Female | 57(54%) | 1 | | 1 | |
| Male | 48(46%) | 3.53(1.58 - 7.86) | | 1.47(0.51 – 4.25) | |
| **IPC age** | | | <0.001 | | 0.050 |
| 18-34 years | 42(40%) | 1 | | 1 | |
| 35+ years | 63(60%) | 0.21(0.09 – 0.46) | | 0.46(0.21 – 1.07) | |
| **IPC education level** | | | 0.044 | | 0.121 |
| Primary level (ref) | 10(10%) | 1 | | 1 | |
| Secondary level + | 95(90%) | 4.28(1.04 – 17.64) | | 0.34(0.06 – 2.04) | |

| | | | | | |
|---|---|---|---|---|---|
| **IPC mobilizing experience** | | | | | |
| <12 months (ref) | 71(68%) | 1 | 0.969 | | |
| At least 12 months | 34(32%) | 0.98(0.40 – 2.40) | | | |
| **IPC district** | | | 0.049 | | 0.001 |
| Buhera (ref) | 18(17%) | 1 | | 1 | |
| Gokwe North | 26(25%) | 0.54(0.18 – 1.59) | | 0.67(0.22 – 2.01) | |
| Mangwe | 11(10%) | 0.05(0.01 – 0.20) | | 0.11(0.02 – 0.63) | |
| Mutasa | 26(25%) | 0.08(0.03 – 0.24) | | 0.17(0.04 – 0.75) | |
| Zvimba | 24(23%) | 0.07(0.02 – 0.22) | | 0.08(0.02 – 0.28) | |

**Additional process evaluation findings**

Uneven performance among IPC agents and districts: there were substantial differences in the performance of IPC agents across all outcomes. In Mangwe for example (where VMMC coverage was already high at the start of the trial), young men often travel to Botswana and South Africa and so were largely unavailable for mobilisation. IPC agents in Buhera and Gokwe North devoted considerable time to VMMC mobilisation, perhaps reflecting the lack of employment opportunities locally. In the other districts, IPC agents were involved in additional income-generating activities. These factors likely explain some of the variability observed between study districts (Table S5).

**Table S5: Conversion proportions by district**

| District | Clients reached | Clients circumcised | Conversion proportion |
|---|---|---|---|
| Buhera | 1717 | 1390 | 81% |
| Gokwe North | 2925 | 1177 | 40% |
| Mangwe | 423 | 44 | 10% |
| Mutasa | 1474 | 169 | 11% |
| Zvimba | 2168 | 137 | 6% |