OPEN

# Increasing voluntary medical male circumcision uptake among adult men in Tanzania

Mwita Wambura[a], Hally Mahler[b], Jonathan M. Grund[c], Natasha Larke[d], Gerry Mshana[a], Evodius Kuringe[a], Marya Plotkin[b], Gissenge Lija[e], Maende Makokha[b], Fern Terris-Prestholt[f], The VMMC-Tanzania Study Group, Richard J. Hayes[d], John Changalucha[a] and Helen A. Weiss[d]

**Objective:** We evaluated a demand-creation intervention to increase voluntary medical male circumcision (VMMC) uptake among men aged 20–34 years in Tanzania, to maximise short-term impact on HIV incidence.

**Methods:** A cluster randomized controlled trial stratified by region was conducted in 20 outreach sites in Njombe and Tabora regions. The sites were randomized 1 : 1 to receive either a demand-creation intervention package in addition to standard VMMC outreach, or standard VMMC outreach alone. The intervention package included enhanced public address messages, peer promotion by recently circumcised men, facility setup to increase privacy, and engagement of female partners in demand creation. The primary outcome was the proportion of VMMC clients aged 20–34 years.

**Findings:** Overall, 6251 and 3968 VMMC clients were enrolled in intervention and control clusters, respectively. The proportion of clients aged 20–34 years was slightly greater in the intervention than control arm [17.7 vs. 13.0%; prevalence ratio = 1.36; 95% confidence intervals (CI):0.9–2.0]. In Njombe region, the proportion of clients aged 20–34 years was similar between arms but a significant two-fold difference was seen in Tabora region (*P* value for effect modification = 0.006). The mean number of men aged 20–34 years (mean difference per cluster = 97; 95% CI:40–154), and of all ages (mean difference per cluster = 227, 95% CI:33–420) were greater in the intervention than control arm.

**Conclusion:** The intervention was associated with a significant increase in the proportion of clients aged 20–34 years in Tabora but not in Njombe. The intervention may be sensitive to regional factors in VMMC programme scale-up, including saturation.



*AIDS* 2017, **31**:1025–1034

**Keywords: adult men, Africa, HIV, voluntary medical male circumcision**

[a]National Institute for Medical Research, Mwanza, [b]Jhpiego, Dar es Salaam, Tanzania, [c]Centers for Disease Control and Prevention, Atlanta, Georgia, USA, [d]MRC Tropical Epidemiology Group, London School of Hygiene and Tropical Medicine, London, UK, [e]National AIDS Control Programme, Ministry of Health, Community Development, Gender, Elderly, and Children, Dar es Salaam, Tanzania, and [f]Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine, London, UK.

Correspondence to Mwita Wambura, PhD, National Institute for Medical Research, PO Box 1462, Mwanza, Tanzania.
E-mail: wmwita51@gmail.com
Received: 17 October 2016; revised: 2 February 2017; accepted: 6 February 2017.

DOI:10.1097/QAD.0000000000001440

## Introduction

From 2005 to 2007, three randomized controlled clinical trials in Sub-Saharan Africa (SSA) demonstrated that male circumcision reduces the risk of female-to-male HIV transmission by about 60% [1–3]. In March 2007, the WHO and the Joint United Nations Programme on HIV/AIDS (UNAIDS) recommended that voluntary medical male circumcision (VMMC) should be considered an important intervention for HIV prevention in settings with high HIV and low circumcision prevalence [4]. Mathematical models have estimated that VMMC scale-up across SSA could prevent up to 6 million new HIV infections and 3 million deaths by 2025 [5]. VMMC has been rolled out in 14 African countries starting in 2009, and WHO estimates that 11.7 million men have been circumcised as of December 2015 [6].

Tanzania has an adult HIV prevalence of 5.1% [7]. HIV prevalence varies by region, from 1.5% (Manyara Region) to 14.8% (Njombe region). Overall prevalence of male circumcision in Tanzania was 71.9% in 2011–2012 [7], but cultural and religious practices contribute to wide variation of circumcision prevalence. Several regions (including Dar es Salaam, Pwani, Lindi and Mtwara) had close to universal prevalence, whereas 12 traditionally noncircumcising regions (including Njombe and Tabora) had lower circumcision prevalence, and constituted the Ministry of Health, Community Development, Gender, Elderly, and Children (MOHCDGEC) priority regions for VMMC [7]. The national VMMC programme was launched by the MOHCDGEC following a situational analysis from 2007–2008 that reported high acceptability for VMMC among men and women in both traditionally circumcising and noncircumcising communities [8,9]. The MOHCDGEC developed a VMMC Country Operational Plan targeting 2.2 million men aged 10–34 years with circumcision between 2014 and 2017 in the priority regions [10]. As of September 2016, 1.8 million VMMCs had been performed in Tanzania [11].

Although the national strategy prioritized 10–34 year olds, modeling suggests that the most immediate reduction to HIV incidence may be achieved by circumcising men aged 20–34 years because of higher HIV incidence in this age group [12–14]. To achieve the maximum number of HIV infections averted (3% of new infections) between 2011 and 2015, VMMC should reach sexually active men [5,14]. However, in Tanzania, the majority of clients are younger men; for example, 76% of VMMC clients in 2014 were under 20 years of age [15,16]. Studies in Kenya, Zambia, and Tanzania have described strategies to increase VMMC demand among men aged 20 years or above [17–19] but these strategies did not explicitly explore the relationship between a comprehensive demand-creation approach and uptake of services by older men. In addition, these studies did not explicitly focus on outreach delivery strategy. Outreach delivery strategy is used when targeting a large volume of VMMC clients [15]. Thus, strategies are needed to increase the number and proportion of male clients aged 20–34 years [15].

We conducted a cluster randomized trial (CRT) to assess whether a targeted demand-creation approach and enhanced service delivery model increased the proportion of VMMC clients aged 20–34 years compared with a standard VMMC delivery model, in two regions of Tanzania.

## Methods

### Study design

The design was a CRT conducted in 20 clusters in traditionally noncircumcising and rural areas in Njombe and Tabora regions, Tanzania (Fig. 1). This design was chosen because the intervention involved cluster-level demand-creation messages and facility-level provision of VMMC. At the time of selection (December 2013), the coverage of VMMC was 41% in Njombe and 50% in Tabora [10]. The trial was conducted at outreach sites where VMMC services had either never been previously provided or had not offered VMMC through outreach in the previous 6 months before study enrolment. These sites were designated as 'outreach' sites, where VMMC services were provided for a limited period in an outreach campaign format, often in areas that are rural and hard to reach. The outreach sites were government health facilities (hospitals, health centres, or dispensaries), where MOHCDGEC-employed service providers delivered VMMC services for a period of 1–4 weeks. Outreach sites operated in an area until saturation was reached, that is less than 30 clients a day were seen, at which time, the site was closed and moved to another location. Outreach sites were supplied by a fixed site from which goods and healthcare providers were transported [20]. During these short-term VMMC campaigns, both 'parent' and 'spin-off' VMMC sites were used. The parent VMMC site was the initial VMMC outreach site established in a catchment area. If saturation was reached, providers opened a spin-off site several kilometres away. The spin-off site stayed open for a minimum of 1 week after start of campaigns and remained open as long as there were at least 10 VMMC clients per day. For the CRT, a cluster included a parent site and related spin-off sites, and was defined as the geographical area of at least 7 km around the parent and all spin-off sites, with a buffer zone of at least 6 km between the boundaries of clusters. No VMMC-related services or demand-creation activities were undertaken in the buffer zones.

Ethical approval was obtained from the London School of Hygiene and Tropical Medicine Research Ethics

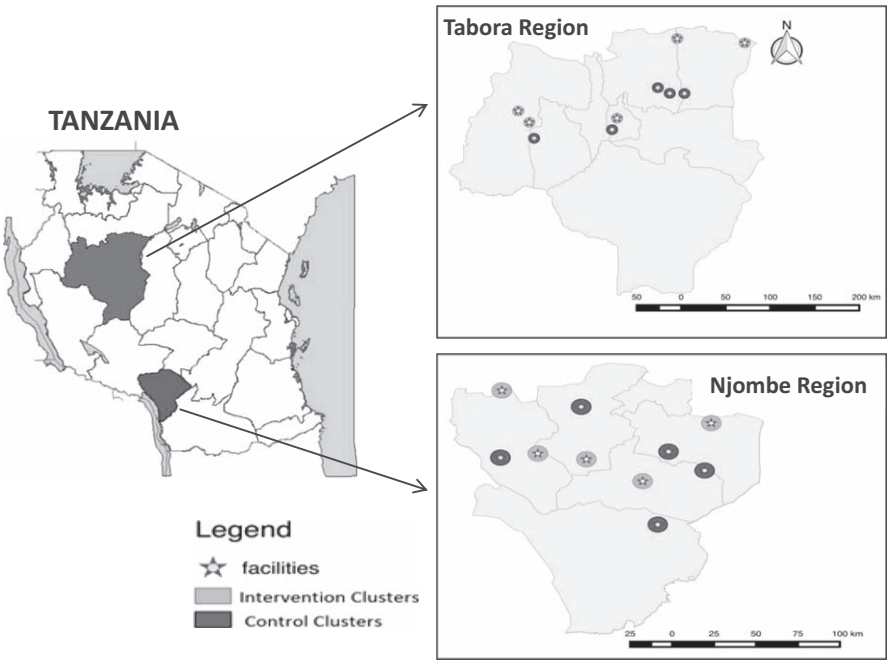


**Fig. 1. Map of Tanzania showing the VMMC study regions and clusters. VMMC, voluntary medical male circumcision.**

Committee; the Tanzanian Medical Research Coordinating Committee, and the Centers for Disease Control and Prevention (CDC) Institutional Review Board. The study was also overseen by a data monitoring and safety committee. The study is registered at ClinicalTrials.gov, number NCT02376348. All participants provided written informed consent in Swahili before study enrolment. The trial was conducted and reported in accordance with the CONsolidated Standards of Reporting Trials (CONSORT) guidelines for CRTs [21].

## Participants

A list of eligible parent sites in Tabora and Njombe regions was compiled. Sites were eligible if they were an outreach VMMC health facility, had not previously provided VMMC services or had not provided VMMC services in the previous 6 months, and were located at least 20 km from other potential parent sites to allow at least 7 km catchment area around the parent and all spin-off sites.

Participants were informed about the study and were recruited following the provision of standard group education session. Eligible participants were men who had voluntarily come to a parent or spin-off site for VMMC, aged at least 10 years, were uncircumcised and who provided voluntary written informed consent to participate in the study. Clients aged less than 18 years provided written informed assent and their parent or guardian provided written informed consent. Eligible clients who consented to be part of the study had nonidentifying information from their individual client record entered into a study database.

## Randomization and masking

In total, 20 clusters were recruited, 10 from each region. The allocation sequence was computer-generated with a 1 : 1 allocation ratio within region. The allocation was unmasked to the field teams delivering the intervention and control strategies and to field staff collecting outcome data. Study participants were masked to study arm.

## Procedures

Formative research was conducted in Nzega district of Tabora and Njombe district of Njombe region in February and March 2014. Formative research used in-depth interviews, participatory group discussions, and discrete choice experiments (DCEs). In-depth interviews and participatory group discussions were used to identify barriers and facilitators to uptake of VMMC among men aged 20–34 years, whereas DCEs assessed the intervention components that could potentially increase VMMC uptake among 20–34 year olds. These findings informed specific components of the intervention [22,23]. The intervention applied information, motivation, and behaviour theory to findings from the formative study [24]. Clusters randomized to the intervention arm received the following components in addition to the control arm activities: enhanced demand-creation messages, including information on non-HIV benefits; involvement of recently circumcised men from the community as auxiliary peer promoters (APPs;

**Table 1. Components of the voluntary medical male circumcision strategy in the control and intervention arms.**

| | Control arm | Intervention arm |
|---|---|---|
| Overall | Clients were circumcised according to protocol of the MOHCDGEC and WHO minimum package [1] | Same as control |
| Radio promotion | Radio messages on local stations advertising the location and dates of VMMC services | Same as control |
| VMMC community promotion | A vehicle with a megaphone visited communities near VMMC sites providing specific information about VMMC and the locations of service delivery | Same as control |
| | BCC materials (flyers and posters) promoting VMMC were distributed prior to football matches organized by peer promoters to promote VMMC in the communities | AND<br>Messages emphasizing non-HIV-related benefits of VMMC such as penile hygiene and cleanliness<br>Messages also included barriers and facilitators to VMMC, including:<br>Promoting the professionalism of VMMC clinicians (men & women)<br>Providing information about separate waiting and counselling areas for men aged 20 and above and, where possible, separate operating theatres |
| VMMC peer promotion | 2–4 peer promoters were assigned to each outreach facility. These male and female peer promoters conducted group and individual demand-creation activities in the communities, and worked with community leaders and organizations to promote VMMC services | Same as control<br>AND<br>Clients aged ≥20 years were encouraged to refer their friends and female partners to use the community's information booth<br>Circumcised men and their female partners were paired with peer promoters to:<br>Conduct one-on-one and small group activities in the community with potential clients aged 20–34 years<br>Visit community leaders to promote VMMC services<br>Prioritize non-HIV benefits in their messaging<br>Run a roving information booth for older clients and their partners on VMMC in the communities. These booths provided information, education, and counselling sessions on wound healing and postcircumcision abstinence targeting women |
| VMMC facility setup | Standard facility preparation | Facility preparation to make services more adult friendly:<br>Separate waiting and counseling areas<br>Private operating theaters |

BCC, behavior change communication; MOHCDGEC, Ministry of Health, Community Development, Gender, Elderly, and Children; VMMC, voluntary medical male circumcision.

community and peer promotion); separate waiting and group education areas for men aged at least 20 years (facility setup); engagement of female partners in community-based demand creation and education for female partners about wound healing and postcircumcision abstinence (Table 1). Clusters in the control arm received the standard demand creation and facility arrangement for outreach VMMC campaigns in Tanzania.

Demand creation activities were conducted by 2–4 male and female peer promoters in the control clusters while the intervention clusters had 6–8 promoters (2–4 peer promoters and 4 APPs). They worked with community leaders, displayed banners, and distributed about 2000 flyers and brochures in each cluster. A vehicle with a megaphone communicating specific VMMC-related messages (including locations and operating hours of VMMC) traversed the intervention communities. The demand-creation team also held shows (playing music, traditional dances) and wore T-shirts with specific messages about the VMMC campaign. A mobile information booth was established in communities surrounding each outreach site to provide education and counselling to female partners of the adult men. Education on benefits of VMMC, wound care and healing, and resumption of sexual activity was provided. The booths were managed by peer promoters and health facility staff.

The communities surrounding parent sites in both arms received demand-creation activities for 2 weeks before the outreach campaigns started, and the parent sites conducted VMMCs for 26–34 days. Spin-off sites were exposed to demand-creation activities for approximately 1 week before the launch of services.

All clients recruited into the study provided separate informed consent for VMMC surgery and study participation. The VMMC service provided by the

MOHCDGEC, which is based on the WHO-recommended minimum package [25], includes the offer of an HIV test, and an individual VMMC client record is completed for every client, recording key demographic and clinical data, including age, referral source, medical conditions precluding VMMC, previous surgery/surgical complications, history of bleeding problems, allergies to medications, and HIV status. Under standard MOHCDGEC procedures, clients who tested HIV positive received additional counselling and surgery if deemed healthy to undergo VMMC by the clinician and if the client still wanted the procedure postcounselling. Clients testing positive were also referred to HIV care and treatment clinics. Individuals with any contraindications to VMMC were referred, and encouraged to return for VMMC, if appropriate.

For this study, selected fields from the VMMC program-based client record were entered into a separate study database at the site. Each participant was identified by a unique study identification number. No identifying information from the client record was entered into either database. For data quality purposes, the data set generated from the study data management system was compared with the programme database. Any discrepancies were resolved at the site using the source data. Costing data for the intervention were collected and are reported elsewhere [26].

VMMC-related adverse events were recorded and reported following national protocol and WHO guidelines [10,27]. All individuals experiencing adverse events were clinically managed until the event was resolved.

### Outcomes

The primary outcome was the proportion of VMMC clients aged 20–34 years. Secondary outcomes were the proportion of clients aged at least 20 years, mean number of clients per cluster aged 20–34 years, and mean number of clients per cluster of all ages. Secondary analyses included analyses stratified by region.

### Statistical analysis

The sample size estimates assumed data collection over a month in each of the 20 clusters. Based on 2014 campaign data, we assumed a harmonic mean of 214 clients per month in each control cluster (SD = 140), of whom 20% would be aged 20–34 years. We further assumed that the intervention would increase the number of clients of all ages by 25% (214 per cluster per month in the control arm vs. 268 in the intervention arm). This sample size provides 85% power to detect a difference in the proportion of VMMC clients aged 20–34 years of 20% in the control arm vs. 30% in the intervention arm, assuming a coefficient of variation ($k$) = 0.35. The sample size also provides over 90% power to detect an increase in the mean number of clients aged 20–34 years seen in the data collection period from 43 (20% of all clients) to 80 (30% of all clients).

Cluster-level summary methods were used to assess the impact of the intervention per analysis plan. The primary outcome was the unadjusted prevalence ratio (PR), estimated as the ratio of the geometric mean proportion of clients aged 20–34 years in the intervention vs. control clusters. The 95% confidence intervals (CI) for the PRs were estimated using a stratified $t$-test, with variance estimated from the residual mean square from an analysis of variance of community log prevalence on stratum (region) and study arm. For continuous outcomes, analogous cluster-level methods were used, with linear regression to estimate the mean difference by arm, with a 95% CI [28].

## Results

A total of 10 485 men sought VMMC services at the 20 sites between 3 November 2014 and 7 March 2015. Of these, 10 219 (97.5%) were enrolled in the study. The primary reason for nonenrollment was being unwilling to provide informed consent (Fig. 2). Of those enrolled, 10 117 (99.0%) were included in the analysis of the primary outcomes (6191 and 3926 men in the intervention and control arms, respectively).

The proportion of clients aged 20–34 years was greater in the intervention than control arm, although this was not statistically significant (17.7 vs. 13.0%; PR = 1.36; 95% CI: 0.93–1.98; $P = 0.11$; Table 2). Similarly, the intervention was associated with the following secondary outcomes: a greater number of clients aged 20–34 years (overall mean difference in number of clients per cluster = 97; 95% CI:40–154; $P = 0.002$), a greater proportion of clients aged at least 20 years (25.5 vs. 16.0%; PR = 1·60; 95% CI:1.09–2.34; $P = 0.02$), and a greater number of clients of any age (overall mean difference in number of clients per cluster = 227, 95% CI:33–420; $P = 0.03$).

The intervention effect varied significantly by region ($P$ value for effect modification = 0.006; Fig. 3 and Table 2). In Njombe, there was little evidence of a difference in the proportion of men aged 20–34 years in the intervention and control arms (11.3 vs. 14.7%; PR = 0.77, 95% CI: 0.37–1.61; $P = 0.44$), whereas in Tabora, there was strong evidence of a difference (27.5 vs. 11.5%; PR = 2.39, 95% CI: 1.66–3.43; $P < 0.001$). Similarly, there was strong evidence of a difference in the mean number of clients aged 20–34 years per cluster in intervention vs. control facilities in Tabora (mean difference = 182; 95% CI 44–320; $P = 0.02$) and little evidence of a difference in Njombe (mean difference = 12; 95% CI:-14–38; $P = 0.32$). In contrast,

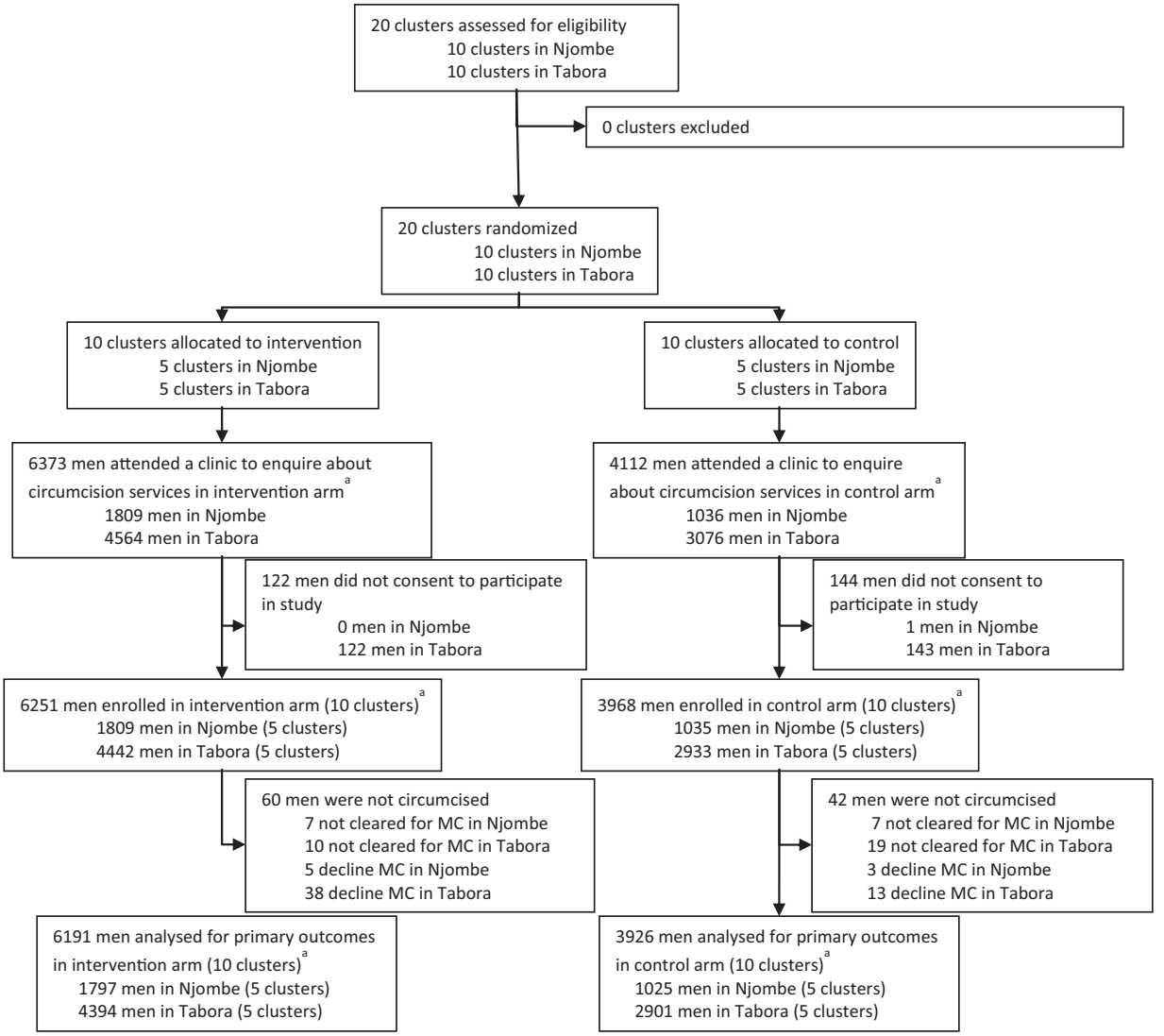


**Fig. 2. Flow diagram showing the flow of participants through each stage of the VMMC trial in Tanzania in 2015. VMMC, voluntary medical male circumcision.** [a]The mean number per cluster and range of cluster sizes is not shown because this is one of the secondary outcomes of the trial.

there was strong evidence of a greater overall number of clients seen in the intervention arm than the control arm in Njombe (mean difference = 154, 95% CI 12–297; $P = 0.04$), but weak evidence of a difference in Tabora (mean difference = 299, 95% CI −102 to 699; $P = 0.12$).

As some components of the intervention (communication strategies targeting adult men, education and counseling to female partners of VMMC clients, and VMMC promotion by recently circumcised peers) took place before participants attended the clinics, there were differences in characteristics of intervention and control participants reflecting the intervention (Table 3). For example, clients in the intervention arm were older [median age 15 years, interquartile range (IQR): 12–21 years] than in the control arm (median 13 years, IQR: 11–17 years; Wilcoxon rank sum $P < 0.001$). Men in the intervention arm were more likely than those in the control arm to be married or cohabiting (22 vs. 8%; $P < 0.001$). Likely because of older age, the proportion of men testing HIV positive was higher among participants in the intervention arm than the control arm (1.6 vs. 0.8%; $P = 0.001$) among participants with unknown HIV serostatus. The proportion who agreed to HIV testing was very high in both arms across all age groups (95–100%). Overall, 79.8% of men in the intervention arm, and 82% of men in the control arm returned for at least one postoperative visit ($P = 0.48$ adjusted for clustering).

**Table 2. Proportion and number of circumcised clients in different age groups, by arm and region.**

| | Both regions (primary analysis) | Region | |
|---|---|---|---|
| | | Njombe | Tabora |
| Proportion of clients aged 20–34 years (primary analysis) | | | |
| Intervention arm ($n=6191$) | 1462[a] (17.7%)[b] | 212 (11.3%) | 1250 (27.5%) |
| Control arm ($n=3926$) | 493 (13.0%) | 153 (14.7%) | 340 (11.5%) |
| Prevalence ratio[c] (95% CI) | 1.36 (0.93–1.98) | 0.77 (0.37–1.61) | 2.39 (1.66–3.43) |
| *P* value | $P=0.11$ | $P=0.44$ | $P<0.001$ |
| *P* value for interaction by region | | $P=0.006$ | |
| Mean number of clients aged 20–34 years (SE) | | | |
| Intervention arm ($n=6191$) | 146[d] (42) | 42 (9) | 250 (51) |
| Control arm ($n=3926$) | 49 (10) | 31 (6) | 68 (15) |
| Mean difference (%; 95% CI) | 97 (40–154) | 12 (−14–38) | 182 (44–320) |
| *P* value | $P=0.002$ | $P=0.32$ | $P=0.02$ |
| *P* value for interaction by region | | $P=0.006$ | |
| Proportion of clients aged ≥20 years | | | |
| Intervention arm ($n=6191$) | 1928 (25.5%) | 393 (19.1%) | 1535 (34.1%) |
| Control arm ($n=3926$) | 601 (16.0%) | 188 (18.3%) | 413 (14.0%) |
| Prevalence ratio (95% CI) | 1.60 (1.09–2.34) | 1.05 (0.49–2.22) | 2.44 (1.71–3.49) |
| *P* value | $P=0.02$ | $P=0.89$ | $P<0.001$ |
| *P* value for interaction by region | | $P=0.03$ | |
| Mean number of clients aged ≥20 years (SE) | | | |
| Intervention arm ($n=6191$) | 193 (50) | 78 (28) | 307 (61) |
| Control arm ($n=3926$) | 60 (12) | 38 (7) | 82 (18) |
| Mean difference (%; 95% CI) | 133 (59–207) | 41 (−35–117) | 224 (57–391) |
| *P* value | $P=0.002$ | $P=0.22$ | $P=0.02$ |
| *P* value for interaction by region | | $P=0.02$ | |
| Mean number of clients, all ages (SE) | | | |
| Intervention arm ($n=6191$) | 619 (110) | 359 (51) | 879 (133) |
| Control arm ($n=3926$) | 393 (83) | 205 (32) | 580 (110) |
| Mean difference (%; 95% CI) | 227 (33–420) | 154 (12–297) | 299 (-102–699) |
| *P* value | $P=0.03$ | $P=0.04$ | $P=0.12$ |
| *P* value for interaction by region | | $P=0.44$ | |
| Proportion of clients aged 20–29 years | | | |
| Intervention arm ($n=6191$) | 1237 (14.5%) | 164 (8.9%) | 1073 (23.6%) |
| Control arm ($n=3926$) | 416 (11.0%) | 133 (12.8%) | 283 (9.5%) |
| Prevalence ratio (95% CI) | 1.31 (0.88–1.95) | 0.69 (0.33–1.47) | 2.49 (1.64–3.76) |
| *P* value | $P=0.16$ | $P=0.29$ | $P=0.001$ |
| *P* value for interaction by region | | $P=0.003$ | |

CI, confidence interval.
[a]Total number of clients aged 20–34 years (over all clusters).
[b]Geometric mean of cluster-level proportions.
[c]Ratio of geometric mean of cluster-specific prevalence in intervention and control arm.
[d]Arithmetic mean number of clients with the outcome per cluster.

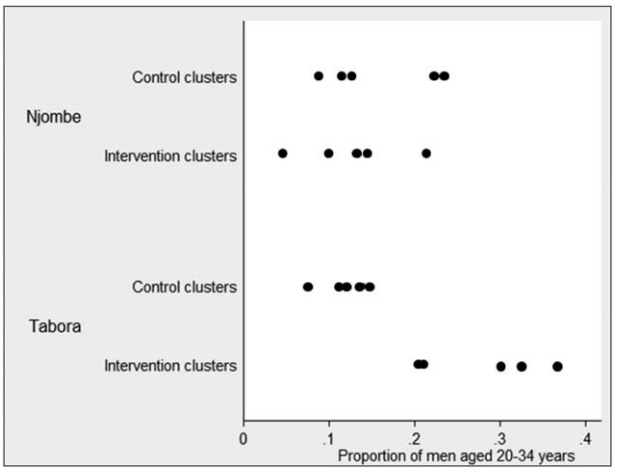


**Fig. 3. Proportion of VMMC clients aged 20–34 years in each cluster, by arm and region.** VMMC, voluntary medical male circumcision.

## Discussion

The proportion of VMMC clients aged 20–34 years was slightly greater in the intervention than control arm overall and there was strong evidence of a difference in Tabora but not Njombe region. The regional differences in the effect of the intervention are likely to be because of different phases of VMMC scale-up between the two regions. The programmatic VMMC implementation started in 2009 in Njombe but in 2011 in Tabora [15]. By the midpoint of study implementation, Njombe region was nearing 80% VMMC coverage [29,30], whereas Tabora region was still at a lower level of coverage. The regional VMMC targets for Njombe and Tabora regions for the period of 2014–2017 were 74 333 and 212 751, respectively [10]. Of these, 45 408 (61% of the target) in Njombe region and 22 861 (11%) men in Tabora region were circumcised in 2014 alone [11]. Therefore, Tabora region still had a large number of uncircumcised men

**Table 3. Characteristics of enrolled voluntary medical male circumcision clients, by arm and region.**

| | Overall | | Njombe region | | Tabora region | |
|---|---|---|---|---|---|---|
| | Intervention $n=6191$ *n* (%) | Control $n=3926$ *n* (%) | Intervention $n=1797$ *n* (%) | Control $n=1025$ *n* (%) | Intervention $n=4394$ *n* (%) | Control $n=2901$ *n* (%) |
| Age group | | | | | | |
| 10–19 years | 4263 (68.9) | 3325 (84.7) | 1404 (78.1) | 837 (81.7) | 2859 (65.1) | 2488 (85.8) |
| 20–34 years | 1462 (23.6) | 493 (12.6) | 212 (11.8) | 153 (14.9) | 1250 (28.4) | 340 (11.7) |
| ≥35 years | 466 (7.5) | 108 (2.8) | 181 (10.1) | 35 (3.4) | 285 (6.5) | 73 (2.5) |
| Median age (IQR; years) | 15 (12–21) | 13 (11–17) | 13 (11–18) | 14 (11–18) | 17 (12–22) | 13 (11–16) |
| Marital status | | | | | | |
| Never married | 4853 (78.4) | 3598 (91.6) | 1545 (86.0) | 935 (91.2) | 3308 (75.3) | 2663 (91.8) |
| Married/cohabiting | 1338 (21.6) | 328 (8.4) | 252 (14.0) | 90 (8.8) | 1086 (24.7) | 238 (8.2) |
| Referral method | | | | | | |
| Peer educator | 6025 (97.3) | 3726 (94.9) | 1731 (96.3) | 976 (95.2) | 4294 (97.7) | 2750 (94.8) |
| Self-referred | 164 (2.6) | 199 (5.1) | 66 (3.7) | 49 (4.8) | 98 (2.2) | 150 (5.2) |
| Other | 2 (0.0) | 1 (0.0) | 0 | 0 | 2 (0.0) | 1 (0.0) |
| HIV testing | | | | | | |
| Accepted testing | 6072 (98.1) | 3902 (99.4) | 1707 (95.0) | 1007 (98.2) | 4365 (99.3) | 2895 (99.8) |
| Did not accept testing | 103 (1.7) | 23 (0.6) | 90 (5.0) | 18 (1.8) | 13 (0.3) | 5 (0.2) |
| Missing | 16 (0.3) | 1 (0.0) | 0 | 0 | 16 (0.4) | 1 (0.0) |
| Of those tested, HIV test results | | | | | | |
| Negative | 5968 (98.3) | 3864 (99.0) | 1677 (98.2) | 988 (98.1) | 4291 (98.3) | 2876 (99.3) |
| Positive | 98 (1.6) | 31 (0.8) | 29 (1.7) | 16 (1.6) | 69 (1.6) | 15 (0.5) |
| Indeterminate | 6 (0.1) | 7 (0.2) | 1 (0.1) | 3 (0.3) | 5 (0.1) | 4 (0.1) |
| Returned for ≥1 postoperative visit | | | | | | |
| No | 1248 (20.2) | 708 (18.0) | 218 (12.1) | 151 (14.7) | 1030 (23.4) | 557 (19.2) |
| Yes | 4943 (79.8) | 3218 (82.0) | 1579 (87.9) | 874 (85.3) | 3364 (76.6) | 2344 (80.8) |
| Any postoperative adverse event[a] | | | | | | |
| No | 4901 (99.6) | 3178 (98.9) | 1566 (99.6) | 857 (98.1) | 3335 (99.6) | 2321 (99.3) |
| Yes | 20 (0.4) | 34 (1.1) | 7 (0.4) | 17 (1.9) | 13 (0.4) | 17 (0.7) |

IQR, interquartile range.
[a]Among those with at least one postoperative visit. Two intraoperative events occurred (one in each arm), and these are excluded from this analysis.

unlike Njombe region. The intervention appeared more effective in areas with low coverage than areas with high VMMC coverage, suggesting that understanding the coverage of VMMC will be extremely important to policy makers and programme planners in designing similar interventions.

The study contributes to the growing evidence on effective demand-creation strategies for VMMC [17,18]. The increase in the number of men of all ages attending VMMC in the intervention arm reflects that many messages in the intervention strategy were attractive to younger as well as older men, and incorporating these elements should be of benefit to general VMMC campaigns. To our knowledge, only three randomized controlled clinical trials in SSA have assessed the effect of a targeted intervention on VMMC uptake among men aged at least 18 years: an economic incentive trial in Kenya [17] and Tanzania [31], and a CRT in Zambia [18]. There are notable differences between these studies and our study. The Zambian study was conducted in urban areas using static/fixed sites delivery model whereas our study was conducted in rural areas using VMMC outreach delivery model. In the Zambian study, VMMC promotion was nested in risk-reduction interventions and reported a VMMC uptake of 40 and 27% in the intervention and control arms, respectively. In the Kenyan and Tanzanian studies, the intervention (economic compensation conditional on undergoing circumcision) happened in the community settings and VMMC at fixed sites. Similar to our study, the Kenyan study showed modest increase in the uptake of VMMC among adult men, ranging from 1.9 to 9% compared with 1.6% reported in the control arm, whereas the Tanzania study increased VMMC among adult men by 47 and 8% in the intervention and control groups, respectively; however, the difference was not statistically significant.

The strength of our trial was the use of formative research to identify optimal communication strategies to overcome barriers to uptake of VMMC among men aged 20–34 years. Such barriers included perceptions of low risk for HIV infection among older men, myths regarding loss of sexual prowess postcircumcision, as well as service-delivery side barriers, including complaints on inconvenient VMMC service hours. Our formative research indicated that older men considered themselves at low HIV risk, and feared that their decision to seek VMMC might be perceived as infidelity to their partners. This led us to incorporate non-HIV benefits of VMMC in addition to HIV and other STIs related-prevention benefits in demand-creation activities targeting older and married men and their female partners. We also used DCEs to assess user preferences for VMMC, which clearly established the desirability of separation of waiting and education areas for younger and older men, use of

APPs to address local myths as well as female partner counselling. Additional measures to improve privacy, including using curtains and screens in the operation theatres, were important in intervention facilities, especially given the high-volume nature of VMMC campaigns.

Our formative work also highlighted the need for an expanded role for women in VMMC communication strategies [23]. This study used mobile information booths to provide counselling and education services to female partners of VMMC clients. The booths were managed by peer promoters and health facility staff and addressed the women's questions on VMMC and were also used to coach women on how to encourage male partners who were undecided or reluctant to seek circumcision. Several studies have shown that women influence their partners' decision to be circumcised [23,32,33]. Providing correct information to women empowers them to play this role and may be an effective way of reaching married adult men.

The study used a dynamic, high-volume outreach model of VMMC campaign in both arms in which parent and spin-off sites are used to increase coverage of VMMC. This is the standard VMMC delivery model in the study regions [15]. This may mean that these findings are not generalizable to static/fixed sites. However, the model described is the standard for service delivery in these regions: of all VMMC clients circumcised in Njombe and Tabora regions during the study period, only 3.6% were circumcised in static sites [11]. Although this design may have increased the uptake of VMMC in both arms, we are unaware of any reason why this design may have increased uptake differentially between the arms. Another limitation is that standard radio messages for VMMC promotion were broadcast in the study regions (intervention, controls, and buffer zone areas) because it was not feasible to prohibit airing the messages in the buffer zone.

## Conclusion

Our trial showed that a targeted demand-creation strategy and an improved layout of outreach facilities increased the uptake of VMMC in men aged 20–34 years and among men of all age groups in areas with lower coverage of VMMC. This intervention should be considered as an additional strategy that can contribute towards reaching the fastest reduction in HIV incidence possible in VMMC scale-up.

# Acknowledgements

Tanzania VMMC Study Group; Augustino Hellar, MMed (Jhpiego, Dar es Salaam, Tanzania), Naomi Bock, MD (Centers for Disease Control and Prevention, Atlanta, Georgia, USA), Sergio Torres Rueda, MSc (Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine, London, UK).

The study was funded by Centers for Disease Control and Prevention, Atlanta, Georgia, USA (Grant No: GH000513). H.A.W. and R.J.H. were funded by the UK Medical Research Council and DFID (Grant Grant No G0700837). We are also grateful to our participants, data collection team, VMMC providers, and health authorities for their dedication to the study.

The funder of the study participated in the study design, data interpretation, and writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

This research has been supported by the President's Emergency Plan for AIDS Relief (PEPFAR) through the Centers for Disease Control and Prevention under the terms of the Cooperative Agreement Number GH000513. The findings and conclusions in this manuscript are those of the authors and do not necessarily represent the official position of the funding agencies.

M.W., H.M., J.M.G., N.L., M.P., H.A.W., R.J.H., G.L., and J.C. contributed to the study design. M.W., H.M., M.M., J.M.G., and M.P. oversaw implementation of the intervention and control strategies. G.M., F.T-P. conducted the formative research. E.K. and M.M. managed the data collection. M.W., H.A.W., and N.L. did the data analysis. M.W. and H.A.W. wrote the first draft of the manuscript. All authors contributed in the interpretation of the results and critical revision of the manuscript for important intellectual content.

Tanzania VMMC study group: Naomi Bock and Sergio TorresRueda contributed to the study design. Augustino Hellar oversaw the implementation of the intervention and control strategies.

## Conflicts of interest

There are no conflicts of interest.

# References

1. Auvert B, Taljaard D, Lagarde E, Sobngwi-Tambekou J, Sitta R, Puren A. **Randomized, controlled intervention trial of male circumcision for reduction of HIV infection risk: the ANRS 1265 Trial.** *PLoS Med* 2005:e298.
2. Bailey RC, Moses S, Parker CB, Agot K, Maclean I, Krieger JN, *et al.* **Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomised controlled trial.** *Lancet* 2007; **369**:643–656.
3. Gray RH, Kigozi G, Serwadda D, Makumbi F, Watya S, Nalugoda F, *et al.* **Male circumcision for HIV prevention in men in Rakai, Uganda: a randomised trial.** *Lancet* 2007; **369**:657–666.

4. WHO, UNAIDS. **New data on male circumcision and HIV prevention: policy and program implications. WHO/UNAIDS technical consultation on male circumcision and HIV prevention: research implications for policy and programming**. *WHO meeting Montreux, Switzerland*; 2007.
5. Njeuhmeli E, Forsythe S, Reed J, Opuni M, Bollinger L, Heard N, *et al*. **Voluntary medical male circumcision: modeling the impact and cost of expanding male circumcision for HIV prevention in eastern and southern Africa.** *PLoS Med* 2011; **8**:e1001132.
6. WHO. *WHO progress brief voluntary medical male circumcsion for HIV prevention in 14 priority countries in East and Southern Africa*. Geneva, Switzerland: WHO; 2015.
7. TACAIDS, ZAC, NBS, OCGS, International I. *Tanzania HIV/AIDS and malaria indicator survey 2011-12: key findings*. Dar es Salaam, Tanzania: National Bureau of Statistics, Ministry of Finance; 2013.
8. Mshana G, Wambura M, Mwanga J, Mosha J, Mosha F, Changalucha J. **Traditional male circumcision practices among the Kurya of North-eastern Tanzania and implications for national programmes.** *AIDS Care* 2011; **23**:1111–1116.
9. Wambura M, Mwanga J, Mosha J, Mshana G, Mosha F, Changalucha J. *Situation analysis for male circumcision in Tanzania*. Dar es Salaam, Tanzania: National Institute for Medical Research Mwanza, Tanzania and Ministry of Health and Social Welfare; 2009.
10. MOHSW. Ministry of Health and Social Welfare/National AIDS Control Program. *Voluntary medical male circumcision country operational plan*. 2014-2017. Dar es Salaam, Tanzania: MOHSW; 2014.
11. Mkungume S. **Experience of scaling up VMMC in Iringa, Njombe and Tabora**. *NIMR Annual Joint Scientific Conference* Dar es Salaam; 2016.
12. Stover J, Kripke K. **Estimating the effects of targeting voluntary medical male circumcision (VMMC) programs to different age groups: the decision makers program planning toolkit (DMPPT 2.0)**. *AIDS Conference* Melbourne, Australia; 2014.
13. UNAIDS/WHO/SACEMA Expert Group on Modelling the Impact and Cost of Male Circumcision for HIV Prevention. **Male circumcision for HIV prevention in high HIV prevalence settings: what can mathematical modelling contribute to informed decision making?** *PLoS Med* 2009; **6**:e1000109.
14. Kripke K, Perales N, Lija J, Fimbo B, Mlanga E, Mahler H, *et al*. **The economic and epidemiological impact of focusing voluntary medical male circumcision for HIV prevention on specific age groups and regions in Tanzania.** *PLoS One* 2016; **11**:e0153363.
15. Ashengo TA, Hatzold K, Mahler H, Rock A, Kanagat N, Magalona S, *et al*. **Voluntary medical male circumcision (VMMC) in Tanzania and Zimbabwe: service delivery intensity and modality and their influence on the age of clients.** *PLoS One* 2014; **9**:e83642.
16. Lija G. **Voluntary medical male circumcision: update on scaling up in 12 regions of Tanzania**. *6th Joint Biennial HIV & AIDS Sector Review Meeting* Blue Pearl Hotel – Dar es Salaam 11 November 2014; 2015.
17. Thirumurthy H, Masters SH, Rao S, Bronson MA, Lanham M, Omanga E, *et al*. **Effect of providing conditional economic compensation on uptake of voluntary medical male circumcision in Kenya: a randomized clinical trial.** *JAMA* 2014; **312**:703–711.
18. Weiss SM, Zulu R, Jones DL, Redding CA, Cook R, Chitalu N. **The Spear and Shield intervention to increase the availability and acceptability of voluntary medical male circumcision in Zambia: a cluster randomised controlled trial.** *Lancet HIV* 2015; **2**:e181–e189.
19. Kundi GJ, Mphuru L, McMahan J, Mwakipesile P, Mwanasalli S, Simbeye. D*, et al*. **Increased uptake of voluntary medical male circumcision (VMMC) services among older men following mobile technology demand creation in Shinyanga and Simiyu, Tanzania**. - *ISDS 2013*; 2013.
20. Mahler HR, Kileo B, Curran K, Plotkin M, Adamu T, Hellar A, *et al*. **Voluntary medical male circumcision: matching demand and supply with quality and efficiency in a high-volume campaign in Iringa Region, Tanzania.** *PLoS Med* 2011; **8**:e1001131.
21. Campbell MK, Piaggio G, Elbourne DR, Altman DG, CONSORT Group. **Consort 2010 statement: extension to cluster randomised trials.** *BMJ* 2012; **345**:e5661.
22. Terris-Prestholt F, Kuringe E, Grund J, Plotkin M, Osaki H, Mshana G*, et al*. *Incorporating user preferences in complex intervention development: Contributions of DCE to stimulating demand for male circumcision in Tanzania*. *In press* 2016.
23. Osaki H, Mshana G, Wambura M, Grund J, Neke N, Kuringe E, *et al*. **"If You Are Not Circumcised, I Cannot Say Yes": the role of women in promoting the uptake of voluntary medical male circumcision in Tanzania.** *PLoS One* 2015; **10**:e0139009.
24. Fisher JD, Fisher WA. **Changing AIDS-risk behavior.** *Psychol Bull* 1992; **111**:455–474.
25. WHO. *Male circumcision quality assurance: a guide to enhancing the safety and quality of services*. Geneva, Switzerland: WHO; 2008.
26. S. Torres-Rueda, H.A. Weiss, Wambura M, Mahler H, Chilongani J, Kuringe E*, et al*. **Spending more to spend less: the unit costs of a tailored demand creation intervention to increase uptake of voluntary medical male circumcision**. *AIDS Conference* Durban: 2016.
27. WHO. *Manual for male circumcision under local anaesthesia*. Geneva, Switzerland: WHO; 2009.
28. Hayes RJ, Moulton LH. *Cluster randomised trials*. Boca Raton, FL: Chapman and Hall/CRC; 2009.
29. Mahler H, Searle S, Plotkin M, Kulindwa Y, Greenberg S, Mlanga E, *et al*. **Covering the last kilometer: using gis to scale-up voluntary medical male circumcision services in Iringa and Njombe regions, Tanzania.** *Glob Health Sci Pract* 2015; **3**:503–515.
30. Lija GJI. *VMMC in Tanzania: moving toward sustainability*. Dar es Salaam, Tanzania: NACP; 2015.
31. Bazant E, Mahler H, Machaku M, Lemwayi R, Kulindwa Y, Gisenge Lija J, *et al*. **A randomized evaluation of a demand creation lottery for voluntary medical male circumcision among adults in Tanzania.** *J Acquir Immune Defic Syndr* 2016; **72 (Suppl 4)**:S280–S287.
32. Cook R, Jones D, Redding CA, Zulu R, Chitalu N, Weiss SM. **Female partner acceptance as a predictor of men's readiness to undergo voluntary medical male circumcision in Zambia: the Spear and Shield Project.** *AIDS Behav* 2015; **20**:2503–2513.
33. Price JE, Phiri L, Mulenga D, Hewett PC, Topp SM, Shiliya N, *et al*. **Behavior change pathways to voluntary medical male circumcision: narrative interviews with circumcision clients in Zambia.** *PLoS One* 2014; **9**:e111602.