Partnerships with religious leaders to promote family planning in rural Tanzania: an open-label, cluster randomised trial

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Summary

Background Family planning benefits maternal–child health, education, and economic wellbeing. Despite global efforts, an unsatisfied demand for family planning persists in sub-Saharan Africa. Based on previous successful partnerships, the aim of this study was to determine whether an educational intervention for religious leaders would increase community knowledge, demand for, and ultimately uptake of family planning.

Methods In this open-label, cluster randomised trial in Tanzania, 24 communities were randomised (1:1) to intervention or control arm. Communities, defined as the catchment area of a single public health facility, were eligible if they were at least 15 km from Mwanza City and had not previously participated in a health intervention for religious leaders. Random allocations were determined by coin toss and were not revealed to clinicians at health facilities in intervention and control communities, nor to the data entry team; however, due to the nature of the intervention, masking of religious leaders in the intervention communities was not possible. All Christian religious institutions were invited to send four leaders to an educational intervention that incorporated cultural, theological, and medical teaching about family planning. The primary outcome was contraceptive uptake at the community health facility during the year post intervention versus the year before the intervention. This trial was registered at clinicaltrials.gov, NCT03594305.

Findings 75 communities in three districts were assessed for eligibility. 19 communities were excluded and 56 were eligible for study inclusion and were placed in random order to be invited to participate. The first 24 communities that were invited agreed to participate and were randomly assigned to receive the educational intervention either during the trial or after trial completion. Between July 10, 2018 and Dec 11, 2021, we provided the intervention in 12 communities and compared contraceptive uptake with 12 control communities. All were followed up for 12 months. In intervention communities, contraceptive uptake increased by a factor of 1·47 (95% CI 1·41–1·53) in the post-intervention (prospective) versus pre-intervention (historical) year (geometric mean of contraceptive uptake, 466 in the prospective year vs 312 in the historical year), versus 1·24 (95% CI 1·20–1·29) in control communities (geometric mean, 521 in the prospective year vs 429 in the historical year). The rate of change in contraceptive uptake was greater in intervention communities (between-group ratio of geometric mean ratios over time, 1·19 [95% CI 1·12–1·25]; p<0·0001). The COVID-19 pandemic was associated with decreased contraceptive uptake (geometric mean, 365 during the pandemic in communities that had the majority of their prospective 12-month data collection periods occur after March 16, 2020, vs 494 before the pandemic; geometric mean ratio, 0·72 [95% CI 0·57–0·90]; p=0·0040).

Interpretation This intervention offers a scalable model, leveraging influence of trusted religious leaders to increase knowledge and uptake of family planning. New strategies such as this could help to overcome setbacks that occurred during the COVID-19 pandemic.

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Introduction

Universal access to sexual and reproductive health care is internationally regarded as an essential human right, underscored by its inclusion in the United Nations 2030 Sustainable Development Goals. Use of family planning saves lives of mothers and children by preventing high-risk pregnancies and spacing births.[1,2] Since 2012, the Family Planning (FP) 2020 and subsequent FP2030 initiatives have worked to promote equitable, person-centred access to modern contraceptives for women worldwide. Despite these efforts, data from 2019 showed that the demand for contraception that is fulfilled with modern methods was only 52% in sub-Saharan Africa.[3] Our focus-group studies in Mwanza, Tanzania, and others in Nigeria and Ethiopia, demonstrate that lack of accurate medical information, refusal by male partners, and uncertainty about compatibility with religious beliefs are major reasons women do not use family planning.[4–6]

Research in context

Evidence before this study

We and others have previously demonstrated, in randomised trials, the effectiveness of partnerships with religious leaders to promote male circumcision in Tanzania, to increase HIV testing among pregnant women in Nigeria, and to decrease intimate partner violence in Uganda. While conducting our cluster randomised trial on male circumcision in rural Tanzanian communities, women frequently asked whether our team could return to teach about family planning. This evidence and experience working with religious leaders encouraged us to investigate whether educational interventions about family planning for religious leaders could be a useful strategy to increase community knowledge about contraception for both men and women, and ultimately to address women's unsatisfied demand for contraception in Tanzania.

We approached this issue cautiously. Numerous examples exist of the politicisation or prohibition of contraception by religious groups. At the interpersonal level, we further recognised: (1) the profound and well documented effect that a religious leader's teaching for or against family planning can have on that leader's community, and (2) the potential power imbalances between religious leaders and community members that could result in reduced decision-making autonomy about contraceptive use. We weighed these challenges against the strong evidence from Africa and Asia that education for both men and women is associated with increased women's autonomy in health decision making. Collectively, these data suggested that an educational intervention, designed and led by religious leaders and medical practitioners in Tanzania, had the potential to provide religious leaders with knowledge about family planning that they could then impart to both men and women in their communities. We recognised the potential of this approach to enhance men's knowledge about family planning, enabling discussions between men and their partners and possibly increasing equitable, person-centred access to modern contraceptives in line with the Sustainable Development Goals.

We searched PubMed, Ovid Medline, and the Cochrane Database of Systematic Reviews for articles published in English between Jan 1, 2000 and May 5, 2023 to investigate current knowledge about this topic. We initially searched using the MeSH terms: "family planning services", "contraceptive agents", "contraception", "reproductive health services", "sex education", "religion", "faith-based organization", or "family planning interventions", or "couple years of protection". We subsequently narrowed our search using the following additional terms: "religious leader", "faith leader", "faith", and "congregation". We also reviewed reference lists of relevant manuscripts.

We found numerous descriptive accounts of projects to educate Muslim, Hindu, and Christian leaders in reports by the Guttmacher Institute, World Vision, and the United Nations

Population Fund. Few manuscripts described and measured efforts to engage religious leaders in increasing community awareness or use of family planning. In a non-randomised study, Lemani and colleagues compared couple-years of protection prescribed at Malawian health facilities in communities that did and did not receive an intervention package of a widely broadcast radio discussion of family planning by faith leaders, "population weekends" during which churches and mosques provided education and brochures about family planning, and training in provision of implants and intrauterine devices for providers at these facilities. Investigators documented an increase in couple-years of protection dispensed before and after the intervention, as well as greater increase in couple-years of protection in intervention than in non-intervention hospitals. Adedini and colleagues implemented advocacy programmes in Nigeria to engage religious leaders in discussions about family planning and later performed a randomised survey of women in selected areas where the programmes were implemented. They documented a 1·7-times higher uptake of contraceptives among women who were exposed to family planning messages from religious leaders than those who were not. Ruark and colleagues implemented a project that educated Kenyan religious leaders about family planning and described how providing education about family planning to religious leaders led to thousands of referrals for family planning by these leaders. Notably, these projects have not involved randomisation or accounted for any overall increase in family planning uptake in sub-Saharan Africa. To our knowledge, a rigorous, randomised evaluation of partnerships with religious leaders to promote family planning has not been performed.

Added value of this study

We conducted a cluster randomised trial to quantify the effect of an educational intervention about family planning for religious leaders on contraceptive uptake in intervention communities versus control communities, where religious leaders did not receive this education until after trial completion. The trial, conducted in rural northwest Tanzania, demonstrated a 19% higher increase in the uptake of contraception in intervention compared with control communities. The magnitude of this percentage change in uptake was higher (about 30%) before the COVID-19 pandemic, which affected the latter half of communities participating in the trial. Extrapolating our approach to all of Tanzania could result in an estimated 1 million new users of modern contraceptives within 1 year who would no longer report an unsatisfied demand.

Implications of all the available evidence

High unsatisfied demand for family planning among women in sub-Saharan Africa, despite broad availability of modern contraceptives, indicates the urgent need to enable informed decision making through contextually appropriate public

health interventions. Previous descriptive studies from Malawi, Kenya, and Nigeria, coupled with our new trial data from Tanzania, indicate the effectiveness and broad generalisability of equipping religious leaders with knowledge about family planning that can fill this gap in communities. We found that empowering religious leaders with knowledge and skills to teach about family planning in the context of their faith builds on leaders' intrinsic motivation to address practical needs in their communities and on their natural skills as trusted community messengers. Furthermore, this approach provided the opportunity for women and men to gain knowledge, enhancing communication between couples and strengthening informed, shared decision making about contraceptive use. Our data suggest that this is an innovative and adaptable strategy that, if implemented broadly, could advance global efforts to satisfy unmet demand for modern contraception and improve the health of women, mothers, and children.

Assuring that health interventions are understood to be concordant with religious beliefs is crucial for successful provision of health care in much of sub-Saharan Africa, where religious organisations have a notable influence on the beliefs and behaviours of most citizens. In a survey in 19 sub-Saharan countries, 76% of people reported having confidence in religious organisations, versus only 51% for confidence in health systems and 44% for confidence in governments.[7] In support of this finding, we have previously documented that, across a variety of health topics and data collection strategies, many Tanzanians trust advice of religious leaders more than doctors.[4,8,9]

Our team in Tanzania has demonstrated the effectiveness of partnerships with religious leaders to increase uptake of male circumcision,[8] a strategy that has now been recommended by the WHO.[10] We found that Christian leaders and congregations were eager to receive information about reproductive health, to discuss health interventions in the context of their faith, and to bring knowledge to their communities. Similar findings were described in a Nigerian church-based trial to increase HIV testing.[11] These and other studies in sub-Saharan Africa suggest that building on the influence of religious leaders might offer a unique opportunity to improve knowledge and access to family planning among women with current unsatisfied demand. This concept has been implemented by other groups,[12,13] but to our knowledge has not been tested rigorously.

Our overarching hypothesis was that Christian religious leaders who received an educational intervention that equipped them with knowledge to consider family planning from theological and medical perspectives would share this knowledge with their communities, which would in turn increase uptake of contraception. We aimed to explore effects of the intervention on the numbers of people seeking family planning who reported being informed by a religious leader, and on couple-years of protection dispensed.

Methods

Study design and participants

We conducted an open-label, cluster randomised trial in 24 communities in the Mwanza region of northwest Tanzania, with accompanying in-depth interviews with Christian religious leaders and community members to understand family planning knowledge and demand, and experiences of the intervention. We designed a community trial because we hypothesised that knowledge provided by the educational intervention to religious leaders would spread beyond the leaders and their religious institutions, and into their communities. We grounded our hypothesis in the social action theory, which incorporates multiple contextual, intrapersonal, and interpersonal influences that affect an individual's health decision-making process.[14] Our team's experience in Tanzania has revealed the importance of anchoring interventions in a contextually appropriate paradigm that promotes health of the individual, family, community, and society.[15,16]

The unit of randomisation was the community, defined as the catchment area of a single public health facility. We worked with Ministry of Health officials from the Magu, Misungwi, and Sengerema districts of the Mwanza region to identify communities that met the following eligibility criteria: (1) located at least 15 km from Mwanza City; and (2) had not previously participated in a health intervention with religious leaders. In these areas, poor transportation and infrastructure leads to little communication between communities and limits risk of contamination.

All interviewees provided written informed consent. All study team members were trained in research ethics, including participants' rights, confidentiality, and informed consent. Ethical approvals for study conduct were obtained from the National Institute for Medical Research in Tanzania (NIMR/HQ/R.8a/Vol. IX/2420) and from Weill Cornell Medicine in New York, USA (1605017246).

Randomisation and masking

Communities were allocated in a 1:1 ratio to the intervention group (intervention communities) or to the control group, which received the intervention after trial completion (control communities).

Eligible communities were placed in random order within each district, and each community's chairperson was approached sequentially and offered the opportunity to participate. Our study team informed the chairperson

about the study objectives and methods and requested the chairperson's oral agreement for the community to participate in the trial, in accordance with CONSORT guidelines.[17] Due to the nature of the intervention, masking of religious leaders or congregations in intervention communities was not possible.

Working in two communities from the same district at one time, our study team performed randomisation via coin toss and then initiated the intervention in one of the communities and collected data prospectively in both communities. To assure communities of unbiased allocation, the coin-toss was performed in front of representatives from both communities, allocating one community to receive the intervention and one community as the control site that would receive the intervention after trial completion. Assignments were stored on a password-protected computer away from the study sites by an investigator (DJD) who was uninvolved in enrolment or data collection. Random allocations were not revealed to clinicians at health facilities in intervention and control communities, nor to the data entry team.

Procedures

In intervention communities, our team worked with the community chairperson to invite all Christian religious institutions in that community, including Catholics, to send two male and two female leaders to receive the educational intervention. The intervention focused on Christian leaders due to our previous qualitative work documenting reliance of both Christians and Muslims on the teaching of their different sacred texts and the need to incorporate specific teaching from the Bible or the Qur'an into the curriculum. We have now developed a similar intervention for Muslim communities appropriate for that tradition.[18] Leaders were chosen by each institution and could be either official or lay leaders. The educational intervention consisted of a 1-day seminar, provided in a large meeting space in each intervention community, plus follow-up mentorship sessions with these same leaders in smaller groups of 20–25 leaders. Mentorship sessions occurred every 2–3 months for 1 year after intervention initiation.

The educational intervention was adapted from our previous educational intervention for religious leaders about male circumcision,[8] and consisted of three sessions: (1) presentation of major themes from focus-group discussions about family planning in the same region including prevalent religious, cultural, and medical beliefs; (2) discussion of biblical and historical traditions about family planning including Catholic viewpoints and scriptural interpretation regarding topics on which scripture is silent; and (3) simple medical teaching about the female reproductive tract, menstrual cycle, and the mechanism, efficacy, and side effects of a variety of family planning methods including the calendar method, withdrawal, breastfeeding, oral contraceptive pills, Depo-Provera injections, intrauterine devices, and implants (appendix 2 pp 3–23). The seminar was co-taught in Kiswahili by a multidisciplinary team of Tanzanian clinicians and Christian religious leaders. Local health-care workers from the community attended the seminar and were invited to speak briefly about family planning at the community's health facility. Ample time was provided throughout the day for questions, including a final discussion of how religious leaders could use the knowledge they had gained to teach about family planning in their communities. Leaders received the printed slide set for reference and were compensated Tsh 10 000 (~US$4·50) for transport and lost work time on the seminar day. During follow-up mentorship sessions, religious leaders had opportunities to discuss challenges faced while teaching about family planning, share strategies they had found effective, and seek answers to questions that had arisen.

A separate data collection team visited the health facility in each participating community to abstract data from the facility's logbook about contraceptives. The Tanzanian Ministry of Health provides contraceptives free of charge and requires that a standardised logbook entry including demographic information and types and numbers of contraceptives dispensed is recorded for each visit for contraception. Our team abstracted logbook data recorded in the year before the intervention, and then prospectively each month from each facility. We refer to data collected during the year before the intervention as historical data, and data collected during the year post-intervention as prospective data. During the prospective year of data collection, clinicians at the health facilities additionally recorded clients' religious affiliation and the person who had informed them about family planning. All abstracted data was completely unlinked from personal identifiers. Members of our study team did not have contact with individuals seeking family planning. At the conclusion of the prospective year of follow-up, a study team member met with a clinician at each health facility to record facility-level data including total population served, number of clinicians, and contraceptive types and availability.

All data from logbooks were double entered by two independent data entry team members into a Research Electronic Data Capture (REDCap) database hosted at Weill Cornell. REDCap is a secure, web-based platform that supports data capture for research, including audit trails and automated export procedures.

For in-depth interviews, we invited religious leaders who had attended the educational intervention to share views on family planning and the intervention. We also invited women seeking family planning or antenatal care at health facilities for interviews. Interviews in each group were continued until data saturation, interpreted as the absence of new or different information obtained through additional interviews, was reached.

3–9 months after the educational seminar, in-depth interviews were conducted with religious leaders who

had attended the seminar and with community members by a member of the research team of the same sex as the interviewee. Religious leaders were purposively selected, ensuring representation by age and sex. Interviews were conducted in a private setting in Kiswahili, digitally recorded, and professionally transcribed and translated into English in Mwanza. Additional details are provided in appendix 2 (pp 45–47).

Outcomes

The primary study outcome was the uptake of contraception at the community health facility. Secondary outcomes included the percentage of people seeking contraception at each health facility who stated that they were informed by a religious leader, husband or partner, friend, nurse or doctor, community announcements, or other, and the couple-years of protection dispensed at the facility. Couple-years of protection were calculated using USAID indicator values, which account for partial or incorrect use of contraceptive methods (appendix 2 p 49).[19] Outcomes were assessed for all logbook data entries.

Statistical analysis

The total number of participants seeking contraception at each community health facility was projected using facility catchment area population sizes from 2018 and the proportion of women of reproductive age in Tanzania. We conservatively anticipated an intra-cluster correlation coefficient (ICC) of 0·17.[8,17] We assumed that 5% of women would seek contraception in control communities and predicted that the intervention would increase the proportion of women seeking contraception by 12·5% to 17·5% in intervention communities. With a mean population of 12000 people per community, consisting of 51·3% women (of whom 46·3% are women of reproductive age)[20] and a mean of 1 couple-year of protection dispensed per visit, we projected that a mean of 143 participants would seek contraception per year per control community and 499 per year per intervention community during the prospective year post intervention. Using simulations, we calculated that enrolling 24 communities, 12 per study arm, would provide 80% power with p<0·05 to detect this difference in the primary outcome.

We summarised characteristics of health facilities, and of people seeking contraception at the health facilities, using descriptive statistics with medians and IQRs. All analyses were intent-to-treat, using a cluster-level analysis containing all communities. For the primary outcome, uptake of contraception was aggregated into a count for each community during the year before the implementation of the intervention and during the year following the intervention. Our primary comparison was difference-in-difference in count outcomes in log-scale or equivalently ratio of geometric mean ratio. The exponential of the mean difference in log-counts gave a geometric mean ratio of contraceptive uptake. We used a

random-effects Poisson regression for panel data and compared the intervention effect using the interaction coefficient between time indicator of post-intervention year and indicator of intervention group.

The first case of COVID-19 in Tanzania was reported on March 16, 2020, 40 days after the intervention had been provided in the eighth of the 12 communities. This timing resulted in the final 12 communities that participated in the trial having the majority of their prospective 12-month data collection periods occur during the COVID-19 pandemic. After visualising outcomes over calendar time, we noticed considerable changes in temporal trends that aligned with the start of the pandemic. Therefore, we classified the first 12 of the study roll-out communities as pre-pandemic communities and the second 12 as intra-pandemic communities. As a post-hoc analysis, we assessed the effect of COVID-19 on the primary outcome, as well as the change in the effect of the intervention on the primary outcome due to COVID-19 using an additional indicator of intra-pandemic communities.

For secondary outcomes, total couple-years of protection dispensed was aggregated at each community during the year before and after the intervention. To compare study groups, we took logarithms of the outcome because the
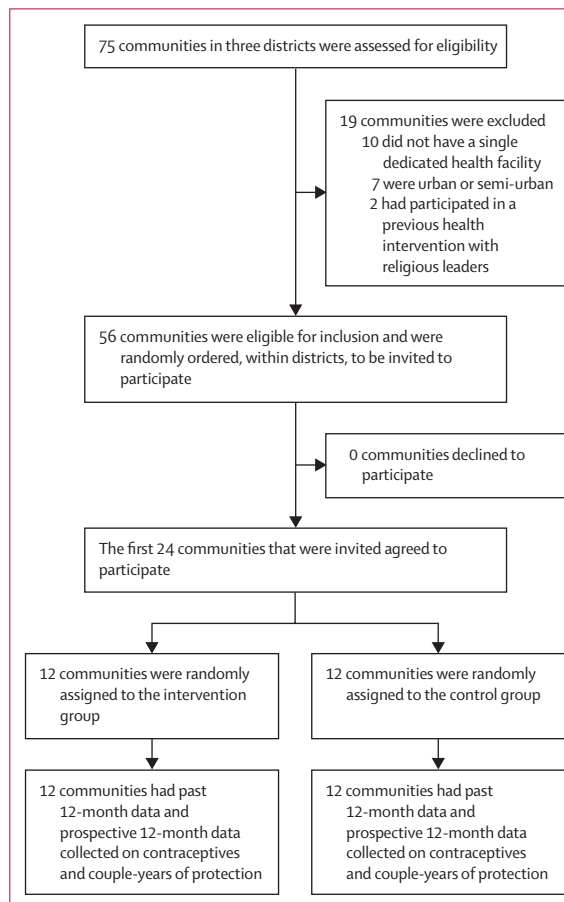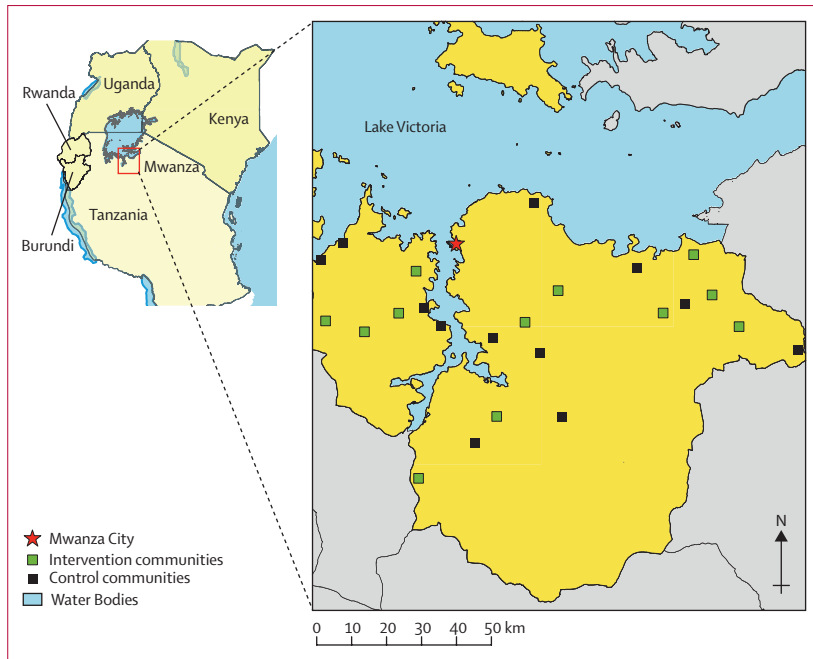

Figure 1: Trial profile

Figure 2: Map of intervention and control communities participating in the trial
All mapping was done using ArcGIS Pro v.3.1.1 (ESRI; Redlands, CA). Intervention communities are shown in green and control communities are shown in black. All communities are at least 15 km by road from Mwanza City.

	Intervention communities (n=12)	Control communities (n=12)
Total catchment area	10 736 (9699–13 669)	12 581 (8748–17 111)
Number of clinicians employed	4 (4–5)	4 (4–6)
Number of clinicians able to place an intrauterine device	2 (1–3)	2 (1–2)
Number of clinicians able to place an implant	4 (2–5)	3 (2–4)
Availability of contraceptives (% in past 3 months)		
Intrauterine device	98 (0–100)	100 (38–100)
Jadelle implant	100 (42–100)	100 (88–100)
Implanon NXT implant	100 (42–100)	100 (85–100)
Depo-Provera injections	50 (17–79)	79 (72–97)
Combined oral contraceptive pills	100 (100–100)	100 (75–100)
Condoms	100 (96–100)	100 (85–100)
Uptake of contraception in the year prior to the intervention	339 (268–393)	456 (344–512)
Couple-years of protection dispensed in the year before the intervention	619 (461–791)	882 (612–1084)

Data are median (IQR).

Table 1: Health facility characteristics in intervention and control communities

distribution was right-skewed. We evaluated effect of the intervention on couple-years of protection based on a difference-in-difference coefficient from the random-effects linear model for panel data, while adjusting for COVID-19 effects using an indicator variable for intra-pandemic communities. The geometric mean ratio was calculated as the antilogarithm of the difference between the mean of the log-transformed couple-years of protection dispensed. For the secondary outcome of the proportion of those seeking contraception who reported being informed by a religious leader, we quantified proportions and compared proportions for intervention versus control communities using mixed-effects logistic regression with communities as random effects while adjusting for COVID-19 effects. To investigate whether the effect of the intervention was sustained over the entire prospective follow-up period, we visualised the community-wise cumulative proportion of individuals seeking contraception who were informed by a religious leader over time and compared slopes of the curves between the two groups by rank-sum test.

In addition to primary and secondary outcomes that we planned to measure a priori, as a sensitivity analysis we measured the effect of the intervention using alternative methods (appendix 2 p 45), including the counterfactual scenario in which the study had not been impacted by the COVID-19 pandemic. Furthermore, we reported the shift in couple-years of protection dispensed before and after March 16, 2020 in control communities where the intervention was not implemented to examine the impact of the pandemic alone.

Qualitative transcripts were imported into NVivo version 12 (QSR International). We used a directed content analysis[21] approach focused on the study's primary and secondary outcomes and on understanding leaders' and community members' experiences related to the intervention. Transcripts were reviewed and coded independently by two investigators (VJL and JAD) who then collaborated with other team members to determine and refine themes and select illustrative quotations. All statistical analyses were performed with R 4.0.2. This trial was registered with clinicaltrials.gov, NCT03594305.

Role of the funding source
The funders had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results
We assessed 75 communities in three districts for eligibility. 19 were excluded due to not having a single dedicated health facility, being classified as urban or semi-urban, or having previously participated in a health intervention with religious leaders. 56 communities were eligible for study inclusion and were randomly ordered for invitation to participate. The first 24 communities that were invited agreed to participate and were subsequently randomly assigned to either the intervention group, which would receive the educational intervention during the trial, or to the control arm, which would receive the intervention after trial completion. 12 communities were allocated to

the intervention group and had past 12-month data collected and prospective 12-month data collected, and 12 communities were assigned to the control group and also had past 12-month and prospective 12-month data collected (figure 1). The first two communities were randomised on July 10, 2018, and final study data were collected on Dec 11, 2021. The final control community received the intervention on June 2, 2022. A map depicting intervention and control communities is shown in figure 2.

We noted no differences in baseline characteristics of health facilities and demographic characteristics in intervention and control communities, including in the number of people living in the facility's catchment area, number of clinicians, and number of clinicians able to place an intrauterine device at each facility (tables 1 and 2). Contraceptive availability was high in all communities. Across the 12 intervention communities, the educational intervention was received by a median of 46 (IQR 34–111) Christian religious leaders. In total, 681 leaders in intervention communities received the intervention.

Contraceptive uptake increased in the intervention communities (geometric mean ratio, 1·47 [95% CI 1·41–1·53], p<0·0001; geometric mean of uptake, 465 in the prospective year vs 312 in the historical year), and in the control communities (geometric mean ratio 1·24, [95% CI 1·20–1·29], p<0·0001; geometric mean of uptake, 521 in the prospective year vs 429 in the historical year; figure 3). The increase in contraceptive uptake was higher in intervention than in control communities (ratio of geometric mean ratios, 1·19 [95% CI 1·12–1·25], p<0·0001), while adjusting for the effect of the COVID-19 pandemic. We observed a decrease in contraceptive uptake overall between communities that were studied pre-pandemic (geometric mean, 494) and those studied intra-pandemic (geometric mean, 365; geometric mean ratio, 0·72 [95% CI 0·57–0·90], p=0·0040). The pandemic was associated with a decreased effect of the intervention on the outcome by a factor of 0·87 (95% CI 0·78–0·97, p=0·015; ratio of geometric mean ratios, 1·14 intra-pandemic vs 1·30 pre-pandemic). In the random-effects Poisson model including COVID-19 interaction, the ICC was 0·070. In a sensitivity analysis limited to the 12 communities studied pre-pandemic, we observed a higher increase (ratio of geometric mean ratios, 1·30 [95% CI 1·21–1·40], p<0·0001) in contraceptive uptake in the six intervention communities than in the six control communities.

We observed an increase in couple-years of protection in intervention communities (geometric mean ratio, 1·47 [95% CI 1·14–1·90]; geometric mean of couple-years of protection dispensed, 866·9 in the prospective year vs 589·6 in the historical year). In control communities we observed an increase (geometric mean ratio, 1·20 [95% CI 0·93–1·55]; geometric mean of couple-years of protection dispensed, 950·6 for prospective year vs 789·7 for historical year), although the difference-in-difference in the increase did not reach significance

(ratio of geometric mean ratios, 1·22 [95% CI 0·85–1·75], p=0·29). Additionally, we found that couple-years of protection dispensed decreased during the COVID-19 pandemic (geometric mean ratio, 0·60 [95% CI 0·41–0·87], p=0·014; geometric mean of couple-years of protection dispensed, 607·3 in intra-pandemic vs 1020·0 in pre-pandemic communities).

Demographic data collected from those seeking contraceptives indicated small differences in age and numbers of children. Distributions of contraceptive

	Intervention communities (n=4037)	Control communities (n=5411)
Age, years	26 (21–30)	26 (21–31)
Number of children	3 (2–5)	3 (2–5)
Contraceptive dispensed		
Intrauterine device	258 (6·4%)	289 (5·3%)
Jadelle implant	815 (20·2%)	930 (17·2%)
Implanon NXT implant	1036 (25·7%)	1763 (32·6%)
Depo-Provera injection	1425 (35·3%)	1706 (31·5%)
Oral contraceptive pills	224 (5·5%)	412 (7·6%)
Condoms	212 (5·3%)	236 (4·4%)
Other*	67 (1·7%)	75 (1·4%)

Data are median (IQR) or n (%). *Other contraceptives dispensed included emergency contraception and male or female sterilisation.

Table 2: **Demographic characteristics of individuals seeking contraceptives in intervention and control communities**
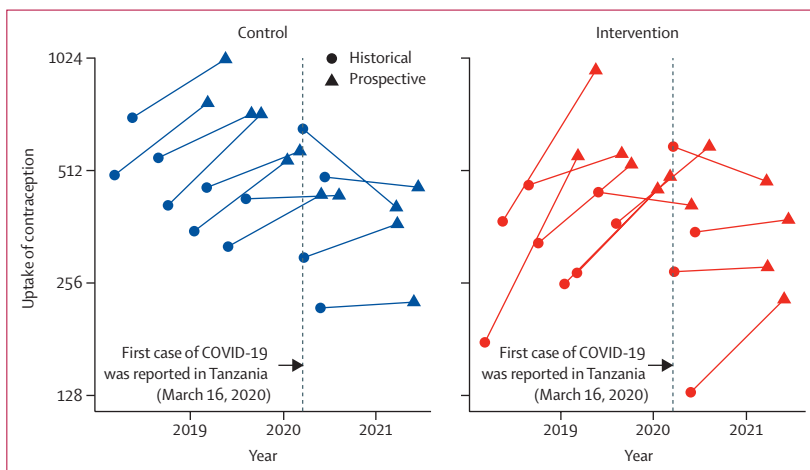

Figure 3: **Uptake of contraception in each community during the prospective year and the historical year**
Uptake of contraception over study period by trial arm. Uptake of contraception in each community is shown on the y-axis using a logarithmic scale versus the midpoint of study period on the x-axis. For each community, a circle indicates data for the historical year and is plotted at the point on the x-axis that indicates the midpoint of that historical year. For each community, a triangle indicates data for the prospective year and is plotted on the x-axis at the midpoint of that prospective year. Each community's two data points from the historical year and prospective year are connected by a line. The date of intervention for each community is the x-axis coordinate of the midpoint of the line. March 16, 2020, was the date when the first case of COVID-19 was reported in Tanzania and is represented by the vertical dotted line. In the first 12 study roll-out communities, the midpoint of the prospective year occurred before the pandemic (triangles on left side of the vertical dotted line) while the midpoint of the prospective period was during the pandemic for the other 12 communities (triangles to the right of the vertical dotted line).
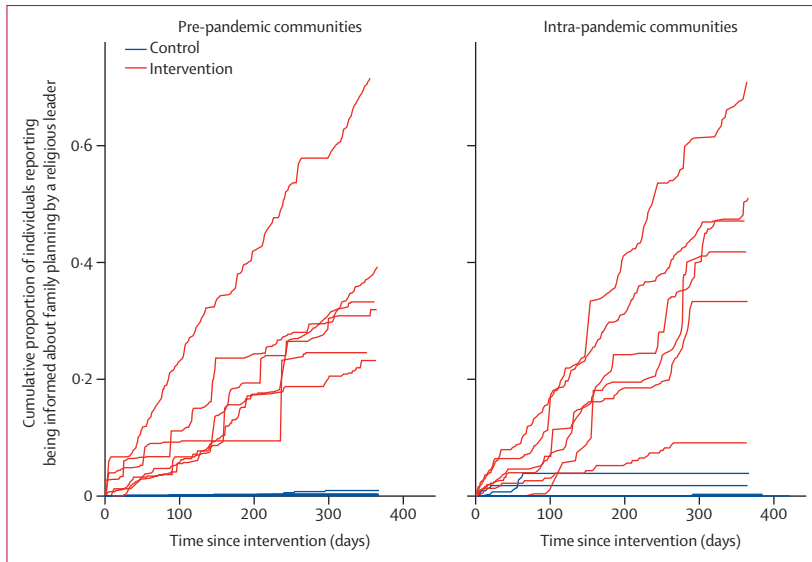
***Figure 4:* Cumulative proportion of individuals seeking contraception who reported being informed about family planning by a religious leader, before and during the COVID-19 pandemic**
At each health facility, we calculated the cumulative proportion function over time defined as the proportion of people who reported being informed about family planning by a religious leader within T days after the initiation of the intervention among people seeking contraception during the prospective year. Cumulative proportions calculated daily are connected by lines. Data are shown for intervention (red) and control (blue) communities, before (left panel) and during (right panel) the pandemic. Using the daily cumulative proportion function over 1 year from the initiation of the intervention, we estimated the slope of the line using linear regression for each community. The slopes of the lines in intervention communities remained relatively stable during the entire year post intervention implementation, indicating a steady increase in the proportion of individuals who reported hearing information from a religious leader about family planning over the entire year after the initiation of the intervention. There was no difference in the slopes of the cumulative proportions of those informed by religious leaders in intra-pandemic (red on right panel) versus pre-pandemic (red on left panel). Notably, the one pre-pandemic intervention community with the highest proportion of individuals reporting information from a religious leader did not correspond to the community that had the steepest increase in uptake of contraception. Similarly, the intra-pandemic intervention community with a notably lower proportion of individuals reporting information from a religious leader did not correspond to the community that had the lowest increase in uptake of contraception.

types dispensed in the prospective year were similar between trial groups (appendix 2 p 48). In intervention communities, 41% (2422 of 5938) of individuals reported hearing about family planning from a religious leader, which was much higher (p<0·0001) than 0·5% (35 of 6718) in control communities. We further observed that this high prevalence of individuals reporting being informed by a religious leader was sustained throughout the year after initiation of the intervention (figure 4). There was no difference in the slope of the cumulative proportion of those informed by religious leaders in intra-pandemic versus pre-pandemic intervention communities (0·11 [95% CI 0·10–0·14] *vs* 0·09 [0·07–0·10], p=0·34).

To investigate the effect of the pandemic aside from any influence of the intervention, we examined couple-years of protection dispensed in the 12 control communities pre-pandemic versus intra-pandemic. Among individuals seeking contraception, the median couple-years of protection dispensed per person was 2·5 (95% CI 0·2–10) pre-pandemic, which dropped to 0·25 (0·2–4·6) intra-pandemic (appendix 2 p 50). This

decrease was predominantly due to decreases in uptake of longer-acting contraceptives (intrauterine devices and implants), with concomitant increases in shorter-acting contraceptives (oral contraceptive pills and condoms), dispensed during the pandemic. Long-term data collection to quantify the effect of the intervention on pregnancy rates (as specified in the protocol) and on neonatal and maternal health in these communities is ongoing.

Qualitative data collected from religious leaders (n=46) and community members (n=72) indicated that both male and female leaders experienced a renewed understanding of how they could consider family planning in the context of their faith (panel; additional manuscripts analysing qualitative data are underway). Leaders' subsequent teaching in their communities was reported to have provided new knowledge, particularly for men, and to enable women to express desires to use family planning more freely to their partners. No instances of coercion related to this intervention were described. Leaders felt free to share information as they saw fit, and women described autonomy in decision making about family planning, which for some, but not all, was bolstered by religious leaders' teaching. Community members reported eagerness to share knowledge they had received, encouraging others in their community to seek more information about family planning from health facilities.

Discussion
This cluster randomised trial demonstrates that equipping Christian religious leaders with medical and theological information about family planning increased the uptake of family planning in rural Tanzania, resulting in an overall 19% increased uptake, and a 30% increased uptake when the analysis was limited to communities that received the intervention before the pandemic. Our data suggest that the intervention increased community knowledge, with 41% of those seeking family planning in intervention communities reporting having received information from a religious leader. This work expands on previous trials, which have shown effectiveness of religious leaders to boost one-off surgical or diagnostic health procedures such as male circumcision or HIV testing,[8,11] to now document that religious leaders can promote a longitudinal, primary care health behaviour. Moreover, this trial validates and quantifies our own and others' previous observations that religious leaders are trusted community messengers who are highly skilled and culturally attuned to address sensitive health topics such as family planning in their own communities.[4,12,13] Trust in religious leaders in addition to the high prevalence of devout faith in Tanzania[22] likely facilitated this trial's effectiveness. Conservatively extrapolating the 19% increased uptake to all of Tanzania and working with both Christian and Muslim leaders, we estimate that our strategy could lead to an increase of 1 million

Panel: Prevailing themes illustrating perspectives of religious leaders and community members on family planning

Religious leaders felt newly equipped after the intervention to consider family planning in the context of their faith and scriptures

"The Bible hasn't kept quiet: it says that a person who doesn't take care of his family is doing something bad, so you are supposed to have the power of taking care of those children so that they can have their basic needs."

Male religious leader

"We were very scared, you tell yourself that, "I will be committing a sin" but the Bible is silent on the use of family planning, rather it says, "be fruitful and increase in number; multiply on the earth and increase upon it". However, the word of God has given us knowledge to understand as human beings. That I can't just have children just because the Bible has ordered us to be fruitful hence to fill the village with children, I can't do that. We have been blessed with understanding, I will just have three children, my children will also have children, my neighbour as well, through that we will be fruitful and increase in number. The word of God teaches us that we should have children that we can be able to take care of."

Female religious leader

Women sought family planning with hope and optimism after receiving teachings that reconciled religious faith with experienced need

"They [religious leaders] were saying that if life is difficult, women should try using family planning. I thought that we should actually try… I have put an implant."

Female community member

"In churches they usually arrange seminars… [our religious leaders] were advocating for family planning. I thought that it was a good thing because they were advocating and educating. Yes [my partner was present at the seminar]. He was very happy and that's why he made a decision that I should use it. They [my friends and relatives who attended the seminar] were happy too and others went to the health centre for family planning [after the seminar]."

Female community member

Women demonstrated autonomy in contraceptive decision making, which for some was bolstered by religious leaders' teaching and which for others occurred despite religious leaders' teaching

"[The pastor's wife] was one of the things that influenced me [to start using family planning]. I went and thought about what she was telling us. [At that time] I hadn't yet started [using family planning]… [the first time I went to the health centre to get family planning] I went there with my husband… the nurse advised us and told us that there are pills, implants and injections… she [the nurse] asked me what I wanted. She said that all the methods I advised you about are good but you have to choose one on your own."

Female community member

"[After hearing a pastor's wife teach about FP], we were happy and women said it is true about what this woman has told us, and when you take a look at her children you see they are doing well and you cannot say that they are close to each other, there is a good interval… to be honest it was one of the influences I got, I went and thought of it and the way she was talking to us women [and later I started using contraceptives]."

Female community member

"[My pastor] said that those [contraceptives] have negative effects and so he advised us to use the calendar. And then we asked that for some of us the calendar is difficult to do, and he said that if it is difficult just leave it, but I wasn't ready to follow his advice [and that is why I use contraceptives]."

Female community member

Family planning information provided via religious leaders, particularly to men, enhanced communication between men and women

"In the past, most families were broken because of misunderstanding of family planning, but after getting this training, most men have understood about the benefits of family planning."

Male religious leader

"He [my partner] received the matter [discussion about FP] well, and we went together to the health centre."

Female community member

"I thought what the pastor said was a good thing and true… After the mass when we were going home we started advising each other that what the pastor said was good… [My partner] was in the church… he said it is true, it was great that we were able to use family planning… Yes, he [the pastor] made me feel proud to be using family planning."

Female community member

Community members were eager to extend religious leaders' teaching beyond religious institutions and into communities

"I have not heard in the church, but when we sit in women's groups, there are women who are church elders. That's when we start talking. They are educating us about how family planning is good and how it is safe to practise family planning in your family."

Female community member

"After this seminar the majority of people received it and enjoyed it, and they have started seeing the importance of teaching each other concerning family planning… I have also heard people seated and discussing and talking saying that this issue is very good."

Male religious leader

additional women in Tanzania with a satisfied demand for modern contraception within 1 year.

Our quantitative and qualitative data suggest that, at the level of the religious leaders, the intervention operates through three key mechanisms. First, it equips leaders, and consequently their community members, with knowledge to evaluate family planning from the dual perspectives of faith and health. The insights that leaders gained from discussions with other leaders about family planning in biblical texts, combined with simple medical teaching, yielded opportunities to consider family planning from a fresh, informed perspective. Second, this intervention draws on religious leaders' intrinsic motivation to alleviate suffering that they observe in their communities. During seminars and in-depth interviews, leaders spoke almost universally of the burdens of ill health and poverty facing families with many closely spaced children. Our data suggest that leaders' informed perspectives on family planning led many to conceptualise themselves as advocates who could provide practical teaching that might alleviate many women's unmet demand for contraception, ultimately improving health and easing poverty.[4] Third, this intervention leverages natural skills that religious leaders possess: they are often excellent teachers, have earned respect and trust, and have deep contextual understanding of local barriers and enablers to family planning. The intervention inherently relies on leaders' contextual expertise in their own communities, recognising that they can best determine how to provide information about family planning in ways most relevant to their communities.

Beyond the religious leaders, our qualitative data suggest that this intervention additionally leveraged community bonds to extend discussions about family planning beyond the boundaries of religious institutions and into community settings. Notably, this extension into the community is a distinctive feature of our intervention, in contrast to interventional trials in the USA[23,24] and sub-Saharan Africa[11,25] that have measured changes in other health behaviours among church attenders. We report an increase in contraceptive uptake at the community level, with qualitative data illustrating that knowledge about family planning was carried by both religious leaders and congregants to families, neighbours, and friends. Through the social action model, we posit that the educational intervention for religious leaders, and subsequent teaching by these leaders, led to shifts in individuals' understanding of family planning. Furthermore, we suggest that surrounding influences from partners, family, and friends also began to align in favour of family planning, creating a setting in which an individual had greater information and autonomy to make an informed choice about which contraceptive method to use, and when to use it.

Our trial's additional major finding is the impact that the COVID-19 pandemic had on family planning in rural Tanzania, evidenced by a 28% lower contraceptive uptake in communities studied during versus before the pandemic. Especially notable is that the pandemic erased the gradual rise in contraceptive uptake that occurred even in control communities in the prospective compared with the historical year. We also observed a decrease in couple-years of protection dispensed, marked by less frequent provision of long-acting reversible contraceptives such as intrauterine devices and implants. Our team was uniquely positioned to collect these detailed quantitative data, amplifying WHO global reports and a scoping review that indicated widespread disruptions in family planning services and increased unintended pregnancies during the pandemic.[26,27] In light of escalating national pressures on education, nutrition, and health care, the Tanzanian President has recently called for increased family planning.[28] Our latest qualitative data and pilot-testing of an adapted educational intervention among Muslim religious leaders[18] suggest that religious leaders throughout the country will be crucial advocates to support the President's initiatives. They could additionally promote broader reproductive health measures, including vaccines for human papillomavirus and hepatitis B, and monitoring for HIV and sexually transmitted infections. Furthermore, they could be ideal allies to address long-term effects of the post-COVID-19 decline in family planning, including maternal and child health, nutrition, family economies, and women's education.

The cluster randomised trial design is both a strength and a limitation. Cluster trials carried out in large units of randomisation, such as communities or health districts, provide a template for how an intervention could be rolled out logistically if shown to be effective.[29] These trials are pragmatic and often viewed as having higher external validity than individual randomised trials, which might stipulate rigorous eligibility criteria for participants. However, cluster trials must be carried out cautiously to minimise potential bias. High similarities between people within a cluster can lessen power and push the entire cluster towards one outcome in a way that can be challenging to account for statistically.[30] Insufficient distance between clusters could bias findings toward the null hypothesis.

Another limitation is our primary focus on contraceptive uptake, and secondary focus on who provided information to those seeking contraception, both numeric indicators. Combined with interview data, our dataset offers some insights but cannot provide large-scale analysis of essential broader family planning goals of promoting reproductive rights and autonomy. Delving into these outcomes in future interventional studies is an indispensable next step. We also could not capture additional family planning practices, such as the calendar method or withdrawal, that might have been encouraged by some religious leaders who received the intervention. Collection of additional pre-intervention

historical data and longer post-intervention prospective data could have further strengthened analyses. We plan to compare longer-term maternal–child health outcomes between intervention and control communities to explore broader effects and sustainability.

In conclusion, we have rigorously demonstrated that an educational intervention about family planning, driven and led by trusted community religious leaders, increased uptake of contraception in Tanzania. Our qualitative data suggest that the intervention increased community knowledge of this topic, enabled informed discussions between partners, and in some cases supported women's decisions to use contraception. We describe an innovative, multidisciplinary approach that built alliances between religious and medical leaders to transform previous obstacles to family planning—including religious beliefs, inadequate health information, and cultural norms—into opportunities to promote family planning, longitudinal primary care, and broader community health. Our data indicate that even through the global COVID-19 crisis, religious leaders continued to provide information about family planning to their communities. The flexibility of this model opens doors to compelling possibilities to improve health and health equity not only in Tanzania but also in other settings in which faith plays a major role. Furthermore, this work compels additional research that adapts this model to address other challenging public health issues, to collaborate with leaders of other faiths, as our team is currently doing with Muslim leaders in Tanzania,[18] and to seek additional creative avenues to promote health in partnership with trusted community messengers.

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