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Improving maternal, newborn and child health outcomes through a community-based women's health education program: a cluster randomised controlled trial in western Kenya

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ABSTRACT

Introduction Community-based women's health education groups may improve maternal, newborn and child health (MNCH); however, evidence from sub-Saharan Africa is lacking. Chamas for Change (Chamas) is a community health volunteer (CHV)-led, group-based health education programme for pregnant and postpartum women in western Kenya. We evaluated Chamas' effect on facility-based deliveries and other MNCH outcomes.

Methods We conducted a cluster randomised controlled trial involving 74 community health units in Trans Nzoia County. We included pregnant women who presented to health facilities for their first antenatal care visits by 32 weeks gestation. We randomised clusters 1:1 without stratification or matching; we masked data collectors, investigators and analysts to allocation. Intervention clusters were invited to bimonthly, group-based, CHV-led health lessons (Chamas); control clusters had monthly, individual CHV home visits (standard of care). The primary outcome was facility-based delivery at 12-month follow-up. We conducted an intention-to-treat approach with multilevel logistic regression models using individual-level data.

Results Between 27 November 2017 and 8 March 2018, we enrolled 1920 participants from 37 intervention and 37 control clusters. A total of 1550 (80.7%) participants completed the study with 822 (82.5%) and 728 (78.8%) in the intervention and control arms, respectively. Facility-based deliveries improved in the intervention arm (80.9% vs 73.0%; risk difference (RD) 7.4%, 95% CI 3.0 to 12.5, OR=1.58, 95% CI 0.97 to 2.55, p=0.057). Chamas participants also demonstrated higher rates of 48 hours postpartum visits (RD 15.3%, 95% CI 12.0 to 19.6), exclusive breastfeeding (RD 11.9%, 95% CI 7.2 to 16.9), contraceptive adoption (RD 7.2%, 95% CI 2.6 to 12.9) and infant immunisation completion (RD 15.6%, 95% CI 11.5 to 20.9).

Conclusion Chamas participation was associated with significantly improved MNCH outcomes compared with the standard of care. This trial contributes robust data from sub-Saharan Africa to support community-based, women's health education groups for MNCH in resource-limited settings.

Trial registration number NCT03187873.

Key questions

What is already known?

- Globally, maternal and infant deaths have declined over the last three decades; however, low and middle-income countries (LMICs) disproportionately incur the highest morbidity and mortality.
- The WHO recommends leveraging lay health workers (LHWs), including community health volunteers (CHVs), to promote maternal, newborn and child health (MNCH) in resource-limited settings.
- Prior research suggests coupling community-based approaches (ie, LHW-led interventions) and women's health education groups during pregnancy and postpartum may improve MNCH outcomes; however, robust evidence from sub-Saharan Africa is lacking.

What are the new findings?

- Using a cluster randomised controlled trial design, we found participation in Chamas for Change (Chamas)—a group-based women's health education programme led by CHVs—was associated with significantly improved rates of facility-based deliveries compared with the standard of care (ie, individual, monthly home visits) in rural Kenya.
- This trial also demonstrated significant associations between programme participation and receiving 48-hour postpartum home visits, breastfeeding exclusively, adopting a contraceptive method postpartum and immunising infants fully by 12 months of life compared with the standard of care.
- These findings support pilot data from a preceding evaluation of the Chamas programme as well as the current literature on community-based MNCH interventions led by LHWs in other LMICs.

Key questions

What do the new findings imply?

- Effective community-based strategies that promote MNCH are needed to continue to improve the health and well-being of women and infants in rural sub-Saharan Africa and other LMICs.
- Chamas offers an innovative approach that leverages existing community infrastructure to improve MNCH in a rural, resource-limited setting with significant health policy implications.
- Collective evidence from this trial and preceding studies support community-based women's health education groups as an effective strategy for improving uptake of facility-based deliveries and other life-saving MNCH practices.

INTRODUCTION

Globally, maternal and infant deaths have declined over the last three decades; however, low and middle-income countries (LMICs) still disproportionately incur the highest morbidity and mortality. Kenya's maternal mortality ratio (MMR) and infant mortality rate (IMR) remain among the highest in the world at 342 per 100 000 live births and 31 per 1000 live births, respectively.[1 2] Fragile health systems, poor access to high quality and specialised care, low health literacy rates, gender-based inequities and generational poverty contribute to this disparity.[3–5] Effective solutions that build on infrastructure to promote the health and well-being of women and infants are needed to continue to improve maternal, newborn and child health (MNCH) outcomes in resource-limited settings.

Mobilising community health volunteers (CHVs) to promote MNCH offers a promising strategy to reduce health inequities.[6–8] In 2006, the Republic of Kenya Ministry of Health (MOH)'s 'Kenya Essential Package for Health' delineated a comprehensive strategy to improve the health of households and communities, commonly known as the 'Community Health Strategy' (CHS).[9] Under the current CHS, CHVs are expected to perform monthly, individual home visits for all pregnant women during pregnancy and throughout the first year postpartum.[10] Despite these efforts, the practice of MNCH interventions associated with reductions in mortality and morbidity (ie, facility-based deliveries with skilled birth attendants) are well-below projected targets to substantively reduce the MMR and IMR.[1] These gaps are pronounced across socioeconomic and geographic strata with women in poorer, rural communities experiencing significantly worse outcomes than those in wealthier, urban centres.

The WHO recommends integrating lay health workers, including CHVs, to promote MNCH interventions.[11] Coupling this strategy with the delivery of group-based women's health education may improve MNCH; however, evidence from sub-Saharan Africa is limited.[12] Aggregate data from cluster-randomised and quasi-randomised trials from Nepal, India, Bangladesh and Malawi underscore the value of community-centred, group-based health promotion to improve maternal and newborn care.[13] Though causal mechanisms to explain the benefit of group-based interventions remain speculative, fostering mechanisms for peer accountability and support may play a significant role.[14]

In 2012, the Academic Model Providing Access to Healthcare (AMPATH)—a long-standing partnership between the Kenyan MOH, Moi University, Moi Teaching and Referral Hospital and North American universities—launched Chamas for Change (Chamas). This programme leveraged the success of existing group-based health education models in an effort to improve MNCH in Kenya as well as generate evidence to support these interventions in sub-Saharan Africa. Chamas is a CHV-led, group-based health education programme that supports women during the first 1000 days of life (ie, pregnancy, infancy and toddlerhood). The programme hybridises best practices from resource-limited settings globally to offer a community-based, multipronged strategy for improving MNCH. This strategy focuses on providing health education, a peer-supportive environment and opportunities to access financial capital to promote MNCH while simultaneously addressing inequities that perpetuate poor outcomes.

A pilot study investigating first-year Chamas participation demonstrated significant associations between participation and the likelihood of practising positive MNCH behaviours such as delivering in a health facility with a skilled birth attendant.[15] To validate whether first-year Chamas participation is positively associated with health facility delivery and the practice of other key MNCH interventions, we conducted a large-scale cluster randomised controlled trial in rural western Kenya. We hypothesised women participating in Chamas would be more likely to deliver in health facilities than those receiving individual, home-based visits (standard of care).

METHODS

Study design

We conducted a two-arm cluster randomised controlled trial in 74 community health units (CUs) across four subcounties (Cherangany, Kwanza, Kiminini and Saboti) in Trans Nzoia County, Western Province, Kenya (figure 1). Figure 1 depicts these 74 CUs allocated to control and intervention trial arms. Cluster randomisation was used to avoid potential contamination of intervention activities between neighbouring villages. Additional study details are available in our trial protocol (online supplemental trial protocol). We obtained written informed consent from all participants prior to data collection. We adhered to Consolidated Standards of Reporting Trials guidelines for reporting results of cluster randomised controlled trials (online supplemental CONSORT checklist).

Participants

We identified 77 CUs among 163 total CUs across our four selected subcounties in Trans Nzoia to serve as

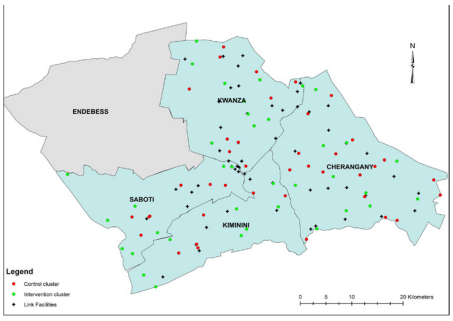

Figure 1 Cluster map.

potential clusters. CUs are geographically defined health service delivery areas, 5–8 km^2 in size, for populations of 5000 people supervised by Community Health Extension Workers (CHEWs) and CHVs. CHEWs and CHVs connect CUs with their assigned health facilities (or 'link facilities'), extending services traditionally based at facilities to the household level. CHVs are nominated members of their communities who serve as liaisons between community members and the health sector. CHEWs are salaried frontline health workers responsible for supervising CHVs. CUs selected for this trial were specifically chosen as their CHVs received formal CHS training from AMPATH.

We recruited participants from 60 public and private health facilities linked to our 77 identified CUs. Pregnant women who were less than or equal to 32 weeks gestation, presenting for their first antenatal care (ANC) visits and residing in one of the 77 CUs were eligible. Among 77 identified CUs, 74 were represented by women deemed eligible for participation. We selected a gestational age cut-off of 32 weeks as the majority (96.0%) of Kenyan women who seek ANC at any point during pregnancy present for at least one ANC visit by this time.[1] Due to slow recruitment resultant of preceding health worker strikes in Trans Nzoia, we increased our original gestational cut-off from 28 to 32 weeks.

Randomisation and masking

We randomised CUs selected to serve as clusters 1:1 to intervention (eg, Chamas programme) or standard of care (eg, monthly CHV home visits). The trial data manager used a simple random allocation sequence generated by PASS V.11.0.10) to designate cluster assignment. Non-study CUs (ie, those not randomised in this trial) served as buffer zones between intervention and control clusters to avoid contamination. There was no stratification or matching. We masked data collectors (trained AMPATH research assistants), investigators and analysts to cluster allocation throughout the trial; however, both arms were identifiable to participants and CHVs by design.

Procedures

Data collectors assessed women for eligibility at their first ANC visit. Women deemed eligible and willing to participate provided consent to be contacted for enrolment. The data manager generated lists of participants organised by residential CUs. These lists were subsequently distributed to CHVs who were tasked with finding women in their respective CUs and enrolling them. Data collectors accompanied CHVs during this process and obtained baseline data at enrolment. One week following the end of the enrolment period, the data manager randomised all CUs to intervention and control arms. Three weeks later, CHVs began facilitating *Chamas* in intervention clusters.

Intervention clusters participated in the Chamas programme (programme details are published elsewhere).[15] Briefly, Chamas is a group-based, CHV-led health education programme that supports women during the first 1000 days of their child's life. Women randomised to the intervention arm participated in *Chamas* in lieu of receiving individual home visits (standard of care). Participants attend 60–90 min sessions two times a month, which include discussions on health and social topics relevant to antenatal, postpartum and early childhood experiences. CHVs use an illustrated flip chart with evidence-based, structured discussion guides to facilitate lessons. Groups are typically comprised of 15–20 women, two CHV facilitators and two mentor mothers (eg, postmenopausal women who have completed child rearing). The first year of the curriculum promotes behaviours associated with demonstrated reductions in maternal and infant morbidity and mortality. These lessons purposefully mirror health topics that CHVs are expected to promote during home visits under the CHS. Following each lesson, women are invited to participate in an optional table-banking programme called Group Integrated Savings for Health and Empowerment (GISHE). GISHE participation is optional so as not to deter women without financial means to contribute to group savings from joining Chamas. Women are encouraged to use savings generated by GISHE to finance health interventions (eg, enrol in health insurance, pay for transportation to health facilities), invest in early childhood education and/or start small businesses.

Strategies to ensure fidelity of Chamas included: using standardised intervention materials (ie, printed curriculum flipcharts), hosting structured CHV training sessions preceding the trial, offering monthly supervision by study staff and designating at least two trained CHVs to every group to avoid potential disruptions due to illnesses or job transfers. In addition to attending the 4-day MNCH refresher training, CHVs facilitating Chamas also received a formal 2-day orientation to the programme and were trained in group facilitation techniques. We provided scheduled support sessions for CHV facilitators throughout the trial (during months 1–3, 6, 9 and 12), which provided opportunities for feedback and communal troubleshooting to enhance programme delivery.

Control clusters had monthly CHV home visits during pregnancy and postpartum, as recommended by the Kenyan CHS standard of care.[10] During monthly visits, CHVs collect basic health information, identify antenatal

and early postpartum danger signs, refer individuals to care and aid in infant growth monitoring. CHVs are also expected to encourage women to adopt the same key health behaviours promoted in Chamas. CHVs working within control clusters received oversight and supervision from CHEWs, as structured by the CHS. CHVs performing door-to-door visits typically oversee a catchment of 15 women who are each visited for 20–30 min on a monthly basis (up to 7.5 hours per month). Those facilitating Chamas substituted door-to-door visits with group sessions; as such, their volunteer effort was reduced to two 60–90 min sessions per month (up to 3 hours per month).

We did not provide incentives (monetary or other) for participation to CHVs, CHEWs or participants in either study arm at any point during the trial. CHEWs continued to receive salaries from the MOH and CHVs, who volunteer in addition to participating in other jobs (ie, as teachers, farmers, labourers), continued to work throughout the trial. Notably, CHVs under the current CHS are not financially compensated for performing door-to-door visits. To reduce potential for confounding, we similarly did not compensate CHVs for facilitating Chamas meetings. We did, however, reimburse all CHVs and CHEWs for travel to meetings and trainings as well as for air-time used to contact participants during recruitment.

Outcomes

We measured outcomes at the individual level. We selected facility-based delivery as our primary outcome because of the significant association between institutional delivery and reductions in maternal and infant morbidity and mortality.[16–18] Secondary outcomes included: attending adequate ANC (defined as attending at least four visits per Republic of Kenya MOH guidelines), receiving a 48-hour postpartum home visit, exclusively breastfeeding for 6 months, adopting a modern contraceptive method, immunising infants with the oral polio vaccine within 2 weeks postpartum, immunising infants with the measles vaccine (measles I) by 12 months of age and completing the infant immunisation series per WHO and Republic of Kenya MOH standards by 12 months of age.[19–21] We additionally collected detailed microfinance data as well as validated questionnaire data on perceived levels of peer support and financial empowerment, which we plan to report in future articles.

Data collectors travelled to participant homes to collect end-line data 12 months following the initiation of Chamas sessions and home visits. Outcome measures were self-reported with the exception of infant immunisations, which were extracted from standard MOH Maternal Child Health Booklets kept by mothers. All data were recorded using electronic, standardised questionnaires. We classified participants as lost to follow-up after we made three attempts to establish contact over a 2-week period. We conducted abbreviated phone surveys if participants relocated outside of Trans Nzoia County; these abbreviated questionnaires omitted questions on infant immunisations.

At enrolment, we collected baseline participant sociodemographic (age, marital status, maternal education, occupation, poverty probability index scores, insurance status) and reproductive health (previous pregnancy and related outcomes) data. We used the Kenya 2015 Poverty Probability Index (PPI) questionnaire and national poverty line scorecard to estimate participants' poverty likelihood at baseline.[22] We recorded attendance at each Chamas session to track individual programme participation. A Data and Safety Monitoring Board recorded and investigated adverse events including CHV-reported participant mortalities as well as the cause of death (if known).

Statistical analysis

We estimated sample size using methods described by Rutterford *et al* for a proposed mixed effects regression analysis[23] using derived baseline estimates.[1 15] Assuming a mean cluster size of 20 individuals, 77 clusters (equally allocated between arms), intracluster correlation coefficient (ICC) of 0.44 (based on pilot data)[15] and 20% attrition, we calculated that a total of 1280 individuals would be needed to detect a 4.7% risk difference (RD) (difference in the rate of facility-based birth at the county vs national-level[1] with 80% power at a (two-tailed) significance level of 0.05). To determine our recruitment timeline, we assumed 6.3% of all women of reproductive age would be pregnant at any given time (or roughly 50 women per CU annually).[1] We determined an enrolment period of roughly 3–4 months adequate to recruit our estimated sample size.

Our primary analyses were intention-to-treat (ITT) and included all participants from randomised clusters who provided baseline and 12-month follow-up data, regardless of the level of participation in Chamas. We summarised all demographic and reproductive health history information between arms with means and SDs as well as medians and IQRs for continuous variables and counts and percentages for categorical variables. We analysed the primary outcome with multilevel logistic regression with a random intercept for cluster, and effects are presented as RDs with 95% bootstrap CIs and ORs with 95% Wald-type confidence intervals and p values. We also report the ICC. We analysed secondary outcomes similarly.

For both primary and secondary outcomes, we conducted several sensitivity analyses. First, to assess the impact of missing outcomes due to loss to follow-up, we used multiple imputation with 10 data sets with the 'jomo' algorithm to account for the multilevel structure of the data; results were then combined using Rubin's rules.[24 25] Second, to assess the possible impact of differences in factors known to be associated with care-seeking behaviours between arms, we adjusted our primary models for PPI score, marital status, null parity and health insurance at time of delivery. A third sensitivity

analyses combined adjustment and imputation. Finally, we performed a sensitivity analysis restricting our intervention sample to women who attended at least one Chamas session during the trial period.

We assessed the effect of Chamas participation on infant vaccination outcomes similarly, but given the large amount of missing data, no sensitivity analyses with imputation were conducted. Adjusted models for vaccination included maternal education, PPI and insurance at delivery as previous studies demonstrate strong associations between these sociodemographic factors and immunisation adherence.[26] Further, since vaccination data were missing in approximately 40% of the sample, we were concerned about selection bias in those reporting the outcome. To account for this, we carried out an additional sensitivity analysis to indicate the amount of unmeasured confounding between trial arm and vaccination that would be needed to explain away the observed differences.[27]

There were no interim analyses. We developed, finalised and signed a statistical analysis plan prior to beginning data analysis [online supplemental statistical analysis plan]. Statistical significance was set at 0.05 and all analyses were conducted using R statistical software (V.3.5.3).[28]

Patient and public involvement

We sought and incorporated feedback from a multidisciplinary study advisory committee including direct beneficiaries (ie, participating women, CHVs) and key stakeholders (ie, local community leaders, Kenyan MOH representatives) in the initial design and conception of this trial. We designed our questionnaires, data instruments and intervention activities based on qualitative feedback provided by programme participants during Chamas pilot studies. These qualitative questionnaires captured participant perceptions of the strengths and weaknesses of the programme as well as priority areas for continued improvement. Prior to initiating trial activities, we invited CHVs, CHEWs, health facility managers, subcounty MOH representatives and community leaders to stakeholder meetings to explain the study's purpose and procedures as well as to facilitate understanding of our trial objectives among leadership at the county, subcounty and community levels. Following these meetings, we asked community leaders for permission to begin enrolling participants. All CHVs who agreed to participate also attended a 4-day refresher training on their roles and expectations in promoting MNCH under the Kenyan CHS. We discussed the trial's risks and benefits with all participants before enrolment, including demands on individual time due to programme participation and data collection. We obtained written informed consent from all participants prior to data collection. At the trial's conclusion, we verbally disseminated our preliminary findings to the programme's direct beneficiaries and key stakeholders. We plan to additionally distribute printed summaries of key findings following the trial's publication.

Role of the funding source

The funders had no role in the research design, collection, analysis or interpretation of data, writing this report or the decision to submit this manuscript for publication. The corresponding author had full access to all data in the study as well as final responsibility for the decision to submit this manuscript for publication.

RESULTS

Details of our enrolment and inclusion procedures are summarised in figure 2**.** Between 27 November 2017 and 8 March 2018, we assessed 4235 women for eligibility; 2923 women from 74 clusters met criteria and agreed to be contacted. Three of the original 77 identified clusters did not have eligible participants. CHVs successfully contacted and enrolled 1920 eligible women from 74 community clusters (996 participants in 37 intervention and 924 in 37 control clusters). We collected follow-up data on all clusters between 7 April 2019and 3 July 2019. A total of 1550 (80.7%) participants completed the study at 12-month follow-up: we included 822 in the intervention (82.5%) and 728 in the control (78.8%) arms for analysis. Among 822 intervention participants who completed the study, 599 (72.9%) attended at least one Chamas session. Among those who attended, mean attendance was 12 (SD 7.8) of 24 total sessions and 48.9% participated in GISHE. Among controls, the mean number of CHV home visits received was 9 (SD 2.3) of 12 total visits. Participants lost to follow-up were similar in number across study groups and attrition was not significantly associated with sociodemographic or reproductive health characteristics (online supplemental table S2). Notably, those lost to follow-up tended to have lower PPI scores than women who completed the trial.

Participants who completed the study (n=1550) were similar in baseline characteristics (table 1). Most participants were married, unemployed, completed primary school, possessed health insurance at the time of delivery and carried a previous pregnancy. The median gestational age at enrolment was 22 weeks (IQR 17, 25). The mean PPI score for our study population was 55.13 (SD 20.11); PPI scores differed across study arms with higher values among control compared with intervention participants at baseline. Cluster-level demographics were also well balanced. Across all clusters, CHVs possessed a mean 11.69 (SD 6.32) years of experience. Finally, in the intervention arm, we noted geographic differences among women who attended Chamas and those who never attended (online supplemental table S3).

Primary and secondary outcomes are summarised in table 2. The overall proportion of health facility delivery was higher among intervention (80.9%, 653 participants) than control participants (73.0%, 514 participants). Among women who did not deliver in a health facility (n=383), the most commonly cited reasons across cohorts included: preference to deliver at home or with a traditional birth attendant (32.1%), structural challenges

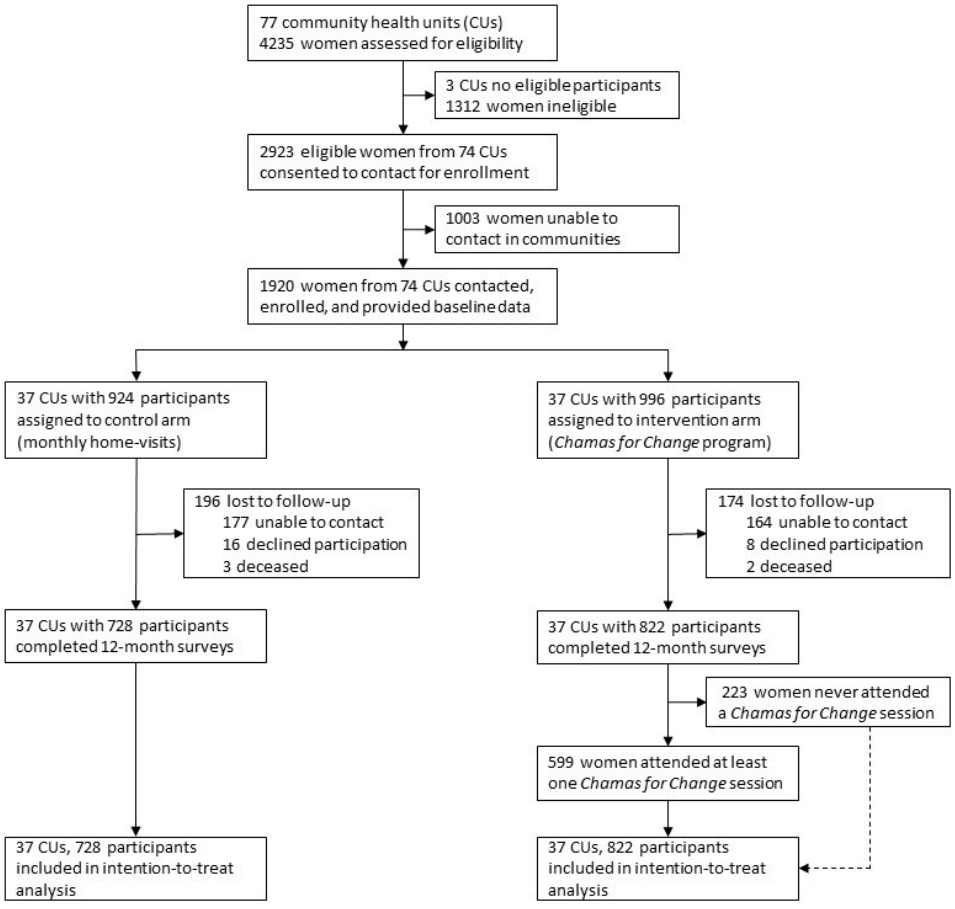

Figure 2 Trial profile.

associated with reaching a health facility (eg, too far, poor road conditions) (32.1%) and medical emergencies (eg, abrupt labour with not enough time to travel) (11.5%). In unadjusted models, we estimated a 7.4% (95% CI 3.0 to 12.5) improvement in facility-based deliveries (OR=1.58, 95% CI 0.97 to 2.55, p=0.057). Following adjustment and adjustment with imputation, this improvement was slightly attenuated to 6.4% (95% CI 2.0 to 10.4) and 7.1% (95% CI 3.0 to 11.4), respectively adjusted OR ((aOR)1=1.59 95% CI 1.02 to 2.47, p=0.042; aOR2=1.62 95% CI 1.06 to 2.49, p=0.004) (online supplemental table S3). Further, a sensitivity analysis restricting the intervention sample to women who attended Chamas at least once attenuated improvement in facility-based delivery by 5.2% (95% CI 1.5 to 9.5) (OR=1.43 95% CI 0.92 to 2.24, p=0.11) (online supplemental file 4online supplemental file 4). We observed a relatively large amount of cluster heterogeneity as indicated by an ICC of 0.18 (figure 3).

We examined the effect of Chamas participation on secondary MNCH outcomes associated with demonstrated reductions in maternal and infant morbidity and mortality. Women in Chamas clusters improved in 48-hours postpartum visits (RD 15.3%, 95% CI 12.0 to 19.6), exclusive breastfeeding (RD 11.9%, 95% CI 7.2 to 16.9) and contraceptive adoption (RD 7.2%, 95% CI 2.6 to 12.9) compared with controls (table 2). Though not statistically significant, the RDs in achieving adequate ANC and adopting a long-acting method of contraception (ie, intrauterine device or implant) were also greater among Chamas participants. Restricting our intervention sample to women who attended Chamas at least once accentuated improvements in 48 hours postpartum visits adjusted RD ((aRD) 19.6%, 95% CI 14.4 to 25.0) and exclusive breastfeeding (aRD 13.6%, 95% CI 7.8 to 19.8); conversely, we observed an attenuated effect with this restriction on contraceptive adoption (aRD 5.7%, 95% CI 0.7 to 11.1) (online supplemental table S4). Other sensitivity analyses did not meaningfully change results (online supplemental table S4).

We additionally assessed infant immunisation outcomes among live infants at follow-up. Infants born to women in Chamas demonstrated significant improvements in receiving the measles I vaccine by 12 months of age (RD 13.2%, 95% CI 9.1 to 18.4) and completing the recommended infant immunisation series per WHO (RD 15.6%, 95% CI 11.5 to 20.9) and Republic of Kenya MOH (RD 15.1%, 95% CI 10.4 to 20.3) guidelines (table 3). These results were unchanged after adjusting for covariates (online supplemental table S4). We estimated an unmeasured confounder (due to selection bias in those that reported the outcome) associated with both increased rate of vaccination and enrolment in intervention trial arm (compared with control) by 30% would

Table 1 Baseline characteristics for intention-to-treat population (74 clusters, n=1550)

	Control (N=728)	Intervention (N=822)	Overall (N=1550)
N clusters	37	37	74
Total population	198288	226930	45218
Women of reproductive age (15-49)	45433	47279	92712
Geographic distribution			
Rural	33	32	65
Peri-urban	3	3	6
Urban	1	2	3
CHV experience (years)	11.73 (6.78)	11.67 (6.13)	11.69 (6.32)
Maternal age	26.63 (6.21)	27.10 (6.55)	26.88 (6.40)
Gestational age (weeks) at enrolment, median (IQR)	22 (18, 25)	22 (18, 25)	22 (18, 25)
Marital status			
Divorced/separation	11 (1.5%)	17 (2.1%)	28 (1.8%)
Married	606 (83.2%)	686 (83.5%)	1292 (83.4%)
Single	109 (15.0%)	115 (14.0%)	224 (14.5%)
Widowed	2 (0.3%)	4 (0.5%)	6 (0.4%)
Maternal education			
College or higher	91 (12.5%)	46 (5.6%)	137 (8.8%)
Secondary or postprimary	211 (29.0%)	250 (30.4%)	461 (29.7%)
Primary	313 (43.0%)	420 (51.1%)	733 (47.3%)
Preprimary or none	113 (15.5%)	102 (12.4%)	215 (13.9%)
Missing	0 (0.0%)	4 (0.5%)	4 (0.3%)
Occupation			
Contract/temporary worker	49 (6.7%)	48 (5.8%)	97 (6.3%)
Permanently employed	22 (3.0%)	10 (1.2%)	32 (2.1%)
Self-employed	201 (27.6%)	247 (30.0%)	448 (28.9%)
Unemployed	456 (62.6%)	516 (62.8%)	972 (62.7%)
Missing	0 (0.0%)	1 (0.1%)	1 (0.1%)
Health insurance coverage at time of delivery			
Yes	412 (56.6%)	519 (63.1%)	931 (60.1%)
No	285 (39.1%)	285 (34.7%)	570 (36.8%)
Missing	31 (4.3%)	18 (2.2%)	49 (3.2%)
Poverty probability index score*	56.79 (20.69)	53.61 (19.45)	55.13 (20.11)
% poverty likelihood at national poverty line	22.6%	25.7%	24.6%
Subcounty			
Cherangany	229 (31.5%)	211 (25.6%)	440 (28.4%)
Kiminini	145 (19.9%)	172 (20.9%)	317 (20.5%)
Kwanza	193 (26.5%)	216 (26.2%)	409 (26.4%)
Saboti	161 (22.1%)	223 (27.1%)	384 (24.8%)
Previously pregnant	584 (80.2%)	623 (75.8%)	1207 (77.8%)
Parity	2.29 (1.62)	2.58 (1.57)	2.35 (1.56)
Previous modern contraceptive use			
Yes	322 (55.1%)	381 (61.2%)	703 (58.2%)

Continued

Table 1 Continued

	Control (N=728)	Intervention (N=822)	Overall (N=1550)
No	214 (36.6%)	210 (33.7%)	424 (35.1%)
Missing	48 (8.2%)	32 (5.1%)	80 (6.6%)
Previous facility delivery			
Yes	228 (39.0%)	279 (44.8%)	507 (42.0%)
No	162 (27.7%)	161 (25.8%)	323 (26.8%)
Missing	194 (33.2%)	183 (29.4%)	377 (31.2%)
Total ANC visits in previous pregnancy			
0	6 (1.0%)	21 (3.4%)	27 (2.2%)
1	18 (3.1%)	22 (3.5%)	40 (3.3%)
2	29 (5.0%)	39 (6.3%)	68 (5.6%)
3	119 (20.4%)	128 (20.5%)	247 (20.5%)
4	135 (23.1%)	172 (27.6%)	307 (25.4%)
>4	74 (12.7%)	54 (8.7%)	128 (10.6%)
Missing	203 (34.8%)	187 (30.0%)	390 (32.3%)
Previous†			
Miscarriage	23 (3.9%)	26 (4.2%)	49 (4.1%)
Stillbirth	9 (1.5%)	16 (2.6%)	25 (2.1%)
Neonatal death	8 (1.4%)	5 (0.8%)	13 (1.1%)
Infant death	8 (1.4%)	5 (0.8%)	13 (1.1%)
Child death under 5	6 (1.0%)	2 (0.3%)	8 (0.7%)
Child death over 5	3 (0.5%)	2 (0.3%)	5 (0.4%)

*Scores and % poverty likelihood calculated using validated 2015 Kenya Poverty Probability Index.
†Miscarriage (up to 28 weeks gestation); stillbirth (after 28 weeks gestation); neonatal death (0–28 days old); infant death (1–12 months old); child death (1–5 years old).
ANC, antenatal care; CHV, community health volunteer.

be required to explain away these observed significant differences.

Maternal and infant mortality and morbidity outcomes are presented in table 4 with no significant differences between trial arms; however, the trial was not powered to detect differences in these relatively rare outcomes. Overall, we observed a protective effect of Chamas participation against maternal (RD −4.7%, 95% CI −9.4 to 0.1) and infant (RD −3.9%, 95% CI −8.6 to 0.3) morbidity. We recorded five participant mortalities during the trial (two in intervention and three in control). Three deaths were attributed to maternal causes of mortality, notably: one due to obstructed labour, one due to postcaesarian infection and one due to eclampsia; the remaining

Table 2 Primary and secondary outcomes: facility-based delivery, care seeking and vaccination

	Control‡	Intervention‡	Risk difference (95% CI)	Odds ratio (95% CI)	P value*
Facility-based delivery	514 (73.0%)	653 (80.9%)	7.4% (3.0% to 12.5%)	1.58 (0.969 to 2.55)	0.057
Adequate ANC care†	507 (69.6%)	587 (71.4%)	3.2% (-1.5% to 7.7%)	1.18 (0.82 to 1.68)	0.375
Postnatal CHV visit	97 (13.6%)	241 (30.1%)	15.3% (12.0% to 19.6%	3.22 (1.50 to 6.93)	0.003
Exclusive breast feeding for 6 months	383 (56.7%)	521 (67.2%)	11.9% (7.2% to 16.9%)	1.77 (1.12 to 2.80)	0.014
Contraceptive use	472 (65.5%)	581 (71.8%)	7.2% (2.6% to 12.9%)	1.41 (1.03 to 1.93)	0.034
Long-acting reversible contraceptive use	242 (51.3%)	326 (56.1%)	7.1% (0.9% to 13.3%)	1.34 (0.95 to 1.91)	0.099

*P value is for OR from mixed effect logistic regression.
†Adequate ANC care is defined as attending at least four ANC visits per Republic of Kenya Ministry of Health guidelines.
‡Denominators are based on number of women reporting the particular outcome. See Online supplemental table S1 for details.
ANC, antenatal care; CHV, community health volunteer.

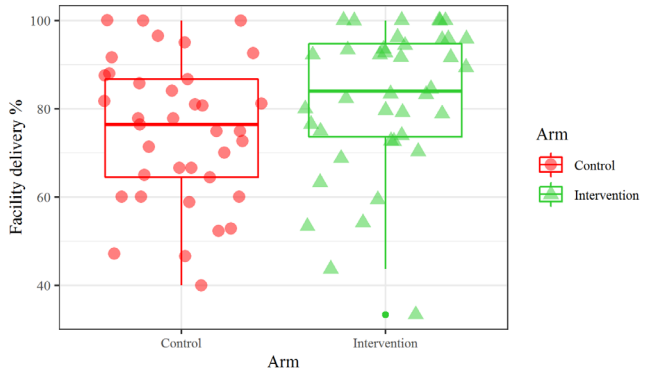

Figure 3 Cluster outcome rates.

two deaths were attributed to complications of cervical cancer. None of these mortalities was directly associated with trial participation. Across both trial arms, we recorded 43 perinatal deaths (ie, deaths during the first week of life), 15 neonatal deaths and 25 infant deaths.

DISCUSSION

In Kenya and other resource-limited settings, effective community-based strategies are increasingly needed to reduce maternal and infant deaths. Encouraging facility-based delivery is one well-known and highly effective strategy to achieve this goal.[29] Despite government-led initiatives that support access to health services—such as the CHS and elimination of delivery-related fees at public facilities announced in 2013—facility-based deliveries nationally (61.2%) and in our study area (56.5%) are still lower than needed to sufficiently reduce the MMR and IMR.[1 30] Against this backdrop of underused intrapartum services, we rigorously tested a community-based women's health education programme designed to improve facility-based deliveries and other MNCH practices. We evaluated outcomes in an ITT sample derived from a geographically diverse catchment area. These analyses produced findings that mimic real-world scenarios in which perfect programme attendance is unlikely. We found that facility-based delivery and other key MNCH practices significantly improved in the intervention arm, supporting our hypothesis.

During the past decade, community health workers have emerged as a focal point of global discussions about advancing primary healthcare systems.[6] There is substantial evidence to support the integration of these workers in the delivery of preventive MNCH interventions including, but not limited to: malaria prevention, health education, breastfeeding promotion, essential newborn care and psychosocial support.[7] Leveraging a well-trained, community-based, health worker corps to mobilise preventive health measures has demonstrated promising reductions in maternal and neonatal mortality, particularly in LMIC contexts; however, much of the existing literature focuses on door-to-door as opposed to group-based delivery models.[8]

Chamas expands on this existing community infrastructure to attempt to reach some of the most vulnerable members of Kenyan society—pregnant and postpartum women in poor, rural communities. The CHS provided an established workforce of trained CHVs who—with bolstered support, supervision and mechanisms to increase work efficiency—significantly improved MNCH outcomes. Notably, CHVs facilitating Chamas spent fewer volunteer hours than counterparts performing door-to-door visits (3 vs 7.5 hours); moreover, women participating in Chamas achieved a greater number of total visits (12 vs 9 CHV contacts) than those visited at home. Several CHV-related barriers to effective implementation of the current CHS model have been identified, including: the absence of consistent supervision, inadequate health training, poor linkages to health facilities, lack of accountability and absence of remunerative pay.[31] Our data support that by providing CHVs with additional oversight, a structured curriculum and an opportunity to economise their time through a group-based delivery model, the Chamas programme helped narrow the margin between aspirational and achievable MNCH improvements.

Moreover, we recognise that opportunities for CHV financial remuneration are critical to ensuring the

Table 3 Infant immunisation outcomes

	Control†	Intervention†	Risk difference (95% CI)	Odds ratio (95% CI)	P value*
Infants who received OPV 0 within 2 weeks of birth	341 (64.6%)	361 (66.0%)	1.7% (-3.6% to 8.4%)	1.08 (0.77 to 1.51)	0.663
Infants who received measles I by 12 months of age	328 (74.0%)	339 (87.6%)	13.2% (9.1% to 18.4%)	2.71 (1.45 to 5.04)	0.002
Fully immunised infants (≤12 months) per WHO standards	324 (73.6%)	352 (88.9%)	15.6% (11.5% to 20.9%)	3.52 (1.74 to 7.12)	<0.001
Fully-immunised infants (≤12 months) per Republic of Kenya MOH standards	320 (73.1%)	348 (87.7%)	15.1% (10.4% to 20.3%)	3.16 (1.61 to 6.21)	<0.001

*P value is for OR from mixed effect logistic regression.
†Denominators are based on number of women reporting the particular outcome. See online supplemental table S1 for details.
OPV, oral polio vaccine.

Table 4 Maternal and infant mortality and morbidity outcomes

	Control	Intervention	Risk difference (95% CI)	OR (95% CI)	P value*
Maternal mortality	3 (<0.1%)	2 (<0.1%)	–	–	–
Maternal morbidity†	136 (18.7%)	110 (13.4%)	−4.7% (-9.4% to 0.1%)	0.68 (0.42 to 1.10)	0.118
Miscarriage	16 (2.2%)	13 (1.6%)	−0.2% (−1.3% to 0.8%)	0.85 (0.30 to 2.38)	0.751
Stillbirth	16 (2.2%)	12 (1.5%)	−0.6% (−1.7 to 0.3%)	0.64 (0.27 to 1.56)	0.331
Perinatal death‡	22 (3.1%)	21 (2.6%)	−0.5% (−1.9% to 0.8%)	0.83 (0.42 to 1.66)	0.601
Neonatal death	6 (0.87%)	9 (1.13%)	0.2% (−0.6% to 0.7%)	1.29 (0.39 to 4.29)	0.674
Infant death	13 (1.9%)	12 (1.5%)	−0.2% (−1.3% to 0.8%)	0.83 (0.27 to 2.5)	0.689
Low birth weight	118 (16.0%)	157 (18.9%)	1.9% (−1.6% to 5.6%)	1.16 (0.70 to 1.90)	0.570
Infant morbidity§	132 (18.68%)	118 (16.74%)	−3.9% (−8.6% to −0.3%)	0.76 (0.51 to 1.15)	0.194

*P value is for OR from mixed effect logistic regression.
†Maternal morbidity defined as any health condition attributed to and/or aggravated by pregnancy and childbirth that has a negative impact on the woman's well-being, including the following complications: miscarriage (<28 weeks), stillbirth (>28 weeks), gestational diabetes, preeclampsia, eclampsia, postpartum infection, postpartum haemorrhage, or obstructed labour.
‡Perinatal deaths (first week of life), neonatal deaths (through 28th day of life), infant deaths (through first year of life).
§Infant morbidity defined as any health condition that affects mortality rate during the first-year of life including low birth weight (<2.5 kg), perinatal disorders (gestational diabetes, preeclampsia, eclampsia), infant immunisation adherence, exclusive breastfeeding, and delivery-related complications (obstructed labour, neonatal resuscitation).

sustainability of this programme and plan to prioritise this in future attempts to scale. Globally, several national governments—including Brazil, Pakistan, Ethiopia and India—have made concerted efforts to move away from the traditional CHV role as an unpaid, lightly trained member of the community and instead towards creating a highly skilled, compensated health worker capable of providing treatments and implementing preventive health measures.[32] We anticipate that financial support—in conjunction with advancements in training and ongoing community involvement—will catalyse even greater success for the Chamas programme. We plan to achieve this vision by continuing our close collaboration with the Republic of Kenya MOH to advocate for increased allocation of local and national funds to bolster community health infrastructure as well as by encouraging MOH representatives to integrate Chamas within existing health strategies.

Our intervention approach—group-based women's health education delivered by CHVs during pregnancy and postpartum—champions a theory of change that prioritises three key areas: (1) empowering women with health and social literacy, (2) establishing a network of supportive peers and (3) providing women with an opportunity to gain financial capital (GISHE). This third component is distinct from preceding strategies that promote a group-based, lay health worker-led model for MNCH.[12] We suspect this multipronged approach that prioritises these three critical components, in addition to leveraging an established CHV workforce, plays a significant role in enhancing positive outcomes. Evidence suggests peer support and peer accountability may enhance the likelihood of practicing positive health behaviours.[14] Further, there is a growing body of evidence that suggests coupling health education with microfinance may improve women's health; however, most literature on associated reproductive health outcomes focus on contraceptive uptake and adherence to HIV/AIDS treatment.[33] Among group members who participated in GISHE, we speculate the opportunity to generate savings likely served a dual purpose of motivating Chamas attendance while helping some participants overcome financial barriers to accessing care. Future analyses will attempt to dissect the influence of each of these components on overall programme success. Finally, while most programmes intervene during distinct time periods (eg, prenatal, intrapartum), Chamas embraces a life-course approach by engaging women throughout the first 1000 days of their child's life. We anticipate families who continue in Chamas likely experience health and social benefits throughout subsequent years. These effects are largely unexplored and will be the focus of future trials.

Preceding trials have examined the effect of similar community-based women's health education groups on key MNCH behaviours, including facility-based delivery.[12] A meta-analysis combining results from seven cluster randomised controlled trials conducted in resource-limited settings (ie, Nepal, Bangladesh, Malawi and India) found no evidence of intervention effects on facility-based delivery (OR 1.02, 95% CI 0.93 to 1.12; I^2=21.4%, 95% CI 0 to 65.8%); similarly, these analyses revealed no evidence of effect on uptake of ANC or exclusive breastfeeding.[12] Although data comparability is limited by differences in trial design, setting and programme structure (ie, absence of table banking), we observed significantly higher odds of facility-based delivery and exclusive breastfeeding in the intervention arm. Our findings strengthen evidence from an earlier Chamas pilot that similarly demonstrated increased odds of achieving these outcomes compared with the standard of care in rural

western Kenya.[15] Collectively, these findings highlight our intervention's potential to improve MNCH outcomes by leveraging existing community health resources and infrastructure in settings like Kenya.

This work has several limitations. First, by focusing our recruitment effort at the facility level, we limited our sample to women attending ANC visits. Though the majority (96.1%) of Kenyan women attend at least one ANC visit during their pregnancy, this estimate is likely lower among rural communities with poorer access to care.[1] Future studies will ideally combine both facility and community-based recruitment strategies to foster a more inclusive cohort. Second, we experienced significant recruitment challenges that substantially reduced our sample size. Processes to contact eligible participants outside of health facilities proved arduous and complicated as locator data (eg, home address, phone number) were often unreliable. This loss to follow-up between health facilities and the community likely introduced selection bias as we suspect women were not missing at random. It is possible these missing data reflect an inability to pay for cell phones (or data) or perhaps limited access in rural, hard-to-reach communities; thus, we may have failed to enrol some of the most socioeconomically disadvantaged members of these communities. These challenges highlight a need to not only improve our strategy but also to strengthen continuity to ensure vulnerable members of society are accounted for. Third, large amounts of missing data compromised the interpretability of certain outcomes, most notably infant immunisations. Despite established processes to monitor data quality, data collectors reported several challenges that compromised questionnaire completion. Obstacles included interruptions due to competing obligations (ie, child care) and lack of a private interview setting. Further, relatively few participants possessed MOH Maternal Child Health booklets and among those who had them, few recorded data. This limitation may have introduced selection bias as mothers with completed records may have had greater access to or higher quality care. Alternatively, this could also reflect limited booklet availability, poor record-keeping or other structural limitations worthy of consideration. Fourth, we examined our primary outcome (facility-based delivery) as an aggregate measure, which limited our ability to discern where improvement occurred in the health system (ie, public vs private health sector). Future studies will collect detailed measures to clarify these data and guide targeted approaches to improving the health system at large. Finally, we observed a large amount of cluster heterogeneity indicating significant though anticipated community-level variation. Compositional effects within or between clusters such as proximity to health facilities, availability of service providers and fidelity of programme implementation may contribute to this variation. These effects may partly explain the unexpected attenuated difference in facility-based delivery in our sensitivity analysis of Chamas attendees. Clarifying community-level factors contributing to variable outcomes may help bridge these observed geographic disparities.

These limitations are balanced by several noteworthy strengths of our study. We detected significant results in our primary and secondary outcomes using an intention to treat approach. These observed effects were generally robust—for example, not meaningfully changed following adjustment or imputation in our sensitivity analyses. The cluster randomised controlled design, implemented in a large and geographically diverse population, enhances generalisability of these findings. We saw no contamination across trial arms and minimised potential for information bias by masking data collectors, investigators and analysts to cluster allocation throughout the trial. Further, by imposing relatively few exclusion criteria and a generous gestational age cut-off, we attempted to broaden inclusion to women who may have sought late ANC due to structural (eg, distance to facility) or behavioural (eg, delayed awareness of pregnancy) factors. Finally, it is worth noting that the proportion of facility-based deliveries, among other outcomes, was higher in both trial arms (80.9% intervention, 73.0% control) relative to county-level (56.5%) and national (61.2%) estimates.[1] It is possible study procedures—such as training, supervision or general awareness of the trial—led to CHVs in control CUs being more likely to deliver standard of care, which might explain these observations.

Chamas offers an innovative approach to improve MNCH in resource-limited settings with significant health policy implications. This intervention demonstrated significant improvements in MNCH outcomes relative to the current standard of care; policymakers should take note of this strategy as they attempt to improve current initiatives. Since the programme's inception, we have emphasised the importance of collaboration with and investment from key stakeholders, including but not limited to: women, community leaders, CHVs and MOH representatives at the county and national level. We respond to qualitative feedback from these stakeholders to ensure the programme iteratively responds to the needs of its beneficiaries and remains community driven. These commitments to collaboration and feedback inspire confidence in our programme's continued success. As we move towards scaling and integrating Chamas, our next steps will focus on addressing cost-effectiveness and enhancing adaptability to new settings.

Finally, though these results highlight Chamas' potential to improve uptake of life-saving MNCH interventions, we must acknowledge the importance of promoting both access to as well as delivery of high-quality care to achieve sustainable health outcome improvement. As the global community works towards integrating more effective and efficient mechanisms for improving health for our most vulnerable populations, it is critical to simultaneously bolster the quality of services provided. Motivating communities to practice behaviours will only prove successful if health facilities and local governments maintain a similar commitment towards providing

adequate staffing, maintaining supplies and promoting a welcoming environment for women. Our hope is that Chamas and other community-based programmes will support communities in demanding higher quality care and hold those in power accountable to strengthening systems for all women and children.

In summary, Chamas participation significantly improved MNCH outcomes compared with the standard of care in western Kenya. This trial contributes robust data from sub-Saharan Africa that strengthens evidence to support community-based, women's health education groups for MNCH in resource-limited settings.

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Competing interests None declared.

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Data availability statement The de-identified data set and a data dictionary will be made available upon reasonable request with publication of the trial. Inquiries can be made to the corresponding author of this manuscript (Dr Lauren Y. Maldonado, lymaldonado@mgh.harvard.edu).

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Chamas for Change: Validating the effect of a community-based women's health education program on facility-based delivery and other maternal, newborn, and child health outcomes

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Introduction

Worldwide, women and children in poor and rural communities face the challenges of pregnancy and infancy without supports in the home, community, or facility. Reflecting this, maternal mortality is the leading cause of death among women of childbearing age in Kenya and 1 in every 19 infants dies before their first birthday. Women bear the primary responsibility of gathering fuel, food and water as well as managing the livelihoods of their families. Thus, the majority of women struggle to care for their own and their children's health. Maintaining breastfeeding past the first few months is particularly challenging; exclusive breastfeeding (EBF) is uncommon, lasting a median of 2.6 months in Kenya. The protective effect of EBF on infant mortality is well established: an exclusively breastfed child is 14 times less likely to die in the first six months.[1] From an equity perspective, these figures are not evenly distributed across socioeconomic strata. Access to care is generally correlated with economic accessibility, and this is particularly true in Kenya. Poorer women have greater barriers to accessing care, receive lower quality care, and are disproportionately constrained by the demands of providing for their families.[2]

We seek to address the inequities that drive maternal and infant mortality in sub-Saharan Africa by validating an intervention that builds community empowerment in MNCH and facilitates processes of accountability using Community Health Volunteer (CHV)-led women's groups. ***Chamas for Change*** (*Chamas*) is a peer-support model that groups together pregnant women in the same community. Translated from kiswahili as 'groups', *chamas* have a longstanding presence in East Africa.[3] They are

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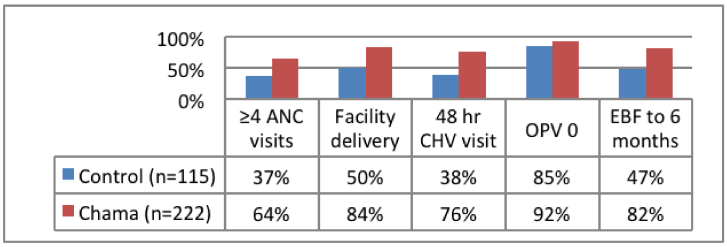
highly gendered institutions that women have relied on for survival to pool resources.[4] Using this existing cultural script, we have developed *chamas* tailored to the needs of pregnant women. Central to our approach is the integration of health, social and financial literacy education with a savings/loans program. *Chamas* are designed to improve MNCH by generating positive peer support for women to advocate for themselves and account for the care they receive. We combined best practices from women's health groups and microfinance programs to design an integrated service delivery platform that is low-cost, self-sustaining and self-managed. *Chamas* do not rely on a major financial institution to manage their funds or their group. They depend on women gaining the agency necessary to own their futures. Members become shareholders in each other's futures not only by the disbursement of loans but by keeping each other accountable to healthy practices and relationships for themselves and their families.

Background

In 2012, 32 Government of Kenya (GoK) CHVs recruited 400 pregnant and breastfeeding women to 16 *chamas* of 20-30 women. These groups met bi-weekly, employed participatory approaches to developing their group charter and were supported by local chiefs. Upon joining, women pledge to participate for one year and uphold the goals of the *chama*: support each other, save and become entrepreneurs, attend ANC, deliver in a facility, breastfeed exclusively (EBF) for 6 months, and adopt long-term family planning (FP). During meetings, women discuss social and health topics, learn accounting and safekeeping skills and receive mentorship from their peers to engage in income generating activities. Groups initiated in 2012 are currently in their fourth cycle (year), focusing on information and supports needed for child growth, education, development, positive parenting and relationship practices. Since 2012, this community strategy within Busia County has continued to recruit pregnant women each year. There are currently 68 CHWs that lead 42 groups, with 12 CHV service managers and 690 active members.



	≥4 ANC visits	Facility delivery	48 hr CHV visit	OPV 0	EBF to 6 months
Control (n=115)	37%	50%	38%	85%	47%
Chama (n=222)	64%	84%	76%	92%	82%

To evaluate the effect, acceptability, and sustainability of *chamas*, we performed a prospective cohort study. We compared data from 222 *chama* women and 115 non-*chama* women matched for age, parity, and location of prenatal care who were pregnant in 2012-13. Compared to controls, *chama* women were 73% more likely to attend 4 prenatal visits, 67% more likely to deliver in facility, 75% more likely to breastfeed exclusively to 6 months and 98% more likely to receive a CHV home visit <48hrs of birth compared with controls. All of these outcomes were statistically significant ($p<0.001$). Further analysis with multiple logistic regression modeling showed that *chama* women compared to control women had five times the odds of delivering in a facility (OR = 5.07, 95% CI: 2.74-9.39) and five times the odds of receiving a CHV home-visit (OR = 4.91, 95% CI: 2.76-8.72) even when controlling for age, parity, marital status, education, employment, prior facility delivery and current facility delivery. These positive effects have been replicated in *chama* women recruited in 2013-2014. Among pregnant women, 98% delivered in a facility, and 91% breastfed

[4] Kitetu, C. (2013). *Organizational Networks of Kenyan Female Migrants in England: The Humble Chama Now Operating at Higher International Levels*. London: United Kingdom. http://codesria.org/IMG/pdf/CATHERINE_KITETU.pdf (accessed 26 June 2014)

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exclusively to 6 months. Among all *chama* women in 2014, 70% decided to use a long-term family planning method (i.e. intrauterine device or hormonal implant).

Significance
We have shown that *chamas* can be tailored to increase the uptake of health services in pregnancy and infancy, sustain themselves beyond the period of funding and become integrated within a county's health strategy. However, further investment is warranted to validate this intervention in a new region to ensure the positive effects on MNCH are a result of *chamas* and can be replicated.

Purpose: To demonstrate that *chamas* is an effective, acceptable, and feasible model for improving women's and children's health and well-being in western Kenya.

Objectives: Investigators of this study aim to assess if women living in clusters randomized to participate in the first year of *chamas* have:

1. Higher health services uptake, as measured by:
    a. Our primary outcome: facility-based deliveries, and
    b. Secondary outcomes: attendance of 4 or more ANC visits, visit by a CHV within 48 hours of birth, exclusive breastfeeding to 6 months postpartum, immunization uptake at 12 months-of-age, contraceptive method uptake
2. Higher levels of self-reported empowerment, as well as decreased parental stress and use of harsh punishment to discipline children
3. Received the program as it was intended to be delivered, measured through process evaluations (e.g. attendance records, GISHE participation, re-enrollment)
4. Engaged in a cost-beneficial program as measured by the costs and benefits/person
5. Lower levels of maternal and infant morbidity as measured by eclampsia, low birth weight, poor growth, diarrhea in the last month, preterm deliveries
6. Lower levels of maternal, perinatal, neonatal and infant mortality
7. A positive experience in *chamas*, qualitatively measured through interviews and focus group discussions with women, participating CHVs, male partners of *chamas* participants, and health authority figures (i.e. MOH representatives)

Research Question: Is participating in *chamas* associated with improved health and social outcomes, including facility-based deliveries, compared to receiving the standard of care (monthly home-visits)?

Hypotheses:
Hypothesis 1: Pregnant women who participate in *chamas* are more likely to demonstrate improved health outcomes, namely: deliver in a health facility, as well as attend at least four ANC visits, receive a 48-hour CHV home-visit, exclusively breastfeed to 6 months, fully-immunize their infants by 12 months of age, and choose a contraceptive method for family planning when compared with women receiving the current standard of care.
Hypothesis 2: Women who participate in *chamas* will have higher levels of financial and decision-making autonomy, increased peer support and lower levels of parental stress when compared with women receiving the current standard of care.
Hypothesis 3: Women who participate in *chamas* will find the program acceptable and feasible.
Hypothesis 4: *Chamas* will be more cost-effective (as in cost the health system less by averting negative health outcomes per person) than the standard or care.

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Methods and Statistics:

Study Design: Cluster Randomized Controlled Trial

We have chosen a cluster randomized controlled design because our intervention is delivered in groups based within Community Health Units (CUs). We know some of the positive effects of *chamas* expand to the community surrounding the *chama*. By randomizing clusters, we will hope to isolate these communities to understand the individual-level effects of *chamas*. Clusters will be randomized 1:1 to each study arm using a random number generator. Clusters will not be matched or stratified. We will mask all investigators, data collectors, and analysts to cluster allocation. We will evaluate individual-level outcomes for all women who complete the trial at 12-months follow-up.

Study Outcomes and Endpoints:

Our primary and secondary outcomes are summarized in Table 1. The *chama* intervention will run for one year and all outcomes will be measured 12-months following the start of *Chamas* sessions or monthly home-visits. At the end of the first year, women in *chamas* can choose whether they re-enroll in the intervention at that time.

Table 1: Primary Outcome
• Facility-based deliveries (defined as deliveries attended by skilled birth attendants in facilities)
Secondary Outcomes
• Changes in care-seeking behaviors: attending at least four ANC visits, receiving a CHV home-visit within 48 hours postpartum, exclusively breastfeeding for at least six months, accepting a modern method of contraception, and immunizing infants (OPV0, Measles I, Fully Immunizing per WHO and Republic of Kenya MOH standards) • Maternal and Infant Morbidity: Eclampsia; Preterm labor, Low birth weight • Mortality: Perinatal, Infant, Maternal • Changes in maternal and child well-being: Women's Empowerment; Peer Support, Financial Status, Parental Stress, and Harsh Punishment • Lived experiences of pregnant women related to access to and utilization of health services • Process outcomes: Attendance (individual-level), GISHE participation, Re-enrollment

Sampling & Randomization:

We will randomize all CUs with an active presence of CHVs trained by AMPATH through the Kenyan Community Health Strategy. There are 77 eligible CUs from which participants will be recruited. Each CU has approximately 5000 households. Since there are 86 inactive CUs and 1 active CU throughout the region of our selected CUs, there will be buffer areas scattered throughout to reduce contamination between intervention and control CUs. Randomization will be performed in PASS 11 using random number generator operated by the trial manager. We will randomize clusters after women have agreed to participate and have been enrolled. Each CU will be allocated one of two possible number combinations. The study population will be recruited from all 60 GOK antenatal clinics in the 4 sub-counties over a 3-4-month period. The County Health leadership has agreed to select clinic staff not involved in clinical duties to help with initial recruitment. We will mask data collectors, investigators, and analysts to cluster allocation throughout the trial; however, both arms will be identifiable to participants and CHVs by design.

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Study Setting:
This study will be carried out in Trans-Nzoia County, which has 198 community units (CUs) in 5 sub-counties, Kiminini, Endebess, Kwanza, Saboti and Cherangany. We will eliminate Endebess Sub-county, which leaves us with 77 active CUs in 4 sub-counties. Endebess sub-county has many ADC farms on which individuals reside and work. As a result, access to health care is not comparable to the other four sub-counties. Trans-Nzoia has a population of 956,559 with 480,857 women and 154,963 children under-five (MOH 2015). It has on-going Maternal, Newborn and Child Health (MNCH) activities led by the GOK and supported by AMPATH in both the community and MOH facilities. Trans-Nzoia county 115 health facilities (DHIS June 2016), 2 district hospitals, 2 sub-district hospitals, 33 dispensaries, 7 health centres, 28 medical clinics and 6 nursing homes. In our 4 sub-counties, there are 60 MOH facilities (level 2, 3, and 4). All the subcounties subside primarily on agriculture and raising livestock. Kitale, part of Saboti sub-county, is urban, Kiminini sub-county is peri-urban, and Cherangany and Kwanza are rural. Agribusiness, real estate and comercial buisnesses are increasing in all the areas.

Trans Nzoia has varying health outcomes among sub-counties, but overall has poor health indicators. Only 56.9% of children are fully immunized, and 58.3% of pregnant women deliver in health facilities. The infant mortality rate is 58 per 1,000 live-births compared to a national average of 39 per 1,000 live-births (KDHS 2014). Furthermore only 29.3% of women receive FP commodities compared to a national average of 58%. (KDHS 2014). Finally, only 17.4% of women have attended the recommended 4 or more antenatal visits. Approximately 6.3% of women of reproductive health age are pregnant at any one time (KDHS 2014).

The trial will be implemented by the AMPATH Maternal and Child Health innovations group in collaboration with the Kenyan MOH. As part of AMPATH, Moi University is ideally positioned to meet the objectives of this proposal. We have an established record managing large MNCH programs and scaling them within the Kenyan MOH.

Study Population & Eligibility:
The target population will be pregnant and recently postpartum women, of any age, living across four sub-counties (Saboti, Cherangany, Kwanza, Kiminini) in Trans Nzoia County, Western Province, Kenya. Pregnant women will be recruited from eligible CUs based on the following criteria:

Participant Eligibility Criteria:

A. Any pregnant woman who:
    a. Presents for her first ANC visit at one of the recruiting health facilities
    b. Is less than or equal to 32 weeks gestation during her first ANC visit
    c. Resides in an intervention or control CU

Cluster Eligibility Criteria:

- Community Health Unit in one of four recruiting sub-counties (Cherangany, Saboti, Kwanza, Kiminini) in Trans Nzoia County, Western Province, Kenya
- Have a workforce of CHVs trained by AMPATH under the Kenyan Community Health Strategy

Intervention Activities:
The *chama* intervention seeks to empower and educate women to improve the health and well-being of their families. Our theory of change is constructed on a framework that focuses on providing women

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peer support, financial literacy and health and social education will empower them to work as a group to improve the health of the communities within which they live.

All clusters randomized to the intervention arm will be invited to participate in *chamas*. Each group will consist of two CHVs, two mentor mothers (i.e. post-menopausal women who have completed child-rearing) and 15-20 pregnant women. These groups will meet bi-weekly and use participatory approaches to develop their individualized group charter/constitution. Upon joining, women pledge to participate for one year and uphold the goals chosen by the *chama*. During each meeting, two CHVs facilitate a 60-90 minute discussion on health and social topics relevant to the antenatal, intrapartum, and postpartum periods. After this discussion, women will have the option to participate in the Group Integrated Savings for Health and Empowerment (GISHE) program. GISHE is a table banking program that gives women an opportunity to save money, pool money together to serve as a social or humanitarian fund and take loans from one another. Throughout the year, they will learn accounting and safekeeping skills and receive mentorship from their peers to engage in income generating activities. CHVs will not be invited to be a member of the GISHE group.

If the CHVs choose to continue the intervention, each community unit will be facilitated to form a new *chama* of pregnant women every 12 months. In addition, women who have completed their first year can choose to participate in a second and third year. After three years of the *chama* program, women will graduate and be encouraged to continue to meet as a group without CHV facilitations.
CHVs have been trained by the MOH and AMPATH to provide services to women and children under five. In addition to providing a refresher training on important MNCH topics covered by the Community Health Strategy, we will also train CHVs facilitating *chamas* on the program and equip them with skills to facilitate groups using a participatory learning approach. We will do this by providing training orientation sessions preceding the trial. In addition, our group will visit each *chama* on a minimum of a quarterly basis to allow them opportunities for feedback and support.

Control Group Activities
GOK community strategy focuses on care provision by community health volunteers (CHVs) who provide standard Ministry of Health (MOH) activities including promoting good nutrition, sanitation, and hygiene and linking families to essential MOH services. In 2014, AMPATH partnered with the county government to train the CHVs on important health topics including maternal, neonatal and infant health.

The CHVs in the control group will be given refresher training on health roles they are supposed to play according to the standard MOH activities. This includes visiting mothers throughout pregnancy, within 48 hours of delivery and in early childhood by conducting home-visits on a monthly basis. We will provide quarterly mentorship meeting for the CHVs to monitor their activities and ensure similar contact with our clinical staff as the implementation groups. If the study shows that *chamas* are beneficial to women and their infants, we will pledge to scale-up the intervention to the control group.

Stratification & Power:
We estimated sample size using methods described by *Rutterford et al*. for a proposed mixed effects regression analysis using derived baseline estimates. Assuming a mean cluster size of 20 individuals, 77 clusters (equally allocated between arms), intra-cluster correlation coefficient (ICC) of 0.44 (based on pilot data), and 20% attrition, we calculated a total of 1,280 individuals would be needed to detect a 4.7% difference on the risk difference scale with 80% power at a (two-tailed) significance level of 0.05.

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To determine our recruitment timeline, we assumed 6.3% of all women of reproductive age would be pregnant at any given time (or roughly 50 women per CU annually). We determined an enrollment period of roughly 3-4 months adequate to recruit our estimated sample size.

Data Collection & Storage

Data collection will occur by enumerators who do not participate in providing maternal and child health services and who do not have a working knowledge of the intervention and where it is being implemented. The same data collection protocol will be used for both intervention and the control groups. Enumerators will be recruited from the health facilities where recruitment takes place and trained to perform detailed interviews.

Data will be collected in two phases: at baseline and at 12-months following the initiation of *chamas* and monthly home-visits. Baseline data will be collected on all women who agree to participate in the study during enrollment. Data collectors will ask women attending their first ANC in health facilities if they consent to be contacted for enrollment; at that time, data collectors will record locator information such as the participant's address and/or phone number. CHVs and data collectors will then attempt to contact women in their communities to formally enroll them in the trial and will collect baseline socio-demographic and reproductive health data at that point in time. Data collectors will visit all women across trial arms in their homes to collect end-line data 12-months later. Data will be collected by interview on paper and/or tablet at both baseline and endline and entered into an encrypted RedCap database.

Paper data will be stored in a locked cabinet in the MNCH offices at AMPATH Primary Care Building. Data entered will be stored under password protection in a database accessible to the Data Management Team and Co-investigators only. All data will be entered into RedCap and stored on a password-protected device with antiviral and security software. All study participants will be given a unique identifier. Only the Data manager and the PIs will have access to the de-identified database.

Impact Evaluation

Prospective outcome data will be collected by enumerators. Enumerators will collect data at baseline and endline. At baseline, we will collect data on demographics of the respondents and their partners, household assets and income, reproductive history and child outcomes. At endline, we will collect data on maternal and child outcomes, utilization of reproductive health services, maternal well-being, and microfinance. We will attempt to collect outcome data on all women who enrolled in the study. CHVs will collect M&E data reported monthly. The data will be used for project monitoring and process evaluation. They will also keep records of financial information on the microfinance component of the *chama*. These records will be submitted to the research assistant at the end of the *chama* cycle, where data on microfinance performance of the *chama* will be mined from the records. Please see the figure below to better understand the flow of implementation and evaluation.

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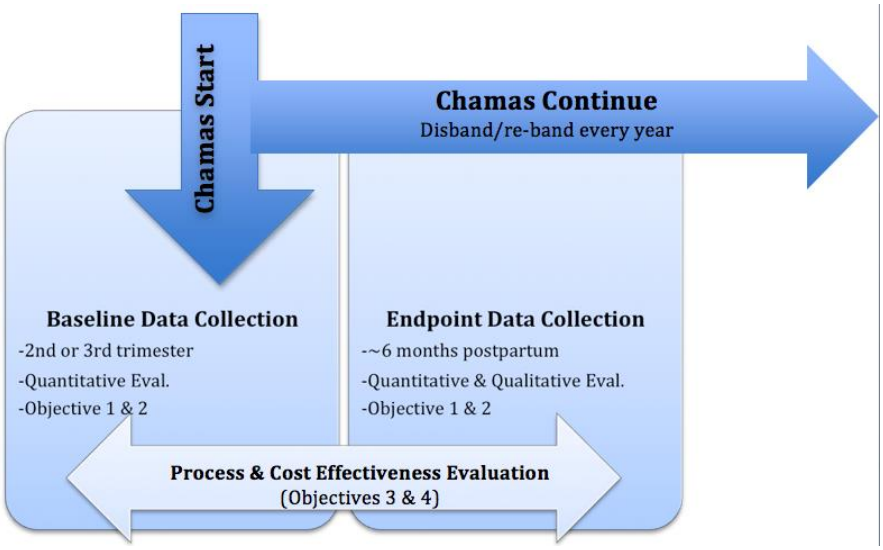

Process Evaluation

We will meet with selected CHVs quarterly in intervention and control sites to provide mentorship and support. In addition, CHVs will record process data on paper on a monthly basis to report on details of their work throughout the year. GOK and program registers will be used to determine adherence level and quality of implementation of the intervention. The Monthly Reporting Tool is included in the Appendix.

Qualitative Analysis

To meet the second research objective, specifically to better understand experiences with *chamas* and understand how *chamas* affect peer support, focus group discussions (FGDs) and key informant interviews (KIIs) will be carried out with women enrolled in the study, CHVs involved in community strategy in intervention and cluster CUs, male partners of women attending chama, and health authority figures (i.e. Sub-County Public Health Nurses - SCPHN). We plan to conduct FGDs with women and CHVs at baseline, and FGDs/KIIs with women, CHVs, male partners, and SCPHNs at endline.

At study baseline, we expect to interview a total of 20 CHVs, 10 from intervention and 10 from control. To assess acceptability of the program, we also intend to hold 4 focus group discussions (FGDs) composed of women in intervention clusters/4 FGDs from control clusters. To avoid homogeneity in the composition of the groups, we will stratify women into two groups based on age (>25 yo or =< 25 yo). We expect to reach saturation point in holding 2 FGDs with younger mothers and 2 FGDs with older mothers from the intervention and control clusters. We will also conduct up to four FGDs with women in the 2017 cohort who were never followed up (for a total of 12 FGDs).

During our endline assessment, we will also conduct FGDs with women enrolled in the chamas intervention group, CHVs that participated in the study between 2017-2019, as well as male partners that attended chama sessions. We also plan to conduct KIIs with health authority figures (i.e. SCPHNs) from each sub-county. During these discussions, we plan to explore themes including perceptions of effectiveness of chamas, experiences with maternal and child health related outcomes, health service utilization outcomes, as well as experiences with service disruptions.

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We anticipate we will conduct 4 endline FGDs with chama women, 4 FGDs with CHVs, 2 FGD with male partners and 4-8 KIIs with health authority figures. We will also conduct 2 FGDs with women who were in the original cohort, which was not recruited into chamas. Women (10-12 per FGD) will be selected from the total sample of enrolled women using a computerized random sampling technique. 4 CHV representatives will be selected from each of the four sub-counties in which we work. We will ensure 2 CHV representatives from each sub-county are allocated to each FGD group (i.e. 2 sub-county representatives from each sub-county in each FGD). We will use a convenience sampling technique to generate our group male partner FGD participants. Women who consistently attend chamas (>50% of total sessions) and who are not selected to participate in FGDs themselves will be asked to invite their male partners to participate. We will enroll the first 10-12 male partners who agree and consent to participation and who have attended at least 3 chama sessions themselves. Lastly, we will conduct 4 KIIs with SCPHNs – one representative per study sub-county. These SCPHNs have been actively involved throughout the duration of the chama study. We will consent all FGD and KII participants prior to conducting interviews.

Economic Evaluation

All intervention costs will be managed and recorded by Research Sponsored Projects Office (RSPO) through AMPATH Transformational Project (ATP) an online accounting system. This will include start-up and maintenance costs throughout the study period. We will be a developing an addendum to this proposal with a plan for a cost effectiveness analysis.

Data Management & Quality

Data Analysis

Intention-to-treat analysis will be used to deal will loss to follow-up, provide unbiased comparisons among the treatment groups and ensure conclusions drawn from the findings is based on information about the potential effects of a treatment policy rather than on the potential effects of specific treatment. Individual level data analysis will be employed controlling for design effect for all outcomes. Details of our analysis plan are delineated in our *Statistical Analysis Plan*. We will additionally conduct a process evaluation to monitor the intervention and control arms, as well as address quality of services throughout the year.

Qualitative data will be coded for themes and used to triangulate quantitative results. A code structure will be developed for the KIIs and FGDs with theory driven content analysis using the constant comparative approach to consolidate codes into a unified structure. Once the coding team has reviewed all the material and a final coding structure has been established by consensus, all the KIIs and FGDs will be recoded in MS Word Tracked Changes using the final structure. The coded material will be synthesized into a narrative format with extensive quotations organized thematically. In all cases, rival explanations will be noted and developed into alternative conclusions in the final analysis.

Ethical Considerations

We will obtain ethical approval through the Institutional Research and Ethics Committee at Moi University School of Medicine and Moi Teaching and Referral Hospital (Kenya) and Indiana University (Indianapolis, IN, USA). In preparation for this proposed intervention, we have obtained signed approval from Trans Nzoia County leadership.

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There will be little risk to women participating in this study and participation is by choice only. The intervention is a supplemental service delivery mechanism that incorporates all aspects of the current gold standard of care. It is not meant to replace the MOH community strategy, but to complement and improve it. Furthermore, in addition to participating in the intervention, women will still receive the GOK standard of care in their homes.

The primary risk of this study is therefore the loss of confidentiality of patient-identifiable information or information that could identify an interview subject or focus group participant with her/his recorded information. The study will employ all standard operating procedures of the AMPATH Research offices and Informatics program in order to ensure that patient data is kept securely in study databases with all appropriate encryption and password protection. All study participants will be given a unique identifier. Loss of confidentiality of the focus group participants and interview subjects will be minimized by restricting the number of investigators that have access to the audio recordings, by de-identifying subjects on the transcripts, and storing the recordings and the subject key in an encrypted and password-protected computer file.

Benefits to the subjects

Since the study provides an intervention aimed to supplement the current care cascade, there may be benefits to women who participate in the intervention. They may have more contact with CHVs and obtain more education than women not in *chamas*. It is unclear whether this will lead to a benefit in health outcomes, which is why we are performing this study. Women will participate voluntarily and will not receive any monetary or non-monetary gifts for their participation. Furthermore should this study show benefit to women and children in the intervention group, we will commit to scaling up the project to the control region should funding be available.

For the qualitative portion of the study, participants in these interviews may benefit from having their ideas and suggestions implemented in the design of future interventions in the communities and facilities. Furthermore, they will receive reimbursement of their transport to the interview and snacks during their session, in keeping with local research practices.

Informed consent

We will obtain informed consent from each woman who enrolls in the intervention and control groups. During the consent process, we will consent women to follow-up on pregnancy and health service utilization outcomes during end-line. CHVs work in the community collecting patient data for Ministry of Health registers. They are from the community and usually during their regular work, they visit pregnant and breastfeeding women to check their ANC status, Immunization status and Family Planning as they give other services. The enumerators will consent women who show up at the facility when they visit for any ANC visit by 32 weeks gestation. We will obtain the consent of the parent or guardian of the infant participating in the evaluation from both the control and intervention groups. The children are under the age of five so obtaining their assent will be difficult, but we will stop the evaluation should a child be vocalizing their assent by crying or refusing to participate in the evaluation.

Additional informed consent of all individuals participating in in-depth interviews and focus group discussions will also be obtained. Separate written consent forms have been included in this application for all individuals participating in the qualitative assessment in the focus group discussions and in-depth interviews.

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All data will be collected by an enumerator being paid by the project. The enumerator will not have an understanding of the intervention being conducted nor will he/she be participating in the intervention or community health service delivery. All our research assistants are trained on the protocols and importance of consent and confidentiality. All of our enumerators will be taught about consent and confidentiality and will sign a statement agreeing to maintain confidentiality.

Confidentiality

All study participants will be assigned a unique ID at the beginning of the study to ensure confidentiality. For those participating in KIIs and FGDs, no one outside of the Principal Investigators, Co-Investigators or research staff will have access to the names of the individuals recorded in the focus group discussions or the interviews. A transcriptionist will be able to hear the voices of individuals on audio recordings, but will not have access to the names or any other identifying information of the individuals in the study. Encryption will be used on all electronic devices that are used to store recorded audio from focus group discussions and interviews. Access to the encrypted data will require a password.

Only the study personnel listed above will have access to the names of all the study participants and their identifiable information. CHVs implementing the *chamas* or conducting their work will not have access to the data collected. Enumerators collecting the data will not have access to the database or to the data they have collected after their point of contact.

Only the Principal Investigators, Co-Investigators, and research staff will have access to the password or the encrypted data. Only de-identified data will be shared outside of AMPATH and only for the purpose of data analysis or for dissemination of the aggregate results of the study.

Study implications

This study is evaluating an innovation in maternal and infant health services in the community, specifically the use of a group-based women's health education model. If data analysis of this care program shows improvement of community-based service delivery, facility-based uptake of services and maternal and newborn health outcomes, there is great potential to expand this program to other regions of Kenya. The evaluation will be used to inform CHV best practices within all of AMPATH Primary Health Care. If the PHC *Chamas for Change* project is found to be acceptable and beneficial, then it is possible that funding can be secured in order to implement *chamas* throughout western Kenya. Expanding *chamas* may facilitate CHVs to improve the delivery of community-based services from HIV to diabetes care. Furthermore, this project may help to provide women around the world a voice in order to keep their communities accountable to their mothers and children.

Project Budget:

This study is funded by Saving Lives at Birth through Grand Challenges Canada. The project budget is 250,000 CAD to be used over 2 years. We are using the funding to both implement the program and to perform the evaluation.

Project Deliverables:

The analyzed data and quarterly data will be submitted in a report to Grand Challenges Canada as required by the grant agreement. We will compile the final data analysis into a manuscript that will be submitted to a journal that is yet to be decided. We may also present analyzed data in the form of posters and presentations at academic conferences.

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Table 1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	Page 1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[1,2]	See table 2	Page 3
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	Page 6
	2b	Specific objectives or hypotheses	Whether objectives pertain to the the cluster level, the individual participant level or both	Pages 6 and 8
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	Page 6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		Page 6
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	Page 6
	4b	Settings and locations where the data were collected		Page 6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	Pages 6-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and	Whether outcome measures pertain to the cluster level, the individual participant level or both	Page 8

		when they were assessed		
	6b	Any changes to trial outcomes after the trial commenced, with reasons		N/A
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	Page 8
	7b	When applicable, explanation of any interim analyses and stopping guidelines		Pages 8-9
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		Page 6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	Page 6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	Page 6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	Page 6
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	Page 6
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete	Page 6

			enumeration, random sampling)	
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	Page 6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		Page 6
	11b	If relevant, description of the similarity of interventions		Pages 7-8
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	Pages 8-9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		Pages 8-9
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	Page 10, Figure 2
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	Page 10, Figure 2
Recruitment	14a	Dates defining the periods of recruitment and follow-up		Pages 3, 10
	14b	Why the trial ended or was stopped		N/A
Baseline data	15	A table showing baseline demographic and clinical	Baseline characteristics for the individual and cluster levels as	Page 10, Table 1

		characteristics for each group	applicable for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	Page 10
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	Pages 10-11, Tables 2-4
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		Pages 10-11, Tables 2-4
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		Pages 10-11, Tables 2-4 and supplementary tables
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[3])		Page 11
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		Page 13
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	Page 13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		Page 14
Other information				
Registration	23	Registration number and		Page 6

		name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	Page 15
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Pages 9-10, Page 15

** Note: page numbers optional depending on journal requirements*

Table 2: Extension of CONSORT for abstracts[1,2] to reports of cluster randomised trials

Item	Standard Checklist item	Extension for cluster trials
Title	Identification of study as randomised	**Identification of study as cluster randomised**
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	**Eligibility criteria for clusters**
Interventions	Interventions intended for each group	
Objective	Specific objective or hypothesis	**Whether objective or hypothesis pertains to the cluster level, the individual participant level or both**
Outcome	Clearly defined primary outcome for this report	**Whether the primary outcome pertains to the cluster level, the individual participant level or both**
Randomization	How participants were allocated to interventions	**How clusters were allocated to interventions**
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	
Results		
Numbers randomized	Number of participants randomized to each group	**Number of clusters randomized to each group**
Recruitment	Trial status[1]	
Numbers analysed	Number of participants analysed in each group	**Number of clusters analysed in each group**
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	**Results at the cluster or individual participant level as applicable for each primary outcome**
Harms	Important adverse events or side effects	
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	
Funding	Source of funding	

[1] Relevant to Conference Abstracts

REFERENCES

1 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008, 371:281-283

2 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG at al (2008) CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Med* 5(1): e20

3 Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; 141(10):781-788.

Chamas for Change: Validating the impact of a group-based health education and microfinance model on improving maternal, newborn, and child outcomes in western Kenya

ClinicalTrials.gov Identifier: NCT03187873

Revised by Lauren Maldonado;Prepared by Jeff Bone & Lauren Maldonado
7-15-2019

1. Objectives of the Statistical Analysis Plan

This document provides details of the statistical analyses planned for data collected from the *Chamas for Change (Chamas)* cluster randomized control trial in Trans Nzoia (western Kenya) to assess the impact of this service delivery platform on improving maternal, newborn, and child health (MNCH) outcomes, perceptions of financial empowerment and parental well-being.

2. Objectives of the *Chamas for Change* Trial

The **primary objective** of the trial is to assess the association of *Chamas* participation and the likelihood of delivering in a health facility with a skilled birth attendant, as compared to controls. We will collect data on the number of women delivering in a health facility (public or private); this indicator will be classified as a dichotomous variable.

The **secondary objectives** of the trial are to evaluate the efficacy of *Chamas* participation on improving a variety of MNCH outcomes, listed in Tables 1-3 below.

Table 1. Maternal and Newborn Health Outcomes.

Outcome	Definition	Variable Type
Primary Outcome		
Facility-based delivery	Women who delivered their infant in a public or private health facility with a skilled birth attendant vs. home alone, home with TBA, or in transit - *among women with live delivery or stillbirth*	Dichotomous Categorical
Secondary Outcomes		
Adequate antenatal (ANC) care visits (per GoK recommendation)	Women who attended at least 4 ANC visits - *among all women in sample*	Dichotomous Continuous
Postnatal home visit by a CHV within 48 hours of birth	Women visited by a CHV within 48 hours of delivery - *among women with either live delivery or stillbirth*	Dichotomous
Exclusive breastfeeding for at least 6 months	Women who did not start giving their infant water, formula, cow/goat milk, herbal medicine, porridge, food, or anything other than breast milk (or medication if child was sick) until at least 6 months of age - *among women with live delivery*	Dichotomous Continuous
Current family planning use (any method)	Women who are currently using a contraceptive method (any method) – *among all women except those currently pregnant*	Dichotomous Categorical
Current use of long-term or permanent family planning methods	Women who are currently using a long-term or permanent method of family planning [i.e. implant (3 or 5 year), IUCD, bilateral tubal ligation, or vasectomy for contraception] –	Dichotomous Categorical

(Postpartum LARC/permanent method uptake)	*among women currently using a family planning method*	

Table 2. Infant and Child Health and Development Outcomes.

Outcome	Definition	Variable Type
Infant Birthweight	Mean (or median) infant birthweight measured in kg – *among all mothers who delivered a live infant*	Continuous
Incidence of infants born with low birth weight	Proportion of infants born <2.5 kg (low birthweight) or ≥2.5 kg (normal birthweight) – *among all mothers who delivered a live infant*	Dichotomous
Fully-immunized infants (≤12 months) per WHO standards (see p. 141 of 2015 KDHS)	Proportion of infants who are fully-immunized per WHO standards: received one BCG vaccine, three pentavalent vaccines (DPT-HepB-Hib), three OPV vaccines, and one measles vaccine – *among all living infants (exclude infant deaths)*	Dichotomous
Fully-immunized infants (≤12 months) per Republic of Kenya MOH standards (see p. 141 of 2015 KDHS)	Proportion of infants who are fully-immunized per Republic of Kenya MOH standards: received one BCG vaccine, three pentavalent vaccines (DPT-HepB-Hib), three OPV vaccines, one measles vaccine, AND three doses of PCV vaccine – *among all infants currently living (exclude infant deaths)*	Dichotomous
Infants who received OPV 0 within 2 weeks of birth (Marker for vaccination regardless of delivery location)	Proportion of infants who received OPV 0 at birth or within 2 weeks of birth – *among all infants currently living (exclude infant deaths)* **Please account for date of vaccination – date should be within 2 weeks of infant's date of delivery.	Dichotomous
Infants who received Measles I by 12 months of age	Proportion of infants who received Measles I by 12 months of age – *among all infants currently living (exclude infant deaths)* **Please account for date of vaccination – date should be within 12 months of infant's date of delivery.	Dichotomous
DSQ questionnaire	*(ANALYZED BY MEGAN SONG MCHENRY ET AL.)*	

Table 3. Social Outcomes.

Outcome	Definition	Variable Type
Health insurance coverage at time of delivery	Women covered by Linda Mama, NHIF, Private, Other insurance vs. No insurance at time of delivery – *among all women in sample*	Categorical Dichotomous
Current health insurance coverage	Women CURRENTLY enrolled in NHIF, Linda Mama, Private, Other insurance vs. No insurance – *among all women in sample*	Categorical Dichotomous
Active NHIF health insurance status	Women with active NHIF status – *among all women currently enrolled in NHIF insurance scheme*	Dichotomous
Microfinance Involvement	Proportion of women involved in merry-go-round, table banking, Chama Cha MamaToto GISHE, other, or no group.	Categorical
Financial Empowerment Scores (Women's Empowerment Scale) *Reference:* *Nanda, Geeta. 2011. Compendium of Gender Scales. Washington, DC: FHI 360/C-Change.*	Scored on two sub-scales adapted from the Compendium of Gender Scales – Women's Empowerment Scale (see attached reference document – pages 8 and 9) Please divide into "Freedom from Family Domination Subscale" and "Economic Security and Contribution Subscale" separately as outlined in the reference document. Both scales translate to dichotomous "Empowered" / "Not Empowered" variable. *Among all women in sample* **Measured at baseline and end-line: Please analyze inter-cohort differences as well as intra-cohort relative change in score from baseline.*	Dichotomous (both subscales)
Perception of harsh punishment (UNICEF Multiple Indicator Cluster Survey) *Reference:* *UNICEF, Multiple indicator cluster survey manual, 2005: Monitoring the situation of children and women. 2005, New York: UNICEF.*	Proportion of women who strongly disagree, disagree, neither agree nor disagree, agree, or strongly agree to the prompted statement (Section I. Endline Survey) – *among all women in sample (only measured at end-line)*	Categorical

Parental Stress Scores (Parental Stress Scale) *Reference:* *Berry, JD, & Jones, W,H, (1995) The Parental Stress Scale : initial psychometric evidence. Journal of Social and Personal Relationships, 12, 463 – 472.*	Mean (or median) parental stress scores based on calculated *Parental Stress Scale* questionnaire. Please refer to source document attached in email, which provides full details on scoring mechanism for the *Parental Stress Scale* (Likert scale with some items reverse scaled) There is a direct relationship between score and stress level - the higher the computed score (scaled 18-90), the higher the measured parental stress. *Only measured at end-line, so please measure relative computed scores between control and intervention cohorts – among all women in sample.*	Continuous (Mean or Median)
Social Support/Peer Support Scores Adaptation of the "Interpersonal Support Evaluation List" *Reference:* *Cohen S., Mermelstein R., Kamarck T., & Hoberman, H.M. (1985). Measuring the functional components of social support. In Sarason, I.G. & Sarason, B.R. (Eds), Social support: theory, research, and applications. The Hague, Netherlands: Martinus Niijhoff.*	Mean (or median) social support scores based on adapted "Interpersonal Support Evaluation List – Shortened Questionnaire" (Questions 1-9 ONLY – seems like question 10 "No one I know would throw a part for me" on the end-line questionnaire was omitted from the baseline questionnaire) Definitely false = 1; Definitely true = 4 *higher score = higher perception of social/peer support (total scores range from 9 to 36) Items 3, 5, 7, 8 are reversed scored (i.e. Definitely false = 4) **Measured at baseline and end-line: Please analyze inter-cohort differences as well as intra-cohort relative change in score from baseline.*	Continuous (Mean or Median)

Exploratory objectives of the trial include comparisons between the *chama* intervention arm and the control arm in terms of clinical outcomes including but not limited to:

Clinical Outcomes	**Definition**	**Relevant variables**
Maternal deaths	Number of mothers who passed away while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes.	Number of maternal deaths; recorded causes of death (see data in "2018_RCT Mortality" database on RedCap)
Perinatal and neonatal deaths	Perinatal deaths – number of stillbirths + infant deaths within first 7 days of life. Neonatal mortality – infant deaths within the first 28 days of life (days 0-27).	Perinatal – pregnancy loss between 28 weeks and birth, child deaths less than 1 week after delivery. Neonatal – deaths less than 1 week after delivery + deaths between 1-4 weeks after delivery.
Infant deaths	Infant deaths under 1 years of age.	Number of women that answer "no" to is your infant alive today?
Miscarriage Rate	Number of mothers reporting pregnancy loss at <28 weeks gestation	(Same as definition)
Stillbirth Rate	Number of mothers reporting pregnancy loss between 28 weeks and birth	(Same as definition)
Maternal morbidity	Any health condition attributed to and/or aggravated by pregnancy and childbirth that has a negative impact on the woman's wellbeing.	Miscarriage rate (<28 week fetal loss), stillbirth rate (>28 week loss), delivery complications (bled a lot, baby got stuck, infection, high BP, seizures)
Infant morbidity	Factors which affect mortality rate of infants (i.e. low-birthweight, perinatal disorders)	Infant birth weight; completeness of infant immunization schedule; EBF rates; delivery complications (bled a lot, baby got stuck, infection, high BP, seizures, baby needed help to breathe/resuscitation)

The remainder of the statistical analysis plan will focus on the analyses to be carried out in an initial report on the data collected after one year of following enrolled pregnant women in both arms.

3. Study design

The study is a cluster randomized control trial conducted in Trans-Nzoia County, Kenya with approximately 1:1 allocation between the intervention and control arms. Data collection and recruitment for the RCT cohorts began in the Fall 2017 (November) and concluded in the early Summer of 2019 (May-July). All data were collected via digital tablets and synchronized to a central REDCap database twice weekly, supervised by a trained team of *Chamas for Change* implementation leads.

We employed a facility-based recruitment strategy in this cluster RCT. We recruited women attending their first ANC visits at public health facilities across four participating sub-counties in Trans-Nzoia (Kwanza, Saboti, Kiminini, Cherangany). To be eligible to participate, women had to meet the following inclusion criteria:

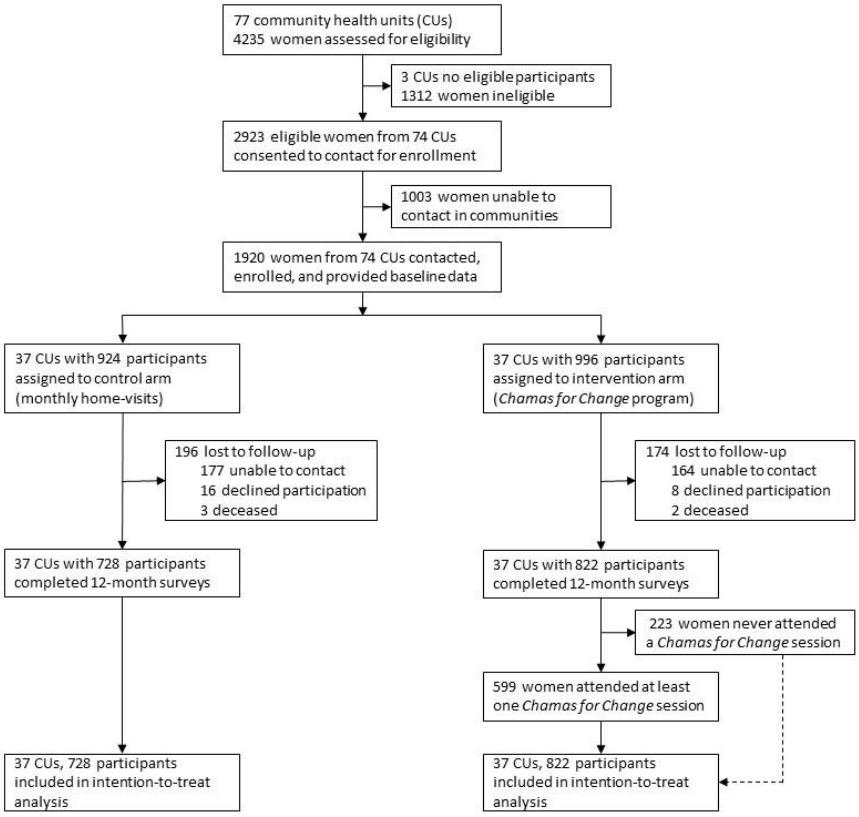
Inclusion Criteria:

- Any pregnant woman who is:
    - less than or equal to 32 weeks gestation when presenting for her first ANC visit
    - Receiving antenatal care at one of the defined study facilities
    - Residing in either an intervention or control community unit

At the time of enrollment, women were provided an overview of our study (but not given explicit details on the *Chamas* intervention), consented to participate, and completed a baseline questionnaire. Participants and the study team were blinded to a woman's allocation to either the intervention or control arm. After collecting baseline data, we randomized women based on their reported community unit (a unit of geographic measure within each sub-county, which is overseen by a community health volunteer). There are 74 total community units or RCT clusters randomized (37 intervention, 37 control), distributed across four the participating sub-counties. Each health facility from which women were recruited serves women across a variety of community units (both intervention and control). Through this process, we aimed to recruit 600 women to the intervention arm and 550 to our control arm. Following the randomization process, women were re-contacted and formally invited to participate in *Chamas*. At that time, women who were randomized to community units assigned to the intervention arm were provided details on how to attend their first *Chamas* meeting.

We will collect individual demographic and outcome data at two study time-points – at the point of contact when community health volunteers locate enrolled women in their community units (baseline assessment) and formally invite those randomized to the intervention arm to attend *Chamas*, and at 12-months after *Chamas* sessions begin (end-line assessment). All intervention groups will have participated in our program for 1 year by June 2019. Community health volunteers and research interns will travel to women's homes to collect end-line data on an electronic tablet. Group attendance data will be transcribed using CHV-recorded paper-based attendance sheets and uploaded into REDcap.

Figure 1. Study flow diagram (ITT sample)



If women relocated at any point in the study, we will attempt to collect data in-person for those that moved within Trans Nzoia. If, however, women moved outside of Trans Nzoia, we will attempt to collect data using an abbreviated phone questionnaire (omitting questions necessitating in-person contact i.e. mother baby booklet questions, DSQ questions). In addition to our demographic and outcome data, financial and process outcomes are assessed for every group at each meeting using paper ledger books and attendance sheets, respectively.

Attendance sheets will be used to determine which women among our intervention sample attended at least one Chama session, as well as provide individualized attendance records. We will use these data to determine a sample of participants to comprise the per-protocol analysis sample (i.e. restrict to women who attended at least 50% of all *Chamas* sessions in the preceding 12 months). In the event attendance sheets are deemed unreliable or incomplete, we will ask participants to retrospectively self-report an estimated number of *Chamas* sessions they attended throughout the last 12 months.

4. Analysis population and timing

The analyses will follow an intention-to-treat principle. That is, all women who completed both a baseline and end-line questionnaire, regardless of whether they ever attended a *Chamas* session will be included in our analyses. In cases where a woman no longer wants to take place in *Chamas*, every effort will be made to collect her data at the end of the study. As previously mentioned, we will make every effort to collect data on women who have relocated outside of their original community unit, either in person or with an abbreviated phone-based questionnaire.

We plan to solely analyze complete cases in regression analyses of our main outcomes, with the assumption that the observed complete cases are a random sample of the originally targeted sample. We chose this analysis approach as it is possible that outcomes are not predictable based on baseline characteristics (and vice-versa); thus, any modeling completed with imputed outcomes may bias our results. Further, complete case analyses tend to be a more conservative approach that biases results toward the null hypothesis (vs. multiple imputation) if data are completely missing at random (Citation: https://www.ncbi.nlm.nih.gov/pubmed/20842622). The distribution of missing values will be summarized for individual fields and between arms in cases where a missing value prevents a subject from being included in an analysis (the number of subjects for that analysis will be reduced accordingly).

5. Descriptive analyses

All data will be summarized with appropriate tables and figures. Summaries will be displayed by arm (intervention/control). Descriptive summaries for continuous variables will include the number of observations, mean, standard deviation, minimum, median, maximum and IQR and will be visualized via side by side boxplots. For categorical variables, frequencies and percentages will be presented. Where appropriate, graphical presentations of frequency data may also be employed.

Outcome data will be further summarized at the cluster level; mean and standard deviations of cluster level values will be presented along with intra-cluster correlation (ICCs). These data will be visualized via dot plots and side by side boxplots.

Additional analyses to increase precision will be based on various statistical models (see below). The potential need for transformations of variables, and the adequacy of model fits will be checked with the appropriate graphical and statistical tests as appropriate.

6. Baseline covariates that may be used for adjustment in models

The following baseline characteristics may be used for adjustment in statistical models to increase precision and assess robustness of the primary results to potential imbalances:

Demographic covariates:

- Age: continuous (collected at end-line)
- Marital status: dichotomous (collected at end-line)
- Employment status: dichotomous (collected at end-line)
- Education: categorical (collected at baseline)
- Socioeconomic status: continuous (collected at end-line)
    - Poverty likelihood % below national poverty line

    - Need to translate scores into scales in the *Poverty Probability Index* (please refer to instructions in emailed attachment)
- Insurance coverage at time of delivery: dichotomous (collected at end-line)
- Participation in microfinance program: dichotomous (collected at end-line)

Health and Social-related covariates:

- Previous pregnancy: dichotomous (collected at baseline)
    - Nulliparous vs. Parous (≥1 previous pregnancy)
- History of complications during previous pregnancy: dichotomous (collected at baseline)
    - "Yes" if women reported experiencing a miscarriage or stillbirth in previous pregnancy
- History of prior facility delivery: dichotomous (collected at baseline)
- Attending at least 4 ANC visits during current pregnancy (test for interaction effect – collected at end-line)
- Perceptions of financial empowerment at baseline (collected at baseline)

7. Analysis of the primary outcome

The analysis of the primary outcome will compare the proportion of women delivering in facility between the intervention and control clusters via a multi-level logistic regression model with a random intercept for cluster and a single covariate for treatment arm. The odds ratio and absolute risk difference will be reported with 95% bootstrap confidence intervals. Statistical significance will be based on a Wald test for the hypothesis that the true odds ratio is 1, with a significance level of 0.05.

Several supportive analyses for the proportion of facility deliveries will be carried out. If feasible, the first will be based on the above model with adjustment for relevant baseline predictors of facility delivery as listed above.

The second supportive analysis will be based on cluster level summaries. For each cluster, we will calculate the log-odds of facility delivery and obtain a weighted average based on Woolf's method (with an additive factor for between-cluster variability) for each arm. The difference between arms will then be assessed via both weighted and unweighted t-tests (pooling/not of variance will be based on relative similarity of the log-odds variance between arms).

8. Analyses of secondary outcomes

Secondary outcomes will be classified as either dichotomous, categorical, continuous or count variables.

For continuous secondary outcomes, the primary analysis will be based on a multi-level linear regression model with a random intercept for cluster to compare the average responses between arms. Average difference between arms, 95% confidence interval and a p-value for the test of the null hypothesis that there is no difference between arms will be reported. Supportive analyses will include adjustment for covariates mentioned above in this regression model as well as t-tests based on cluster level averages.

For binary outcomes, the primary analysis will be based on a multi-level logistic regression model with a random intercept for cluster and a single covariate for treatment arm. The odds ratio and absolute risk difference will be reported with 95% bootstrap confidence intervals. Statistical significance will be based

on a Wald test for the hypothesis that the true odds ratio is 1. Supportive analyses will include adjustment for the covariates mentioned above as well as cluster level analyses for the log-odds as in the preceding section.

For count outcomes, the primary analyses will be based on a multi-level Poisson regression model with a random intercept for cluster and a single covariate for treatment arm. Where appropriate, this model will include an offset for baseline differences. The results will be summarized as a relative rate, 95% confidence interval and a p-value for the null hypothesis that the true relative rate is 1. Supportive analyses will include adjustment for the covariates mentioned above.

9. Analysis of mortality and morbidity data

Given the relatively low predicted number of events, it is unlikely that we will be able to feasibly model the mortality and morbidity data at the individual level. We intend to examine mortality and morbidity independently. Therefore, mortality and morbidity for both women and infants will be summarized at both the arm and cluster level. If feasible, the log-odds of mortality/morbidity for each cluster will be calculated and these will be used to test the hypothesis that the true odds ratio between arms is 1. Variances will be computed via Woolf's method with an adjustment for between cluster variability.

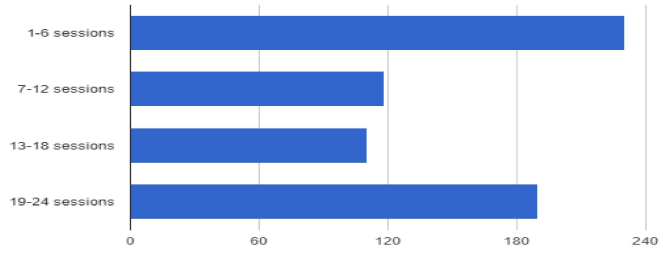
10. Analysis of time trends

Temporal analyses of the primary and secondary outcome will be conducted to determine possible lagged effects of the intervention. Data will be grouped either monthly or quarterly based on delivery date and outcome rates will be plotted over time and by arm. Statistical significance for differences between arms over time will be based on the likelihood ratio test applied to a multi-level model (see primary analysis) including arm and time, and a multi-level model including arm, time and an interaction between the two.

11. Per-protocol analysis

A subgroup analysis will be conducted to compare women in the control arm to women in the intervention arm who participated in *Chamas* throughout the intervention period (i.e. report attending at least 50% of sessions). We will use attendance data collected by CHVs to determine this subgroup. Intervention effect will be assessed based on the same metrics used in the ITT analysis, including adjustment for any imbalances in baseline characteristics. If large differences in baseline between groups exist, then propensity score matching may be used to rebalance groups.

Figure 2. Proportion of sessions attended among women who attended Chamas sessions at least once.



Counts/frequency: 1-6 sessions (230, 35.5%), 7-12 sessions (118, 18.2%), 13-18 sessions (110, 17.0%), 19-24 sessions (190, 29.3%)

12. Additional subgroup analyses

In addition to our per-protocol analysis, we may additionally perform the following sub-group analyses:

Sub-group analyses:

- Restriction of intervention sample to women who attended at least one *Chamas* session
- Sub-county level analyses
- Microfinance participation (participating in GISHE vs. not participating)
- Delivery during health services disruptions (sub-study)

Supplementary Tables

Table S1: Counts of missing data for primary, secondary outcomes and vaccine outcomes

	Control (N = 728)	**Intervention (N = 822)**
Facility delivery	24 (3.30%)	15 (1.82%)
Adequate ANC care	0 (0%)	0 (0%)
Postnatal CHV visit	14 (1.92%)	20 (2.43%)
Exclusive breast feeding for 6 months	53 (7.28%)	47 (5.72%)
Current use of family planning	7 (0.96%)	13 (1.58%)
Current use of long-term family planning methods	256 (35.16%)	241 (29.32%)
Missing vaccine	-	-
Infant < 12 months at end line	-	-
Infants who received OPV 0 within 2 weeks of birth	79 (10.85%)	117 (14.23%)
Infants who received Measles I by 12 months of age	160 (21.98%)	252 (30.66%)
Fully-immunized infants (≤12 months) per WHO standards	159 (21.84%)	244 (29.68%)
Fully-immunized infants (≤12 months) per Republic of Kenya MOH standards	159 (21.84%)	243 (29.56%)
Child at least 12 months at end line		
Infants who received OPV 0 within 2 weeks of birth	92 (12.64%)	136 (16.55%)
Infants who received Measles I by 12 months of age	96 (13.19%)	155 (18.86%)
Fully-immunized infants (≤12 months) per WHO standards	101 (13.87%)	161 (19.59%)
Fully-immunized infants (≤12 months) per Republic of Kenya MOH standards	103 (14.15%)	161 (19.59%)
Missing age at end line		
Infants who received OPV 0 within 2 weeks of birth	34 (4.67%)	27 (3.28%)
Infants who received Measles I by 12 months of age	34 (4.67%)	27 (3.28%)
Fully-immunized infants (≤12 months) per WHO standards	34 (4.67%)	27 (3.28%)
Fully-immunized infants (≤12 months) per Republic of Kenya MOH standards	34 (4.67%)	27 (3.28%)

Table S2. Baseline characteristics for complete trial cohort (including individuals lost to follow-up)

	Completed Trial (N = 1550)	**Lost to follow-up (N = 370)**
Maternal age	26.89 (6.40)	24.25 (5.74)
Gestational age (weeks) at enrollment, median [IQR]	22.0 [18.0, 25.0]	22.0 [16.0, 24.0]
Poverty probability index score*	63.80 (17.06)	55.10 (20.09)
Sub-county		
Cherangany	419 (27.0)	67 (18.1)
Kiminini	349 (22.5)	105 (28.4)
Kwanza	398 (25.7)	82 (22.2)
Saboti	384 (24.8)	116 (31.4)
Previously pregnant	1193 (76.9)	283 (76.5)
Parity	2.35 (1.56)	1.88 (1.39)
Previous modern contraceptive use		
Yes	703 (58.9)	121 (42.8)
No	424 (35.5)	143 (50.5)
Missing	66 (5.5)	19 (6.7)

Previous facility delivery		
Yes	507 (42.5)	89 (31.4)
No	323 (27.1)	66 (23.3)
Missing	363 (30.4)	128 (45.2)
Total ANC visits in previous pregnancy		
0	27 (2.3)	3 (1.1)
1	40 (3.4)	13 (4.6)
2	68 (5.7)	14 (4.9)
3	247 (20.7)	45 (15.9)
4	307 (25.7)	45 (15.9)
>4	128 (10.7)	26 (9.2)
Missing	376 (31.5)	137 (48.4)
Previous^		
Miscarriage	49 (4.1)	10 (3.5)
Stillbirth	25 (2.1)	4 (1.4)
Neonatal death	13 (1.1)	3 (1.1)
Infant death	13 (1.1)	0 (0.0)
Child death under 5	8 (0.7)	1 (0.4)
Child death over 5	5 (0.4)	0 (0.0)

*Scores and % poverty likelihood calculated using validated 2015 Kenya Poverty Probability Index.
^Miscarriage (up to 28 weeks gestation); stillbirth (after 28 weeks gestation); neonatal death (0-28 days old); infant death (1-12 months old); child death (1-5 years old).

Table S3: Baseline characteristics of intervention analysis cohort (by *Chamas* attendance)

	Never attended *Chamas* (N=223)	Attended *Chamas* at least once (N=599)
Maternal age	26.95 (7.05)	27.16 (6.37)
Marital status		
Divorced/separation	5 (2.2%)	12 (2.0%)
Married	180 (80.7%)	506 (84.5%)
Single	36 (16.1%)	79 (13.2%)
Widowed	2 (0.9%)	2 (0.3%)
Maternal education		
College or higher	15 (6.7%)	31 (5.2%)
Secondary or post-primary	72 (32.3%)	178 (29.7%)
Primary	108 (48.4%)	312 (52.1%)
Pre-primary or none	27 (12.1%)	75 (12.5%)
Occupation		
Contract/temporary worker	9 (4.0%)	39 (6.5%)
Permanently employed	6 (2.7%)	4 (0.7%)
Self employed	65 (29.1%)	182 (30.4%)
Unemployed	143 (64.1%)	373 (62.3%)
Health insurance coverage at time of delivery		
Yes	129 (57.8%)	390 (65.1%)
No	85 (38.1%)	200 (33.4%)
Poverty probability index score	55.74 (18.20)	52.79 (19.87)
Sub-county		
Cherangany	87 (39.0%)	124 (20.7%)
Kiminini	55 (24.7%)	117 (19.5%)
Kwanza	60 (26.9%)	156 (26.0%)
Saboti	21 (9.4%)	202 (33.7%)

Table S4: Sensitivity analyses of primary and secondary outcomes

	Unadjusted (primary)		Adjusted*		Unadjusted with imputation**		Adjusted* with imputation		Including only women attending at least one Chama	
	Odds ratio (95%CI); p-value	Risk difference (95% CI)	Odds ratio (95% CI); p-value	Risk difference (95% CI)	Odds ratio (95%CI); p-value	Risk difference (95% CI)	Odds ratio (95%CI); p-value	Risk difference (95% CI)	Odds ratio (95%CI); p-value	Risk difference (95% CI)
Facility-based delivery	1.58 (0.969, 2.55); 0.057	7.4% (3.0%, 12.5%)	1.59 (1.02, 2.47); 0.042	6.4% (2.0% 10.4%)	1.55 (0.96, 2.50); 0.072	7.55% (3.02%,12.32%)	1.62 (1.06, 2.49); 0.004	7.1% (3.0%,11.4%)	1.43 (0.92,2.24); 0.112	5.2% (1.5%,9.5%)
Adequate ANC care	1.18 (0.82,1.68); 0.375	3.2% (-1.5%, 7.7%)	1.19 (0.84, 1.69); 0.331	3.2% (-1.5%,7.9%)	1.18 (0.82, 1.68); 0.375	3.57% (-1.17%,8.62%)	1.18 (0.84, 1.64); 0.336	3.5% (-1.1%,8.0%)	1.18 (0.79,1.75); 0.423	3.0% (-1.4%,8.0%)
Postnatal CHV visit	3.22 (1.50,6.93); 0.003	15.3% (12.0%, 19.6%	3.37 (1.55, 7.34); 0.002	15.7% (12.1%,21.8%)	3.13 (1.91, 5.12); <0.001	16.02% (11.44%,20.79%)	3.13 (1.81, 5.42); <0.001	16.0% (11.3%,20.6%)	4.05 (2.00,8.20); <0.001	19.6 (14.4%,25.0%)
Exclusive breast feeding for 6 months	1.77 (1.12,2.80); 0.014	11.9% (7.2%, 16.9%)	1.75 (1.10, 2.80); 0.019	11.6% (7.0%,17.1%)	1.75 (1.11, 2.76);0.016	11.9% (6.64%,17.16%)	1.77 (1.12, 2.80); 0.014	11.96% (6.8%,17.0%)	1.96 (1.20,3.21); 0.007	13.6% (7.8%,19.8%)
Modern contraceptive use	1.41 (1.03,1.93); 0.034	7.2% (2.6%, 12.9%)	1.44 (1.00, 2.05); 0.047	6.8% (3.1%,13.1%)	1.41 (1.02, 1.94); 0.035	7.6% (2.59%,12.38%)	1.44 (1.04, 1.98); 0.026	7.2% (3.1%,12.2%)	1.35 (0.92,1.98); 0.122	5.7% (0.7%,11.1%)
Long-acting reversible contraceptive use	1.34 (0.95,1.91); 0.099	7.1% (0.9%, 13.3%)	1.31 (0.92, 1.86); 0.134	6.5% (1.2%,14.2%)	Not estimated***	Not estimated***	Not estimated***	Not estimated***	1.22 (0.85,1.77); 0.283	4.9% (-0.5%,13.6%)

*Models are adjusted for poverty probability index score, marital status, nulliparity, and insurance at delivery.

**Imputation models included poverty probability index score, marital status, nulliparity, and insurance at delivery, maternal age, sub-county, occupation, all the outcomes, a random intercept for cluster and were run 10 times.

***Not included in imputation as this variable was restricted to those who had current use of family planning

Table S5: Sensitivity analyses of infant immunization outcomes

	Adjusted odds ratio (95%CI)*	Risk difference (95% CI)	p-value	E-value lower bound**	E-value point estimate**
Infants who received OPV 0 within 2 weeks of birth	1.09 (0.77,1.53)	1.7% (-3.6%, 7.3%)	0.64	-	-
Infants who received Measles I by 12 months of age	2.88 (1.58,5.26)	14.1% (9.1%,19.6%)	< 0.001	1.25	1.69
Fully-immunized infants (≤12 months) per WHO standards	3.73 (1.90,7.32)	0.163 (12.6%, 21.8%)	< 0.001	1.37	1.93
Fully-immunized infants (≤12 months) per Republic of Kenya MOH standards	3.39 (1.77,6.47)	16.0% (11.2%, 21.1%)	< 0.001	1.33	1.84

* Results are adjusted for poverty probability index score, maternal education, and insurance at time of delivery.

** E-value represents amount of unmeasured confounding needed to explain away the observed effect size (either point estimate or lower confidence bound). Only estimated when result is statically significant.

Table S6: **Complete cluster outcome primary outcome rates**

Control		Intervention	
Cluster	**Outcome rate**	**Cluster**	**Outcome rate**
Birbiriet (n = 21)	17 (80.95%)	Bikeke (n = 31)	29 (93.55%)
Birunda (n = 31)	18 (60%)	Chematich (n = 25)	20 (83.33%)

Bondeni (n = 15)	10 (66.67%)	Ekegoro (n = 3)	1 (33.33%)
Chisare (n = 4)	3 (75%)	Geta (n = 22)	22 (100%)
Gatua (n = 18)	18 (100%)	Gitwamba (n = 34)	26 (76.47%)
Grassland (n = 31)	28 (96.55%)	Hututu (n = 26)	23 (92.30%)
Kaisagat (n = 17)	13 (76.47%)	Kabolet (n = 15)	14 (93.33%)
Kananachi (n = 27)	21 (84%)	Kabuyefwe (n = 30)	16 (53.33%)
Kapkarwa (n = 9)	7 (77.78%)	Kahuho (n = 24)	23 (95.83%)
Kaplamai (n = 31)	25 (80.65%)	Kapkoi A (n = 50)	39 (79.59%)
Kapomboi (n = 15)	7 (46.67%)	Kapkoi B (n = 15)	10 (83.33%)
Kapterit (n = 10)	7 (70%)	Kapretwa (n = 24)	17 (73.91%)
Kaptumbo (n = 16)	13 (81.25%)	Kesogon (n = 18)	14 (82.35%)
Karaus (n = 5)	5 (100%)	Kimaran (n = 24)	13 (54.17%)
Kdh (n = 41)	38 (95%)	Kiptoi (n = 21)	21 (100%)
Keiyo (n = 9)	6 (66.67%)	Kiriita (n = 28)	26 (92.86%)
Kipkeikei (n = 16)	14 (87.5%)	Kobos Sabwani (n = 11)	8 (72.73%)
Kipsigilai (n = 20)	13 (65%)	Koykoy (n = 28)	20 (71.42%)
Kolongolo A (n = 15)	13 (86.67%)	Kwanza (n = 26)	24 (92.31%)
Kolongolo B (n = 12)	9 (81.82%)	Lunyu (n = 18)	17 (94.44%)
Lyavo (n = 35)	20 (58.82%)	Maridadi (n = 32)	19 (63.33%)
Machungwa (n = 7)	6 (85.71%)	Matisi (n = 12)	9 (75%)
Marambach (n = 20)	12 (60%)	Matisi Corner (n = 27)	24 (90.00%)
Matunda (n = 12)	6 (60%)	Milimani (n = 19)	15 (78.95%)
Michai (n = 12)	11 (91.67%)	Mitambo (n = 23)	22 (95.65%)
Motosiet (n = 25)	22 (88%)	Mitume (n = 26)	20 (86.96%)
Muroki (n = 25)	11 (52.38%)	Munasa (n = 27)	25 (96.15%)
Muthangare (n = 9)	7 (77.78%)	Mutua (n = 18)	9 (64.29%)
Mwitho (n = 45)	29 (64.44%)	Ngonyek (n = 6)	6 (100%)
Nairobi (n = 11)	8 (72.73%)	Nyabomo (n = 19)	16 (88.89%)
Namanjalala 1 (n = 58)	25 (47.17%)	Nyasi (n = 12)	11 (91.67%)
Namanjalala 2 (n = 27)	10 (40%)	Nzoia (n = 13)	12 (92.31%)
Noigam (n = 30)	25 (92.59%)	Olkesem (n = 16)	6 (46.15%)
Rafiki (n = 17)	9 (52.94%)	Sarura (n = 22)	16 (72.73%)
Sibanga (n = 7)	5 (71.43%)	Sukura (n = 38)	22 (59.46%)
Wesakulila (n = 8)	6 (75%)	Tunen (n = 15)	12 (80%)
Wiyeta (n = 17)	17 (100%)	Wehoya (n = 24)	19 (79.17%)