

BMJ Open Can an integrated intervention package including peer support increase the proportion of health facility births? A cluster randomised controlled trial in Northern Uganda

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ABSTRACT

Objective To assess the effect of an integrated intervention package compared with routine government health services on the frequency of health facility births.

Setting Three subcounties of Lira district in Northern Uganda.

Design A cluster randomised controlled trial where a total of 30 clusters were randomised in a ratio of 1:1 to intervention or standard of care.

Participants Pregnant women at ≥28 weeks of gestation.

Interventions Participants in the intervention arm received an integrated intervention package of peer support, mobile phone messaging and birthing kits during pregnancy while those in the control arm received routine government health services ('standard of care').

Primary and secondary outcome measures The primary outcome was the proportion of women giving birth at a health facility in the intervention arm compared with the control arm. Secondary outcomes were perinatal and neonatal deaths.

Results In 2018–2019, 995 pregnant women were included in 15 intervention clusters and 882 in 15 control clusters. The primary outcome was ascertained for all except one participant who died before childbirth. In the intervention arm, 754/994 participants (76%) gave birth at a health facility compared with 500/882 (57%) in the control arm. Participants in the intervention arm were 35% more likely to give birth at a health facility compared with participants in the control arm, (risk ratio 1.35 (95% CI 1.20 to 1.51)) and (risk difference 0.20 (95% CI 0.13 to 0.27)). Adjusting for baseline differences generated similar results. There was no difference in secondary outcomes (perinatal or neonatal mortality or number of postnatal visits) between arms.

Conclusion The intervention was successful in increasing the proportion of facility-based births but did not reduce perinatal or neonatal mortality.

Trial registration number NCT02605369

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Robust study design: The cluster randomised controlled design of this study helped create a balance between study arms.
- ⇒ Minimal loss to follow-up: All but one participant had an outcome measurement which lowered the likelihood of selection bias as an alternative explainer of the study findings.
- ⇒ The large sample size allowed for sufficient power to investigate the primary objective.
- ⇒ A proportion of participants were enrolled late in the third trimester and therefore could not receive the entire intervention package.

INTRODUCTION

Universal coverage of good quality facility-based care is important to improve maternal and newborn survival as around 46% of maternal deaths and 40% of all stillbirths and neonatal deaths happen during labour and on the day of birth.¹ Globally, such care could prevent nearly 113 000 maternal deaths, 531 000 stillbirths and 1.3 million neonatal deaths annually.² In the last two decades, progress in maternal and newborn survival in Uganda has been slow. During this time, the maternal mortality ratio has remained high at 336/100 000 live births (95% CI 272 to 401).³ Similarly, the neonatal mortality rate also continues to be high at 22/1000 live births.⁴ In the Lango region of Northern Uganda, one-third of all women give birth outside health facilities, mostly at home³ with the subsequent increased risk of both maternal and perinatal adverse outcomes. Decisions on place of delivery are complex. Factors that may contribute to home delivery

in Uganda and other similar countries include timing of the first antenatal care visit,⁵ lack of awareness of the time of delivery, lack of awareness of the importance of facility births,⁶ perceived poor quality of care at the health facilities,^{7 8} low maternal education,^{9 10} low socioeconomic status,^{7 11} rural residence and lack of transport.^{7 8 12}

While multiple studies have examined the association between these factors and utilisation of health facilities around the time of birth, there is inadequate implementation research exploring the best systematic methods to promote increased use of facility-based births. Previous studies have mostly consisted of single interventions and often their effect has been small. We posited that an integrated package of interventions could have multiplicative effects that are greater than the sum of individual interventions. As such, we undertook a trial with an integrated intervention package consisting of (1) peer counselling by pregnancy buddies on facility-based births, (2) mobile phone messaging promoting facility-based births and (3) provision of birthing kits, locally called mama kits to pregnant women. We hypothesised that peer support during pregnancy would increase attendance of health facilities at birth through provision of social relationships that positively impact the decision-making process. Indeed, there have been some studies that have linked peer support with positive maternal and fetal outcomes.¹³ A few studies have also shown that mobile phone messaging to pregnant women increased skilled attendance at birth.¹³ In addition, we posited that providing mama kits to pregnant women at the household level would motivate them to give birth at health facilities.¹⁴ The intervention was meant to mitigate the first two delays for health facility utilisation in Thaddeus and Maine's model.^{2 15-17} This model postulates three delays: (1) delay in deciding to seek care on the part of the individual, the family or both, (2) delay in reaching an appropriate healthcare facility and (3) delay in receiving adequate healthcare at the facility.

We compared an integrated intervention package of peer support, mobile phone messaging and provision of mama kits at household level to routine government health services on the frequency of health facility births in a cluster randomised controlled trial. Our primary objective was to examine the effect of an integrated intervention package including peer support on the proportion of health facility births. We also explored the effect of this intervention on neonatal outcomes and access to postnatal care as secondary objectives. This integrated low-cost intervention—if successful—could translate into policy promoting facility-based births in Uganda and beyond.

MATERIALS AND METHODS

Trial design: Between January 2018 and February 2019, we carried out a community-based cluster randomised controlled intervention trial of pregnant women enrolled at ≥ 28 weeks of gestation and followed up to 50

days post partum in Lira district, northern Uganda. The trial report adheres to the Consolidated Standards of Reporting Trials and its extension to cluster randomised trials.¹⁸

Trial site: Lira district is located in Lango subregion, Northern Uganda, approximately 350 km North of the capital city, Kampala. It covers approximately 1300 km² with a population of about 400 000 inhabitants, predominantly Langi whose main language is Langi, a Luo-dialect, and most of the people are subsistence farmers. Lira municipality is the administrative centre of Lira district. At the time of the trial, the district composed of 3 constituencies: Lira municipality, Erute north and Erute south, 13 subcounties, 89 parishes and 751 villages. The district was served by 31 healthcare facilities including 1 referral hospital, 3 health centres with operation rooms, 17 health centres with maternity wards but without surgical facilities and 10 health centres with outpatient services only (dispensary). Participants were recruited from the subcounties of Aromo, Agweng and Ogur located in the northern part of the district, with four government health centres and three private-not-for profit health facilities. These subcounties were purposively selected because they were rural and had the poorest maternal and perinatal indicators in the district.

Trial participants: In each cluster, pregnant women were identified by a community recruiter (pregnancy monitor) who was a woman living within the cluster, and selected by community members for this role. A total of 250 pregnancy monitors were trained on how to identify pregnant women in their communities and inform the trial team. They were each given a mobile phone to enable them to communicate with the trial team. Whenever a pregnant woman was identified, the community recruiter informed the research assistant and together organised and visited the pregnant woman at home. The research assistant determined eligibility, obtained consent and conducted the recruitment interview.

Inclusion and exclusion criteria: All pregnant women at 28 or more weeks of gestation, resident in the selected clusters that consented to participate, were included in the trial. Pregnant women under 18 years of age were included since they are considered as emancipated minors according to the guidelines of Uganda National Council for Science and Technology, the regulatory body for research in Uganda. Pregnant women with an intention to move from the study area within 1 year, as well as mothers with conditions that prevented them from providing informed consent (such as psychiatric illnesses) were excluded.

Intervention: The trial assessed the effect of an integrated package consisting of (a) peer support by pregnancy buddies with a minimum of three planned visits, (b) mobile phone messages encouraging facility-based births and (c) provision of mama kits at household level (as opposed to health facility distribution). We randomised 30 clusters (ratio of 1:1) to the intervention or control arm. Mothers in the control clusters received routine care

during antenatal care and had no peer support by pregnancy buddies.

Peer support for facility-based births by pregnancy buddies/peer supporters

Peer supporters were identified and selected from the 15 clusters randomised to the intervention. Peer supporters/pregnancy buddies were women in the reproductive age group (aged 25–45 years) who, themselves, had given birth before, were residents in the study area for at least 12 months, unlikely to relocate from the study area in the next 3 years, literate in the local language and willing to train as peer supporters/buddies. They were women of good repute and approachable by community members. They were selected in conjunction with the community leaders and village health team members. The selected women were provided with approximately 20 hours of training. Approximately 30 peer supporters were trained (about double the number needed), to allow for attrition, sickness, etc. After informed consent, at least three home visits were scheduled for the women assigned to the peer support group. The first visit was immediately after recruitment, the second was after 2–4 weeks and the third visit was within 1 week after giving birth. These visits were arranged at the convenience of the mother. Peer supporters would provide substantial information about pregnancy and childbirth and encourage mothers to deliver at a health facility. They had been trained on good communication skills such as listening and how to address specific concerns of the mothers, correct misinformation without making mothers feel defensive or inadequate. At the same time peer supporters worked with the women to plan for a health facility delivery (birth preparedness plan) to mitigate the physical and economic barriers that contributed to the first two delays. They encouraged the pregnant women to plan and set aside funds for transport to the health facility and for other necessities such as warm clothes for the baby. They also delivered messages on the advantages of facility-based births, provided simple technical information for overcoming constraints, and provided reminders and encouragement to deliver at health facilities. They did not only target the pregnant women, but also the husband, the mother-in-law and other influential adults in the household. Extra visits were organised and synchronised with the mobile phone personalised information for women without access to the mobile phones.

Mobile phone messaging

The second component of the intervention was mobile phone messaging using a series of 11 short messages which were sent weekly to the telephone numbers provided by the pregnant women, starting at week 28 of gestation. The messages were simple health education messages concerning childbirth, expected date of delivery reminders and encouragement to prepare for and deliver at a health facility. The messages were unidirectional, from the research centre to the participants. The text

messaging system was automated and messages were delivered according to the gestational age. Text message content was targeting the pregnant woman, her husband and mother-in-law in the local language (Langi). The participants had three telephone contacts of the investigators whom they were free to contact or consult in case they had any issues to discuss.

Mama kits

All women in the intervention clusters were each provided with a mama kit consisting of clean plastic sheets, a razor blade, cord ligatures, swabs, two pairs of gloves, cotton and gauze. The kits were given to the women during the third trimester, after 28 weeks of gestation. We anticipated that household distribution of mama kits would motivate women to give birth at a health facility.

Control arm: Participants in the control area received the standard of care, which involved occasional radio health promotional messages by the Ministry of Health, as well as information obtained during the antenatal, natal and postnatal health facility visits. This information was commonly delivered to pregnant women during each visit, in-group sessions and often in a didactic format. Topics covered majorly included malaria, HIV, immunisation with less emphasis on newborn care.

Sample size: The sample size was based on a proportion of facility births of 40% in the control clusters [Uganda Demographic and Health Survey (UDHS) 2016], an estimated 30% increase (risk difference (RD)) in facility births in the intervention clusters, a power of 90%, 95% CIs, an intraclass correlation coefficient (ICC) of 0.09,¹⁹ an average cluster size of 50 pregnant women and 20% loss to follow-up. Approximately 1800 pregnant women in 30 clusters were required for this outcome.

Randomisation: The unit of randomisation ('cluster') was made up of 5–10 villages with a population of at least 1000 people. All the villages in the three participating subcounties were considered in the formation of clusters. The clusters were chosen in such a way that each cluster represented a social and administrative unit. Using population size, proximity to health facilities, roads, schools, markets and trading centres 15 intervention and 15 control clusters were created. Clusters with similar characteristics were paired; within each pair one cluster was randomised to the intervention and the other to the control arm. The random allocation sequence was generated by an independent researcher not involved in the trial.

Masking: Ascertainment of outcome was done by research assistants (data collectors) not involved in the exposure allocation. The data collectors were uninformed of the allocation of clusters. The trial took place simultaneously in all the clusters; therefore, there was no need for allocation concealment.

Outcomes: The primary outcome was the proportion of women giving birth at a health facility in the intervention arm compared with the control arm. Secondary outcomes in this study include neonatal death and newborn

check-up by a healthcare worker at 48 hours and again after 7 days of life. Neonatal death was defined as death of a live born infant within the first 28 days.

Data collection and management

All data were collected using standardised questionnaires and forms for consistency. Data were collected electronically using the open data kit (ODK) platform (<https://getodk.org/>) on smartphones. The interviewers entered the data directly on ODK. The ODK app had in-built consistency checks which could not allow certain types of erroneous responses to be entered. A trial coordinator supervised the field team daily to ensure good quality data.

All mothers were interviewed at recruitment to obtain data on possible confounding factors as well as descriptive statistics. They were interviewed again on days 7, 28 and 50 to determine the place of birth, pregnancy outcome, vital status of the child and any maternal or early infant illness. Additional information was obtained on infant feeding patterns including initiation of and exclusive breast feeding.

Both perinatal and neonatal mortality data were obtained using a standard WHO verbal autopsy questionnaire. This questionnaire has both an open-ended section for reporting verbatim and a section with close-ended questions with filter questions.

Data management

Data collected electronically on handheld devices in the field were temporarily stored in a secure and encrypted database on a memory card on the handheld device and automatically uploaded to the site-office database daily. On the handheld, device data were encrypted and protected with a strong password and username combination. The site office was secured to prevent theft and unwanted access to hardware and data. Access to collected data at the site was strictly controlled by the onsite data manager. Data were checked for completeness daily and transferred from the handheld devices to the server for storage.

Quality control

The research assistants were recruited from Lira and neighbouring districts and could efficiently communicate in the local language. They were trained on the study objectives, electronic data collection and anthropometry. Home visits were carefully scheduled to avoid the peer counsellors from coinciding with the research assistants' visits. The informed consent form and questionnaires were translated into Langi and back-translated into English. The questionnaires were pretested and piloted prior to the trial. Standard operating procedures were developed prior to trial implementation and adhered to throughout the trial. Weighing scales were checked daily for accuracy using standard weights, zeroed before each field visit and before each measurement was taken.

Statistical analysis

Data were analysed by using Stata V.15 (StataCorp). Continuous variables were summarised into means, medians, and SD and categorical variables were summarised into proportions. Baseline characteristics of the mother, household and newborn were compared between intervention and control groups to check for group comparability and identify variables that could lead to baseline imbalance. Descriptive statistics for timing, frequency and coverage of the intervention was computed. Analysis for the main outcome was analysed on an intention-to-treat basis.

The risk of having a facility birth in the intervention group was compared with a similar risk in the control group using generalised estimating equations (GEEs) of the binomial family to accommodate for clustering assuming an exchangeable correlation structure. We used a log link to obtain risk ratios (RRs) and an identity link to obtain RDs. Variables that showed baseline imbalance in arms including marital status ($p < 0.001$) and having electricity in a household ($p < 0.001$) were adjusted for in a multivariable GEE model. A random effects model was then fitted, adjusted for marital status and having electricity in the household to estimate the ICC using the Stata command 'melogit'.

We explored potential differential intervention effects by mobile phone ownership. To do this, we summarised the outcome across levels of mobile phone ownership in the intervention arm, and also rerun the unadjusted GEE model of the binomial family with a log link, including the intervention, mobile phone ownership and a mobile phone ownership by intervention interaction term. This analysis was planned a posteriori as an attempt to explore whether there was evidence of a greater benefit in the intervention arm among those who owned a phone or had access to a phone in their homes. To quantify any biological interaction between mobile phone ownership and the intervention, we estimated the absolute excess risk due to interaction by using Stata's icp command to fit a log binomial model and we adjusted for clustering as shown in the Stata code below.

icp, show: binreg place_birth intervention phone_ownership, nolog cformat(%7.3f) vce(cluster cluster) rr

To measure relative inequality, we used the concentration curve and the concentration index (CI), which we calculated using the STATA DASP package (we also used this package for all the other equity-related analysis). The CI is defined as twice the area between the concentration curve and the diagonal line of equality.¹⁷ It measures the extent of health or healthcare utilisation that is systematically associated with socioeconomic status and it is preferred to other measures of inequality because it reflects the experiences of the entire population and the socioeconomic dimension in health inequities.¹⁷ The CI is represented by the formula:

$$C = \frac{2}{\mu} \text{Cov}(h, r)$$

Where C is the CI, $\text{Cov}(h, r)$ is the covariance between the place of birth variable (h) and the fractional rank of the person in the living standard distribution (r), and μ is the mean of the healthcare utilisation variable.^{20 21} A positive CI shows that the health variable is more concentrated among the rich, while a negative CI shows that the health variable is more concentrated among the poor.¹⁷ Socioeconomic status was calculated from an asset-based index using principal component analysis. The following assets and house characteristics were considered: cupboard, bicycle, radio, mobile phone, motorcycle, cement floor, iron sheets for the roof, burnt bricks for the wall and land ownership. The concentration graph was drawn using the STATA Lorenz command. We used Stata's conindex command to calculate the CI, the difference between the concentration indices in the intervention and control group, and to conduct a significance test of the differences. The Stata code for these calculations is as follows:

```
Pca cement floor ironsheets Wburnt bricks own land
cupboard bicycle radio e phone motorcycle
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Predict score 1
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Igini place_birth rank (score 1)
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Lorenz place_birth over (intervention) gini vpar (score 1) graph (noci)
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```
Conindex place_birth rank (score 1) truezero compare (intervention) cluster (cluster) robust
```

We used an equiplot to graphically represent the effect of the intervention on relative inequality in utilisation of healthcare facilities for childbirth.

Patient and public involvement

The public was not involved in the design and conceptualisation of the study but they were involved in the recruitment of participants. We held community meetings in each village during which a recruiter was elected from among the village members. The recruiter was responsible for recruitment in their village. The results of this study will be disseminated to the wider community through community dialogue meetings at parish level in each participating village.

RESULTS

Characteristics of trial participants

Of the 2354 pregnant women identified from January 2018 to February 2019, 1887 women were recruited into the trial (figure 1). In the 15 clusters randomised to the intervention, there were 995 pregnant women and in the 15 control clusters there were 882 pregnant women. Place of birth was ascertained for 1876 participants and one participant died before childbirth.

Participants were largely similar between the two arms, but we observed some baseline differences. Mothers in the intervention arm were less likely to be single (living alone) (69/995) 6.9% compared with mothers in the control arm (95/882) 10.8%. In the intervention arm, 155/995 participants (16%) had electricity at home compared with 55/882 (6%) in the control arm (table 1).

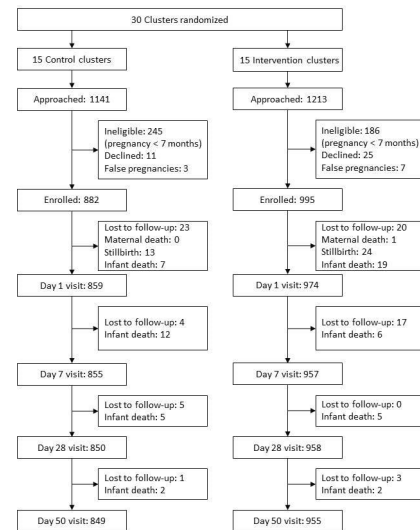


Figure 1 Trial profile.

Primary outcome

In the intervention arm, 754/994 participants (76%) gave birth at a health facility compared with 500/882 (57%) in the control arm. Participants in the intervention arm were 35% more likely to give birth at a health facility compared with participants in the control arm (RR 1.35 (95% CI 1.20 to 1.51)) and (RD 0.20 (95% CI 0.13 to 0.27)) (table 2). Adjusting for baseline differences (marital status and electricity at home) generated similar results (RR 1.33 (95% CI 1.19 to 1.49)) and (RD 0.19 (95% CI 0.12 to 0.26)) (table 2). The ICC was estimated to be 0.04 (95% CI 0.02 to 0.09).

Modification of intervention effects by mobile phone ownership

Of the 994 participants in the intervention arm, 582 (58.6%) owned a mobile phone in their homes whereas 412 (41.4%) did not have a mobile phone in their homes. Of those with a mobile phone in their homes, 78.0% (454/582) gave birth from a health facility whereas among those without a mobile phone in their homes, 72.8% (300/412) gave birth in a health facility. The interaction term between mobile phone ownership and the intervention was not statistically significant ($p=0.408$). Relative excess risk due to interaction between mobile phone ownership and the intervention was estimated to be -0.025 (95% CI -0.168 to 0.117 , $p=0.7270$).

Secondary outcomes

In the intervention arm, 49/995 participants (4.9%) experienced a perinatal death compared with 32/882 (3.6%) in the control arm but this was not statistically significant (RR 1.4 (95% CI 0.87 to 2.1)). Neonatal mortality was similar between the intervention arm 30/974 (3.1%) and the control arm 24/859 (2.8%) (RR 1.1, 95% CI 0.61 to 2.0).

Giving birth at a health facility was more common among women in the upper socioeconomic strata, it was pro-rich (CI 0.026, Robust SE (0.017)) and the intervention slightly

Table 1 Characteristics of the participants in a trial assessing the effect of an integrated intervention package on the proportion of health facility births in Northern Uganda

Participant characteristics	Total N=1877	Control N=882	Intervention N=995	P value	
Continuous variables					
Age of mother					
Median (IQR)	23 (19–29)	23 (19–29)	23 (19–29)	0.391	
No of live children at enrolment*	N=1451	N=685	N=766		
Median (IQR)	2 (1–4)	2 (1–4)	3 (1–5)	0.093	
Categorical variables					
Mother's highest level of education					
None	248 (13.2)	131 (14.9)	117 (11.8)	0.119	
Primary	1459 (77.7)	669 (75.9)	790 (79.4)		
Secondary and tertiary	170 (9.1)	82 (9.3)	88 (8.8)		
Husband's highest level of education†					
None	35 (2.0)	14 (1.8)	21 (2.3)	0.249	
Primary	1109 (64.7)	520 (66.1)	589 (63.6)		
Secondary	457 (26.7)	211 (26.8)	246 (26.6)		
Tertiary	112 (6.5)	42 (5.3)	70 (7.6)		
Marital status					
Married	1467 (78.2)	677 (76.8)	790 (79.4)	0.012	
Cohabiting	246 (13.1)	110 (12.5)	136 (13.7)		
Single	164 (8.7)	95 (10.8)	69 (6.9)		
Mobile phone ownership at home (1024)					
Yes	1024 (54.6%)	442 (50.1)	582 (58.5)	<0.001	
Who owns the phone (1024)					
Mother	93 (9.1)	34 (7.7)	59 (10.1)	0.745	
Husband	739 (72.2)	324 (73.3)	415 (71.3)		
Mother-in-law	15 (1.5)	6 (1.4)	9 (1.6)		
Father-in-law	24 (2.3)	11 (2.5)	13 (2.2)		
Others	153 (14.9)	67 (15.2)	86 (14.8)		
Electricity at home					
Yes	210 (11.2)	55 (6.2)	155 (15.6)	<0.001	
Source of drinking water					
Borehole	969 (51.6)	470 (53.3)	499 (50.2)	0.331	
Tap/piped water	219 (11.7)	96 (10.9)	123 (12.4)		
Protected natural spring	339 (18.1)	148 (16.8)	191 (19.2)		
Unprotected water source	350 (18.7)	168 (19.1)	182 (18.3)		
Mother has attended antenatal					
Yes	1481 (78.9)	696 (78.9)	785 (78.9)	0.993	
Socioeconomic status					
Lowest 40%	753 (40.1)	372 (42.2)	381 (38.3)	0.176	
Middle 40%	752 (40.1)	347 (39.3)	405 (40.7)		
Top 20%	372 (19.8)	163 (18.2)	209 (21.0)		
Place of birth of previous child‡					
Health facility	632 (47.0)	292 (47.1)	340 (47.0)	0.960	
Home	712 (53.0)	328 (52.9)	384 (53.0)		

Continued

Table 1 Continued

Participant characteristics	Total N=1877	Control N=882	Intervention N=995	P value
Vital status of previous child†	N=1344	N=620	N=724	
Alive	1175 (87.4)	544 (87.7)	631 (87.2)	0.746
Dead	169 (12.6)	76 (12.3)	93 (12.9)	
Child characteristics				
Sex	N=1833	N=859	N=974	
Male	913 (49.8)	429 (49.9)	484 (49.7)	0.915
Female	920 (50.2)	430 (50.1)	490 (50.3)	
Birth weight	N=1518	N=719	N=799	
Mean (SD)	3.3 (0.6)	3.3 (0.5)	3.3 (0.6)	0.811

*Excludes those who never had a pregnancy before.
†Excludes those who did not know their husband's level of education.
‡Excludes those who had an abortion during the previous pregnancy.

decreased this pre-existing inequality (figures 2 and 3) though the difference was not statistically significant (CI in control group: 0.036, CI in intervention group: 0.0121, difference -0.024, $p=0.2658$). The intervention did not increase the proportion of mothers who sought care at the health facility on the third postpartum day either for themselves or their newborns: 78/909 (8.6%) of women in the intervention arm had a postnatal visit in the first week of life compared with 56/824 (6.8%) adjusted RR (aRR) 1.25 (95% CI 0.68 to 2.31). Among those who gave birth at home 18/214 (8.4%) had a postnatal visit in the intervention compared with 25/353 (7.1%) in the control group: aRR 1.17 (95% CI 0.62 to 2.2).

DISCUSSION

This trial estimated the effect of an integrated intervention package consisting of peer support, mobile phone messaging and provision of mama kits to pregnant women at the household level on the frequency of health facility births in a cluster randomised controlled trial. Women in the intervention clusters were 35% more likely to deliver at a health facility in comparison to those in the control clusters. In addition, the intervention slightly decreased the pre-existing inequality in facility births between

higher and lower socioeconomic strata. The effect of the intervention package on increasing the frequency of facility-based births can be partially attributed to its ability to target the first two delays in Thaddeus and Maine's three delays model.¹⁶ Factors that may contribute to the first delay that our intervention specifically targeted include lack of awareness of the time of delivery, lack of awareness of the importance of facility births²² and a negative impression of the health facilities. Factors that may lead to the second delay that we specifically tackled include residence in rural areas and lack of transport. In the following, we review each component of the integrated intervention.

The first component of the intervention, peer support by pregnancy buddies: The significance of social relationships in health promotion and countering of the first two delays cannot be overemphasised.²³ While the literature on peer support and facility deliveries is scanty, multiple studies have found a beneficial effect on other maternal and early childhood outcomes.²³ Positive associations have been reported between peer support and (1) prenatal care²⁴ (2) perinatal outcomes²⁵ and (3) breast feeding.^{26 27} Peer support may impact health outcomes by influencing the decision-making process that underpins

Table 2 Unadjusted and adjusted risk ratios and risk differences in relation to the primary outcome, place of birth in Northern Uganda

	N	Facility birth n (%)	Unadjusted RR (95% CI)*	Adjusted RR (95% CI)‡	Unadjusted RD (95% CI)*	Adjusted RD (95% CI)‡
Trial arm						
Control	882	500 (56.7)	*	*	*	*
Intervention	994	754 (75.9)	1.35 (1.20 to 1.51)‡	1.33 (1.19 to 1.49)‡	0.20 (0.13 to 0.27)‡	0.19 (0.12 to 0.26)‡

*Accounting for clustering.
†Adjusted for clustering and baseline differences (marital status and electricity at home).
‡Significant ($p<0.001$).
RD, risk difference; RR, risk ratio.

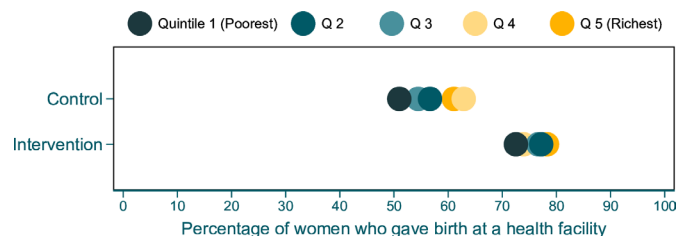


Figure 2 Effect of the intervention in reducing inequality of health facility utilisation in Lira district across wealth quintiles.

the first delay described earlier. It is known that during times of indecision and need, as may occur during pregnancy, women may turn to their social networks for support in response to multiple barriers. At such a time, peer supporters may provide crucial emotional, appraisal and informational support to these women. Such support could explain the reported increase in facility-based births in the intervention clusters.

The second component of the intervention, mobile phone messaging for promoting facility-based births: It is estimated that nearly 60% of the Ugandan adult population own a mobile phone.²⁸ Mobile phones may be used to reduce the first two delays by cheaply and timely relaying information promoting facility-based births from healthcare workers to the pregnant women. However, data on the use of mobile phone technology on maternal and newborn outcomes is scanty. A Nigerian study found that mobile phone messaging to pregnant women significantly increased skilled attendance at birth.²⁹ This widespread low-cost technology could be instrumental in reducing the high maternal morbidity and mortality through increasing facility-based births.

The third component of the intervention, provision of mama kits: Use of mama kits (birth kits or birthing kits) during delivery has been associated with reduced newborn morbidity, mortality and maternal puerperal sepsis in some areas^{30 31} but not in others.³² While mama kits are an essential part of delivery care in many resource-limited countries, they are very often unavailable in many health facilities and mothers may be required to procure them on their own from private pharmacies. This may constitute an additional barrier to accessing health facilities for

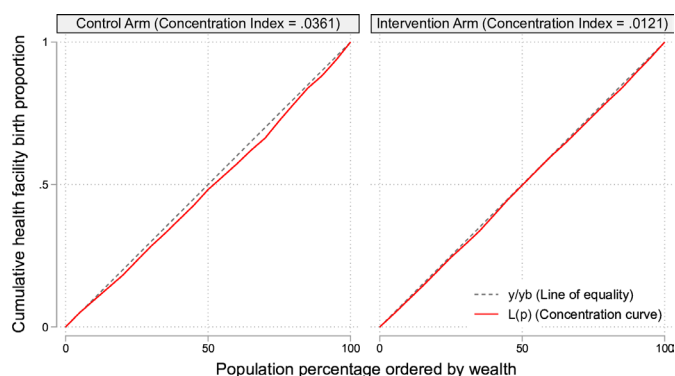


Figure 3 Lorenz curves showing distribution of health facility births by wealth status stratified by trial arm.

birth. In this trial, mama kits were provided to the women and this could have contributed to the observed increment in facility-based births.

In an integrated package of interventions, it is not possible to scientifically distinguish the impact of the different components. But as a research team, we still have the impression that peer support was the most important component. The buddies established an excellent rapport with the women and the women were really happy for the interaction. The least important component, according to our impression, was the mobile phone messaging. Women did not have mobile phones to the extent expected and charging the phone without electricity at home was a logistic challenge. Even if the messages came through to the women in their own language, they often had difficulties reading or understanding them. We conducted a posteriori exploratory analysis to assess whether households that owned a mobile phone had added benefit from the intervention arm and found that there was no added benefit.

Similar to the study in Pakistan that examined the effect of an integrated neonatal care kit,³² our trial did not find an association between the intervention and perinatal mortality or neonatal mortality. Similarly, there was no association between the intervention and the number of postnatal visits. This finding is also congruent with findings from a recent secondary analysis of data from 119 244 pregnant women that participated in two large, population-based cluster randomised trials in Ghana in which higher proportions of facility-based births did not translate to any mortality reductions.³³

The main strengths of the trial were the minimal loss to follow-up and the ability to ascertain the primary outcomes. The main limitation of the trial was the lack of concurrent 'supply-side' intervention packages that could have improved the health facilities' ability to provide emergency obstetric and newborn care. In addition, a proportion of women were recruited late into their third trimester and they did not have enough time to receive the full intervention package. Another potential limitation is the analysis using GEE ignored pairing of clusters because the methods to account for this are not well explained in the literature. Finally when we interviewed participants in the intervention group to assess study fidelity and quality 766/805 (95.2%) in the intervention group reported that a peer counsellor visited them. Only half of the participants had a mobile phone in the homesteads and less than 10% of the mothers had personal mobile phones. This means that most of the mobile phone messages did not reach the intended parties and the trial lost out on the benefit of mobile phone messages reinforcing the peer counselling.

CONCLUSION

This trial has shown that an integrated intervention consisting of peer support, mobile phone messaging and provision of mama kits at household level was successful in

increasing the proportion of facility-based births. Future studies seeking to lower mortality outcomes need to carefully consider adding 'supply-side' intervention packages that improve the health facilities' ability to provide emergency obstetric and newborn care.

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JKT is the guarantor and takes full responsibility of the study and this paper. VN, JKT, GN, TT, MBS, JNW and PW conceptualised and participated in the design and implementation of the trial. DM, BO, AAA, VA and LM participated in the planning and data collection. Analysis and first draft were done by LM, VN, DM, GN and TT. All authors participated in subsequent write-ups, reviewed and approved the final manuscript. JKT is the guarantor and takes full responsibility for the overall content of the study and this paper.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by School of Medicine Research and Ethics Committee, Makerere University: SOMREC 2015-121, Uganda National Council of Science and Technology: SS 3954 Regional Committee for Medical and Health Research Ethics West, Norway: 2017/2079/REK vest. Participants gave informed consent to participate in the study before taking part.

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Data availability statement Data are available on reasonable request. The data set will be provided or shared on request.

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