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Couples' counselling during pregnancy in Uganda

Submission date
21/09/2021

Recruitment status
No longer recruiting

Registration date
22/09/2021

Overall study status
Completed

Last Edited
07/11/2023

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims

We aim to evaluate a complex intervention for reducing deaths in mothers and babies, by improving birth planning and uptake of contraception after delivery in Uganda.

Every year, thousands of women and children in Uganda die as a result of problems during pregnancy and childbirth. Our research in 2011-2015 showed that about 20% of these deaths could have been avoided by use of contraception, to prevent unwanted pregnancies. Another 25% or so could be prevented by ensuring mothers go to the most appropriate health facility for their delivery. In Uganda, many women will not take these decisions without the approval and support of their husband; 43% of women still do not give birth in a health facility. Of those who do deliver in a health facility, many high-risk women deliver in a small health centre which is unable to offer emergency surgery if needed.

If a woman does deliver in a health facility, although she may never return for postnatal check-ups, there is a key opportunity to provide contraception immediately after delivery. Although several projects have trained health workers to provide the contraceptive coil immediately after delivery, few women go home with a method of family planning in Uganda.

To understand why, our team interviewed 80 women, men and health workers in Uganda in 2015. Many women wanted time to discuss contraception with their husband (who was often absent at the time of delivery) and to recover from the birth. Women feared side-effects such as bleeding, and the impact these would have on their marriage; men were also concerned about side-effects and the cost of managing these.

Many people we interviewed suggested that more awareness-raising on family planning was needed. Several people also suggested that men should accompany their wives to antenatal clinics (which rarely happens in Uganda) to discuss future family planning with a health worker. This would also be an ideal opportunity to discuss the birth plan with the couple, and to gain the husband's understanding and cooperation in deciding on the safest place for the delivery.

We have now developed health education documentaries and dramas on contraception, in two local Ugandan languages. The films have been edited to incorporate feedback from local audiences and are ready to be evaluated on a larger scale. However, it is likely that films alone would have a limited impact, unless they are followed up with counselling of couples to address their specific questions and concerns.

We have sought feedback on the concept of antenatal couples' counselling in 18 focus groups with women, men and health workers in central and southern Uganda. Almost everyone liked

this concept, but there remain several challenges. Firstly, men are often reluctant to attend antenatal clinics, because of transport costs, location and timing. They suggested that their attendance could be increased by holding "outreach" antenatal clinics in villages which are far from health facilities, and by holding antenatal clinics at weekends. Secondly, some men are reluctant to be tested for HIV together with their partners. Thirdly, some health workers felt that they would not have time to provide in-depth couples' counselling in addition to their existing workload.

In this project, we are piloting a complex intervention to deliver couples' counselling in antenatal clinics in Uganda, in order to increase appropriate place of delivery, and increase uptake of post-partum contraception. This intervention includes (a) training of village health teams to counsel antenatal couples and encourage them to attend antenatal clinic together; (b) health education films on family planning; (c) training of health workers in antenatal clinics to provide effective couples' counselling on birth planning and post-partum family planning.

Who can participate?
Pregnant women (at less than 7 months of pregnancy) residing in the study areas in Mbarara district, Uganda, who have been in a relationship with the father of the expected child for at least 6 months and give their informed consent.

What does the study involve?
Pregnant women taking part in the study will be visited by their village health team (VHT) twice during their pregnancy, and three times in the year after delivery (about one week, 6 months and 12 months after delivery). At each visit the VHT will complete a questionnaire with the woman and her partner (if he is available) about their intentions and actions regarding birth planning and use of family planning after the delivery.
In the intervention group only, the VHT will also offer counselling to the couple about birth planning and family planning and will invite them to attend counselling with a health worker at the antenatal clinic. The VHT will also offer to show them some films about family planning. If the couple attends the antenatal clinic together, the health worker will offer them counselling as a couple about birth planning and family planning.

What are the possible benefits and risks of participating?
There are no risks to participants from taking part. Participants are unlikely to feel upset by questions asked. Participants are free not to answer any question or stop the study at any time. Participants will benefit from regular follow-up from a VHT. In the intervention group, the VHT will provide advice on the pregnancy and on family planning and participants will also benefit from counselling from a health worker. We hope this study will help us improve antenatal and postnatal couples' counselling locally and elsewhere. Participants and others in their community might benefit from these improved services in the future.

Where is the study run from?
Mbarara University of Science and Technology, Mbarara, Uganda

When is the study starting and how long is it expected to run for?
March 2020 to August 2022

Who is funding the study?
The study is funded by the UK Medical Research Council as part of the UK's Joint Global Health Trials scheme.

Who are the main contacts?
Dr Merlin Willcox (M.l.willcox@soton.ac.uk) and Dr Vincent Mubangizi (vmubangizi@must.ac.ug)

Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
54459

Study information

Scientific Title
Antenatal couples’ counselling in Uganda: feasibility trial

Acronym
ACCU

Study objectives
We hypothesise that a complex intervention (comprising training for health workers and village health teams on birth planning, post-partum family planning and couples' counselling) is feasible and culturally acceptable to deliver in antenatal clinics and postnatal follow-ups in Uganda. We also hypothesise that village health teams will be able to follow up participants for up to one year after delivery of their baby, and collect relevant outcome data using a smartphone app.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 14/08/2020, Mbarara University Research Ethics Committee (PO Box 1410, Mbarara, Uganda; +256 485433795; sec.rec@must.ac.ug), ref: MUREC 1/7, 16/06-20
2. Approved 21/08/2020, Faculty of Medicine Research Ethics Committee, University of Southampton (Southampton General Hospital, Mailpoint 801, South Academic Block, Tremona Road, Southampton SO16 6YD, UK; +44 (0)23 8059 2819; ERGOII@soton.ac.uk), ref: ERGO 54459.R3

Study design
Feasibility interventional cluster-randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Pregnancy and childbirth: uptake of birth planning advice (at delivery) and post-partum family planning (after delivery) amongst mothers in Uganda

Interventions
Health centres are randomised to one of two groups:
1. Usual care (control)
2. Intervention.

We will use stratified randomization according to urban/rural location. Participating health facilities will be randomized during a meeting in which the District Health Officer is invited to draw pieces of paper out of a hat – so that the randomization process is open and understood by all.

The intervention consists of the following components:
(a) Training Village Health Teams (VHTs) to provide basic information and counselling to antenatal couples in the community, encouraging them to attend a formal antenatal clinic, deliver in an appropriate place according to their level of risk, attend postnatal care clinic and use postpartum family planning. The information delivered by VHTs will also include birth preparation and complication awareness. They will also be trained to show health education films on their smartphones. If the husband does not want to attend antenatal clinic, they will be given the option of speaking to the health worker to answer any questions over the phone if appropriate. The VHTs will also provide counselling on PPFP at the postnatal visits, if the woman has not yet started it.
(b) A training course for health workers, covering general communication skills, couples' counselling, information and refresher practical training on antenatal risk assessment, birth preparedness and post-partum contraception provision. Health workers will be asked to provide couples' counselling to couples who come together to the antenatal clinic.
(c) Payment for health workers' extra work in providing couples' counselling at weekends and helping with data collection.
(d) Screening of health education films in antenatal clinics and postnatal wards: Health Facilities will be provided with a screen and health education films about the contraceptive implant. They will be asked to screen the films daily. The films will also be shown in the waiting room of the antenatal clinic and of the postnatal clinic, so the couples will see them if and when they attend antenatal and postnatal clinics. These consist of a documentary and a short drama film, both of which have undergone extensive development in Uganda using the person-based approach to intervention development and have been approved by the Ministry of Health.

Follow-up is at 1 week, 6 months and 12 months after delivery.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility outcomes measured using participant logs at the end of the study (12 months):
1. % of eligible women who consent to participate and are recruited
2. % of included women who can be followed up and provide outcome data on place of delivery and uptake of family planning

Key secondary outcome(s))
Measured using participant logs at the end of the study (12 months):
1. % of included women:
1.1. Whose partners agreed to participate in the project
1.2. Who received individual counselling from the VHT on one or more occasions
1.3. Received couples counselling from the VHT on one or more occasions
1.4. Attended the antenatal clinic at the health centre one or more times
1.5. Attended the antenatal clinic at the health centre with their partner one or more times
1.6. Received individual counselling at the antenatal clinic on PPFP
1.7. Received individual counselling at the antenatal clinic on birth planning
1.8. Received couples' counselling at the antenatal clinic on PPFP

1.9. Received couples' counselling at the antenatal clinic on birth planning
1.10. Were given correct advice on the recommended place of delivery (according to their level of risk)
1.11. Watched the health education films with the VHT/at the antenatal clinic
2. % of included couples who:
2.1. Were offered and attended antenatal clinics and counselling at weekends.
2.2. Were counselled and consented for long-acting reversible methods of post-partum family planning (PPFP)
3. Proportion of women/couples attending antenatal clinic who were offered counselling on both birth planning and use of long-acting reversible methods of post-partum family planning at the same visit.
4. Proportion of women/couples counselled who agreed on PPFP in a single session, and proportion of women/couples counselled who agreed after attending extra sessions.
5. % of working days when the films on family planning are screened in antenatal clinics (in intervention areas).
6. % of VHT visits when:
6.1. Counselling was delivered to the woman/couple about birth planning/family planning
6.2. Data was correctly entered directly into the COSMOS app on the smartphone
7. Costs incurred measured by self report in follow up questionnaires and by qualitative interviews at follow-up (between 1 week and 1 year after delivery)

Completion date
31/08/2022

Eligibility

Key inclusion criteria
The health facilities to be included should meet the following criteria;
1.1. Offering the continuum of ANC, delivery, and PNC services
1.2. Offering antenatal care services to more than 50 mothers per month
1.3. Have at least two midwives on the station excluding those on study and/or long-term sick leave.
1.4. Providing modern contraceptive methods, including a long-term method such as implants
1.5. The facility must be connected to electricity so that they are able to show films
1.6. Health workers are willing to be involved in the study
1.7. VHTs are active and willing to be involved in the study

Individual participants to be included should meet the following criteria:
2.1. She is a resident of the area.
2.2. The pregnancy is seven months or less (self-reported).
2.3. The woman plans to attend ANC and PNC at study health sites.
2.4. The pregnant woman is in a relationship with the father of their expected child. It is not required that they live together but they must have been together at least 6 months in a relationship, and see each other as their primary partner.
2.5. Are 18 years old and above or they are emancipated minors able to consent.
2.6. Informed consent is obtained.

Participant type(s)
Mixed

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Presents with severe medical/physical condition(s) making her unable to answer the questions at the time of the interview
2. Has known causes of cognitive and functional impairment such as functional psychoses, depression and delirium, alcoholism thus is not able to give informed consent

Date of first enrolment
08/02/2021

Date of final enrolment
30/09/2021

Locations

Countries of recruitment
Uganda

Study participating centre
Mbarara University of Science and Technology
PO Box 1410
Mbarara
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Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository. At the time of publication, we will make the anonymised datasets freely available on a data repository of University of Southampton, eprints.soton.ac.uk. In accordance with the University of Southampton's data policy, the data will be archived from a minimum of ten years after publication or last access, whichever is longer. DOIs will be issued for the dataset and data subsets as per the University's DOI policy. As this is a feasibility study, the study team will have exclusive use of data until the end of the follow-on trial as sharing may prejudice the subsequent study and related publications. The data can be accessed by other researchers on reasonable request to the corresponding author at the end of study.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		29/04/2022	03/05/2022	Yes	No
Participant information sheet		20/07/2020	07/11/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes