COMPREHENSIVE REINTEGRATION ASSISTANCE FOR WOMEN WITH FEMALE GENITAL FISTULA: INTERVENTION PILOTING

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List of Abbreviations

BTQ: Brief trauma questionnaire
CEmOC: Comprehensive Emergency Obstetric Care
DASH: UCSF Open Data Repository
DHS: Demographic and Health Surveys
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, 5th Edition
FIGO: International Federation of Gynecologists and Obstetricians
HE: Health education
ICIQ: International Consultation on Incontinence Questionnaire
ICJME: International Committee of Medical Journal Editors
IDI: In-depth interview
IRB: Institutional review board
NGO: Non-governmental organization
NIH: National Institutes of Health
PC: Psychosocial counseling
POFIRT: Post-fistula repair reintegration tool
PI: Principal Investigator
PM: Project manager
PT: Physiotherapy
QA: Quality assurance
SOMREC: Makerere University School of Medicine Research and Ethics Committee
UCSF: University of California San Francisco
UNCST: Uganda National Council for Science and Technology
WHO: World Health Organization
WHO QOL-BREF: WHO quality of life assessment - brief

PROJECT SUMMARY

Female genital fistula affects an estimated 2-3 million women globally. Commonly caused by prolonged obstructed labor, female genital fistula has broad physical and psychosocial ramifications, and affected women are stigmatized due to incontinence of urine and/or feces. Despite successful surgery, physical disabilities and poor mental health may persist, making reintegration to family and community difficult for women. The purpose of this project is to conduct a pilot study of a reintegration intervention within the context of clinical fistula care with the objective of improving women's physical and psychosocial recovery. The pilot test is a preliminary phase of a broader research agenda, and the primary outcomes of this study are intervention feasibility and acceptability. We will recruit 30 women to participate in the intervention at the time of fistula repair and will follow them for 6-months. All women will receive the intervention; no comparison group will be included at this stage of the research. Perspectives of up to 10 additional key stakeholders will be sought. Such an intervention has important implications for improving women's health following fistula repair, and may inform service provision for women who undergo surgical repair at the referral hospital level. The proposed intervention pilot lays the groundwork for a subsequent robust trial of intervention effectiveness on women's post-surgical reintegration, physical and mental disabilities, and economic status which is the next step in our research program.

STUDY GOALS AND OBJECTIVES

Female genital fistula is a debilitating and traumatic birth injury that affects an estimated 2 to 3 million women, mostly in sub-Saharan Africa.[1] Primarily due to prolonged obstructed labor from cephalopelvic disproportion or malposition combined with delays in accessing comprehensive emergency obstetric care, up to 100,000 new cases occur each year globally. During the obstruction process, ischemia from compression of soft vaginal, bladder or rectal tissue between the fetal head and pelvic bone results in necrosis, and a fistula is formed upon sloughing of this tissue.[2] Women with fistula experience uncontrollable leakage of urine and or feces, which contributes to the development of genital sores and infection.[3,4] In addition to pain and general weakness,[5] women may experience nerve damage, cervical injuries and pelvic bone trauma which present as secondary infertility and gait disorders [6]. For most deliveries resulting in fistula, the baby does not survive [7]. Women with fistula are often stigmatized and marginalized from their families and communities and live in isolation, unable to participate in social, economic, or religious activities,[5,7] and report high psychiatric morbidity including depression, which may persist after surgery.[8-10]

Access to female genital fistula surgery has improved in sub-Saharan Africa overall, including in Uganda, the site for the proposed research. However, despite having undergone surgical repair, women may continue to face myriad physical and psychological challenges to resuming their previous roles or adjusting to new circumstances. They may also require further medical care depending on the severity of their injuries and surgical outcomes, and require health care access for subsequent pregnancies and births. Results from a formative research in Uganda revealed that by twelve-months post-surgery, one-third of women continued to experience urinary incontinence (32.8%), 17.2% reported weakness, and 8.6% reported general pain [11]. Furthermore, experience of persistent physical symptoms was associated with substantially lower psychosocial health. For example, at twelve months, women with persistent physical symptoms had mean reintegration score of 21.9 points lower (95% CI -30.2, -13.5),[12] mean self-esteem of 21.2 points lower at twelve months (95% CI -30.1, -12.4), and mean quality of life of 22.5 points lower (95% CI -28.9, -16.1) compared to women with no persistent symptoms. These findings highlight the need for post-surgical reintegration and rehabilitation services; however, there remains a stark knowledge and practice gap around how to best assist women to reintegrate into their families and communities after surgery. Research to inform the reintegration process, evaluation, and service provision is of paramount importance; as is meeting the future health needs of women who have experienced female genital fistula.

The current proposal seeks to address the gap in evidence-based practice for reintegration following female genital fistula surgery through pilot testing of a multi-component intervention compiled by our experienced team of clinicians and researchers. Building on the existing evidence around reintegration programming, it will comprise four components: health education, physical rehabilitation, psychosocial counseling, and economic empowerment. The pilot intervention is strengthened by our prior work among women with fistula, including our expertise in assessment of recovery from female genital fistula surgery.[11,13-15] Our study objective is to understand feasibility and acceptability of the intervention in preparation for a subsequent effectiveness trial. Using a quasi-experimental design, we will pilot the intervention protocol among 30 women undergoing fistula surgery at Mulago/Kawempe Hospital, assessing feasibility and acceptability using a convergent mixed-methods approach, capturing data from up to 15 intervention participants and up to 10 key stakeholders (e.g., intervention moderators, providers, administrators). Our specific aims are as follows:

SPECIFIC AIMS

Aim 1. To assess the feasibility of the pilot reintegration intervention. The intervention protocol will be piloted with 30 women seeking fistula care at Mulago/Kawempe Hospital in order to understand feasibility of the intervention and intervention assessment activities. Feasibility outcomes will include process assessment of recruitment and retention, data collection, outcome measures, study procedures, study resources and study management.

Aim 2. To assess the acceptability of the pilot reintegration intervention. Within the pilot intervention study, we will assess the acceptability of the intervention to patients, intervention implementers, providers, and hospital administration. Acceptability domains to be assessed include affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy.

Aim 3. To explore the preliminary effectiveness of the pilot reintegration intervention. Within the pilot intervention study, we will explore preliminary effectiveness of the intervention on increases in our primary outcome of reintegration score and secondary outcomes of quality of life and depression through 1) comparison of baseline to six-month scores among intervention participants; and 2) comparison of six-month reintegration, quality of life, and depression scores to six-month data from a different study among women who participated in a longitudinal cohort study of recovery and reintegration in the year following fistula repair.

This proposed research is a first step in moving forward robust strategies for optimizing women's health and quality of life following fistula repair, providing important information on feasibility and acceptability of a multi-component intervention to improve women's physical and psychosocial quality of life in conjunction with fistula surgery within a referral hospital context.

The results from the pilot study will be used to understand and improve feasibility and acceptability of the intervention package, and will inform the development of a subsequent project to test the effectiveness of the intervention among a robust sample size. Data from this study will be an important component of that next proposal.

CENTRAL STUDY HYPOTHESIS. Our central study hypothesis is that the provision of reintegration assistance to women repaired for genital fistula incorporating health education, physiotherapy training, psychosocial counselling and economic empowerment will be feasible and acceptable to intervention recipients and stakeholders.

BACKGROUND AND JUSTIFICATION

Women living in sub-Saharan Africa are at the highest risk of developing female genital fistula. Due to complex interactions between medical, social, economic and environmental factors in sub-Saharan countries that limit women's access to timely high-quality obstetric care, women living in these regions experience the highest rates of female genital fistula worldwide.[16] While measurement of female genital fistula is notoriously challenging,[17,18] the World Health Organization estimates that 2-3 million women are living with female genital fistula and up to 100,000 new cases occur each year globally.[1] Recent population-based estimates indicate that between 0.1-2.0% of women of reproductive age have experienced female genital fistula across the region,[19] with high proportions (2.0%; regional range 0.4%-4.0%) observed in Uganda, the focal site of the proposed research.[20] About 5,000 cases occur per year in Uganda.[21]

The Ugandan health care system faces many challenges to preventing female genital fistula, including chronic shortage of qualified physicians and nurses and poor clinical infrastructure, particularly in rural areas.[22] Other important factors associated with female genital fistula in Uganda include early marriage, low prevalence of modern contraceptive use (39%), high total fertility rate of 5.4, and high maternal mortality at 336 maternal deaths per 100,000 live births.[23] From 2011 - 2016, 25% of births in Uganda occurred at home, and only 6% of births were delivered by cesarean section.[23] National data on service availability is limited; however, the latest Demographic and Health Surveys Service Provision Assessment survey identified limited access to comprehensive emergency obstetric care with only 9% of facilities offering all 7 signal functions (life-saving services) and 47% of facilities having emergency transport.[24]

Significant efforts have been made over the past decade to improve surgical capacity for female genital fistula in Uganda. A Ugandan national Fistula Technical Working Group was established in 2002 with representatives from the Ministry of Health, international and national NGOs, medical professionals and media. To date, much of their focus has been on increasing availability of fistula surgery; between 2010 and 2013 the number of women who underwent female genital fistula surgery per year in Uganda increased from 1377 to 2019.[25] Fistula surgery is available at 6 centers of excellence in Uganda, with 26 trained surgeons at national and regional referral hospitals. Successful fistula repair ranges 50% - 90% at Mulago Hospital, depending upon fistula severity; regional literature suggests an overall success rate of approximately 70%.[26] Despite this wonderful progress in increasing surgical access, very few additional services are being offered to women post-surgically, despite a demonstrated need.

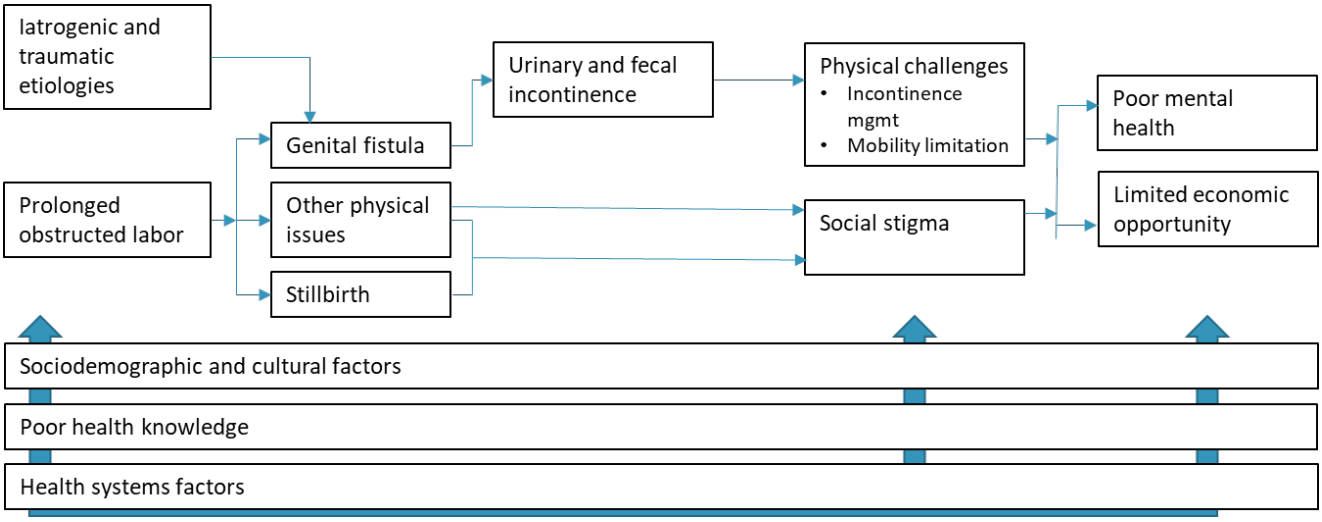
Due to the significant physical and psychological disabilities that women experience due to the fistula (Figure 1), targeted rehabilitation efforts are necessary to improve recovery and quality of women's lives. In addition to severe tissue damage, obstructed labor resulting in fistula can cause nerve damage, injury to the uterine cervix and pelvic bone trauma which present as gait disorders, secondary infertility or other reproductive challenges such as increased rates of spontaneous abortion and stillbirth in future pregnancies.[6,27-29] Many women report experiencing substantial general pain and weakness that persists even after surgery[5,30] gynatresia and dyspareunia, and high rates of psychiatric morbidity including depression, which may not completely resolve after surgical treatment.[2,5,8-10,31,32] Our formative research in Uganda revealed that by twelve-months post-surgery, one-third of women continued to experience urinary incontinence, 17% reported weakness, and 9% reported general pain.[11] Furthermore, experience of persistent physical symptoms to be associated with substantially lower psychosocial health. For example, at twelve months, women with persistent physical symptoms had mean reintegration score of 21.9 points lower (95% CI -30.2, -13.5) [12], mean self-esteem of 21.2 points lower at twelve months (95% CI -30.1, -12.4), and mean quality of life of 22.5 points lower (95% CI -28.9, -16.1) compared to women

with no persistent symptoms. All of these factors limit women's ability to resume their previous roles despite successful surgery, particularly in the context of economic hardship.[33] However, despite a clear need for holistic fistula treatment programming, which would combine a broad range of other services in addition to surgery to assist women with recovery, the majority of fistula repair services are surgically-based with little complementary or follow-up care. Treatment facilities generally recognize reintegration assistance as an important adjunct to surgery, yet inadequate and inconsistent implementation is problematic, and most interventions to date have focused on facility-based strategies where the sustainability of intervention impact is not known once women return to their communities.[34-37] We present a conceptual framework informing intervention needs of women with fistula in Figure 1.

To the best of our knowledge, the evidence-base on post-surgical multi-component interventions at the referral hospital level with the purposes of improving women's reintegration, including support for both physical and mental health, is lacking. Evidence from Nigeria, Eritrea and Tanzania supports the use of short-term facility-based psychological intervention to improve women's mental health,[38-41] and evidence from the Democratic Republic of the Congo supports implementation of health education and physiotherapy for improved pelvic floor strength and reducing post-repair incontinence.[42-45] While the specific value added of economic empowerment lacks robust evidence, it is theoretically and anecdotally considered an important adjunct of fistula programming,[46,47] and is a primary feature of social programming external to the health care setting.

We propose concurrently targeting four specific areas to improve the lives of women that have suffered from fistula including health education, physical rehabilitation, psychsocial therapy, and economic empowerment. Informed by theoretical frameworks adopted from the interdisciplinary fields of health behavior, women's empowerment, and implementation science and the developing evidence base previously discussed, addressing each of these areas will assist women in overcoming the mental and physical disabilities that they may have suffered as a result of the fistula (physical rehabilitation and psychological therapy), ensure they are appropriately educated about fistula and reproductive health for optimizing recovery and enhancing post-repair health (health education) and address their economic needs to improve quality of life and prevent fistula recurrence in subsequent delivery by achieving the status and financial standing to access timely obstetric care (economic empowerment). In addition, certain components of our anticipated intervention will be directly targeted to women's partners or close family members, who are important sources of social support and critical links between afflicted women and their communities. This will be the first rigorously designed and evaluated multi-component intervention to address all these theoretically important supports for female genital fistula reintegration to our knowledge.

Figure 1. Conceptual Framework Informing Intervention Needs of Women with Genital Fistula



APPROACH

OVERVIEW OF STUDY DESIGN

Given the pilot nature of the current project and our primary objective to understand intervention feasibility and acceptability outcomes, we propose a quasi-experimental design for the current study. The study is being done to inform the subsequent development of a cluster-randomized controlled trial to estimate impact on effectiveness; however, no randomization will be undertaken at this stage of the research, and all women enrolled in the study will participate in the intervention. Assessment of preliminary effectiveness (Aim 3) in the current pilot study is exploratory, and will include change over time from pre-surgery as well as comparison with existing data from similar women that was collected within the context of a different research study.

STUDY SETTING

Our research program seeks to improve physical and psychosocial outcomes of women undergoing surgery for female genital fistula in Uganda. The data collection activities for the pilot test of the intervention will be based at two hospitals in Kampala, Uganda: Mulago Specialized Women and Neonatal Hospital and Kawempe National Referral Hospital, as fistula repair surgeries are conducted at both of these locations by the same team. These facilities were selected based on volume of fistula repair and prior clinical and research collaboration. They provide fistula repair as an ongoing urogynecological service, supplemented by several annual fistula repair camps. Surgeons are International Federation of Gynecologists and Obstetricians (FIGO) certified fistula surgical trainers who routinely supervise trainees country-wide. From 2010 through 2015, an average of 190 women per year underwent genital fistula surgery at Mulago Hospital.[49]

In this setting, the current standard of care for women accessing fistula surgery includes some unstructured health education and counseling on post-repair behaviors, and women are instructed on kegel exercises for pelvic floor strengthening. Women with significant needs are referred. However, these adjunct services are not offered as a structured program and referral is only made for the most severe cases, leaving women who might benefit from some psychological and physiotherapy services without.

STUDY PARTICIPANTS

Study participants will include 30 women who receive surgical care for female genital fistula at Mulago and Kawempe Hospitals in Kampala, Uganda. Women are referred to these services from providers at Mulago/Kawempe, nearby clinics or hospitals, or learn about the services from friends, relatives, and radio advertisements. Women will be considered eligible for participation after undergoing fistula surgery, if they are above age 18 or considered emancipated minors under Ugandan law, and if they are able to provide consent for the study. Up to 15 of the intervention recipients will be invited for subsequent in-depth interview for a more nuanced understanding of their experience participating in the intervention and its impact; they will be purposively selected with variability in the range of outcomes observed in the quantitative data collection: reintegration score, depression/anxiety, and economic status. This sample size has been selected for feasibility.

Acceptability assessment (Aim 2) will incorporate interviews with up to 10 key stakeholders including facility staff implementing the intervention (n=3-5), providers working in fistula care at the facility, who will have spoken with women receiving the intervention but who have not directly delivered the intervention, (n=2-4) and hospital administrators *who may have important insight on implementation of the intervention outside of a research context and its sustainability* (n=1-2). This sample size has been selected for feasibility.

One of our exploratory comparisons for preliminary effectiveness (Aim 3) will be among the same participants (pre-post); however, the other comparison will be with existing data collected during a longitudinal cohort study we conducted among 60 women undergoing fistula care at Mulago Hospital in 2015-2016 and followed for a 1-year period.[11,14]

RECRUITMENT AND ENROLLMENT

Intervention recipients: Potential intervention recipients will be recruited for participation in the study at the fistula ward at Mulago/Kawempe. Given current and historical rates of women's presentation for fistula care, we plan to recruit all women who present for care who meet our eligibility criteria. Our research staff will identify which women meet the eligibility criteria of the study based on personal knowledge, review of surgical logbooks and through discussion with other fistula ward personnel. Women will be approached for recruitment when identified as eligible, potentially several days prior to surgery. Study staff will describe the study goals and procedures, ensuring women's understanding of the study procedures and risks, and ascertain women's interest in participating through the informed consent process. Women who are interested in participating will be requested to provide written confirmation of consent through signature or thumbprint (with witness).

Key stakeholders: 10-15 key stakeholders, who are individuals known the the study investigator team, will be invited for in-depth interview through in-person, phone, or email. We will purposively select representation from a range of stakeholders including facility staff implementing the intervention (n=3-5), providers working in fistula care at the facility (n=2-4) and hospital administrators (n=1-2). Individuals who are interested will be scheduled for interview, and the qualitative interviewer will lead the individual through the informed consent process prior to starting the interview.

STUDY PROCEDURES

Immediately after study enrollment, women will be requested to complete an interviewer-administered baseline questionnaire including sociodemographic characteristics, assessment of physical and psychosocial health and reintegration status. Follow-up data collection will occur at hospital discharge, 6w, 3m, and 6m following surgery. Data collection at the 6-week time point will be conducted in-person as women come to the facility then for their clinical follow-up visits. Data collection at the 3 and 6 month study visits will be captured via mobile phone, which we have previously shown to be feasible and acceptable among this population,[50] to reduce participant burden. Data on fistula characteristics and procedures will be abstracted from participant medical records and collected from providers. In order to facilitate study communication and follow-up data collection, women who do not possess a personal phone will be provided with one by the study, and $6 monthly airtime will be provided for the length of the study.

The multi-component intervention incorporates health education, psychosocial counseling, physical therapy, and economic empowerment across the 14-day period that women typically stay at the facility for fistula surgery and through their 6-week and 3-month follow-up visits. The content, rationale and general delivery structure of each component is described in Table 1 below, with our detailed intervention timeline presented in Figure 1.

Table 1. Specific Components of Post-Surgical Reintegration Intervention

Component	Content and rationale	General delivery structure
Health education	The health education activities have been adapted from materials previously developed for health education and reproductive health counseling for women with fistula[51] and generally for low-literate women, including counseling components developed by EngenderHealth's FistulaCare project which were previously implemented in Eritrea.[39,51] We have modified these materials for relevance, understandability, and acceptability to our target population as well as in consideration of participant burden for intervention participation. This health education sessions will focus on educational and behavioral messages to improve women's understanding of fistula and important reproductive health topics including comprehensive information about the development, treatment and rehabilitation of fistula, family planning and birth plans for subsequent deliveries, identification of obstetric emergencies, and nutrition to allow women to make informed decisions. One session will include partners and/or primary caregivers who are helping women on the ward as they share the burden of fistula with their afflicted family member, are critical sources of social support and may serve as links between the afflicted woman and other community members.	During women's stay at the health facility for fistula repair, they will receive daily health education and counseling sessions. Total health education content averages to ~30 minutes per day (with the exception of the day of surgery and the following day). Educational sessions comprise a total of 15 different relevant topics (Appendix 1A). Health education will be delivered by facility nurses/midwives in a group setting.

Psychosocial counseling	Psychosocial counseling activities build on therapeutic strategies previously developed for women with fistula[1,38,39] and based on treatment modalities demonstrated to be efficacious for the treatment of depressive, anxiety and traumatic stress disorders among similar populations, and which may be delivered both individually and within group-administered therapy, including delivery by trained lay persons.[52-58] Short-term facility-based psychological intervention has resulted in improved mental health among women with fistula. [38,39]	During the 14 days that women stay at the health facility post-repair, they will participate in a total of six hours of group counselling sessions and two individual counseling sessions. Each of these sessions has been prepared to address an important component of helping women accurately reframe their fistula experience, and to prepare for returning home through developing plans for positive coping and development of social support (Appendix 1B). Psychosocial counseling will be delivered by the facility nurses/midwives or the facility social worker. Most content will be delivered in a group setting. Two sessions will be individual.
Physiotherapy	Targeted physical rehabilitation can be extremely helpful for women with fistula.[5,42,59] This intervention component is based on programming developed by pelvic floor physiotherapists with expertise in the treatment of women with fistula.[60] The program will comprise a sequential series of exercises focused on recovering mobility, balance and strength and building and maintaining pelvic floor musculature. A low-literacy instructional manual will be developed and provided to the women that they can follow after their hospital discharge to guide them through walking, range of motion, and strength building exercises to stabilize the muscles of the pelvic floor and lower lumbar spine.	Instruction on the exercise series will be delivered in a group setting at hospital stay for fistula care and reviewed and progressed as appropriate at the 6-week follow-up visit. Individual assessment and additions will be made to this plan. The instruction will be delivered by trained physical therapists supported by facility nurses/midwives. Referrals will connect women to more intensive care as needed (i.e. in cases of foot drop or more severe mobility concerns).
Economic empowerment	Many women with fistula lack skills or investment funds to build home businesses, and many have depleted savings or incurred debt in care-seeking for fistula. Qualitative research suggests small businesses, animal husbandry, or skills training are desired,[30] and supporting women in achieving their economic goals is necessary for improving their recovery and lives. Livelihood development programs are broadly accessible in Uganda,[61,62] and women often have prior business experience that they would like to develop further, thus an investment funding combined with a short informational session on financial literacy was seen to be the optimal strategy to meet the individual needs of women.	We will provide $150 in investment funding to each woman. This will be provided to the woman at her 6w post-repair visit after having received a short informational session covering the basics of financial literacy. The instruction will be provided by the social worker, and s/he will follow-up with the participants to understand their use of the economic incentive, and provide any additional support they may need during study follow-up.

A detailed intervention timeline by day is provided in Table 2 below, and the composition of each intervention session is detailed in Appendix 1, by component. During their time at the facility, women will spend approximately 75 minutes per day in total participating in the intervention sessions, largely within a small group context. For the purposes of this intervention, a small group is defined as anywhere between 2-15 individuals. Given varied numbers of women attending fistula camps, and the fact that women may seek surgical care for fistula outside of fistula camps, we will seek but cannot guarantee balanced group

size. However, for a feasibility study such as ours, we anticipate this will provide important information regarding optimal group size. Furthermore, in the event that women are the lone fistula patients, we will adapt the intervention content to an individualized setting. Two individual psychological counseling sessions will be delivered – the initial session pre-op and the final session prior to discharge. The health education and psychosocial counseling component of the intervention will occur within the fistula-repair hospital admission; however, the physiotherapy component will extend through the 6-week post-surgical visit, and the economic investment and associated informational session will be provided at the 6-week post-surgical visit.

Table 2. Intervention Timeline

Component Session No.	Pre-op 1 1	Pre-op 2 2	Surgery & Post-Op 1	Post-op 2 3	Post-op 3 4	Post-op 4 5	Post-op 5 6	Post-op 6 7	Post-op 7 8
HE	Admission and pre-op mgmt, 30m	Pre-op mgmt, 25m	Surgery + Post-op Day 1: No intervention sessions	Post-op mgmt, 30m Repro system anatomy & function, 30m		Fistula causes, 30m Common fistula myths/misconcept 30m		Health and social consequences of fistula, 20m Fistula prevention, 40m	
PC	Intro to counseling, 40m *individual*				Explore fistula experience, 60m		Cognitive reframing of fistula experience, 30m		Identifying thoughts/emotions, 40m Practice reframing problematic thoughts, 20m
PT	Intro to PT, 20m Mobility and pelvic floor assessment, 15m Daily: Breathing & functional mobility exercises, 15m			Daily: Breathing & functional mobility exercises, 15m					
Total time	75m + 40m ind	75m + 40m ind	0m	75m	75m	75m	75m	75m	75m

Component Session No.	Post-op 8 9	Post-op 9 10	Post-op 10 11	Post-op 11 12	Post-op 12 13	Post-op 13 14	Post-op 14 15	Other Sessions TBD
HE	Sexual/RH after fistula, 30m Family planning, 30m		Obstetric care, 30m Nutrition, 30m		Post-discharge management, 30m Recap, 30m	Recap, 30m	Recap, 30m	Health education for family/caretaker, 60m
PC		Coping skills, 40m Social support and relationships, 20m		Planning for future, 60m		Pre-discharge review, 60m *individual*		Building social support with family/caretaker, 60m
PT	Daily: Breathing & functional mobility exercises, 15m				Daily: Breathing & functional mobility exercises, 10m Individual assessment, treatment plan, 40m		Daily: Breathing & functional mobility exercises, 15m	Individual assessment, treatment plan, 40m @ 6w
Total time	75m	75m	75m	75m	75m + 40m individual	45m + 40m ind	45m + 40m ind	

EE: Economic empowerment component will be distributed at the 6-week visit

HE: Health Education, PC: Psychosocial Counseling; PT: Physiotherapy; EE: Economic Empowerment

Data collection

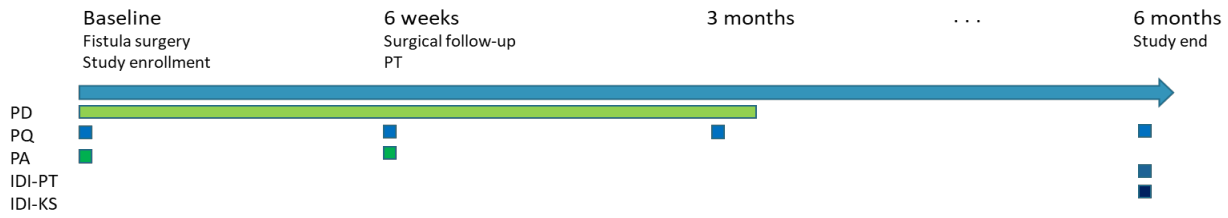
The data collection timeline is displayed in Figure 2. As previously mentioned, baseline data and 6-week data will be collected in person, and subsequent interviews (3 and 6 months) will be administered over the phone. To facilitate data collection, participants will be provided with a basic telephone (adequate for texting and calls) if needed which they will keep even if they choose to stop participation in the study, and airtime sufficient for study participation and some discretionary use. Additional airtime will be provided monthly.

We will collect the longitudinal data via surveys on intervention feasibility and acceptability, reintegration, mental health (i.e., quality of life, depression, traumatic stress, anxiety), physical health (incontinence), social support, stigma, and income measures (i.e., food security, income) through 6 months following surgery. Respondents will be re-interviewed about demographic questions that may change over time (i.e., partnership, labor force participation) to detect reverse causation. We do not anticipate issues around retention given the high retention rates seen in our own[50] and other fistula studies.[63]

We will conduct in-depth interviews (3-6m after surgery) among approximately 10-15 participants using an open-ended semi-structured guide to understand women's experiences with the intervention, and to explore acceptability and effectiveness of each of the intervention components in a more nuanced and subjective manner. In-depth interview participants will be purposively selected for observed variability in outcomes observed during data collection, including reintegration score, depression/anxiety scores, economic status.

In-depth interviews with key stakeholders (intervention implementers, providers, and hospital administration) will be conducted within this same timeframe to understand their perspectives on intervention acceptability.

Figure 2. Data Collection Timeline



PD: process data; PQ: patient questionnaire; PA: physical assessment; IDI-PT: in-depth interview, patient; IDI-KS: in-depth interview, key stakeholder

STUDY MEASURES

The intervention evaluation will use quantitative and qualitative methodologies, following Proctor's implementation outcome framework, [64,65] including measures of acceptability, adoption, appropriateness, costs, feasibility, fidelity, penetration and sustainability.

Quantitative: Process data will be collected on intervention participation and engagement in intervention components and intervention evaluation throughout to inform adoption, cost, fidelity, and penetration. We will collect longitudinal data via surveys on intervention acceptability and experiences, suggestions for improvement, and study outcomes: reintegration, mental health (i.e., quality of life, depression, traumatic stress, anxiety), physical health (incontinence), social support, stigma, income measures (i.e.,

food security, income) through 6 months. Table 2 below outlines the details of the measures. Respondents will be re-interviewed about demographic questions that may change over time (i.e., partnership, labor force participation) to detect reverse causation. The longitudinal design prevents biases inherent to retrospective studies. We do not anticipate issues around retention given the high retention rates seen in other female genital fistula studies,[63] including our own previous research.[50] The surveys will be read to respondents in the local language by interviewers who will follow-up with women via phone or in person. Medical record abstraction will be conducted to obtain data on surgical outcomes.

Qualitative: Approximately 10-15 in-depth interviews with women will be conducted among intervention participants using an open-ended semi-structured guide to understand women's experiences with the intervention, and to explore acceptability and effectiveness of each of the intervention components in a more nuanced and subjective manner. Additional interviews with key stakeholders will focus on their perspectives and reflections on intervention acceptability, appropriateness, feasibility, penetration, and potential for sustainability.

Table 2. Measures for intervention assessment

A. Intervention Feasibility and Acceptability	Proctor's implementation science framework is being used to inform our implementation outcomes, and these measures will be assessed through quantitative and qualitative inquiry.[64] Primary outcomes for the assessment are feasibility and acceptability; however, process data will be captured to inform all eight implementation outcomes. Feasibility of the intervention will be assessed through recruitment, retention, and adherence. Acceptability of the intervention will be assessed through satisfaction with the intervention overall and each component. Secondary implementation outcomes are as follows: adoption (intention to implement the intervention), appropriateness (perspectives on fit and relevance of the innovation to the patient, problem, and setting), costs, fidelity (delivery per intent). Penetration and sustainability will be assessed as potential.
B. Demographics	At baseline, information on education, age, marriage, labor force participation, income and wealth, financial and food security, debt, household composition (including number of living children), partnership status and fistula-specific questions (e.g., age at fistula, length of time with fistula) will be captured for all participants. At each 3-month data collection a shortened version of the demographic survey including those indicators that might have changed over time will be collected. Other measures incorporated within this section of the tool will include social support and perceptions of internal and external stigma. Social support will be evaluated by the multi-dimensional scale of perceived social support, previously adapted and validated in Uganda.[66,67] Stigma will be evaluated using an adaptation of the HIV/AIDS Stigma Instrument (HASI-P), developed and validated in East Africa.[68-70]
C. Reintegration	Reintegration success will be evaluated objectively using two different instruments. The first is our recently developed standardized fistula reintegration success measure, the Post-Fistula Repair Reintegration Tool (POFIRT).[12] The tool has high internal consistency reliability (α=0.87) and face validity.[71] It is a 19-item instrument developed through qualitative work among key informants in Uganda combined with literature review, and incorporates measurement of physical mobility, satisfaction with self-care, participation in work and meeting personal and family needs, participation in social and religious activities, satisfaction with roles in family and community, and comfort with personal relationships. Because only preliminary evidence is available on the POFIRT tool, we will also use the WHO QOL BREF tool to measure quality of life,[72] which has been already translated and validated in Luganda by Martin et al.[73]
D. Mental Health	Individual mental health measures will target depression, anxiety and traumatic stress, given the substantial rates of these morbidities reported by women with fistula.[8,74-76] We will measure depression and anxiety using the Hopkins Symptom Checklist, which has been used in Uganda[77-80] and translated and validated in Luganda.[81] History of traumatic experiences will be measured by the Brief Trauma Questionnaire (BTQ).[82-86] Symptoms of trauma will be measured by the PCL-5, a 20-item self-report measure that assesses the 20 DSM-5 symptoms of PTSD and is used to monitor symptom change during and after treatment. [87-91] In addition, women will subjectively rate mental health.

E. Physical Health and Health Behaviors	Physical health will be assessed using the Stanford Self-Rated Health measure for general health[92], the International Consultation on Incontinence Questionnaire (ICIQ),[93] the WHO Disability Adjustment Scale 2.0,[94] and a list of individual fistula-specific symptoms. Health knowledge and behaviors: Understanding, retention, intent, and behaviors related to health education messaging content will be captured via survey. Adherence: Home implementation of physiotherapy program will be assessed through self report at all non-baseline surveys.

SAMPLE SIZE

Our sample size of 30 participants with fistula and up to 1 key stakeholders for the pilot study has been calculated based on feasibility.[95]

DATA ANALYSIS PLANS

Quantitative data. Data from surveys will be entered into a password-protected database. Confidentiality will be protected by secure data handling. Data quality practices will include range and logical checks built into data entry, double entry, and error checks. We will examine overall status at each time point for each variable, investigate patterns and types of missing data and non-response, and inspect distributions of mediating and outcome variables to identify outlying or unusual values and assess distributional characteristics. Data analysis: We will describe respondent characteristics and primary outcomes (Aims 1&2 - acceptability and feasibility; section a in Table 2) using frequency tables and descriptive statistics (e.g. means, standard deviations, medians, inter-quartile ranges, and proportions). Preliminary effectiveness (Aim 3) will be conducted by bivariate comparisons of pre vs. post assessments (within our main sample) of reintegration score (primary), quality of life and depression (secondary) and comparison between our external control group using similar data from the same time since surgery using the appropriate distributional tests (paired sample t-test and Stuart-Maxwell tests for pre-post comparison, and two sample t-test and chi-square test for external comparison).

Qualitative data will be recorded and transcribed, and translated into English (if necessary). Thematic analysis will involve a two-stage process [96]: First, data will be coded and classified with transcript review for potential conceptual categories, using the guideline questions as initial categories. Two types of codes will be employed. Deductive codes that represent expected influences on the outcomes will be applied to the data: these will be taken from from our qualitative guide informed by Proctor's framework.[64] Inductive codes emerging organically from the data will be applied: these codes will represent themes unexpected by the researchers and will be identified by recurrence rate and on similarities and differences across the texts. A codebook will include a detailed description of each code, inclusion and exclusion criteria, and examples of the code in use. Coded data will be analyzed to describe the different dimensions and commonalities of each theme, their distribution across participant type and the patterns and linkages between themes. This will allow us to build concepts grounded in the data to explain phenomena. Comparisons will be made with the data to detect divergent views among the participants and to contrast observations that relate to variables within the sample population.

TIMELINE

The planned study timeline is detailed below. We hope to begin participant recruitment in Dec 2020 and anticipate reaching our target sample size within four months. Baseline data collection will occur at recruitment, thus will span this full time period. Data collection for 6w, 3m, and 6m time points are detailed below. Quantitative analysis will occur throughout data collection, with analysis finalized in September 2021. Qualitative data collection will occur from Feb – Jul 2021, with concurrent analysis. Integration of quantitative and qualitative analyses will be done in Sept – Oct 2021. We plan to develop our research proposal for a larger trial to test effectiveness of the intervention from Aug – Oct 2021, submitting to the U.S. National Institutes of Health in October 2021.

Table 3. Study timeline, October 2020 – October 2021

	2020					2021							
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	Mar	Jun	Jul	Aug	Sep	Oct
IRB review	X	X	X	X	X								
Staff training on intervention protocol			X	X	X								
Participant recruitment					X	X	X						
Quantitative data collection													
Data collection, baseline					X	X	X						
Data collection, 6w						X	X	X					
Data collection, 3m							X	X	X				
Data collection, 6m										X	X	X	
Data analysis							X		X			X	X
Qualitative data collection													
In-depth interviews, staff						X	X						
In-depth interviews, providers							X	X					
In-depth interviews, participants								X				X	
Data analysis						X	X	X	X	X	X	X	
Manuscript preparation											X	X	X
Proposal development											X	X	X

SAFETY MONITORING PLAN

POTENTIAL RISKS TO HUMAN SUBJECTS

Potential risks to participants as a result of the pilot study are anticipated to be minimal. Participation is voluntary and participants may decide to discontinue the study at any time. As patients may be sharing potentially distressing experiences and emotional status, they will be provided with counseling within the program, and information on accessing mental health services beyond the program will be shared. Risks to privacy due to personal nature of some questions will be minimized by asking closed ended questions over the phone and conducting in-depth interviews in a private location.

Potentially identifying data that will be collected from participants include names, dates, postal addresses, phone numbers, email addresses, and medical record numbers.

The proposed pilot intervention carries a minimal level of risk; however, we will prioritize participant and data safety, and will implement the following plans for monitoring of our pilot study. No Data and Safety Monitoring Board will be implemented for the current project due to the nature of the intervention and the focus on feasibility and acceptability; however, the PIs and Co-Investigators will closely monitor data and safety related risks to human subjects. Serious adverse events will be reported promptly to the Makerere School of Medicine Research Ethics Committee, the UCSF IRB and the NIH project officer. Risks, monitoring procedures, reporting, and action plans are described below for data and safety-related risks.

DATA AND SAFETY MONITORING

Data-related risks. Potential data-related risks to participants include circumstances where insufficient data was collected for answering the research questions or high/systematic attrition in the trial or intervention participation affecting receipt of adequate intervention dose.

Data monitoring procedures. Overall recruitment goals will be monitored monthly, as well as missing data and follow-up failures. Ongoing monitoring of study progress will be coordinated by Dr. Alison El Ayadi, ScD, Co-PI. No personal identifiers will be included within our databases or in audio recordings of our interviews/focus groups, but linkable identifiers exist separately and the data may be sensitive in nature *(e.g., mental health, incontinence status, gender-based violence)* such that disclosure could provide some risk to the individual. The codes will be stored on a computer that is password protected with a secure server. Transfer or storage on portable devices (e.g., laptops, flash drives) is encrypted. The devices on which this information is stored are accessible only to individuals who need access to these data. Data will not be destroyed until all analyses are complete. Identifiable data will be stored for the amount of time required by the ethical review board. After that point, paper copies will be shredded and electronic copies will be deleted, per UCSF and Makerere policy. A de-identified dataset with associated documentation will be made available to research users, hosted within the UCSF Open Data Repository (DASH).

Data-related risk reporting and action plan. Research assistants will be responsible for compiling numbers of participants recruited, completing required assessments, maintaining databases, and identifying missing data and missing follow-up assessments. Research assistants will prepare recruitment and missing data reports for weekly review by the PIs and Co-Is. All data will be de-identified and stored on a firewall-protected server. Upon recognition of unacceptable recruitment or follow-up rates, or of missing data, the Co-PIs will intervene with strategies to remedy the shortcomings. Intervention completion rates will be monitored.

Safety-related risks. Safety-related risks may include: 1) sensitivity related to questioning about physical and psychological health, 2) release of confidential information about the participant, and 3) recognition of the need for treatment for physical or psychological health concerns.

Safety monitoring procedures. All safety-related risks will be routinely monitored at assessment or intervention session. The security of confidential information will be monitored regularly. Research assistants and intervention moderators will be trained in asking questions about sensitive topics in a caring and non-threatening manner and will stop questioning at the first sign of discomfort or on request. Privacy and confidentiality will be emphasized in intervention sessions with facilitators requesting that participants agree to respect the privacy and confidentiality of other group member, and not to disclose information shared with the group in confidence to anyone outside of the group. Participants will be informed that confidentiality will be maintained for survey and in-depth interview responses. Research assistants will be trained to identify a participant who reports any physical or psychological health concerns, and protocols will be developed to refer participants for treatment.

Safety-related risk reporting and action plan. Research assistants and intervention moderators will report any breaches of confidentiality risks to the Project Coordinator who will then inform the PIs. Any participant in need of treatment due to physical or psychological health concern will be referred for appropriate services per protocol, and the Project Coordinator and PIs will be informed. The PI will be responsible for informing the IRBs through IRB adverse reporting procedure, and the Project Officer through immediate email for life-threatening incidents and through annual report of other incidents per IRB policy. The PI will take appropriate action to stop the study, release a participant from the study, or modify procedures to reduce and/or eliminate the abovementioned risks if they occur at an unacceptable level.

Adverse events. Adverse events will be tracked and referral and follow-up will occur. An adverse event form will be developed to record each incident, actions taken, supervisor notes, and follow-up steps. The form, supplemented by any notes, will be sent immediately to appropriate agencies, including the IRBs, and NIH, with any action recommended by IRB conveyed to the NIH.

Reporting. All problems related to participant safety will be reported to the Makerere University College of Health Sciences School of Medicine Research and Ethics Committee and the UCSF Committee on Human Research and the Committee by the PI within 7 working days. Specifically, we will report in writing: 1) all serious adverse events associated with study procedures, and 2) any incidents or problems involving the conduct of the study or patient participation, including problems with recruitment or consent processes. The PI will provide a discussion of any side effects or problems noticed in the course of the study to the Committee on Human Research on an annual basis.

TRAINING, QUALITY ASSURANCE (QA) AND SUPERVISION

The investigators are experienced in staffing, training, and supervising clinical research studies, including behavioral intervention trials. Our current QA proposal is based on this experience.

Data collector training. Research assistants will be selected based on their prior experience with data collection and familiarity with the study population. We will develop a training manual for the training and ongoing supervision of research staff. An initial training to be led by the PIs and Co-Is will cover: 1)

general research interviewing skills; 2) specific training relevant to this study; 3) extensive training in research ethics and human subjects' protection certification; and 4) observed practice and certification as research assistants.

Assessment quality assurance. The PIs and PM will oversee the QA of data collection and provide feedback and supervision as appropriate.

Intervention training. A training workshop occurs for all intervention staff, and an intervention manual will guide the training and ongoing supervision. This training includes detailed overviews of the intervention approach and procedures, the content covered, and general topics related to intervention research and research ethics. Techniques for adhering to a manualized intervention while allowing flexibility to address individual participant needs will be taught, role-played, and supplemented by instructional readings. Ongoing training will provide updates and troubleshooting on the content area and address any individual supervision or procedural issues in intervention implementation.

Quality assurance of intervention procedures. Intervention fidelity is crucial to maintaining internal validity in intervention trials. Given the nature of the intervention and the clinical issues that arise with this population, facilitators are clinically trained and have knowledge in clinical trials and behavioral science. QA procedures of intervention delivery across facilitators and over time during the course of the study include: 1) development of detailed manuals for each of the sessions; 2) intensive training; 3) incorporation of mock sessions that enable us to ensure that moderators meet performance criteria for intervention delivery, leading to certification of staff based on common performance standards; and 4) QA feedback are incorporated into routine supervision.

Supervision. Separate weekly supervision meetings will be held for data collection and intervention staff, covering progress of the study assessment and intervention protocol problems, providing a setting for staff support and development, and an atmosphere conducive to constructive discussions of dealing with problematic participants and situations. The investigators and project coordinator will schedule individual supervision meetings as appropriate.

POTENTIAL BENEFITS TO HUMAN SUBJECTS

Participants may directly benefit from participation in the intervention if the intervention activities improve their physical and psychosocial symptoms, and improve their quality of life. Potential benefits to society are the development of a model implementable within a referral facility level that can be implemented to improve women's fistula-related outcomes.

PAYMENT

Participants will be provided with a phone and airtime throughout the length of the study, and transportation to and from all clinic visits will be provided. The phone will be kept by the participant after the study is completed (or the participant withdraws from participation). Intervention participants in the nested qualitative research will receive refreshments during the in-depth interviews, be paid the equivalent of $20 in cash for their participation and will have any transportation-related expenses reimbursed.

ETHICS REVIEW

Approval to carry out this study will be sought from the Makerere University College of Health Sciences School of Medicine research and Ethics Committee (SOMREC) and the Uganda National Council for Science and Technology (UNCST). In the US, we will submit for ethical review at the University of California, San

Francisco Committee on Human Research. Any modifications after initial approval will be reported to the ethical review board(s), trial registry, and all investigators, and approval for modifications will be sought.

DISSEMINATION PLAN

The study team plans to communicate trial results to participants where possible through community meetings and to healthcare professionals and researchers via presentation of findings via academic conferences and publication in peer-reviewed, scholarly journals. Lastly, we will maintain the engagement of several key stakeholders in the development and dissemination of this project, including in data interpretation and ongoing analyses throughout the trial. We will use the International Committee of Medical Journal Editors (ICMJE) criteria for authorship.

APPENDICES

We include the following appendices:

1. Detailed intervention plan
    a. Health education
    b. Psychological counseling
    c. Physiotherapy
    d. Economic empowerment
2. Informed consent form for study participants
3. Informed consent for key stakeholders (moderators, providers)
4. Study instrument
5. Physical assessment instrument
6. In-depth interview guide
7. Physical examination and physiotherapy referral

Appendix 1A. Overview of Reintegration Intervention: Health Education Sessions

Session	Objective	Length	Timing[a]	Delivery[1]
1. Admission and Preoperative Management: Preparing for Upcoming Surgery and Recovery (Part 1)	• Introduce patients to fistula • Introduce patients to care providers • Provide a comprehensive overview of procedure, risks, and outcomes • Address any patient concerns and questions about procedure and recovery	30m	Pre-op Day 1	Group
2. Admission and Preoperative Management: Preparing for Upcoming Surgery and Recovery (Part 2)	• Familiarize patients to the patient ward and the surgical theatre • Discuss preoperative preparations • Discuss postoperative management • Address any patient concerns and questions about procedure and recovery	30m	Pre-op Day 2	Group
Surgery Day 0				
Post-op Day 1				
3. Overview of Postoperative Management	• To discuss outcomes of surgery • To discuss postoperative care management at the facility • Address any patient concerns and questions	30m	Day 2 (post-op)	Group
4. Reproductive system anatomy and function	• Familiarize participants with the female reproductive system and female pelvis, anatomy and functions	30m	Day 2 (post-op)	Group
5. Development of Fistula	• Identify the causes of obstetric fistula	30m	Day 4 (post-op)	Group
6. Common Myths and Misconceptions about Fistula	• To dispel any common rumors and myths about obstetric fistula • To explaining how these may hamper women's ability to prevent fistula and to access treatment	30m	Day 4 (post-op)	Group
7. Health and Social Consequences of Fistula	• To identify and discuss the health consequences of fistula • To identify and discuss the social consequences of fistula	20m	Day 6 (post-op)	Group
8. Fistula Prevention	• To discuss ways to prevent obstetric fistula after repair • To introduce birth spacing	40m	Day 6 (post-op)	Group

[1] Where group is indicated but women are in undergoing fistula repair without other fistula patients concurrently on the ward, they will receive a modified version of the activity appropriate for delivery to the individual.

9. Sexual and Reproductive Health after Fistula	• To educate patients on sexual health • To familiarize participants reproductive tract issues • To identify personal timelines for family planning and fertility preferences	30m	Day 8 (post-op)	Group
10. Family Planning	• To identify different family planning methods • To dispel myths and misconceptions regarding contraceptives • To facilitate discussion of which family planning method might be right for the participant	30m	Day 8 (post-op)	Group
11. Future Obstetric Care	• To understand the components and reasons for antenatal care during pregnancy • To recognize the danger signs during pregnancy • To discuss the importance of planning and preparation for safe delivery • Facilitate participant creation of birth plan	30m	Day 10 (post-op)	Group
12. Nutrition	• To understand optimizing nutrition for recovery	30m	Day 10 (post-op)	Group
13. Post-discharge management	• To identify ways on how to take care of herself at home • To discuss the importance of follow-up visits • To recognize surgical warning after discharge • Facilitate participants in creating a complication	30m	Day 12 (post-op)	Group
14. Recap of Health Education Sessions	• To prepare the patient for her return home, which maximizes the likelihood of a positive reintegration experience. • To review all of the materials and information discussed during the health education sessions • For participants to share their experiences, ask questions	30m	Day 12, 13, or 14 (post-op)	Group
15. Health Education Counseling for the Participant's Family &/ Caretaker *(optional)*	• To communicate patient's health condition and treatment (only if requested to be shared with family member(s) &/or caretaker • To communicate any risks and possible side effects • To address any concerns and questions brought up by patient's social support • To identify warning signs • To develop plan in case of complications	60m	TBD	Group

	• To provide guidance on how to support patient at home • To discuss sexuality after surgical repair • To discuss reproductive tract and sexually transmitted infections			

Appendix 1B. Overview of Reintegration Intervention: Psychological Counseling Sessions

Session	Objective	Length	Timing[a]	Delivery[2]
1. Introduction to Psychological Counseling	• Introduction to counseling • Assessing the patient's needs and concerns • Set Initial Treatment Plan/Goals • Facility nurse will determine if patient is ready for group counseling session.	40m	Pre-op	Individual
Surgery Day 0				
Post-op Day 1				
2. Exploring the Fistula Experience	• To get familiar to each other • To normalize the patient's experience • To acknowledge the negative and possible positive impacts of the fistula experience on relationships with others • To begin exploration of how the patient's experience of an obstetric fistula impacts her feelings and thoughts about herself	60m	Day 3 (post-op)	Group
3. Cognitive reframing the Fistula Experience	• To promote cognitive reframing of the fistula experience through medical education • Help the patient reframe her personal narrative	60m	Day 5 (post-op)	Group
4. Identifying Thoughts and Emotions	• To introduce the patient to the cognitive-behavioral model • To begin teaching patient how to reframe negative or unhelpful thoughts • Review key emotions • Identify negative and problematic thoughts • Link thoughts to resulting emotions	60m	Day 7 (post-op)	Group

[2] Where group is indicated but women are in undergoing fistula repair without other fistula patients concurrently on the ward, they will receive a modified version of the activity appropriate for delivery to the individual.

	• Begin practicing reframing problematic thoughts • To manage the emotions associated with their situation			
5. Develop Coping Strategies	• To help the patient to recognize and respond to stressors in her life by utilizing appropriate and effective coping skills. • Discuss the patient's negative vs. positive coping strategies • Coach patient to recognize stressors and respond by utilizing appropriate and effective coping skills.	40m	Day 9 (post-op)	Group
6. Explore Social Relationships	• To examine the effect of social relationships on the patient's life • To generate specific strategies to strengthen social relationships • Discuss how one's social network influences thoughts and feelings • Formulate strategies to expand and optimize patient's social support network • Review tools to discuss her condition with others • To practice communication skills. • Mobilize home support by identifying partner &/ caregiver to participate in optional combined counseling session	20m	Day 10 (post-op)	Group
7. Planning for the Future	• To prepare the patient for her return home, which maximizes the likelihood of a positive reintegration experience. • Make practical plans for the patient's return to her community • Discuss the possibility of incomplete cure & post-surgery medical recommendations	60m	Day 11 (post-op)	Group
8. Patient Pre-discharge Assessment	• Review therapy action plan and discuss progress in reaching goals • Patient assessment and addressing patient's remaining needs and concerns • Identify if patient requires additional psychiatric counseling/emotional support/medication if patient suffers from trauma-related fistula	60 minutes	Day 13 or 4 (post-op)	Individual

9. Building Social Support Opportunities (OPTIONAL)	• Intended to facilitate social support for patient returning home after repair	60m	Offered between days 10-15 (post-op)	Group (with patient and partner &/ caretaker)

Appendix 1C. Overview of Reintegration Intervention: Physical Rehabilitation Sessions

Session	Objective	Length	Timing	Delivery[3]
1. Introduction to Physical Therapy	• Introduction to physical therapy • Introduction to functional pelvic anatomy • Goal setting and expectations • Introduce breathing exercises • Assessment of mobility and pelvic floor function	35m	Day 1 (pre-op)	Individual
2. Breathing & functional mobility exercises	• Breathing exercises	15m	Day 1 and 2 (pre-op)	Individual
Surgery Day 0				
Post-op Day 1				
3-8. Breathing & functional mobility exercises for Acute/Inflammatory Phase	• Functional mobility exercises • Diaphragmatic breathing exercises to load the pelvic floor without straining the healing tissues • Sub-maximal pelvic floor muscle exercises while lying in bed	15m	Days 2-7 (post-op)	Group
9-14. Breathing & functional mobility exercises for Sub-Acute Phase	• Functional mobility exercises • Diaphragmatic breathing exercises • Sub-maximal to maximal pelvic floor muscle exercises • Exercises for the abdominal, hip and low back muscles • Stretching areas of scar tissue and muscle and joint tightness (or contracture)	15m	Days 8-13 (post-op)	Group
15. Physical Therapy for Sub-Acute Phase with Treatment Plan for Discharge	• **Group:** Same objectives from Sessions 9-14 • **Individual**: Patient assessment (functional mobility, external and internal pelvic floor assessment), and development of home treatment plan	15m 40m	Day 14 (post-op)	Group and Individual
Follow-up	• Physical assessment • Reinforcement/adjustment of exercises	60m	6w, 3m	Individual

[3] Where group is indicated but women are in undergoing fistula repair without other fistula patients concurrently on the ward, they will receive a modified version of the activity appropriate for delivery to the individual.

Appendix 1D. Overview of Reintegration Intervention: Economic Empowerment

Session	Objective	Length	Timing	Delivery
1. Livelihood assessment	• Support patient skills development OR business investment ($150 value)	30m	6w visit (post-op)	Individual

MULAGO WOMEN & NEONATAL SPECIALISED HOSPITAL/KAWEMPE NATIONAL REFERRAL HOSPITAL
COMPREHENSIVE REINTEGRATION ASSISTANCE FOR WOMEN WITH OBSTETRIC FISTULA
INFORMED CONSENT 1, INTERVENTION PARTICIPANTS: ENGLISH

Study Title: Comprehensive Reintegration Assistance for Women with Obstetric Fistula
Participant number: …….

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This is a research study focused on how to help women recover and reintegrate to their families and communities after genital fistula surgery. The study researchers, Justus Barageine, PhD, MD, from Makerere University School of Medicine, Uganda, and Alison El Ayadi, ScD MPH from the University of California San Francisco, USA, or their representative, will explain this study to you.

STUDY SUMMARY

Introduction: We are asking you to consider taking part in a research study being done by Alison El Ayadi at UCSF and Justus Barageine at Makerere University.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Purpose of the study: The purpose of this study is to pilot test a multicomponent intervention to help women reintegrate to their families and communities after genital fistula surgery to understand feasibility, acceptability, and preliminary effectiveness.

You are being asked to take part in this study because you have recently undergone surgery for female genital fistula or are confirmed for female genital fistula surgery in the upcoming days.

Study Procedures: The study participants will participate in health education, psychosocial counseling, and physical therapy sessions during the duration of their fistula care hospitalization and at their follow-up care visits. In addition, facilitation of livelihood training or an economic investment will be made.

If you choose to be in this study, the researchers will ask you to complete several questionnaires on your social and demographic characteristics, your physical and mental health, and related experiences.

You will be in this study for approximately six months. The research team will help you to complete the first questionnaires while you are still at the hospital for surgery and when you return for your follow-up visits. They will call you by phone to complete the additional questionnaires, or you may come to the facilitiy in person if you prefer that. This means you will be asked to complete a total of five questionnaires, at study enrollment, hospital discharge, 6 weeks, 3, and 6 months. We expect that the questionnaires will take approximately 1 hour each to complete. A subset of participants will also be asked to participate in in-depth interview to discuss their experiences with participating. If you are selected to participate in this component, participation time will be approximately 1-2 hours longer.

Possible risks: Risks to being in the study include discussion of emotional or sensitive experiences which may be emotionally upsetting to you, and risks to privacy based on the group-oriented intervention delivery approach. For more information about risks and side effects, ask one of the researchers.

Possible benefits: Benefits of the study include the educational and counseling content that you will be provided with, physiotherapy, and the economic investment. Additionally, the information that you provide will help us to understand the impact of a pilot intervention for improving women's recovery and reintegration experiences following surgery for genital fistula.

Your other options: You do not have to participate in this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

DETAILED STUDY INFORMATION

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you have recently undergone surgery for female genital fistula or are confirmed for female genital fistula surgery in the upcoming days.

Why is this study being done?
The purpose of this study is to pilot test a multicomponent intervention to help women reintegrate to their families and communities after genital fistula surgery.

This study is funded by the U.S. Eunice Shriver Kennedy National Institute of Child Health and Development.

How many people will take part in this study?
We will pilot test the intervention with 30 women.

What will happen if I take part in this research study?
If you choose to be in this study, the following procedures will occur:

- The researcher or their proxy will ask you to complete a baseline survey that describes your social and demographic characteristics, your physical and mental health, and related experiences.

- You will attend individual sessions on health education, psychosocial counseling and physiotherapy during your hospitalization for fistula surgery.
- You will attend physiotherapy at your 6w visit.
- At hospital discharge, the researcher or their proxy will ask you to complete a survey on your treatment experiences and outcomes.
- The researcher or their proxy will provide you with a phone if you do not have one to help you participate in the study, and will pay for airtime.
- You will have the opportunity to participate in a livelihood training program or receive investments funds for a small business.
- The researcher or their proxy will follow up with you at 6w, 3m and 6m to ask you to complete a follow-up survey to understand your current physical and mental health, and related experiences. This may be done in-person or on the phone, depending on your clinical care. If you prefer to respond to the survey in person, please tell the researcher and they will help to coordinate this.
- You may be asked to participate in an in-depth interview at 6 months to discuss your experiences with intervention participation.
- Your data may be used to respond to subsequent research questions after removing all identifying information.

Study location
Research-team administered interviews will take place either in-person in a private location at Mulago/Kawempe Hospitals, or over the phone.

How long will I be in the study?
You will be in this study for approximately six months. Each questionnaire will take approximately one hour to complete. In-depth interview will take between 1-2 hours to complete.

Can I stop being in the study?
Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study. Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?
We do not anticipate any side effects or risks from being in the study; however, the research questionnaire does include questions about your experience with fistula, your physical and emotional status, which may be emotionally distressing to discuss. If you believe that discussing these topcis will be distressing for you, you can decide not to participate in the study. In the event you choose to participate in the study and find that discussing these events is too difficult for you, you may pause of stop the interview. The interviewer may decide to pause or stop the interview if they sense that you are very upset. Furthermore, they may refer you to a mental health professional if you feel that speaking with someone might help. Furthermore, there may be risks to privacy based on the group-oriented intervention delivery approach. For more information about risks and side effects, ask one of the researchers

Are there benefits to taking part in the study?
You will receive health education and direct care: counseling and physiotherapy. Additionally, you will be given assistance in starting up a small livelihood project. Furthermore, the information that you provide

will help health professionals to test the impact of a reintegration program for women undergoing surgery for female genital fistula.

What other choices do I have if I do not take part in this study?
You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. [If relevant: You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.]

How will my information be used?
Researchers will use your information to understand the feasibility and acceptability of the intervention, and compare your physical and mental health status combined with data from other women to understand intervention effectiveness. Any personally-identifying information collected for this study will only be used for this study. Data with no personally-identifying information may be used to answer additional related research questions.

Research results: There may be times when researchers using your information may learn new information. The researchers may or may not share these results with you, depending on a number of factors. If researchers learn new findings that may affect your decision to remain in the study, you will be informed about them.

Will information about me be kept private? We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of Mulago Hospital or Makerere University
- Representatives of University of California
- Representatives of National Institutes for Health

Are there any costs to me for taking part in this study?
There is no cost to taking part in this study.

Will I be paid for taking part in this study?
In return for your time and effort, you will be provided with a phone and monthly airtime in the amount of 20,000 Ugandan Shillings (UgX) to help you participate in the study and as a token of our thanks for having participated in this study. Additionally you will be assisted to start up a small livelihood project. We will also cover your transportation costs to and from the facility for fistula repair at your 6-week clinical follow-up, and for any participation in in-depth interview. In-depth interview participants will receive an additional 40,000 UgX as participation incentive

What are my rights if I take part in this study?
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. [If relevant: You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.]

Who can answer my questions about the study?
You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. Contact Dr. Justus Barageine at +256 702 454 869.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Makerere University College of Health Sciences School of Medicine research and ethics committee Chair, Assoc Professor Ocama Ponsiano, on Telephone +256, 0772494120 or the Secretariat at Uganda National Council for Science and Technology, Plot 3 Kimera Road, Ntinda on telephone 041-705-513.

STATEMENT OF CONSENT
I have read or have been read to this consent form and I have fully understood the study purpose, procedures, benefits and the risks involved and I have been given a chance to ask questions and they have been fully answered. I also understand that my participation in this study is voluntary and I will not be penalised or lose any benefits to which am otherwise entitled if I decline to participate in the study. I too understand that am free to withdraw from the study any time if I so wish and that I will be given a copy of this consent form to keep.

I hereby sign below as proof of my consent.

Date Participant's name and Signature or thumbprint

Date Witness's name and signature if Participant used a thumbprint

Date Name and signature of a Person Obtaining Consent

May we contact you for participation in future studies?

___Yes ___No

MULAGO WOMEN & NEONATAL SPECIALISED HOSPITAL/KAWEMPE NATIONAL REFERRAL HOSPITAL
COMPREHENSIVE REINTEGRATION ASSISTANCE FOR WOMEN WITH OBSTETRIC FISTULA
INFORMED CONSENT, INTERVENTION STAFF AND MODERATORS

Study Title: Comprehensive Reintegration Assistance for Women with Obstetric Fistula
Participant number: …….

Research Project Directors:	Justus Barageine, MBChB, MMed, PhD, Senior lecturer/ Obstetrician, Gynaecologist and fistula surgeon Makerere University College of Health Sciences, Mulago Hill Road, Kampala, Uganda Phone: +256 702 454 869 Email: barageinej@gmail.com Alison El Ayadi, ScD, MPH, Associate Professor of Obstetrics, Gynecology and Reproductive Sciences UCSF, 550 16th Street, San Francisco, CA 94158 Phone: 415.659.8367 Email: alison.elayadi@ucsf.edu

This is a research study focused on the feasibility and acceptability of an intervention to help women recover and reintegrate to their families and communities after genital fistula surgery. The study researchers, Justus Barageine, PhD, MD, from Makerere University School of Medicine, Uganda, and Alison El Ayadi, ScD MPH from the University of California San Francisco, USA, or their representative, will explain this study to you.

DETAILED STUDY INFORMATION

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you either participated in delivering the pilot intervention or work in the department/facility where the pilot intervention was delivered.

Why is this study being done?
The purpose of this study is to understand the feasiblility and acceptability of a multicomponent intervention to help women reintegrate to their families and communities after genital fistula surgery.

This study is funded by the U.S. Eunice Shriver Kennedy National Institute of Child Health and Development.

How many people will take part in this study?
We will pilot test the intervention with 30 women, and up to 10 stakeholders (intervention moderators, providers) will participate in in-depth interviews.

What will happen if I take part in this research study?
If you choose to be in this study, the following procedures will occur:

- The researcher or their proxy will ask you to participate in an in-depth interview regarding your perspectives on the pilot intervention. They will ask you a series of questions about your perspectives on the intervention overall, its components, and how it fits within the setting.

Study location
Research-team administered interviews will take place either in-person in a private location at Mulago/Kawempe Hospitals, or at another mutually agreed upon location.

How long will I be in the study?
The interview will take approximately 1 hour.

Can I stop being in the study?
Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study.

What side effects or risks can I expect from being in the study?
We do not anticipate any side effects or risks to you from being in the study given your role as key stakeholder.

Are there benefits to taking part in the study?
You will receive no individual benefits to participating in the study; however, you will be contributing to research which seeks to improve women's health and well-being following fistula repair.

What other choices do I have if I do not take part in this study?
You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you.

How will my information be used?
Researchers will use your information to understand the feasibility and acceptability of the intervention. Data on your role will be used to contextualize the findings, but personally-identifying information will not be used.

Will information about me be kept private? We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of Mulago Hospital or Makerere University
- Representatives of University of California
- Representatives of National Institutes for Health

Are there any costs to me for taking part in this study?
There is no cost to taking part in this study.

Will I be paid for taking part in this study?

In return for your time and effort, you will be compensated with 40,000 UgX.

What are my rights if I take part in this study?
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way.

Who can answer my questions about the study?
You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. Contact Dr. Justus Barageine at +256 702 454 869.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Makerere University College of Health Sciences School of Medicine research and ethics committee Chair, Assoc Professor Ocama Ponsiano, on Telephone +256, 0772494120 or the Secretariat at Uganda National Council for Science and Technology, Plot 3 Kimera Road, Ntinda on telephone 041-705-513.

STATEMENT OF CONSENT
I have read or have been read to this consent form and I have fully understood the study purpose, procedures, benefits and the risks involved and I have been given a chance to ask questions and they have been fully answered. I also understand that my participation in this study is voluntary and I will not be penalised or lose any benefits to which am otherwise entitled if I decline to participate in the study. I too understand that am free to withdraw from the study any time if I so wish and that I will be given a copy of this consent form to keep.

I hereby sign below as proof of my consent.

Date Participant's name and Signature

Date Name and signature of a Person Obtaining Consent

MULAGO WOMEN & NEONATAL SPECIALISED HOSPITAL/KAWEMPE NATIONAL REFERRAL HOSPITAL
COMPREHENSIVE REINTEGRATION ASSISTANCE FOR WOMEN WITH OBSTETRIC FISTULA
QUALITATIVE INFORMED CONSENT 2, STUDY PARTICIPANTS: ENGLISH

Study Title: Comprehensive Reintegration Assistance for Women with Obstetric Fistula
Participant number: ……

Research Project Directors:	Justus Barageine, MBChB, MMed, PhD, Senior lecturer/ Obstetrician, Gynaecologist and fistula surgeon Makerere University College of Health Sciences, Mulago Hill Road, Kampala, Uganda Phone: +256 702 454 869 Email: barageinej@gmail.com Alison El Ayadi, ScD, MPH, Associate Professor of Obstetrics, Gynecology and Reproductive Sciences UCSF, 550 16th Street, San Francisco, CA 94158 Phone: 415.659.8367 Email: alison.elayadi@ucsf.edu

This is a research study focused on how to help women recover and reintegrate to their families and communities after genital fistula surgery. The study researchers, Justus Barageine, PhD, MD, from Makerere University School of Medicine, Uganda, and Alison El Ayadi, ScD MPH from the University of California San Francisco, USA, or their representative, will explain this study to you.

STUDY SUMMARY

Introduction: We are asking you to consider taking part in a research study being done by Alison El Ayadi at UCSF and Justus Barageine at Makerere University.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Purpose of the study: The purpose of this study is to explore the experiences of a multicomponent intervention to help women reintegrate to their families and communities after genital fistula surgery to understand feasibility, acceptability, and preliminary effectiveness.

You are being asked to take part in this study because you have recently undergone surgery for female genital fistula and have participated in the initial component of the reintegration intervention.

Study Procedures: The study participants will be asked to come to the study site to participate in indepth interviews where they will share their experiences with the intervention, and to explore acceptability and effectiveness of each of the intervention components in a detailed manner.

You will be in this part of the study for approximately 1-2 hours. If you choose to be in this study, the researchers will ask you to meet at [local fistula repair facility] Hospital or at another convenient private location to have a conversation about your experiences with participating in the various intervention components The research team will facilitate the indepth interview and will be audio recording the entire interview so as not to miss any important information that you will be sharing during the interviews. However caution will be taken not to mention your name or any personal identifiers on the recording to ensure confidentiality.
Possible risks: Risks to being in the study include discussion of emotional or sensitive experiences which may be emotionally upsetting to you, You can pause or stop participating at any time, and you may be referred to a mental health professional for counseling if desired.
. For more information about risks and side effects, ask one of the researchers.

Possible benefits: There may be no direct benefits in taking part in this study component but, the information that you provide will help us to understand the impact of a pilot intervention for improving women's recovery and reintegration experiences following surgery for genital fistula.

Your other options: You do not have to participate in this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

DETAILED STUDY INFORMATION

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you have recently undergone surgery for female genital fistula and have participated in the initial component of the reintegration intervention.
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Why is this study being done?
The purpose of this study component is to understand women's experiences participating in the multi component reintegration intervention after genital fistula surgery and to explore your views about the feasibility and acceptability of the intervention
This study is funded by the U.S. Eunice Shriver Kennedy National Institute of Child Health and Development.

How many people will take part in this study?
We will invite about 15 women to participate in indepth interviews at the study site.

What will happen if I take part in this research study?
If you choose to be in this study, the following procedures will occur:

- The researcher or their proxy will ask you to participate in an in-depth interview so as to discuss your experiences with intervention participation and to explore your views about acceptability and feasibility of the intervention.

- Your data may be used to respond to subsequent research questions after removing all identifying information.

Study location
The indepth interviews will take place in a private location at Mulago Hospitals.

How long will I be in the study?
You will be in this study for approximately 1-2 hours...

Can I stop being in the study?
Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study. Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?
We do not anticipate any side effects or risks from being in the study; however, the questions asked during the indepth interviews may be emotionally distressing to discuss. If you believe that discussing these topics will be distressing for you, you can decide not to participate in the study. In the event you choose to participate in the study and find that discussing these events is too difficult for you, you may pause of stop the interview. The interviewer may decide to pause or stop the interview if they sense that you are very upset. Furthermore, they may refer you to a mental health professional if you feel that speaking with someone might help. For more information about risks and side effects, ask one of the researchers.

Are there benefits to taking part in the study?
There may be no direct benefits for participating in this study but the information that you provide will help health professionals to test the impact of a reintegration program for women undergoing surgery for female genital fistula.

What other choices do I have if I do not take part in this study?
You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. [If relevant: You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.]

How will my information be used?
Researchers will use your information to understand your experiences participating in the intervention and to explore your views about the feasibility and acceptability of the intervention. Any personally-identifying information collected for this study will only be used for this study. Data with no personally-identifying information may be used to answer additional related research questions.

Research results: There may be times when researchers using your information may learn new information. The researchers may or may not share these results with you, depending on a number of factors. If researchers learn new findings that may affect your decision to remain in the study, you will be informed about them.

Will information about me be kept private? We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your

personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of Mulago Hospital or Makerere University
- Representatives of University of California
- Representatives of National Institutes for Health

Are there any costs to me for taking part in this study?
There is no cost to taking part in this study.

Will I be paid for taking part in this study?
In return for your time and effort, you will be compensated with 40,000 UgX as participation incentive and also be reimbursed for your transport to and from the facility for fistula repair.

What are my rights if I take part in this study?
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. [If relevant: You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.]

Who can answer my questions about the study?
You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. Contact Dr. Justus Barageine at +256 702 454 869.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Makerere University College of Health Sciences School of Medicine research and ethics committee Chair, Assoc Professor Ocama Ponsiano, on Telephone +256, 0772494120 or the Secretariat at Uganda National Council for Science and Technology, Plot 3 Kimera Road, Ntinda on telephone 041-705-513.

STATEMENT OF CONSENT
I have read or have been read to this consent form and I have fully understood the study purpose, procedures, benefits and the risks involved and I have been given a chance to ask questions and they have been fully answered. I also understand that my participation in this study is voluntary and I will not be penalised or lose any benefits to which am otherwise entitled if I decline to participate in the study. I too understand that am free to withdraw from the study any time if I so wish and that I will be given a copy of this consent form to keep.

I hereby sign below as proof of my consent.

Date Participant's name and Signature or thumbprint

Date Witness's name and signature if Participant used a thumbprint

Date Name and signature of a Person Obtaining Consent

May we contact you for participation in future studies?

___Yes ___No

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COVID 19 RISK MANAGEMENT PLAN FOR THE STUDY TITLED, "**COMPREHENSIVE REINTEGRATION ASSISTANCE FOR WOMEN WITH FEMALE GENITAL FISTULA: INTERVENTION PILOTING**

STUDY SUMMARY

Title of research project: Comprehensive Reintegration Assistance for Women with Female Genital Fistula: Intervention Piloting

Research objectives

Objective 1: **To assess the feasibility of the pilot reintegration intervention**.

Objective 2: **To assess the acceptability of the pilot reintegration intervention.**

Objective 3: **To assess the preliminary effectiveness of the pilot reintegration intervention.**

Research design

This study employs a quasi-experimental design that aims at understand intervention feasibility and acceptability outcomes, using both quantitative and qualitative research designs which involves conducting structured interviews with 30 study participants and 15 in-depth qualitative interviews with key stake holders and study participants

Study population and site

We will recruit 30 women to participate in the intervention at the time of fistula repair and will follow them for 6-months. All women will receive the intervention; no comparison group will be included at this stage of the research. 15 women will be invited to participate in the indepth interviews plus some key stakeholders (intervention implementers, providers, and hospital administration) in order to understand their perspectives on intervention acceptability.

THE COVID 19 RISK MANAGEMENT PLAN FOR THE STUDY

BACKGROUND

Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered coronavirus which spreads primarily through droplets of saliva or discharge from the nose when an infected person coughs or sneezes. (WHO 2020)

COVID 19 symptoms

The COVID-19 disease symptoms include the following: Fever, cough, myalgia or fatigue, shortness of breath, sore throat and headache. Other COVID 19 symptoms may include: flu-like symptoms, diarrhoea and nausea, muscle ache, loss of taste, pneumonia and Acute Respiratory Distress Syndrome (ARDS), renal failure, pericarditis and Disseminated Intravascular Coagulation (DIC). (MOH 2020).

Objectives of the risk management plan

The risk management plan objective is to detail steps that will to be taken to reduce the risk of getting COVID 19 by both the study team and the study participants.

MEASURES TO BE PUT IN PLACE AT THE STUDY SITE

Protective Measures to be taken on arrival at the study site

Hand washing or sanitisation

All study staff members and study participants will have to first wash or sanitise their hands before entering the study room. The sanitisers, water and soap will be availed at the study site entrance.

Measurement of the body temperature

All study staff and study participants' body temperatures will be measured daily by one of the available study using the temperature monitor availed by the study. Any person whose temperature will be above 37.5 degrees Celsius will be isolated and referred for further investigations within the hospital.

Use of Personal protective equipment

The study staff and study participants will have to put on medical face masks at all times covering the nose, mouth and chin plus face shields to avoid direct contact with body fluids, secretions (including respiratory secretions) and non-intact skin. The medical face masks and face shields will be provided by the study to any study staff and study participants who do not have them.

Maintaining social distancing

At the study site waiting area plus the rooms where the consenting, interviewing, counselling, health education and physiotherapy training sessions will take place, chairs will be placed at least 2 meters apart to maintain social distancing between the study staff and the study participants. Both the study staff and the study participants will be required to keep on their face masks and shields with the nose, mouth and chin completely covered through-out the entire sessions.

Maintaining the working environment clean

The study rooms will be kept clean by mopping the floor on a daily basis plus sanitizing tables, chairs, door locks, filing cabins using water and alcohol solutions before and after working with each study participant.

The study staff will sanitise the chairs, tables and pens to be used during the consenting and interviewing process before and after handling each study participant.

Proper ventilation of the rooms will be ensured by keeping the windows and ventilators of the room wide open.

Safe waste management

Used disposable masks will be removed safely and disposed appropriately in infectious waste bins that will be provided by the study to avoid transmission of infections.

Implementation

The above risk management plan is going to be implemented after having a practical training session with the study staff and before commencement of any study recruitment activities.

References

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