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# Studying Accompaniment model Feasibility and Effectiveness (SAFE) Study: study protocol for a prospective observational cohort study of the effectiveness of self-managed medication abortion

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## ABSTRACT

**Introduction** A range of barriers deter or prevent people from accessing facility-based abortion care. As a result, people are obtaining and using abortifacient medications to end their pregnancies outside of the formal healthcare system, without clinical supervision. One model of self-managed abortion has come to be known as the 'accompaniment' model, in which grassroots organisations provide pregnant people with evidence-based counselling and support through the medication abortion process. Data are needed to understand the safety and effectiveness of this increasingly common model of abortion care.

**Methods and analysis** This is a large, prospective, observational study in Argentina and Nigeria. All people who contact one of two accompaniment groups seeking information for their own self-managed medication abortion, are ages 13 years and older, have no contraindications for medication abortion, are within the gestational range supported by the group (up to 12 weeks' gestation for the primary outcome) and are willing to be contacted for follow-up will be recruited. Participants will respond to an interviewer-administered baseline survey at enrolment, and 1–4 additional surveys over 6 weeks to ascertain whether they obtain medications for abortion, dosing and route of administration of medications, physical and emotional experience of medication abortion self-management, and effectiveness and safety outcomes. Analyses will include estimates of the primary outcome: the proportion of participants that report a complete abortion without surgical intervention at last recorded follow-up; as well as secondary outcomes including a pseudo-experimental test of non-inferiority of the effectiveness of self-managed medication abortion as compared with clinical medication abortion.

**Ethics and dissemination** We describe the ethical considerations and protections for this study, as well the creation of a study-specific Data Monitoring and Oversight Committee. We describe dissemination plans to ensure that study results are shared widely with all relevant audiences, particularly researchers, advocates, policymakers and clinicians.

**Trial registration number** ISRCTN95769543.

## Strengths and limitations of this study

- This study will provide new information on the safety and effectiveness of self-managed medication abortion with support from trained volunteers, outside of the formal healthcare system.
- The primary outcome will be the proportion of people who report a complete abortion without surgical intervention after self-use of misoprostol, alone or in combination with mifepristone, outside of the healthcare setting.
- Secondary outcomes will include an evaluation of whether self-managed medication abortion effectiveness is non-inferior to medication abortion effectiveness in a clinical setting, as well as information on medication dosing and timing, duration of the abortion process, details of the physical experience, including pain management, and experiences of healthcare seeking.
- Findings from this study could shift the global conversation around de-medicalised abortion, and inform revisions to global task-shifting guidelines for who can be a safe abortion provider.
- A limitation of this study is the inability to recruit a formal control group, due to legal restrictions on abortion in the study settings; thus, we rely on historical controls for the pseudo-experimental non-inferiority analysis.

## INTRODUCTION

Access to safe and effective methods of abortion is an essential component of sexual and reproductive healthcare, and necessary for

the realisation of the human right to bodily autonomy. However, legal restrictions, lack of willing and trained providers, high costs, long wait times for services and abortion stigma all serve as barriers to accessing safe abortions within the formal healthcare system.[1–4] People around the world are increasingly obtaining and using the abortifacient medications mifepristone and/or misoprostol to end their pregnancies outside of the formal healthcare system, without clinical supervision (eg,[5–10]). Some people use the medications on their own with information from the Internet or friends, while some seek guidance from pharmacists, safe abortion hotlines and websites, and accompaniment groups.[9] We describe the use of medications to induce abortion outside of the formal healthcare system without clinical supervision as *self-managed abortion*.

An emerging body of evidence suggests that nearly half of abortions worldwide are self-managed,[11] and up to 70% or 80% in some settings.[12] People self-manage their abortions for many reasons, ranging from a preference for the privacy inherent in the model to using a method of last resort when facility-based care is inaccessible.[9] One model of information and support for self-managed abortion has come to be known as the 'accompaniment' model, in which grassroots organisations provide people with evidence-based counselling and support through the medication abortion process outside of the formal healthcare system.[13 14] There is growing awareness of these accompaniment models and increasing recognition of the role of the individual in safely managing their own abortion. In 2015, the World Health Organization (WHO) released guidelines that outlined task-shifted roles for health workers in the provision of safe abortion.[15] For the first time, these guidelines included the pregnant person as an actor in their own abortion process, and acknowledged that the experience of self-management of abortion can be empowering and could lead to a more optimal use of scarce health resources.[15]

Decades of evidence have demonstrated that medication abortion with misoprostol alone or in combination with mifepristone is an effective and safe method of abortion when administered in a clinic setting.[16–20] Yet, concerns remain that people may not be able to use these medications to safely and effectively induce abortion outside of the formal healthcare system without clinical supervision, either due to inaccurate self-assessment of gestational age, inability to follow dosing instructions, or concerns about access to care in the event of a complication or adverse event.[21] We hypothesise, however, that with counselling from accompaniment groups, people can safely and effectively self-manage abortion with medication. This hypothesis is informed by a strong and growing body of evidence on the effectiveness and safety of self-managed medication abortion.[5 6 8 9 22 23] Existing research has analysed records of self-managed medication abortion from online telemedicine groups, as well as community health workers, and more.[5 6 8 9] However, some limitations of existing data, such as a reliance on retrospective records not collected for research purposes, and a scarcity of research on accompaniment models specifically, hinder the field's understanding of the effectiveness and safety of this particular model of abortion care: self-managed medication abortion with accompaniment group support.

Well-designed, rigorously collected research that evaluates the effectiveness and safety of self-managed medication abortion via accompaniment models is needed to understand the experiences of people who use this increasingly common model of abortion care, and to decide if and how to support new non-clinical models of abortion care in a range of legal settings.

### Objectives

In this manuscript, we present the protocol for the Studying Accompaniment model Feasibility and Effectiveness Study (the SAFE Study). The main objective of the SAFE Study is to estimate the effectiveness of both mifepristone with misoprostol, and misoprostol-only, regimens when used to terminate a pregnancy outside of the formal healthcare system, without clinical supervision but with support from accompaniment groups. A secondary objective is to compare the effectiveness of self-managed medication abortion with accompaniment group support to the effectiveness of medication abortion when administered in the clinical setting (a pseudo-experimental non-inferiority analysis). Beyond these core aims, additional objectives include describing the physical experience of self-managed abortion, including incidence and severity of side effects and potential signs of complications, interactions with the formal healthcare system, including surgical and other interventions, emotions throughout the self-managed abortion process, and more.

## METHODS AND ANALYSIS

The SAFE Study is a large, prospective observational cohort study in two countries: Argentina and Nigeria. These countries were selected for the study based on (1) the existence of accompaniment groups that serve a sufficiently high number of clients required to reach the target sample size, (2) geographical representation, (3) organisational interest in the research question and (4) diversity in availability of abortion medications outside of the formal healthcare setting. In both countries, abortion is allowed only on the grounds of preserving health or saving the pregnant person's life; as a result, abortion is not widely available within the formal healthcare setting.[24]

The accompaniment groups selected as recruitment partners for this study vary in their modes of operation, but both provide step-by-step guidance for how to use medication to safely induce abortion based on the WHO protocols (table 1).[25 26] Counsellors are trained to provide empathetic, non-judgemental, gestational age-specific, and evidence-based information to individuals who contact these groups in need of information and support in ending their pregnancy with medications.

Table 1 Medication abortion protocols

| Mifepristone+misoprostol for pregnancies up to 84 days | Misoprostol alone for pregnancies up to 84 days |
|---|---|
| ► Swallow 1 tablet of mifepristone (200 mg) with a glass of water<br>► After 36–48 hours, put 4 pills of misoprostol (800 µg) under the tongue (sublingual) and let them dissolve for 30 min, keep swallowing saliva until the pills dissolve.<br>If after 3 hours there are no signs of reaction, side effects or expulsion, put 2 additional misoprostol pills (400 µg) under the tongue, and let them dissolve for 30 min. | ► Put 4 pills (800 µg) under the tongue (sublingual) and let them dissolve for 30 min, keep swallowing saliva until the pills dissolve. Wait for 3 hours.<br>► After 3 hours, put the second dose of 2–4 pills (400–800 µg) under the tongue and let them dissolve for 30 min, keep swallowing saliva until the pills dissolve. Wait for 3 hours.<br>► After 3 hours, put a third dose of 2–4 pills (400–800 µg) under the tongue and let them dissolve for 30 min, keep swallowing saliva until the pills dissolve.<br>Continue with 2–4 misoprostol pills under the tongue every 3 hours until expulsion occurs. |

In addition to information about medication abortion protocols, counsellors may also provide information on how to obtain medications, how the drugs function, how to manage pain, how to recognise complication signs, how to prepare for potential interactions with medical personnel in case of emergency-treatment seeking, how to confirm abortion completion, what to expect after the abortion and prevention of future unwanted pregnancy.

## Patient and public involvement

A research consortium that includes researchers, activists and accompaniment providers collaboratively developed the study protocol detailed below to ensure that it reflects the priorities, experiences and preferences of people who self-manage abortions with medication. Study investigators invited individual consortium members to participate based on their expertise in self-managed medication abortion and accompaniment models in a range of legal and cultural settings, to ensure the design of a study that reflected the lived experiences of people who self-manage, the accompaniers who support them, and contexts similar to those in which the study will take place. Consortium members also played an active role in ensuring that study instruments would collect data that could be useful for people involved with self-managed medication abortion around the world, and minimally burdensome. Each consortium member drew on their knowledge of people's priorities, experiences and preferences to finalise the research question and outcome measures. Individual 'patients' participated in cognitive interviews and pilot testing to ensure that study questions and procedures were acceptable to and relevant for those pursuing this model of abortion care. The recruitment sites recruited 227 participants during a 60-day pilot study between April and June 2019 to assess the feasibility and acceptability of the study procedures, and conducted post-pilot in-depth interviews with participants to understand the participant experience.[27] The research consortium discussed pilot study results and experiences in-depth; and as a result, the consortium proposed modifications in eligibility criteria and timing of questions for the full study as detailed below, to minimise burden to participants and improve data quality.

In addition to the research consortium that designed the study, study investigators also invited four individuals to serve on a study-specific Data Monitoring and Oversight Committee (DMOC) to provide expert guidance to the SAFE Study research consortium throughout the research process. The overall role of the DMOC is to assist the SAFE Study investigators in protecting the interests of study participants and in preserving the integrity and credibility of the study. The four DMOC members have expertise in epidemiology, survey methods, statistics, participant advocacy and self-managed medication abortion, as well as personal connections to the countries included in this study, and have reviewed the pilot study protocol, pilot study results and full study protocol. They will also review interim study results to evaluate participant safety and other protections.

## Study participants

Each person that contacts one of the organisations during the study period will be screened for eligibility by the organisation staff. Eligible participants will be those who: contacted the accompaniment group seeking information about induced abortion for their own pregnancy; are at least 13 years of age; are able to give informed consent; are able to speak one of the local languages; meet accompaniment group eligibility criteria for starting a medication abortion process (ie, no contraindications to medication abortion, within a gestational age range that the accompaniment group supports—up to 24 weeks in Argentina in limited circumstances, and up to 15 weeks in Nigeria); and are starting a new medication abortion process. Counselors ask each caller to provide an estimated gestational age for the pregnancy and to indicate whether this gestational age estimate has been confirmed by ultrasound. If a caller has not had an ultrasound, counselors enter the caller's self-reported date of last menstrual period into a calendar-based gestational age calculator to confirm estimated gestational age. Individuals will be excluded if they are beyond the gestational

age range supported by the accompaniment group, experiencing ongoing symptoms (bleeding, cramping) from a prior attempt at induced abortion or that could indicate a miscarriage; have a known ectopic pregnancy or symptoms of an ectopic pregnancy; do not want to share their contact information with study staff; do not want to be contacted again by the accompaniment group or by study staff; are not willing to comply with study procedures; or cannot access a phone and private location to answer questions during follow-up in the approximately 3–6 weeks of follow-up.

Across all sites, screening and invitation to participate will take place after each person has received the initial counselling from the organisation, which includes details on evidence-based protocols for medication abortion. Screening and invitation will take place either over the phone or in person, depending on the organisation's model of providing counselling. Accompaniment group counsellors will assess client eligibility over the course of the counselling process; if the person is eligible, they will invite them to participate, and if they express interest, they will proceed through an informed consent process. Verbal consent will be obtained. Special emphasis will be placed on potential participants less than 18 years of age, for whom counsellors will be trained to describe study participation in familiar terms, to ensure that any young person enrolled understands the risks and benefits, and is actively willing to participate, rather than merely failing to object. For people that consent to participate, the counsellor will sign and date a paper informed consent form as record of informed consent, will record a participant-approved identifier for that person, assign a unique study identification (ID) number, collect detailed contact information for follow-up and notify the study coordinators at each site of the new enrollee to schedule subsequent follow-ups.

## Sample size

To assess the sample size needed to estimate the overall effectiveness of self-managed medication abortion through 84 days' (12 weeks, 0 days) gestation, across medication abortion regimens and accompaniment groups, we looked to clinical effectiveness estimates of medication abortion from clinical trials. Existing data suggest that we might expect to see an effectiveness of 93% for mifepristone and misoprostol users through 84 days' gestation and 80% effectiveness for users of misoprostol alone through 84 days' gestation.[16 18–20 28 29] Under these assumptions, we will need to recruit a minimum of 213 subjects in the mifepristone and misoprostol setting (Argentina), and approximately 419 misoprostol-only users and 77 mifepristone and misoprostol users (Nigeria), based on observed proportions of callers in each site using the combined regimen, versus misoprostol alone. Thus, we will recruit and prospectively follow a *minimum* of 709 accompaniment model callers across the two countries.

However, to account for expected loss to follow-up of 10% based on a 60-day pilot study conducted at both sites, and to be able to evaluate secondary outcomes with greater statistical power, we have increased our target sample size beyond the minimum numbers. Thus, our target sample size for each site is 400 in Argentina and 600 in Nigeria. This sample size will allow us to (1) assess our primary outcome (the proportion with a complete abortion without surgical evacuation) within a 5% margin, 90% power and an alpha of 5%; while also allowing us to evaluate our secondary outcome, (2) the pseudo-experimental non-inferiority test, to assess whether self-managed medication abortion with accompaniment support is no more than 5% less effective than the clinical setting for each regimen, with 80% power, an alpha of 5% and assuming no correlation within counsellors (based on pilot study results by site).

The study, like other medication abortion studies,[30] will not be powered to detect a difference in safety outcomes between regimens as major adverse events attributable to medication abortion are extremely rare, but we will document the occurrence of these rare events.[31] Participants beyond 84 days' gestation will be eligible to participate to gather needed data on self-managed medication abortion outcomes within these understudied gestational ranges, but will not count toward the minimum sample size or be included in the evaluation of the primary effectiveness outcome.

## Data collection and data management

At each site, study coordinators will be responsible for monitoring enrolment and conducting follow-up calls. All enrolled participants will be asked a set of questions immediately after enrolment in the study; additional baseline information will be extracted from the caller's counselling record by the accompaniment counsellor or study coordinator. Baseline questions include sociodemographic characteristics, reproductive history, gestational age and preferred mode of contact (phone call, short message service or messaging application). All study instruments are included in online supplemental file 1. In Argentina, in addition to the baseline information collected at all three sites, a sub-sample of 25% of participants will be asked to take a pregnancy test at baseline to confirm that participants are pregnant.

At enrolment, the counsellor will record the estimated date that the participant plans to start their medication abortion process. Approximately 1 week after the estimated/confirmed date of starting the medication abortion process, the study coordinator will follow up with the participant via their preferred mode of contact. At this first follow-up, the study coordinator will record the following outcomes as reported by the participant: (1) if and when the participant successfully obtained abortion medications; (2) if and when the participant has taken the medication (time, date and route for each dose); (3) if and when the participant completed the abortion, and how the completion was confirmed; (4) if, when, why and what type of healthcare was sought at a healthcare facility;

and (5) details on the symptoms and side effects experienced during the medication abortion process.

For participants at enrolment who do not know if or when they plan to obtain or take the pills, or who do not remain in touch with a counsellor about their plans, the study coordinator will follow up 2 weeks after the date of enrolment to conduct the first follow-up. At this first follow-up, if the participant reports that they have not obtained pills and do not plan to continue with the medication abortion, or that they have obtained the pills but do not plan to use them, the study coordinator will not contact them again, and their outcome will be recorded as 'Decided to continue their pregnancy', 'Miscarriage', 'Decided to obtain a surgical abortion' or another outcome, as appropriate. If the participant reports that they have the pills and have taken them (or plan to), follow-up will be reset to 7 days following the date they report taking (or planning to take) the pills, and will proceed as outlined above.

For all participants that report taking the medications, the study coordinator will conduct a second follow-up approximately 3 weeks following the first dose of medication (2 weeks after the first follow-up), to assess the primary outcome (self-report of complete abortion) and any subsequent complications, as well as secondary outcomes. For participants whose abortion outcome cannot be ascertained by the second follow-up, the study coordinator will reach out for a third follow-up 1 week later (4 weeks from first dose of medication) to document primary and secondary outcomes. If the participant's outcome still cannot be ascertained at the third follow-up, the study coordinator will contact them one final time 2 weeks later (6 weeks after taking the pills). For any follow-up point, if after four attempts the study coordinator has still not been able to contact the participant, that participant will have missing data for that time point. Contact will be attempted again for all participants for any following surveys, even if a participant was 'missing' for a prior follow-up. When possible, the study coordinators will input any missing data based on data available in the counselling record for a particular participant. All participants will be compensated for their time in a form and amount that is deemed appropriate for each setting, approximately US$10–25 total in telephone credit or mobile money voucher over the course of the study. Figure 1 displays a representation of the study procedures.

Study coordinators will record all survey responses first on paper forms, and then will manually enter data from all paper records into Qualtrics (Qualtrics, Provo, Utah, USA). A unique study ID number for each participant will link data across follow-ups by participant. All physical study data (screening forms, counselor-signed informed consent forms and completed paper surveys) will be stored in locked filing cabinets and only the local study coordinators will have the key. Once transferred to an encrypted, password-protected electronic file, all paper forms that link participant alias to study ID number will be destroyed. Electronic survey data in Qualtrics will be stored in Qualtrics' password-protected and encrypted cloud storage.

Data will be entered electronically to allow for ongoing monitoring of data quality, and to utilise electronic checks to promote complete data entry. Quantitative data completeness will be assessed first by the study coordinators at each follow-up, reviewing data from the prior follow-up to assess completeness, and on the aggregate level by the team leads on a monthly basis. Interim review of the paper surveys, consent forms, and data entry and storage processes will further ensure the quality of data collected, and will allow for opportunities to swiftly resolve any gaps or challenges that arise during data collection.

## Data analysis

The primary outcome of this study is the proportion of participants who report a complete abortion without surgical evacuation at last recorded study follow-up. This will be determined by the proportion of participants who report 'yes' to the question 'Do you feel that your abortion process is complete?' at their last recorded study follow-up, and who do not report any surgical intervention. Research suggests that people are able to self-assess medication abortion completion accurately.[32] For the primary outcome, consistent with other studies of medication abortion effectiveness,[28] we will calculate the proportion with a complete abortion without surgical intervention among all participants who reported taking medications and have a known abortion outcome. Sensitivity analyses will evaluate this proportion among all participants who reported taking medications (were exposed), and will conservatively assume that those with missing outcome data had a failed abortion.

Exploratory subgroup analyses will evaluate this proportion by accompaniment model, by regimen, and at each time point (1 week after taking the first dose, 3 weeks after taking the first dose and study end). Additional subgroup analyses will include effectiveness by gestational age (<7 weeks' (up to 48 days), 7–9 weeks' (49–63 days) and 9+ through 12 weeks' (64–84 days) gestation); effectiveness by number of misoprostol doses for misoprostol-only regimens (comparing up to three doses vs four or more doses); effectiveness by number of attempts for combined mifepristone and misoprostol regimens (comparing first attempt: one tablet of mifepristone followed by up to three doses of misoprostol vs the second or any subsequent attempt: defined as a process that begins with an additional dose of mifepristone). We will also assess overall effectiveness, defined as the proportion of participants who report a complete abortion by the end of follow-up, inclusive of participants that reported a surgical intervention.

To assess a secondary outcome, whether self-managed medication abortion with accompaniment group support is non-inferior to medication abortion administered in clinical settings, we will calculate a pseudo-experimental non-inferiority test. We refer to this as a 'pseudo-experimental' non-inferiority test, rather than a standard

| SAFE Study Activity | Person responsible | Study procedures | |
|---|---|---|---|
| | | *For in-person workshop attendees* | *For callers receiving phone-support* |
| (1) Screening for eligibility | Counselor | During 1:1 counselling session | During intake phone call |
| (2) Invitation to participate | Counselor | At the end of the group workshop | After counseling is completed |
| (3) Informed consent | Counselor | Immediately after invitation | Immediately after invitation |
| (4) Enrolment | Counselor | Immediately after consent is given | Immediately after consent is given |
| (5) Baseline survey | Counselor | Right after enrolment, counselor asks participant additional study-specific questions that have been added to the usual intake form. First incentive transferred to participant. | |
| (6) Pregnancy test (Argentina only) | Participant | At workshop, after baseline questions. Pregnancy tests taken on-site. | N/A |
| (7) Confirm pills taken | Counselor informs coordinator | Record date participant plans to take pills (Coordinator confirms with counselor)<br>[If the counselor knows date that the pills are taken → proceed to Step 8a]<br>If no contact, follow-up 14 days after enrolment (Step 8b)<br>[If not taking pills, record final information needed] | |
| (8) 1st Follow-Up | (8a) Study Coordinator | [IF DATE OF PILLS KNOWN]: One week after pills taken, study coordinator contacts participant to administer the one-week survey (either over the phone or via secure messaging). Second incentive transferred to participant. | |
| | (8b) Study coordinator | [IF DATE OF PILLS NOT KNOWN]: Two weeks after enrolment, study coordinator will contact participant and ask if pills have been obtained and taken. (If taken, return to Step 8a, if not taken but planning to take, return to Step 7. If not taken and NOT planning to take, administer study close-out questions and conclude follow-up.) | |
| (9) 2nd Follow-Up | Study Coordinator | Three weeks after pills taken, study coordinator contacts participant to administer the second follow-up survey (either over the phone or via secure messaging). | |
| (10) Potential 3rd & 4th Follow-Ups | Study Coordinator | If abortion outcome is not ascertainable at 2nd follow-up, study coordinator to contact participant one-week after 2nd follow-up (four weeks after pills taken), to administer a third follow-up survey.<br><br>If abortion outcome is still not ascertainable at 3nd follow-up, study coordinator to contact participant two-weeks after 3rd follow-up (six weeks after pills taken), to administer a fourth and final follow-up survey. | |

**Figure 1** SAFE Study procedures. N/A, not available; SAFE Study, Studying Accompaniment model Feasibility and Effectiveness Study.

non-inferiority test, because we will compare the proportion who have a complete abortion within our prospective observational study to the proportion who had a complete abortion in a non-concurrent, historical control from randomised clinical trials. This is non-traditional, and pseudo-experimental, because treatment was not randomised in our observational study, and we are not comparing to a concurrent control arm wherein treatment was randomised. For this pseudo-experimental non-inferiority test, we will calculate the difference ($D$) in the proportion of those with complete abortions in the study sample ($p_T$), as compared with the proportion of participants with complete abortions in historical controls ($p_C$), and assess whether the difference is less than or equal to a prespecified margin of interest ($\delta$).[33–35] Data for the historical controls will be pulled from randomised clinical trials selected to most closely match the two medication abortion regimens endorsed by the accompaniment groups in the SAFE Study.[28 36–38] Similar to the primary effectiveness outcome, non-inferiority analyses will include only those participants who took the medications and have a known abortion outcome. Additionally, we will match participants on gestational age to comparison clinical trial data. The below equations specify the null and alternative hypotheses:

$$H_0 : D = p_C - p_T \geq \delta$$
$$H_A : D = p_C - p_T < \delta$$

The null hypothesis ($H_0$) states that the proportion with complete abortions in the SAFE Study ($p_T$) is *inferior* to the proportion with complete abortions in the comparison clinical studies ($p_C$). The alternative hypothesis ($H_A$) states that the proportion with complete abortions in the SAFE Study ($p_T$) is *non-inferior* to the proportion with complete abortions in the comparison clinical studies ($p_C$).[34] To test for non-inferiority, we will compute a one-sided 95% CI for the difference in proportions ($p_C$–$p_T$). The one-sided upper confidence bound for the difference is given by:

$$UB = \hat{p}_C - \hat{p}_T + {}^{z_1-\alpha}\sqrt{\frac{\hat{p}_T(1-\hat{p}_T)}{n_T} + \frac{\hat{p}_C(1-\hat{p}_C)}{n_C}}$$

where $\hat{p}_C$ and $\hat{p}_T$ are the observed proportions of success in the SAFE Study and the clinical standard (93% for mifepristone and misoprostol regimens, 80% for misoprostol-only regimens), respectively; $n_C$ and $n_T$ are the sample sizes of the corresponding groups, and $z_{1-\alpha}$ is the (1−α)-percentile of a standard normal distribution.[33–35] We will reject the null hypothesis if UB ≤$\delta$.

We hypothesise that the effectiveness of self-managed medication abortion with accompaniment group support is non-inferior to the effectiveness of medication abortion administered in a clinical setting within a 5% margin of interest ($\delta$=0.05). A 5% difference in effectiveness is small enough as to be well within the variation in medication abortion effectiveness measured in clinical studies and meets assumptions with regard to the superiority of the control regimen to placebo, thereby meeting core clinical and statistical considerations in the determination of the margin of interest ($\delta$).[34]

Additional secondary outcomes will include descriptive analyses of signs of complication, time to expulsion, ongoing pregnancy and medical treatment/surgical intervention. All outcomes will be measured by participant self-report at each follow-up. These secondary outcomes are defined below:

- Signs of complication: the proportion of participants who report experiencing heavy bleeding, extreme pain, foul-smelling discharge or high fever at any point in follow-up.
- Time to expulsion: range of time (in hours) from time from first medication dose to expulsion; as well as the proportion that experienced expulsion relative to medication dose (expulsion after the first, second, third or additional doses) as reported at last recorded follow-up. Kaplan-Meier methods will be used to model time to expulsion by regimen, stratified by gestational age.
- Ongoing pregnancy: proportion of participants who report an ongoing pregnancy at last recorded study follow-up.
- Medical treatment/surgical intervention: the proportion of participants who report receiving medical treatment and/or surgical intervention (actual receipt of medical care, beyond observation) at any point in follow-up.

We will report results by medication regimen (mifepristone and misoprostol in combination vs misoprostol alone); and pooled across regimens. Analysis of intraclass correlation coefficients for completion outcomes by counsellor in the pilot study suggests no correlation in outcomes within counsellors.[27] All analyses will be conducted using the Stata and/or R statistical software programs, and results will be reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology guidelines.

### Sensitivity/bias analyses

We plan to conduct probabilistic multiple bias analyses to model the effectiveness of self-managed medication abortion under different combinations of misclassification, loss to follow-up and inclusion scenarios. The necessary bias parameters are: (a) sensitivity and specificity of self-report of abortion completion, (b) inclusion probabilities of all eligible clients based on abortion completion status and (c) loss to follow-up probabilities based on abortion completion status. These bias parameters will be estimated using appropriate probability distributions. Inclusion probabilities and lost to follow-up probabilities will be estimated using supplementary anonymised data from all clients who received medication abortion information from the organisations during the study period. Sensitivity and specificity of participant self-report of abortion completion will be estimated based on estimates from the literature, as well as compared with completion assessed by negative pregnancy test, reported ultrasound results, descriptions of products of conception and other abortion experiences assessed in follow-up.

## ETHICS AND DISSEMINATION

There are several relevant ethical concerns for this study. First and foremost, there is a risk that if non-study personnel with negative intentions somehow access study data and are able to ascertain participant identity, that individual participants could face legal repercussions and/or negative social pressure. However, we will not collect any personally identifying information beyond contact information, and rigorous data security protocols minimise the risk of a data breach. Further, we will not collect data that would place participants at any additional risk beyond the data that the organisations are already collecting as part of their standard of care.

An additional potential risk is that participants might feel uncomfortable when responding to certain questions; however, participants are reminded that they can skip any question they do not wish to answer, and can withdraw from the study with no consequences for the counselling services they receive from the accompaniment group. Further, data collectors will be trained to guide participants to find safe and confidential spaces where they can speak (or message) freely, without fear of discovery.

We have been authorised to obtain verbal consent from participants. As the most serious risk associated with participation in the study is the potential loss of confidentiality, and because names and signatures on a consent form would be clearly identifiable information, we will substantially reduce this risk by not obtaining written consent. Rather, the accompaniment counsellor that enrols the participant will sign a consent form to indicate that the person has granted their verbal consent.

As the study eligibility criteria allow for any participant aged 13 years and up, it is possible that minors will participate in the study. These accompaniment services are accessible to and used by minors without parental consent. Requesting parental consent from minors to take part in this study could signify a potential risk to them, as obtaining consent to participate in the study would

result in unwanted disclosure of pregnancy and abortion seeking. Within the countries in which the proposed research will be conducted, a waiver of parental consent can be granted when the proposed study (a) poses no more than minimal risk; (b) holds potential to benefit the minors being involved in the study and (c) the study objectives could not otherwise be achieved if parents were consented. Minors are an important group to include in research as little is known about the experiences of minors in self-managed abortion. Given the potential additional risks if parental consent is required, and the right of minors to assent to accompaniment services, we will use the same consent/assent form for all participants of the study regardless of their age. We do not foresee any additional risk to minors who choose to participate in this study.

This study protocol has been approved by the Allendale Investigational Review Board - the institutional review board (IRB) of record for the study - in March of 2019 and amended in July of 2019. In Argentina, the Fundación Huésped IRB approved the country-specific protocol. On requests from local implementing partners in Nigeria, the Allendale Investigational Review Board served as the IRB of record for the study. The protocol has also been submitted and reviewed by the study-specific DMOC, comprised of researchers with expertise in reproductive health research who reside in and/or are from Argentina, Nigeria and Southeast Asia.

The findings from this multinational study will inform the global conversation around the de-medicalisation of abortion services in both legally permissive and restrictive settings. Results will provide detailed information on the effectiveness and safety of self-managed medication abortion, and insight into if and how effectiveness and safety vary depending on other aspects of the experience. Findings related to the physical experience of abortion (onset and duration of bleeding, cramping, pain) can be used to better counsel and prepare people considering self-managed medication abortion. These findings can also help people better identify which physical symptoms are a cause for concern versus those that are a normal part of the medication abortion process. Findings related to people's experiences seeking care within the formal health system, including how they described their situation, the care they received and more will provide important insights into how to ensure that people are able to access medical care when they need it, without fear of mistreatment or legal prosecution.

Findings from the SAFE Study will be widely disseminated to researchers, advocates, healthcare providers, and stakeholders in non-clinical and clinical abortion provision alike to contribute to the evidence base on the effectiveness and safety of alternative models of medication abortion provision. In scientific settings, study results will be published in peer-reviewed journals in the global health field and submitted as scientific abstracts to relevant conferences. Beyond these scientific avenues of dissemination, we will also work closely with our partners and members of our research consortium to design a lay dissemination strategy that is appropriate and wide-reaching, including interactive web-based and paper-based briefs that highlight key findings; press releases to ensure that key findings from the study are shared with the public more broadly; and the development of blog posts, short video segments, and/or web graphics or other formats deemed appropriate by our partners that can be shared widely in digital format, via social media or other means, across multiple countries.

A definitive evaluation of the safety and effectiveness of self-managed medication abortion with accompaniment support could be instrumental in encouraging researchers, clinicians, advocates, and policymakers to revise and update current guidelines on the use of abortifacient medications outside of the formal health system. If found to be effective and safe, liberalisation of medication abortion guidelines could dramatically expand access to medication abortion, with enormous implications for reductions in morbidity and mortality due to unsafe abortion, and revolutionary implications for the human right to bodily autonomy.

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**SAFE Study Baseline Instrument**

**Study ID:** _____

**Baseline interview completed by: (Counselor name)** _____

**Date (dd/mm/yyyy):** ____/____/_____

**Data entered into Qualtrics by: (name)** _____

1. How old are you? _____ years
2. What city do you live in now? _____
3. How many times have you been pregnant, including this pregnancy? _____
4. How many times have you given birth through the vagina (not a C-section)? _____
5. We trust you to make the best choices for yourself. So please, feel safe to answer freely: How many abortions (not miscarriages) have you had? _____
6. How many children do you have? _____
7. What is the highest level of education you have completed? ***Select only one response.***
   - ☐ No schooling
   - ☐ Completed primary
   - ☐ Completed secondary
   - ☐ More than high school (any university, any AA, any graduate)
   - ☐ No response

**Abortion Characteristics**

8. When did you find out you were pregnant? It's ok if you can't remember exactly, please just give us your best estimate. (dd/mm/yyyy): ____/____/_____
9. When did you decide you wanted to end the pregnancy? It's ok if you can't remember exactly, please just give us your best estimate: (dd/mm/yyyy): ____/____/_____
10. From when you decided to end the pregnancy, how long did it take you to contact [hotline name]? (Enter number of **days** only. For example, if they report one week, enter 7 days, if two weeks, report 14 days, etc.) _____ days
11. Where did you find out info about [hotline name]? *Select all that apply.*
    - ☐ A friend
    - ☐ A family member
    - ☐ Facebook
    - ☐ Women on Web
    - ☐ Internet search
    - ☐ Flier/handbill/sticker/t-shirt
    - ☐ Hotline website
    - ☐ Other:_____
    - ☐ No response
12. What is the date of your last menstrual period, or your best approximation of it? It's ok if you can't remember exactly, please just give us your best estimate: (dd/mm/yyyy): ____/____/_____
13. How many weeks pregnant are you (if you know)? *Enter in number of weeks only. Round to nearest week, i.e.: if 6 weeks and 3 days, just mark "6". If 6 weeks 4 days or up, mark "7"* : _____

14. How do you know you are pregnant? *Let participant answer freely, Select all that apply.*
    - ☐ Took pregnancy test at home
    - ☐ Took blood test in a facility
    - ☐ Took urine test in a facility
    - ☐ Late/missed period
    - ☐ Ultrasound
    - ☐ Pregnancy symptoms
    - ☐ Other _____
    - ☐ No response

15. Have you previously done anything to end this pregnancy, even if it didn't work?
    - ☐ Yes

      *If yes:* What did you do? Select all that apply.
        - ☐ Misoprostol
        - ☐ Herbs
        - ☐ Chili/hot pepper
        - ☐ Teas
        - ☐ Emergency contraception (Plan B)
        - ☐ Vitamin C
        - ☐ Intense exercise
        - ☐ Substance use
        - ☐ Went to a clinic/hospital

          *If "went to a clinic/hospital":* What happened? Select all that apply.

            - ☐ The provider refused to provide abortion care
            - ☐ I decided I didn't want to have help from the facility
            - ☐ It was too expensive
            - ☐ Other _____
            - ☐ No response
        - ☐ Other (including other medications)_____
        - ☐ No response

      *If yes:* When was the most recent attempt to end this pregnancy?

        - ☐ In the past 7 days
        - ☐ 8 - 14 days ago
        - ☐ 15 - 30 days ago
        - ☐ More than 30 days ago
        - ☐ No response
    - ☐ No
    - ☐ No response

16. *(If reported going to a clinic/hospital above in Q15, just record that answer here. No need to ask again.)* Did you try to go to a health facility for help in ending your pregnancy?
    - ☐ Yes

      *If yes:* What happened? Select all that apply.
        - ☐ The provider refused to provide abortion care
        - ☐ I decided I didn't want to have help from the facility
        - ☐ It was too expensive
        - ☐ Other _____
        - ☐ No response
    - ☐ No
    - ☐ No response

**Contact Follow-Up Details**

17. As a participant in this study, it is important that we are able to follow-up with you so we can learn about your experience and how to improve this care for all women. What is the best way for [study coordinator name] to be in touch with you one week from today?
    - ☐ Phone call: (Write phone number here)_____
    - ☐ SMS: (Write phone number here)_____
    - ☐ Whatsapp: (Write phone number here)_____
    - ☐ Wire
    - ☐ Other _____
    - ☐ No response

18. Is there another way we can reach you in case that method doesn't work?
    - ☐ Phone call
    - ☐ SMS
    - ☐ Whatsapp
    - ☐ Wire
    - ☐ Other: _____
    - ☐ No response

19. When [study coordinator name] contacts you, who should she say is calling?

| |
|---|
| |

20. Is it ok for [study coordinator name] to send a text message to you?
    - ☐ Yes
    - ☐ No
    - ☐ No response

21. When would be a good time for [study coordinator name] to contact you? Select all that apply.
    - ☐ Anytime
    - ☐ Weekend mornings
    - ☐ Weekend afternoons
    - ☐ Weekend evenings
    - ☐ Weekday mornings
    - ☐ Weekday afternoons
    - ☐ Weekday evenings
    - ☐ No response

22. At some point in the future, we may contact you for participation in an interview about experiences with [hotline name]. We would offer you an incentive of [$10 USD]. Would you be interested in this?
    - ☐ Yes
    - ☐ No
    - ☐ Not sure
    - ☐ No response

23. When are you planning to take pills? (update when you know): (dd/mm/yyyy): ____/____/_____

24. Is the number you gave me the best number for [study coordinator name] to send your incentive (mobile money payment)?
    - ☐ Yes
    - ☐ No *If no*: What is the best number to send your incentive to? _____

| |
|---|
| Was the incentive sent to the participant?(circle one) Yes No<br>Date incentive sent: (dd/mm/yyyy): ____/____/____ Incentive sent by: (name) _____ |

**SAFE Study 1st Follow-Up**

**Unique ID:** _____

**7-day follow-up interview completed by: (name)** _____

**Date of interview: (dd/mm/yyyy):** ____/____/_____

**Data entered by: (name)** _____

1. Have you gotten the pills yet?
   - ☐ No

     *If no:* Why not? *Let participant answer freely, Select all that apply*
     - ☐ Decided to continue the pregnancy → END SURVEY
     - ☐ Could not find the pills
     - ☐ Did not have enough money for the pills
     - ☐ Not enough time to go get the pills
     - ☐ Had a miscarriage so no longer need the pills → END SURVEY
     - ☐ Concerns about using the pills
     - ☐ I am not sure I am still pregnant
     - ☐ Other _____
     - ☐ No response

     ***For everyone who did not report deciding to continue the pregnancy or miscarriage:*** Despite these challenges, do you still plan to get the pills and take them?
     - ☐ Yes
     - ☐ No
     - ☐ Don't know
     - ☐ No response

       If **yes**, when do you PLAN to take the pills? ____/____/_____
       *dd mm yyyy*

       If **no** or **don't know**, please tell me a bit more about why you do not, or are not sure if you plan to get the pills and take them [open response]:

     **IF PARTICIPANT DID NOT GET THE PILLS AND DOES NOT PLAN TO TAKE THE PILLS, END SURVEY HERE. IF THEY PLAN TO GET THE PILLS, SCHEDULE NEXT FOLLOW-UP FOR 7 DAYS AFTER PLAN GET/TAKE PILLS.**

   - ☐ Yes

     *If yes:* When did you get them? ____/____/_____
     *dd mm yyyy*

     *If yes:* Where did you get them? *Select all that apply*
     - ☐ Pharmacy

       *If pharmacy*: How many pharmacies did you need to go to before you got all of the pills that you needed? _____
     - ☐ A friend
     - ☐ Ordered from the internet
     - ☐ Health care provider
     - ☐ Other _____
     - ☐ No response

     *If yes:* How were they stored?
     - ☐ Loose pills
     - ☐ Blister pack
     - ☐ Other _____
     - ☐ No response

     *If yes:* What was the brand name? *If more than one brand was purchased, select all that apply*.
     - ☐ Cytotec

- ☐ Mariprist
- ☐ Mife Kit
- ☐ Mife Pack
- ☐ Misoclear
- ☐ Misofem
- ☐ Mistol
- ☐ Other: _____
- ☐ Don't know
- ☐ No response

*If yes*: How did you pay for the pills? (the abortion pills only) _____

2. Have you taken the pills yet?
   - ☐ No

   *If no:* Why not? *Let participant answer freely, Select all that apply*.
   - ☐ Decided to continue the pregnancy → END SURVEY
   - ☐ Had a miscarriage so no longer need the pills → END SURVEY
   - ☐ Concerns about using the pills
   - ☐ Haven't had time yet
   - ☐ I am not sure I am still pregnant
   - ☐ Other (specify) _____
   - ☐ No response

   *If no:* Do you plan to take the pills?
   - ☐ Yes

     *If yes:* When do you plan to take the pills? ____/____/_____
     dd mm yyyy
   - ☐ No
   - ☐ No response

**IF PARTICIPANT HAS NOT TAKEN THE PILLS, END SURVEY HERE.**

- ☐ Yes

  *If yes:* What regimen did you use?
  - ☐ Misoprostol alone
  - ☐ Mifepristone + Misoprostol
  - ☐ No response

3. In total, how many medication doses did the woman report taking? _____

**Dose Timing**

4. **1st dose:** Which medication did you take? ☐ Mife ☐ Miso ☐ No response
   How many pills did you take? _____ pills
   Route of administration:
   - ☐ Oral
   - ☐ Buccal
   - ☐ Sublingual
   - ☐ Vaginal
   - ☐ Other _____
   - ☐ No response

   What date did you take this dose?: ____/____/_____ What time did you take this dose?_____
   *dd mm yyyy* *time*

5. **2nd dose:** Which medication did you take? ☐ Mife ☐ Miso ☐ No response
   How many pills did you take? _____ pills
   Route of administration:
   - ☐ Oral
   - ☐ Buccal
   - ☐ Sublingual

□ Vaginal
□ Other _____
□ No response
What date did you take this dose?: ____/____/_____ What time did you take this dose?_____
*dd mm yyyy* *time*

6. **3rd dose:** Which medication did you take? □ Mife □ Miso □ No response
How many pills did you take? _____ pills
Route of administration:
□ Oral
□ Buccal
□ Sublingual
□ Vaginal
□ Other _____
□ No response
What date did you take this dose?: ____/____/_____ What time did you take this dose?_____
*dd mm yyyy* *time*

7. **4th dose:** Which medication did you take? □ Mife □ Miso □ No response
How many pills did you take? _____ pills
Route of administration:
□ Oral
□ Buccal
□ Sublingual
□ Vaginal
□ Other _____
□ No response
What date did you take this dose?: ____/____/_____ What time did you take this dose?_____
*dd mm yyyy* *time*

8. **5th dose:** Which medication did you take? □ Mife □ Miso □ No response
How many pills did you take? _____ pills
Route of administration:
□ Oral
□ Buccal
□ Sublingual
□ Vaginal
□ Other _____
□ No response
What date did you take this dose?: ____/____/_____ What time did you take this dose?_____
*dd mm yyyy* *time*

9. Did you (or do you) need to take any additional doses?
□ Yes
□ No
□ No response

*If yes:* Give details of the medicine, number of pills, route, date, and timing.

_____
_____
_____
_____
_____

**Bleeding**

10. Did you experience any bleeding?
□ No
□ No response

- ☐ Yes

  *If* yes*:* When did you first notice ANY bleeding?
  - ☐ After the first dose of the medication
  - ☐ After the second dose of the medication
  - ☐ After the third dose of medication
  - ☐ After the fourth dose of medication
  - ☐ After the fifth dose of medication
  - ☐ After the sixth dose of medication
  - ☐ After the seventh dose of medication
  - ☐ After the eighth dose of medication
  - ☐ I don't remember
  - ☐ No response

  *If yes:* Over how many DAYS did you have ANY bleeding? (days) _____

  *If yes:* Was the bleeding continuous throughout this period, or did it stop and start multiple times?
  - ☐ Continuous
  - ☐ Stop and start
  - ☐ No response

  *If* yes*:* Over how many DAYS did you have THICK/HEAVY bleeding? (days) _____

  *If greater than 0:* When did you first notice the THICK/HEAVY bleeding?
  - ☐ After the first dose of the medication
  - ☐ After the second dose of the medication
  - ☐ After the third dose of medication
  - ☐ After the fourth dose of medication
  - ☐ After the fifth dose of medication
  - ☐ After the sixth dose of medication
  - ☐ After the seventh dose of medication
  - ☐ After the eighth dose of medication
  - ☐ I don't remember
  - ☐ No response

**Cramping**

11. Did you experience any cramping?
    - ☐ No
    - ☐ No response
    - ☐ Yes

      *If yes:* When did you first notice ANY cramping/contractions?
      - ☐ After the first dose of the medication
      - ☐ After the second dose of the medication
      - ☐ After the third dose of medication
      - ☐ After the fourth dose of medication
      - ☐ After the fifth dose of medication
      - ☐ After the sixth dose of medication
      - ☐ After the seventh dose of medication
      - ☐ After the eighth dose of medication
      - ☐ I don't remember
      - ☐ No response

      *If yes:* Over how many hours did you have cramping/contractions? (hours) _____

      *If yes:* Over how many days did you have cramping/contractions? (days) _____

      *If yes:* Was the cramping continuous throughout this period, or did it stop and start multiple times?
      - ☐ Continuous
      - ☐ Stop and start
      - ☐ No response

**Pain**

12. Did you do anything to prevent pain BEFORE you started the process? (Like taking pills, watching a movie, using a heating pad, shower or bath, massage, special teas, etc.)
    - ☐ No
    - ☐ No response
    - ☐ Yes
      *If yes:* What did you do? *Let participant answer freely, Select all that apply.*
        - ☐ Took painkillers
        - ☐ Watched a movie/tv
        - ☐ Took a shower
        - ☐ Used a heating pad
        - ☐ Used massage
        - ☐ Took herbs
        - ☐ Drank tea
        - ☐ Listened to music
        - ☐ Other _____
        - ☐ No response

13. Did you feel any physical pain during the process?
    - ☐ No
    - ☐ No response
    - ☐ Yes
      *If yes:* Did you do anything to alleviate the pain, once it began? (Like taking pills, watching a movie/tv, using a heating pad, shower or bath, massage, special teas, etc.)
        - ☐ No
        - ☐ No response
        - ☐ Yes
          *If yes:* What did you do? *Select all that apply.*
            - ☐ Took painkillers
            - ☐ Watched a movie/tv
            - ☐ Took a shower
            - ☐ Used a heating pad
            - ☐ Used massage
            - ☐ Took herbs
            - ☐ Drank tea
            - ☐ Listened to music
            - ☐ Other _____
            - ☐ No response

**Side Effects and Completion**

14. During or after your process, did you experience any of the following? *Read all options, select all that apply.*
    - ☐ Nausea
    - ☐ Diarrhea
    - ☐ Vomiting
    - ☐ Fever
    - ☐ Chills
    - ☐ Itchiness/hives
    - ☐ Difficulty breathing
    - ☐ Face numbness
    - ☐ Client didn't experience any of these symptoms
    - ☐ No response

15. During or after the process, did you experience: *Read all options, Select all that apply*
    - ☐ Bleeding that soaked more than 2 pads per hour for more than 2 hours
    - ☐ Pain that didn't go away with pain relievers and made it difficult to do normal activities
    - ☐ Fever higher than 38C for more than 24 hours
    - ☐ Foul smelling yellow/green discharge
    - ☐ Client didn't experience any symptoms
    - ☐ No response

**16. Do you feel that your abortion process is complete?**
    - ☐ No response
    - ☐ Unsure

      *If you are unsure:* Why are you not sure?

      | |
      |---|
      | |

    - ☐ No

      *If no:* Why do you feel that your abortion process is not complete? *Let participant answer freely, then Select all that apply.*
        - ☐ Counselor told me I was STILL pregnant
        - ☐ Pregnancy symptoms did NOT go away
        - ☐ Doctor/nurse told me I was STILL pregnant
        - ☐ I did NOT feel the pregnancy come out
        - ☐ I did NOT see the gestational sac
        - ☐ POSITIVE pregnancy test at facility, blood
        - ☐ POSITIVE pregnancy test at facility, urine
        - ☐ POSITIVE pregnancy test, home
        - ☐ Ultrasound
        - ☐ Other _____
        - ☐ No response
    - ☐ Yes

      *If yes:* Why do you feel that your abortion is complete? *Let participant answer freely, then Select all that apply..*
        - ☐ Counselor told me I was no longer pregnant
        - ☐ Pregnancy symptoms went away
        - ☐ Doctor/nurse told me I was no longer pregnant
        - ☐ I felt the pregnancy come out
        - ☐ I saw the gestational sac
        - ☐ NEGATIVE pregnancy test at facility, blood
        - ☐ NEGATIVE pregnancy test at facility, urine
        - ☐ NEGATIVE pregnancy test, home
        - ☐ Ultrasound
        - ☐ Other _____
        - ☐ No response

17. Since taking the medications, have you had an ultrasound?
    - ☐ Yes

      *If* yes*:* What was the result of the ultrasound?
        - ☐ Complete abortion
        - ☐ Incomplete abortion
        - ☐ Ongoing pregnancy
        - ☐ Other _____
        - ☐ No response

      *If yes:* What was the date of the ultrasound? ____/____/_____
      *dd mm yyyy*

18. At any point in the process, did you notice (feel or see) the pregnancy come out/expel?
    - ☐ No

- ☐ Don't know
- ☐ No Response
- ☐ Yes

*If yes:* At what point in the process did you notice the pregnancy (products of conception) come out?

- ☐ After the first dose of medication
- ☐ After the second dose of medication
- ☐ After the third dose of medication
- ☐ After the fourth dose of medication
- ☐ After the fifth dose of medication
- ☐ After the sixth dose of medication
- ☐ After the seventh dose of medication
- ☐ After the eighth dose of medication
- ☐ I don't remember
- ☐ No response

*If yes:* Approximately how many HOURS after your first dose of medication did the pregnancy come out? (hours)_____

19. At any point during or after your abortion process, did you seek care at a health facility?
    - ☐ No→ Go to Q20 (Emotions)
    - ☐ No response → Go to Q20 (Emotions)
    - ☐ Yes

    *If yes:* Why did you seek care at a health facility? *Select all that apply.*

    - ☐ To confirm abortion completion
    - ☐ Concern about bleeding
    - ☐ Concern about pain
    - ☐ Concern about fever
    - ☐ Concern about discharge
    - ☐ Concern about nausea
    - ☐ Concern about diarrhea
    - ☐ For MVA
    - ☐ For D&C
    - ☐ Other _____
    - ☐ No response

    *If yes:* Did the clinicians keep you under observation? (i.e. asked you to stay for some time so they could continue to assess your symptoms, without actively treating you)

    - ☐ Yes
    - ☐ No
    - ☐ I don't know
    - ☐ No response

    *If yes to seeking care at a health facility:* Did they give you misoprostol?

    - ☐ Yes
    - ☐ No
    - ☐ I don't know
    - ☐ No response

    *If yes:* Did they give you antibiotics?

    - ☐ Yes
    - ☐ No
    - ☐ I don't know
    - ☐ No response

    *If yes:* Did they give you pain medications?

    - ☐ Yes
    - ☐ No
    - ☐ I don't know
    - ☐ No response

*If yes: Did they give you other medications (beyond miso, antibiotics, or pain medications)?*

- ☐ Yes (Specify which medications) _____
- ☐ No
- ☐ I don't know
- ☐ No response

*If yes:* Did you have an MVA?

- ☐ Yes
- ☐ No
- ☐ I don't know
- ☐ No response

*If yes:* Did you have a D&C?

- ☐ Yes
- ☐ No
- ☐ I don't know
- ☐ No response

*If yes:* Did they do an ultrasound at the health facility?

- ☐ Yes
- ☐ No
- ☐ I don't know
- ☐ No response

*If yes:* Did they give you IV fluids?

- ☐ Yes
- ☐ No
- ☐ I don't know
- ☐ No response

*If yes:* Did you receive a blood transfusion?

- ☐ Yes
- ☐ No
- ☐ I don't know
- ☐ No response

*If yes:* Did you stay overnight at the health facility?

- ☐ Yes
- ☐ No
- ☐ No response

*If yes:* Did you receive any other type of treatment that we haven't listed?

- ☐ Yes (specify what kind of medical treatment)_____
- ☐ No
- ☐ I don't know
- ☐ No response

*If yes to seeking care at a health facility:* What type of facility did you go to?

- ☐ Government/public clinic
- ☐ Private clinic
- ☐ Government/public hospital
- ☐ Private hospital
- ☐ Other _____
- ☐ No response

*If yes:* Did the doctor or nurse know you had taken anything to try to end your pregnancy?

- ☐ Yes, I told them

  *If yes, I told them:* Why did you tell the provider? *Let participant answer freely, Select all that apply.*

  - ☐ They asked me directly if I had done anything
  - ☐ I wanted them to have all of the information
  - ☐ I felt comfortable sharing the information
  - ☐ I knew the provider
  - ☐ I trusted the provider
  - ☐ I felt that I had to tell the provider

- ☐ Other _____
- ☐ No response

☐ Yes, they suspected/found out
☐ No, I told them I had a miscarriage → see below
☐ No, I didn't tell them anything → see below
*If "No, I told them I had a miscarriage" and "No, I didn't tell them anything" :* Why did you not tell the provider*? Let participant answer freely, Select all that apply.*

- ☐ I was afraid
- ☐ I knew the provider personally
- ☐ There was no medical need to tell them
- ☐ I did not want to be judged
- ☐ Other _____
- ☐ No response

☐ Other_____
☐ No response

20. What are the top 3 emotions you feel now about your abortion experience? To be clear, we mean the top 3 emotions you feel about the abortion (not about having an unwanted pregnancy).
☐ Relief
☐ Guilty
☐ Calm
☐ Happy
☐ Satisfied
☐ Anxious
☐ Nervous
☐ Relaxed
☐ Fear
☐ Sadness
☐ Disappointment
☐ Anguish
☐ No emotion
☐ Other _____
☐ No response

**END OF SURVEY**

**SAFE Study 2nd/Additional follow-up Instrument**

**Unique ID:** _____

**2nd/Additional follow-up interview completed by: (name)** _____

**Date of interview (dd/mm/yyyy):** ____/____/_____

**Which additional follow-up is this (refers to the follow-up, not number of times trying to contact)**

- ☐ **Second (21-day)**
- ☐ **Third (28 day)**
- ☐ **Fourth (42 day)**

**Did the participant report a complete abortion at the 7 day follow-up?**

- ☐ **Yes**
- ☐ **No**
- ☐ **No response at 7 day follow-up**

**Did the participant report an expulsion at the 7 day follow-up?**

- ☐ **Yes**
- ☐ **No**
- ☐ **No response at 7 day follow-up**

**What was the date of their 7-day follow-up?** dd/mm/yyyy): ____/____/_____

21. Since we last spoke, have you taken any additional doses?
    - ☐ No → Go to Q8 (Bleeding)
    - ☐ No response → Go to Q8 (Bleeding)
    - ☐ Yes
      *If yes:* How many additional doses did the participant take? _____
      (answer questions about each dose below)

**Dose Timing (Skip this section if the participant did not take any additional doses)**

22. **1st additional dose:** Which medication did you take? ☐ Mife ☐ Miso ☐ No response
    How many pills did you take? _____ pills
    Route of administration:
    - ☐ Oral
    - ☐ Buccal
    - ☐ Sublingual
    - ☐ Vaginal
    - ☐ Other _____
    - ☐ No response

    What date did you take this dose?: ____/____/_____ What time did you take this dose?_____
    *dd mm yyyy* *time*

23. **2nd additional dose:** Which medication did you take? ☐ Mife ☐ Miso ☐ No response
    How many pills did you take? _____ pills
    Route of administration:
    - ☐ Oral
    - ☐ Buccal
    - ☐ Sublingual
    - ☐ Vaginal
    - ☐ Other _____
    - ☐ No response

What date did you take this dose?: ____/____/_____ What time did you take this dose?_____
*dd mm yyyy* *time*

24. **3rd additional dose:** Which medication did you take? ☐ Mife ☐ Miso ☐ No response
How many pills did you take? _____ pills
Route of administration:
☐ Oral
☐ Buccal
☐ Sublingual
☐ Vaginal
☐ Other _____
☐ No response
What date did you take this dose?: ____/____/_____ What time did you take this dose?_____
*dd mm yyyy* *time*

25. **4th additional dose:** Which medication did you take? ☐ Mife ☐ Miso ☐ No response
How many pills did you take? _____ pills
Route of administration:
☐ Oral
☐ Buccal
☐ Sublingual
☐ Vaginal
☐ Other _____
☐ No response
What date did you take this dose?: ____/____/_____ What time did you take this dose?_____
*dd mm yyyy* *time*

26. **5th additional dose:** Which medication did you take? ☐ Mife ☐ Miso ☐ No response
How many pills did you take? _____ pills
Route of administration:
☐ Oral
☐ Buccal
☐ Sublingual
☐ Vaginal
☐ Other _____
☐ No response
What date did you take this dose?: ____/____/_____ What time did you take this dose?_____
*dd mm yyyy* *time*

27. Did you (or do you) need to take any additional doses?
☐ Yes
☐ No
☐ No response

*If yes:* Give details of the medicine, number of pills, route, date, and timing.

**Bleeding**

We last spoke on [**date of 1st follow up**]. The next set of questions are about **NEW** experiences that happened since we last spoke.

28. Since we last spoke, did you experience any more bleeding?
    - ☐ No
    - ☐ No response
    - ☐ Yes

    *If yes:* Over how many DAYS since we last spoke did you have ANY bleeding? (days) _____

    *If yes:* Was the bleeding continuous throughout this period, or did it stop and start multiple times?
        - ☐ Continuous
        - ☐ Stop and start
        - ☐ No response

    *If* yes*:* Over how many DAYS since we last spoke did you have THICK/HEAVY bleeding? (days)__

    *If greater than 0:* When did you first notice the THICK/HEAVY bleeding?
        - ☐ After the first dose of the medication
        - ☐ After the second dose of the medication
        - ☐ After the third dose of medication
        - ☐ After the fourth dose of medication
        - ☐ After the fifth dose of medication
        - ☐ After the sixth dose of medication
        - ☐ After the seventh dose of medication
        - ☐ After the eighth dose of medication
        - ☐ I don't remember
        - ☐ No response

**Cramping**

29. Since we last spoke, have you experienced any more cramping?
    - ☐ No
    - ☐ No response
    - ☐ Yes

    *If yes:* Over how many hours since we last spoke did you have cramping/contractions? (hours) ____

    *If yes:* Over how many days since we last spoke did you have cramping/contractions? (days) _____

    *If yes:* Was the cramping continuous throughout this period, or did it stop and start multiple times?
        - ☐ Continuous
        - ☐ Stop and start
        - ☐ No response

**Pain**

30. Since we last spoke, have you experienced any physical pain related to the abortion?
    - ☐ No
    - ☐ No response
    - ☐ Yes

    *If yes:* Did you do anything to alleviate the pain, once it began? (Like taking pills, watching a movie/tv, using a heating pad, shower or bath, massage, special teas, etc.)
        - ☐ No
        - ☐ No response
        - ☐ Yes

        *If yes:* What did you do? *Select all that apply.*
            - ☐ Took painkillers
            - ☐ Watched a movie/tv
            - ☐ Took a shower
            - ☐ Used a heating pad
            - ☐ Used massage
            - ☐ Took herbs
            - ☐ Drank tea

- ☐ Listened to music
- ☐ Other _____
- ☐ No response

31. Since we last spoke, did you do anything to prevent pain BEFORE you started the process? (Like taking pills, watching a movie, using a heating pad, shower or bath, massage, special teas, etc.)
    - ☐ No
    - ☐ No response
    - ☐ Yes

      *If yes:* What did you do? *Let participant answer freely, Select all that apply.*
        - ☐ Took painkillers
        - ☐ Watched a movie/tv
        - ☐ Took a shower
        - ☐ Used a heating pad
        - ☐ Used massage
        - ☐ Took herbs
        - ☐ Drank tea
        - ☐ Listened to music
        - ☐ Other _____
        - ☐ No response

**Side Effects and Completion**

32. Since we last spoke, did you experience any NEW episodes of: *Read all options, Select all that apply*
    - ☐ Bleeding that soaked more than 2 pads per hour for more than 2 hours
    - ☐ Pain that didn't go away with pain relievers and made it difficult to do normal activities
    - ☐ Fever higher than 38C for more than 24 hours
    - ☐ Foul smelling yellow/green discharge
    - ☐ Client didn't experience any symptoms
    - ☐ No response

33. **[If participant's abortion was complete at 7 days:]** "When we last spoke, you said that you felt your abortion was complete. Today, approximately ____ weeks after you took your pills, do you STILL feel that your abortion process is complete?"

    **[If participant's abortion was NOT complete at 7 days:]** "When we last spoke, you said that you felt your abortion was NOT complete. Today, approximately ____ weeks after you took your pills, do you now feel that your abortion process is complete?"

    - ☐ No response
    - ☐ Unsure

      *If you are unsure:* Why are you not sure?

      | |
      |---|
      | |

    - ☐ No

      *If no:* Why do you feel that your abortion process is not complete? *Let participant answer freely, then Select all that apply.*
        - ☐ Counselor told me I was STILL pregnant
        - ☐ Pregnancy symptoms did NOT go away
        - ☐ Doctor/nurse told me I was STILL pregnant
        - ☐ I did NOT feel the pregnancy come out
        - ☐ I did NOT see the gestational sac
        - ☐ POSITIVE pregnancy test at facility, blood
        - ☐ POSITIVE pregnancy test at facility, urine
        - ☐ POSITIVE pregnancy test, home

- ☐ I have not yet gone for a pregnancy test
- ☐ Ultrasound
- ☐ Other _____
- ☐ No response

☐ Yes

*If yes:* Why do you feel that your abortion is complete? *Let participant answer freely, then Select all that apply.*.

- ☐ Counselor told me I was no longer pregnant
- ☐ Pregnancy symptoms went away
- ☐ Doctor/nurse told me I was no longer pregnant
- ☐ I felt the pregnancy come out
- ☐ I saw the gestational sac
- ☐ NEGATIVE pregnancy test at facility, blood
- ☐ NEGATIVE pregnancy test at facility, urine
- ☐ NEGATIVE pregnancy test, home
- ☐ Ultrasound
- ☐ Other _____
- ☐ No response

34. At any point since taking the pills, have you taken a pregnancy test?
    - ☐ No
    - ☐ No response
    - ☐ Yes

    *If yes:* What type?
    - ☐ Blood test in clinic
    - ☐ Urine test in clinic
    - ☐ Pregnancy test at home
    - ☐ I don't know
    - ☐ No response

    *If yes:* What was the result?
    - ☐ Positive (still pregnant)
    - ☐ Negative (not pregnant)
    - ☐ Inconclusive
    - ☐ No response

    *If yes:* How much did you pay for the pregnancy test? _____
35. Since we last spoke, have you had an ultrasound?
    - ☐ Yes

    *If yes:* What was the result of the ultrasound?
    - ☐ Complete abortion
    - ☐ Incomplete abortion
    - ☐ Ongoing pregnancy
    - ☐ Other _____
    - ☐ No response

    *If yes:* What was the date of the ultrasound? ____/____/_____
    *dd mm yyyy*

    *If yes:* How much did you pay for the ultrasound? _____

**FOR THE INTERVIEWER**

**Did the participant report an expulsion (feeling the pregnancy come out) at the 7 day follow-up?**

- ☐ **Yes → Skip to Q17 (Healthcare seeking)**
- ☐ **No → continue to Q16**
- ☐ **No response at 7 day follow-up → continue to Q16**

**What was the date of their 7-day follow-up?** dd/mm/yyyy): ____/____/_____

36. Since we last spoke, did you notice (feel or see) the pregnancy come out/expel?
    - ☐ No
    - ☐ Don't know
    - ☐ No Response
    - ☐ Yes

    *If yes:* At what point in the process did you notice the pregnancy (products of conception) come out?
        - ☐ After the first dose of medication
        - ☐ After the second dose of medication
        - ☐ After the third dose of medication
        - ☐ After the fourth dose of medication
        - ☐ After the fifth dose of medication
        - ☐ After the sixth dose of medication
        - ☐ After the seventh dose of medication
        - ☐ After the eighth dose of medication
        - ☐ I don't remember
        - ☐ No response

    *If yes:* Approximately how many HOURS after your first dose of medication did the pregnancy come out? (hours)_____

**Healthcare Seeking**

37. At any point during or after your abortion process, did you seek care at a health facility?
    - ☐ No → Go to Q18 (Emotions and Preferences)
    - ☐ No response → Go to Q18 (Emotions and Preferences)
    - ☐ Yes

    *If yes:* Why did you seek care at a health facility? *Select all that apply.*
        - ☐ To confirm abortion completion
        - ☐ Concern about bleeding
        - ☐ Concern about pain
        - ☐ Concern about fever
        - ☐ Concern about discharge
        - ☐ Concern about nausea
        - ☐ Concern about diarrhea
        - ☐ For MVA
        - ☐ For D&C
        - ☐ Other _____
        - ☐ No response

    *If yes:* Did the clinicians keep you under observation? (i.e. asked you to stay for some time so they could continue to assess your symptoms, without actively treating you)
        - ☐ Yes
        - ☐ No
        - ☐ I don't know
        - ☐ No response

    *If yes:* Did they give you misoprostol?
        - ☐ Yes
        - ☐ No
        - ☐ I don't know
        - ☐ No response

    *If yes:* Did they give you antibiotics?
        - ☐ Yes
        - ☐ No
        - ☐ I don't know
        - ☐ No response

    *If yes:* Did they give you pain medications?
        - ☐ Yes
        - ☐ No

- ☐ I don't know
- ☐ No response

*If yes: Did they give you other medications (beyond miso, antibiotics, or pain medications)?*

- ☐ Yes (Specify which medications) _____
- ☐ No
- ☐ I don't know
- ☐ No response

*If yes:* Did you have an MVA?

- ☐ Yes
- ☐ No
- ☐ I don't know
- ☐ No response

*If yes:* Did you have a D&C?

- ☐ Yes
- ☐ No
- ☐ I don't know
- ☐ No response

*If yes:* Did they do an ultrasound at the health facility?

- ☐ Yes
- ☐ No
- ☐ I don't know
- ☐ No response

*If yes:* Did they give you IV fluids?

- ☐ Yes
- ☐ No
- ☐ I don't know
- ☐ No response

*If yes:* Did you receive a blood transfusion?

- ☐ Yes
- ☐ No
- ☐ I don't know
- ☐ No response

*If yes:* Did you stay overnight at the health facility?

- ☐ Yes
- ☐ No
- ☐ No response

*If yes:* Did you receive any other type of treatment that we haven't listed?

- ☐ Yes (specify what kind of medical treatment)_____
- ☐ No
- ☐ I don't know
- ☐ No response

*If yes:* What type of facility did you go to?

- ☐ Government/public clinic
- ☐ Private clinic
- ☐ Government/public hospital
- ☐ Private hospital
- ☐ Other _____
- ☐ No response

*If yes:* Did the doctor or nurse know you had taken anything to try to end your pregnancy?

- ☐ Yes, I told them

  *If yes, I told them:* Why did you tell the provider? *Let participant answer freely, Select all that apply.*

  - ☐ They asked me directly if I had done anything
  - ☐ I wanted them to have all of the information
  - ☐ I felt comfortable sharing the information
  - ☐ I knew the provider

- ☐ I trusted the provider
- ☐ I felt that I had to tell the provider
- ☐ Other _____
- ☐ No response

☐ Yes, they suspected/found out
☐ No, I told them I had a miscarriage → see below
☐ No, I didn't tell them anything → see below

*If "No, I told them I had a miscarriage" and "No, I didn't tell them anything" :* Why did you not tell the provider*? Let participant answer freely, Select all that apply.*

- ☐ I was afraid
- ☐ I knew the provider personally
- ☐ There was no medical need to tell them
- ☐ I did not want to be judged
- ☐ Other _____
- ☐ No response

☐ Other_____
☐ No response

**Emotions and Preferences**

38. If abortion care in a health facility was comparable to self-managed abortion with [hotline name] support in terms of safety and cost, AND both were legal, where would you PREFER to have your abortion?
    - ☐ In a health facility
    - ☐ Self-managed at home or place of my choosing (not a clinic) with support from [hotline name]
    - ☐ Self-managed at home or place of my choosing (not a clinic), on my own
    - ☐ Other _____
    - ☐ No response

39. What are the top 3 emotions you feel now about your abortion experience? To be clear, we mean the top 3 emotions you feel about the abortion (not about having an unwanted pregnancy).
    - ☐ Relief
    - ☐ Guilty
    - ☐ Calm
    - ☐ Happy
    - ☐ Satisfied
    - ☐ Anxious
    - ☐ Nervous
    - ☐ Relaxed
    - ☐ Fear
    - ☐ Sadness
    - ☐ Disappointment
    - ☐ Anguish
    - ☐ No emotion
    - ☐ Other _____
    - ☐ No response

**Cost**

40. In preparing for, during, or in the weeks since you ended the pregnancy, did you have to do any of the following as part of the abortion process? *[Select all that apply]*
    - ☐ Take time off of work
    - ☐ Forfeit lost wages for time off of work
    - ☐ arrange childcare

- ☐ find lodging outside of your home
- ☐ borrow money
- ☐ sell something
- ☐ travel more than thirty minutes
- ☐ Other burden:_____-
- ☐ None of the above

41. Reflecting on the whole process, including buying the pills, care received at a health facility, and transportation to/from those places, how much did you spend?

_____

**Disclosure**

42. Did you keep your abortion a secret from someone you wish you could have told?
    - ☐ Yes
    - ☐ No
    - ☐ No Response

43. Did someone find out about your abortion that you did not want to tell?
    - ☐ Yes
    - ☐ No
    - ☐ No Response

**Support**

**44.** If your friend was in this situation, where would you tell her to go?
    - ☐ [hotline name]
    - ☐ Online (women on web, women help women, etc)
    - ☐ Public clinic
    - ☐ Public hospital
    - ☐ Private clinic
    - ☐ Private hospital
    - ☐ Other _____
    - ☐ No response

45. Did you feel you had all the support you needed from [hotline name]?
    - ☐ Yes
    - ☐ No response
    - ☐ No
      *If no:* What else did you need? _____

46. Did you feel you had all the support you needed from other people?
    - ☐ Yes
    - ☐ No response
    - ☐ No
      *If no:* What else did you need? _____

**END OF SURVEY**