Form FHS015: Research Protocol – Section C

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1. Purpose of the Study

This research project aims to increase access and uptake of contraception after abortion through the systematic development and testing of a new telemedicine service for contraceptive counselling (TECC). We will perform a pilot study in South Africa, and multicenter randomized controlled trial in South Africa and Kenya with the following specific aims:

1. To design and test a user-friendly online service for contraceptive counseling informed by systematic research into the preference and experience of women in our study setting.
2. To compare uptake of long-acting reversible contraception (LARC) after TECC and in-person contraceptive counseling.
3. To compare rates of choice, uptake, and continuation of LARC or any contraceptive, satisfaction, preference for counseling, recurrent unintended pregnancy, and recurrent abortion after TECC and in-person contraceptive counseling.

2. Background

Effective contraception is a crucial part of sexual and reproductive health and rights (SRHR), women's empowerment and poverty reduction (1, 2). The periabortion period entails opportunities to provide women with choice and access to modern contraceptives. Long-acting reversible contraception (LARC) methods defined as hormonal intrauterine device (IUD), copper IUD and contraceptive implant, are particularly effective in reducing unintended pregnancies(3). Despite this, unmet need of postabortion contraception and underutilization of LARC remain high globally (4). Most contraception postabortion can be initiated immediately at the time of the abortion (all oral contraception, implant, injection as well as IUD after surgical abortion), whereas a delay of insertion of the IUD is recommended until a medication abortion is complete, a minimum of 1 week and in our study setting health care professionals (HCPs) often recommend 2-6 weeks.

The Covid-19 pandemic has exacerbated global inequity in access to care, particularly for women, and highlighted the potential of remotely provided care and counseling, i.e., telemedicine (5, 6). Telemedicine for abortion can circumvent barriers to access and minimize pressure on facilities, with similar clinical outcomes as in in-person care (7, 8). However, the feasibility, effectiveness, and optimal timing of TECC in the post/periabortion period remains to be investigated(9).

Among South African women, 66% report having had an unintended pregnancy in the past five years. There is low uptake of LARC methods particularly for the IUD which is used by only 3-4% of women using contraceptives in both South Africa and Kenya (10). Barriers to effective contraceptive uptake and use persist and include poor provider attitudes, lack of training in LARC insertion, long waiting hours, little or insufficiently individualized contraceptive counseling, and high rates of discontinuation(11).

Structured contraceptive counseling has been shown to improve uptake of LARC and reduce subsequent rates of unintended pregnancy(12, 13). However, not enough is known about optimal timing and format for postabortion contraceptive counseling in a low-income setting and no telemedicine interventions exist to answer to the unmet need of contraception after abortion.

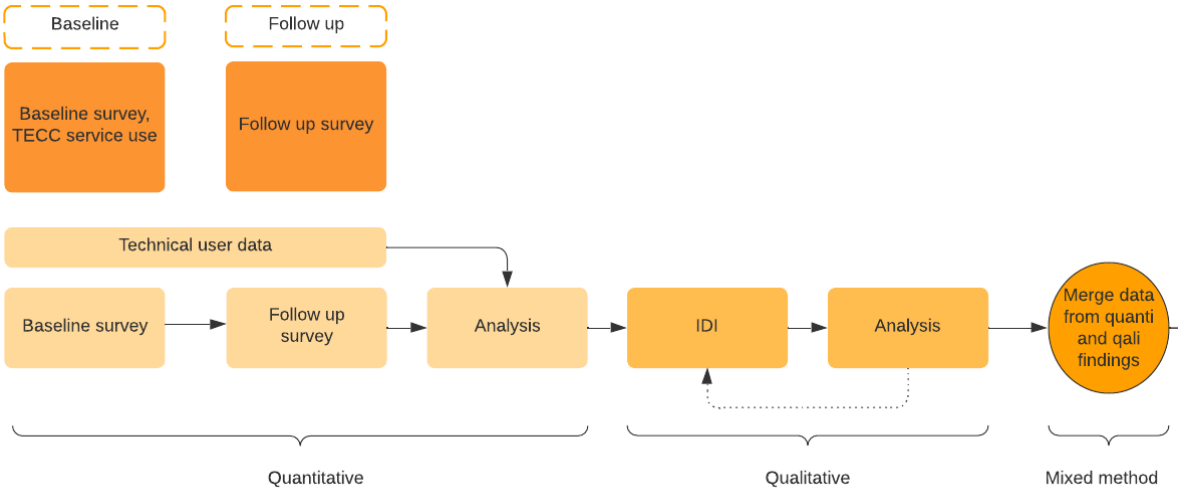
3. Methodology PILOT STUDY

3.1. Study design - Pilot study

We plan to perform a pilot study of a new telemedicine service for contraceptive counselling (TECC) around the time of an abortion The pilot is designed as a mixed method study encompassing quantitative and qualitative methodology. The design and development process is planned as an iterative process based on findings from ongoing studies as well as testing the service with volunteers, harmonizing with the ISO-standard 9241-210:2019 for human-centered design (14). This means that the TECC service will be developed in together with the population it aims to serve, with user representatives involved in the service design and development process.

The development of the TECC service will be underpinned by current evidence about telemedicine and contraceptive counseling. Findings from two ongoing studies will serve as an evidence-based guide for the development. One study is a literature review investigating the effects of telehealth interventions for contraceptive counseling on choice, uptake and continued use of effective contraceptive methods compared to standard care. The other study is our ongoing mixed methods study *Barriers and Facilitators to using telemedicine for contraceptive counseling in South Africa: A multi-methods study, sub-study linked to HREC 671/2019.* The qualitative component of this study investigates the preferences and experiences regarding using telemedicine for medical counseling and specifically contraceptive counseling among a subset of women randomized to telemedicine when participating in our randomized controlled trial about telemedicine for medical abortion in South Africa (HREC 671/2019)(8). In-depth interviews about postabortion contraception and family planning captures data about context-specific user needs and preferences.

Figure 1. Overview of study design – pilot study



Underlying the design of the pilot study is the theoretical framework by Sekhon et al. in 2017, developed to test the acceptability of health care intervention across seven different dimensions; how participants feel about the intervention (affective attitude), how

much effort is required to participate in the intervention (burden), how well the intervention fits with the participants value system (ethicality), how well the intervention is understood (coherence), what benefits must be given up to utilize the intervention (opportunity costs), how likely the intervention is to work (effectiveness), and the participants confidence in being able to use the intervention (self-efficacy) (15). The theoretical framework is shown in Figure 2.

Figure 2. Theoretical framework for assessment of acceptability of healthcare interventions

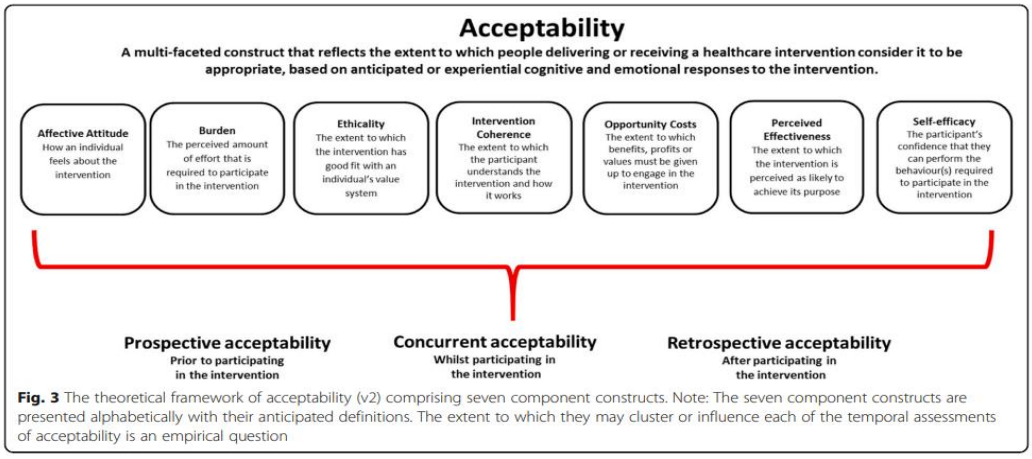


Fig. 3 The theoretical framework of acceptability (v2) comprising seven component constructs. Note: The seven component constructs are presented alphabetically with their anticipated definitions. The extent to which they may cluster or influence each of the temporal assessments of acceptability is an empirical question

During the development phase, a beta version of the service will be tested by female volunteers, sharing their opinion on the TECC service in group discussions. All volunteer participation will be completely anonymous, no personal data on volunteers participating in the development phase will be collected or saved, and participating volunteers will not be considered study participants. Volunteers will be found among participants in our previous study who have spontaneously expressed an interest to take part in the development phase of the service and offered to invite others from their social network to participate, as well as volunteers from the research and development teams' social and professional networks.

3.2. Characteristics of the study population – PILOT STUDY

Participants for this study will be recruited among women seeking abortion at Mitchell´s Plain CHC. The quantitative component will encompass 30 participants. For the qualitative study, a subset of the study population will be selected for in-depth interviews. Preliminary sample size will be 10 participants but will be decided by the number at which saturation is achieved. The population for this study represents a low-income demographic but does not include especially vulnerable populations.

Inclusion criteria:
Women seeking abortion either medical or surgical, ≥ 18 years of age, able to communicate and understand spoken and written English, with private access to a smart phone, and willing to participate in the study.

Exclusion criteria: No smartphone, not willing to participate in follow up, not able to understand spoken or written English.

3.3. Recruitment and enrolment – PILOT STUDY

All women will be informed about the study while waiting to be seen for a consultation at the abortion clinics. Interested women will be screened for eligibility. Eligible women will be recruited to the study after going through a private informed consent procedure with study staff in native or preferred language (English, isiXhosa or Afrikaans).

3.4. Research procedures and data collection methods – PILOT STUDY

Research procedures

The baseline survey and intervention will take place at the clinic on the day of recruitment, while the participants are waiting to be seen for the abortion consultation. The intervention will consist of an online interactive contraceptive counselling (TECC) session on the day of the abortion. Participants will use their phone to connect to the TECC service in which they will be informed and guided to their method of choice based on their reported preferences, reproductive history, and health conditions.

After completion of the counseling session, the participant will receive an online certificate stating that professional contraceptive counseling has been completed and, if no contraindications to use exist, that she's eligible for the method of her choice. If she has a medical condition that requires examination prior to prescription her certificate will indicate that she must see a nurse prior to initiation of her method. Depending on choice, she will then be directed either to the clinic nurse for LARC administration, or to a pharmacy.

Research procedures – description of the intervention

The telemedicine component of our telemedicine contraceptive counseling (TECC) service is yet to be developed. The design and development of the TECC service is planned as an iterative process based on findings from ongoing studies as well as testing the service with volunteers. In this description of the interventions will lay out our preliminary intentions for the design of the TECC service. If the development and design process results in a service which differs significantly from the layout of the design presented in this proposal, we will submit an amendment to HREC.

The service will be designed to be interactive. One central component of our intended design of the TECC service is that the experience will be *tailored*– i.e., individualized to the participant's preferences and medical situation in the sense that her answers to questions provides an individual path through the counseling session in the TECC service. We propose an algorithm where the participant asks and answers questions in a similar way as with in person contraceptive counseling – and based on her answers the consultation results in a few suggestions of methods meeting her preferences and needs.

Examples of questions and domains that will likely form part of the TECC service, guiding the algorithm for each participant's individually tailored path through the service are:

- Questions regarding what is most important for the participant with her family planning method (Effectiveness, ease of use, not to think about it daily, that it is discrete etc.)

- Questions regarding bleeding pattern and preferences (less bleeding, regular bleeding, not a concern)
- Questions regarding pain during periods (would like less, not a concern)
- Questions regarding contraindications for certain methods (migraines with aura, concurrent diseases and medications, family history of deep vein thrombosis, smoking etc.)

We intend the resulting recommendation to provide information about various aspect of the methods, encompassing information about effectiveness, side effects, health benefits, how the method works, how it is used, and what may be expected when using it. We intend to for the user to be able to choose different paths for learning more about each of the recommended methods, go back and change answers in the consultation if she so wishes, ask additional questions about each method, or reach out to a health care professional for further counseling or questions for asynchronous online counseling.

If the participant chooses to reach out to a health care professional at some stage of counseling or follow up – she will primarily have access to asynchronous online counseling with an HPCSA affiliated health care professional through the TECC service. In our previous RCT about telemedicine for medical abortion in South Africa with the same study population, we found that asynchronous online counseling and follow up for medical abortion was safe and acceptable to women in this context. We have primarily planned on the individualized component will take place as an asynchronous online consultation with a health care professional as video calls and voice calls require more data use or airtime, which we know is a concern for participants in this study population. However, we do not rule out that the option of such forms of interactions may also be part of the TECC service.

The service may also include testimonials from users of different methods, sharing their experiences, and/or a section addressing common misconceptions and myths. We want to design the service to make information accessible to participants who learn and take in information in different ways, i.e., using infographics, voice notes, video, and written information, as well as support behavior change.

Ideally, an electronic prescription service would also be integrated in the service. If this is not possible, the consultation will result in a certificate document. The certificate will summarize the medical information provided, indicate the method the used has selected, and certify that the user has been provided professional medical counseling and been deemed eligible for the selected method. With this layout, referrals may be part of the TECC service. The user may then use the certificate to ask to a health care professional at a reference facility for prescription/administration of selected method. During the study period this certificate will be shaped to also be used as a basis for documentation of counseling and form part of medical charts at our study sites.

Inspiration for the TECC service design may be drawn from existing websites, apps and online resources offering information about contraception. Examples of such resources are the *contraceptive tool* on B-wise (a website about sexual and reproductive health owned by the South African National Department of Health) and the *what's right for me?* tool on Contraceptive choices (a website about contraception developed by University College of London) as well as others online resources for contraceptive learning and counseling(16, 17).

Quantitative component

Data collection

Quantitative data will be collected from a baseline survey on recruitment day and a follow-up survey after two weeks, as well as data from the TECC service itself. The baseline survey will record participant demographic variables, reproductive history, prior and current use of contraception and frequency of internet use, as well as measures of anticipated acceptability of the intervention. Information will be captured by participants themselves filling out questionnaires in Redcap after receiving a link to their phones, alternatively by being asked questions by the research assistant (depending on participant preference). At baseline, data for accessing the baseline survey on RedCap and using the TECC service will be provided to participants from the study staff by means of data hotspot/WIFI provided from study staff devices. The baseline survey is expected to take about 10-15 minutes. The follow up survey will capture choice of method after completion of TECC session as well as measures of experienced acceptability of the service in several dimensions, reason for choice of method, preference regarding timing of repeat session and challenges encountered. Data collection from the service will measure rate and time for completion of the TECC consultation session, and any points of contact between baseline and follow up. The reimbursement amount will assist participants to cover costs for data required for the follow up survey and any contact with the TECC service after baseline. The participants also have the choice to participate in follow up surveys by phone interview with study staff.

Primary outcome collected at 2 weeks

Main outcome variable will be a compound variable reflecting the proportion of women who choose a method after completing the TECC intervention and report 1) being satisfied or very satisfied with the service (affective attitude), 2) understanding the content and purpose of the intervention (coherence), 3) feeling confident in their ability to use the service (self-efficacy), experiencing the service as easy to use (burden), assessing service as likely to be of use in the community (effectiveness)

Secondary outcomes collected at 2 weeks

1) Contraceptive method chosen by type (%)
2) Choice of LARC (%), defined as choice of an IUD or a subdermal implant for contraception
3) Change of method with respect to previous use (%)

Subsidiary outcomes collected at 2 weeks

We will record the following subsidiary outcomes: repeat interaction with service, time spent on consultation, negative aspects reported, reason for choice of method, and main categorical challenges encountered.

Qualitative component

Data collection - qualitative component

Data will be collected through semi structured in depth interviews (IDIs), held in person or by phone after the second quantitative data collection point. The sample size is estimated

to be until data saturation or up to 10 interviews. The interview guide for the IDIs will be developed to capture measures of the acceptability of the TECC service according to Sekhon et al.'s framework, i.e. how participants feel about the intervention (affective attitude), how much effort is required to participate in the intervention (burden), how well the intervention fits with the participants value system (ethicality), how well the intervention is understood (coherence), what benefits must be given up to utilize the intervention (opportunity costs), how likely the intervention is to work (perceived effectiveness), and the participants confidence in being able to use the intervention (self-efficacy). Emphasis will be on enhancing the quantitative findings and gaining a more comprehensive understanding of the acceptability of the TECC intervention. Especially aspects of the framework that are more difficult to explore quantitatively, such as ethicality and opportunity costs will be explored. Questions will be open ended, allowing new themes to emerge from the data, and the interview guide may be adapted to accommodate and explore themes emerging in the interviews.

3.5. Data safety and monitoring – PILOT STUDY

The accuracy and reliability of the data collected will be periodically validated during the study. The two research assistants will be trained in how to use the study questionnaires in a standardized way, for when interviews are conducted verbally. The investigators will supervise study procedures at the study sites continuously.

The research assistants have previous experience in screening for eligibility, going through informed consent procedures and capturing information in surveys, or will be provided training with regards to procedures and confidentiality prior to commencement of the study. The study doctors will be responsible for completing medical records at the clinic for participating women.

3.6. Data analysis – PILOT STUDY

3.6.1. Data analysis - Quantitative component

The sample size for the quantitative component of the pilot is a convenience sample that we assess will suffice to allow for an assessment of the acceptability of the intervention, as well as a preliminary assessment of effectiveness, preceding the larger RCT. Quantitative data will be analyzed and summarized descriptively as absolute numbers and rates. Continuous variables will be presented as mean (standard deviation) or median (interquartile range) depending on the distribution of the data. The sample size of the pilot will not allow for group-wise comparisons or multivariate analysis.

3.6.2. Data analysis - Qualitative component

Interviews will be transcribed verbatim and analyzed using thematic analysis. Transcription and analysis will take place while data collection is ongoing, to allow for themes emerging from the data to inform the development of the interview guide. Analysis will be made using NVivo software (QSR International Version 12). Data will be coded and categorized into themes. Two investigators will code and theme the interviews to allow for investigator triangulation. To check against coder variation, transcripts will be cross checked for author's coding accuracy, any discrepancies were resolved by discussion between the investigators.

3.6.3. Data analysis - Mixed methods component

The pilot study will have a mixed methods design using a sequential exploratory design with equal weight. The study design is chosen to enhance the understanding of the acceptability of the TECC intervention by exploring the study participants' experiences, preferences, and considerations regarding choice of contraceptive, as well as to assess the feasibility and areas of improvement for the TECC service. The quantitative findings will inform the qualitative part of the study and the development of the interview guide for in-depth interviews.

The sampling will be nested, meaning that the qualitative study sample will be a subset of the quantitative sample. This sampling method is chosen with the purpose of achieving a qualitative sample that can enhance and explain the quantitative findings. The data will be analyzed separately and then together (method triangulation), to assess convergence, complementarity, and divergence of results, and to assess the relationship between these dimensions.

4. Methodology RCT

4.1. Study design RCT

Following the pilot study, we will perform an RCT comparing TECC with standard care contraceptive counseling. The study design of the RCT will adhere to the CONSORT statement for randomized controlled trials for non-pharmacological interventions (15). In line with the theory surrounding controlled investigation into models of care, we include in our outcomes measures of adherence of participants to interventions, a description of attempts to limit bias because blinding will not be possible, and specifications of the delay between randomization and initiation of the intervention. The trial and trial protocol will be registered at clinicaltrials.org and the Pan-African Clinical Trials Registry (PACTR).

4.2. Characteristics of the study population RCT

Women in South Africa (n=510) and Kenya (n=510) seeking abortion at one of two community health clinics (CHCs), Mitchell´s Plain CHC and Michael Mapongwana CHC in South Africa, and two CHCs in Kilifi and Mombasa (Kenya). The study population represents a low-income demographic but is not considered to include vulnerable populations.

Inclusion criteria:

Women seeking abortion either medical or surgical, ≤13 gestational weeks (GW), ≥ 18 years of age, able to communicate and understand spoken and written English, with private access to a smart phone, and willing to participate in the study.

Exclusion criteria:

No smartphone, not willing to participate in follow up, not fulfilling language criteria

4.3. Recruitment, enrolment, and randomization RCT

Women will be informed about the study either at the abortion clinic (South Africa) or by phone through the collaborating abortion care hotline Reproductive Health Network Kenya (RHNK). All women in the South African arm of the study will be informed about the study while waiting to be seen for a consultation at the abortion clinics on a recruitment day. Interested women will be screened for eligibility. Eligible women will be recruited to the study after going through a private informed consent procedure with study staff.

Participants will be randomly allocated 1:1 to either TECC or in-person contraceptive counseling. The randomization sequence will be computer-generated 1:1 in permuted blocks of varying sizes by a researcher not involved in data collection and imported into the electronic research data capture tool RedCap. A research assistant will perform the randomization, in the presence of the participant on the same day as the intervention, by clicking on a link in the RedCap system which generated the next sequential number according to central allocation. Blinding of either the research assistant or participant to group allocation will not be possible.

4.4. Research procedures and data collection methods RCT

4.4.1. Research procedures and data collection methods <u>RCT – all participants</u>

On the day of recruitment, a baseline survey will record participant demographic variables, socio-economic status, reproductive history, prior and current use of contraception, and frequency of use of the internet. Follow up surveys will be conducted 12 weeks, 6 months, and 12 months. Baseline and follow up surveys will be recorded either by women receiving a link to RedCap and filling out the questionnaires on their phones, or through a telephonic interview with the research assistant, depending on participant preference. At baseline, data for accessing the baseline survey on RedCap and using the TECC service will be provided to participants from the study staff by means of data hotspot/WIFI provided from study staff devices. The reimbursement amount will assist participants to cover costs for data required for the follow up survey and any contact with the TECC service after baseline. The participants also have the choice to participate in follow up surveys by phone interview with study staff. The baseline survey is expected to take about 10-15 minutes. The follow up survey at 12 weeks is expected to take about 20-25 minutes and follow up surveys at 6 months and 12 months are expected to take about 5-10 minutes. The questionnaires will capture primary and secondary outcomes as described below.

<u>Outcomes</u>

Primary outcome at 12 weeks

Uptake of LARC, defined as uptake of an IUD or a subdermal implant for contraception, within 12 weeks

Secondary outcomes at 12 weeks

1. choice of LARC

2. uptake of any contraception
3. choice or uptake of new method with regards to previous use
4. satisfaction with TECC service (using a a multi-question validated scale)
5. Rated use of service for decision making (using a multi-question validated scale)
6. Degree of agency in decision making (using a a multi-question validated scale)
7. preference for counselling

Secondary outcomes at 6 months

1. continued use of LARC
2. continued use of any contraception
3. recurrent unintended pregnancy
4. recurrent abortion

Secondary outcomes at 12 months

1. continued use of LARC
2. continued use of any contraception
3. recurrent unintended pregnancy
4. recurrent abortion
5. Change of method at any timepoint up to 12 months
6. Reason for change of method

Subsidiary outcomes

We will record the following subsidiary outcomes: repeat/recurrent interaction with service, time spent on consultation

Our outcome data will be recorded and extracted as described above at 12 weeks, 6 months, and 12 months. Links for follow-up surveys on RedCap will be sent to the participants phone. Three attempts will be made to contact the participant by phone for each follow up survey in case of missing data. For participants who cannot be reached to complete missing data, clinical records on contraceptive uptake and recurrent pregnancy within 12 months will be retrieved from Cape Town electronic records and records from the clinics affiliated to RHNK in Kenya. All outcome data will be registered in the research data collection tool RedCap hosted at University of Cape Town Redcap@uct.ac.za.

4.4.2. Research procedures and data collection methods RCT – Intervention group

The intervention will consist of online contraceptive counseling - TECC. On the day of the abortion, while waiting for their abortion consultation with the clinic nurse, participants will use their phones to complete a contraceptive counseling session through the TECC service. At baseline, data for using the TECC service will be provided to participants from the study staff by means of data hotspot/WIFI provided from study staff devices. Participants will be informed and guided to their method of choice based on their reported preferences, reproductive history, and health conditions. The TECC will be designed to be interactive, i.e., provide a personalized path through contraceptive counseling the content of which depends on the individual needs and preferences of the participant.

After completing a counseling session, participants in the TECC group will receive an online medical certificate certifying that she has received professional contraceptive counseling and, if no contraindications to use exist, that she's eligible for the method of

her choice. If she has a medical condition that requires examination prior to prescription her certificate will indicate that she must see a nurse prior to initiation of her method. Depending on her choice, she will then be directed with this certificate to the nearest clinic for initiation of the method (intrauterine device, progestin injectable, or progestin implant), or to a pharmacy to pick up her method (progestin-only pill, combined oral contraceptive pill. In Kenya, women will receive home distribution or distribution to a local pick-up point, through our partner organization and distributor of contraceptives Triggerise.org. A question in the TECC chat will allow participants to ask the TECC backoffice (study doctor) to contact them for further support. The chat algorithm will also automaticallt alert the study doctor in case of a severe liver disease or cancer, which would require further attention.

After a period of time (expected to be 8-10 weeks after the abortion and to be determined by an ongoing study and the pilot study leading up to this trial), women will be contacted through the service and offered the opportunity to go through the screening and information session again to confirm, or reconsider, their method of choice. Based on our previous research, we expect many women will leave the abortion clinic with the 3-months progestin injectable as contraceptive method. A second counseling session will allow them to reconsider their method of choice before the next planned injection. The TECC service will send three supportive messages or nudges during the first three months to remind women to initiate their chosen method and offer them support or a renewed counseling session if they are not content with their previous choice of method.

4.4.3. Research procedures and data collection methods <u>RCT – comparison group</u>

The control group will receive in-person contraceptive counselling information and initiation at the clinic where they perform the abortion (South Africa) or a clinic to which they are directed by the abortion care hotline (Kenya). Mode of contraceptive counseling may vary between clinics but the routine procedure at each clinic will be documented in the study. To keep the study as close to clinical practice as possible we will not modify the care received by the control group by standardizing the counseling delivered at the clinics.

4.5. Data safety and monitoring RCT

The accuracy and reliability of the data collected will be periodically validated during the study. The research assistants will be trained in how to use the study questionnaires in a standardized way. The two principal investigators will continuously for the first three months of the study, and then periodically, supervise study procedures at the study sites.

Study staff from the DSBS will also conduct periodic quality controls of the data and ensure that the data are being collected in accordance with both South African and international ethical guidelines. This will include review of:

1. Essential documents file (Initiation letter, CVs, training records, agreements, etc.),
2. All ethics committee approvals and communication,
3. Data collection methods (via observation),

4. Blank data collection and consent materials (for version control),
5. Completed CRFs (to ensure adherence to GCP),
6. All completed consent forms and link logs,
7. Source documents,
8. Storage facilities for data,
9. Study product inventory and storage facilities,
10. Protocol deviations,
11. Adverse and serious adverse events logs and reports, and
12. Any other documents as needed.

A co-investigator and consultant to the trial will act as monitor to the trial and perform periodic assessments of the validity and consistency of data collection.

A data and safety monitoring board (DSMB) will be formed for the study. The DSMB will review adverse outcomes at an interim stage of the study (after 6 months) but will not a priori perform an interim data analysis. This is because we 1) do not expect the intervention to put the participant at increased risk of severe adverse events, and 2) that the intervention would differ from standard care to an extent that would require early closure of the study.

4.6. Data analysis RCT

Continuous data will be presented as median (interquartile range) and dichotomous data as absolute (n) and relative (%) frequencies. Baseline data will be compared group-wise to ascertain successful randomization. Outcome data will be compared group-wise using Chi-square test according to intention to treat (ITT) among all randomized women according to allocation, and per-protocol (PP) according to the intervention women actually received. The risk ratio between groups of our main outcome and 95% confidence interval will be calculated using the STATA csi command.

Based on a previous RCT in the same setting we expect the baseline rate for our main outcome, uptake of LARC after abortion, to be 12%. We hypothesize that the intervention group using TECC will double their uptake of LARC. We also wish to be able to analyze our two study settings independently of each other. To show a doubling of uptake in a study group (effect size or odds ratio 2.0) corresponding to an absolute increase of 12%, with 95% confidence and 90% power we will need to analyze 212 women in each arm. This 95% confidence interval for that risk difference would in that case have a lower margin of 5% increase (corresponding to an OR of 1.5), which in a context of low use is considered clinically significant, i.e., the effect size of the intervention that we consider of clinical importance starts at 5%.

Based on previous studies we estimate that our loss to follow up will be up to 20% at 12 months bringing our sample to 510 women. Accounting for the statistical independency of the South African and Kenyan cohorts we double the sample for a total sample size of 1020 women of which 510 will be recruited in each country. This would give us 80% power and 95% confidence to determine a 12% difference in uptake of LARC in the intervention and control group at 12 weeks.

5. Description of Risks and Benefits

5.1. Potential risks and discomforts

Participants in the pilot study and the intervention arm of the RCT will take part in a new model of contraceptive counseling that will differ from standard practice by taking place through an online service, and not face to face, a model of care which women may be unfamiliar with.

Women may experience online eligibility screening and counseling as less personal and more stressful than a face-to-face consultation. Several studies have however shown that women appreciate the easy access and confidentiality of online services and that many express a preference for online consultations (32, 33) . Several studies support South African women´s ability to use online questionnaires for self-assessment of abortion completion as well as self-assessment of gestational age (23,24).

We hope that the TECC will result in a higher percentage of participants choosing LARC methods, including IUDs. Although this entails great positive effects long term, it requires a second visit for administration, which may in the short term pose an inconvenience for the participant, and a possibly entail a risk for a delay in uptake of contraceptive method.

5.2. Risk classification

We assess that the risks associated with the study intervention (i.e., online consultation for contraceptive counseling) are minimal. It is possible that the intervention is a less effective and acceptable model of care, which would primarily result in a higher rate of discontinuation and/or dissatisfaction with the service in the telemedicine arm compared to the standard care arm. This outcome of the study will be measured by the study, and potential harm to study participants will be minimized in the ways outlined below.

5.3. Minimizing risk

Study procedures have been designed to minimize the risks of the intervention while not impacting on the accurate assessment of the study question.

- The format and content of the online service will be adapted specifically to the women in the study setting. The service will be developed according to the principles of human centered design which means involving end users/representatives of the study population already in the development of the service.
- The service will be tested in a pilot study designed to assess usability and acceptability for our patient group as a part of pre-trial procedures.
- If the participant is unable to complete the online counseling, she will cross over to the other arm of the study and receive standard contraceptive counseling.
- Eligibility screening will be done by the study doctor and the study Co-PI.
- The study doctor will be responsible for completing the medical records for the telemedicine group of patients so that participating clinics will have a physical record of the participants visit.

- Study participants in the TECC arm will have access to an online helpdesk, staffed by the study doctor, as part of the TECC service.
- Participants in the study will be of adult age and have unimpaired ability to understand and read one of the languages in which the intervention is delivered.
- Participants in the study setting will predominantly have low financial means but will have good access to emergency care services.
- Participants will be followed up after during the study period
- Participants will have constant access to study staff by telephone if necessary but will be instructed to contact public health care or the TECC helpdesk primarily.

5.4. Potential benefits

We hope that our results can provide evidence for an acceptable and effective model of contraceptive counseling in the context of abortion, an increase knowledge and uptake of modern and effective contraceptive methods. With more individualized counselling, follow up and support we hope to achieve increased satisfaction with chosen method and decreasing discontinuation of use.

Women in the TM arm will receive their contraceptive consultation online. For the individual women this may have the benefit of increased privacy and autonomy (32, 33). Using the TECC service might offer more in-depth information and knowledge, as well as take into consideration individual concerns that may not always be addressed in a clinic setting. Many women appreciate being part of studies that aim to advance women's health and rights.

On a societal level we hope that our results can provide evidence for a modern, private, and individualized model of contraceptive counseling in settings where access to contraceptive counseling services are in some way restricted. Integrated into existing services, our intervention would increase autonomy, privacy, and individualization in choice of contraceptive methods. If our results enable providers and organizations to recommend telemedicine for contraceptive counselling, this intervention could be used in various settings in health care relating to family planning as well as to strengthen women’s sexual and reproductive rights both in South Africa and in other similar settings. The components of this intervention could also be applied to settings with only basic health infrastructure

This may have several positive long-term effects on women's health in these areas:

1. An increase in use of modern contraceptive methods (LARC) which are effective in reducing unintended pregnancies and repeat abortions

2. Improved satisfaction, knowledge, reproductive agency affecting pregnancy spacing with effects on social and economic empowerment

3. Increased autonomy, awareness and empowerment and a decrease in the experience of stigmatization related to unintended pregnancies and abortions

5.5. Alternatives to participation

The alternative to participation in the study is standard care. Women will be offered information and participation if eligible and will have access to standard contraceptive counseling post abortion should they not wish to participate in the study. Participation is completely voluntary and there will be no pressure to participate and access to standard care will not be delayed because of non-participation in the study.

5.6. Harm: benefit ratio

Unintended pregnancies are common in South Africa. Structured contraceptive counselling and use of modern contraceptive methods are known to reduce the number of unintended pregnancies and repeat abortions, however use of LARC in the South African setting remains low(10, 12). It is therefore important to increase access to structured, individualized contraceptive counseling and choice of modern contraceptive methods. This study offers individualized, private, and up to date contraceptive counselling with repeated sessions, offering women the opportunity to have greater knowledge and empowerment in their choice of contraceptive method post abortion. Risk of harm is considered minimal in this study, and possible benefits include increased knowledge and health literacy, reproductive autonomy, reduced unintended pregnancies and repeat abortions. The TECC intervention will be designed in English and understanding written English will therefore be part of the inclusion and exclusion criteria. This will exclude a minority of women in our study setting, potentially a vulnerable minority in high need of this reproductive service. If the intervention is successful, our plan is to translate the service to local languages in the countries or regions in which the service could be implemented.

6. Informed Consent Process

6.1. The process

The screening and informed consent process (ICP) will take place at the community health center where the woman is presenting for a consultation to have an abortion, before she has her abortion consultation and contraceptive counselling with the clinic nurse. See appendices 5 and 6 for informed consent form drafts. The ICP will take in place in a face-to-face consultation with women individually, in a private space at the clinic and will be held in the preferred language of the participant (English, IsiXhosa Afrikaans or Swahili). If the participant consents to participation she will be given a permanent Study ID. The enrolling research assistant will then collect the participant's contact information, including the participant's telephone number. The research assistant will call the participant´s stated telephone number to ascertain it is a working cell phone. They will also ask for the number of another friend or family member to be used if the participant cannot be reached.

6.2. Comprehension of information and capacity to consent

All eligible participants will have the autonomous capacity to understand and consent to participation in the study. The ICP will be performed by two research assistants who are experienced in performing this role during clinical trials in the field of reproductive health in general, and abortion-related research in particular. Their experience includes assessing participants ability to understand the content of the ICP by asking them to relay back what they have understood from the text. The ICP will be performed in the participant´s native or preferred language. The research assistant will at standardized points in the process pause to ascertain that the participant understands what is being read to her by having her summarize the main content in her own words. The research assistants have previous experience in screening for eligibility, going through informed consent procedures and capturing information in surveys, or will be provided training with regards to procedures and confidentiality prior to commencement of the study.

6.3. Withholding information

No information will be withheld from the participants. There is no blinding of participants. Participants in the intervention group and the standard care group will have the same alternatives with regards to choice of methods.

6.4. Consent and assent form

Informed consent forms will be available in English, isiXhosa, Afrikaans, and Swahili (depending on setting). In our previous randomized controlled trial in South Africa examining telemedicine for early medication abortion compared to standard care in the same study population, out of 900 enrolled participants only a minimal number choose to use translated material (isiXhosa and Afrikaans) for ICF as well as the intervention. Since this is a study in the same population and within the same area, we assume that also for this study there will be a preference towards English as the base language for ICF and intervention. However, the ICF will be available in chosen/preferred language to ascertain full understanding regarding consent to participate in the study. Since we are testing a new innovation, the TECC service will use the language which we based on experience know most women would choose for their language setting, i.e., English. Understanding written English will therefore be part of the inclusion and exclusion criteria.

7. Privacy and Confidentiality

Forms for collection of data about participants will not include names or addresses, only the participant's medical record number and her study ID number. Signed informed consent forms will record participants´ names and signatures only and will be filed separately from other study documents. Likewise, a locator form with the participant's name, study ID, South African ID number, medical record numbers, address, and phone number, will be filed separately from all other study documentation. South African ID numbers will be needed to follow-up on the outcome emergency or unscheduled clinical visits after the medical abortion, in e-records and facility records. All study forms will be kept in a locked cabinet at the research office at DSBS and no one outside of the core research team members will have access to these forms.

Follow up surveys will be recorded either by the participant herself directly onto Redcap, or by telephonic interview with a research assistant if the participant prefers this. All follow-up interviews with participants will take place by telephone during a time when it can be ensured that both interviewer and participant are in a private space to avoid disclosure of private information to anyone outside the core research group. All data will be entered into the Redcap database and will be exported to STATA for analysis.

Study documents will be archived securely in a locked cupboard, accessible to the investigators only, for five years, and then shredded.

All questionnaires completed on paper forms will be stored in a locked cabinet at DSBS under the oversight of the study coordinator and PI. Staff involved in data entry and/or transcription will not have access to any identifying information on the participants or facilities. All electronic data files, including recordings and transcription files, will be password-protected.

We will not advertise the study at the clinics or surrounding communities. We also do not plan to require women to take a copy of the study consent form or other study summary information as many women are averse to taking home documentation which indicates that they have sought an abortion.

8. Reimbursement for Participation

Women recruited to the study will receive compensation for the inconvenience, time loss and any additional cost for data use that the study procedures are expected to incur. Participants will be compensated as follows:

Pilot*:* (1) Informed consent, recruitment, and baseline interview (R150), Follow up interview after 2 weeks (R150), In-depth interview after 2-4 weeks (R150)

RCT*:* (1) Informed consent, recruitment, and baseline interview (R150) (2) Follow up interview after 12 weeks (R150), (3) Follow up interview after 6 months (R75), (4) Follow up interview after 6 months (R75)

9. Emergency Care and Insurance for Research-related Injury

The University of Cape Town carries a no-fault insurance policy to cover injuries incurred in research not sponsored by a pharmaceutical company. This study does not involve the testing of a new pharmaceutical drug, a new drug dosage regimen or method of administration.

10. What Happens at the End of a Study?

The study is taking place in public facilities and as such we will work directly with the staff and management of the facility to build their capacity and obtain their input on the study protocol and implementation. They will also be informed of the study results, and the study team will work with the facility and policy makers to consider how the results may be taken up or implemented. At the time of recruitment, we will inform participants when we anticipate having final results for the study, and we will encourage them to contact us

at the contact numbers on the consent form so they can be informed about the study results if they wish to know them.

We expect that this study will demonstrate that structured telemedicine contraception counseling at the time of and abortion is effective and acceptable for women and has positive long-term effects with regards to uptake of effective contraceptive methods, unintended pregnancies and repeat abortions. If this is the case, we will work towards providing access for women to this new model of contraceptive counseling care, by integrating it into existing services in South Africa and Kenya. We will also proceed to implementation research on a larger scale, expanding the study setting to encompass other areas in South Africa and as well as other countries in Africa.

Following analysis of study results, departmental heads and program leaders at the study institution and provincial Department of Health structures will be invited to a meeting with the research team with a view to initiating policy and program changes that are supported by the study findings. We will ensure timely sharing and publication of results, and the data collected will ultimately be available for public use. Study findings will be made public through scientific meetings and peer-reviewed journals, as well as through a structured dissemination process with facility staff and policy makers. The study findings will be used to inform guidelines for contraceptives in South Africa, Kenya and elsewhere.

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12. Appendix Material

In addition to Sections A, B (synopsis) and C, please attach all appendix material relevant to the protocol service. This includes but is not limited to the following:

Main documents

1. Cover Letter TECC v1 12 September 2022
2. FHS013 Application + Debit Form v1 TECC 12 September 2022
3. FHS014 TECC Synopsis v2 - Section B - 12 September 2022
4. FHS015 TECC Protocol v6 - Section C – 6 December 2022

Appendices

5. Informed Consent Form draft v1 TECC Pilot – English Version - 12 September 2022

6. Informed Consent Form draft v2 English Version TECC RCT 220912
7. Motivation for expedited review v1 12 September 2022
8. Baseline Interview TECC PILOT draft v1 - 12 September 2022
9. Baseline Interview TECC RCT draft v1 - 12 September 2022
10. Follow up Interview draft v1 TECC PILOT 12 September 2022
11. Follow up Interview draft v1 TECC RCT 12 September 2022
12. In-depth interview guide draft TECC PILOT v1 220912
13. Data management plan draft v1 TECC Pilot + RCT 12 September 2022
14. Budget summary v1 - 12 September 2022