Friends/Family in the Abortion Procedure Room (FAIR): Assessing pain level, patient, staff and support person satisfaction with support person in abortion procedure room: A randomized controlled trial

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PROJECT SUMMARY

Having an abortion is a complexly emotional experience for many women. Women with strong social support, from a partner, friend or family member, report better psychological adjustment [1]. During medication abortion, patients reported high satisfaction levels, in part, because of being able to share the experience with another person [2, 3, 4]. During in-clinic abortion, patients report lower levels of anxiety when they have a support person (partner, spouse, friend or family member) in the post-abortion recovery room. Additionally, support persons indicate feeling they can successfully comfort the woman [5]. In the abortion procedure room, doula support has a positive psychological impact on patients and decreases the need for additional clinic support resources [6]. Because doula support in the abortion procedure room and social support in the post-abortion recovery room improves patient experience, it is reasonable to believe that having a support person in the procedure room may also improve patient experience. However, there are no data about the patient, support person, and health care provider's experience and satisfaction with a support person in the abortion procedure room.

This study aims to explore patient, support person, and health care providers' experience and satisfaction with social support in the abortion procedure room. Although some providers do allow a support person in the abortion procedure room, no study has formally examined the effects of this practice.

If this study demonstrates higher patient satisfaction and lower perceptions of pain and anxiety levels in patients who have social support in the in-clinic abortion procedure room, this could change standard procedures in the in-clinic abortion procedure room, allowing for more positive patient experiences.

1. DESCRIPTION OF THE PROJECT

1.1 Rationale and objectives of the study

1.1.1 *Rationale*

Following elective abortions, patients with strong social support report greater psychological adjustment than those without support [1]. In medication abortions, there is a psychological benefit to both men and women in being able to support one another and share the abortion process together [2].

The contraceptive partner often has similar motives and feelings as the female partner and is interested in being involved in the abortion experience [3, 4]. Following in-clinic abortion, patients report lower levels of anxiety when they have a social support person in the post-abortion recovery room, and support persons indicate feeling they can successfully comfort the patient [5].

In out-patient surgery procedures, patients with strong social support have less anxiety, take lower doses of narcotics, and recover more quickly from operations [7]. Doula support has had a similar impact on patient experience in the abortion procedure room, resulting in less need for additional clinic support resources. No studies, however, have examined the impact of social support on the patient and provider experience in the in-clinic abortion procedure room. Due to the significant positive outcomes of having a support person in the post-abortion recovery room, doula support in the abortion procedure room and social support in out-patient surgical procedures, a more in-depth exploration of the patient, support person, and health care provider's experience and satisfaction with social support in the in-clinic abortion procedure room is advantageous to improving the patient's abortion process. Additionally, some patients have chosen a facility that allows a support person in the room over facilities that do not support this practice.

In this study, we propose a randomized, controlled trial permitting a social support person of the patient's choosing to join the patient in the in-clinic abortion procedure room.

1.1.2 *Hypotheses and Objectives*

Hypotheses:

Social support in the abortion procedure room will decrease perceived pain and anxiety levels and increase satisfaction for the patient.

1. Social support in the procedure room influenced the patient's health outcomes in the following areas:
    1. Decreased pain
    2. Decreased anxiety
    3. Increased patient satisfaction
2. The social support person will report that they were able to give effective support to the patient.
3. The physician and the nurse will find the support person effective in supporting the patient.

Null Hypothesis:

1. Social support in the abortion procedure room will not change patient levels of perceived pain, anxiety, or satisfaction.
2. The social support person will report they did not give adequate support.
3. The health care provider and the surgical assistant will not find the support person effective

in supporting the patient.

Objectives

Primary Aims:

- To assess a change in expected pain level from baseline, immediately after the procedure, and again ten minutes after arrival to the recovery room as determined by a 100mm visual analog scale (VAS) for patients with in-room social support during the procedure as compared to those who do not.
- To assess pre- and post-procedure state anxiety levels as determined by the 20-question State-Trait Anxiety Inventory (STAI) for patients with in-room social support as compared to patients without in-room social support.

Secondary Aims:

- To measure acceptability and effectiveness of having social support in the procedure room as reported by the surgical assistant and healthcare providers as determined by a post-procedure questionnaire.
- To evaluate if support was effectively given to the patient as reported by the support person as determined by a post-procedure questionnaire.

1.2 Previous similar studies

Veiga et al. (2011) evaluated the effects of social support in the post-abortion recovery room using a Medical Outcomes Survey (MOS), STAI, and a brief post-procedure questionnaire. The study found benefits to having a support person in the recovery room, with a significantly lower anxiety levels in accompanied patients. Evaluation of nurses′ perspective on accompaniment found that nurses thought the patients may benefit from accompaniment, however, the study also found the nurses had concerns related to noise level, patient privacy, and space [5]. Chor et al. (2015) examined the effects of doula support in the abortion procedure room. The study found that doula support addressed patient psychological needs as those with doula support required less additional clinic supportive resources. Despite the positive psychological impact, doula support did not significantly affect patient pain or satisfaction [6].

As these are the only studies examining support in the abortion clinic, the question regarding the benefit to patients having social support in the abortion procedure room remains unanswered.

This study will also use the STAI and an adapted post-procedure questionnaire in addition to the 100mm VAS.

1.3 Design and methodology

1.3.1 Research design and General Methodological Approach

This study will be designed as a randomized, controlled trial to compare pain and anxiety levels before, during, and after in-clinic abortion in patients with and without a support person in the abortion procedure room. Each procedure day will be randomized into "support person day" ("intervention group") or "non-support person day" ("control group"). This randomization process was chosen as the most effective way to randomize without compromising patient care and study validity. Limitations to the physical space of the health center prevent patient randomization because there is no way to avoid patients knowing which arm of the study they are in: the intervention arm or the control arm.

Randomization will occur at the beginning of each procedure day by a research assistant who will pull from an opaque envelope that contains ten slips of paper, five will be marked with 'A' and the other five marked with 'B'. The half marked 'A' will indicate the procedure day will be assigned as an "intervention" day, and the other half marked 'B' will indicate the day will be assigned as a "control" day. After all ten slips of paper are pulled and ten of the procedure days have been randomized, the research assistant will replace the ten slips of paper and begin the same randomization process until the designated number of participants have been enrolled. The research assistant will initiate enrollment of patients in the study after they have consented for the abortion procedure.

All patients who present at PPSWCF's Tampa Health Center for a dilation and curettage (D&C), whether for elective pregnancy termination or management of early pregnancy complications and who are proficient enough in English to consent and understand the study procedures are eligible for participation and enrollment. Support people will be eligible for participation and enrollment if they are 18 years of age or older, are privately selected by the patient to be their support person, and ~~who~~ are proficient enough in English to consent and understand the study procedures. Support people for minors will be privately selected by the patient in conjunction with their parent/guardian consent.

1.3.2 Sample Size

A total of 400 subjects will be enrolled in this study; 200 participants will enroll in the control arm and 200 will enroll in the intervention arm. Within these two arms, 100 subjects will be "patients" and "support persons." "Patients" are defined as people who will receive an in-clinic abortion on the day of their participation. "Support persons" are the individuals whom the patient chooses to accompany them during the in-clinic abortion procedure. Support persons will only actually accompany patients in the in-clinic procedure room if they are randomized to the

intervention arm of this study. Health care providers will also be invited to participate in this research study—and enrollment numbers will depend upon the amount of unduplicated staff who will perform or assist with the D&C procedure on days when enrollment will occur. "Health care providers" include the physician performing the abortion and nurses assisting the physician within the abortion procedure room.

Prior studies indicate a 20mm difference in VAS is clinically significant and that the common standard deviation for VAS scores is 23 mm [8]. Based on these assumptions, a sample size of 28 with 14 women in each arm will have 90% power to detect at least a 20mm difference between the change in pain score from baseline, to during the procedure, to after the procedure between the two groups, using a Student's t-test evaluated at the 2-sided 0.05 significance level.

We have chosen a larger sample size to also provide a representative sample of our patient population for our secondary aims of patient and support person satisfaction as well as nurse and physician satisfaction. This sample size was calculated based on the total number of in-clinic abortion patients seen in the Tampa Health Center in 2015 with a Confidence Level of 95% and a Confidence interval of 10.

1.3.4 Criteria for the selection of subjects

This study will investigate perceptions of pain, anxiety, and satisfaction in patients with a support person in the abortion procedure room ("intervention group"). Recruitment will take place at PPSWCF's Tampa Health Center.

Inclusion criteria:

Patients:

- Any patient who presents and consents for dilation and curettage
- Patient participants 17 and younger must have a legal guardian provide consent for participation, and the patient must provide assent
- Ability to provide written informed consent in English and comply with all study procedures

Support Persons:

- Any person 18 years and older who the patient selects to accompany as their support person
- Ability to provide written informed consent in English and comply with all study procedures

Health Care Providers:

- Any health center staff attending to the enrolled patient in both intervention and control arms of the study
- Ability to provide written informed consent in English and comply with all study procedures

Exclusion criteria:

- Patients without a support person on-site willing to participate
- Patients or support persons that are unable to provide written informed consent in English and comply with all study procedures.

1.3.5. ***Criteria for discontinuation***

Participation will be discontinued following an eligibility screening for any of the following reasons:

- Unable to receive an abortion at the health center as determined by the physician
- Subject no longer wishes to have an in-clinic abortion procedure
- The support person is perceived by staff as being dangerous or threatening to the safety of staff or patients
- Subject is found to meet exclusion criteria after informed consent has been signed
- The study is discontinued
- Subjects chooses to end participation

1.3.6. Subject recruitment

All patients presenting for an in-clinic abortion at the PPSWCF Tampa Health Center will be approached by research staff and asked if they are interested in participating in the study after they have completed the informed consent for the D&C procedure. They will be given an information sheet describing the study as well as inclusion and exclusion criteria, and will then inform research staff if they are interested in participating. If the patient is interested in participating in the study, their chosen support person will be given an information sheet describing the study, inclusion, and exclusion criteria, and will privately inform research staff if they are interested in serving as a support person. If both parties express interest in participating in the study, they will undergo the informed consent process together in a private setting.

1.3.7 ***Admission Procedure***

Enrollment: See section 1.3.6 for details on recruitment. Enrollment in the study will occur in person.

1.3.8 Procedure:

Eligibility confirmation and consent:

After the potential patient-subject consents to have a D&C abortion procedure and both the patient and support person pass the eligibility screening, the patient and support person will undergo

the process of informed consent together where both subjects will have an opportunity to ask questions. In the cases of minors, a parent/guardian will also be present during this consent process. Both subjects will be reminded that participation is voluntary and that if either one decide not to participate, their decision will not affect the quality of the patient's routine care, however neither will be eligible to participate, as all subjects must enroll in pairs (support person and patient). The research assistant will confirm that participating subjects understand the study and meet the inclusion and exclusion criteria. Informed consent for study participation will be signed before any study-related procedures are performed and a copy of the consent will be offered to the subject. Participation is considered to start when the subject signs the Informed Consent Form.

Study procedures:

1.3.8.1 Patient Procedure and Questionnaires

1) After patients have consented for the D&C procedure and the study, they will complete a paper questionnaire. This questionnaire will contain demographic information and type of sedation chosen. Additionally, subjects will record their baseline level of expected pain prior to the start of the procedure. The subject will also complete the State Trait Anxiety Inventory (STAI) after the informed consent process and before the procedure starts.
2) On randomized intervention days, the patient will be accompanied in the procedure room by a support person.
3) The study physician will enter the room and perform the abortion procedure in the usual manner. The abortion procedure will remain the same on intervention days as on control days. Immediately after the procedure, the patient will complete the second 100mm VAS. Any deviations from this protocol will be recorded.
4) Once the patient is in the post-abortion recovery room, the patient will complete the STAI again, a post-procedure questionnaire, and the final pain level on the 100mm VAS will be recorded at least ten minutes after arrival to the recovery room. After all questionnaires have been completed and returned to research staff, the subject will be given their reimbursement gift card for participation.
5) The patient's complete questionnaires will be manually entered in the Qualtrics data management software which will only be managed by designated research staff. Study documents, including surveys, will be stored in a locked filing cabinet and will be accessed by research personnel only.

1.3.8.2 Support Person Questionnaires

1) After the support person undergoes the informed consent process for the study, they will complete a paper questionnaire containing demographic information.

2) If the support person is in the control arm they will complete and return their paper surveys to the research staff before the patient is discharged, and will be given a gift card for their participation.
3) If the support person is in the intervention arm they will then accompany the patient to the procedure room and will be given the option of sitting or standing near the head of the patient. The support person will return the paper survey to the research staff once completed, and will be given a gift card for their participation.
4) The support person's complete questionnaires will be manually entered in the Qualtrics data management software which will only be managed by designated research staff. Study documents, including surveys, will be stored in a locked filing cabinet and will be accessed by research personnel only.

1.3.8.3 Health Care Staff Questionnaires

1) Before the health care staff participates in the study- they will undergo informed consent and sign a copy of the informed consent form. Health care staff who choose not to participate will be informed that they will not receive any negative consequences for not participating. A copy of the informed consent form will be provided to the health care staff.
2) After each procedure, the physician, ~~and~~ nurse, and other health center staff in the abortion procedure room caring for the patient will complete a post-procedure questionnaire.
3) The complete questionnaires will be manually entered in the Qualtrics data management software which will only be managed by designated research staff. Study documents, including surveys, will be stored in a locked filing cabinet and will be accessed by research personnel only.

A sample of the demographic survey, STAI, VAS, and the post-procedure questionnaires for the patient, support people, and health care staff is attached at the end of this proposal (see section 4).

1.3.9 *Subject Reimbursement*

All participating patients and support people will be eligible to receive a $10 Target gift card after completion of study activities. Subjects who receive a gift card will sign a document acknowledging receipt of their reimbursement, and gift card logs will be stored in a locked research cabinet, as well as within the health center database. Gift card tracking data may be viewed by members of PPSWCF's finance department for tracking and record keeping purposes.

1.3.10. *Data management*

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The PPSWCF Tampa Health Center research personnel, under the direction of the principal investigator, will create and maintain a database on the health center system, as well as in Qualtrics. Qualtrics is web-based software for building and managing online surveys and databases, and provides the ability for statistical data analysis. Collection of questionnaires and VAS data will be done on paper, and will then be directly entered into Qualtrics by research personnel. Access to this database and the paper surveys will be restricted to research staff and study investigators. Informed consent documents, the enrollment log, completed surveys and other study related documents will be maintained in a locked filing cabinet. Monitoring of data will be performed by the principal investigator and research manager to assure that the research personnel adheres to the protocol, that data are entered completely and accurately into the database, that regulatory requirements for conducting clinical research are followed, that facilities are adequate to conduct the trial, and that IRB approval is obtained. Record storage in Qualtrics is maintained for a maximum of one year. Only the research personnel are authorized entry into the research computers in the office. Appropriate firewall and virus scanning software are installed and updated routinely by the affiliate's IT department.

The Chesapeake IRB will be notified of any serious adverse experiences as per the Chesapeake IRB Policy and Procedures Manual Section. If any severe adverse events or complications occur, one of the investigators will notify the IRB within 24 hours and the investigators will meet with the Chair of the IRB to assess if the study can continue.

The principal investigator and the research manager will be responsible for the daily monitoring of subject safety, data collection, recruitment, and confidentiality and will therefore serve as the foundation of the data and safety monitoring plan. Enrollment, outcomes, and adverse events will be reviewed in weekly meetings. The research manager will be responsible for providing summaries of monitoring reports to the Chesapeake IRB at the time of annual review.

1.3.11 ***Data Analysis***

Analysis will be performed using Qualtrics statistical software. Analyses will be performed on all control and experimental group data. The control group is defined as the standard care without presence of support person, whereas the intervention group is all those receiving standard care with the presence of a support person in the procedure room. Demographic, behavioral, and clinical characteristics will be compared between the two arms using frequency tests, Student′s t-test, chi-squared tests, and two-way ANOVA, where appropriate. The change in pain score, as assessed by VAS, from baseline to recovery room will be compared within each group using paired Student′s t-test if the data are normally distributed or Wilcoxon signed-rank test if the data do not follow a Gaussian distribution. Similarly, the difference in the change in VAS scores between the

study arms will be compared using Student′s t- or Mann-Whitney U tests, where appropriate. Questionnaire answers will be compared between both arms of the study using chi-squared statistical analysis. Statistical analysis will be performed by both the Principal Investigator and statistician.

1.3.12 ***Study Limitations***

Potential weaknesses in the internal validity of this study are addressed through the study design of a randomized controlled trial. Through randomization, the two study groups should theoretically have similar subject characteristics. One potential weakness is that blinding cannot occur. Also, patients in the control group may be dissatisfied and more anxious at baseline due to knowing that they may not have their desired support person in the procedure room.

One limitation in this study is the potential variation among different providers during in-clinic abortion; however, all providers will follow the same set standards for the in-clinic abortion procedures. This, combined with the fact that there are only a small number of rotating providers should decrease this potential limitation.

1.3.13 ***Duration of project***

Please refer to the attached timeline.

1.4 Project Management

Sujatha Prabhakaran, MD, MPH is the Principal Investigator for the project. Ashley Sweet, MA, is the research manager who will oversee the recruitment and enrollment on this project. Two research assistants from PPSWCF will assist in data collection and database maintenance. The facilities in this study are staffed by the primary investigator and other PPSWCF physicians.

PPSWCF has appropriate and secure storage space for research documentation. Study documents will be kept at the PPSWCF Tampa Health Center in a locked filing cabinet.

1.5 Links with other projects

This study is not linked with any other ongoing projects.

1.6 Problems Anticipated

One of the greatest concerns regarding this study is provider support. Providers at the Tampa Health Center will be required to permit support persons in the room.

Other potential problems include the potential frustration on the part of patients who may desire to have support person in the room but are not permitted to do so.

1.7 Expected outcomes of the study and dissemination of findings

This study aims to evaluate pain and anxiety levels in patients undergoing in-clinic abortion as well as assess provider and support person satisfaction when support person is in procedure room compared to when support person not in the procedure room. If this study demonstrates that having a support person in the room decreases pain and/or anxiety, this may help to support the inclusion of a support person in the procedure room and improve patient experience. In addition, if providers have a good experience, it may help allay provider concerns about having a support person in the room.

The final results will be presented at a national conference and submitted for publication in a peer-reviewed journal.

2. ETHICAL CONSIDERATIONS

This protocol will be submitted to the Chesapeake Institutional Review Board. The trial will also be approved by Planned Parenthood of Southwest and Central Florida (PPSWCF) and Planned Parenthood Federation of America's Clinical Research Department.

No effective health care will be withheld from study subjects. In clinical practice, support persons are not often allowed in the procedure room. If a patient states that she would prefer a support person in the room, but does not want to participate then she will not be eligible for the study and will then be able to have a support person in the procedure room only at the discretion of the provider.

2.1 Informed decision-making and confidentiality

Potential subjects interested in the study will be educated about the risks, benefits, and alternatives of study participation. All subjects will be encouraged to ask questions and all questions will be answered. The potential subject will be reminded that their participation is voluntary, and not participating in the trial will not alter the medical care that the patient will receive.

3. REFERENCES

[1] Major B, Cozzarelli C, Sciacchitano AM, Cooper ML, Testa M, Mueller PM, Reis HT. Perceived social support, self-efficacy, and adjustment to abortion. *J Pers Soc Psychol* 1990; 59(3): 452-463.

[2] Kero A, Lalos A, Ho¨gberg U, Jacobsson L. The male partner involved in legal abortion. *Hum Reprod* 1990;14:2669–75.

[3] Kero A, Lalos A. Reactions and reflections in men 4 and 12 months post-abortion. *J Psychosom Obstet Gynecol* 2004;25:135–43.

[4] Kero A, Lalos A, Wulff M, Home abortion—experiences of male involvement. *Eur J Contracep Repr* 2010; 15(4): 264-270.
[5] Veiga MB, Lam M, Gemeinhardt C, Houlihan E, Fitzsimmons BP, Hodgson ZG. Social support in post-abortion recovery room: evidence from patients, support persons, and nurses in a Vancouver clinic. *Contraception* 2011; 83(3): 268-273.
[6] Chor J, Hill B, Martins S, Mistretta S, Patel A, Gillian M. Doula support during first-trimester surgical abortion: a randomized controlled tiral. *Am J Obstet Gynecol* 2015; 212(1): 45.e-16.
[7] Krohne HW, Slagen KE. Influence of social support on adaptation to surgery. Health Psychology 2005; 24(1): 101-105.
[8] Jensen MP, Miller L, Fisher LD. Assessment of pain during medical procedures: a comparison of three scales. *Clin J Pain.*1998; 14(4): 343-9.

Last updated: 4/10/2017

4. RESEARCH INSTRUMENTS/QUESTIONNAIRES

4.1 SUBJECT DEMOGRAPHIC QUESTIONNAIRE – INTERVENTION ARM

Please fill in the information below, if applicable:

Age: _____

Gestational age (How many weeks pregnant are you?) _____

Number of children: _____

Number of previous abortions: _____

Religion: _____

Please circle your answers below:

Ethnicity: Hispanic
Non-Hispanic

Race: American Indian or Alaska Native
Asian
Black or African American
Native Hawaiian or other Pacific Islander
White
Two or more races

Marital Status: Single Married Divorced Widowed Separated

Are you using your insurance for the procedure? Yes No

Are you receiving sedation for the procedure? Yes No

What is your relation to the patient/support person? _____

4.1 SUBJECT DEMOGRAPHIC QUESTIONNAIRE – CONTROL ARM

Please fill in the information below, if applicable:

Age: _____

Gestational age (How many weeks pregnant are you?) _____

Number of children: _____

Number of previous abortions: _____

Religion: _____

Please circle your answers below:

Ethnicity: Hispanic
Non-Hispanic

Race: American Indian or Alaska Native
Asian
Black or African American
Native Hawaiian or other Pacific Islander
White
Two or more races

Marital Status: Single Married Divorced Widowed Separated

Are you using your insurance for the procedure? Yes No

Are you receiving sedation for the procedure? Yes No

What is your relation to the patient/support person? _____

4.2 POST-PROCEDURE QUESTIONNAIRE FOR PATIENT - INTERVENTION ARM
Please circle your answers below:

1. I would rate my overall satisfaction with the procedure as:
   Very satisfied

   Somewhat satisfied

   Neutral

   Somewhat dissatisfied

   Very dissatisfied

2. The amount of discomfort I experienced during the procedure was acceptable.
   Definitely yes

   Probably yes

   Neutral

   Probably not

   Definitely not

3. I feel that the amount of support I received from my support person in the procedure room helped decrease my pain.
   Definitely yes

   Probably yes

   Neutral

   Probably not

   Definitely not

4. I feel that I received all the support I needed from my support person in the procedure room.
   Definitely yes

   Probably yes

   Neutral

   Probably not

   Definitely not

5. The presence of my support person in the procedure room made me feel uncomfortable.

Definitely yes

Probably yes

Neutral

Probably not

Definitely not

6. If you were uncomfortable in the procedure room, were you uncomfortable due to any of the following: (Circle all applicable options)

- Facility (ex. too cold, too small, uncomfortable chair, etc)
- Staff (instructions, attentiveness, respect, etc.)
- Beliefs (religious ideology, aversion to medical procedures, etc.)
- Other:_____
- Not applicable

Please provide any additional information:

_____

_____

_____

7. During my procedure with my support person in the room, I felt concerned about the following: (Please circle all that apply)

Privacy

Security

Other: _____

Not applicable

8. If I had to re-live this experience, I would prefer/choose to be accompanied in the procedure room again.

Definitely yes

Probably yes

Neutral

Probably not

Definitely not

9. Do you have any additional comments or concerns about having a support person in the procedure room?

_____

_____

_____

_____

_____

_____

Thank You!

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4.3 POST-PROCEDURE QUESTIONNAIRE FOR PATIENT - CONTROL ARM

Please circle your answers below:

1. I would rate my overall satisfaction with the procedure as:
   Very satisfied

   Somewhat satisfied

   Neutral

   Somewhat dissatisfied

   Very dissatisfied

2. The amount of discomfort I experienced during the procedure was acceptable.
   Definitely yes

   Probably yes

   Neutral

   Probably not

   Definitely not

3. I believe that having a support person in the procedure room would have helped decrease my pain.
   Definitely yes

   Probably yes

   Neutral

   Probably not

   Definitely not

4. If I had to re-live this experience, I would prefer/choose to be accompanied in the procedure room.
   Definitely yes

   Probably yes

   Neutral

   Probably not

   Definitely not

5. Do you have any additional comments or concerns about having a support person in the procedure room?

Thank You!

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4.4 VISUAL ANALOG SCALE (VAS)

For these questions we are going to ask you to make an X on a line. For example, let's say you are asked how much you like Oreo cookies:

How much do you like Oreo cookies? (Make an X on the line)

very — very
little — much

Answer the question by making an "X" on the line according to how much you like or dislike Oreo cookies. If you liked Oreo cookies a lot, then you might make an "X" on the line like so:

If you liked Oreo cookies more than life itself(!), then you might make an "X" on the line like so:

If you hated Oreo cookies, then you might make an "X" like so:

If you thought Oreo cookies were just "OK," then you might make an "X" like so:

The idea is that if you like Oreo cookies, you make an "X" on the line closer to the phrase "very much." The closer you make the "X," the more you are saying you like Oreo cookies. If you don't like Oreo cookies, you make an "X" on the line closer to the phrase "very little." The closer you make the "X," the more you are saying you don't like Oreo cookies.

Please mark an X on the line to indicate your response to the following questions.

1. **How much pain do you <u>think</u> you will have during procedure?**

no worst pain

pain in my life

ACTUAL TIME OF ASSESSMENT __ __:__ __

2. **How much pain you are having <u>now</u> (immediately at the end of the abortion procedure)?**

no worst pain

pain in my life

ACTUAL TIME OF ASSESSMENT __ __:__ __

3. **How much pain you are having <u>now</u> (in the post-abortion recovery room)?**

no worst pain

pain in my life

ACTUAL TIME OF ASSESSMENT __ __:__ __

4.5 POST-PROCEDURE QUESTIONNAIRE FOR SUPPORT PERSON- INTERVENTION

Please circle your answers below:

1) I had a clear understanding of my role as a support person during the procedure.

Definitely yes

Probably yes

Neutral

Probably not

Definitely not

2) I feel I provided effective support to the patient in the procedure room.

Definitely yes

Probably yes

Neutral

Probably not

Definitely not

3) I feel that the patient was comforted by my presence in the room.

Definitely yes

Probably yes

Neutral

Probably not

Definitely not

4) I was comfortable in the procedure room.

Definitely yes

Probably yes

Neutral

Probably not

Definitely not

Don't know/no opinion

5) If you felt uncomfortable in the procedure room, were you uncomfortable due to any of the following: (circle all that apply)

- Facility (ex. too cold, too small, uncomfortable chair, etc)
- Staff (ex. instructions, attentiveness, respect, etc.)
- Beliefs (ex. religious ideology, aversion to medical procedures, etc.)
- Other:_____
- Not applicable

Please provide additional information:

_____

_____

_____

6) Based on my experience today, I would serve as a support person during an abortion procedure again.

Definitely yes

Probably yes

Neutral

Probably not

Definitely not

Don't know/no opinion

10) Do you have any additional comments or concerns about being a support person in the procedure room?

_____

_____

_____

_____

Thank You!

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4.6 POST-PROCEDURE QUESTIONNAIRE FOR SUPPORT PERSON- CONTROL
Please circle your answers below:

1. I had a clear understanding of what my role as a support person would have been during the procedure.

Definitely yes

Probably yes

Neutral

Probably not

Definitely not

2. I feel I would have provided effective support to the patient in the procedure room.

Definitely yes

Probably yes

Neutral

Probably not

Definitely not

3. I feel that the patient would have been comforted by my presence in the room.

Definitely yes

Probably yes

Neutral

Probably not

Definitely not

4. I believe I would be comfortable being in the procedure room during the in-clinic abortion procedure.

Definitely yes

Probably yes

Neutral

Probably not

Definitely not

Don't know/no opinion

5. Do you have any additional comments or concerns about being a support person in the procedure room?

_____

_____

_____

Thank You!

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4.7 POST-PROCEDURE QUESTIONNAIRE FOR HEALTH CARE STAFF - INTERVENTION ARM

Please circle your answers below:

1. The presence of the support person in the procedure room was helpful to me.

   Definitely yes

   Probably yes

   Neutral

   Probably not

   Definitely not

2. The presence of a support person in the procedure room was helpful to the patient.

   Definitely yes

   Probably yes

   Neutral

   Probably not

   Definitely not

3. I felt uncomfortable with the support person's presence in the procedure room.

   Definitely yes

   Probably yes

   Neutral

   Probably not

   Definitely not

4. During the patient's procedure, I felt concerned about the following due to the support person's presence: (Please circle all that apply)

   Privacy; please specify _____

   Security; please specify _____

   Other _____

   Not applicable

Please provide additional information:

_____

_____

_____

5) I felt that I had to provide support to the support person in the procedure room.

Definitely yes
Probably yes
Neutral
Probably not
Definitely not

6) I would like the accompaniment in the procedure room to become a permanent arrangement.

Definitely yes
Probably yes
Neutral
Probably not
Definitely not
Don't know/no opinion

7) MVA:

YES or NO

8) Complications:

YES or NO

9) Do you have any additional comments or concerns about having a support person in the procedure room?

Thank You!

Last updated: 4/10/2017

4.8 POST-PROCEDURE QUESTIONNAIRE FOR HEALTH CARE STAFF - CONTROL ARM

Please circle your answers below:

1. The presence of the support person in the procedure room would have been helpful to me.
   Definitely yes
   Probably yes
   Neutral
   Probably not
   Definitely not
2. The presence of a support person in the procedure room would have been helpful to the patient.
   Definitely yes
   Probably yes
   Neutral
   Probably not
   Definitely not
3. I would have felt uncomfortable with the support person's presence in the procedure room.
   Definitely yes
   Probably yes
   Neutral
   Probably not
   Definitely not
4. During the patient's procedure, I believe I would have concerns in the following areas if the support person was present: (Please circle all that apply)
   Privacy; please specify _____
   Security; please specify _____
   Other _____
   Not applicable
   Please provide additional information:

_____

_____

_____

5. If the patient was accompanied by a support person, I feel like I would have had to provide additional support for the support person.

Definitely yes

Probably yes

Neutral

Probably not

Definitely not

6. I would like the accompaniment in the procedure room to become a permanent arrangement.

Definitely yes

Probably yes

Neutral

Probably not

Definitely not

7. MVA:

YES or NO

8. Complications:

YES or NO

9. Do you have any additional comments or concerns about having a support person in the procedure room?

_____

_____

_____

Thank You!

Last updated: 4/10/2017

5. PROJECT TIMELINE

Project Title: Assessing pain level, patient and staff satisfaction with support person in abortion procedure room: A randomized controlled trial

Time Period: October 2014 – January 2018

Year 1 &2	**Oct - 14**	**Nov - 14**	**Dec - 14**	**May - 16**	**Jun-16**	**Jul-16**	**Aug - 16**	**Sept-16**	**Oct - 16**	**Nov -16**
Protocol development	x			x	x	x	x	x	x	x
Consent material development		x	x	x	x	x	x			
Year 3	**Feb 17**	**May -17**	**Jun -17**	**Jul -17**	**Aug - 17**	**Sep -17**	**Oct -17**	**Nov-17**	**Dec-17**	**Jan-18**
IRB Submission	x									
Staff training		x	x							
Database Development		x	x							
Subject recruitment & Enrollment				x	x	x				
Data collection				x	x	x				
Data analysis						x	x			
Final report and manuscript writing								x	x	x

Last updated: 4/10/2017