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Addressing violence against pregnant women in antenatal care: testing an intervention in South Africa

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Registration date 23/05/2016	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 21/10/2022	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims

There is growing evidence that violence against pregnant women is a major global challenge, impacting 4-35% of pregnant women globally. Intimate partner violence in pregnancy has been associated with many adverse health outcomes for the pregnant woman and her baby, including physical trauma, poor mental health, and the physiological effects of stress from current or past abuse on fetal growth and development. Violence during pregnancy has been associated also with maternal death, fetal loss and miscarriage, as well as infant illness and death. In addition, intimate partner violence has been associated with increased rates of HIV infection and poor HIV-related health behaviors. The maternal, infant, and reproductive health risks of intimate partner violence make it imperative that these issues are addressed during antenatal care. Antenatal care visits provide a window of opportunity to identify women experiencing violence. For women in resource-constrained settings, antenatal care is a key point of contact with the healthcare system. Since antenatal care provides health services throughout the duration of a pregnancy, potential for follow-up is high. Our formative research in antenatal clinics in Johannesburg suggests that pregnant women and health professionals are supportive of addressing violence in antenatal care. The overall goal of this study is to determine the impact of a counseling intervention on pregnant women experiencing violence.

Who can participate?

Women aged 18 or older who are pregnant (less than 33 weeks gestation) and have experienced any act of physical or sexual violence by a partner in the past year

What does the study involve?

Participants are randomly allocated to either the intervention or control group. The intervention group receive a counselling intervention and information on local referrals for addressing violence, and the control group receive only information on local referrals for addressing violence.

The counselling intervention is carried out by trained nurses who conduct brief (about 30 minutes) empowerment counseling session during routine antenatal care visits. Following intensive training, nurses cover a series of topics with women, tailored to their individual

situation: validating the experience and providing positive reinforcement for navigating the situation, discussing options the woman has for support, assisting women to develop safety strategies, understanding warning signs that a renewed phase of violence might be imminent (given cyclical patterns of violence subsiding for a period of time, only to resume again later). Safety is also discussed in relation to abused women's increased vulnerability to HIV, or inability to seek appropriate treatment among HIV-positive women. Recognising that brief counseling may not address all aspects of the women's needs, nurses actively refer clients to existing organisations for additional psychological, legal, social, and health services.

What are the possible benefits and risks of participating?
Benefits of participation include the potential to be asked about violence by a trained nurse (both groups) and the ability to take part in the intervention (intervention group only). The risks include possible emotional distress associated with recounting sensitive issues. Several steps have been taken to ensure that participants in the intervention group receive safe and confidential support. A private room has been established in each of the three antenatal sites. The intervention is called Safe & Sound, a neutral name to allow for introduction of the study without stigmatising participants. Ongoing mentorship of nurses will occur via bi-monthly debriefing. A detailed process evaluation will document the types of referrals offered and the quality of counseling services delivered, as well as any safety or confidentiality concerns.

Where is the study run from?
Wits Reproductive Health & HIV Institute (South Africa)

When is the study starting and how long is it expected to run for?
March 2014 to September 2016

Who is funding the study?
Flemish Government

Who is the main contact?
1. Claudia Garcia-Moreno
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Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
A65780; DOH-27-0414-4720

Study information

Scientific Title
Addressing violence against pregnant women in antenatal care: testing an intervention in South Africa

Acronym
Safe & Sound Trial

Study objectives
The primary objective of the trial is to determine whether a brief nurse-led counselling intervention in pregnancy is effective in reducing the recurrence of intimate partner violence and the frequency and severity of this violence. The secondary objective of the trial is to determine whether the intervention is effective in improving safety, mental health, and health-seeking behaviour of abused pregnant and postpartum women.

Two substudies are conducted alongside the parent trial. The first substudy objective is to assess whether, at baseline, women experiencing intimate partner violence differ from women who do not experience intimate partner violence in regard to mental health, self-efficacy and HIV risk behaviour (as a nested cross-sectional sub-study). The second substudy objective is to assess whether HIV-positive women who have experienced intimate partner violence differ from HIV-positive women who have not experienced intimate partner violence with regard to PMTCT uptake and adherence as measured at follow up (as part of a nested longitudinal observational study).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of the Witwatersrand Human Research Ethics Committee, 30/11/2012, M121179
2. World Health Organization Ethics Research Committee, 11/11/2013, RPC471

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Past 12-months intimate partner violence, defined as self-reported incidence one or more times of any physical or sexual act of partner abuse

Interventions
This interventional, randomized control trial will be conducted in four antenatal care settings within the public health system in Johannesburg, South Africa. Approximately n=1680 women attending routine antenatal services will be invited to take part in the baseline questionnaire by a trained Safe & Sound nurse. Those women screening positive for physical and/or sexual violence in the past 12 months, and who satisfy the eligibility criteria, will be randomized to the intervention or control group. Randomization is implemented through blocked randomization concealed in specially-developed trial envelopes. Every woman will be screened for eligibility and will be asked to participate in the randomized controlled trial. The informed consent form will be discussed with each woman and her questions addressed. Since the same nurse researcher will be administering the informed consent forms, the questionnaires, and the intervention, the participants will be able to discuss any concerns at any point during this process.

Women who are at least 18 years old and who are receiving antenatal care will be read the informed consent form. Then they will be screened for eligibility. Women who are at immediate risk for lethal violence by a partner, women whose children are at risk of lethal violence from the partner, or women who are suicidal will be considered ineligible for the study and will be immediately referred for specialized services. Immediate risk is defined as potentially occurring within the next 24 hours following the study visit. Women’s exposure to violence will be

assessed using a standardized instrument adapted for this study. Those screening positive for violence by a partner in the past year will be randomized to the intervention or control group. The intervention group will receive a counselling intervention and information on local referrals for addressing violence, and the control group will receive only information on local referrals for addressing violence by the health provider. Existing referral options include referrals for mental health counselling, shelters and services for women experiencing violence, as well as legal resources, child protective services, police, and other relevant NGOs.

The intervention, provided by a nurse researcher trained in counselling and empathetic listening, will cover a combination of the following elements that will be individually tailored depending on women's experience and her readiness to contemplate change:

1. Evaluating danger: the nurse will help the woman assess her level of risk in her relationship with the violent partner and whether there are signs that the violence will escalate with potential health consequences for her and her pregnancy. If the woman or her children are in immediate danger for their life or if the woman reveals suicidal ideation, she will not be part of the study and will be referred appropriately as discussed previously (see below for more detail).
2. Discussing options: based on the woman's current risk and the support available to her, the nurse will discuss options for reducing abuse, without providing directives or value judgements. The nurse will recognize that women cannot always safely leave their abusive partners but that they have options for reducing abuse in their relationship. These options include protecting children from violence, developing safety strategies, accessing community resources for social support, and addressing relationship dynamics with partners.
3. Developing safety strategies: the nurse will help the woman to develop a safety strategy tailored to her situation and based on culturally appropriate actions for increasing personal safety of herself and her children. These strategies include developing a code with family and friends to indicate increased risk, alerting neighbours to the situation and seeking support from them in the case of an abusive incident, having a bag and documents ready in case of the need to flee with children in the event of imminent danger. Safety will also be discussed in relation to abused women's increased vulnerability to HIV or inability to seek appropriate treatment among HIV-positive women, especially PMTCT. The nurse researcher will help the woman identify those behaviours and strategies that she can best implement.
4. Cyclical nature of partner violence: the nurse researcher will discuss how abusive relationships often follow predictable patterns in which abuse might subside for a period of time, only to resume again later. She will also discuss possible warning signs that could indicate that a renewed phase of violence might be imminent. By better understanding these patterns, the woman should be better prepared to prevent subsequent violence and to predict signs of increased danger.
5. Available resources: based on the findings of the formative research, the woman will be given a list of organizations or social services available locally that can provide help with the psychological, legal, social, or health-related needs resulting from violence. Again, these agencies have been sensitized to the study and have demonstrated capacity to serve as referrals.

The intervention will address each of these areas as well as other topics relevant to the woman's protection and the prevention of subsequent violence. The intervention will be offered to each participant two times, at two separate antenatal care visits where feasible.

Intervention Type
Behavioural

Primary outcome measure

Intimate partner violence (measured by the World Health Organization Multi-country Study Instrument, a 12-item self-reported tool that has been validated in multiple country settings [1]) at baseline (antenatal clinic visit) and follow-up (4-20 weeks postpartum)

1. Garcia-Moreno, C., et al., Prevalence of intimate partner violence: findings from the WHO multi-country study on women's health and domestic violence. Lancet, 2006. 368(9543): p. 1260-9.

Secondary outcome measures
Measured at baseline (antenatal clinic visit) and follow-up (4-20 weeks postpartum):
1. Mental health: Depression will be measured at baseline and follow-up. Continuous variable representing depressive symptomology, derived by summing seven items from the Hospital Anxiety and Depression Scale (HADS), a 14-item measure for assessing mental health in primary health care settings [2] that has been used in South Africa [3]. Probable depression will be defined by a cut-off of 8+ on HADS-D.
2. Mental health: Anxiety will be measured at baseline and follow-up. Continuous variable representing anxiety symptomology, derived by summing seven items from the Hospital Anxiety and Depression Scale (HADS). Probable anxiety will be defined by a cut-off of 8+ on HADS-A.
3. Self-efficacy will be measured using the Generalized Self-Efficacy Scale at baseline and follow-up. This instrument is used to assess women's perceived self-efficacy and has been shown to be a valid measure of women's coping and problem-solving when faced with stressful life events [4].

2. Zigmond, A.S. and R. Snaith, The hospital anxiety and depression scale. Acta Psychiatrica Scandinavica, 1983. 67(6): p. 361-370.
3. Abratt, R. and G. Viljoen, Assessment of quality of life by clinicians--experience of a practical method in lung cancer patients. S Afr Med J, 1995. 85(9): p. 896-8.
4. Schwarzer, R. and M. Jerusalem, Causal and control beliefs: Generalized self-efficacy scale, in Measures in health psychology: A user’s portfolio., J. Weinman, S. Wright, and M. Johnston, Editors. 1995, NFER-NELSON: Windsor, UK. p. 35-37.

Overall study start date
01/03/2014

Completion date
29/07/2016

Eligibility

Key inclusion criteria
1. Age of 18 years or older
2. Less than 33 weeks gestation
3. Ability to communicate in English, Tswana, Sotho or Zulu
4. No positive response to any of the following exclusion criteria based on lethal risk:
4.1. At immediate risk of lethal violence by a partner
4.2. Child at immediate risk of lethal violence by her partner
4.3. Suicidal risk (as determined by having ideation with a plan to commit suicide)

Furthermore, participation in the RCT is dependent on IPV status. Only women who have a positive response that they have experienced any act of physical or sexual violence by a partner

in the past year on either the screening instrument or the extended WHO instrument will be eligible for randomization. IPV-negative women can participate in the sub-studies but not in the RCT.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
500

Key exclusion criteria
Pregnant women who do not agree to be screened, enrolled and randomised, are less than 18 years of age, or who screen positive for immediate safety risk will be ineligible. These women will be recorded in a study log along with date, reason for exclusion, and nurse researcher notes on the case.

Date of first enrolment
01/03/2014

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
South Africa

Study participating centre
Wits Reproductive Health & HIV Institute
22 Esselen Street
Hillbrow
Johannesburg
South Africa
2192

Sponsor information

Organisation
World Health Organization (Switzerland)

Sponsor details
20 Ave Appia
Geneva
Switzerland
27-1211

Sponsor type
Research organisation

Website
http://www.who.int/reproductivehealth/about_us/en/

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Government

Funder Name
Flemish Government

Results and Publications

Publication and dissemination plan
Protocol paper: 2016
Baseline papers (3): 2017
Primary trial paper: 2017
Substudy papers (2): 2017
Secondary trial papers: 2018

Intention to publish date
01/12/2017

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/11/2016		Yes	No