

Safe and Sound: a randomized-controlled trial of a VAW intervention in antenatal care

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Twitter [@HRPresearch](#)



Study Team Acknowledgements

WHO/HRP

- ❑ Claudia García-Moreno
- ❑ Christina Pallitto
- ❑ Sihem Landoulsi
- ❑ Armando Seuc

LSHTM

- ❑ Heidi Stöeckl
- ❑ Manuela Colombini

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Participants

WRHI

- ❑ Nataly Woollett
- ❑ Abigail Hatcher
- ❑ Marcia Mokgatle
- ❑ Thesla Palanee
- ❑ Research nurses: Charlotte Checha, Shirley Mphahlele, Zanele Mlambo, Lele van Eck, Moleboheng Makoatle

Formative research only:

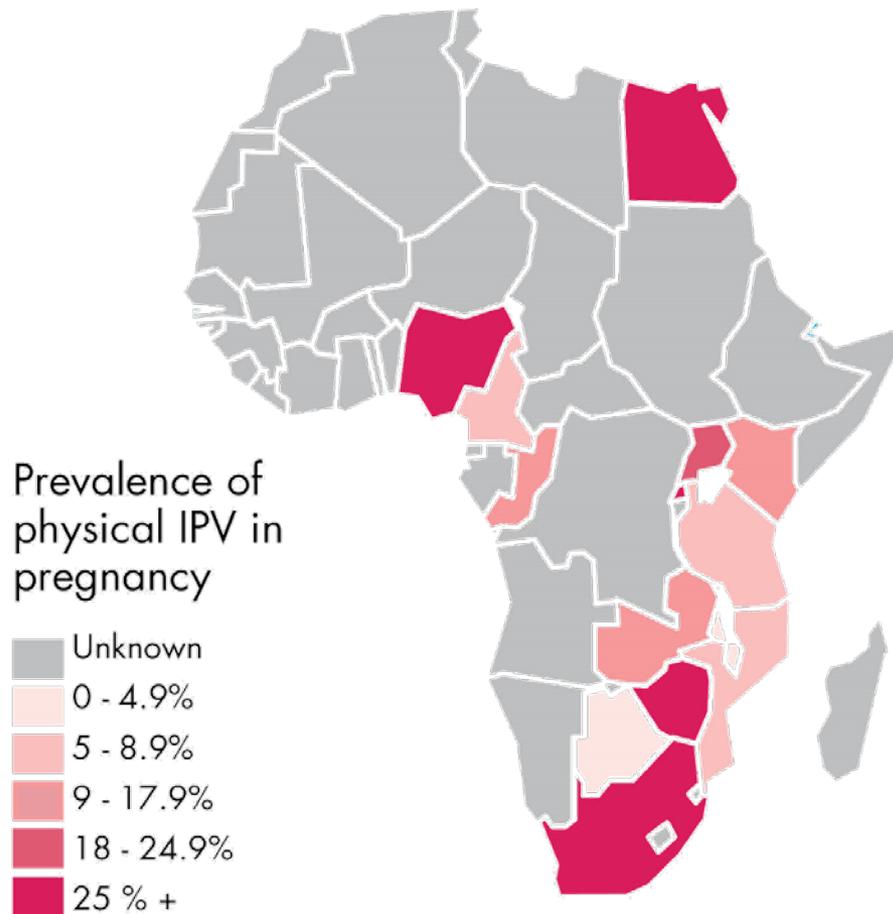
- ❑ Catherine McPhail



GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA



IPV in South Africa is more common than most conditions routinely screened for in pregnancy



South Africa:



Sources: 1. Shamu S (2011) PLoS One; 2. Devries KM (2010) Repro Health. 3. Groves AK (2012) J Inter Violence. 4. Hoque ME (2009) SA J of Epi. 5. Mbokota M (2003) SA Med J

Safe and Sound: testing feasibility and efficacy of a 2-session counselling intervention in ANC

Phase 1 randomized controlled trial

- Implemented by HRP with WRHI
- Recruited 423 pregnant women with IPV
- 4 public antenatal clinics, Johannesburg
- Follow up at 6 week post-partum



In addition to the RCT, study included:

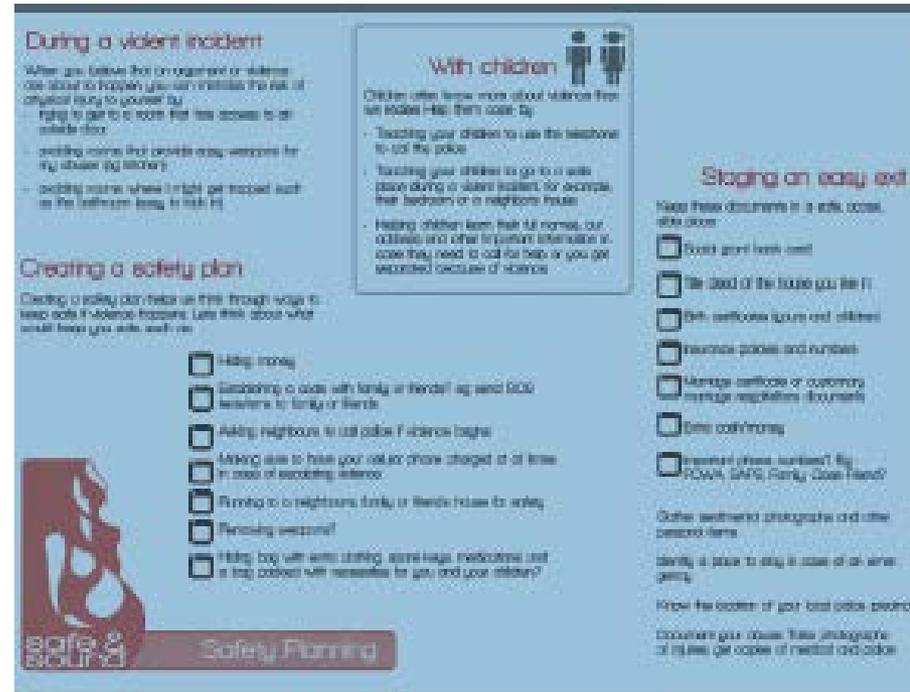
- Formative research:
 - Interviews with patients, providers, MoH and clinic managers (36)
- Process evaluation:
 - Interviews with study participants (20), providers
 - Monitoring of study implementation,



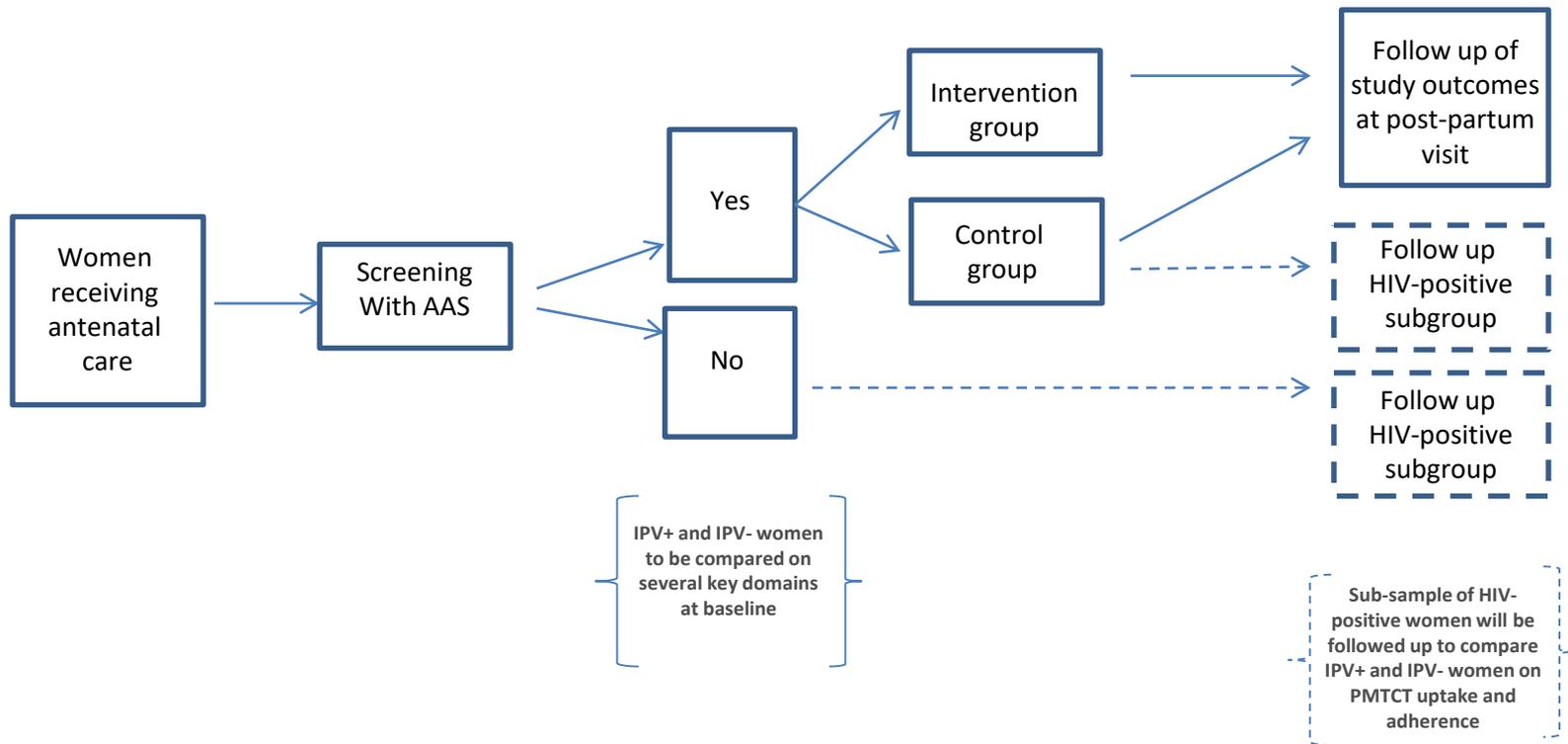
Study objectives

To determine whether a counselling intervention was effective in :

- ❑ reducing the recurrence, frequency and severity of physical/sexual intimate partner violence at follow-up (primary outcome).
- ❑ Secondary outcomes:
 - improving women’s mental health and self-efficacy;
 - increasing safety behaviours;
 - accessing community resources; and
 - improving health seeking behaviour of pregnant women experiencing abuse.



Study design





Formative research and training of nurses

Abigail M Hatcher, PhD



Gaps and what we need to learn

- ❑ In South Africa, IPV is rarely addressed adequately in the health sector.³
- ❑ South African nurses express resistance to intervening in IPV, due to emotional burdens of listening to stories of abuse as well as lack of proper training and support.⁴
- ❑ To conduct effective IPV work in health settings, it is crucial to understand how to ensure the skill and well-being of those implementing interventions.

3. Jewkes R. (2002) BMJ

11 4. Joyner K & Mash R. (2012) PLoS One
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Laying the groundwork: Formative research on IPV in Johannesburg

Participant Group	Size	Method
Policy makers	(n=10)	Semi-structured interviews
Health care providers	(n=8)	
NGOs	(n=6)	
Community leaders	(n=4)	
Pregnant women seeking ANC	(n=13)	Focus group discussions
Pregnant abused women	(n=5)	Semi-structured interviews

Antenatal care (ANC) health workers see IPV but are uncertain how best to respond

Probe insensitively

Insist the woman “just leave”

Offer little concrete help

- ❑ *When they speak, you know that there is some violence going on there but there is nothing you can do. And they become teary and things like that, but you never know [what to do]. –Health worker 3*

Avoid the issue

- ❑ *Most of the time, where it's very sensitive, we try to avoid it though we can see it. – Health worker 8*

Receptivity is tempered by health worker concerns

“Women might deny it”

Asking will open “can of worms”

Fear for
personal
safety

- ❑ *If we don't know how to counsel properly, maybe we will be giving suggestions to this woman, then the partner will end up coming to the clinic looking for you.*

Discomfort
in probing

- ❑ *It is very uncomfortable because now you are probing in their personal lives and people are not really open.*

ANC could be a ‘window of opportunity’ for intervention

Healthy baby is priority

Pregnancy is
time of
reflection

- ❑ *This [pregnancy] is certainly a time when women are grappling with, reflecting, thinking about their relationships. –Policy maker 5*
- ❑ *If they’re located where the woman is receiving other services already, and they can do that secretly and confidentially, that would go a long way. We would be assisting people immensely. – Policy maker 9*

Woman is
already at
clinic

Pregnant women want to be asked – in the right way

Improves infant health

Addresses a difficult issue

Kindness is
key

- ❑ *If you are friendly people are able to be honest and speak to you about their problems...If a person is warm like the way you talk to me right now they will find a way to talk about their problems. –Pregnant woman, FGD 2*

Safety is key

- ❑ *What I know you must say is, “What's happening to your life is important for your safety and the safety of your child.” That's the only thing. –Pregnant woman, FGD 3*

The Safe & Sound intervention:



- Based off previous work in U.S. and Hong Kong
- Brief IPV screening at ANC first booking
- Empowerment counseling (~30 min)
- Active referrals by trained Nurses
- Control group receives “enhanced standard of care” – referral list

TENSION BUILDS

- Man may begin to get angry, agitated
- Woman is anxious and fearful that violence may begin
- Woman tries to keep man calm
- Woman behaves cautiously



CALM PHASE

- Man may apologize, promise to change
- Man may buy gifts, behaves lovingly
- Woman is least likely to leave during this time
- Woman may forgive man and believes that he will change



CONFLICT EPISODE

- Man loses control, blames woman for provoking him
- Man may deny or minimize abuse
- Woman may be very frightened or emotionally numb
- Woman may flee and decide to leave



Cycle of Violence

Adapted from Lenore Walker, *The Battered Woman*,
New York: Harper and Row, 1979

- ❑ Team: Nurses with no prior experience in IPV
- ❑ 40-Hour Manualised Training
 - IPV Knowledge & Beliefs
 - Mental Health
 - Pregnancy & HIV
 - Rights-based Skills
 - Counseling Skills
 - Referral Skills
 - Self-Care Skills



Ongoing Training methods

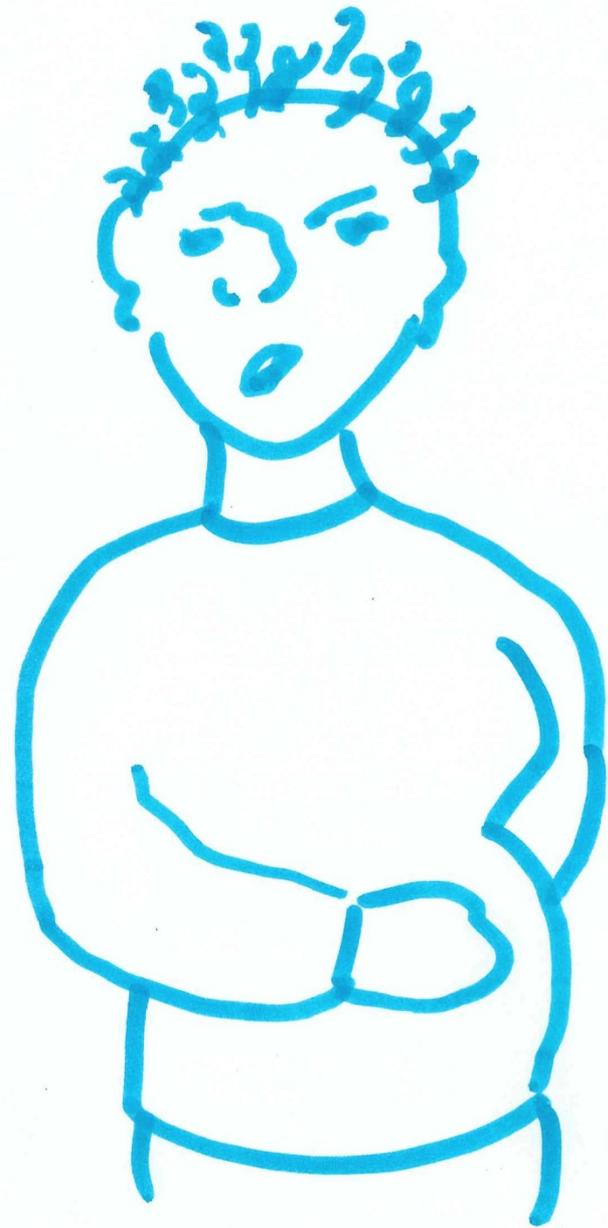
- ❑ Mentorship
 - Original intervention designer (Dr. McFarlane) led one-week mentoring
 - Psychologist with clinical experience led ongoing mentorship (Ms. Woollett)
- One-on-one supervision
 - Option to obtain bimonthly psychological/social worker supervision
 - Key for preventing vicarious trauma
- ❑ Supervision & Debriefing
 - Weekly; Led by Co-PIs
 - Safe space for sharing concerns, dilemmas
 - Case studies of challenging clients
 - Continual training opportunities for arising issues

✓ -
past 12 mo.



ANC
never tested
before





25

(kidnap)
(threats)
with
knife

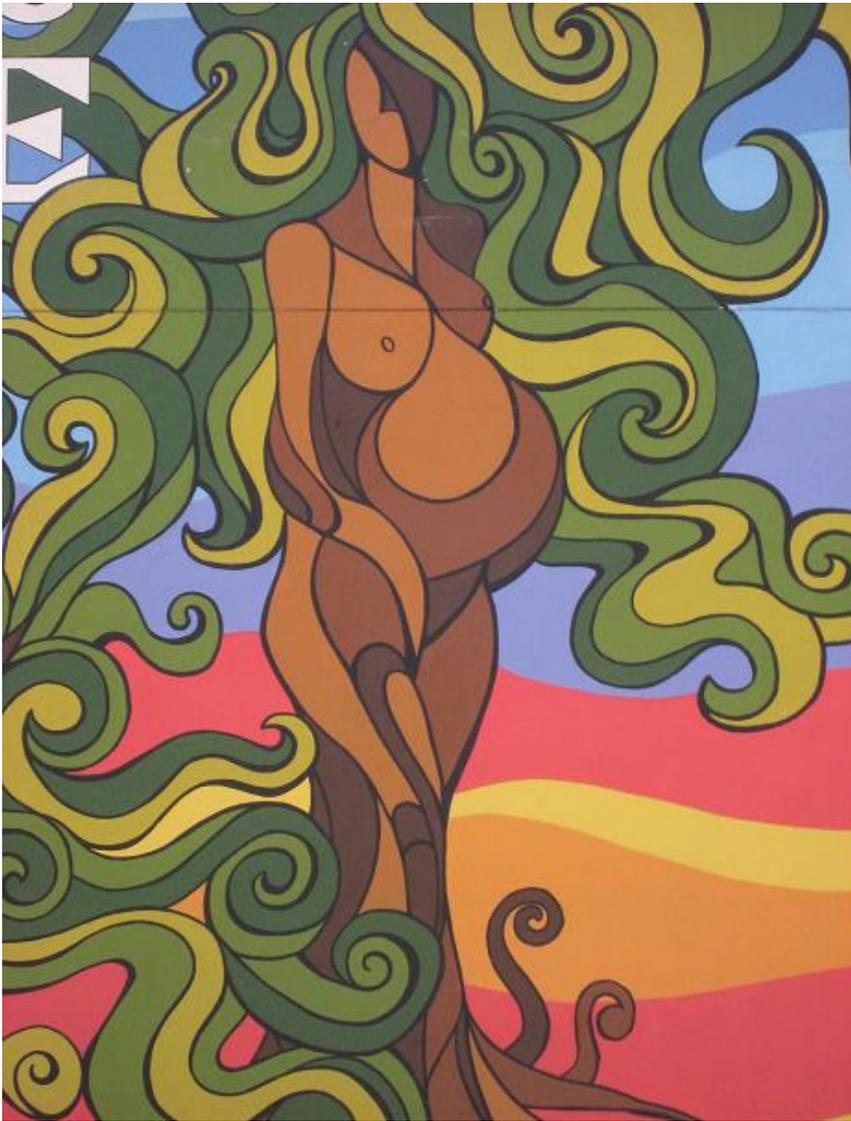
protection
order

(Emotional)



Conclusions

- ❑ Health workers in this setting are receptive to learning about IPV but have important concerns around anxiety, discomfort, and safety.
- ❑ Safe & Sound may address such concerns by training and supporting nurses in concrete ways.
- ❑ Co-worker support and regular de-briefing meetings gave IPV-trained nurses the space to work through their anxiety and share difficult cases.
- ❑ IPV-trained nurses seemed to internalize that, for abused women, the act of ‘telling their story and feeling understood’ is therapeutic.



Safe + Sound: socio-demographic characteristics and mental health status of baseline sample

Nataly Woollett
SVRI Conference Brazil
September 2017



University of the Witwatersrand
WITS RHI



World Health Organization



Background

- ❑ The South African Stress and Health Study (SASH) concluded 12 month prevalence of any disorder was 16.5%. Nearly 75% of the sample had experienced a traumatic event, with most (55.6%) experiencing multiple traumas. Multiple exposure leads to greater distress (Williams et al, 2007).
- ❑ Rates of maternal depression, anxiety and PTSD range from 3-50% in LMICs (Baron et al, 2016; Biaggi et al, 2016).
- ❑ In South Africa, maternal depression has been found in 39% women (Hartley et al, 2011), and maternal anxiety in 23% (van Heyningen et al, 2017).

Setting



Hillbrow



South Rand



Rosettenville

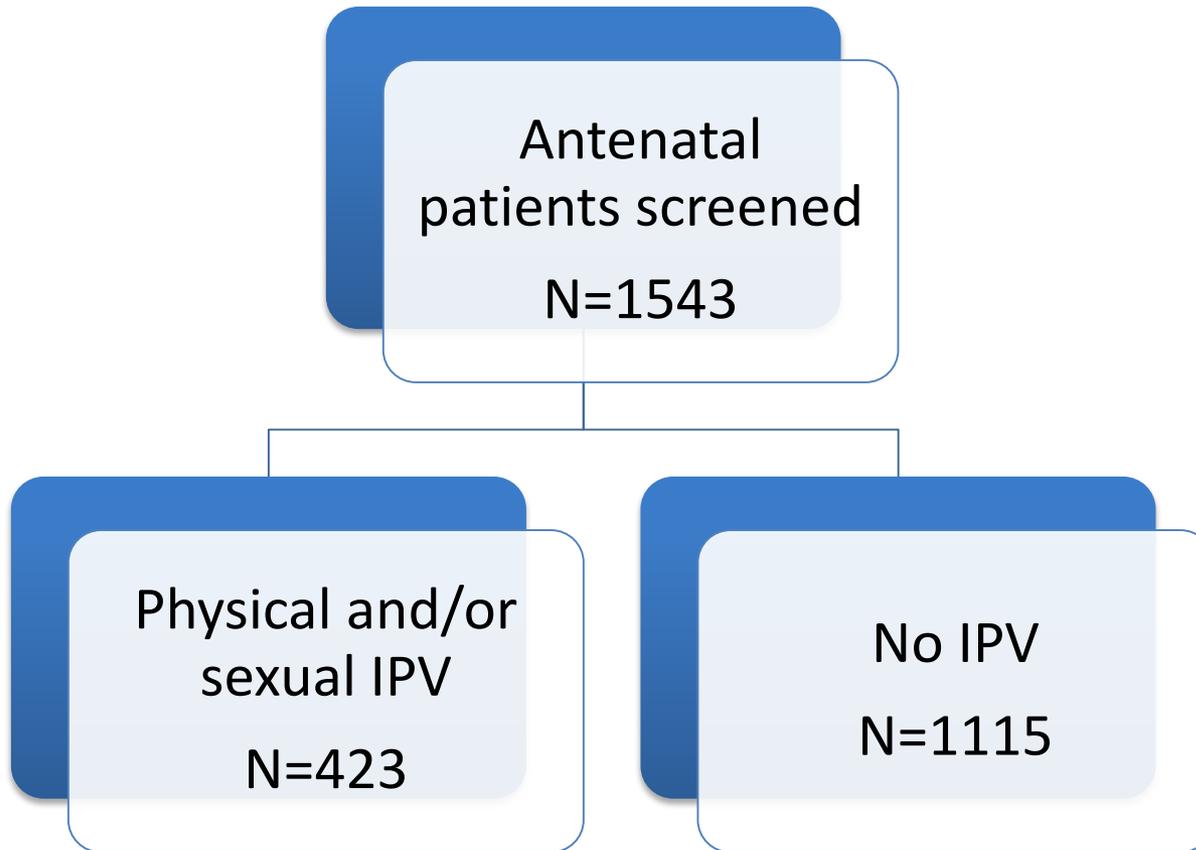


Yeoville

Eligibility

- over 18 years of age
- are pregnant at baseline
- do not exhibit an immediate safety risk (suicidality or fearing for the safety of one's children)
- Physical or sexual IPV in the previous 12 months

Baseline sample



Sociodemographic characteristics

98% Black



71% living in single room



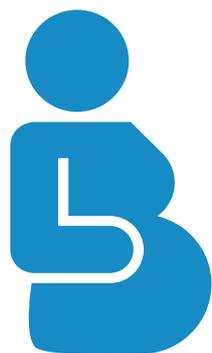
61% born outside of South Africa

Average stay in Johannesburg 7 years

47%

75%

Pregnancy related characteristics



24 weeks
at first ANC
visit

HIV
positivity
rate

34%

96%

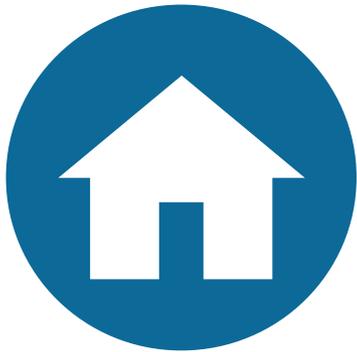
On ARVs in this pregnancy

67%

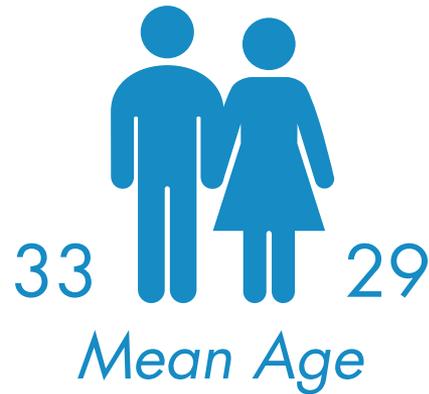
Have other
children

27% had not
disclosed HIV
status to partner

Relationship characteristics

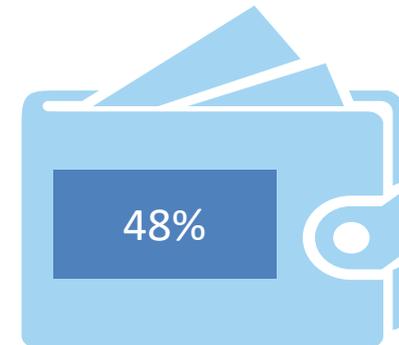
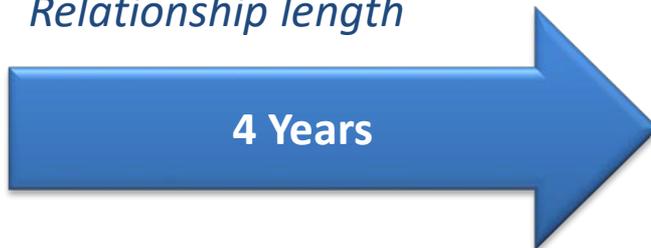


62% live
with their
partner



Recent IPV
27%

Relationship length



*Financially dependent
on partner*

Harvard trauma questionnaire (HTQ)

- ❑ The questionnaire rates levels of exposure to trauma as well as traumatization (PTSD)
- ❑ Questions on exposure include:
 - I have been beaten up
 - Someone has threatened to stab or shoot me
 - When I was young, grownups in my house used to hit each other
- ❑ Questions on symptom experience include:
 - Recurrent nightmares
 - Difficulty concentrating
 - Feeling jumpy, easily startled
 - Avoid activities that remind you of traumatic event

HTQ outcomes

	IPV negative		IPV positive		
	N	%	N	%	
Mean number traumas					P<0.001
Up to 2.06	1028	92.2	275	64.6	
>2.06	87	7.8	151	35.4	
Total	1115	100	426	100	

Perhaps as is to be expected 35% of IPV positive participants experience multiple traumas

HTQ outcomes

	IPV negative		IPV positive		
	N	%	N	%	
PTSD					P<0.001
Up to 28	993	89.1	228	53.5	
>28	122	10.9	198	46.5	
Total	1115	100	426	100	

47% of IPV positive participants met the clinical cut off for PTSD compared to 11% of IPV negative participants

Results – adjusted multilevel regression

	IPV negative		IPV positive		Difference (positive-negative)	95%CI for difference	p
	Mean	SE	Mean	SE			
Anxiety	4,393	0,728	6,846	0,742	2,452	1.952-2.954	<0.001
Depression	5,625	0,855	8,516	0,871	2,890	2.322-3.458	<0.001
PTSD	22,890	0,419	27,737	0,485	4,847	3.870-5.824	<0.001

Controlling for age, food insecurity, education, country born, with partner, earn income, first pregnancy, IPV status

- Significant differences between IPV groups on adjusted mean scores
- IPV positive participants have higher levels of combined anxiety and depression, anxiety, depression and PTSD

Results – adjusted MLR results for OR of IPV (positive vs. negative)

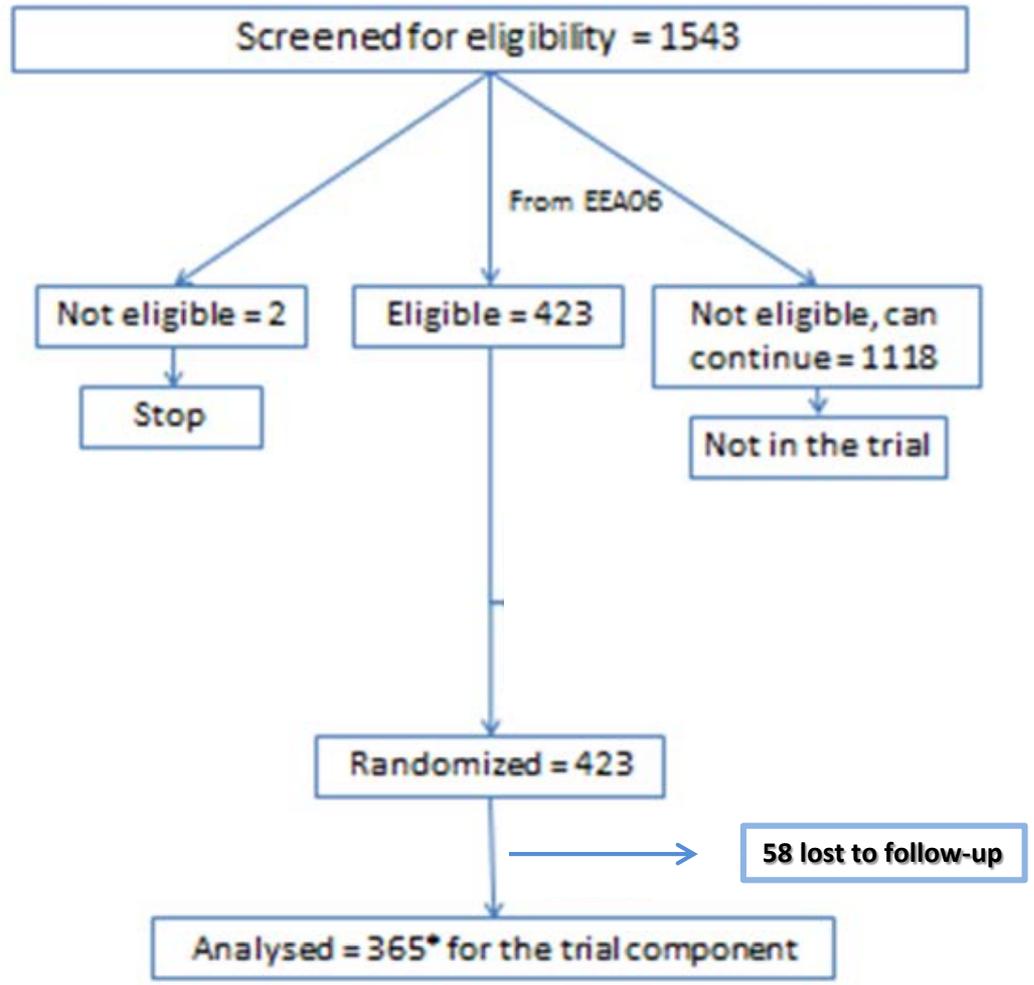
	OR	95% CI	
Anxiety and depression	2,89	2,17	3,83
Anxiety	2,78	2,08	3,72
Depression	2,78	2,1	3,69
PTSD	2,95	2,2	3,97

- IPV positive participants showed almost 3 times greater odds of experiencing anxiety or depression compared to their IPV negative counterparts.
- IPV positive participants showed 3 times greater odds of experiencing PTSD compared with IPV negative participants.

Conclusion

- ❑ Pregnant women experiencing physical or sexual IPV show significantly greater mental health problems at baseline
- ❑ IPV highly related to poor mental health outcomes, indicating that pregnant women who experience IPV are at heightened vulnerability; including poverty and HIV.
- ❑ The healthcare setting offers a window of opportunity in accessing pregnant women and intervening to address IPV as well as mental health.

Trial Findings



* : Subject 1008 is not included in some per-protocol analysis because she is negative in all acts of violence at ADM; protocol violation

Sample characteristics: IPV prevalence at baseline

- 27% prevalence of physical and/or sexual IPV in the past 12 months
 - 13.8% sexual violence in past 12 months
 - 22.9% physical violence in past 12 months
 - 13.8% 'severe' physical IPV
- Emotional IPV
 - 39.9% have any emotional IPV in past 12 months
 - 22.8% have more than one form in past 12 months
- 61.1% more than 1 controlling behaviour

Primary outcome: IPV prevalence (unadjusted)

Physical and/or sexual IPV at follow-up

	Control		Intervention	
	N	%	N	%
no	113	62.8%	139	75.1%
yes	67	37.2%	46	24.9%
Total	180	100.0%	185	100.0%
p=0.015				

Physical IPV at follow-up

	Control		Intervention	
	N	%	N	%
no	136	75.6%	155	83.8%
yes	44	24.4%	30	16.2%
Total	180	100.0%	185	100.0%
p=0.068				

Sexual IPV at follow-up

	Control		Intervention	
	N	%	N	%
no	139	77.2%	162	87.6%
yes	41	22.8%	23	12.4%
Total	180	100.0%	185	100.0%
p=0.014				



Primary outcomes: Multi-level logistic regression analyses

Physical and/or sexual IPV at follow up

AOR = 0.52

95% CI = (0.32 – 0.83)

P = 0.006

Physical IPV at follow up

AOR = 0.58

95% CI = (0.34– .98)

P = 0.042

Sexual IPV at follow up

AOR = 0.43

95% CI = (0.24 – 0.78)

P = 0.005

All models control for age, immigration status (born out of SA), education level, whether first pregnancy or not, earns own money, poverty status (hunger index). Site as random effect.

Mental health: anxiety and depression

Anxiety

	Control				Intervention			
	N	Avg	SD	p	N	Avg	SD	p
Baseline	177	7.8757	3.9652	<0.001	183	7.7377	4.3129	<0.001
Follow-up	177	5.5367	3.4592		183	4.8852	3.7141	
Difference	177	-2.3389	4.7968		183	-2.8524	4.5386	

p=.297

Depression

	Control				Intervention			
	N	Avg	SD	p	N	Avg	SD	p
Baseline	175	9.4971	4.2506	<.001	178	9.2247	4.569	<.001
Follow-up	175	7.7657	4.2692		178	6.6742	4.6414	
Difference	175	-1.7314	5.4753		178	-2.5505	4.9586	

p=0.141

Safety behaviours

	Control				Intervention			
	N	Avg	SD	p	N	Avg	SD	p
Baseline	165	6.7818	1.3438	0.518	171	6.7602	1.286	0.027
Follow-up	165	6.8545	1.3536		171	7	0.994	
Difference	165	0.0727	1.4422		171	0.2398	1.4083	

P=0.284



Conclusions

- ❑ Counselling intervention reduced physical/sexual violence at follow up
- ❑ Anxiety and depression reduced in both intervention and control group and more in the intervention group but no statistically significant difference between groups
- ❑ Self-efficacy improved but no difference between groups
- ❑ Safety behaviours went up marginally

Process evaluation

Manuela Colombini, LSHTM



Methodology of the process evaluation

- ❑ Mixed-method evaluation
- ❑ Process evaluation research questions centred around intervention fidelity, acceptability, and mechanisms:
 - *how* the intervention was delivered;
 - *how* key stakeholders felt about its delivery;
 - mechanisms of intervention influencing participant behaviour.

Qualitative component:

- 33 semi-structured interviews:
 - ❑ 20 purposively selected participants who received the intervention
 - ❑ 5 research nurses offering the intervention
 - ❑ 8 interviews with clinical teams in study sites (not participating in the study)
- Observation notes from regular bi-weekly debriefings
- Chart review, review of study documents

Thematic analysis using Nvivo 10

Acceptability of the intervention

Women reported:

- ❑ a positive experience with the study
- ❑ the intervention was very helpful, for themselves and for the baby.

Participants appreciated:

- ✓ having an opportunity to talk about their experience (and relief),
- ✓ receiving help/guidance with actions to improve their situation
- ✓ learning about existing resources for support and to seek help (self-efficacy)
- ✓ wished for other pregnant women to get the intervention

*"I found it [intervention] **helpful** in many ways. Just like I've said, **letting my emotions out. That's how I found it helpful.** [...] Talking to someone was helpful. And I didn't realize that this [IPV] was hurting me so much until I talked to a sister there". [pp 6]*

*"This Safe & Sound thing really helps a lot. **The way I got so much help, I wish for some other mothers that they could get the help that I got from it. It really helped me. It really changed me for the person that I am today. Think that this could be beneficial to other women. And should be offered to other women as well**". [pp 12]*

Factors that helped women make use of the intervention

- ❑ **Nurses' interpersonal skills:** empathetic listening, non judgemental, kindness, caring, comforting, encouraging
- ❑ **Trust** built by nurses during the first session

"I felt like I've got someone who I can talk to if I've got a problem, like a bigger problem that I can't talk to my sister, my aunt or someone else. I felt like I got a friend in [name of nurse]. I can talk to her. She won't tell anyone, she won't publish my problem. She can't laugh at me. She can't discuss it with someone. That was very important to me." [pp 16]
- ❑ **Feeling of autonomy** to make independent choices on their relationships

"She said if that is my option, then I must do it. Because she can't force me to do anything that I don't want. It's always my decision what I want to do, then she can help from there." [pp 17]
- ❑ **High respect for nurses** and thus patients followed their advice

"It is very supportive [talking to the nurse] because you can share the way you feel with someone [else]. It can support you and give you some plan. It tells you to do things [with your life]". [pp 1]



Factors that helped the nurses provide the interventions effectively

- Participatory training
- Time and continuous practice (crucial for intervention internalisation and improving confidence)
- On-the-job support and mentoring through regular debriefings (support system)
- Safe place to vent frustrations to relieve emotional burden

- *“I was not going to be able to apply the intervention “To be honest, it was not easy at first, because like I said, the violence was shocking, so at first, it was not easy, but I think when you learn and practice, it’s different, so what we learned, when we put it into practice, I think it needed time. [...] Theory on its own is not effective. Theory needs to be practiced and practice is not just once off, it is continuous, so the more we practiced intervention, the more experienced we became”.*
[Nurse 01]

Challenges that affected intervention delivery

- ❑ **Lack of blind randomisation** – emotional burden of not offering intervention to control women
- ❑ **Lengthy sessions:** it takes time when women are ‘shy’
- ❑ **Keeping fidelity** to the intervention when trying to adapt to each personal story, especially in extreme cases where women did not want to leave their abusive partner (still has to offer safety promotion)

*“I: How did you feel not giving the intervention to the control women?
R: **Terrible**, especially at first you look at the situation and you feel this is a naïve young woman that needed someone to hold her hand, because you are giving her the referral slip, **you are not even sure they might be able to use that referral slip** and you are not sure that they actually know where the referrals are, **because we just give them the slips.**” [Nurse 01]*

Challenges that affected intervention delivery [cont.]

‘When they actually cling on you it’s difficult, because they’re not supposed to be clinging on you. They’re supposed to go out and do what you tell them, but they actually cling on you. They prefer you than the counsellors.[...] It’s exhausting because, we used to answer calls even on weekends.[...] Instead of going for counselling, they ask you the questions that are supposed to be asked to the counsellors’ [Nurse 01].

“Some of the people are not brave enough to keep on going. They may take that advice [from the nurse] but in the next coming days they may go back into that situation”. [pp 3]

- Nurses’ **burnout** (when only source of support)
- **Content:** uncomfortable topics (HIV status, forced sex)
- **Contextual:** poor quality and accessibility of referral services
- ❖ **No follow-up support:** to sustain change after follow up visit

Pathways to change: IPV awareness and self-efficacy

➤ **Enhanced coping mechanism in decisions on relationship**

"Yes for now, I am just looking what he is going to do. When he gets violent, I know that I am going to take action, because it is too much for me " [pp 04]

➤ **Impact on help seeking behaviour and raised awareness on support services**

- acquired awareness of referral services, though only a few accessed them
- not afraid of seeking help around IPV (police)
- Increased informal support through disclosure to friends and family

➤ ***"opening their eyes"*: aware of early signs of abuse and social norms condoning violence**

"It was very helpful to be in the study to talk to the nurse [...] and I know that I don't have to accept violence by my partner, and that if it does happen, that I can get help". [pp2]

➤ **Trickle effect onto community:** shared learned knowledge on IPV and referral services with other women from the community

Perceived support and emotional well being

- ❑ **Emotional relief** – through disclosure, discussions with nurses (stress relief), family-type bond – even when IPV still occurring
- ❑ Acquired **greater self-esteem**
- ❑ **Calmer** with partner and children
- ❑ Financial independence and **hope**: *“She [nurse] gave me hope that things will get better, that maybe one day I will get a job”* [pp1]

*“Before I was slim. I was **too stressed** because of that thing [violence]. Now I feel better. I am fine. I accepted that things can happen. It’s not the end of the world”. [pp1]*

*“Because they [nurses] changed my life like really **they changed my life**. My life was in hell before, yes. I was always, you know I was always crying and didn’t know who to talk to. So after I met them I **feel like I have got my sisters I have got my mothers, I have got my everything**”.* [pp 20]

IPV decrease and relationship

- ❑ Minor IPV stopped when baby was born (for cases of unsupportive partner or partner who left during pregnancy)
 - ❑ Learned how to 'handle interactions' to reduce abuse (control)
 - ❑ Improved couple communication
 - ❑ Although IPV reduced, for a minority of women it was still a worrying issue
 - ❑ No IPV reduction where IPV was the result of a partner's drinking problem (severe)
 - ❑ Even when little change, women hoped for a change
- ❑ **Financial dependence** was still a cause of tension for some:
*"It [my relationship] has improved, but **since I'm not working, the tension is still there**, because you cannot force someone to buy you something that you want. If he says I cannot afford it, even though you see that he has the money, you cannot force him [...] Even if he abuses you verbally, emotionally or if he beats you, **there is nowhere to go, you are just forced to stay in that situation**, because you want something from that person". [pp3]*



Lessons learned

- ❑ Separate intervention provision, from data collection and randomization
- ❑ Time consuming to recruit sufficient sample size (envision longer recruitment period)
- ❑ Challenges in follow up with highly transient population (nurses got 5 phone numbers at baseline)
- ❑ Importance of doing formative research to identify challenges, adapt intervention, engage stakeholders
- ❑ Process evaluation important for: subsequent scale up, for framing success or failure of study, understanding for whom and why it works
- ❑ Understanding pathways, e.g. building self-efficacy , improving mental health as a means to IPV reduction as an intermediary outcome

Conclusion

- ❑ All women and study nurses found intervention was **acceptable** and should be offered to others
- ❑ Intervention is **feasible** though various facilitators (including training, interpersonal skills etc.)
- ❑ While potentially feasible, a **few concerns** should be highlighted:
 - ❖ **Time consuming** in a busy ANC setting (though shorter without research component)
 - ❖ Study indicates **need for dedicated staff**
 - ❖ Proper **training** important and support (study related manual)
 - ❖ Importance of identifying /building **referrals**
- ❑ **ANC confirmed as important entry point** for reaching women and following them up.
- **Involving policy makers** at the outset of the study opened the door for providing a health system response to VAW