# A randomized controlled trial of motivational interviewing to prevent risk for an alcohol-exposed pregnancy in the Western Cape, South Africa

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## ABSTRACT

Aim To test the effectiveness of motivational interviewing (MI) to reduce the risk of an alcohol exposed pregnancy (AEP) in a high-risk population.

Design Randomized controlled trial.

Setting Rural population in the Western Cape, South Africa.

Participants A total of 165 women aged 18-44 years at risk of AEP.

Intervention Five-session MI intervention.

**Measurements** Structured questionnaires were administered pre-intervention and at 3 and 12 months follow-up. The primary outcome measure was AEP at 12 months. Secondary outcomes were AEP at 3 months, and alcohol use and effective contraception at 3 and 12 months.

**Findings** There was a significant difference in the decline in the proportion of women at risk for an AEP in the MI group at 3 months (50 versus 24.59%; P = 0.004), maintained at 12 months (50.82 versus 28.12%; P = 0.009). In an intention-to-treat analysis these differences were also significant (32.93 versus 18.07%; P = 0.029; and 37.80 versus 21.69%; P = 0.024, respectively). The odds ratio for no longer being at risk of an AEP (MI versus control) at 12 months was 2.64 [95% confidence interval (CI): 1.18–5.94]. In the intention-to-treat analysis this ratio was 2.19 (95% CI: 1.05–4.65).

**Conclusions** A five-session motivational interviewing intervention was found to be effective with women at risk of an alcohol-exposed pregnancy, and could be implemented as part of routine primary care clinic services in similar populations. The message of 'no alcohol in pregnancy' should be adapted to include better family planning and early recognition of pregnancy.

Keywords Alcohol, family planning, motivational interviewing, pregnancy, South Africa.

A multi-level FAS prevention programme was implemented over a 4-year period in a rural (Western Cape) and an urban (Gauteng) site in South Africa. One sub-study aimed to test the efficacy of a motivational interviewing intervention to reduce the likelihood of an AEP in high-risk childbearing-age women. This paper focuses on results for the rural Western Cape site only.

The intervention used in this study was based on motivational interviewing (MI), an approach found to be effective for health-related behaviour change in many contexts internationally [13]. MI is a client-centred, directive counselling method that guides individuals to explore and resolve ambivalence about changing health-related behaviour [14]. The MI approach entails adhering to four key principles: empathy through reflective listening, rolling with resistance, developing discrepancies between goals and behaviour and supporting self-efficacy [15]. In a randomized controlled trial in the United States by Project Changing High-risk Alcohol Use and Improving Contraception Effectiveness Study (CHOICES) (2002–05), non-pregnant women at high risk for AEP were allocated randomly to receive either MI or information only. Across the follow-up period, significantly more women in the MI group were at reduced risk for an AEP than the control group [odds ratio (OR) 1.90, confidence interval (CI): 1.36–2.66 at 9 months] [5]. Our study is modelled on the Project CHOICES methodology but with simplified data collection tools.

## **METHODS**

#### **Study design**

A randomized controlled trial was conducted in 2007–08 to determine the impact of the MI intervention on the risk of an AEP at 3 and 12 months follow-up (primary outcome measure) and on risky drinking and ineffective contraception use (secondary outcomes) in non-pregnant high-risk women at 3 and 12 months. A third arm included a group-based life-skills training intervention; however, this paper reports on the results from the MI intervention compared to controls only, as the logistics of carrying out the life-skills intervention proved too difficult.

## **Study setting**

The study was conducted within the Bergrivier Municipality, a rural area located in the Western Cape province of South Africa with a population of about 45 000 [16]. The local economy is predominantly commercial agriculture, and most women who work in this sector live on the farms or in small towns. Wages are typically very low and living conditions generally poor. The now abolished *dop* system, which involved part-payment of farm workers with low-grade wine, facilitated an ongoing culture of excessive alcohol consumption among this region's communities [17]. High alcohol use by rural women in this area, when coupled with low contraceptive use, indicates that risk for an AEP among women in the study area is high [7,18,19].

#### Sample size

Sample size estimates were based on an anticipated reduction in prevalence of risk for AEP from 100% at baseline to 70% in the intervention groups and a reduction to 90% in controls, with a power of 0.80. Initially, sample size calculations anticipated a minimum of 30 subjects in each arm. However, because of relatively easy recruitment and recognition that greater study power would be needed to detect an effect size of the order of an OR of 2, recruitment continued until there were 196 subjects randomized between the three groups.

## Randomization

Women who qualified were allocated randomly to the MI, life-skills or control group. A system of sealed envelopes to indicate random group allocation had been prepared in advance based on

computerized individual randomization. The life-skills arm of the study was stopped after recruitment reached approximately 30 women in each group, because of poor adherence to the life-skills intervention and practical difficulty with implementation precluded continuing with recruitment. Randomization continued for the MI and control groups. This decision was also motivated by wanting to achieve comparability to the Project CHOICES methodology in which only two arms were included [5].

## Recruitment

Participants were recruited from six primary care clinics and from farms within the study area between June and November 2007. Eligibility criteria included: (i) age 18–44 years; (ii) not pregnant; (iii) engaged in risky drinking (defined under Measures); (iv) ineffective or no contraceptive use (defined under Measures); (v) had not undergone sterilization or hysterectomy; (vi) had vaginal sex in the past 3 months; and (vii) resided within a 25-km radius of the main town. Eligible women were given a follow-up appointment at which time consent for trial participation was obtained, the pre-intervention questionnaire was administered and a pregnancy test was conducted. Women found to be pregnant were excluded from further participation and referred to the antenatal services.

## **Intervention design**

Women in all groups received an information pamphlet on FAS prevention and a woman's health handbook.

The five MI sessions included the following:

Session 1 aimed to build rapport and set the agenda for participants' five-session programme.

Session 2 focused on assessing the participants' readiness to change and perceived confidence in enacting behaviour change.

Session 3 involved the development of a behaviour change (BC) plan and assisted the client with action plans.

Session 4 focused on implementation of the BC plan, assessing challenges and problem solving.

The final session reviewed the counselling experience and progress, reinforced an after-care plan and referred the client, where necessary. The content of the sessions was based on the Project CHOICES study. However, contraception was integrated into the five sessions and was not a stand-alone session, as in Project CHOICES [5].

The sessions were conducted by locally recruited and trained lay counsellors. A manual was developed and was used to guide the process for the five sessions. An educational flipchart depicting alcohol and contraceptive information was used. The sessions were held over2 months at locations and times convenient for each of the participants. Although both behaviours leading to risk for AEP were targeted, the counsellors were guided by the priority behaviour of concern to the participant. Quality control of the intervention was ensured through regular meetings between the MI trainer and lay counsellors. All participants were given a grocery voucher worth R30 (US\$ 5) for each session or interview, as compensation for their time and travel costs.

## **Data collection process**

Data were collected at baseline (pre-intervention questionnaire) and at 3 and 12 months after the intervention using follow-up questionnaires in a face-to-face interview. Blinding of the fieldworkers regarding the group allocation of the participants was difficult in this small rural community setting. However, fieldworkers were different from the counsellors and trained specifically to administer the questionnaire, and did not conduct the counselling. Interviews were conducted in the chosen language of the participants and lasted approximately 1 hour. The study was approved by the Faculty of Health Sciences Research Ethics Committees of the Universities of Pretoria (121/2005) and Cape Town (381/2005).

#### Measures

The structured questionnaire included measures adapted from questionnaires used among similar populations in South Africa [19]. The questionnaire covered: demographic characteristics, economic factors, household factors, community and culture, self-esteem, assertive ness, health, alcohol use, smoking and other drug use, sexual behaviour, use of contraceptives, the participant's current partner, social support and religious orientation. Although the time-line follow-back method was used in Project CHOICES and is recognized as a reliable method for capturing behaviours of interest, it was deemed too lengthy and demanding for our target population because the questionnaire took at least 1 hour to complete. Being farm-workers or residents, most women had to be interviewed during their tea or lunch breaks or after hours.

Quantity and frequency questions were used to establish if a woman met the criteria for risky drinking over the past 3 months (more than five drinks at one sitting in the past 3 months, or more than seven drinks in a week). Ineffective contraception was defined as not using any contraception or using an ineffective contraceptive method (i.e. any method other than contraceptive pill, injectable or intra-uterine device) or the incorrect use of such methods, in the previous 3 months. Other non-hormonal methods are extremely uncommon in South Africa [20], so were not included in the definition. The respondent had to describe the regular use, based on published guidelines, before being deemed to be effectively using one of the three methods.

The primary outcome was being at risk of an AEP at 12 months. The secondary outcomes were risky drinking and ineffective contraception at 3 and 12 months and being at risk of an AEP at 3 months. A participant was considered to be still at risk for AEP if she had engaged in risky drinking and had not been using effective contraception at follow-up.

Additional alcohol questions included the Alcohol Use Disorders Identification Test (AUDIT) and the Cut-down, Annoyed, Guilt, Eye-opener (CAGE) screening tool. The 10 AUDIT questions are each scored on a scale of 0–4. Total scores between 0 and 7 indicate low or no risk for alcohol problems; 8–15 indicate hazardous drinking; 16–19 indicate harmful drinking, while more than 19 indicates probable alcohol dependence [21]. The CAGE screening tool consists of four questions and a positive response to two or more indicates potential alcohol problems [22].

#### Data analyses

Statistical analyses were carried out using STATA version 12. The Z-test normal approximation method for large samples was used to estimate the 95% CIs and P-values for the differences between proportions. Where ORs were estimated, the exact 95% CIs have been used. These ORs were estimated without adjustment for covariables, as the number of covariables for which we had information was large relative to the sample size, and there was a great deal of correlation between them. The purpose of randomization was to minimize the effect of confounding variables.

The reduction in AEP analyses were carried out in two different ways: first, analyses were performed using only those subjects for whom data were available at both enrolment and at follow-up. Secondly, the analyses were carried out on the conservative assumption that missing follow-up data (for risky drinking and/or for ineffective contraception) represented women who had not changed their risky behaviour since enrolment (intention-to-treat, or ITT analysis).

The change in AUDIT score (12-month follow-up versus baseline) was calculated for each woman. The changes were then compared between the MI and control groups using the Wilcoxon rank-sum test. This analysis (of the AUDIT score changes) was repeated with the inclusion of those for whom one or both of the AUDIT scores was/were missing. In these cases the change in AUDIT score was assumed to be zero.

## RESULTS

#### **Participant retention**

Of 1197 women screened, 222 met the inclusion criteria prior to pregnancy testing, while 975 were excluded. Fifteen did not return for the pre-intervention questionnaire and 11 were pregnant; thus, the final sample consisted of 196 participants. These subjects were allocated randomly to MI group (n = 82), the life-skills group (n = 31) or the control group (n = 83). Retention at 3 months was between 69.5 and 73.5%, depending on group, whereas at 12 months, retention improved slightly to between 74.4 and 77.1%. Of the 82 participants allocated to the MI group, 61 were followed-up successfully at 12 months. Of the 61, 42 had completed all five MI sessions, 10 did not attend any of the sessions and the remaining nine attended between one and four sessions. This paper reports on comparing MI (n = 82) to controls (n = 83) only, a total of 165 participants (Fig. 1).

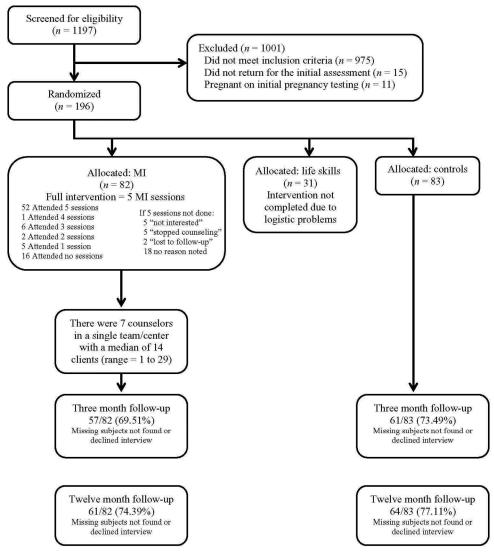


Figure | Participant flow diagram

#### **Baseline characteristics of participants**

Table 1 depicts the socio-demographic and behavioural characteristics of the MI and control group at baseline. The average age of participants was 29.8 years, and were predominantly of mixed-race ancestry (98.8%). Only 54.9% of participants had completed 8 or more years of education, and the majority had had employment in the previous 12 months. The household income for the majority was between R501 (US\$70) and R2500 (US\$350) per month, indicating low socio-economic status.

By definition, all participants met the criteria for risky drinking, ineffective contraceptive use and AEP risk at baseline. Almost all participants admitted to at least one binge drinking episode (drinking five or more on one occasion) in the previous month. The mean AUDIT score at baseline was 19.88, with about 50% having a score indicating possible alcohol dependence. In addition, 80% of the participants were current smokers and 18% had used cannabis in the previous month.

Characteristic		Intervention $n = 82$	Control $n = 83$
Age (years)	Mean (SD)	29.12 (7.92)	30.52 (8.08)
	Median (IQR)	30.0 (22-35)	29.0 (24-38)
Older than $>36 = 1; \le 36 = 0$	Number (%)	41/81 (50.62%)	40/83 (48.19%)
Population group coloured = 1	Number (%)	82/82 (100.00%)	80/82 (97.56%)
Years of education (years)	Mean (SD)	nn (SD) 8.07 (2.87) 7.55 (2.23	
	Median (IQR)	8 (7-10)	8 (6-9)
Education (binary) > 8 years = $1$	Number (%)	45/81 (55.56%)	45/83 (54.22%)
Income category 7 categories	Median (IQR)	Category 2 (2–2)	Category 2 (1–2)
(category 2 = R501 - R2500/month)		10.02 (0.12)	10.04 (0.22)
AUDIT score	Mean (SD)	19.92 (8.12)	19.84 (8.22)
	Median (IQR)	20 (14–27)	19 (13–28)
	$\% \ge 20$	41/76 (53.95%)	38/82 (46.34%)
Socio-economic status (binary) $6+=1$	Number (%)	20/81 (24.69%)	14/82 (17.07%)
Social capital score (range 0–7)	Mean (SD)	3.90 (1.85)	3.78(1.69)
	Median (IQR)	4 (2-5)	4 (2–5)
Social capital score (binary) $5+=1$	Number (%)	37/81 (45.68%)	32/80 (40.00%)
Average drinks/week category (category $5 = 8 + drinks$ )	Median (IQR)	Category 5 (4–5)	Category 5 (4-5)
Binge episodes in 3 months category (category $4 = >1/month < 1/week$ )	Median (IQR)	Category 4 (3–5)	Category 4 (3–5)
Drinks/drinking day category (category $3 = 7$ to $9$ )	Median (IQR)	Category 3 (2–3)	Category 3 (3-3)
CAGE score (0–4 numerical category)	Mean (SD)	3.13 (0.90)	2.99 (0.97)
(category $3 = 3/4$ items checked)	Median (IQR)	Category 3 (3-4)	Category 3 (2-4)
CAGE score binary CAGE $4 = 1$	Number (%)	31/82 (37.80%)	29 (35.80%)
History past treatment alcohol	Number (%)	0/81 (0.00%)	2/83 (2.41%)
Dagga (cannabis) last 12 months	Number (%)	17/81 (20.99%)	13/82 (15.85%)
Ever smoked	Number (%)	74/82 (90.24%)	77/83 (92.77%)
Current smoker	Number (%)	62/81 (76.54%)	68/82 (82.93%)
Sexual partners last 3 months	Mean (SD)	1.06(0.23)	1.05 (0.28)
-	Median (IQR)	1 (1-1)	1 (1–1)

Alcohol Use Disorders Identification Test (AUDIT) score: subjects are asked to respond to 10 items and each response is assigned a value between 0 and 4. The assigned values are added together. The lowest possible score is zero and the highest is 40. Final scores are interpreted as: 0-7 non-hazardous/harmful alcohol use; 8-15 hazardous drinking; 16-19 harmful drinking and 20+ potential dependence. Socio-economic status index: ownership of eight different material items, 1 point for each item owned; range thus = 0-8. Average drinks/week categories: 1 = 1; 2 = 2 or 3; 3 = 4 or 5; 4 = 6 or 7; 5 = >7. Binge episodes in the last 3 months categories: 0 = never; 1 = once; 2 = once a month; <math>3 = >once a month; 4 =once a week; 5 = >once a week; 6 = daily. Drinks taken per drinking day categories: 0 = 1 or 2; 1 = 3 or 4; 2 = 5 or 6; 3 = 7 to 9; 4 = 10 or more. Cut-down, Annoyed, Guilt, Eye-opener (CAGE) score: subjects respond 'yes' or 'no' to four items. The total number of 'yes' responses is the score. A score of >1 is considered indicative of an alcohol problem. IQR: interquartile range; SD: standard deviation.

#### Outcomes

Table 2 compares MI and control group outcomes. Overall, there was a significant difference in the decline in the primary outcome measure—namely, the proportion of women at risk for an AEP in the MI group (50.82%) compared to the control group (28.12%) at 12 months (P = 0.009). This risk reduction was maintained from the 3-month follow-up, in which there was a 50% reduction in the MI group and a 24.59% reduction in the control group (P = 0.004) (Table 2a).

Also, there were declines for both groups in the proportion of participants who met the criteria for risky drinking at 3- and 12-month follow-up compared to baseline. At the 12-month follow-up, the reduction in the MI group (14.75%) was modestly larger when compared to the control group (10.94%), but this difference was not statically significant. The difference was also not statistically significant at 3 months.

However, there was a significantly greater reduction in the percentage of participants in the MI group (42.62%) than in the control group (25%) (P = 0.037) who were not using effective contraception at the 12-month follow-up, and at the 3-month follow-up: 35.71 and 11.48%, respectively (P = 0.002).

These patterns were similar, but with lower effect measures, when ITT analyses were carried out, except that the reduction in the proportion of participants who were using ineffective contraception at 12 months was no longer statistically significant (P = 0.067). At 3 months 32.93 versus 18.07% were no longer at risk of an AEP (P = 0.029), and 37.80 versus 21.69% at 12 months (P = 0.024) (Table 2b).

The change in median AUDIT score from baseline to 12 months was greater for the MI group compared to the control (decline of 5 versus 1.5, respectively; Wilcoxon's rank-sum test, P = 0.007). Following an ITT analysis the median decline was still greater in the MI group compared to the control (1 versus 0, respectively, P = 0.012).

The OR for no longer being considered at risk for AEP after 12 months, intervention versus control, was estimated at 2.64 (95% CI: 1.18–5.94) for the 125 participants with follow-up data available at 12 months. This OR was slightly attenuated at 2.19 (95% CI: 1.05–4.65) when estimated using an ITT analysis (Table 3).

## DISCUSSION

The main finding is that the MI group was more than twice as likely as the control group to lower their risk for an AEP at 12 months follow-up (OR = 2.64, 95% CI: 1.18–5.94). In an ITT analysis, this OR was modestly reduced to 2.19 (95% CI: 1.05–4.65), but remained significant. This suggests that a five-session intervention of MI can be effective in reducing risk for AEP when offered to high-risk women at a community level by lay counsellors. A similar result was evident in the Project CHOICES study in the United States, where the odds of being at reduced risk for AEP at 9 months after the MI intervention was also twofold greater compared to the control group (95% CI: 1.47-3.03) [7].

The ease with which we were able to find eligible women for the study is due partly to the high rates of drinking in the target community. Of all the non- pregnant women screened (1186), 17.8% (211) were found to be both high-risk drinkers and poor contraceptive users, a rate higher than a community survey (8.5%) in the same community2 years earlier [19]. Of concern is that 11 women (0.9%) who were thought to be eligible were found to be pregnant and would have already been exposing their fetuses to high levels of alcohol. The integrity of the trial was reasonably good, with participant retention rates of more than 74% at 12 months in both groups, and good comparability of groups at baseline.

Bearing in mind that a woman's risk for AEP can be reversed either by a reduction in risky alcohol use or effective contraception, it is noteworthy that the reduction in risk for AEP in this study was due mainly to the improved use of contraceptives rather than a reduction in risky

	At 3-month follow-up		At 12-month follow-up					
	MI	Control	95% CI (P-value)	MI	Control	95% CI (P-value)		
(a) Analysis includes only those subjects who were seen at follow-up								
Numbers (%) at risk for AEP	28/56 (50.00%)	46/61 (75.41%)	-42.39 to $-8.43%$ ( $P = 0.004$ )	30/61 (49.18%)	46/64 (71.88%)	-39.39 to $-6.01%$ ( $P = 0.009$ )		
Numbers (%) with risky drinking	43/57 (75.44%)	55/63 (87.30%)	-25.73 to $2.01%$ ( $P = 0.094$ )	52/61 (85.25%)	57/64 (89.06%)	-15.54 to 7.92% (P = 0.524)		
Numbers (%) with ineffective contraception	36/56 (64.29%)	54/61 (88.52%)	-39.11 to $-9.35%$ ( $P = 0.002$ )	35/61 (57.38%)	48/64 (75.00%)	-33.95 to $-1.29%$ (P = 0.037)		
(b) Analysis of the full 165 subjects: those not seen at follow-up are assumed to remain at risk for AEP								
Numbers (%) at risk for AEP	55/82 (67.07%)	68/83 (81.93%)	-27.97 to $-1.75%$ (P = 0.029)	51/82 (62.20%)	65/83 (78.31%)	-29.85 to $2.37%$ ( $P = 0.024$ )		
Numbers (%) with risky drinking	68/82 (82.93%)	75/83 (90.36%)	-17.76 to 2.90% (P = 0.160)	73/82 (89.02%)	76/83 (91.57%)	-11.58 to $6.48%$ ( $P = 0.580$ )		
Numbers (%) with ineffective contraception	63/82 (76.83%)	76/83 (91.57%)	-25.65 to $-3.83%$ ( $P = 0.009$ )	56/82 (68.29%)	67/83 (80.72%)	-25.60 to $0.74%$ ( $P = 0.067$ )		

CI: confidence interval for the difference between the percentages; AEP: alcohol-exposed pregnancy; MI: motivational interviewing.

#### Table 3 Odds ratios for no longer being at risk for an AEP (MI versus control groups).

Follow-up time	Sample size	Odds ratio	95% CI	P-value
3 months	112 (includes only those with 3-month follow-up)	3.05	1.23 to 7.32	0.005
3 months	165 (Includes all enrolled subjects <sup>a</sup> )	2.23	1.02 to 4.95	0.029
12 months	125 (includes only those with 12-month follow-up)	2.64	1.18 to 5.94	0.009
12 months	165 (includes all enrolled subjects <sup>a</sup> )	2.19	1.05 to 4.65	0.024

AEP: alcohol-exposed pregnancy; MI: motivational interview; CI: confidence interval (for the odds ratio). \*Subjects for which there were no follow-up data were included on the assumption that they remained at risk for an AEP.

alcohol use. Because the intervention is aimed at reducing risk for AEP and not treatment of alcohol use disorders, this is a positive outcome. A similar finding of a greater change in contraceptive use rather than in risky alcohol use has been found in other studies, such as Birth Control and Alcohol Awareness: Negotiating Choices Effectively (BALANCE) intervention [23]. Access to various contraceptive methods in our study setting is relatively easy through the public health service. The evidence of benefits among control group participants in this study is not uncommon in behavioural intervention trials. Being screened, answering detailed personal questions on multiple occasions and receiving educational materials may have served as an intervention in itself [6]. Although up to 92% of women using the public health service in South Africa attend at least one antenatal clinic visit, only about 50% confirm their pregnancy at a clinic before 20 weeks of gestation, and up to three-quarters of pregnancies are unplanned [11,12]. More effort is needed to reduce risky levels of drinking by women in general and to promote family planning and earlier pregnancy testing, so that first-trimester fetal development is not compromised while women use alcohol, unaware that they are pregnant.

The model of intervention in which a lay counsellor follows-up high-risk women at their homes was effective, but required considerable effort and commitment from the coordinator and counsellors. A systematic review of 72 trials of MI applied to a variety of health conditions showed that medical doctors had greater success in effecting behaviour change in patients than other health professionals [13]. None of these studies used lay health workers as MI counsellors, but it may be that our counsellors were not viewed as having sufficient authority to effect alcohol-related behaviour change. There is a need to explore operational adaptation of the MI intervention under 'routine' clinic service conditions. Existing lay counsellors and nurses, who provide HIV and AIDS-related counselling, could be trained to include alcohol-and contraceptive-related MI in their daily interaction with patients [24].

There were potential biases in this study. In common with many studies on substance abuse, there are limitations with relying on self-reported data. In addition, our failure to use a time-line follow-back method to assess the women's alcohol consumption may have reduced the reliability of self-reports. Interview fatigue may have influenced them to answer what they thought the field-worker would prefer to hear. In addition, the study design involved the randomization of individuals rather than the randomization of sites. It is possible, therefore, that those in the control option may have been influenced by contact with those randomized to the intervention, although this would have led to an underestimation of effect. The small grocery voucher offered to participants for each interview or session could have served as an incentive to participate and may affect replicability in the services.

# CONCLUSION

A five-session MI programme offered to non-pregnant women at high risk of an AEP, by trained lay counsellors, was effective in reducing the risk for AEP by almost 50% (40% in the ITT analysis). The odds of intervention group women being no longer at risk for an AEP after 3 months were more than twice those of the control group women, and this finding was maintained at 12 months. The public health message of 'no alcohol in pregnancy' should be combined with the promotion of planned pregnancies and early confirmation of pregnancy in order to reduce AEP risk, especially in high-risk populations. We propose further research to explore the best models for integrating screening and MI into routine primary care services for childbearing age women as part of a comprehensive programme for FAS prevention [25].

## **Declarations of interest**

None.

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# References

- 1. Peltzer K., Davids A., Njuho P. Alcohol use and problem drinking in South Africa: findings

- Peltzer K., Davids A., Njuho P. Alcohol use and problem drinking in South Africa: findings from a national population-based survey. *Afr J Psychiatry* 2011; 14: 30–7.
   Kalichman S., Simbayi L. C., Jooste S., Vermaak R., Cain D. Sensation seeking and alcohol use predict HIV transmission risks: prospective study of sexually transmitted infection clinic patients, Cape Town, South Africa. *Addict Behav* 2008; 33: 1630–33.
   Morojele N. K., Kacheng'a M., Mokoko E., Nkoko M. A., Parry C., Nkowane A. M. Alcohol use and sexual behaviour among risky drinkers and bar and shebeen patrons in Gauteng province, South Africa. *Soc Sci Med* 2006; 62: 217–27.
   Ingersoll K., Floyd L., Sobell M., Velasquez M. M., Project CHOICES Intervention Research Group. Reducing the risk of alcohol-exposed pregnancies: a study of a motivational intervention in community settings. *Pediatrics* 2003; 111: 1131–35.
   Floyd R. L., Sobell M., Velasquez M. M., Ingersoll K., Nettle-man M., Sobbell L. *et al.* Preventing alcohol-exposed pregnancies: a randomised controlled trial. *Am J Prev Med* 2007; 32: 1–10.
- **32**: 1–10.
- 6. Mengel M. B., Searight H. R., Cook K. Preventing alcohol-exposed pregnancies. J Am Board Fam Med 2006; 19: 494–505.
- 7. May P. A., Gossage J. P., Marais A. S., Adnams C. M., Hoyme H. E., Jones K. L. *et al.* The epidemiology of fetal alcohol syndrome and partial FAS in a South African community. *Drug Alcohol Depend* 2007; 88: 259–71.
- alcohol Depend 2007; 88: 259–71.
  Viljoen D. L., Craig P., Hymbaugh K., Boyle C., Blount S. Fetal alcohol syndrome—South Africa, 2001. Morb Mortal Wkly Rep 2003; 52: 660–2.
  Urban M., Chersich M. F., Fourie L. A., Chetty C., Olivier L., Viljoen D. Fetal alcohol syndrome among grade 1 schoolchildren in Northern Cape Province: prevalence and risk factors. S Afr Med J 2008; 98: 877–82.
  Croxford J., Viljoen D. Alcohol consumption by pregnant women in the Western Cape. S Afr Med J 1999; 89: 962–5.
  Blaauw D., Penn-Kekana M. Maternal health. In: Fonn S., Padarath A., editors. South African Health Review 2010. Durban: Health Systems Trust; 2010, p. 3–28.
  Chersich M. F., Urban M., Olivier L., Davies L., Chetty C., Viljoen D. Universal prevention is associated with lower prevalence of fetal alcohol spectrum disorders in Northern Cape, South Africa: a multicentre before–after study. Alcohol Alcohol 2012; 47: 67–74.
  Rubak S., Sandbaek A., Lauritzen T., Christensen B. Motivational interviewing: a systematic review and meta-analysis. Br J Gen Pract 2005; 55: 305–12.
  Miller W. R., Rollnick S. Motivational Interviewing: Preparing People for Change, 2nd edn. New York: Guilford Press; 2002.
  Emmons K. M., Rollnick S. Motivational interviewing in health care settings. Opportunities and limitations. Am J Prev Med 2001; 20: 68–74.
  Statistics South Africa. Census 2001: Census in Brief. Pretoria: Statistics South Africa; 2003.
  London L. The dop system, alcohol abuse and social control amongst farmworkers in South Africa: a South Africa. Census 2001: Census in Brief. Pretoria: Statistics South Africa; 2003.

- 17.London L. The dop system, alcohol abuse and social control amongst farmworkers in South Africa: a public health challenge. Soc Sci Med 1999; 48: 1407–14.
  18.Ojo O. A., Louwagie G., Morojele N., Rendall-Mkosi K., London L., Olorunju S. et al. Factors associated with female high-risk drinking in a rural and an urban South African site. S Afr Med J 2010; 100: 180-2.

- Morojele N. K., London L., Olorunju S. A., Matjila M. J., Davids A. S., Rendall-Mkosi K. M. Predictors of risk of alcohol-exposed pregnancies among women in an urban and rural area of South Africa. Soc Sci Med 2010; 70: 534–42.
   Department of Health, Republic of South Africa. South African Demographic and Health Survey 2003. Pretoria: Department of Health; 2005.
   Babor T. F., Higgins-Biddle J. C., Saunders J. B., Monteiro M. G. The Alcohol Use Disorders Identification Test: Guidelines for Use in Primary Care, 2nd edn. Geneva: World Health Organization; 2001.
   Mayfield D., McLeod G., Hall P. The CAGE questionnaire: validation of a new alcoholism screening instrument. Am J Psychiatry 1974; 13: 1121–23.
   Ingersoll K. S., Ceperich S. D., Nettleman M. D., Karanda K., Brocksen S., Johnson B. A. Reducing alcohol-exposed pregnancy risk in college women: initial outcomes of a clinical trial of a motivational intervention. J Subst Abuse Treat 2005; 29: 173–89.
   Peltzer K., Seoka P., Babor T., Obot I. Training primary care nurses to conduct alcohol screening and brief interventions in South Africa. Curationis 2006; 29: 16–21.
   Anderson A., Aromaa S., Rosenbloom D., Enos G. Screening and Brief Intervention: Making a Public Health Difference. Princeton, NJ: Join Together, Robert Wood Foundation; 2008.