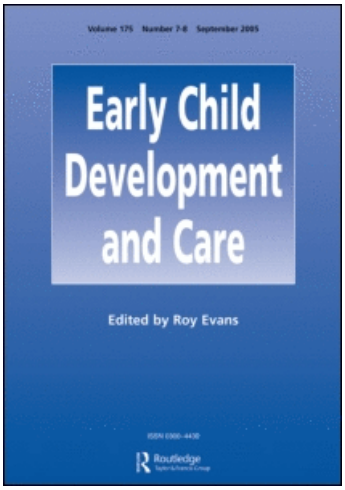

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The effect of brief interventions on the drinking behaviour of pregnant women in a high-risk rural South African community: a cluster randomised trial

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The purpose of this paper is to assess the impact of a series of brief interventions (BIs) on anti-natal alcohol consumption of women from a disadvantaged and high-risk background attending state health clinics in a rural district, Western Cape Province, South Africa. A pragmatic cluster randomised trial design was followed. All pregnant women, who were less than 20 weeks pregnant and more than 15 years of age, were eligible for the study. The intervention comprised a comprehensive assessment for current and lifetime alcohol use plus information (control group) or comprehensive assessment plus four BI sessions over the pregnancy period (intervention group). The Alcohol Use Disorders Identification Test (AUDIT) was completed pre- and post-intervention. Although both groups demonstrated declines in AUDIT scores, findings showed a statistically significant difference in the total AUDIT scores between the intervention and control groups post-intervention ($F = 9.54$, $p = 0.002$). The difference was two units (SE = 0.6). The follow-up rate was 92% ($N = 179$ of the original 194 eligible women). The impact of BIs is shown to be a powerful tool. Information and an understanding, supportive attitude seem to be crucial agents for behaviour change.

Keywords: pregnant women; drinking behaviour; brief interventions; AUDIT

Introduction

South Africa has the highest measured foetal alcohol syndrome (FAS) rates in the world (McKinstry, 2005; Rosenthal, Christianson, & Cordero, 2005). The earliest references to specific cases of newborns with FAS in South Africa were made in 1978 by Beyers and Moosa, and Palmer in 1985. Subsequently, collaborative efforts from local and international clinicians and epidemiologists have established prevalence rates in excess of 40 cases per 1000 of school entry children in targeted towns in the Western and Northern Cape Provinces (May et al., 2005; Urban et al., 2008; Viljoen et al., 2005). This is in sharp contrast to the average rate of FAS for the USA quoted as between 0.05 and 2.0 per 1000 children (May et al., 2005) and the average rate for the developed world as 0.97 (McKinstry, 2005). Prevalence rates among selected

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high-risk groups in the USA are between 2.3 and 8.5 per 1000 live births (May et al., 2000; Viljoen et al., 2005). FAS caused by maternal alcohol use during pregnancy is one of the leading causes of preventable birth defects and developmental disabilities globally (Centres for Disease Control, 2003).

Alcohol abuse results in a considerable health burden in South Africa despite the fact that many South Africans do not consume alcohol (Schneider, Norman, Parry, Bradshaw, & Plüddeman, 2007). While consumption per adult is only 7.1 litres of pure alcohol per year, the amount of alcohol consumed *per drinker* in South Africa is estimated at about 20 litres of absolute alcohol per year (Schneider et al., 2007) – among the highest in the world. Binge-drinking is a well-recognised problem drinking pattern in South Africa. In a South African Comparative Risk Assessment study for 2000 (Schneider et al., 2007), FAS ranked third at 18.1% (after alcohol use disorders at 44.6% and interpersonal violence at 23.2%) in terms of alcohol attributable disability. Changing the pattern of drinking in South Africa is essential if the alcohol-related burden is to be reduced (Schneider et al., 2007).

Prenatal drinking varies among and within populations globally. According to May et al. (2008) 20–32% of pregnant women drink alcohol in the USA, England, and Canada. In some European countries the rate is higher, sometimes exceeding 50%. In South Africa, women reported varying degrees of alcohol ingestion during their pregnancy and in one study 43% of pregnant women acknowledged that they drink alcohol (Croxford & Viljoen, 1999).

There is no integrated national strategy or policy to deal with the problem of FAS in South Africa at present. Given the high-prevalence rates of FAS and the lack of a comprehensive prevention strategy, the pressure is on researchers to find a workable solution or model to the problem.

A combination of screening followed by brief interventions (BIs) is widely recommended as the first approach to identification and treatment for mild to hazardous drinking problems (Babor & Higgins-Biddle, 2001; Chang, Goetz, Wilkins-Haug, & Berman, 2000; Handmaker & Wilbourne, 2001). This paper reports on the effect of a series of BIs on the alcohol drinking behaviour of pregnant women in a high-risk rural district in the Western Cape Province of South Africa. Pregnant women attending state antenatal health clinics in the district either received a series of BIs or, alternatively, one-off information on the harmful effects of alcohol use during pregnancy. The protocol for the study was ethically approved by a university ethics committee.

Methods

Study design

A pragmatic cluster randomised trial design was followed. As the women were recruited at the clinics and attended the same clinics throughout their pregnancy, clinics were randomised to the intervention or control arm of the study in order to limit contamination bias.

Participants and study site

All pregnant women attending any one of the eight clinics in the area, who were less than 20 weeks pregnant and more than 15 years of age, were eligible for the study. It

was decided *not to exclude* women who reported no drinking for the following reasons:

- This was a pragmatic study design. The pragmatic attitude favours design choices that maximise applicability of the trial's results to usual care settings, i.e. it is generalisable to the general clinic setting in this area (Zwarenstein et al., 2008).
- Reported drinking behaviour by pregnant women varied, as indicated by the results from a feasibility study in 2005 (13% reported current drinking) and a study by Croxford and Viljoen in 1999 (43% reported current drinking). A low reported rate is unlikely because of the extremely high prevalence of FAS in the greater geographical area. Underreporting is mostly due to the mistrust within the clinic settings between nurses and clients (Jewkes, Abrahams, & Mvo, 1998).
- In this poor socio-economic situation, pregnancy might be the trigger for women to either start drinking or increase their drinking.
- The intervention, therefore, can also be seen as a preventive exercise.

The sub-district chosen for the intervention is homogenous in the sense that it includes towns as well as farming areas around the towns. The selected women attend state health facilities, are poor and from a disadvantaged background, are mostly involved in seasonal work, are semi-literate, have a history of risky and binge-drinking patterns, and are predominantly from the "Coloured" population group (one of four population group categories legislated by the pre-1994 South African government and still in use for historical reasons). The other three groups are African, White, and Indian.

Subject recruitment and interventions

All eight clinics in the chosen geographical area were included in the study. The eight clinics served a population of 1219 women attending antenatal services in 2007, varying in size from 35 in the smallest clinic to 160 in the largest clinic. All women meeting the inclusion criteria were recruited to the sample during the study period. Women attending the clinics for routine visits from March to September 2007 were either directly approached by the fieldworkers or, alternatively, were followed up later if they were not seen by the fieldworkers during their routine visits. The recruitment plus follow-up interviews stretched over a period of nine months, with last visits in February 2008.

Brief interventions, developed by the World Health Organization (WHO), were chosen as an intervention tool (Babor & Higgins-Biddle, 2001; Babor, Higgins-Biddle, Saunders, & Monteira, 2001). Brief interventions, a time-limited, patient-centred counseling strategy focusing on changing patient behaviour and increasing patient compliance with therapy, were used in feedback sessions to negotiate and set goals with respondents in the intervention group (IG) and to reinforce their behaviour in follow-up sessions (Babor & Higgins-Biddle, 2001; Fleming & Manwell, 1999; O'Connor & Whaley, 2007).

The detailed intervention process for each group is discussed below. Interviews were conducted by two trained fieldworkers. Incentives in the form of a food parcel were given to all participants in the trial.

The intervention group (IG)

(1) Initial assessment interview – lasting an hour – included the consent form, the personal questionnaire, the Alcohol Use Disorders Identification Test (AUDIT), explaining the meaning of AUDIT results, BI with setting drinking goals, and making notes in a take-home alcohol booklet.
(2) In two follow-up interviews (a month and a half apart), BIs consisted of feedback on drinking behaviour, negotiations, goal setting, and reinforcement. A questionnaire on changes in drinking behaviour and bonding was completed. These interviews lasted 20 minutes on average.
(3) The last follow-up interview before the birth comprised a BI and feedback on drinking behaviour, completing a questionnaire on changes in drinking behaviour, and completing a second AUDIT.

The control group (CG)

Involvement with respondents was kept to the minimum that was allowed ethically:

(1) The initial assessment interview included the consent form, the personal questionnaire, the AUDIT, written material, i.e. the take-home alcohol booklet, and appointment for the follow-up interview.
(2) The last follow-up interview just before the birth consisted of a second AUDIT and a questionnaire on changes in drinking behaviour.

Objectives and outcomes

The main objective of the intervention was to test the effectiveness of a series of BIs with pregnant women on their alcohol consumption and drinking behaviour during pregnancy. The AUDIT score at post-intervention was used to measure the intervention effect (IE). The AUDIT was found to be useful for measuring the IE in our specific population because it:

- measures quantity as well as frequency of alcohol use (first three questions);
- performs adequately in Black or White women (Area Under the Receiver Operating Charecteristic Curve (AUROCs): 0.87–0.93 for recent alcohol use) and also with pregnant women (the T-ACE and AUDIT correctly identified 65–70% of current drinkers (Bradley, Boyd-Wickizer, Powell, & Burman, 1998; Chang, Goetz, Wilkins-Haug, & Berman, 1999a; Nicole & Bourret, 2004);
- was specifically developed to identify problem drinkers in primary care settings; and
- was developed for early intervention and detection of harmful and hazardous drinking.

Sample size

Sample size justification was based on the following: a 20% reduction in alcohol use and an intra-cluster correlation coefficient of 0.01 was used for sample size estimation. A sample size of 96 in each group, obtained by sampling four clinics per group,

achieved 80% power to detect a post-intervention difference of 20% between the IG and CG. The significance level of the test was 0.0500.

Randomisation and blinding

Randomisation of clinics was done by a statistician as independent researcher in the study. Four clinics were randomised to each arm of the intervention. One of the clinics (Clinic E) serves mostly African clients, and although these families are also poor and semi-literate, the women do not have a history of risky drinking patterns. This clinic was randomised to the control arm. Blinding was impossible as recruitment and the first intervention session coincided.

Statistical methods

Descriptive statistics are reported for the groups at baseline. This information gives an overview of the socio-economic profile of the study group and compares the groups at baseline (Table 1).

Figure 1, with the 45° line of no change in scores, depicts the baseline and post-intervention AUDIT scores separately for the IG and CG.

The IE was estimated as the post-intervention difference between the average AUDIT score for control and intervention clinics, i.e. a positive estimate being a decrease in the score, on average. A mixed-model analysis of variance, with random effects to reflect the correlation of observations among women from the same clinic, was conducted to assess whether the IE was significantly different from zero and to obtain the 95% CIs. The baseline AUDIT score was included in the model to adjust for the differences in the means of the scores at baseline (Table 2), since the randomisation of Clinic E (mostly Black women) to the CG resulted in an imbalance between the groups.

Furthermore, to estimate separate IEs for different drinking groups, we defined three groups at baseline: a *non-drinker group*, an *unconfirmed drinker group*, and a *confirmed drinker group*. To be a confirmed drinker, women had to respond positively to being a drinker on two occasions: on the personal questionnaire and on the AUDIT baseline questionnaire. The indicator variable for drinking groups was entered into the model with the indicator variable for the intervention as an interaction effect to assess whether the IE is different for the three drinking groups (Table 2).

Lastly, because of the high proportion zero values in the post-intervention AUDIT score (about 80%), changes in the upper conditional percentiles (85th, 90th, and 95th) of the post-intervention AUDIT scores were also modelled as an estimate of the IE (Table 2). The *t*-value in Table 2 indicates whether the difference between the IG and CG was significant at the given quantile.

An intention-to-treat analysis was done. This meant that, although some of the selected women had a miscarriage or the baby was stillborn, they remained in the study and were included in the analysis.

Results

Cluster sizes

The cluster sizes in the control arm were 8, 9, 32, and 47 (average = 24), and in the intervention arm the cluster sizes were 12, 13, 27, and 46 (average = 24.5) (see Figure 2).

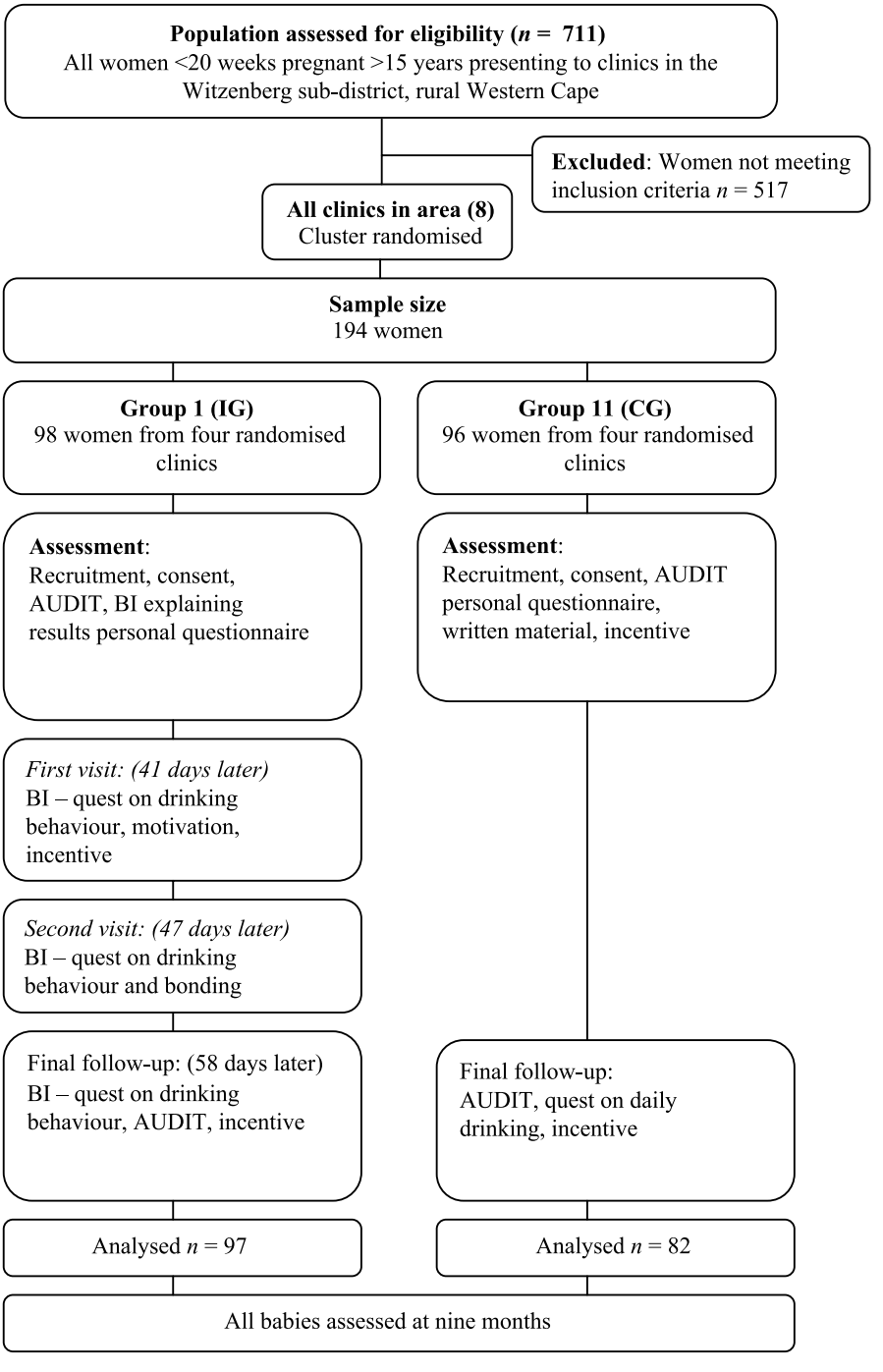

Figure 2. Flow chart – flow of progress through phases of the trial.

Participant flow

The total number of women recruited was 194. There were no refusals.

Intervention group

Of the 98 recruited respondents, four women had miscarriages during the study period. One woman could not be traced for follow-up. Therefore, a total of 97 respondents were analysed for the primary outcome (a follow-up rate of 99%).

Control group

Of the 96 recruited respondents, two women had miscarriages and 12 women could not be traced for the last interview because they moved away or did not give birth in the designated geographical area. A total of 82 respondents were analysed for the primary outcome (a follow-up rate of 85%). The baseline AUDIT score was not considered different for the analysed and total group (7.3 versus 6.9, Table 1).

On average, the women were 15 weeks pregnant at recruitment. For most women, this was their second pregnancy. The mean age was 25 years. The majority of women were Afrikaans-speaking and from the Coloured population group, although the control group (CG) had more Xhosa speakers than the IG (see section "Participants and Study Site" for explanation). Almost a quarter of the women (22%) had less than eight years of schooling. About half of the respondents (49%) indicated that they were in a relationship but that they were not living together. Forty-three per cent of the women were employed at the time of recruitment. There was a 2.7 difference in the baseline AUDIT score between the groups, and as a result adjustments for this difference were made in the final analysis. The difference in AUDIT scores was as a result of the lower average AUDIT score of Clinic E (see Table 1 for AUDIT scores without Clinic E). More than half of the respondents have heard of FAS. On average,

Table 1. Baseline descriptive information.

	Control (n = 96)			Intervention (n = 98)		
	N	Mean or %	SD	N	Mean or %	SD
Weeks pregnant	93	14.8	4.6	98	14.8	4.1
Number of times pregnant	96	2.1	1.1	98	1.9	1.1
Number of children	96	0.98	1.04	98	0.80	0.94
Age at first interview	96	25.3	5.8	98	24.3	6.3
AUDIT score all women	96	6.9	8.6	98	9.6	8.8
AUDIT score without Clinic E	64	8.7	9.0	98	9.6	8.8
AUDIT score for analysed women	82	7.3	8.9	97	9.4	8.6
Age at first drink	71	17.9	3.8	83	16.9	2.5
Anyone close with alcohol problem	96	22 (23%)		98	56 (57%)	
Language group Afrikaans	96	65 (68%)		98	98 (100%)	
Coloured population group	96	64 (67%)		98	96 (98%)	
Employed (mostly seasonal)	96	45 (47%)		98	38 (39%)	
Heard about FAS	96	58 (60%)		98	52 (53%)	
In relationship/not living with partner	96	43 (45%)		98	51 (52%)	
Schooling less than Grade 8	96	19 (20%)		98	24 (24%)	

these women were 17 years old when they had their first drink and 40% of the sample indicated that they have somebody close to them who has a problem with alcohol.

From Figure 1, it is clear that almost all women (72%) in the IG had a reduced AUDIT score after intervention compared to their baseline score, and that some (41%) of the CG also decreased their AUDIT score, although 10% in this group increased their score (three women started drinking during this period).

The estimated average difference between the groups in the post-intervention AUDIT score (IE = 1.97; SE = 0.64) adjusted for the baseline difference was significant ($p = 0.002$), indicating that the AUDIT score of the IG dropped significantly more compared to that of the CG (Table 2: Overall).

The IE for the unconfirmed drinking group is not significant (IE = 1.23; SE = 0.90), but the IE for the confirmed drinking group is highly significant (IE = 5.28; SE = 1.31). It follows that the group of women whose drinking was confirmed benefitted most from the intervention (Table 2: Drinking group).

The regression coefficient at the 85th quantile indicated that the average AUDIT score for the IG is five points lower than the average AUDIT score for the CG ($t = 5.2$, $p = 0.0001$). Thus, the quantile regression results confirm the mixed-modelling results (Table 2: Quantile).

Discussion

Changes in drinking behaviour – measured by the AUDIT score – of an IG and CG were compared. Both the intervention and CGs demonstrated, on average, declines in

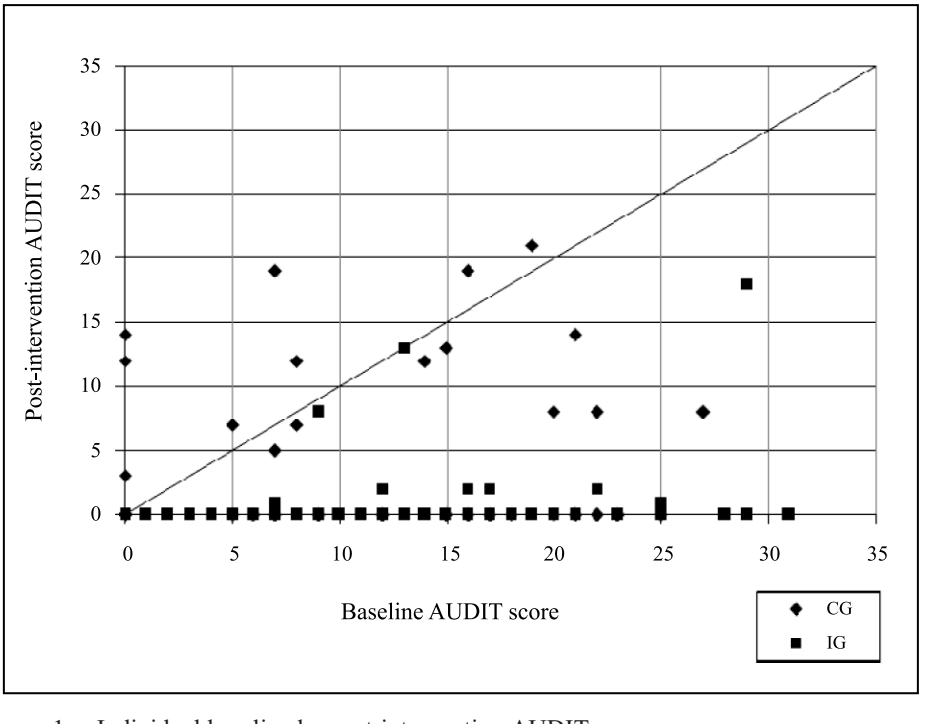

Figure 1. Individual baseline by post-intervention AUDIT scores.

Table 2. Intervention results: comparison of post-intervention AUDIT scores between intervention and control group.

	Model estimates and SEs for post-intervention AUDIT scores[a]				
	C	I	IE	*F* or *t*; d.f.	*p*
Overall intervention effect for mixed model					
Overall *N* = 179	2.43	0.46	1.97 (0.64)	*F* = 9.54; d.f. = 170	0.002
Intervention effect for drinking groups[b]					
No drinking *N* = 81	0.69 (0.55)	0 (—)	0.69 (0.85)	*t* = 0.81; d.f. = 166	0.42
Unconfirmed drinking *N* = 81	1.86 (0.76)	0.63 (0.48)	1.23 (0.90)	*t* = 1.37; d.f. = 166	0.17
Confirmed drinking *N* = 31	6.59 (0.86)	1.31 (0.99)	5.28 (1.31)	*t* = 4.02; d.f. = 166	0.0001
Intervention effect for three quantiles					
85			5.25 (SE 1.01)	*t* = 5.20	0.0001
90			9.67 (SE 1.46)	*t* = 6.62	0.0001
95			9.07 (SE 2.37)	*t* = 3.84	0.0002

[a]Estimates adjusted for baseline differences in AUDIT scores.

[b]Positive response for drinking on two occasions.

C, control clinics; I, intervention clinics; IE, intervention effect = C–I; d.f., degrees of freedom; SE, standard error.

AUDIT scores, although results showed that assessment plus BI (IG) was more effective than assessment and written material alone (CG). Looking distinctly at a group of women, who are confirmed drinkers, enhanced the estimate of the difference between the groups, and additionally showed that women who are open about their drinking are ready to change their drinking habits.

These results are similar to those from other attempts to modify prenatal alcohol consumption reported by O'Connor and Whaley (2007), Chang, Goetz, Wilkins-Haug, and Berman (1999b), Handmaker and Wilbourne (2001), and the WHO Brief Intervention Study Group (1996), demonstrating declines in both IG and CGs.

Furthermore, 60% of the women in the IG had stopped drinking by the last follow-up visit just before birth (AUDIT score = 0). A third of this group (36%) reported a change in their drinking behaviour after the first BI session. Qualitative information showed that most women "made a decision" to stop their drinking after the first BI session. It seems to be beneficial to have more than one session of BIs, especially in the case of excessive drinking. One to three patient consultations have consistently shown significant reductions in problem drinking in comparison to no consultations (Dore, 2000; Handmaker & Wilbourne, 2001).

A limitation of this study is that a diagnostic test for alcohol consumption was not used in the assessment phase due to limited funds. We relied on the difference in AUDIT scores after the intervention to indicate change in drinking behaviour. This score might not be a valid reflection of total alcohol consumption, but we assumed that the results were equally biased in both groups.

The specific contribution of this study is that it is an RCT testing the effect of screening and BIs (few controlled studies have been done on pregnant women), that

it tests the effectiveness of BIs among *pregnant women*, and that *disadvantaged* and not middle-class pregnant women are interviewed (Chang et al., 1999b; O'Connor & Whaley, 2007).

On average, the respondents were recruited at 15 weeks of pregnancy and most of them already had a previous child. We recognise that alcohol consumption before recruitment could have damaged the foetus. It is also a concern that many women are often unaware of their pregnancy status and may consume alcohol well into the first trimester (Chang et al., 1999a). However, any reduction in alcohol consumption at any point during pregnancy is beneficial to the foetus (Chang et al., 1999b).

The study was clinic-based. The sample of women recruited were those who attended clinics regularly. Heavier drinking women tend to not attend clinics regularly and usually come late to report a pregnancy if at all (Waterson & Murray-Lyon, 1990). A follow-up study should target the infrequent or non-attenders.

This study, the first randomised control trial to be conducted on drinking patterns of pregnant women in South Africa, confirms the importance of routine screening for prenatal alcohol use patterns and the necessity of offering information and support during pregnancy in a sustainable way.

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Notes on contributors

Sandra Marais works as a senior specialist scientist at the South African Medical Research Council since 1998. She has a DLitt Phil in sociology (sociology of health) and has worked extensively in rural areas in South Africa. Her interests are causes and prevention of injuries and violence and alcohol-relatedness of injuries and violence. She has been principal investigator on a number of research projects such as rural injury surveillance projects on farms and in small towns in the Western Cape, international collaborative studies on alcohol and injuries with the World Health Organization, and the impact of violence and crime on the health services in Cape Town. At the moment she is involved in two projects: first, the identification and prevention of risk factors for elder abuse and neglect in collaboration with Northumbria University, UK, and second, a randomised controlled trial measuring the impact of screening and brief interventions on the drinking behaviour of pregnant women. She has published on alcohol-related injuries in general, the influence of prenatal alcohol consumption and foetal alcohol syndrome, violence prevention partnerships, and risk factors for elder abuse.

Esmé Jordaan has an MSc degree in statistics and has been working at the Biostatistics Unit of the South African Medical Research Council for the past 25 years. She is currently a specialist statistician, collaborating on projects in the field of epidemiology and medical and clinical biostatistics. She teaches various under- and postgraduate courses in statistics. She is affiliated to the South African Statistical Association and presents talks on statistical aspects of her consultation work at national as well as international statistical conferences. She reviews papers for the *South African Statistics Journal*, *Archives of Environmental Health* and other journals. She is the author and co-author for many proposals and publications, both nationally and internationally. Her publications over the last four years include a wide variety of topics where she participated in the research design, data analysis, and interpretation of results. These topics include the impact of a home visitation programme on household hazards associated with unintentional childhood injuries, the development of an instrument measuring unintentional injuries in young children in low-income settings, alcohol as a risk for rail injury fatalities, magnitude, predictors, and implications for traffic safety.

Dennis Viljoen (MBChB; FCP; MDGenetics) is the chairman and executive director of the Foundation for Alcohol Related Research, South Africa. He is also the director of the Centre for Human Genetics Research and Education, Faculty of Health Sciences, University of Stellenbosch. He has acted as the principal investigator on numerous projects on the aetiology and demography of foetal alcohol syndrome with funds from CDC and has published widely on the topic. He is involved in an ongoing research support to organisations such as the Industry Association for Responsible Alcohol Use, the South African Department of Social Development, and is also an advisor to the South African Department of Health on foetal alcohol syndrome.

Leana Olivier has a background in nursing and psychology. She is the national manager of the Foundation for Alcohol Related Research (FARR) in South Africa. In her previous position as a senior provincial health manager at the Department of Health, she was actively involved in the field of foetal alcohol syndrome. FARR currently runs centres in various towns in the Western and Northern Cape Provinces in South Africa, where research, awareness, prevention, and intervention projects are managed by her. She has been co-author on several journal articles on foetal alcohol syndrome.

Johanna de Waal is a qualified social worker and has been in social work practice for 34 years. She is currently finalising her MPhil in social science research methods with a thesis topic: FASD: Mediating Interventions through Pregnant Women's Responses and Choices. She is presently a social worker in private practice.

Caroline Poole is a social scientist. She has a BA degree (majors in sociology, philosophy and psychology), a postgraduate diploma in community and development and is currently enrolled for an MPhil in social research methods. She has worked as a researcher and project manager in a number of institutions including the University of Stellenbosch, Western Cape, in association with Datadesk in the Department of Sociology. In her work as a researcher, she has acquired a wide-ranging research experience in both quantitative and qualitative research methodologies. She has participated in a number of research and development projects serving clients such as the South African government, the corporate sector, and universities. She was part of the research team responsible for the testing of an intervention on the prevention of foetal alcohol syndrome with pregnant women in the Ceres area of the Western Cape, in association with the South African Medical Research Council and Foundation for Alcohol Related Research.

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