DRUG & ALCOHOL FINDINGS *Research analysis*

This entry is our analysis of a study considered particularly relevant to improving outcomes from drug or alcohol interventions in the UK. The original study was not published by Findings; click Title to order a copy. Free reprints may be available from the authors – click prepared e-mail. The summary conveys the findings and views expressed in the study. Below is a commentary from Drug and Alcohol Findings.



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## Preventing alcohol-exposed pregnancies: a randomized controlled trial.

**Floyd R.L., Sobell M., Velasquez M.M. et al.**

**American Journal of Preventive Medicine: 2007, 32(1), p. 1–10.**



*Foetal exposure to alcohol is a leading cause of birth defects and developmental disabilities. Targeting interventions at women before they become pregnant – as with Project CHOICES – could shift the focus in clinical practice from treatment of substance-exposed pregnancies to prevention of a major (and costly) public health concern.*

**SUMMARY** Alcohol is a leading preventable cause of birth defects and developmental disabilities in the United States (1 2). Foetal exposure to alcohol can result in a spectrum of adverse effects known as foetal alcohol spectrum disorders.

Most women reduce alcohol consumption after learning that they are pregnant, but many will drink during the early critical weeks of gestation when they are not yet aware that they are pregnant. In the United States, almost half of pregnancies are unplanned, of which about half occur in women who are using contraception ineffectively or intermittently. Enhancing effective contraceptive use in women of 'childbearing age' who are risky drinkers could avert many alcohol-exposed pregnancies.

The efficacy of brief interventions for reducing risky drinking has been well established in previous clinical trials (1 2 3), but few have addressed both drinking and effective contraception use in one intervention. The Project CHOICES trial examined the effectiveness of a brief motivational intervention designed to encourage women to change the target behaviours of risky drinking and ineffective contraceptive use. An earlier feasibility study found that, six months after enrolment in the intervention, 69% of women had reduced their risk of an alcohol-exposed pregnancy by reducing their drinking, using effective contraception methods, or both.

### Key points
**From summary and commentary**

Prenatal alcohol exposure is a leading preventable cause of birth defects and developmental disabilities in the United States. Project CHOICES trialled a brief motivational intervention designed to encourage women to change risky drinking and/or ineffective contraception use.

The intervention had a demonstrable risk-reduction impact. At the three, six, and nine-month follow-ups, the odds of being at a reduced risk of an alcohol-exposed pregnancy were twofold greater in the intervention group than in the control group.

The findings were encouraging, indicating that women who are at risk of an alcohol-exposed pregnancy can be made aware of it and make changes to reduce their risk.

### What was Project CHOICES?

The Project CHOICES intervention focused on increasing participants' commitment to change. It consisted of four motivational interviewing counselling sessions and one contraception counselling visit (unfold the supplementary text). Although both behaviours leading to risk for alcohol-exposed pregnancy were targeted, counsellors could emphasise the target behaviour favoured by the participant.

Close supplementary text

Session one:
✓ rapport building;
✓ review of 'women and alcohol' fact sheet;
✓ review of contraceptive methods fact sheet;
✓ advice to schedule contraceptive counselling visit;
✓ daily journal for drinking, sexual intercourse, and contraception;
✓ pros and cons of drinking;
✓ pros and cons of contraceptive use;
✓ brochures on alcohol, contraceptive methods, and community resources;
✓ gift pack containing bus tokens, condoms, maps for follow-up appointments.

Session two:
✓ personalised feedback;
✓ review and discussion of information recorded in the daily journal;
✓ arrangement of contraception counselling visit;
✓ review of 'pros and cons' exercises;
✓ completion of self-evaluation rulers addressing readiness to change drinking and contraception;
✓ completion of initial goal statement and change plan;
✓ discussion of temptation and confidence profiles.

Session three:
✓ discussion of contraception counselling appointment;
✓ discussion of information recorded in daily journal;
✓ review and update of pros and cons, self-evaluation exercises, goal statements, and change plans.

Session four:
✓ review of previous sessions;
✓ review of goals and finalisation of change plans;
✓ problem solving, reinforcement of goals, strengthening commitment to change, and discussion of the participant's next steps.

Contraceptive counselling visit:
✓ determine appropriate and suitable contraceptive methods;
✓ provide prescriptions or services;
✓ provide follow-up clinical care or referral as needed.

Close supplementary text

Typically, the contraception visit occurred between the second and third counselling sessions, giving the motivational interviewing counsellors the opportunity to discuss the visit with the participant. The intervention was delivered by 21 trained counsellors supervised by the Project CHOICES Efficacy Study Research Team, and six contraceptive care providers (physicians and family planning nurses). Reimbursement for participants' time was offered for intervention sessions.

### How was the trial conducted?

Women aged 18–44 years and currently at risk for an alcohol-exposed pregnancy, were recruited from jails, drug and alcohol treatment centres, suburban primary care practices, a hospital-based gynaecology clinic, and a Medicaid health maintenance organisation in Florida, Texas, and Virginia (United States).

Women were eligible to participate in the study if they: had no condition causing infertility (tubal ligation, hysterectomy, menopause, or other reason); were not pregnant or planning on becoming pregnant in the next nine months; had vaginal intercourse during the previous three months without using effective contraception; had been drinking in a risky way; and were available for the nine-month follow-up period.

A total of 830 women participated, and were randomly allocated to either the intervention group (416) or the control group (414). Women in the control group were given brochures on drinking and women's health, as well as a referral guide to local resources. Almost all participants in the intervention group (98%) received at least one session of counselling, and 63% received all four sessions. On average, participants attended three counselling sessions, and approximately 70% attended a contraception consultation visit.

There were no significant differences in the sociodemographic and clinical characteristics of the intervention and control groups at baseline. Study participants had an average age of 30 years, were predominately African American (48%), had never been married (51%), and had annual incomes of under $20,000 (55%). Over half (56%) met the criteria for alcohol dependence, and both illicit drug use (greater than 90%) and tobacco smoking (greater than 70%) were highly prevalent in the population. Around a third (30%) consumed an average of eight drinks per occasion, and roughly the same proportion (33%) reported no contraception use, with the remainder using contraception inconsistently or ineffectively.

Participants were interviewed at baseline, and then (if possible) assessed again at three-, six-, and nine-month follow-ups. The analysis included 665 participants who completed the three-month follow-up interview, 604 who completed the six-month follow-up interview, and 593 who completed the nine-month follow-up interview, with approximately equal numbers in treatment and control groups at each of the phases.

The primary outcomes were: (1) risk of alcohol-exposed pregnancy; (2) risky drinking; and (3) ineffective contraception use. Women consuming more than five drinks on any day or more than eight drinks per week on average, were considered risky drinkers. Women who had intercourse without effective contraception were considered at risk of an unplanned pregnancy. Reversing either or both types of risk was deemed to result in a reduced risk of an alcohol-exposed pregnancy.

Analyses were conducted to determine the overall odds of an alcohol-exposed pregnancy – showing the risk-reduction impact of receiving the intervention versus not receiving the intervention. Analyses were also repeated to determine the odds of an alcohol-exposed pregnancy when various 'confounding variables' were removed (ie, factors that could have a hidden effect on the outcomes). These confounding variables were:
- number of male intercourse partners;
- AUDIT questionnaire scores;
- readiness to change ineffective contraceptive use;
- processes of change for alcohol;
- the perceived pros and cons of alcohol;
- temptation to drink alcohol.

## Main findings

The Project CHOICES intervention was associated with statistically significant benefits across all primary outcomes, with and without the influence of confounding variables (see ▸ above).

At every follow-up point, the odds of being at reduced risk of an alcohol-exposed pregnancy were roughly twofold greater in the intervention group than in the control group. After removing the effects of confounding variables, these odds increased further, with women in the intervention group again significantly more likely than women in the control group to be at reduced risk of an alcohol-exposed pregnancy.

Differences in the risk-reduction impact in the intervention group versus the control group were considerable – 18%, 17%, and 15% at the three, six, and nine-month follow-ups. However, many women in the control group also reduced their risk of an alcohol-exposed pregnancy over the course of the study (see ▸ chart).

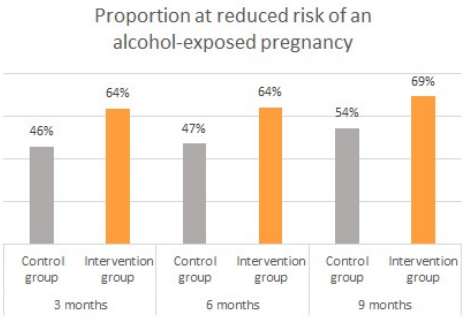
Women who completed the study and women who did not participate in follow-up assessments were very similar. The only significant difference was that women who couldn't be followed-up were not educated to more than a high school level.

Of the 82 participants lost to follow-up after they participated in the three-month follow-up interview, 53% in the control group and 70% in the intervention group had reduced their risk of an alcohol-exposed pregnancy. When it was assumed that all participants lost to follow-up were at risk of an alcohol-exposed pregnancy, the odds of a risk-reduction impact in the intervention group versus the control group were found to be lower but still significant at the three, six, and nine-month follow-ups, indicating that there was a benefit to being

assigned to the intervention. Taken together, these findings do not suggest that the loss to follow-up caused a major bias to the study findings.

## The authors' conclusions

The featured study demonstrated that a brief behavioural motivational intervention, delivered over several sessions, could produce significant reductions in the risk of an alcohol-exposed pregnancy. Although women in both intervention and control groups reduced their risk of an alcohol-exposed pregnancy by instituting changes in the targeted risk behaviours, the odds of being at reduced risk of an alcohol-exposed pregnancy were more than double in the Project CHOICES intervention group than the control group.




**Significantly more women reduced their risk of an alcohol-exposed pregnancy in the intervention group than the control group at each follow-up point, but a considerable proportion of women in the control group also reduced their risk of an alcohol-exposed pregnancy.**

Women who are not planning to become pregnant may think they have little reason to be concerned about either their drinking or contraceptive practices. Findings from this study indicate that women who are at risk of an alcohol-exposed pregnancy can be made aware of this risk, and make subsequent changes to reduce their risk.

Further research is needed to determine which components of the intervention were most effective, how a minimal intervention could remain effective in the long term, and the extent to which this intervention can prove effective in populations not included in this study.

In view of the results, and considering that brief interventions are cost effective (1 2), the Project CHOICES intervention appears to be a good candidate for large-scale implementation to reduce the risk of alcohol-exposed pregnancies in high-risk populations.

**FINDINGS COMMENTARY** The featured study found that a motivational counselling intervention, delivered over several sessions, can reduce the risk of an alcohol-exposed pregnancy by simultaneously tackling risky drinking and ineffective use of contraception. While around half of women in the information-only control group also reduced their risk of an alcohol-exposed pregnancy, the odds of being at a reduced risk of an alcohol-exposed pregnancy were roughly twofold greater in the intervention group at each follow-up point.

Possible explanations for the reduction in risk among women in the control group include:
• A phenomenon in research known as 'regression to the mean', which is the tendency for unusually extreme measurements to be followed by measurements closer to the population average. In other words, women who were identified as 'high risk' at baseline may have become less so over time.
• The control condition itself having an impact, through women being alerted to the fact that they were 'high risk' during the course of giving their consent to participate and/or through receiving information indicating that they might be risking their health. Women in the control group were given brochures on drinking and women's health, as well as a referral guide to local resources. (Is a leaflet all it takes? Unfold the supplementary text for a brief discussion).

Close supplementary text

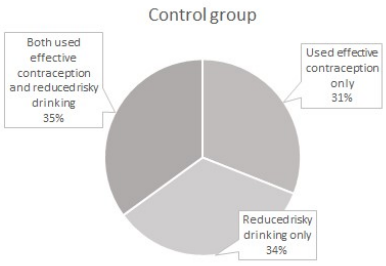
### Is a leaflet all it takes?

The English Screening and Intervention Programme for Sensible drinking (SIPS) trials found that a terse 30-second warning that the participant was risking their health through excessive drinking, plus an alcohol information and advice leaflet, was just as effective as a fully-fledged brief intervention. Did this mean that 'less is more'? Drug and Alcohol Findings discuss why this may be over-reading the study's implications in the Alcohol Treatment Matrix. Whatever benefits there were came after patients or offenders had been quizzed by research staff about their drinking and related problems and their readiness to do something about these – possibly thought-provoking interventions in themselves.

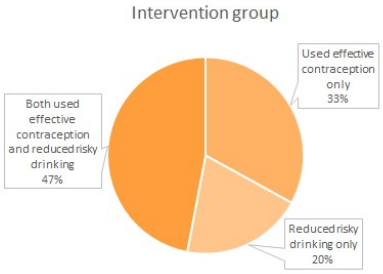
Experts have also stressed that the findings do not mean handing over an alcohol advice leaflet is all it takes. Screening plus the script of SIPS's control intervention incorporated assessment, strong feedback on that assessment, an implicit call to action to stop "excessive" drinking above "safe", "recommended" and "sensible" levels, as well as a reminder in the form of the leaflet.

Close supplementary text

At the final follow-up there did not appear to be a big difference in the average number of binge-drinking episodes between the intervention group and control group: the number of episodes decreased from 30 at baseline to seven at the nine-month follow-up in the intervention group, versus 29 binge-drinking episodes at baseline and 10 at the nine-month follow-up in the control group. The 'median' number of drinks per week (or midpoint in the range of values) were quite similar too – they decreased from 36 drinks at baseline to two drinks at the nine-month follow-up in the intervention group, compared to 38 drinks at baseline and three drinks at the nine-month follow-up for the control



group. However, if we examine the way that risk-reduction was distributed more differences become apparent. Proportionately more women in the control group reduced their risky drinking only, and this was relatively stable at three and nine months (35% and 34% respectively, versus 28% and 20%). But, a greater proportion of women in the intervention group reduced their risk through addressing both their drinking and contraceptive use (see ▶ chart). As the featured authors said, "women receiving the intervention were more likely to adopt changes in both targeted behaviors simultaneously, thereby maximizing the likelihood of avoiding an [alcohol-exposed pregnancy]".




**Proportionately more women in the intervention group reduced their risk at nine months through addressing both their drinking and contraceptive use.**

Project CHOICES focused on the period before conception, aiming to increase participants' motivation and commitment to change risky drinking and ineffective contraception in order to prevent an alcohol-exposed pregnancy from occurring in the first place. Also analysed in the Effectiveness Bank is CHOICES Plus, which offered a bundle of services in primary care settings, addressing drinking and ineffective contraception plus smoking, in *half* the number of sessions. After nine months, women assigned to the intervention had a significantly lower risk of alcohol- and tobacco-exposed pregnancies than women assigned to brief advice.

With evidence across a range of settings that CHOICES can significantly reduce the risk of alcohol-exposed pregnancies, the original programme has already been embraced in the US, and implemented with funding from the Substance Abuse and Mental Health Services Administration and the Centers for Disease Control and Prevention.

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