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Project title: Brief alcohol intervention to reduce risky drinking in pregnancy: a pilot randomised controlled trial.

Authors:
Professor Eileen Kaner - Newcastle University
Professor Judith Rankin - Newcastle University
Mrs Moira Hodgson - Newcastle upon Tyne Hospitals NHS Foundation Trust
Professor Elaine McColl - Newcastle University
Mrs Kirsty Laing - Newcastle University
Dr Mark Deverill - Newcastle University
Ms Denise Howel - Newcastle University

Plain language summary
In the 2005 Infant Feeding Survey, 8% of mothers said they drank alcohol when pregnant at levels that can affect fetal development. These effects have considerable impact on children's health and on service use. Asking women in antenatal care how much they drink, then offering brief tailored health advice to those drinking excessively, can help them to reduce or stop their alcohol use. This study aimed to show whether enough pregnant women would take part and stay involved in a UK trial for the trial to be able to conclude whether this approach is acceptable and has benefits.

Between February 2012 and June 2013, 103 community midwives in northeast England reviewed the medical records of women coming to antenatal clinics. With the women's consent, they asked three standard questions about how much alcohol they drank; and asked any who said they drank above 1-2 units once or twice a week for written consent to participate, before giving their usual advice on alcohol. Participants completed a questionnaire on alcohol consumption and health-related quality of life. Half the midwives, randomly selected, were trained to give 5 minutes of tailored advice on alcohol with a prepared information sheet that participants could take home; women receiving this were contacted by an alcohol counsellor to offer 20 minutes of discussion at their GP surgery to motivate them to drink less and identify ways to do so. After 20-24 weeks, and six months after birth, a researcher telephoned participants with no pregnancy or birth complications to repeat the questionnaire, and to ask them what services they had used. Weight and gestational age at birth of their babies were obtained from medical records.

1421 women were approached. Of 1373 who answered the alcohol questions, 21 said they drank at a risky level. Nine were not asked to take part because they were under 18, had come late to antenatal care, had a history of substance misuse or had difficulty with English. 12 women were eligible to take part and nine agreed to this. None of the four women offered the 20 minute session wished or agreed a time for this. Five women were followed up at 20-24 weeks; two were followed up six months after birth.

Too few women were eligible to suggest a full trial could reach conclusive results. Investigating pregnant women's views on alcohol and pregnancy would show whether they are now less likely to drink alcohol, or are less likely to tell their midwife about this, than in the previous decade.

Keywords
Pregnancy, Alcohol, Screening, Brief Intervention, Trial, Midwife, Motivational Interviewing, Public Health.

Summary of research findings
BACKGROUND
In 2005 8% of mothers in England and Wales reported that, while pregnant, they had exceeded medically recommended levels for low risk drinking in pregnancy [1]. With a birth population of about 650,000 in 2010, this translates to 58,000 registered births [2] that might have been significantly alcohol exposed. Given the dose-dependent teratogenic effects of heavy alcohol consumption [3-5], there is a need for clear, consistent and effective alcohol advice in antenatal care [1]. A robust evidence-base supports screening and brief alcohol intervention in other populations [6], whereby risky drinkers receive short personalised advice or counselling to promote reduced drinking [7, 8]. One-off brief (<30 min) interventions (BIs) with pregnant women in healthcare settings in other countries have shown positive effects on antenatal drinking and birth outcomes [9-12] and may have a similar effect to more intensive interventions such as CBT [13]. However, this promising international evidence for BI in antenatal care has not been tested in the UK health system. To evaluate complex interventions, a feasibility study is recommended prior to a full trial [14]. The RADiANT study aimed to investigate whether it is possible to recruit and retain pregnant women in a randomised controlled trial (RCT) of BI aimed at reducing risky drinking in women receiving antenatal care. The objectives were:

1. To conduct a feasibility RCT comparing BI to standard advice about alcohol in antenatal care
2. To estimate patient eligibility, recruitment, randomisation, retention and response rates to inform a future definitive trial
3. To develop methods and instruments for data collection for an economic evaluation of BI in a definitive trial
4. To develop the protocol for a definitive trial

METHODS
The feasibility trial rehearsed a parallel group, non-blinded trial comparing five minutes of simple structured and tailored alcohol advice from a midwife plus a 20 minute BI delivered by a trained alcohol counsellor (intervention) with standard advice on drinking in pregnancy delivered by midwives (treatment as usual). Community midwives (n=103) from four NHS acute Trusts in northeast England were randomised in a 1:1 ratio to either control or intervention group with no concealment of allocation, and trained in the appropriate procedures. They sought verbal consent to screen all women undergoing routine antenatal care and completed an anonymised eligibility screening form. Inclusion criteria were: aged ≥18 years, attending routine antenatal care at ≤16 weeks gestation, able to provide verbal agreement to be screened for alcohol, screening positive for risky alcohol use during pregnancy (score >2 on AUDIT-C) [15], and able to give written consent to participate. Exclusion criteria were: pregnancy complications or multiple pregnancy; difficulty understanding English; lacking cognitive capacity to understand the research; history of substance use and/or alcohol dependence; experiencing a severe mental or physical illness.

Midwives invited any women eligible to give written consent to participate. Treatments were delivered immediately after screening, consent and questionnaire completion. The alcohol counsellor contacted intervention group participants by phone to offer a 20 minute BI, based on motivational interviewing, at their GP surgery within two weeks of recruitment.
The primary outcomes were rates of eligibility, recruitment, intervention delivery and participant retention at last follow-up; the proposed outcomes for a future trial were also measured to estimate completion rates. Baseline measures were: the 7-day Time-Line Follow-Back (TLFB) tool [16-19], a simple diary detailing alcohol use since pregnancy was known; AUDIT-C [20], completed regarding drinking in the six months before pregnancy; the EQ-5D-3L instrument measuring quality of life [21].
Midwives abstracted data from participants' booking notes on health status and social circumstances. The project manager re-administered screening and outcome measures to eligible participants by telephone in 3rd trimester and six month postpartum follow-ups, asking participants latterly about research acceptability; hospital staff abstracted birth outcome data from records;. Feedback was gathered via in-depth interviews with 18 consenting midwives after screening had ended.
It was estimated that 8% of women were likely to screen positive [1], of whom 10% were expected to be ineligible due to a history of substance misuse [22], and 20% due to other criteria. A 22% refusal rate of those eligible was predicted [23], and an attrition rate of 33% at the first follow-up was anticipated [24]. 25% attrition from the first to second follow-up was conservatively estimated. It was therefore estimated that 2742 women would need to be screened to recruit 120 participants, 60 of whom would provide data at second follow-up. Support for continuing to a main trial was to constitute recruitment of 78% of those eligible and retention of 67% and 75% of participants at the two follow-up stages; or a finding that these rates would be achievable with feasible modifications to protocol

The study received a favourable ethical opinion from Newcastle & North Tyneside 2 NHS Research Ethics Committee (MREC reference number: 11/NE/0205).

KEY FINDINGS
The total number identified by midwives was 1421 women; Table 1 gives summary statistics (missing data ≤1%). Not all 103 midwives recruited over the whole period as the number of sites increased from 1 to 4 over the study.

Table 1 Summary characteristics

Mean age in years: n = 1406, statistic = 28.5, range = 14-48, SD = 5.68
Mean BMI (weight/height2): n = 1385, statistic = 26.0, range = 15.4-49.5, SD = 5.56
Median previous pregnancies: n = 1417, statistic = 1, range = 0-11
Median previous live births: n = 1415, statistic = 1, range = 0-9
Ethnicity White: n = 1417, statistic = 85%
Married/living with partner: n = 1416, statistic = 81%
Employed: n = 1419, statistic = 64%
Educated post-16: n = 1353, statistic = 72%
Degree or equivalent: n = 1342, statistic = 48%
Currently smoking: n = 1403, statistic = 15.3%

Table 2 gives numbers of women at each trial stage. Of 1421 women approached, 23 declined screening; AUDIT-C responses were missing for 17; and eight had answered in respect of the pre-pregnancy period. Of 1373 women supplying baseline AUDIT-C data, 239 (17.4%) reported drinking alcohol since pregnancy was confirmed; 21 women scored >2 on AUDIT-C (1.5% of screened, rather than the 8% predicted). Nine women screening positive were excluded: two were aged < 18, six were past their first trimester, three had a history of substance misuse and one had difficulty with English. Twelve women were fully eligible (57% of those screening positive). Rates of eligibility were similar across sites.
Nine women were recruited; of the four recruited by midwives allocated to the intervention group, three declined the 20 minute intervention and one repeatedly deferred this. All nine were eligible for follow-up in their third trimester; two women withdrew when contacted and two could not be contacted. Five women completed the interview and consented to the final follow-up (56% of those recruited). At six months postpartum, birth outcome data were abstracted for four women (the study ended too early to do so for the fifth participant); two could not be contacted, and two women completed the final interview (50% from the first follow-up, or 22% of those recruited).

Table 2 Numbers of women at each stage of recruitment

Approached: n = 1421
Screened: n = 1373, % of screened = 100
Scored >2 on AUDIT-C: n = 21, % of screened = 1.5
Fully eligible: n = 12, % of screened = 0.9, % of fully eligible = 100
Recruited: n = 9, % of screened = 0.7, % of fully eligible = 75
Followed up 3rd trimester: n = 5, % of screened = 0.4, % of fully eligible = 42
Followed up 6m postpartum: n = 2, % of screened = 0.1, % of fully eligible = 17

Both the women who completed follow-ups found the research tasks acceptable. In interviews, midwives generally reported that the training had prepared them for the research tasks and that materials were appropriate. They found screening practical to accommodate after the first few cases. Recruitment was more demanding; one intervention arm midwife reported taking 40 minutes to do so, with at least 10 minutes on the brief advice. Midwives said women expected them to ask about drinking; one said she would want to ‘probe further’ as to why any woman declined to answer. Some midwives may not have screened women they expected to be ineligible. One found the brief advice at odds with Trust policy in relation to no alcohol in pregnancy (M7).

Some midwives thought women would disclose any alcohol use to them, and that few now drink while pregnant due to greater awareness of the risks:

“… I don’t come across many women who drink in pregnancy” (M9)

Others thought women may not disclose risky alcohol use because they think the midwife wants to hear otherwise:

“…they are gonna say no I’m only drinking 1 or 2 units because they know that’s what they were told at the beginning is what we would expect…” (M5)

It was thought that possible social services involvement might be a concern for some women but not for most.

EXPECTED IMPACT
The numbers of women who could be screened by midwives and identified as eligible in this feasibility trial were not large enough to inform estimates of recruitment and retention. The rate of screening positive was markedly lower than predicted in the protocol, and below the 3% reported in the 2010 Infant Feeding Survey [1]. While alcohol screening and intervention in antenatal care is a national priority, the results show further exploratory research is needed to inform this.

CONCLUSIONS
The results do not support continuing to a main trial. For a full trial of alcohol BI in antenatal care to be feasible, study design should be informed by a more detailed understanding of influences on women's attitudes to alcohol, health and discussion of pregnancy. Other pathways should be explored, such as screening by other health professionals, online self-completion, or pre- pregnancy intervention.

Patient and public involvement
The design of this project was discussed with a participant advisory group for an earlier project, applicant Kirsty Laing's NIHR doctoral fellowship (ref. RDA/07/03/010), which focused on understanding alcohol-related risk in pregnancy. The group consisted of six women who had given birth within the preceding year, recruited equally from two postnatal centres in Newcastle. We also worked closely, in the development and execution of this project, with both specialist Drug and Alcohol liaison midwives and community midwives employed by four NHS acute trusts. In the development of the current proposal, we conducted an interview and a focus group with seven community midwives to gain their opinion about the screening and brief intervention process and tools.

Three women who were pregnant or had given birth within the preceding year were invited, at the start of the trial, to join the Trial Steering Committee (TSC) as lay members; two were able to join the committee. Their input has been invaluable, particularly in conveying vividly to TSC members how midwives and the antenatal setting may appear to women. For instance, they described to the group their own experiences of being asked about alcohol at booking by their midwives and feeling that this was rushed without the consequences of the discussion being clarified. This led to the decision to screen at a later point in antenatal care when women might be less anxious (Amendment 2). They also highlighted that women might feel too intimidated to talk about alcohol intake with their midwife because of the nature of their relationship and the possible consequences and fear of social services involvement. This led to the training of a research midwife and a research nurse to support the research by taking on demographic data transfer, identification and screening at some antenatal clinics, and thus provide an indication of whether women responded differently to questions about alcohol from someone other than their own midwife. The lay members also commented on issues for women such as the burden of proposed research questionnaires, leading to the baseline questionnaire being scaled down in Amendment 1, and at what stage women were approached about the research, contributing to the decision to screen at 16 weeks gestation rather than at booking (Amendment 2) . They were also instrumental in identifying within TSC meetings that a qualitative study to investigate pregnant women's

views on alcohol and pregnancy would be an important direction for future research given the trial results. One of the lay members has reviewed this report and added text to this section to clarify her contribution.

The research team have learnt through the process the importance of facilitating lay member's involvement in such meetings, for instance by briefing them in advance, ensuring that they are able to attend with their children, and ensuring that they have space to contribute to meetings and that academic TSC members seek their views.

Data sharing statement

See link [https://www.nihr.ac.uk/documents/nihr-position-on-the-sharing-of-research-data/12253] for the NIHR position of the sharing of research data. The NIHR strongly supports the sharing of data in the most appropriate way, to help deliver research that maximises benefits to patients and the wider public, the health and care system and which contributes to economic growth in the UK. All requests for data should be directed to the award holder and managed by the award holder.

Disclaimer

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This final report has not been peer-reviewed. The report was examined by the Programme Director at the time of submission to assess completeness against the stated aims.

This project was carried out between September 2011 and September 2013.

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