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# Brief alcohol intervention to reduce risky drinking in pregnancy: a pilot randomised controlled trial

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 17/08/2011 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 17/08/2011 | Stopped | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 29/10/2018 | Mental and Behavioural Disorders | [ ] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
10788

# Study information

### Scientific Title
Brief alcohol intervention to reduce risky drinking in pregnancy: a pilot randomised controlled trial

### Acronym
RADiANT

### Study objectives
RADiANT: Reducing Alcohol Drinking in ANTenatal women v1.0, this study will investigate whether it is possible to recruit and retain pregnant women in a pilot trial of brief intervention aimed at reducing risky drinking in women receiving antenatal care. The comparison condition will be the usual advice delivered by midwives. We will train midwives to assess pregnant women s alcohol consumption and obtain consent from those drinking at risky levels to participate in the pilot trial. A trained alcohol counsellor will deliver the brief intervention which will help women understand the nature of alcohol-related risk to their baby and to themselves and identify simple ways of cutting down on their drinking. Subsequently, we will establish if pregnant women are willing to be followed up in the third trimester of pregnancy and six months after their baby is born. We will also measure womens alcohol consumption, their quality of life and use of NHS services using validated questionnaires. From medical records we will, with participating women's consent, collect information relating to their social circumstances including their age and the number of children they have had. Lastly, we will also record the baby s birth weight and the age at which the baby was born measured in terms of the number of weeks of pregnancy, and data on fetal loss and abnormality. The information we collect will be used to determine if it will be possible to conduct a full trial which will measure the impact of brief intervention at reducing risky drinking in pregnancy compared to standard advice delivered by midwives.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
11/NE/0205

### Study design
Randomised; Interventional; Design type: Prevention, Screening

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
GP practice

### Study type(s)
Prevention

### Participant information sheet

### Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

### Interventions
Brief alcohol advice, Control condition - 5 minutes of simple structured alcohol advice delivered by midwife [Treatment As Usual (TAU)].

Brief alcohol intervention, Experimental condition - 5 minutes of simple structured alcohol advice delivered by midwife (TAU) plus a 20 minute client-centred intervention based on motivational interviewing delivered by alcohol counsellor within 2 weeks of initial appointment.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
Participants recruited & retained; Timepoint(s): Baseline, 3rd trimester of pregnancy (6 months), 6 months post partum

### Secondary outcome measures
Alcohol consumption; Timepoint(s): In third trimester (6 months from baseline)

### Overall study start date
02/01/2012

### Completion date
31/08/2012

### Reason abandoned (if study stopped)
Participant recruitment issue

## Eligibility

### Key inclusion criteria
1. Women attending routine antenatal care
2. Women who book an antenatal appointment before 16 weeks gestation
3. Women who are aged 18 years or above
4. Women who provide verbal agreement to be screened for alcohol (written consent is not gathered for screening as this is usual practice in antenatal care)
5. Women who screen positive for risky alcohol use [score of 5+ on the Alcohol Use Disorders Identification Test(AUDIT-C)]
6. Women who give written consent to participate in the research; Target Gender: Female ; Lower Age Limit 18 years

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Female

### Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

### Key exclusion criteria
1. Women with pregnancy complications (e.g. diabetes, congenital anomaly)
2. Women with multiple pregnancies
3. Women who book an antenatal appointment after 16 weeks gestation
4. Women with a history of substance use and/or alcohol dependence
5. Women who do not speak English sufficiently to participate
6. Women who are experiencing a severe mental or physical illness which is likely to impact upon the intervention or ability to be followed-up
7. Women who are already participating in other alcohol-related research
8. Women who lack the cognitive capacity to understand the research and what is involved (and are therefore unable to provide informed consent to participate)

### Date of first enrolment
02/01/2012

### Date of final enrolment
31/08/2012

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Institute of Health and Society**
Newcastle Upon Tyne
United Kingdom
NE2 4AA

## Sponsor information

### Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

### Sponsor details
Midwifery Research Dept
Leazes Wing
Queen Victoria Road
Newcastle upon Tyne
England
United Kingdom
NE1 4LP

### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/05p40t847

## Funder(s)

### Funder type
Government

### Funder Name
National Institute of Health Research (NIHR) (UK)

## Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 24/09/2012 | | Yes | No |