

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

<b>Submission date</b> 17/08/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 17/08/2011	<b>Overall study status</b> Stopped	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 29/10/2018	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

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 women's 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

## **Study type(s)**

Prevention

## **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(s)**

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

**Key secondary outcome(s)**

Alcohol consumption; Timepoint(s): In third trimester (6 months from baseline)

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

### **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**

United Kingdom

England

### **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)

### **ROR**

<https://ror.org/05p40t847>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

National Institute of Health Research (NIHR) (UK)

## Results and Publications

**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?
<a href="#">Protocol article</a>	protocol	24/09/2012		Yes	No