ISRCTN43218782 https://doi.org/10.1186/ISRCTN43218782

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

Contact name
Dr Graeme Wilson

Contact details
Institute of Health and Society
21-23 Claremont Place
Newcastle Upon Tyne
United Kingdom
NE2 4AA
-
g.b.wilson@ncl.ac.uk

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