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Newcastle Twin Antenatal Programme (TAP): a randomised controlled trial (RCT) study

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 24/02/2015	**Condition category** Pregnancy and Childbirth	

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
RRCC/01F/31

Study information

Scientific Title
Newcastle Twin Antenatal Programme (TAP): a randomised controlled trial (RCT) study

Study objectives
The primary hypothesis of the study is that the incidence of postnatal depression is reduced in women participating in a twin antenatal programme compared to women with twins in a control group receiving standard care and relative to women expecting one baby receiving standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Postnatal depression

Interventions
1. Twin antenatal programme
2. Women with twins receiving standard care

Intervention Type
Behavioural

Primary outcome measure
Post-natal depression

Secondary outcome measures
1. Maternal anxiety
2. Emotional well-being

3. Maternal satisfaction
4. Parental stress.

Overall study start date
10/01/2001

Completion date
10/01/2003

Eligibility

Key inclusion criteria
Women who have given birth to healthy babies

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
10/01/2001

Date of final enrolment
10/01/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
19 Tankerville Terrace
Newcastle upon Tyne
United Kingdom
NE2 3AJ

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (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?
Results article	results	01/09/2014		Yes	No