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A DEcision aid for Prenatal Testing

Submission date 02/02/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/05/2005	**Overall study status** Completed	
Last Edited 18/12/2017	**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
237124; ACTRN12606000234516

Study information

Scientific Title
A randomised controlled trial of a decision aid for prenatal screening and diagnosis

Acronym
ADEPT

Study objectives
Compared with pregnant women receiving a pamphlet, pregnant women who receive a decision aid on prenatal testing for foetal abnormality will have:
1. A higher rate of informed choice
2. Less decisional conflict

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Royal Australian College of General Practitioners gave approval on the 20th December 2004 (ref: NREEC 03-16)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Prenatal testing of foetal abnormalities

Interventions
Decision aid versus pamphlet:
1. The decision aid for prenatal testing of foetal abnormalities has been developed using the three steps of the Ottawa Decision Support framework:
1.1. Identifying needs
1.2. Providing decision support
1.3. Evaluating decision support
2. The pamphlet has been developed by Genetic Health Services Victoria (GHSV). The pamphlet contains information on maternal age related risk, screening and diagnostic tests, a table summarising the tests available and what conditions they detect.

Data will be collected from women using questionnaires at 14 weeks and 24 weeks gestation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Informed choice, measured by the percentage of women in each arm of the trial identified as making an informed choice using the multi-dimensional measure of informed choice (MMIC) scale
2. Decisional conflict, measured by the difference in mean scores of the Decisional Conflict Scale between women in each arm

Secondary outcome measures
1. Anxiety
2. Depression
3. Attachment to the pregnancy/foetus
4. Acceptability of the decision aid to both woman and GP

Overall study start date
01/08/2004

Completion date
30/04/2006

Eligibility

Key inclusion criteria
Pregnant women attending a participating general practice (GP) were eligible to participate provided they were:
1. Aged 18 years or older
2. Equal to or less than 12 weeks gestation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
500

Key exclusion criteria

1. Non-English speaking
2. Were unable to give written informed consent
3. Required genetic counselling due to a family history of an inherited condition or recurrent risk for foetal abnormality
4. Having already undertaken testing for foetal abnormality in this pregnancy
5. Experiencing vaginal bleeding
6. Currently having a known multiple pregnancy

Date of first enrolment
01/08/2004

Date of final enrolment
30/04/2006

Locations

Countries of recruitment
Australia

Study participating centre
Public Health Genetics Unit
Parkville
Australia
3052

Sponsor information

Organisation
Murdoch Childrens Research Institute (MCRI) (Australia)

Sponsor details
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Sponsor type
Research organisation

Website
http://www.mcri.edu.au/

ROR
https://ror.org/048fyec77

Funder(s)

Funder type
Research council

Funder Name
National Health and Medical Research Council (NHMRC) (Australia)

Alternative Name(s)
NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

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	13/04/2006		Yes	No
Results article	Results	01/02/2008		Yes	No