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Assisting decision making in menorrhagia in primary care: a randomised controlled trial to compare computerised decision analysis with patient information leaflet. MENTIP study: Menorrhagia Treatment Information and Preferences

Submission date
19/02/2003

Recruitment status
No longer recruiting

Registration date
19/02/2003

Overall study status
Completed

Last Edited
03/03/2008

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Joanne Protheroe

Contact details
NPCRDC
5th Floor Williamson Building
The University of Manchester
Oxford Road
Manchester
United Kingdom
M13 9PL
+44 (0)161 2757601
j.protheroe@man.ac.uk

Additional identifiers

Protocol serial number
G106/1048

Study information

Scientific Title

Acronym
MENTIP

Study objectives
Aims:
Since patient information leaflets are highly accessible and relatively cheap, they may be considered the standard against which more complex decision aids must be evaluated.
The purpose of this study is to evaluate whether the addition of decision analysis to written information improves the process of decision-making in women consulting their doctor with heavy periods, compared with written information alone.

Objectives:
To answer the following question: Is the addition of decision analysis to written information significantly more effective at reducing decisional conflict compared with written information alone.

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Menorrhagia

Interventions
1. Control group: Patient Information Leaflet (PIL)
2. Intervention group: PIL and Clinical Guidance Tree (computerised Decision Analysis)

Intervention Type
Other

Phase

Not Specified

Primary outcome(s)
The primary outcome measure will be the Decisional Conflict Scale (DCS), a questionnaire developed by O'Connor (1999) for use in studies of decision-making processes. This instrument measures a person's perception of: personal uncertainty in making a choice about health care options, the modifiable factors (such as feeling uninformed, unsupported and unclear about personal values) and the quality of the decision made (in terms of satisfaction with the choice and expectation to maintain).

Key secondary outcome(s))
Not provided at time of registration

Completion date
09/09/2005

Eligibility

Key inclusion criteria
Women aged 30-49 years presenting to GP with heavy periods

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Women with confirmed or provisional diagnoses of physical pathology (including cancer, endometriosis, fibroids, prolapse and cysts).
2. Women considered by their GP to be unsuitable due to physical or psychological impairment.
3. Women unable to understand English. Because of the nature of the intervention (i.e. a written computer programme), some proficiency in English is required.

Date of first enrolment
01/02/2003

Date of final enrolment
09/09/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NPCRDC
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) Special Training Fellowship (UK) (ref: G106/1048)

Funder Name
National Primary Care Research And Development Centre (NPCRDC) (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?
Results article	Results	01/09/2007		Yes	No