

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	<input type="checkbox"/> Prospectively registered
Registration date 19/02/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/03/2008	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

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 measure

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).

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/02/2003

Completion date

09/09/2005

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

300

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

England

United Kingdom

Study participating centre

NPCRDC

Manchester

United Kingdom

M13 9PL

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

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Sponsor type

Research council

Website

<http://www.mrc.ac.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

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	01/09/2007		Yes	No