

# 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

<b>Submission date</b> 19/02/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 19/02/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/03/2008	<b>Condition category</b> 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**

20 Park Crescent

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[clinical.trial@headoffice.mrc.ac.uk](mailto:clinical.trial@headoffice.mrc.ac.uk)

**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?
<a href="#">Results article</a>	Results	01/09/2007		Yes	No