

# A multi-centre randomised controlled trial assessing the costs and benefits of using structured information and analysis of women's preferences in the management of menorrhagia

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<b>Registration date</b> 25/04/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/11/2022	<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

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

HTA 93/18/12

# Study information

### Scientific Title

A multi-centre randomised controlled trial assessing the costs and benefits of using structured information and analysis of women's preferences in the management of menorrhagia

### Study objectives

Each of the medical and surgical therapies available for the treatment of menorrhagia has different outcomes, risks and benefits. Women are likely to have different attitudes towards the trade-offs that present themselves when choosing a treatment. It is important, therefore, that women's preferences are taken into account when treatment decisions are being made. However, in order to share in decision making, women need structured and full information on menorrhagia and its treatment.

### 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)

Not specified

### Study type(s)

Not Specified

### Participant information sheet

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

Urological and genital diseases: Menstrual disorders

### Interventions

Randomised controlled trial. This study is made up of two phases. Phase I will involve developing structured information on menorrhagia in the form of a booklet and a video, together with an interview protocol to be used to assess women's preferences regarding the treatment of the condition. In Phase II, 600 women with menorrhagia referred to one of five hospitals will be randomised to standard management or to a new management strategy involving the provision of structured information and the assessment of preferences using the package developed in

Phase I. Women will be followed-up over 2 years to assess the effectiveness and cost-effectiveness of the new management strategy. The extensive data collected in Phase II of the study will facilitate secondary analyses that will provide information to improve the effectiveness and cost-effectiveness of the management of menorrhagia.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Women will be followed-up over 2 years to assess the effectiveness and cost-effectiveness of the new management strategy. The primary outcome was health status, measured using the 36-item short-form general health survey (SF-36) instrument.

**Secondary outcome measures**

Secondary outcomes included women's treatment preferences, treatments undergone and satisfaction. In the economic analyses, health outcomes were measured in terms of quality-adjusted life-years (QALYs) based on women's responses to the EQ-5D (EuroQol-5 dimensions) instrument.

**Overall study start date**

01/10/1995

**Completion date**

31/08/2000

**Eligibility****Key inclusion criteria**

Women with menorrhagia

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

200

**Key exclusion criteria**

Not provided at time of registration.

**Date of first enrolment**

01/10/1995

**Date of final enrolment**

31/08/2000

## Locations

**Countries of recruitment**

Switzerland

United Kingdom

**Study participating centre**

Council on Health Research for Development

Geneva

Switzerland

CH-1201

## Sponsor information

**Organisation**

Department of Health (UK)

**Sponsor details**

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**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/en/index.htm>

**ROR**

<https://ror.org/03sbpja79>

## Funder(s)

**Funder type**

Government

**Funder Name**

NIHR Health Technology Assessment Programme - HTA (UK)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan**

Not provided at time of registration

**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>	HTA monograph	01/12/2003		Yes	No