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# 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

**Submission date**
25/04/2003

**Recruitment status**
No longer recruiting

**Registration date**
25/04/2003

**Overall study status**
Completed

**Last Edited**
08/11/2022

**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**
Mr Andrew Kennedy

**Contact details**
Council on Health Research for Development
11 Rue de Cornavin
Geneva
Switzerland
CH-1201
+41 591 8900
kennedy@cohred.org

## Additional identifiers

**Protocol serial number**
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

## Study type(s)
Not Specified

## 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(s)

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.

### Key secondary outcome(s))
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.

### Completion date
31/08/2000

## Eligibility

### Key inclusion criteria
Women with menorrhagia

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Female

### 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
United Kingdom

Switzerland

### Study participating centre

**Council on Health Research for Development**
Geneva
Switzerland
CH-1201

# Sponsor information

**Organisation**
Department of Health (UK)

**ROR**
https://ror.org/03sbpja79

# Funder(s)

**Funder type**
Government

**Funder Name**
NIHR Health Technology Assessment Programme - HTA (UK)

# Results and Publications

**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? |
|---|---|---|---|---|---|
| Results article | HTA monograph | 01/12/2003 | | Yes | No |