

# Evaluation of guidelines for the referral and management of breast disorders: a pragmatic practice-based randomised trial

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/11/2019	<b>Condition category</b> Cancer	<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

PSI02-69

# Study information

### Scientific Title

Evaluation of guidelines for the referral and management of breast disorders: a pragmatic practice-based randomised trial

### Study objectives

The aim of this project is to implement and evaluate existing national guidelines for referral and management of breast disorders. Evaluation will be via a pragmatic practice based randomised trial. The guidelines include algorithms for the management of breast pain/diffuse lumpiness and breast lumps. A preliminary study will measure women's and GP's perceptions of risk for these presentations and the practical basis for a risk communication package will be developed. This will be followed by a practice based randomised trial in Wales.

### 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)

Other

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Breast cancer

### Interventions

Not provided at time of registration

### Intervention Type

Other

**Phase**

Not Specified

**Primary outcome measure**

1. Medical Interview Satisfaction Scale
2. SF36 Health Profile
3. Euroqol Health Status Index
4. Cost Utility Analysis
5. Rates of Referral

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/04/1995

**Completion date**

01/10/1999

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

30 Group practices

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

30 group practices

**Key exclusion criteria**

Does not match inclusion criteria

**Date of first enrolment**

01/04/1995

**Date of final enrolment**

01/10/1999

**Locations****Countries of recruitment**

United Kingdom

Wales

**Study participating centre**  
**University of Wales College of Medicine**  
Wrexham  
United Kingdom  
LL13 7YP

## Sponsor information

### Organisation

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

### Sponsor details

The Department of Health  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL

### Sponsor type

Government

### Website

<http://www.doh.gov.uk>

## Funder(s)

### Funder type

Government

### Funder Name

NHS Primary and Secondary Care Interface National Research and Development Programme (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	01/08/2002	28/11/2019	Yes	No