

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

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/11/2019	Condition category 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?
Results article	results	01/08/2002	28/11/2019	Yes	No