

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	☐ Prospectively registered ☐ Protocol
Registration date 23/01/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 28/11/2019	Condition category Cancer	☐ 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

Protocol serial number

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

Study type(s)

Other

Health condition(s) or problem(s) studied

Breast cancer

Interventions

Not provided at time of registration

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/10/1999

Eligibility

Key inclusion criteria

30 Group practices

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

Funder(s)

Funder type

Government

Funder Name

NHS Primary and Secondary Care Interface National Research and Development Programme (UK)

Results and Publications

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