

Randomised evaluation of a one-stop clinic for breast lump investigation

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 24/10/2019	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
C/OPD/17-3-94/CAWTHORN/D; N0467011719

Study information

Scientific Title

Randomised evaluation of a one-stop clinic for breast lump investigation

Study objectives

This will be through a RCT in comparison with a conventional model of care involving two clinic attendances and a separate mammography.

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)

Hospital

Study type(s)

Diagnostic

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

Women were randomised to attend either the one-stop or two-stop clinic

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Levels of anxiety, depression, quality of life. Styles of coping were compared in the 2 clinic groups, at first attendance, 6 days and 8 weeks after

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/1994

Completion date

30/09/1997

Eligibility

Key inclusion criteria

All women with a symptomatic breast condition referred for examination at a specialist breast clinic - either the same day diagnosis (1-stop clinic) or a wait for results clinic (2-stop clinic)

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

Not provided at time of registration

Key exclusion criteria

None so long as participants were able to complete the assessment

Date of first enrolment

01/10/1994

Date of final enrolment

30/09/1997

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department of Psychology

Bristol

United Kingdom

BS16 2JP

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

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

Government

Website

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

Funder(s)

Funder type

Government

Funder Name

NHS Executive South West (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	01/12/1998		Yes	No
Results article	results	01/02/1999		Yes	No