

# Joint and muscle aches, pains and stiffness in women with primary breast cancer

<b>Submission date</b> 28/09/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/10/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/10/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-joint-muscle-aches-pain-stiffness-women-breast-cancer-jacs>

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

7170

## Study information

### Scientific Title

A longitudinal cohort study of joint and muscle aches, pains and stiffness in women with primary breast cancer

**Acronym**

JACS

**Study objectives**

1. To establish the natural history of joint and muscle aches, pains and stiffness (JaMAPS) over time in women being treated for early breast cancer (BC)
2. To investigate whether and how the prevalence and natural history of JaMAPS differs in women receiving adjuvant therapy for invasive early BC from that in women following treatment for ductal carcinoma in situ (DCIS)
3. To explore the impact of JaMAPS on quality of life (QoL) in women with invasive early BC
4. To explore their impact on functional ability
5. To undertake an exploratory analysis of how the natural history of JaMAPS differs between adjuvant treatment groups

Study findings will be used to educate health professionals about the natural history and impact of these under-researched and under-treated symptoms, better equipping them to support patients and enabling them to provide more accurate information to patients to inform treatment decisions. Findings will inform future research into both the causes of JaMAPS in BC and into effective interventions.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

MREC approved on 04/08/2009, ref: 09/H0501/44

**Study design**

Observational multicentre non-randomised longitudinal cohort study

**Primary study design**

Observational

**Study type(s)**

Treatment

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

Breast cancer

**Interventions**

Interventions will be determined by findings.

Follow up length: 3 months

Study entry: other

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Descriptive statistics will be used to describe the prevalence at Times 1 - 5 of joint stiffness

**Key secondary outcome(s)**

1. The statistical significance (if any) of differences in pain prevalence, severity and interference
2. Descriptive statistics will be used to describe the QoL and functional status of women at each time
3. Descriptive statistics will be used to compare joint pain, pain severity and interference
4. Exploratory analysis, again using descriptive statistics and the mixed method approach to modelling

**Completion date**

31/12/2012

**Eligibility**

**Key inclusion criteria**

1. Diagnosis of BC (invasive or DCIS)
2. Aged at least 18 years old
3. No evidence of metastatic disease
4. Able to complete written records in English
5. Female

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**Total final enrolment**

543

**Key exclusion criteria**

Men will be excluded from this study because their numbers are likely to be extremely low: effects of gender on joint pain can explored in a future multi-centred study.

**Date of first enrolment**

27/01/2010

**Date of final enrolment**

31/12/2011

# Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

University Road

Southampton

United Kingdom

SO17 1BJ

# Sponsor information

## Organisation

Southampton University Hospitals NHS Trust (UK)

## ROR

<https://ror.org/0485axj58>

# Funder(s)

## Funder type

Charity

## Funder Name

Breast Cancer Campaign (UK) (ref: 2008MayPR49)

## Alternative Name(s)

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Other non-profit organizations

## Location

United Kingdom

# 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?
<a href="#">Results article</a>	results	25/06/2014		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Plain English results</a>			25/10/2022	No	Yes