

# GCaPPS: Genetic Cancer Prediction through Population Screening

<b>Submission date</b> 15/07/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/07/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/10/2022	<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-testing-ashkenazi-jewish-people-for-cancer-gcapps>

## Contact information

### Type(s)

Scientific

### Contact name

Prof Ian Jacobs

### Contact details

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## Additional identifiers

### Protocol serial number

08/0141

## Study information

Scientific Title

# Genetic Cancer Prediction through Population Screening

## Acronym

GCaPPS

## Study objectives

1. Systematic population testing detects more mutations than testing on the basis of family history alone
2. There is no increase in psychological morbidity with systematic population testing compared to genetic testing based on family history

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Great Ormond Street Hospital and Institute for Child Health Research Ethics Committee, 09/06 /2008, ref: 08/H0713/44

## Primary study design

Interventional

## Study design

Randomised controlled trial

## Study type(s)

Screening

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

Genetic testing for BRCA founder mutations

## Interventions

10,000 volunteers will be recruited in total; this number includes a pilot phase of 1,000 volunteers in the first year.

This is a randomised controlled trial comparing a systematic population based approach to genetic testing for germ-line cancer predisposition to the current approach based on family history. Interventions include the following:

1. Genetic counselling: All volunteers will receive pre-test education and counselling prior to decision making regarding testing.
2. Genetic testing: Genetic analysis for the 3 Jewish FM: 185 delAG, 5382 insC (in BRCA1) and 6174 delT (in BRCA2) will be performed on peripheral blood samples obtained in those individuals who consent to testing following counselling. All individuals in the systematic screening group and those individuals who have a positive family history of cancer in the family history group will undergo testing.
3. Questionnaires used include:
  - 3.1. Baseline questionnaire (collected before counselling)
  - 3.2. Post-counselling assessment questionnaire (after counselling, at decision making)
  - 3.3. Exit questionnaire (for those declining testing after counselling)
  - 3.4. Follow-up Questionnaire-1 (day 7 and 3 months after receiving test result)
  - 3.5. Follow-up Questionnaire-2 (1 year after receiving test result)
  - 3.6. Follow-up Questionnaire-3 (2 and 3 years after receiving test result)

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome(s)**

1. Number of founder mutations (FM) detected, assessed by the genetic test result
2. Acceptability
  - 2.1. Perception, attitudes towards BRCA1/2 testing: benefits, risks, limitations; cultural/religious influences; interest and intention, assessed by the baseline questionnaire and post-counselling assessment questionnaire
  - 2.2. Satisfaction with counselling: Genetic Counselling Satisfaction Scale (GCSS), assessed as part of post-counselling assessment questionnaire and exit questionnaire (for those declining testing after counselling)
  - 2.3. Uptake of testing
  - 2.4. Reasons for declining testing, assessed by the exit questionnaire (for those declining testing after counselling)
3. Psychological impact, assessed by the baseline questionnaire, Follow-up Questionnaires 1, 2 and 3. These included the following:
  - 3.1. Hospital Anxiety and Depression Scale (HADS): General well being, depression and anxiety
  - 3.2. Short Form 12 (SF12): Psychological Quality of life (QoL) tool
  - 3.3. Health Anxiety Inventory (HAI)
  - 3.4. Multidimensional Impact of Cancer Risk Assessment (MICRA). This measure is used in Follow-up Questionnaires 1, 2 and 3 to assess the impact of test result
4. Uptake of screening and preventive strategies. Behavioural outcomes assessed by the baseline questionnaire, Follow-up Questionnaires 2 and 3. They included the following assessments:
  - 4.1. Lifestyle behaviours (diet, exercise, alcohol, vitamins, etc.)
  - 4.2. Cancer screening behaviours
  - 4.3. Prophylactic surgery and chemoprevention
5. Health economics will be assessed by the baseline questionnaire, Follow-up Questionnaires 1, 2 and 3. This will involve within trial analysis of the counselling, screening and preventive strategies undertaken as well as modelling to estimate resource impact based on standard practise.
  - 5.1. Quality adjusted life years (QALYs)
  - 5.2. Cost-effectiveness, cost per case detected
6. The following will also be recorded:
  - 6.1. Socio-demographics, identity scale and women's health by the baseline questionnaire
  - 6.2. Knowledge assessment by the baseline questionnaire, post-counselling assessment questionnaire, and exit questionnaire (for those declining testing after counselling)
  - 6.3. Perceived risk, assessed by the baseline questionnaire, post-counselling assessment questionnaire, Follow-up Questionnaires 1, 2 and 3
  - 6.4. Fertility intention, assessed by the baseline questionnaire, Follow-up Questionnaire-2
  - 6.5. Impact of result on fertility intention, assessed by the Follow-up Questionnaires 1 and 2

See Interventions for timepoints at which the questionnaires will be carried out.

## **Key secondary outcome(s)**

No secondary outcome measures

**Completion date**

01/09/2016

## Eligibility

**Key inclusion criteria**

This is a healthy volunteer trial for Ashkenazi Jewish men and women. Inclusion criteria include:

1. Individuals over 18 years
2. Ashkenazi Jewish ethnicity (based on self-reported history of 4 Ashkenazi Jewish grandparents)

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**Total final enrolment**

1034

**Key exclusion criteria**

1. Known BRCA mutation in an individual
2. First degree relative (FDR) of an individual with known BRCA mutation
3. Individuals who have already undergone BRCA founder mutation (FM) testing

**Date of first enrolment**

01/09/2008

**Date of final enrolment**

01/09/2016

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

University College London  
London  
United Kingdom  
W1T 7DN

## Sponsor information

### Organisation

University College London (UK)

### ROR

<https://ror.org/02jx3x895>

## Funder(s)

### Funder type

Charity

### Funder Name

Eve Appeal (UK)

## 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	01/07/2016		Yes	No
<a href="#">Results article</a>		10/11/2021	11/11/2021	Yes	No
<a href="#">Results article</a>	Long term secondary lifestyle behavioural outcomes	04/07/2022	06/07/2022	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>			26/10/2022	No	Yes

[Study website](#)

Study website

11/11  
/2025

11/11  
/2025

No

Yes