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GCaPPS: Genetic Cancer Prediction through Population Screening

Submission date	Recruitment status	[X] Prospectively registered
15/07/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/07/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/10/2022	Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-testing-ashkenazi-jewish-people-for-cancer-gene-gcapps

Study website
http://www.instituteforwomenshealth.ucl.ac.uk/gcapps/index.htm

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
Patient information can be found at: http://www.instituteforwomenshealth.ucl.ac.uk/gcapps/layversion.htm

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 measure
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.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/09/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10,000

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
England

United Kingdom

Study participating centre
University College London
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Sponsor information

Organisation
University College London (UK)

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Sponsor type
University/education

Website
http://www.ucl.ac.uk

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Eve Appeal (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	01/07/2016		Yes	No
Results article		10/11/2021	11/11/2021	Yes	No
Results article	Long term secondary lifestyle behavioural outcomes	04/07/2022	06/07/2022	Yes	No
Plain English results			26/10/2022	No	Yes