

Genetic testing for breast and ovarian cancer amongst black African women in Luton (UK)

Submission date 27/03/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/03/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/03/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and Study aims

Breast cancer has been identified as the most common cancer among women worldwide. Breast cancer accounts for approximately 15% of all new cancer cases in the UK every year. Approximately 54,000 new cases of invasive breast cancer and 700 new cases of pre-invasive breast cancers are diagnosed yearly. Although most breast cancers are diagnosed at an early stage, breast cancer remains the leading cause of death in women aged 35-49. Ovarian cancer accounts for more deaths than other gynaecological malignancies and is the 6th most common cancer amongst women in the UK. With incidence rates higher in women aged 75-79 in 2016, 5% of all cancer-related deaths in the UK were from ovarian cancer. 60% of most ovarian cancers are diagnosed at later stages in the UK compared to other countries. These facts suggest the importance of early diagnosis to improve prospects of long-term survival and decrease the mortality rate of both breast and ovarian cancer.

There are two types of screening used to respectively detect cancers (routine cancer screening) and detect a gene that could cause an individual to be at a higher risk of developing certain types of cancers (genetic testing).

The rationale of this study is based on the lack of research investigating Black African women's awareness and knowledge of genetic testing and the scarcity of interventions to increase uptake of genetic testing for breast and ovarian cancer in Luton.

Who can participate?

Women self-identifying themselves as Black African women aged 18 - 69 years, residing in Luton with a good understanding and speaking level of English.

What does the study involve?

A "Health Party" intervention conducted virtually via Zoom due to the pandemic restrictions consisting of an educational session in a party setting. Participants were taught about genetic testing and how to access genetic testing services in the NHS by qualified healthcare professionals.

What are the possible benefits and risks of participating?

Benefits include a potential increase in awareness, knowledge and uptake of genetic testing amongst Black African women and help them to make informed choices about genetic testing

whilst improving early diagnosis of breast and ovarian cancer. Risks include the possibility of distress in both the participants and facilitators due to the topic discussed. The researcher used a distressed protocol in place to identify signs of distress amongst the participants and facilitators.

Where is the study run from?
University of Bedfordshire (UK)

When is the study starting and how long is it expected to run for?
August 2020 to May 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title

A "Health Party" intervention on genetic testing for breast and ovarian cancer amongst black African women in Luton (UK): feasibility study protocol

Study objectives

A "Health Party" intervention aiming to increase knowledge, awareness and uptake of genetic testing for breast and ovarian cancer amongst Black African women in Luton.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 13/08/2020, Institute for Health Research (IHR) Ethics Committee at the University of Bedfordshire (Room 120, Putteridge Bury, Luton, Bedfordshire, LU2 8LE, UK; +44 (0)1582 743797; gurch.randhawa@beds.ac.uk), ref: IHREC947

Study design

Quasi-experimental feasibility study

Primary study design

Observational

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Genetic testing for breast and ovarian cancer

Interventions

The "Health Party" intervention consists of an educational session in a party session that was performed virtually via zoom due to the pandemic restrictions. Participants were taught about genetic testing and how to access genetic testing services in the NHS by qualified healthcare professionals. 5 virtual sessions were conducted each with about 10-12 participants. A quantitative pre-post evaluation with measurements prior, at 2 - 3hrs and at 6 months following the intervention were conducted to assess the preliminary effectiveness on knowledge, awareness and uptake of genetic testing.

Intervention Type

Behavioural

Primary outcome(s)

1. Feasibility by assessing the recruitment and retention rate. Descriptive statistics were used to assess the participant's uptake rate (recruitment rate) and participant's retention over the period of the intervention by recording the participants filling the 2-3hour post-intervention form and the 6 month follow up form (retention rate). The recruitment rate was assessed by tracking the number of potential participants who confirmed their attendance to the health party that attended and those that did not attend. The retention rate was assessed by tracking the number of participants who took part in all the requirements of the intervention. This

included how many participants filled the 2-3 hour post-intervention form and the 6 month follow up form. The 6 month follow up is yet to be conducted.

2. Acceptability by conducting focus groups discussions amongst the participants and the facilitators to provide insight in their experience of the intervention. The data gathered was analysed thematically with the use of the Nvivo 10 software using the thematic analysis approach. Acceptability of the intervention was also assessed quantitatively using the SPSS version 24 to assess the scores obtained by both the participants and facilitators through a survey.

3. The fidelity of training, delivery and receipt were assessed in this intervention.

3.1. Fidelity of training was assessed qualitatively in the focus group discussions conducted by the researcher with the facilitators. A survey was also given to the facilitators to evaluate fidelity of training and was measured quantitatively.

3.2. Fidelity of delivery. The researcher tailored a checklist of the components of the educational content of the interventions to assess fidelity of delivery . The researcher conducted this assessment during the presentation of the educational content. Each session was audio-recorded to ensure that this assessment was accurate. This was measured by calculating the difference between the content covered and the intended content

3.3. Fidelity of receipt was assessed qualitatively during the focus group discussions with the participants and quantitatively through a survey sent to the participants after the intervention

Key secondary outcome(s)

1. Participants' knowledge, awareness, and uptake of genetic testing measured using a questionnaire at baseline, 2 - 3 hours post-intervention, and 6 month follow up

Completion date

03/05/2021

Eligibility

Key inclusion criteria

1. Black African women aged 18 - 69 years
2. Residing in Luton
3. Good understanding and speaking level of English

Participant type(s)

All

Healthy volunteers allowed

No

Age group

Mixed

Sex

Female

Total final enrolment

54

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/09/2020

Date of final enrolment

26/10/2020

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University of Bedfordshire

Putteridge Bury

Luton

United Kingdom

LU2 8LE

Sponsor information

Organisation

University of Bedfordshire

ROR

<https://ror.org/0400avk24>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository.

IPD sharing plan summary

Stored in repository