ISRCTN61738692 https://doi.org/10.1186/ISRCTN61738692

Does receiving a leaflet about the symptoms of gynaecological cancers affect women's attendance at their GP practice?

Submission date
17/08/2017

Recruitment status
No longer recruiting

Registration date
23/08/2017

Overall study status
Completed

Last Edited
13/08/2018

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cancers that start in a woman's reproductive system are called gynaecological cancers. In the UK gynaecological cancers have a combined incidence in women second only to breast cancer. Evidence shows that earlier diagnosis could reduce the survival gap between England and the European average. An information leaflet detailing the symptoms of gynaecological cancers and encouraging women to go to their GP has been developed. It aims to increase awareness and reduce the barriers to seeking help, with the goal of reducing the delay in presentation for gynaecological cancers. The aim of this study is to measure the impact of sending this leaflet to women through their GP, on consultation rates, use of diagnostic tests and referral rates.

Who can participate?
Women aged 40 and over from five GP practices

What does the study involve?
Participants are randomly allocated to either receive the leaflet or to not receive the leaflet. After the leaflet is sent out, changes in attendance rates, relevant tests ordered and referrals made are monitored in the following 6 months and compared to a similar period in the previous year. The data is collected in anonymised form from the practice databases.

What are the possible benefits and risks of participating?
The leaflet increases awareness of gynaecological cancer in women who had read it and may therefore benefit those who receive it as they may have an earlier diagnosis of these cancers with an increased chance of survival. The topic of cancer can be a sensitive one and receiving the leaflet may cause some anxiety in some women. However, the purpose of the leaflet is to encourage women to report their symptoms so it is hoped that if they are concerned by anything they read, they are encouraged to go to their GP for help. The leaflet also contains the contact details of Cancer Research UK’s helpline which can be accessed if women feel uncomfortable going to their GP.

Where is the study run from?
1. Albany House Medical Centre (UK)
2. Danetre Medical Practice (UK)
3. Weedon Medical Centre (UK)
4. Leicester Terrace Health Care Centre (UK)
5. Rothwell Health Care Centre (UK)

When is the study starting and how long is it expected to run for?
February 2013 to October 2014

Who is funding the study?
Cancer Research UK

Who is the main contact?
Prof. Jackie Campbell
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Contact information

Type(s)
Scientific

Contact name
Prof Jackie Campbell

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Gynae Cancer Awareness VNo. 4 DATE 1/11/13

Study information

Scientific Title
Evaluating the impact of a leaflet to raise awareness in women of symptoms of gynaecological cancers in primary care: a record-based randomised control trial

Study objectives
Is the proportion of women who consult their GP for symptoms indicative of gynaecological cancer the same whether or not they have received an educational leaflet?

Ethics approval required
Old ethics approval format

Ethics approval(s)
HRA NRES Committee East Midlands - Nottingham 1, 16/12/2013, REC ref: 13/EM/0432, IRAS project ID: 142767

Study design
Multicentre record-based cross-sectional randomised control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Gynaecological cancers

Interventions
Intervention: Educational leaflet on the symptoms of gynaecological cancer sent by post from their GP practice.
Control: No leaflet sent.

Eligible women were identified from GP electronic records and randomised into equal intervention and control groups using SystmOne which also printed address labels for the leaflet mail-out to the experimental group and flagged membership of the study and group membership on the electronic record for subsequent data extraction. The data was extracted for the 4-month time period starting on the day after the GP practice mail out date (for both experimental and control groups).

Intervention Type
Other

Primary outcome measure
The proportion of eligible women who consult their GP for symptoms indicative of gynaecological cancers. This was measured by the presence, and dates, of one or more Read codes in the women's electronic patient record that related to the symptoms described in the educational leaflet and which were indicative of gynaecological cancers. The data was extracted for the 4-month time period starting on the day after the GP practice mail out date (for both experimental and control groups)

Secondary outcome measures
The proportions of eligible women whose GP practice electronic record contained evidence of referrals, diagnostic tests and diagnoses assosiated with gynaecological cancers. These was measured by the presence, and dates, of one or more Read codes in the women's electronic patient record that related to referrals, diagnostic tests and diagnoses associated with gynaecological cancers. The data was extracted for the 4-month time period starting on the day after the GP practice mail out date (for both experimental and control groups)

Overall study start date
18/02/2013

Completion date
31/10/2014

Eligibility

Key inclusion criteria
1. Women registered with one of the study GP practices
2. Aged 40 years or over

Participant type(s)
Patient

Age group
Mixed

Sex
Female

Target number of participants
16,054

Key exclusion criteria
1. Women on the oncology and palliative care registers
2. Learning difficulties
3. Mental health problems

Date of first enrolment
03/06/2014

Date of final enrolment

16/06/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Albany House Medical Centre
United Kingdom
NN29 7QH

Study participating centre
Danetre Medical Practice
United Kingdom
NN11 4DY

Study participating centre
Weedon Medical Centre
United Kingdom
NN7 4RX

Study participating centre
Leicester Terrace Health Care Centre
United Kingdom
NN2 6AL

Study participating centre
Rothwell Health Care Centre
United Kingdom
NN14 6JQ

Sponsor information

Organisation

University of Northampton

Sponsor details
Boughton Green Road
Northampton
England
United Kingdom
NN2 7AL

Sponsor type
University/education

ROR
https://ror.org/04jp2hx10

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The protocol, including the analysis plan, will be deposited in the data repository. The manuscript is currently under preparation for submission to a high impact peer-reviewed journal and is expected to be published by the end of 2017.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in the open access Zenodo repository (doi: 10.5281/zenodo.846744) as a .csv file and will include the protocol and metadata details. The data will contain no personal identifiable information and the GP practices from which the data was sourced will be anonymised. Individual consent from participants was not required as confirmed by the HRA REC approval.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/08/2018		Yes	No
HRA research summary			28/06/2023	No	No