

Pilot study: impact of gynaecological cancers leaflet in GP practices

Submission date 20/12/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/12/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/02/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12750

Study information

Scientific Title

Evaluating the impact of a leaflet to raise awareness in women of symptoms of gynaecological cancers on consultation rates, use of diagnostic tests and referrals in primary care. A pilot study in GP practices

Study objectives

Gynaecological cancers have a combined incidence in women second only to breast cancer in the UK. 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 present to their GP has been developed. It aims to increase awareness and reduce help-seeking barriers, with the goal of reducing delay in presentation for gynaecological cancers. This study, funded by the National Awareness and Early Diagnosis Initiative, evaluates the impact of sending this leaflet to women through their GP, on consultation rates, use of diagnostic tests and referral rates. The results will inform a future larger RCT, testing the impact of the leaflet more widely.

Ethics approval required

Old ethics approval format

Ethics approval(s)

12/EE/0231

Study design

Non-randomised interventional and observational; Design type: Diagnosis

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

GP practice

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions

Women aged 40 years and over will be identified from the lists of nine GP practices (N~16250) and mailed the leaflet with a cover letter from their GP. Patients on the palliative care, mental health or oncology registers will be excluded. After the leaflet is sent out, any changes in

attendance rates, relevant investigations ordered and referrals made in the six months following will be monitored, and compared to a similar period in the previous year. Women will not be approached during this study, but rather the outcome data will be collected and collated in anonymised form from the practice databases.

Intervention Type

Behavioural

Primary outcome measure

Rates of relevant consultations.

Secondary outcome measures

Not provided at time of registration

Overall study start date

25/06/2012

Completion date

30/04/2013

Eligibility

Key inclusion criteria

All women 40 years and over in nine GP practices across north west London

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

Planned Sample Size: 16520; UK Sample Size: 16520

Key exclusion criteria

Women on the palliative care, mental health or oncology registers at these practices

Date of first enrolment

25/06/2012

Date of final enrolment

30/04/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
City Community and Health Sciences
London
United Kingdom
EC1V 0HB

Sponsor information

Organisation
City University London (UK)

Sponsor details
City Community and Health Sciences
10 Northampton Square
London
England
United Kingdom
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Sponsor type
University/education

ROR
<https://ror.org/04489at23>

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (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

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration