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Writing to patients to encourage them to report symptoms to their GP

Submission date	Recruitment status	☒ Prospectively registered
07/07/2016	No longer recruiting	☐ Protocol
Registration date	**Overall study status**	☐ Statistical analysis plan
07/07/2016	Completed	☒ Results
Last Edited	**Condition category**	☐ Individual participant data
30/08/2023	Cancer	

Plain English summary of protocol

Background and study aims
Diagnosis of cancer during late stages of the disease and the resultant poor survival is more common in those from disadvantaged backgrounds, among certain ethnic groups, among those suffering from more other health conditions and among those first presenting with cancer to emergency medical services. Other possible factors which may make patients more likely to first present to healthcare services during the late stages of cancer include infrequent contact with their general practice, lack of engagement in cancer screening, and possibly a tendency to use acute or emergency services in preference to primary care. Previous initiatives (such as The Be Clear on Cancer Campaigns) took the form of television and radio advertisements and posters which were aimed at the public in general. For both financial and public health reasons, it is advantageous to target these programs towards those least likely to seek help for symptoms and those most at risk of advanced stage disease at diagnosis. If successful this might then lead to cancer diagnoses being made an earlier point when the cancer is at a more treatable stage. Targeted programs also provide the opportunity to tailor the programs so that it is most likely to appeal to the specific audience. The aim of this study is to find out whether a targeted program aimed at those at risk of presenting with late-stage cancer results in increased engagement with primary care.

Who can participate?
General Practices from three geographical clusters (London, Manchester and The North of England) have been invited to participate. From their patients they will select approximately seventy who are eligible. These are adults aged between 50 and 84 who have not seen their GP for a year and come from a disadvantaged background; missed their last cancer screening; have a history of using out of hours or emergency services rather than seeing a GP; missed their last appointment for long-term disease management; have low social support; or have ever smoked.

What does the study involve?
Selected patients are randomly allocated to one of two groups. Those in the first group receive normal care only. Those in the second group receive normal care and also receive a cancer awareness leaflet and letter by post. At the end of six months, patients' usual care teams record

the number of and type of consultations attended by all selected patients during that six month period to compare whether there are any significant differences between the amount of patients going to see their GP in the two study groups.

What are the possible benefits and risks of participating?
Of those patients that are randomly assigned to receive the intervention some may already have symptomatic cancer but have not reported it to a health professional. As a result of the intervention these patients may arrange a consultation with their general practitioner. This in turn could lead to an earlier diagnosis of cancer and result in improved health outcome and a better chance of survival. Some other patients that are randomly assigned to receive the intervention may have symptoms that appear cancerous but are in fact benign or represent a different disease. This group may benefit from being reassured by their doctor that their symptoms are not a cause for concern or alternatively from appropriate treatment. Though both leaflet and letter are designed to re-engage members of hard to reach populations with primary care it is possible that it could generate anxiety in patients. In order to reduce these risks both the leaflet and letter have been written deliberately in a way that aims to minimise anxiety.

Where is the study run from?
Wolfson Institute of Preventive Medicine (UK)

When is the study starting and how long is it expected to run for?
June 2016 to December 2017

Who is funding the study?
Department of Health (UK)

Who is the main contact?
Dr Jean-Pierre Laake

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number

Study information

Scientific Title
Writing to Encourage Late Consultation Outpatients to Make Engagement with their GP (WELCOME-GP)

Acronym
WELCOME-GP

Study objectives
The aim of this study is to determine the effect of a personal letter and cancer awareness leaflet (sent from one's general practitioner) on primary care consultations in twenty general practices among adults who rarely use primary care and who are at risk of late presentation of cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland 3 Research Ethics Committee, 14/06/2016, ref: 16/WS/0110

Study design
Randomised; Both; Design type: Prevention, Process of Care, Education or Self-Management, Psychological & Behavioural, Case-controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Primary Care, Primary sub-specialty: Cancer; UKCRC code/ Disease: Other/ General symptoms and signs

Interventions
1400 patients with no diagnosis of cancer but at risk or late presentation of cancer will be recruited to this randomised control trial from twenty general practices (seventy patients per practice) in England.

Within each practice the 70 recruited patients will be randomly assigned to either receive the intervention (study group) or not to receive the intervention (control group).

The intervention consists of a letter and leaflet posted to patients from their general practitioner. The letter and leaflet mention important cancer symptoms, encourage help-seeking for these symptoms at primary care, and give reassurance that consultation at primary care will not be considered a waste of the doctor’s time, or used as an opportunity for judgemental or coercive responses from the doctor.

After six months, patients' usual care teams will record the number of and type of consultations attended by all participants during that 6 month period. This data will then be sent to the research team in de-identified form.

Intervention Type
Behavioural

Primary outcome(s)
Total number of appointments made in primary care within 6 months (183 days) of mailing of the intervention.

Key secondary outcome(s))
Total amount of appointments, investigations, referrals, treatments made within 6 months (183 days) of the mailing of the intervention.

Completion date
29/12/2017

Eligibility

Key inclusion criteria
1. Subject must be registered with general practitioner
2. Age 50-84
3. Have not had primary care consultation in last 12 months
4 Satisfy at least two of the following:
4.1. Low socio-economic status
4.2. Missed last breast, bowel, cervical or abdominal aortic aneurysm screen
4.3. History of use of emergency or out of hours services instead of primary care
4.4. Missed last appointment for chronic disease monitoring/management
4.5. Low social support (only person registered with general practice at their address)
4.6. Smoker (ever)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
1513

Key exclusion criteria

1. Inclusion criteria not met
2. Already have a diagnosis of cancer
3. GP considers inappropriate in view of patient’s health, attitude or cognitive ability

Date of first enrolment
11/07/2016

Date of final enrolment
30/04/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Wolfson Institute of Preventive Medicine
Policy research Unit
Centre for Cancer Prevention
Queen Mary University of London
Charterhouse Square
London
United Kingdom
EC1M 6BQ

Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name

Department of Health

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/04/2021	30/08/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes