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Improving Awareness and Beliefs About Cancer (ABACus) symptoms by using a bespoke online cancer health check interactive tool with personally tailored advice regarding lifestyle risk factors from a trained lay advisor

Submission date
27/11/2017

Recruitment status
No longer recruiting

Registration date
12/01/2018

Overall study status
Completed

Last Edited
24/02/2023

Condition category
Cancer

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

Plain English summary of protocol
Background and study aims
Evidence shows that cancer survival rates are lower in disadvantaged communities, possibly due to low awareness of symptoms and delayed help-seeking. It is important that people increase their knowledge of cancer symptoms, so that they know when to go seek medical advice about their concerns, and therefore possibly detecting cancer earlier, which will improve their outlook. We have developed an interactive online health check questionnaire to be delivered in these communities by trained advisors which is designed to help people recognise possible cancer signs early. The health check is a short questionnaire completed on an iPad with the help of a trained advisor. There are 29 questions which ask participants about their background, lifestyle and health. They are then given a summary page at the end which colour codes their responses using a traffic light system (red, amber, green) to highlight areas where action and or advice should be taken. There is already some research to test what people think about the health check. Based on this changes have been made to improve it. The aim of this study is to see if the health check increases people's knowledge of cancer signs and lifestyle risks and to see if increased knowledge encourages people to ask for help earlier.

Who can participate?
Adults aged 40 and older who live in a socioeconomically deprived areas of South and West Yorkshire (UK).

What does the study involve?
Participants are asked to complete a questionnaire on an iPad. This can be done by themselves or with the help of an advisor. It will ask about their knowledge of cancer symptoms and cancer lifestyle risks. It will also ask some background information about them. This will take around 20 minutes. Participants are then randomly allocated to one of two groups. Participants who are allocated to the first group do not do anything else on the day. Participants allocated to the

second group are then asked to complete the online health check with the help of an advisor. Their results are summarised at the end on a single page. A red, amber, green traffic light system are used to show their results and the advisor will discuss their results with them. This takes around 25 minutes. Some sessions are recorded or observed. All participants are contacted again in two weeks and six months' time to complete the questionnaire again. This is done on the telephone. In addition to the main study, some of the participants (around 45-50) are asked if they want to take part in an interview with one of the researchers. Interviews either takes place after the two week or six month questionnaire and lasts around 30 minutes. Participants are asked about their experiences of taking part and if they have any experiences of wider cancer awareness campaigns.

What are the possible benefits and risks of participating?
Participants will be providing important information about what people know and think about cancer symptoms. The questionnaires will help us test if the online health check improves people's knowledge of cancer symptoms and cancer-related lifestyle risks. Those participants who are in the treatment group will also receive a one page summary of their health check results. Participants also receive high street shopping vouchers for completing the study. There is no direct risk to taking part in this trial, however, some people don't like talking about cancer or find talking about cancer upsetting. If participants get upset they can talk directly to the advisor or contact local services for support, which are listed on the information booklet.

Where is the study run from?
The study is being coordinated by the Centre for Trials Research (CTR) in Cardiff University (UK).

When is the study starting and how long is it expected to run for?
May 2017 to August 2020

Who is funding the study?
Yorkshire Cancer Research (UK)

Who is the main contact?
Ms Yvonne Moriarty (Scientific)
abacus@cardiff.ac.uk

Study website
http://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/abacus

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
36714

Study information

Scientific Title
Awareness and Beliefs About Cancer phase 3 (ABACus 3): Randomised controlled trial of a health check intervention to improve cancer symptom awareness and help-seeking among people living in socioeconomically deprived communities

Acronym
ABACus 3

Study objectives
The aim of this study is to undertake a phase 3 randomised controlled trial of the ABACus Health Check (previously developed and tested for feasibility/acceptability) as a means of improving cancer symptom awareness and help-seeking behaviour among adults living in socioeconomically deprived communities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Surrey NHS Research Ethics Committee, 12/10/2017, ref: 17/LO/1507

Study design
Randomised; Interventional; Design type: Not Specified, Not Specified

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Treatment

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

Health condition(s) or problem(s) studied
Specialty: Cancer, Primary sub-specialty: Primary Care; UKCRC code/ Disease: Cancer/ Neoplasms of uncertain or unknown behaviour

Interventions
The ABACus Health Check is an innovative community outreach intervention designed to improve cancer symptom knowledge, encourage positive beliefs in relation to cancer early detection, and increase motivation to seek help among adults (aged 40 years and older) living in deprived communities. The health check has been informed by a theoretical understanding of the barriers and enablers to timely help-seeking among people living in disadvantaged communities, and comprises an interactive touchscreen questionnaire with behavioural support delivered face-to-face by a trained advisor, taking around 35 – 45 minutes to complete. The intervention is primarily designed to reduce the “patient interval”, defined as the time between appraising a bodily change as a potential symptom of cancer and presenting in primary care, but also attempts to synergise cancer screening and early symptom detection by including cancer symptom content and screening messages. Individualised results are provided in a traffic light system, with ‘green’ indicating results where no signposting or change is suggested, ‘amber’ indicating an area where signposting or change could be considered, and ‘red’ results indicating that action should be taken. Results can be printed on a one page summary format for participants to take away. Information and signposting to relevant services (for example, General Practitioner, stop smoking and weight loss services) are provided based on individual results.

Participants are recruited from community (i.e. local groups) and health (i.e. GP surgeries) settings and randomised to either intervention (online health check) or control (usual available care/support) on a 1:1 ratio. Quantitative data is collected at baseline, two weeks and six months post randomisation. Measured used include: Adapted Awareness and Beliefs about Cancer measure (ABC), 6-item State-Trait Anxiety Inventory (STAI-6), Lifestyle using Theory of Planed Behaviour, self-rated health, screening behaviour, Client Service Receipt Inventory, Demographics, Contact Details and Recruitment Information (setting type etc). The primary analysis will predict follow-up cancer symptom recognition at 2 weeks using baseline cancer symptom recognition as well as key demographic variables in a linear analysis of covariance model (ANCOVA). All participants receive a total of £15 high street shopping vouchers (£10 at baseline and £5 at six months) as a thank you for taking part.

Qualitative data supports the process evaluation and includes: interviews with lay advisors (n=3) pre and post-delivery, audio recordings/observations (n=24-25/n=12-13) of health check delivery sessions, interviews with participants at 2-4 weeks post randomisation (n=30), interviews with participants post 6 months (n=15-20). All participants who take part in an interview additionally receive £10 as a thank you for completing an interview).

Intervention Type
Other

Primary outcome measure

Cancer symptom knowledge (calculated as the mean aggregated symptom recognition score), measured using the adapted (Awareness and Beliefs about Cancer) measure at 2 weeks.

Secondary outcome measures
1. Cancer Beliefs, measured using the adapted ABC measure at 2 weeks and 6 months
2. Barriers to presentation, measured using the adapted ABC measure at 2 weeks and 6 months
3. Help-seeking intentions, measured using the adapted ABC measure at 2 weeks and 6 months
4. Cancer worry, measured using the State Trait Anxiety Inventory (STAI) measure at 2 weeks and 6 months
5. Intervention implementation costs, measured using the Client Service Receipt Inventory at 6 months

Exploratory outcomes measures:
1. Cancer screening intentions, beliefs and self-reported behaviours measured using the Theory of Planned Behaviour Questionnaire at 2 weeks and 6 months
2. Lifestyle intentions (stop smoking, weight loss, reduce alcohol consumption), measured using the Theory of Planned Behaviour Questionnaire at 2 weeks and 6 months
3. Cancer risk factor awareness, measured using the adapted ABC at 2 weeks and 6 months

Overall study start date
31/05/2017

Completion date
31/08/2020

Eligibility

Key inclusion criteria
1. Aged 40 years and over
2. Recruited from socioeconomically deprived areas of South and West Yorkshire (i.e. Sheffield, Barnsley, Rotherham, Wakefield) or Southeast Wales (i.e. Merthyr Tydfil and Newport)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 246; UK Sample Size: 246

Total final enrolment
234

Key exclusion criteria

1. Non-English speakers
2. Unable to give informed consent
3. A participant from the phase 2 feasibility study (only relevant in South East Wales)

Date of first enrolment
07/12/2017

Date of final enrolment
31/01/2019

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Cwm Taf University Health Board R&D
Research & Development Department
Royal Glamorgan Hospital
Ynysmaerdy
Rhondda Cynon Taf
Llantrisant
United Kingdom
CF72 8XR

Study participating centre
Aneurin Bevan University Health Board R&D
Research & Development Office
Aneurin Bevan University Health Board
Clinical Research and Innovation Centre
St Woolos Hospital
Newport
United Kingdom
NP20 4SZ

Study participating centre
West Yorkshire R&D
Douglas Mills
Bowling Old Lane
Bradford

United Kingdom
BD5 7JR

Study participating centre
South Yorkshire R&D
Research & Development Unit
Sheffield Health & Social Care FT
Fulwood House
Old Fulwood Road
Sheffield
United Kingdom
S10 3HT

Sponsor information

Organisation
Cardiff University

Sponsor details
-
Cardiff
Wales
United Kingdom
CF10 3AT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
Yorkshire Cancer Research

Alternative Name(s)
YCR

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Exact details of the publication policy are still being developed. However, broadly the researchers plan on publishing a protocol paper in a high impact paper once they are into recruitment (2018/2019) and the main trial results in a high-impact paper at the end of the trial (post-2020).

Intention to publish date
01/01/2021

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from the study manager Yvonne Moriarty (Moriartyy@cardiff.ac.uk) with an agreed/signed data-sharing agreement. De-identified participant data will be made available to the scientific community with as few restrictions as feasible, whilst retaining exclusive use until the publication of major outputs. Cardiff University holds data for 15 years.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/03/2019	15/03/2019	Yes	No
Results article		27/08/2021	01/09/2021	Yes	No
Other publications		04/11/2020	24/02/2023	Yes	No
HRA research summary			28/06/2023	No	No