

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/01/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/02/2023	Condition category Cancer	<input type="checkbox"/> 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

Contact name

Ms Yvonne Moriarty

Contact details

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United Kingdom
CF14 4YS

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 Planned 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

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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