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A randomised controlled trial of the effect of providing online risk information and lifestyle advice for the most common preventable cancers

Submission date
05/01/2018

Recruitment status
No longer recruiting

Registration date
30/01/2018

Overall study status
Completed

Last Edited
28/02/2024

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Previous research has shown that providing cancer risk information to people can improve their understanding of their risk of cancer, increase their intention to attend cancer screening, and increase their fruit and vegetable intake and physical activity. A risk calculator has been developed and tested based on modifiable behavioural risk factors, such as weight and smoking, which estimates the risk of an individual developing one of the five most common preventable cancers in the UK over a 10-year period. These cancers are lung, bowel, bladder, kidney and oesophageal cancer for men and breast, lung, bowel, endometrial and kidney cancer for women). Alongside 66 healthcare professionals who have taken part in focus groups and interviews, a web-based tool has been developed which allows people to enter details of their current lifestyle and then see their estimated risk of developing one of the cancers over the next 10 years, the effect changes in their lifestyle would make on that risk, and lifestyle advice. The aim of this study is to use that web-based tool to test whether people given their personalised cancer risk estimate in combination with lifestyle advice are more motivated to make changes in their behaviour than people given lifestyle advice alone. The study also compares different ways of presenting the risk information.

Who can participate?
Men and women aged 30-74 who do not have a past history of cancer

What does the study involve?
Participants answer a set of questions about their diet, lifestyle and beliefs about their risk of cancer. They are then randomly allocated to be presented with their personalised 10-year cancer risk and lifestyle advice, or go straight to the lifestyle advice without seeing their personalised risk. The cancer risk is presented in one of three formats. The first format is a bar chart, the second format is pictures of either 1000 or 100 faces depending on the individual's estimated risk, and the third format is a bar with a scale from below average to above average with arrows. Participants then answer a further set of questions about their thoughts about their risk of

cancer and motivation to make lifestyle change. They are then asked if they agree to take part in a follow-up task 3 months later where they answer a similar set of questions to check how their lifestyle and ideas about cancer risk have changed with time. After completing that task, if they are one of the people who did not see their personalised risk in the first task, they are offered the opportunity to see it then.

What are the possible benefits and risks of participating?
The benefits are that participants receive a summary of their estimated risk of developing one of the five most common preventable cancers in the future and information about how they may be able to reduce that risk. Participation also provides an opportunity for people to contribute to and help influence cancer risk research. Being presented with the risk of developing cancer can be a sensitive or stressful issue. If participants become distressed by anything when completing the task they can exit it at any stage and there will be no consequences associated with doing so. Participants are also provided with details of how to access support if needed.

Where is the study run from?
University of Cambridge (UK)

When is the study starting and how long is it expected to run for?
November 2017 to October 2018

Who is funding the study?
1. Cancer Research UK
2. National Institute for Health Research (UK)

Who is the main contact?
Dr Juliet Usher-Smith
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.0

Study information

Scientific Title
A randomised controlled trial of an online risk information and lifestyle advice intervention for the most common preventable cancers

Acronym
I-CaPP online trial

Study objectives
To assess whether communicating a personalised cancer risk estimate based on modifiable lifestyle factors in combination with lifestyle advice motivates greater change in behaviour than lifestyle advice alone. Secondary objectives are to determine the effects of personalised cancer risk information on risk perception and psychological well-being and compare the impact of different formats of risk information.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Psychology Research Ethics committee of the University of Cambridge, 12/12/2017, ref: PRE.2017.093

Study design
Parallel-group open randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Internet/virtual

Study type(s)
Prevention

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied
Lifestyle behaviours that influence risk of the five most common preventable cancers in the UK (lung, colorectal, bladder, kidney and oesophageal for men and breast, lung, colorectal, endometrial and kidney for women)

Interventions
Participants will first be asked to complete an online consent form. They will then answer a set of questions about their diet, lifestyle and beliefs about their risk of cancer. They will then be randomised 1:1:1:1 with stratification by risk relative to an individual with a recommended lifestyle and age (Added 21/02/2018: Participants are also stratified by sex):
1. A control group who receive cancer specific web-based lifestyle advice alone
2. One of three intervention groups who receive the same web-based lifestyle advice alongside their estimated 10 year risk of developing one of the five most common preventable cancers in one of three different formats:
2.1. The first format is a bar chart showing current estimated risk, new estimated risk after setting lifestyle targets, and risk if they followed a recommended lifestyle
2.2. The second is iconographs of either 1000 or 100 faces depending on the individuals estimated risk again for current estimated risk, new estimated risk after setting lifestyle targets and risk if they followed a recommended lifestyle
2.3. The third is a bar with a qualitative scale from below average to above average with arrows showing current estimated risk, new estimated risk after setting lifestyle targets and risk if they followed a recommended lifestyle

Participants will then answer a further set of questions about their thoughts about their risk of cancer and motivation to make lifestyle change. They will then be asked if they agree to take part in a follow up task 3 months later where they will answer a similar set of questions to check how your lifestyle and ideas about cancer risk have changed with time. After completing that task, if they were one of the people who did not see their personalised risk in the first task, they will be offered the opportunity to see it then.

Intervention Type
Behavioural

Primary outcome measure
Change in risk relative to an individual with a recommended lifestyle, measured via self-report of lifestyle at 3 months

Secondary outcome measures
Measured immediately after the intervention and again at 3 months, all measured via self-report:
1. Perceived risk of cancer
2. intention to change behaviour
3. Anxiety, measured using the six-item Spielberger State-Trait Anxiety inventory
4. Cancer-related worry, measured using the Lerman cancer worry scale
5. Awareness of cancer risk factors, measured using question 6 from the Cancer Awareness Measure

Overall study start date
01/11/2017

Completion date
31/10/2018

Eligibility

Key inclusion criteria
1. 30-74 years of age
2. Resident in the UK
3. Registered with Prolific
4. Prolific approval rating ≥95%

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
1000

Total final enrolment
1018

Key exclusion criteria
Past history of cancer

Date of first enrolment
01/03/2018

Date of final enrolment
01/04/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Cambridge
The Primary Care Unit
Department of Public Health and Primary Care

Cambridge
United Kingdom
CB2 0SR

Sponsor information

Organisation
University of Cambridge

Sponsor details
School of Clinical Medicine
Box 111, Cambridge Biomedical Campus
Cambridge
England
United Kingdom
CB2 0SP

Sponsor type
University/education

ROR
https://ror.org/013meh722

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

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of the protocol in a peer-reviewed journal before completion of recruitment which will then be available online. Planned publication of the findings in high-impact peer reviewed journals.

Intention to publish date
01/02/2020

Individual participant data (IPD) sharing plan
The anonymised patient level data will be stored in the University of Cambridge data repository (https://www.repository.cam.ac.uk). It will be open access and available to researchers approximately 2 years after the completion of the study. The trialists have submitted an amendment to the ethics committee to obtain patient consent for this.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2020	05/08/2020	Yes	No
Protocol article		26/06/2018	10/08/2022	Yes	No
Participant information sheet			28/02/2024	No	Yes