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ASCOT: Lifestyle study for cancer survivors

Submission date 29/07/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/07/2015	**Overall study status** Completed	
Last Edited 19/03/2024	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-a-lifestyle-programme-for-people-who-have-had-cancer-treatment-ascot

Study website
https://www.ucl.ac.uk/epidemiology-health-care/research/behavioural-science-and-health/research/energy-balance-cancer/advancing-survival-after

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17783

Study information

Scientific Title
Advancing Survivorship after Cancer: Outcomes Trial

Acronym
ASCOT

Study objectives
The Advancing Survival in Cancer Outcomes Trial (ASCOT) is aimed helping cancer patients adhere to the World Cancer Research Fund (WCRF) guidelines for a healthy lifestyle. ASCOT involves a:
1. Lifestyle survey
2. Habit based lifestyle intervention

The ASCOT survey will be sent to patients diagnosed with breast, prostate or colorectal cancer in 2012/2013 in an NHS Trust in London or Essex. The survey contains questions on lifestyle (diet, physical activity, alcohol, smoking, sleep and weight), psychosocial outcomes (fatigue and quality of life) and information on advice received, and desire for lifestyle advice (timing, format, type). Patients will also be given the opportunity to participant in the ASCOT trial. The ASCOT trial is an individually randomised controlled trial examining whether a leaflet (with phone consultation and website) that provides the WCRF lifestyle recommendations for lifestyle for cancer survivors, using habit theory to help patients find simple ways to incorporate healthy habits into their routines, can improve lifestyle.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Oxford B, 05/12/2014, ref: 14/SC/1369;

Study design
Both; Interventional and Observational; Design type: Process of Care, Cohort study

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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Topic: Cancer; Subtopic: All Cancers/Misc Sites; Disease: All

Interventions
ASCOT is a lifestyle intervention (a leaflet developed in consultation with clinicians and patients, a phone consultation and a website) aimed at helping cancer patients adhere to the World Cancer Research Fund lifestyle guidelines for cancer survivors. ASCOT uses habit theory to incorporate simple habits and tips to facilitate behaviour change.
Follow Up Length: 6 month(s)
Study Entry : Single Randomisation only

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures (as of 10/01/2018)
Composite health behaviour risk index; Timepoint(s): 0, 3, 6 and 24 months

Previous primary outcome measures
Composite health behaviour risk index; Timepoint(s): 0, 3 and 6 months

Secondary outcome measures
Current secondary outcome measures (as of 10/01/2018)
1. Alcohol (AUDIT C questionnaire); Timepoint(s): 0, 3, 6 and 24 months
2. Dietary intake (24 hour dietary recall phone calls); Timepoint(s): 0, 3, 6 and 24 months
3. Physical activity (pedometer and questionnaire); Timepoint(s): 0, 3, 6 and 24 months
4. Quality of Life (EQ-5D-5L); Timepoint(s): 0, 3, 6 and 24 months
5. Sleep (questionnaire); Timepoint(s): 0, 3, 6 and 24 months
6. Smoking status (questionnaire); Timepoint(s): 0, 3, 6 and 24 months

Previous secondary outcome measures
1. Alcohol (AUDIT C questionnaire); Timepoint(s): 0, 3 and 6 months
2. Dietary intake (24 hour dietary recall phone calls); Timepoint(s): 0, 3 and 6 months
3. Physical activity (pedometer and questionnaire); Timepoint(s): 0, 3 and 6 months
4. Quality of Life (EQ-5D-5L); Timepoint(s): 0, 3 and 6 months
5. Sleep (questionnaire); Timepoint(s): 0, 3 and 6 months
6. Smoking status (questionnaire); Timepoint(s): 0, 3 and 6 months

Overall study start date
13/02/2015

Completion date
31/08/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 18/12/2020:
ASCOT patient survey:
All individuals diagnosed with breast, prostate or colorectal cancer in 2012-2015 at an NHS trust in London or Essex.

ASCOT pilot trial:
1. Adults aged at least18 years (no upper age limit)
2. Individuals diagnosed with non-metastatic breast, prostate or colorectal cancer in 2012-2015
3. Individuals not receiving active anti-cancer treatment (except for those oral anti-cancer treatments taken at home who can be included)
4. Individuals who are able to understand spoken and written English

Previous inclusion criteria:
ASCOT patient survey:
All individuals diagnosed with breast, prostate or colorectal cancer in 2012 or 2013 at an NHS trust in London or Essex.

ASCOT pilot trial:
1. Adults aged at least18 years (no upper age limit)
2. Individuals diagnosed with non-metastatic breast, prostate or colorectal cancer in 2012 or 2013
3. Individuals not receiving active anti-cancer treatment (except for those oral anti-cancer treatments taken at home who can be included)
4. Individuals who are able to understand spoken and written English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 5000; UK Sample Size: 5000; Description: We will recruit up to 5000 for the cohort study. We will aim to recruit up to 950 patients into the trial. Based on previous lifestyle trials using a composite score we aim to detect a modest increased in risk index of 0.2 standard deviations at 3 months, and with 80% power and 5% two sided statistical significance we will required around 350 participants in each group.

Total final enrolment
1348

Key exclusion criteria

ASCOT pilot trial:
1. Individuals with metastatic disease
2. Individuals on active anti-cancer treatment requiring hospital admission
3. Individuals with severe cognitive impairment

Date of first enrolment
20/05/2015

Date of final enrolment
01/04/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Broomfield Hospital
Court Road
Chelmsford Essex
United Kingdom
CM1 7ET

Study participating centre
Basildon Hospital
Nethermayne
Essex
United Kingdom
SS16 5NL

Study participating centre
University College London Hospital
250 Euston Road
London
United Kingdom
NW1 2PG

Sponsor information

Organisation

University College London Joint Research Office

Sponsor details
Gower Street
London
England
United Kingdom
WC1E 6BT

Sponsor type
University/education

ROR
https://ror.org/02jx3x895

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

Results and Publications

Publication and dissemination plan
The results of the trial will be disseminated in relevant scientific conferences and meetings. The results will also be written up as paper publications and submitted to scientific, peer reviewed journals. This is planned for the first half of 2018.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan

We will not be sharing participant level data as participants have not consented to this, and it would therefore be against data protection legislation. The data will be held at UCL on a data safehaven which uses a walled garden approach to secure data storage. We may share anonymised data after our primary data are published, but only if formally requested so we can control the nature of the analyses.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/11/2016		Yes	No
HRA research summary			28/06/2023	No	No