

ASCOT: Lifestyle study for cancer survivors

Submission date 29/07/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 29/07/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/03/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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 participate 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 least 18 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 least 18 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
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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