

# ASCOT: Lifestyle study for cancer survivors

<b>Submission date</b> 29/07/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/07/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/03/2024	<b>Condition category</b> 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>

## Contact information

### Type(s)

Public

### Contact name

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## Additional identifiers

### Protocol serial number

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

**Study type(s)**

Treatment

**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(s)**

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

## **Key secondary outcome(s)**

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

## **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

**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

**ROR**

<https://ror.org/02jx3x895>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Cancer Research UK

**Alternative Name(s)**

CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

## Results and Publications

### 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?
<a href="#">Protocol article</a>	protocol	23/11/2016		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes