# Online intervention to enhance confidence to manage problems associated with cancer related fatigue following primary cancer treatment

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>			
03/10/2012		[X] Protocol			
Registration date 05/10/2012	Overall study status Completed	Statistical analysis plan			
		[X] Results			
Last Edited	Condition category	Individual participant data			
26/10/2022	Cancer				

#### Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-online-support-people-extreme-tiredness-after-cancer-treatment-restore

## Contact information

## Type(s)

Scientific

#### Contact name

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#### Contact details

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## Additional identifiers

Protocol serial number 12769

# Study information

#### Scientific Title

RESTORE: An exploratory randomised controlled trial of an online intervention to enhance confidence to manage problems associated with cancer related fatigue following primary cancer treatment

## **Study objectives**

The Macmillan Survivorship Research Group has been funded by Macmillan Cancer Support to undertake a programme of research to understand recovery following primary cancer treatment and develop an internet based resource to support people living with problems following treatment. This study is a fundamental part of the programme.

The purpose of this study is to determine if an online resource called RESTORE which provides clinical information, examples of how others manage, and support with setting personal goals increases confidence to self-manage problems associated with cancer related fatigue.

Cancer-related fatigue is a common problem often reported during chemotherapy and radiotherapy treatment and many people report fatigue persists once treatment is over. Fatigue may have an impact on individuals in a number of ways such as how they feel about themselves, whether and how they engage in everyday activities, and may also affect their relationships with others. This study will test an online resource (RESTORE) with a focus on increasing confidence to manage cancer related fatigue for those people who use the internet, or are willing to use the internet. Participants who use RESTORE will be compared with those receiving a booklet; Macmillan Cancer backup Coping with Fatigue in order to assess the effectiveness of RESTORE. Those with access to RESTORE are expected to demonstrate greater confidence to self manage problems associated with cancer related fatigue compared to those receiving the booklet alone.

More details can be found at http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=12769

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

NRES Committee South Central Oxford A, First MREC approval date 18/07/2012, ref: 12/SC/0374

## Study design

Randomised; Interventional; Design type: Prevention, Process of Care

## Primary study design

Interventional

## Study type(s)

Quality of life

## Health condition(s) or problem(s) studied

Topic: National Cancer Research Network; Subtopic: All Cancers/Misc Sites; Disease: All

#### **Interventions**

Participants who use online resource (RESTORE) will be compared with those receiving a booklet; Macmillan Cancer backup Coping with Fatigue

Online intervention to enhance self-efficacy (confidence) to manage problems associated with cancer-related fatigue following primary cancer treatment.

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome(s)

Test the value (provide proof of concept) of the intervention, measured using questionnaire (validated method) which is completed by the participants

## Key secondary outcome(s))

No secondary outcome measures

## Completion date

28/06/2013

# Eligibility

## Key inclusion criteria

- 1. Have had a clinical diagnosis of invasive cancer within the last 5 years
- 2. Have completed or are nearing complement of treatment (surgery/chemotherapy/radiotherapy) with curative intent
- 3. Have no evidence of metastatic disease
- 4. Aged 18+, no upper age limit
- 5. Are experiencing fatigue: defined as scoring  $\geq$  4 on a unidimensional 11-point numeric rating scale (NRS) for fatigue
- as suggested by the National Comprehensive Cancer Network and/or have low self-efficacy to manage their fatigue <4 on a unidimensional 10 point rating scale.
- 6. Able to complete written records in English
- 7. Have access to the internet at home, from a community resource such as a library or through patients information services linked to health services e.g. Macmillan information services
- 8. Have or are willing to create an email account

## Participant type(s)

Patient

## Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

Sex

#### Total final enrolment

163

#### Key exclusion criteria

- 1. In the opinion of a relevant clinician they are unable to give informed consent (e.g. due to severe cognitive impairment or learning disability)
- 2. Are too ill to engage in the intervention
- 3. The intervention will be developed and tested in the English language this means that non-English speakers will be excluded from this study. We would hope to be able to make the intervention accessible in a number of languages once testing is complete and we have established effectiveness.

## Date of first enrolment

13/09/2012

#### Date of final enrolment

28/06/2013

## Locations

#### Countries of recruitment

**United Kingdom** 

England

# Study participating centre University of Southampton

Southampton United Kingdom SO17 1BJ

# Sponsor information

#### Organisation

Southampton University Hospitals NHS Trust (UK)

#### **ROR**

https://ror.org/0485axj58

# Funder(s)

## Funder type

Charity

#### Funder Name

Macmillan Cancer Support (UK)

## **Results and Publications**

## Individual participant data (IPD) sharing plan

Not provided at time of registration

## IPD sharing plan summary

Not provided at time of registration

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/11/2015		Yes	No
Results article	results	01/06/2016		Yes	No
<u>Protocol article</u>	protocol	21/06/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			26/10/2022	No	Yes