

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

Submission date 03/10/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 05/10/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/10/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

No secondary outcome measures

Overall study start date

13/09/2012

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 ≥ 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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 125; UK Sample Size: 125

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

England

United Kingdom

Study participating centre

University of Southampton

Southampton

United Kingdom

SO17 1BJ

Sponsor information

Organisation

Southampton University Hospitals NHS Trust (UK)

Sponsor details

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/0485axj58>

Funder(s)

Funder type

Charity

Funder Name

Macmillan Cancer Support (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	21/06/2013		Yes	No
Results article	results	14/11/2015		Yes	No
Results article	results	01/06/2016		Yes	No
Plain English results			26/10/2022	No	Yes