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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

Registration date
05/10/2012

Overall study status
Completed

Last Edited
26/10/2022

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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)

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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