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REFRESH: Recovery from Cancer-Related Fatigue Trial

Submission date 06/10/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 06/10/2015	**Overall study status** Completed	
Last Edited 10/01/2018	**Condition category** Signs and Symptoms	

Plain English summary of protocol

Background and study aims
Fatigue is one of the most debilitating and frustrating symptoms patients endure following cancer treatment. For some, these symptoms can last for months or even years after treatment. This can have an emotional and functional impact on peoples' lives and such overwhelming fatigue can hold people back from resuming 'normal life' after cancer. In order to help people to learn more about their fatigue and what they can do to cope with it, an online programme called REFRESH: Recovery from Cancer-Related Fatigue has been developed. The aim of this study is to find out whether REFRESH is successful at reducing fatigue in post-treatment cancer survivors.

Who can participate?
Post-treatment cancer survivors aged over 18 who are experiencing fatigue.

What does the study involve?
Participants are randomly allocated to one of two groups. One group receives eight free online treatment sessions in the comfort of their own home. The content is based on the principles of cognitive-behavioural therapy, a psychological therapy that has proven to be effective in the management of symptoms such as fatigue. The online sessions focus on what people do and think in response to their fatigue symptoms. Participants are provided with instructions on a range of activity-pacing techniques to encourage more consistent levels of activity from day-to-day. Information on useful relaxation techniques and how to sleep better are also provided. The other group receives brief general recommendations about fatigue management.

What are the possible benefits and risks of participating?
Given that there is currently no recommended approach to deal with fatigue in people after cancer treatment, this study will offer all participants the opportunity to participate in a study that may produce advances in knowledge in the area, which could benefit individuals in the future. Participants may also benefit from the recognition, identification and understanding of their fatigue. Participants are encouraged to maintain contact with their doctor throughout the course. This study is to be conducted in conjunction with standard practice, and not as a replacement treatment. The study recommends some light exercise, and also encourages self-reflection. If participants do not feel comfortable with these, they are invited to discuss it with the research team. Further, the difficulties associated with motivation and effort in participating

in a study when fatigued are recognised. Participants are free decide not to complete a session or to withdraw without penalty.

Where is the study run from?
National University of Ireland (Ireland)

When is the study starting and how long is it expected to run for?
October 2015 to November 2016

Who is funding the study?
Cancer Care West/Galway University Foundation Hardiman Scholarship.

Who is the main contact?
Teresa Corbett

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
REFRESH: Recovery from Cancer-Related Fatigue - a pilot randomised trial of an Internet-based self-management cognitive-behavioural therapy intervention to enable self-management of fatigue in post-treatment cancer survivors

Acronym
REFRESH

Study objectives

Cancer-related fatigue is defined as “a persistent, subjective sense of physical, emotional and/or cognitive tiredness or exhaustion related to cancer or cancer treatment that is not proportional to recent activity, and interferes with usual functioning”

This is a two-armed randomized controlled pilot trial that is designed to study the feasibility and efficacy of an online intervention that aims to reduce fatigue in post-treatment cancer survivors. (Analysis:Multi-level modelling).

It is hypothesized that an online intervention designed using a theoretical, systematic and person-based approach could have the potential to reduce fatigue in post-treatment cancer survivors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee at National University of Ireland Galway, 20/01/2014, ref: 13/NOV/16

Study design
Two-armed randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cancer-related fatigue

Interventions
The control group will receive a PDF copy of information with brief general recommendations about fatigue management that was designed by the Irish Cancer Society.

The REFRESH online intervention group will access a website designed in line with the MRC Framework. The intervention requires 45-60 minutes per week over 8-10 weeks. The online intervention is accessed through the main welcome page at where users enter their unique username and password to gain access to the full system. Each of the 8 sessions acts as an online analog for the weekly sessions conducted in traditional in-person CBT. The intervention content incorporates the essential treatment elements of CBT: educational, behavioural, and cognitive techniques. Each session follows a similar structure: "objectives and outline", "main content", "review" and "to-do list". Throughout the programme the participants are encouraged to challenge cognitions and learn to prioritize certain behaviours in order to maintain a healthy energy balance. REFRESH includes a range of behaviour change techniques (BCTs) designed to enhance relevant information, motivation and behavioural skills.

Intervention Type
Behavioural

Primary outcome(s)

1. Feasibility and functionality outcomes will be assessed throughout the duration of the trial:
1.1. Recruitment and uptake
1.2. Adherence and attrition
1.3. Trial procedures and process analysis: functionality and usability of website
1.4. Participant satisfaction with website
2. To assess the efficacy of the “Refresh: Recovery from Cancer-Related Fatigue intervention” in long-term adult survivors of cancer, by comparing intervention and wait-list control groups: Functional impact of fatigue (primary outcome): Piper Fatigue Scale, assessed at baseline (prior to randomisation) and at 8 week follow-up

Key secondary outcome(s))
1. Quality of life will be assessed using the Quality of Life in Adult Cancer Survivors (QLACS) measure at baseline (prior to randomisation) and at 8 week follow-up
2. The Illness Perceptions Questionnaire for CrF will be used to assess perceptions relating to CrF Cognitive and Emotional Representations, assessed at baseline (prior to randomisation) and at 8 week follow-up
3. The Cognitive and Behavioural Responses to Symptoms Questionnaire (CBSQ) will be used to assess which cognitions and behaviours mediate the effect of cognitive behavioural therapy on fatigue, assessed at baseline (prior to randomisation) and at 8 week follow-up

Completion date
19/11/2016

Eligibility

Key inclusion criteria
1. Over 18 years of age
2. Experiencing fatigue defined as scoring ≥4 on a unidimensional 11-point numeric rate scale for fatigue as suggested by the National Comprehensive Cancer Network (1)
3. Able to complete written records in English
4. Have or are willing to create an email account and have access to the internet
5. Have basic ability to use a computer
6. Have completed primary treatment for cancer (patients are eligible for the study if they are receiving maintenance therapy such as hormone therapies) at least 3 months prior to baseline assessment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

Key exclusion criteria
1. Do not provide informed consent or refuse to be randomised
2. Have history of cancer recurrence
3. Do not confirm that they have received medical clearance for participation
4. Are currently participating in any other psychosocial intervention

Date of first enrolment
08/10/2015

Date of final enrolment
21/10/2015

Locations

Countries of recruitment
Ireland

Study participating centre
National University of Ireland
School of Psychology
Galway
Ireland
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Sponsor information

Organisation
National University of Ireland (Ireland)

ROR
https://ror.org/00shsf120

Funder(s)

Funder type
University/education

Funder Name
Cancer Care West/Galway University Foundation Hardiman Scholarship

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Teresa Corbett (email: t.k.corbett@soton.ac.uk)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/06/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes