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A novel online program for fatigue; a feasibility study

Submission date	Recruitment status	[_] Prospectively registered
10/02/2020	Suspended	[_] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
06/03/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
08/07/2024	Nervous System Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Fatigue can be a very difficult and debilitating symptom to live with. It can have a big impact on day to day life, including how we engage with the world. To manage fatigue, some people develop certain ways of processing information. For example, skim reading or predicting future energy levels. These are types of mental 'short-cuts' your brain makes. These ways of processing can be helpful, such as in helping you manage everyday tasks and planning to do activities when you are most able. However, by continually using these 'short-cuts' our brain gets used to following the same path and the 'short-cuts' can become automatic. So, rather than apply different ways of processing information, taking different paths, our brains become reliant on the same one. This can be unhelpful, for example when the situation changes, or an unexpected event occurs. This research is designed to assess whether we can change how the brain deals with or processes information and whether training the brain in more flexible processing is helpful for people with fatigue. To do this the researchers are using a computer program which aims to train flexible information processing through repeated practice. The primary aim of this study is to test whether this type of online training is acceptable to patients. Secondly the researchers want to establish whether the training changes how people process information and importantly whether changing how people process information is helpful to patients- does it improve fatigue, distress or functioning?

Who can participate?
People can take part if they have a diagnosis of Chronic Fatigue Syndrome (CFS) or they have another long-term condition (i.e. a condition that requires ongoing management) and high levels of fatigue. Participants must be over 18 years of age.

What does the study involve?
Participants are asked to complete some computerised training. There are two types of this training and participants are randomly assigned to complete one of them. One is an active version of the training and one is a neutral version. This is so that the researchers can compare them. Both types of training consist of 12 sessions completed over 3 weeks (4 sessions per week). The sessions will last about 20 minutes and can be completed at home on a computer or tablet. In addition, participants complete some assessments online, before and after the 12 training sessions and again at 1-month and 3-months follow-up. After completing the training

participants are invited to complete a brief telephone interview with a researcher to tell us about their experience of the program.

What are the possible benefits and risks of participating?
This study is investigating whether a program like may be useful for people with fatigue, however, in its current form it is not viewed as a therapeutic intervention. Whist participants may not directly benefit from this study, the research is aimed at further understanding factors which contribute to fatigue. This knowledge can help identify ways to help reduce the distress and disability fatigue can cause in people's lives. The risk of taking part is extremely minimal. The online program has been used before without any adverse effects. The assessments have also been used previously and should not cause any distress. Taking part in this study does not affect routine medical care in any way.

Where is the study run from?
The study is conducted by researchers at King's College London. All parts of the study are completed by the participant at home at a time and day that suits them.

When is the study starting and how long is it expected to run for?
June 2019 to March 2022

Who is funding the study?
National Institute for Health Research (NIHR) Biomedical Research Centre at South London and Maudsley NHS Foundation Trust and King's College London (UK)

Who is the main contact?
Miss Serena McGuinness
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 43194

Study information

Scientific Title
A novel online program for fatigue; a feasibility study

Study objectives
Overarching research question: Can a novel cognitive bias modification intervention be used to reduce negative interpretation biases in people with high levels of fatigue?

The primary objective is to explore the acceptability of the online intervention study materials, intervention frequency, duration and platform, randomisation to the active or control conditions, and use of the outcome measures. In addition, to inform the feasibility of an effectiveness trial in terms of the number of potentially eligible participants and recruitment rate, retention rate, response rates to initial and follow-up questionnaires, adherence rates to the online intervention.

A nested qualitative study will explore feasibility through semi-structured interviews focusing on participants experiences of the intervention and study design.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/12/2019, London Camden & King's Cross Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle Upon Tyne, NE2 4NQ, UK; Katie Arnold (+44 (0)207 104 8068), Danielle Bromage (+44 (0)207104 8222) camdenandkingscross.rec@hra.nhs.uk), REC ref: 19/LO/1430

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Chronic fatigue (CF) including both patients with chronic fatigue syndrome (CFS)/myalgic encephalomyelitis (ME) and idiopathic chronic fatigue (ICF)

Interventions
Current interventions as of 08/07/2024:
This feasibility study of the online program will involve participants with chronic fatigue (CF) including diagnoses of chronic fatigue syndrome (CFS) or idiopathic chronic fatigue (ICF); n=50. It will also involve participants with a number of long-term physical health conditions (LTC's); defined as a condition that cannot, at present be cured; but can be controlled by medication and other therapies; and requires ongoing management over a period of years or decades; n=50 per LTC.

From each group, 25 participants will be randomised into the active arm of the program and 25 into the sham/ control arm of the program. All participants will complete sessions of the computerised training programme (4 sessions per week, over 3 weeks) with each session lasting approximately 20 minutes. All sessions will be completed at home, online on a computer or tablet. All participants will complete online assessments before and after the 12 training sessions as well as at 1 month and 3-months follow-up.

Participants in the active arm of the study (N=25) will be invited to participate in a qualitative interview post training. The qualitative interview will ask about prior expectations, experience of the program, likes and dislikes as well as any perceived usefulness going forward. The full interview schedule will be developed based on PPI.

Participants with CFS/ICF will be recruited from Adult fatigue specialist services in England; including London Greater trusts (Hillingdon Hospital, Uxbridge; Royal Free Hospital and South London and Maudsley NHS Trust (research site)) as well as Oxfordshire (Oxford University Hospitals Fatigue Service), Somerset (CFS/ME Service Royal National Hospital for Rheumatic Diseases Bath; Bristol CFS/ME Service).

Recruitment will also take place across King's Health Partners in secondary care. Clinical Research Network (CRN) sites who show an interest in being involved in the study will be assessed for their ability to meet recruitment targets. If deemed appropriate the CRN site will be included and researchers trained on the study protocol.

Participants will be recruited from secondary care as well as via adverts in patient support groups and online forums.

Recruitment procedure
Information about the study and details of how to register an interest will be provided either:

1. Verbally by clinic or research staff when the person attends their routine appointment; if the person indicates they are interested they are provided with an invitation letter and participant information sheet (PIS). If they would prefer an electronic copy of the invitation letter and PIS they can provide their email address and the invitation letter can be emailed to them (at PICs); At SLaM (research site) the clinician will identify patients and introduce them to the researcher who will follow this same procedure.
2. At SLaM, the 'Consent for Contact (C4C)' initiative may also be used. The researcher will look at the register and inform the clinician that they will be approaching or contacting that patient to determine their interest. This will be logged on ePJS.
3. Via invitation letter and PIS mailed out to potentially eligible patients; staff with appropriate levels of access will screen current clinic records to identify potentially eligible participants and will mail out an invitation letter and PIS to them (at PICs).
4. Via an advertisement.

All participants will need to log on to the study website in order to register their interest. The design and layout of the website will be finalised during PPI. To register their interest patients will be required to read the participant information sheet before providing consent to screening and contact.

Informed consent
Participants will be fully informed before giving consent. Potential participants will receive information about the study via one of the methods outlined above. Those who are informed of the study during their outpatient visit will be told of the study verbally and have an opportunity to ask questions. The researchers contact information will be provided on the invitation letter and participant information sheet. Interested patients will register their interest on the study website by reading the participant information sheet and provide consent to screening and contact. Eligible patients will be contacted by a member of the research team, who will further discuss the study with them and invite them to participate. Patients will have the opportunity to ask questions and can take as long as they need to decide whether or not to take part. If the patient would like to participate in the study they will be sent a link to the participant information sheet, full consent form and assessment T0.

Screening and eligibility procedure
To register their interest participants access the website, read the participant information sheet, and consent to the screening questionnaires and contact from a researcher.

Once consent is provided they are asked for their contact details and complete the following screening questionnaires:
1. Contact details, demographic and medical information: Diagnosis, gender, level of English language
2. The Chalder Fatigue Scale (Chalder et al. 1993) - to assess caseness of fatigue.
3. Ambiguous scenarios recognition task (Mathews & Mackintosh's, 2000) - to assess for negative interpretation bias

This information is required to check for basic eligibility criteria. Those below the age of 18 will not be permitted to register their details. These questionnaires take approximately 20 minutes to complete. Participants are told that someone from the research team will be in touch once the questionnaires are completed. Researchers will review the results of the questionnaires in order to check they meet the eligibility criteria. Once researchers have checked for eligibility they will contact patients to inform them of whether they are eligible or not. Those who are not eligible for the study will be thanked for their interest and time but informed they cannot continue with the study. They will be given an explanation as to why.

Randomisation and testing procedure
Those who are eligible and who agree to participate will given an anonymous ID number and sent a link to the participant information and consent form. Once consent is given they will proceed to complete the baseline assessment (T0). The participants will then be randomly allocated into one of the 2 conditions (active or sham training). A randomisation website will be used to randomise participants to one of the 2 conditions. The researcher will activate the participants online account and they will receive an email with their log-in details.

The assessment sessions 1, 2, 3 and 4 will consist of:
1. Ambiguous scenarios recognition task (Mathews & Mackintosh, 2000)
2. Chalder Fatigue Scale (Chalder et al. 1993)
3. PHQ-9 (Kroenke & Spitzer., 2002).
4. GAD-7 (Spitzer et al., 2006)
5. SF-36 physical functioning sub scale (Ware et al., 1993)
6. Work and Social Adjustment Scale (WSAS; Mundt et al., 2002)
7. Cognitive Behavioral Responses Questionnaire (shortened version CBRQ; Ryan, Vitoratou, Goldsmith & Chalder, 2018)
8. Fatigue Acceptance questionnaire (Brooks, Rimes & Chalder, 2011)
9. Committed Action Questionnaire, short (McCracken, Chilcot & Norton, 2015)
10. Cognitive Fusion questionnaire (Gillanders et al., 2014)

The training consists of 12 sessions, each lasting approximately 20 minutes. The sessions are completed over the course of 3 weeks. Participants will manage their own homework schedule, however, only one assignment may be completed per day. The online platform will send out automated text reminders for encouragement and to maintain good adherence. These will be sent following completion of sessions 3, 5, 7 and 10. If a participant is having difficulty completing the sessions within the 3 weeks they will be given another 1 week to complete the sessions. When participants have completed all 12 homework sessions, they will be asked to complete the post-intervention assessment (T1). One month later they will be sent a link to complete the first follow-up assessment (T2) and then the 3 month follow up (T3).

Those in the active arm of the training program will be contacted 1-2 weeks post-completion, to arrange a follow-up interview. The interviews will be semi-structured and will ask about prior expectations, experience of the program, likes and dislikes as well as any perceived usefulness going forward.

Online training procedure
Active training arm:
Each homework session (12 sessions in total) consists of repetitive practice whereby the participant is encouraged to resolve ambiguous information in a more positive and less negative way. In each session participants are instructed to listen to a batch of ambiguous scenarios from everyday life, whilst imagining themselves as the main character in the situation. In half of the situations the participant is asked a comprehension question, with the positive interpretation reinforced. In the other half participants will be required to form their own positive ending.

Sham training arm:
A sham training arm of the study will act as the control condition. The sham training is formatted in the same way as the active condition, however the ambiguity remains unresolved. Comprehension questions will be factual. Participants receive feedback for incorrect responses, but no feedback for correct responses.

Previous interventions:
This feasibility study of the online program will involve participants with chronic fatigue (CF) including diagnoses of chronic fatigue syndrome (CFS) or idiopathic chronic fatigue (ICF); n=50. It will also involve participants with a number of long-term physical health conditions (LTC's); defined as a condition that cannot, at present be cured; but can be controlled by medication and other therapies; and requires ongoing management over a period of years or decades; n=50 per LTC.

From each group, 25 participants will be randomised into the active arm of the program and 25 into the sham/ control arm of the program. All participants will complete sessions of the computerised training programme (4 sessions per week, over 3 weeks) with each session lasting approximately 20 minutes. All sessions will be completed at home, online on a computer or tablet. All participants will complete online assessments before and after the 12 training sessions as well as at 1 month and 3-months follow-up.

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8. Fatigue Acceptance questionnaire (Brooks, Rimes & Chalder, 2011)
9. Committed Action Questionnaire, short (McCracken, Chilcot & Norton, 2015)
10. Cognitive Fusion questionnaire (Gillanders et al., 2014)
11. Cognitive fatigability task (Computerized Delayed Item Recognition, Holtzer & Foley, 2009; adapted for online use)
12. Borg Rating of Perceived Exertion Scale (Borg, 1998)

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Intervention Type
Other

Primary outcome measure
Feasibility and acceptability of the intervention measured by:
1. Recruitment rate measured by screening questionnaire at baseline
2. Completion rate measured by number and stage of withdrawals
3. Qualitative analysis of semi-structured interviews post-intervention or at point of drop-out

Secondary outcome measures
Estimated effect sizes of changes in secondary outcome variables:
1. Interpretation bias is measured by Ambiguous Scenarios Task at baseline (T0), post-

intervention (T1), 1 month (T2) and 3-months follow-up (T3)
2. Severity of fatigue is measured by Chalder Fatigue Scale at baseline (T0), post-intervention (T1), 1 month (T2) and 3-months follow-up (T3)
3. Disability is measured by Work and Social Adjustment Scale (WSAS) at baseline (T0), post-intervention (T1), 1 month (T2) and 3-months follow-up (T3)
4. Disability is measured by Short Form-36 Physical Functioning Scale (SF-36) at baseline (T0), post-intervention (T1), 1 month (T2) and 3-months follow-up (T3)
5. Depression is measured by Patient Health Questionnaire (PHQ9) at baseline (T0), post-intervention (T1), 1 month (T2) and 3-months follow-up (T3)
6. Anxiety is measured by Generalised Anxiety Disorder (GAD7) at baseline (T0), post-intervention (T1), 1 month (T2) and 3-months follow-up (T3)
7. Illness related cognitions and behavioural responses measured by Cognitive Behavioural Responses Questionnaire (shortened version) at baseline (T0), post-intervention (T1), 1 month (T2) and 3-months follow-up (T3)
8. Acceptance of fatigue is measured by Fatigue Acceptance Questionnaire (FAQ) at baseline (T0), post-intervention (T1), 1 month (T2) and 3-months follow-up (T3)
9. Flexible persistence in goal-directed behaviour is measured by Committed Action Questionnaire- short version (CAQ-8) at baseline (T0), post-intervention (T1), 1 month (T2) and 3-months follow-up (T3)
10. Influence of thoughts on actions is measured by the Cognitive Fusion Questionnaire (CFQ) at baseline (T0), post-intervention (T1), 1 month (T2) and 3-months follow-up (T3)

Overall study start date
01/06/2019

Completion date
31/03/2022

Eligibility

Key inclusion criteria
All participants must:
1. Meet caseness for fatigue (i.e. a score of 4 or more on the Chalder Fatigue Scale, 1993)
2. Be aged 18 years or older
3. Be fluent in English
4. Have normal or corrected-to-normal vision, hearing, manual dexterity
5. Not be currently undergoing psychological treatment
6. Have access to a computer or tablet with an internet connection

In addition:
Participants must either:
1. Have a diagnosis of chronic fatigue, including a diagnosis of chronic fatigue syndrome (CFS) or idiopathic chronic fatigue (ICF)
Or:
2. Have one or more long-term physical health condition defined as a condition that cannot, at present be cured; but can be controlled by medication and other therapies; and requires ongoing management over a period of years or decades

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 200; UK Sample Size: 200

Key exclusion criteria
1. Under 18 years old
2. Do not meet caseness for fatigue (i.e. they score less than 4 or more on the Chalder Fatigue Scale, 1993)
3. Do not have an interpretation bias (i.e. they do not a negative bias index on the ambiguous scenarios task, Mathews & Mackintosh, 2000)
4. Not happy to be randomized to control group
5. Currently undergoing concurrent CBT treatment or other psychological therapies
6. Poor level of English (as assessed by researcher during initial interaction)
7. Impaired vision/hearing that would hinder use of tablet or computer
8. Impaired dexterity that would hinder use of a tablet or computer
9. No access to a tablet or computer with internet connection
10. Does not have a diagnosis of chronic fatigue or a long-term physical health condition
11. Involved in another research study (with the exception of observational studies)

Date of first enrolment
10/12/2019

Date of final enrolment
31/08/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
Health Psychology Department
Department of Psychology
5th Floor Bermondsey Wing
Guy's Hospital
London
United Kingdom
SE1 9RT

Study participating centre
South London and Maudsley NHS Foundation Trust
Maudsley Hospital
Denmark Hill
London
United Kingdom
SE5 8AZ

Study participating centre
Mount Vernon Cancer Centre
Rickmansworth Rd
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HA6 2RN

Sponsor information

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Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
NIHR Maudsley Biomedical Research Centre

Results and Publications

Publication and dissemination plan
1. Peer-reviewed scientific journals
2. Conference presentation
3. A summary of the research will be made available to the participants who took part in the research

Intention to publish date
01/03/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as participants have not provided consent for their raw data to be accessible outside of the research team for this study.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan			08/07/2024	No	No