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Can a self-management program help people manage fatigue after critical illness? A small, early study to check if a larger research study is possible

Submission date 01/04/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol
Registration date 01/04/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 01/04/2025	**Condition category** Signs and Symptoms	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to explore whether it is possible to carry out a study testing a fatigue self-management programme for people who survive an intensive care unit (ICU) admission. Patients with life-threatening illnesses require care in an ICU. About half of those who survive (about 82,000 per year) report fatigue lasting for a year or more. Fatigue is described as an overwhelming physical and mental exhaustion, not relieved by rest or sleep. Fatigue has a devastating impact on every aspect of life, including being able to engage in rehabilitation, hobbies, work and affects people's ability to look after themselves safely. Healthcare professionals (HCPs) do not know the best way to manage this problem. Working together with HCPs and former ICU patients, we developed a fatigue self-management programme to help people as they recover at home. The programme was well received during early tests with a small group of people suffering from fatigue after critical illness. In the future, we plan to test how effective this programme is by comparing the experience of people affected by fatigue who receive it with those who only receive standard aftercare. Before starting this large study, we need to ensure it is designed properly.

Who can participate?
People aged 18 years and over affected by fatigue after critical illness from three large hospitals in England

What does the study involve?
In addition to standard aftercare, half of the participants will receive the self-management programme. This involves access to a website, containing educational materials about fatigue and how to manage it, and activities to help goal setting and action-planning for 6 months after hospital discharge. Three months after discharge from hospital, they will receive a 30-minute phone/video call from an HCP, who will help with goal setting and action planning. The researchers will ask people affected by fatigue and HCPs their thoughts about the programme and the study using interviews and questionnaires.

What are the possible benefits and risks of participating?
There are no direct benefits of taking part; however, participants in similar studies often comment that discussing their experiences and contributing to the future development of healthcare is helpful and personally satisfying. Participating will provide healthcare professionals with a unique understanding of this area of healthcare practice. There are no financial benefits to taking part. There are minimal risks associated with taking part in this study. However, during the interview and when completing the questionnaires, patient participants may be reflecting on their own experiences of critical illness and fatigue. There is a chance that they may find this upsetting in some way. If this is the case, they will be given the opportunity to take a break from the interview or stop it completely if they prefer. They may also decline to answer any questions in the questionnaire if they are too distressing. In these circumstances, the researchers would also encourage the participant to contact ICU Steps Charity, or https://www.criticalcarerecovery.com/, which may offer support and informational resources. If appropriate, the participant may be advised to contact their local critical care follow-up clinic or general practitioner.

Where is the study run from?
Oxford Brookes University (UK)

When is the study starting and how long is it expected to run for?
October 2024 to May 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Louise Stayt, lstayt@brookes.ac.uk

Contact information

Type(s)

Contact name
Dr Louise Stayt

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
328471

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 56131; Grant Code: NIHR206382

Study information

Scientific Title
What is the feasibility and acceptability of conducting a randomised controlled trial evaluating a healthcare professional-supported, self-management intervention for people suffering from fatigue after critical illness?

Acronym
FACT Feasibility

Study objectives
Null hypothesis: It is not feasible or acceptable to conduct a randomised controlled trial evaluating a HCP-supported fatigue after critical illness self-management intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/12/2024, Leeds East Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, E20 1JQ, UK; +44 (0)207 104 8012; leedseast.rec@hra.nhs.uk), ref: 24/YH/0242

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied
Fatigue after critical illness

Interventions
Half of the participants will be randomly assigned to the intervention group where they will receive access to the fatigue self-management intervention alongside receiving the usual care offered to patients recovering from critical illness. The other half will be randomly assigned to the usual care group. These people will only receive the usual care offered to patients recovering from critical illness.

The supported fatigue self-management intervention consists of web-based psychoeducational resources that participants may work through at their own pace, supplemented by a supportive phone call from an HCP who will assist with goal setting and action planning.
The web-based resources include four core self-management modules available in a variety of formats. These stand-alone 'bite-sized' modules may be accessed in any order.
1. About fatigue: Includes psychoeducational information, case studies and opportunities for self-monitoring.
2. Managing energy with the 5 P's: Outlines several strategies to manage energy levels and includes opportunities for self-monitoring and reflection.
3. Strategies for everyday life: Provides a variety of strategies relating to physical activity, home life, leisure, relationships, work, study and finances, thoughts, and feelings, eating, nutrition, and sleep. This section also includes resources about supporting a person affected by fatigue to share with family, friends, carers, children, and employers.
4. Goal setting and making plans: Includes psychoeducational materials, case studies, examples and opportunities for self-monitoring and reflection. HCPs will attend an online training event and follow a defined protocol to facilitate goal-setting and personal action-planning.

The supportive phone call from an HCP from the critical care follow-up clinic will occur prior to the patient's follow-up clinic appointment, at around 3 months after their hospital discharge. The purpose of the phone call will be to assist with fatigue-related goal setting and action planning.

Intervention Type
Behavioural

Primary outcome measure
1. Recruitment and randomisation rate is measured as a proportion of participants recruited and randomised compared to those assessed as eligible, overall and by centre at baseline
2. Retention rate is measured as a proportion of participants who complete the study to its conclusion at 3 and 6 months after randomisation
3. Semi-structured interview of patients' experiences utilising a topic guide based on the theoretical constructs of acceptability at 6 months after randomisation

Secondary outcome measures
1. Level of coping is measured using Carver's Brief Coping Orientation to Problems Experienced (COPE) inventory at baseline, 3 and 6 months after randomisation
2. Health-related quality of life is measured using EuroQoL-5 Dimensions (EQ-5D) at baseline, 3 and 6 months after randomisation

3. Level of fatigue is measured using Functional Assessment of Chronic Illness Therapy- Fatigue (FACIT-F) (Full 40-item scale) and Prototype F-ACT Scale (adapted version of Inflammatory Bowel Disease-Fatigue Scale) at baseline, 3 and 6 months after randomisation
4. The impact of fatigue on a person's ability to function is measured using the Work and Social Adjustment Scale (WSAS) at baseline, 3 and 6 months after randomisation
5. A person's cognitive and behavioural response to fatigue is measured using the Cognitive and Behavioural Responses to Symptoms Questionnaire (CBRQ)(Short version) at baseline, 3 and 6 months after randomisation
6. The acceptability of the intervention and trial procedures will be measured using the Theoretical Framework for Acceptability Questionnaire (TFAQ) at 6-months after randomisation
7. The usability of the intervention will be measured in the intervention group using the System Usability Scale (SUS) at 6 months after randomisation
8. Experiences of participating in the trial will be explored using semi-structured interviews using a topic guide based on the theoretical constructs of acceptability at 6 months after randomisation
9. Healthcare professionals' experiences of delivering and supporting the intervention will be explored using semi-structured interviews using a topic guide based on the theoretical constructs of acceptability at 6 months after randomisation

Overall study start date
01/10/2024

Completion date
01/05/2026

Eligibility

Key inclusion criteria
Patient Participant Inclusion Criteria:
1. Adults >=18 years
2. Have been an inpatient in the ICU for a minimum of 72 hours
3. Have required Level 3 care (Failure of two or more organs and/ or requiring advanced respiratory care) (Intensive Care Society, 2021) during their ICU stay
4. Self-reporting symptoms of fatigue at point of discharge (+/- 7 days) from hospital (< 34/ 52 on FACIT-F additional concerns subscale)
5. Ready for discharge (+/- 7 days) from hospital

HCP Participant Eligibility Criteria:
1. Healthcare professional registered with a professional body (Nursing and Midwifery Council, General Medical Council, Health, and Care Professionals Council)
2. Directly involved with the intervention delivery for this study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 70; UK Sample Size: 70

Key exclusion criteria
Patient Participant Exclusion Criteria:
1. Expected to survive for < 30 days according to their clinical team
2. A neurological diagnosis occurring as a cause or result of the patient ICU admission (e.g., stroke, traumatic brain injury) or any neurodegenerative condition (E.g. multiple sclerosis, amyotrophic lateral sclerosis) as these specialist groups have different clinical and biological characteristics

Date of first enrolment
15/04/2025

Date of final enrolment
31/01/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Guys and St Thomas' NHS Foundation Trust
249 Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre

University Hospitals Coventry and Warwickshire NHS Trust
Walsgrave General Hospital
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CV2 2DX

Sponsor information

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Sponsor type
University/education

Website
https://www.brookes.ac.uk/

ROR
https://ror.org/04v2twj65

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/05/2027

Individual participant data (IPD) sharing plan
The anonymised datasets generated during and/or analysed during the current study will be available upon request from Dr Louise Stayt (lstayt@brookes.ac.uk). Each individual request will be evaluated on a case by case basis to determine the type of data shared, duration and mechanisms of access. A data sharing agreement will be required in these instances.

IPD sharing plan summary
Available on request