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Holistic approach for improving the care of people with multiple conditions after critical illness

Submission date
29/08/2025

Recruitment status
Not yet recruiting

Registration date
01/09/2025

Overall study status
Ongoing

Last Edited
01/09/2025

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
People who survive a critical illness require special care and support. After leaving hospital they may experience many significant problems including weakness, depression and memory changes. Everyone who has been admitted to the Intensive Care Unit (ICU) should be offered support which meets their needs. However, currently there is no standard approach in the UK. What people are offered depends on where they live, and many people receive little support when they return home. Critical illness survivors with multiple medical conditions (also known as multimorbidity) face unique challenges when they leave ICU. This includes the burden of having to manage the multiple conditions and attend multiple appointments. Their medical conditions may get worse and lead to another admission to hospital.
We have developed a programme which aims to support critical illness survivors with multiple medical conditions as they transition from hospital to home. We want to test whether the programme can be delivered in the community. We also want to find out whether the programme is acceptable for patients and their families or carers.

Who can participate?
Adults aged over 18 years who have been admitted to the Intensive Care Unit for more than 2 days and who have two or more current medical conditions

What does the study involve?
Participants will be asked by the research team to complete a consent form and the trial questionnaires. The research team will review medical records to collect information about the participants health during the study. Participants will be asked about how being in an intensive care unit affected their physical and mental health and quality of life. This will take about 30 minutes to complete. They will also be asked to do a short physical test that involves standing up and sitting down from a chair called a ‘sit-to-stand’ test, and it tells us about their general fitness. They will be asked to complete study questionnaires at the start of the study, and then again at 6 weeks and 6 months. With consent the researchers will also send questionnaires to their carer or relative (if available) and healthcare providers to explore their views on the programme. Participants will be invited to meet with a member of the research team to discuss

your experience of the programme. With consent, the researchers will also invite their care or relative (if available) and healthcare providers to an interview to explore their views on the programme.
After the first questionnaire and sit-to-stand test, participants will be put into one of two groups by chance.

Group 1: People in this group will be provided with the usual care that is currently given to patients who have been in intensive care. This includes care provided by your GP and hospital teams. They will not be asked to participate in the HARMONISE programme describe below.

Group 2: In addition to receiving usual care, people in this group will be offered a programme which aims to support them as they transition from hospital to home. The programme will last for up to 6 weeks after leaving hospital.
The HARMONISE programme has several components to try and achieve these aims:
1. Screening for unmet needs
2. Personalized care plan
3. Self-management support
4. Involvement of carer or relatives

Meetings with the HARMONISE team will be audio or video recorded. The information from the recordings will be used by the research team to find out what worked well and what didn't work as well.

What are the possible risks and benefits of participating?
We cannot promise that the study will help participants. However, the information we get from the study will be useful in deciding whether to undertake a larger study which would determine whether HARMONISE improves outcomes for patients.
We do not anticipate any serious risk to participants. One possible disadvantage of taking part is the inconvenience it may cause to complete the questionnaires. Sometimes, people can find the questionnaires or support sessions upsetting. Our specialist staff are fully trained and will provide appropriate support and assistance if needed.
If it can be delivered, we will design a clinical trial to test whether it improves the outcomes for patients, including reducing the risk of being readmitted to hospital, and improves quality of life, physical strength, and emotional wellbeing of patients. The programme could be offered across the UK and could lead to improved outcomes for patients.

Where is the study run from?
Participants will be recruited from hospitals in Northern Ireland. Delivery of the study will also take place in peoples homes after leaving hospital.

When is the study starting and how long is it expected to run?
February 2024 to August 2028

Who is funding the study?
The study is funded by the HSC Research and Development Office within the Public Health Agency in Northern Ireland and Belfast Health and Social Care Trust Charitable Funds.

Who are the main contacts?
1. Dr Jonathan Stewart, jstewart52@qub.ac.uk
2. Prof. Danny McAuley, d.f.mcauley@qub.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
336523

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Holistic AppRoach for Multimorbidity OptimisatioN after IntenSivE care

Acronym
HARMONISE

Study objectives
1. Assess the feasibility of an intervention (called HARMONISE) to optimise the care of critical illness survivors with multimorbidity following hospital discharge.
2. Assess the feasibility of delivery of HARMONISE alongside other care provision following hospital discharge, including rehabilitation.
3. Assess the feasibility of procedures for a future clinical trial alongside delivery of HARMONISE.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/02/2024, Health and Social Care Research Ethics Committee A (HSC REC A) (Office for Research Ethics Committees Northern Ireland (ORECNI), Lissue Industrial Estate West, 5 Rathdown Walk, Lisburn, BT28 2RF, United Kingdom; +44 (028) 95 361400; info.orecni@hscni.net), ref: 24/NI/0008

Study design
Randomized feasibility trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Sequalae of critical illness

Interventions
Patients will be randomised on a 1:1 ratio using Sealed Envelopes software.

Group 1: Usual Care
People in this group will be provided with the usual care that is currently given to patients who have been in intensive care. This includes care provided by your GP and hospital teams. They will not be asked to participate in the HARMONISE programme describe below.

Group 2: The HARMONISE programme
In addition to receiving usual care, people in this group will be offered a programme which aims to support them as they transition from hospital to home. The programme will last for up to 6 weeks after leaving hospital.
The HARMONISE programme has several components to try and achieve these aims:
1. Screening for unmet health and social needs
2. Care integration and optimization of care
3. Personalised care and shared decision making
4. Self-management support, patient education and care navigation
5. Informal carer orientation

Intervention Type

Mixed

Primary outcome measure

Process evaluation: feasibility and acceptability of intervention delivery
The following will be assessed for every intervention visit:
1. Fidelity (protocol adherence), assessed as the proportion of intervention components which are delivered as intended (i.e. as per the protocol). Reasons for delivery outside protocol will be recorded within explanatory notes
2. Time required for intervention delivery
3. Factors influencing intervention delivery (including participant and contextual factors, assessed through healthcare utilisation data, intervention checklist explanatory notes and semi-structured interviews. This includes examination of the content of existing care provision and follow-up (e.g. medical, rehabilitation and social) and its interactions and compatibility with the intervention.
4. Perceived benefits and harms, evaluated through participant, carer, and healthcare professional semi-structured interviews
5. Acceptability of Intervention delivery for participants, evaluated through the acceptability questionnaires and semi-structured interviews

Process evaluation: feasibility and acceptability of procedures for a future trial
1. Reach (recruitment rate) and reasons for refused consent, measured at baseline
2. Participant attrition rate and reasons for attrition, measured throughout the study period
3. Completeness of the proposed baseline and outcome measures data for future trial and reasons for failure to collect baseline and outcome measures, measured at 6 weeks, 3, 6 and 12 months
4. Acceptability of clinical trial procedures for participants, measured at all intervention visits

Process evaluation: feasibility and acceptability from the perspective of informal carers
To assess how the change in the patient’s care impacts their informal carers (if available) we will request that the participant’s carer also completes two questionnaires (EQ-5D-5L and multimorbidity treatment burden questionnaire) at 6 weeks and 6 months, an acceptability questionnaire and a semi-structured interview at the end of intervention delivery to explore their experience and evaluate how it affects their wellbeing.

Process evaluation: feasibility and acceptability from the perspective of healthcare professionals involved in the patients' care.
To assess how the change in the patients care impacts healthcare providers involved in their care, we will request that these healthcare providers also complete an acceptability questionnaire and a semi-structure interview (at the end of intervention delivery) to explore their experience of the intervention.

Secondary outcome measures

Main trial outcomes:
The following will be measured at 6 weeks, 3, 6 and 12 months:
1. Hospital readmissions (scheduled and unscheduled)
2. Hospital-free days
3. Mortality
4. Healthcare resource utilisation (scheduled and unscheduled) including emergency department attendances, hospital admissions, outpatient appointments, General Practitioner attendances, and General Practice Out of Hours attendances.
5. Concomitant medications

The following will be measured at baseline, 6 weeks and 6 months:
1. Health-related quality of life measured using the EQ-5D-5L questionnaire
2. Treatment burden measured using the Multimorbidity Treatment Burden Questionnaire (MTBQ)
3. Self-efficacy measured using the Self-Efficacy to Manage Chronic Disease Scale
4. Psychological function measured using the Patient Health Questionnaire (PHQ-9) and Generalised Anxiety Disorder Questionnaire (GAD-7)
5. Cognitive function measured using the Montreal Cognitive Assessment BLIND (MoCA-BLIND)
6. Physical Function measured using the 30 second sit to stand test

Overall study start date
22/02/2024

Completion date
01/08/2028

Eligibility

Key inclusion criteria
1. Adults >18 years old
2. Currently admitted to hospital following admission to an intensive care unit for at least 48 hours
3. Multimorbidity: two or more current medical conditions
4. Able to participate in the intervention and with trial procedures

Participant type(s)
Patient, Health professional, Carer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Unable to provide consent
2. Life expectancy of less than 6 months (as determined by the patients treating clinician)
3. Discharged to a rehabilitation unit, or care home with/without nursing care
4. Prisoners

Date of first enrolment
05/09/2025

Date of final enrolment

01/02/2028

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Belfast Health and Social Care Trust
Trust Headquarters
A Floor - Belfast City Hospital
Lisburn Road
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United Kingdom
BT9 7AB

Sponsor information

Organisation
Queen's University Belfast

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Sponsor type
University/education

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
Government

Funder Name
Public Health Agency

Alternative Name(s)
PHA

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Belfast Health and Social Care Trust Charitable Funds

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the nature of the data collection and decision of the research team. Requests for data sharing will be managed in accordance with Queen's University Belfast policy on data sharing. The datasets generated during and/or analysed during the current study will be available upon request after publication of the main study results.

IPD sharing plan summary
Not expected to be made available