METHOD ARTICLE

REVISED Development of a patient centred, structured, individually tailored, multi-component intervention to promote rehabilitation and recovery after critical illness: content, theory, and construction.

[version 2; peer review: 1 approved, 2 approved with reservations]

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Abstract

Background/aims

This paper describes the development (content, theory, and construction) of a patient-centered, structured, individually tailored, multicomponent intervention (the iRehab intervention) to promote rehabilitation and recovery after critical illness.

Methods

The intervention was informed by the MRC framework for complex interventions and underpinned by existing literature and psychological theories. Key stakeholders included patients who had been in intensive care and multidisciplinary staff with experience in

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providing healthcare and undertaking research.

Results

The final intervention includes four core components: 1. weekly discussion and guidance regarding symptom management; 2. targeted exercise and physical activity; 3. support for psychological well-being; 4. peer support and information provision. These are packaged as a program to support rehabilitation and recovery after ICU discharge.

Programme duration: Six weeks.

Format: Weekly one-to-one remote needs assessment to identify individual participant symptoms and provide management plans, exercises, and strategies to best support recovery. Participants are encouraged to attend weekly group-based remote exercise sessions and group-based remote support sessions (iRehab Café).

Mode of delivery: Remote delivery facilitated by online platforms such as Microsoft Teams or Zoom supported with video platform BEAM©, and delivery can also be supported by telephone. The preferred mode of remote delivery is agreed with the participant, and potential barriers to implementation are considered. Manuals are posted to all participants to support intervention delivery.

Discussion/conclusion

This paper reports the content, theory and construction of the iRehab intervention. The iRehab intervention is currently being tested in a multicenter RCT (iRehab ISRCTN11266403), and the details reported in this paper will help with understanding of the intervention, interpretation of the findings, and replication of the intervention. Detailed intervention manuals will be available upon the completion of the trial.

London, UK

Any reports and responses or comments on the article can be found at the end of the article.

Plain Language Summary

People treated in intensive care units need a great deal of special care and support. After discharge from the hospital, some people find their muscles weak, and they cannot do everyday activities. They can also confuse memories of their time in the intensive care unit. Many patients are likely to experience PTSD-like symptoms.

Patients often report feeling abandoned after discharge because the intensive nature of their care has ended. This paper describes how a support and exercise rehabilitation program was developed. This is called the iRehab intervention.

Many ex-ICU patients and their families helped us to find out what should be included in the iRehab intervention. We also included views

from staff who provide care to patients in intensive care, as well as researchers and findings from other studies.

There are four main parts:

1. Discussion with the patient and iRehab sepcialist about how to manage symptoms or problems.

2. Help to do the right exercises and activities.

3. Support for emotional wellbeing.

4. Peer support and information provision e.g. sign-posting to relevant services, websites.

Each week, an iRehab specialist speaks to each patient to find out what their needs are. The iRehab specialist helps patients with treatments to help their recovery and rehabilitation. Patients get a manual with words and pictures to follow. This lasts for six weeks and can be delivered by a computer or telephone.

This paper describes a collaborative approach for the development of the iRehab intervention. These details will help others, such as healthcare professionals, patients, and their families, to understand all parts of the intervention. The iRehab intervention is currently being tested in a large trial in the UK. When the trial has ended, the manuals that were created will be accessible to others.

Keywords
Intervention Development, Rehabilitation, Critical illness, Intensive Care Unit (ICU), Recovery

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REVISED **Amendments from Version 1**

Minor amendments have been made per below based on suggestions following peer review.

1. Discussion, Page 10, paragraph 1: amended to
"A logic model was developed to propose how the intervention could lead to its effects and under what conditions during the iRehab trial (Table 3). If the intervention is effective the expectation is that improvements at 8 weeks will be observed in Health-related quality of life per the EQ-5D-5L; also measures of leg strength/exercise capacity (30second sit to stand test), Illness Perception (Brief Illness Perception Questionnaire), Fatigue (FACIT-F), Hospital Anxiety and Depression Scale (HADS), patients satisfaction/acceptability (TFAQ) ".

2. Table 2, Column 3 "Content" Line 1: amended to
"Participants identify symptoms of relevance to them in their recovery e.g. difficulty swallowing, breathlessness, pain..."

3. Conclusion/page 11:added
"This paper reports the development of a rehabilitation program that is currently under evaluation within a rigorous clinical trial framework (10)....."

4. page 7 "(iii) Constructing the intervention: amended to
The intervention was developed to embed progressive intervention strategies capable of being delivered by a trained intervention team from a broad range of backgrounds. "One iRehab specialist is assigned to one patient and provides their intervention across the 6 week programe" A multiprofessional group, each with specific expertise, is expected to support and guide each iRehab specialists in the management of patient symptoms and problems as required. iRehab specialists utilize resources ....."

5. Discussion section, page 11, after paragraph 2:added
"If the intervention is effective the trial manuals, resources and training package could be be adapted for different healthcare systems beyond the UK NHS by considering for example translations and cultural adaptations and using a similar centralized staffing model for intervention delivery."

Any further responses from the reviewers can be found at the end of the article

Background

People experience common and varied symptoms after critical care, often referred to as post intensive care syndrome (PICS)[1]. There is a need to develop and evaluate interventions to support rehabilitation and recovery after discharge from the ICU, this has been ranked a key priority for research by patients, their families, and researchers[1,2].

The National Institute of Clinical Excellence (NICE) guidelines recommend that the recovery pathway following critical illness should include regular assessment of physical and non-physical morbidity, goal setting, multiprofessional rehabilitation input according to individualized needs, and transition of information between care delivery stages[3]. However, this practice has been applied poorly following hospital discharge, and rehabilitation services post critical illness in the UK are ad hoc, geographically inconsistent, and variable in terms of structure, content, and format of delivery[4]. Feasible and alternative approaches to provide rehabilitation are needed to reach all those who could benefit and to optimize geographic access[5]. More recently, technology-enabled care has been shown to be effective and accessible for the delivery of rehabilitation in other illnesses such as cardiac rehabilitation, balance rehabilitation in older people, chronic obstructive pulmonary disease, and in people after COVID[6–9] but this needs to be tested in the context of rehabilitation after critical illness prior to widespread implementation in the NHS.

We developed the iRehab intervention which is currently being evaluated in a large-scale clinical trial with embedded process evaluation[10]. The iRehab intervention is a patient-centered, structured, individually tailored, multicomponent intervention that aims to promote rehabilitation and recovery in the early period following hospital discharge after critical illness through enabling patient self-management, clarifying illness symptoms, offering targeted support and treatments, and co-developing action plans.

The aim of this paper is to describe the development of the iRehab intervention, including its theory, content, and construction. This information will help other clinicians and researchers to understand the rationale for the intervention, aid in the interpretation of trial findings, and allow replication of the intervention.

Methods

Patient and public involvement

Patient and Public partners had a pivotal role from concept and throughout the design and development stages of this multicomponent intervention. This partnership continues while the intervention is tested during a RCT and its subsequent dissemination[10].

Patients and family members with lived experiences of critical illness indicated that they want access to a rehabilitation program that could support recovery after discharge home. They indicated that they would have attended such an intervention if it had been available to them, and this motivated them to be involved in the development of the iRehab intervention. Patient and Public partners inputted to qualitative research that also underpinned the intervention content. Based on their experiences and views, they identified that key facilitators of the intervention include supervision, tailoring of support and rehabilitation to personal needs, and access to manual/materials that can be referred to. They wanted the intervention to include help with motivation or mental health challenges if these were barriers to someone taking part, and help to modify exercises and activities depending on the stage of recovery. Other examples of active contributions by our Patient and Public partners were input into the content and design of the patent materials, the format for delivery of the intervention, and advice about practical issues such as access to computers. Patient and Public partners have formed our current iRehab Patient Advisory Group (PAG), which supports the implementation of this intervention in the iRehab trial[10]. Together, we will plan dissemination to linked communities in formats that are accessible to a wide audience. To support the dissemination

of this manuscript, two of our PAG members have co-written the plain language summary (see acknowledgements).

Intervention development

This manuscript adheres to recommended guidance for explicit and comprehensive reporting as per the Template for Intervention Development and Replication (TiDIER)[11]. The intervention embedded a range of influences to address the core elements (*a-f*) recommended by the MRC for the development and testing of complex interventions[12]. To (*a*) '*identify content*' and (*b*) '*develop and refine the content, and programme theory'*, we included theories and evidence underpinning treatments, existing literature around post ICU outcomes, and patient feedback and experiences. Our key (*c*) '*stakeholders'* included multiprofessional staff with experience providing healthcare to post ICU patients and undertaking research, patient partners and a Patient Advisory Group (PAG) with former ICU survivors (including experience of mechanical ventilation), and relatives of ICU survivors and members of the public. Input from our patient partners relating to the lived knowledge of a patient journey following critical illness affirmed the need to have an individualized multicomponent approach to rehabilitation to address the complexities of the recovery process for survivors.

The construction of our intervention focused on *(d)* '*identifying key uncertainties'* and *(e) 'refining'* the intervention, and (*f*) '*economic considerations'* were made by considering the efficiency of using a core trained team to remotely deliver the intervention online.

Ethics approval was not required for this manuscript which reports intervention development and does not involve research data or participation.

(i) Underpinning theory

Components 1–4: goal setting and weekly action planning

The iRehab intervention was informed by Leventhal's Common-Sense Model (CSM) of self-regulation[13,14]. Leventhal's CSM describes the process by which individuals respond to a perceived health threat, in this case their critical illness[13]. It models how we think about our health by using common sense to interpret health threats and react to them in ways that may not always seem rational from the outside but have their internal logic. The model emphasizes several mechanisms that are important for adaptation to illness, including knowledge, past experiences, memories, and personal history. The model asserts that when a person is faced with a health problem, "an illness-related memory schema or 'prototype' is activated"[13,14]. Patients generally act to try to manage their condition or manage their 'problem'; this is a self-regulation process, and it can evolve over time as illness progresses.

Patients use their perceptions of the illness (cognitive and emotional representations of the illness) to help them develop action and coping plans to manage the illness and find potential solutions (e.g., "I should call my doctor"; "maybe I'll feel better if I rest"). Then, the 'successes of these actions are appraised through constant feedback loop e.g.' Am I less tired now' 'Am I better now?')[13]. Appraisal considers whether the strategy led to improvement, no change, or deterioration in symptoms, resulting in adjustment of the individual's representation – this is a dynamic process. It has been proposed that clinicians can support and improve management/self-management by communicating with patients, clarifying their illness, supporting treatments, and helping with action plans[15]. We incorporated these strategies into the intervention and included goal setting and weekly action planning[16–19].

(ii) Content based on post ICU outcomes, patient experience and evidence

Component 1: Weekly discussion and individual symptoms management

People experience common and varied symptoms after critical care, including dysphagia[20], breathlessness[21], fatigue[22], reduced appetite[23], delirium[24], and psychological symptoms including anxiety[25] and low mood/depression[26]. Participants in our qualitative research identified the potential benefits of symptom management for recovery[27,28]. People wanted communication and guidance from healthcare professionals after critical illness "*Encouragement from more people, within the health system*" *and "getting to know what your symptoms are*"[29]. Views from our PAG about how helpful information sharing and weekly support from health professionals would be, informed the intervention. The iRehab intervention will address commonly occurring symptoms after critical illness, and care pathways will be prescribed based on individual needs[29]. Evidence-informed treatment strategies have been embedded to help with individual symptom management. For example, breathing techniques for the management of breathlessness[30] and dietary advice for the management of poor appetite[31,32].

Component 2: Exercise and physical activity

Physical impairment and deconditioning are common after critical care[33] and patients want advice about exercise and return to usual activities; they have indicated "there are certain physical things I would like to know about"[27,28]. Exercise and physical activity programs can aid physical and emotional recovery in people with chronic obstructive pulmonary disease, chronic fatigue, and congestive heart failure[34–37]. We previously tested an exercise intervention for people after critical care, which informed the exercise component for iRehab[38]. We also drew on international experiences of remote multicomponent interventions e.g. pulmonary rehabilitation, liver surgery prehabilitation and cardiac rehabilitation; this informed the platform for remote delivery[8,39–43]. Therefore, the inclusion of exercise and physical activity components was based on research and patient feedback.

Component 3: Support for psychological wellbeing

Patients often face a long journey from critical illness to recovery. Patients with lived experiences of critical illness told us about their challenges with their psychological wellbeing "*I had terrible dreams when I was in ICU; nobody asked me once I came round about my ICU experience. And I have to say I was quite traumatised by it*," and they wanted advice from someone who understood the sequelae after critical illness[28].

Integrating an Acceptance and Commitment Therapy (ACT) based approach into a multidisciplinary intervention provides a clear framework for supporting individuals to set their own meaningful goals during that journey[44]. The potential utility of the ACT approach is supported by previous research in related areas of physical health, demonstrating that ACT supports functioning and quality of life in life-limiting conditions, palliative care, chronic pain, and physical and mental health[15,44–46]. Strategies for well-being activities, such as mindfulness or relaxation[45,47–49] as well as psycho-education related to delirium[50], are included in the iRehab program. The iRehab specialists delivering the intervention utilize resources based on ACT principles and committed action plans are reviewed with participants evolved on a weekly basis.

Component 4: Group based peer support sessions and other information needs

Participants in our qualitative research identified the potential benefit of speaking to others who have experience of recovery following discharge after an admission to ICU "maybe if I could speak to someone who had gone through the same experience as me"[28]. In an international stakeholder engagement project involving patients, and families (n=66 interviews across the UK, Australia, and the US), the reported benefits of a peer-support intervention were 1) sharing experiences; 2) care debriefing (e.g., care understanding/navigation of health care system, external and internal validation of progress and feelings), and 3) altruism (e.g., a sense of purpose, giving back/helping others)[51]. There is some evidence that peer support may reduce psychological morbidity in patients with critical illness[52]. The inclusion of a peer support group in the iRehab intervention is based on this existing research, feedback from patients participating in our previous research on rehabilitation after critical illness, as well as input from our PAG members. Patients said that there was a "lack of information" about what happened in the ICU and what to expect during recovery, and they wanted this information to guide their recovery. Hence, information provision and peer support groups were included in the iRehab intervention.

(iii) Constructing the intervention

The multiprofessional intervention development team (BO'N, JMB, BC, RC, ET, PF, SAD) used an iterative process (embedding the information above) to prepare, meet, obtain feedback, refine, and construct the intervention and its components. Input on a draft of the intervention was then sought from patient partners (n =11 current and past patient partners) and additional team members with relevant experience (DMcA, JB, JC). The content and construction of the iRehab intervention was also presented to an independent review panel of expert clinicians (n=5) (see acknowledgements) with critical care rehabilitation and intervention development expertise for feedback.

Materials were prepared for patients, and these underwent iterative review with specific input sought from the patient partners. The patient materials were assessed using the Drivel Defence Index to optimize the level of plain English[53]. Our patient partners also provided feedback on video-based materials, such as exercise videos, recordings of treatment strategies, and the approach to providing these to participants. Intervention resources and a detailed intervention manual and training package were developed for use by trained iRehab intervention specialists to deliver key skills related to common problems managed after critical illness.

The intervention was developed to embed progressive intervention strategies capable of being delivered by a trained intervention team from a broad range of backgrounds. One iRehab specialist is assigned to one patient and provides their intervention across the 6 week programme. A multiprofessional group, each with specific expertise, will support and guide iRehab specialists in the management of patient symptoms and problems as required. iRehab specialists utilize resources which are defined as Level 1, where the content of the resource duplicates that of the patient materials, and Level 2, where the multiprofessional group member(s) provide additional specific guidance to the iRehab specialist to complement the use and implementation of the Level 1 resources. Level 2 could include an additional instruction, skill, or advice to iRehab specialists to facilitate their provision of individualized support to a participant, for example, instructions from the dietician about dietary modifications for a patient wanting to increase their intake of plant-based protein; advice from the physiotherapist about how to modify a specific exercise to change the muscle load or joint lever due to patient reporting tendinitis, neuropathy, or pain; or advice from the clinical psychologist to undertake a brief patient assessment, for example, completion of the generalized anxiety disorder questionnaire (GAD-7) to enable the psychologist to guide escalation of care. NICE (2011) recommends stepped models of care, which are of increasing relevance globally in response to high demand against a background of limited resources[54].

Key uncertainties were identified during intervention development, and refinements were made. For example, a key uncertainty is the use of remote delivery and our patient panel informed us about practical information to optimise remote delivery and communication with participants such as options to access computers or a phone, use of email and texts, opportunity for technical assistance from family or carers, and it was highlighted that specifically scheduling a weekly appointment slot is an important intervention element. It was also suggested that written intervention materials be provided to participants by post, with help available from the iRehab specialist to go through these printed materials with participants to optimize their understanding and application. Information for the intervention needed to be deliverable via phone/remotely; therefore, sections within the printed manuals were required to be color coded for easy identification of relevant sections during calls with participants.

Results

The iRehab intervention

The iRehab intervention is a patient centered, structured, individually tailored, multicomponent intervention designed to promote rehabilitation and recovery after critical illness. An overview of the rehabilitation intervention delivery format is shown in Table 1. It is intended to include a broad range of

information, strategies, and support for people discharged home after mechanical ventilation in the ICU and at an early stage of the dynamic critical care recovery journey.

The intervention is designed to allow for progression according to individual ability, building over six weeks, with weekly online, one-to-one appointments with a trained iRehab specialist, usually lasting up to one hour or more based on individual needs. Participants are required to continue with the agreed individual rehabilitation techniques at home and their progress should be reviewed, and action plans amended at weekly appointments. Participants are encouraged to attend a weekly group-based remote exercise session and a group-based remote peer support session (iRehab Peer Support Café).

The final iRehab intervention includes four core components (See Table 2 for further details).

1. Weekly discussion and guidance regarding symptom management;

2. Exercise and physical activity;

3. Support for psychological wellbeing;

4. Group based peer support and other information.

The intervention includes a range of strategies that can be adapted based on individual patient needs. The iRehab specialist can consult with the relevant expert member(s) of the multiprofessional team to assure their delivery of the 'Level 1' resources/intervention or identify an additional 'Level 2' intervention strategy. If there is a need for an onward referral, the intervention team can connect with the critical care team at the patient's hospital site to identify an appropriate pathway or onwards referral or direct the patient to their GP. The intervention strategies provided to individual participants should be appraised at the weekly appointments through a constant feedback loop e.g. has the strategy helped or not, does the goal or treatment strategy need adjusted or the patient's expectations; this is a dynamic process.

iRehab Intervention team, training, materials, and mode of delivery

***Intervention team and training*:** The iRehab specialists will receive bespoke training, including access to the detailed intervention manual to support delivery, presentations, rehearsals, and interactive problem solving via case studies prior to delivering the intervention. They should be certified to deliver the iRehab intervention and supported with frequent and ongoing mentorship from an expert multiprofessional team, as well as training updates.

***Materials*:** An iRehab specialist's detailed intervention manual contains instructions and information designed to enable them to support participants over a six-week period to set goals and plan their actions for exercise, physical activity, psychological

Table 1. Overview of iRehab rehabilitation intervention (Table 1 is sourced directly from https://doi.org/10.3310/nihropenres.13910.1).

Timing	Session format	Content
Week 1	1-to-1 appointment, online	Explain programme Assess symptoms and identify needs Provide individual symptom management Agree and start exercise and activity plan Agree review appointments
	Independent or online group/ recorded exercise session	Home exercise plan/attend group exercise session /access recorded exercise sessions
	Online peer support group (iRehab peer support cafe)	Attend iRehab peer support cafe
Weeks 2 to 6	1-to-1 appointment, online	Weekly review of symptoms and progression through treatment plans Continue needs assessment, symptom management and psychological support Complete live exercise and continue plan for weekly exercise/physical activity Agree review appointments
	Independent or online group/ recorded exercise session	Home exercise plan or attend group exercise session/access recorded exercise sessions
	Online peer support group (iRehab peer support cafe)	Attend iRehab peer support cafe
Week 6	Final 1-to-1 weekly session to include review and discharge	Encourage participant to continue with prescribed management plans Identify further sources of support Discharge from intervention.

Table 2. Details of the core components of the iRehab intervention.

Component	Aims	Content
1. Weekly focused discussion and guidance to determine individual symptoms and management plans.	To support rehabilitation and management of symptoms after critical illness through focused discussion and expert guidance to determine individual symptoms, and provide management strategies Objectives • Identify main symptom/issue from patient's perspective • Provide strategies to address main symptoms and agree a goal/task for the week ahead using an Action Plan (AP)	• Participants identify symptoms of relevance to them in their recovery e.g. difficulty swallowing, breathlessness , pain • Agree appropriate personalised management plan • Standardised treatment strategies, individualised to the patient's needs will be provided. We have a menu of Level 1* intervention strategies to address each symptom. • Option to consult with the relevant expert member of the multiprofessional team to provide a Level 2* intervention; option to contact the site to identify an appropriate pathway if onwards referral is pending. • A goal/task for the week ahead will be discussed and agreed using an Action Plan (AP)
2. Exercise and physical activity	To support rehabilitation and recovery and management of symptoms after critical illness through exercise and physical activity Objectives: • Deliver weekly exercise sessions and promote physical activity (walking) • Help the patient set goals and plan their exercise and physical activity for the week ahead and coping strategies to overcome barriers by using an Action Plan (AP)	• Participants will be supported to undertake progressive exercise and/or physical activity to manage physical weakness, deconditioning and reduced function and support wellbeing • Weekly live exercise session tailored to patient needs during the 1:1 session, plus plan to undertake at least one additional exercise session (either group based exercise, access a recorded session or use the exercise manual to guide their independent session) and/or increase physical activity (usually walking via time, distance, step counts). • Help the patient set goals and plan their exercise and PA for the week ahead using an Action Plan (AP) including coping strategies to help overcome barriers
3. Support for psychological wellbeing	To support rehabilitation and recovery through psychological and wellbeing approaches Objectives: • Conceptualise the individual's situation utilising an Acceptance and Commitment Therapy focus using the ACT Matrix. • Identify appetitive (towards) and aversive (away) control • Define patients values and what gets in the way of connecting to a rich and meaningful life including cognitive fusion (internal) and experiential avoidance (external). • Develop a committed action plan and related psychoeducation on workable and unworkable strategies.	• Participants will be supported to manage any psychological symptoms e.g. anxiety, or low mood, delirium • Support for psychological wellbeing will specifically include an Acceptance and Commitment Therapy (ACT) focus. The iRehab specialists will be trained to use resources with interventions based on Acceptance and Commitment Therapy (ACT) principles and will have regular access (support and consultation) with an experienced clinical psychologist to provide further advice • Taught strategies or wellbeing activities e.g. mindfulness or relaxation will be incorporated into the patient action plan. • Strategies related to delirium include provision of the leaflet on delirium form ICU steps. • Action plans are reviewed weekly. If further input is needed and local services are available, the patient will be signposted onwards
4. Group based peer support sessions and other information	To support rehabilitation and recovery through peer support and addressing information needs Objectives: • Provide information about peer support and encourage attendance at the remote iRehab peer support group • Identify information needs and provide discussion, information, and sign posting to other relevant resources and services e.g. how and when to seek help and support, ICU steps, GP	• Participants will be encouraged to attend a weekly online iRehab peer support Café. A loose topic guide will be used to facilitate the session. • Based on individual needs and/or preference participants will also be provided with information about the critical care journey, how and when to seek help, and ongoing peer support.

*Level 1 is where the iRehab specialists' resource or treatment strategy duplicates the patient materials; Level 2 is where the multiprofessional team member(s) provide additional specific guidance to compliment the use and delivery of the Level 1 resource such as an additional skill, instruction, or advice to facilitate the delivery or individualization of the skill/advice/support, for example, instruction from the dietician about diet modifications for a patient wanting to increase their intake of plant-based protein; or advice from the physiotherapist about how to modify a specific exercise to change the muscle load or joint lever due to pain, tendinitis, or neuropathy; or occasionally a suggestion from the clinical psychologist to undertake a brief assessment, for example, completion of the GAD to enable the psychologist to guide escalation of care.

well-being, and symptom management for the week ahead, along with any other activities in line with the components of the intervention. To minimize performance bias in intervention delivery, the core components in the manual are standardized and incorporate suggested scripts and protocols to guide overarching delivery, while still enabling flexibility in how these are applied to individual participants. The intervention is designed to be used alongside a range of participant materials, either printed copies or accessed via electronic versions for reference during remote rehabilitation sessions, after which supplemental information is provided according to patients' feedback and individual needs.

***Access/Mode of delivery*:** The preferred mode of remote delivery (video or telephone) should be agreed with the participant. Guidance and help with troubleshooting the use of technology can be provided and/or an invite to have a relative or caregiver to assist.

Discussion

A detailed description has been provided of the development (theory, content, and construction) of an intervention to support and promote rehabilitation and recovery after critical illness – the iRehab intervention. It was developed based on the core elements recommended by the MRC framework[12]. The intervention is currently being tested in a RCT that will include rigorous process evaluation (10, iRehab Trial ISRCTN11266403). A logic model was developed to propose how the intervention could lead to its effects and under what conditions during the iRehab trial (Table 3). If the intervention is effective the expectation is that improvements at 8 weeks will be observed in health-related quality of life per the EQ-5D-5L; also measures of leg strength/exercise capacity (30second sit to stand test), Illness Perception (Brief Illness Perception Questionnaire), Fatigue (FACIT-F), Hospital Anxiety and Depression Scale (HADS), patients satisfaction/acceptability (TFAQ)

There is no agreed methodology for the development of interventions; several options exist, such as SQUID[55], Intervention Mapping[56], intervention taxonomy[57], the person-based approach[58], and the MRC framework[12]. Key criteria often include understanding the problem, identifying what aspects could be changed and what change(s) would be helpful, identifying how to make changes by proposing a mechanism of change, designing and testing the intervention, and understanding the process of change through a process evaluation[12,55–58]. However, a thorough description of the development process will help others to understand the level of complexity of the intervention and the rationale for its content.

We developed the iRehab intervention using evidence from existing literature, our previous research, views from patients with lived experience of critical illness, and clinical and research expertise from a broad multidisciplinary team and are confident that the intervention can be delivered as intended. Nonetheless, a lack of intervention adherence and low fidelity can influence trial outcomes[59,60]. To optimize the successful delivery of the iRehab intervention, the core components are fully protocolized to guide the delivery. In the iRehab trial, the intervention delivery team are trained to ensure that the delivery of core components is standardized. The trial includes a comprehensive process evaluation to fully assess all aspects of intervention fidelity and delivery. Active monitoring and early feedback will be implemented to prevent drift, ensure quality of delivery across staff and time, and monitor the inclusion of proscribed elements[59,60]. This manuscript describes intervention content in accordance with TIDieR guidance, and the results of the process evaluation will be published to ensure that all relevant insights into the intervention are available for interpretation[61]. If the intervention is effective the trial manuals, resources and training package could be adapted for different healthcare systems beyond the UK NHS by considering for example, translations and cultural adaptations, and using a similar centralized staffing model for intervention delivery.

Since the development of this structured rehabilitation intervention, one randomized controlled trial testing rehabilitation in patients with critical illness has been published. Khan *et al*. 2024 found there was no improvement in QoL (SF36) in an intervention group that received a 12-month nurse-led collaborative care intervention (m-CCRP) supported by an interdisciplinary team compared to a control group[62]. The trial population differs from the iRehab trial (e.g., shorter time with mechanical ventilation - 24 compared to >48 hours in iRehab), and while similarities include the use of protocols to support individual symptom management, there are several other differences, for example, there is no exercise component and contact (face to face initially) is infrequent and across 12 months. The iRehab remote intervention is designed to cover a broad range of possible strategies, delivered individually and in a group, with flexibility based on patient needs, and including goal setting and action plans, and delivered at levels one or two. The intervention is intended to be delivered to participants within 12 weeks of discharge from the hospital to facilitate positive readjustment once a patient has returned to life at home after critical illness. Testing our structured, individually tailored, multicomponent intervention will provide evidence whether rehabilitation delivered remotely is clinically and cost-effective for survivors following critical illness post ICU care.

The strengths of the iRehab intervention include its development by relevant key stakeholders and the inclusion of components that can be adapted and progressed according to individual ability and delivered remotely by a core trained intervention team. If effective, it has been designed to support efficient delivery when ICU staff resources are limited. It is delivered relatively early in a person's post-hospital recovery journey. While theories and frameworks other than Leventhal's CSM could have been used to inform this complex intervention, such as social learning theories[63], treatment and enablement theories[64], and the behavior change framework (COM-B)[65], it is difficult to make an optimal selection. However, in this intervention, the intention is to support participants with treatment strategies and the development of action and coping plans to help their rehabilitation and recovery, which is underpinned by Leventhal's CSM. We anticipate that we will be able to successfully measure changes in illness perception and health outcomes using this approach[66,67].

Table 3. Logic model: to propose how the intervention could work within the iRehab trial, and relationships between resources, activities and outcomes.

INTERVENTION OBJECTIVE	INPUTS	OUTPUTS		OUTCOMES	IMPACT
	INTERVENTION RESOURCES	ACTIVITIES IN THE INTERVENTION	PARTICIPANTS	WHAT CHANGES DO WE EXPECT TO SEE	WHAT WILL BE DIFFERENT IF WE ARE SUCCESSFUL
To improve the health-related quality of life, physical function, fatigue, mood, and other health-related outcomes after critical illness	- iRehab specialist (trained and certified) and expert MDT - Ongoing mentorship - iRehab intervention manual - Patient manuals, trial documents and equipment (pulse oximeter) - Infrastructure & technology - Funding, Patient and public partners, Warwick Clinical Trials Unit, Research team, Hospital sites	Four key components - Symptom management - Exercise and physical activity - Psychological support - Peer support & information Delivery -Weekly 1:1 with iRehab specialist +/- -Weekly group exercise +/- -Weekly peer support group Taught skills and resources to address patient symptoms and needs. Weekly action plan for each patient.	Participants are people who have had an admission to the intensive care unit and are within 0–12 weeks of discharge home	Improvements at 8 weeks - Health-related quality of life – EQ-5D-5L - Physical Function – 30 second sit to stand test - Illness Perception – Brief Illness Perception Questionnaire - Fatigue – (FACIT-F) scale - Hospital Anxiety and Depression Scale (HADS) - Views of patients – satisfaction/acceptability via TFAQ - Views of others (Staff)	Participants will -perceive improved HR-QoL - be able to exercise and be stronger, fitter and more active -have increased self-management, self-regulation and confidence -feel satisfaction and improved wellbeing having received increased support and guidance from clinicians/others - feel their symptoms, mood and mental wellbeing will have improved There will be overall evidence that multicomponent rehabilitation delivered remotely is effective and cost effective

Moderating factors	Physical performance at study outset Mental wellbeing at study outset	Perceived control and Self Efficacy	Credible source (iRehab specialist) Importance of feedback	Level of support available versus needed

Assumptions

Patients will be interested and agree to take part and will participate in the intervention; staff will deliver the intervention as intended; sites will support recruitment of study participants; outcome measures will be collected as planned.

External factors

Remote delivery in the participants home: there are advantages and disadvantages
Not all participants will have IT for video call/likely at least 50% will take part via video call as planned and 50% by phone
Intervention could become available locally across duration of study if service models change

Reference: How to develop a program logic for planning and evaluation Australian Institute of Family Studies https://aifs.gov.au/resources/practice-guides/how-develop-program-logic-planning-and-evaluation [last accessed 23.10.2024]

The theoretical model underpinning the psychological work with patients is based on ACT, an acceptance-based behavior therapy[68], and part of what is often known as the third wave of cognitive behavioral therapy (CBT). ACT therapy allows individuals to reconnect with their sense of self, identify meaningful values, and set goals in line with these values. The ACT Matrix will be utilized as a framework for guiding discussions with patients[69]. Active engagement and goal setting require a reoriented physical and psychological sense of self; however, ICU experiences often result in a profound disruption to coping and identity, requiring guidance to support the development of purpose and meaning[70,71].

Our intervention construction has limitations. First, we did not publish the specific methodology plan a priori for intervention development, although we did include key recommended criteria for intervention development, stakeholder involvement, and reviews[12]. Second, other issues may need to be addressed, such as ways to support families of patients who have been in the ICU (although family members can be present to support participants if the patient wishes) and social prescribing (although participants are signposted to their GP for onward referrals)[72,73].

Conclusion

The consequences of critical illness are substantial and multifactorial. This paper reports the development of a rehabilitation program that is currently under evaluation within a rigorous clinical trial framework[10]. The effectiveness and cost-effectiveness of the iRehab intervention compared to usual NHS care on quality of life and other health-related outcomes will be reported, and this intervention description will enable the interpretation of the trial findings.

Ethics and consent

Ethics approval was not required for this manuscript which reports intervention development and does not involve research data or participation.

Availability of data and materials

No data are associated with this article

Acknowledgements

Thank you for the invaluable contributions from all our patients and family partners (past members and our current patient advisory group members). Thank you to our patient partners Roger Kenyon and Rebecca Langley for their assistance with the preparation of the Plain English summary for this manuscript. Thank you to the following multiprofessional experts for independent peer review of components of the intervention: James Bruce Bristol Royal Infirmary, Eleanor Douglas Nottingham University Hospitals NHS trust, Peter Heine WCTU, Paul Twose Cardiff and Vale UHB, and Zoe van Willigen University Hospital Southampton Foundation Trust.

References

1. Needham DM, Davidson J, Cohen H, *et al.*: **Improving long-term outcomes after discharge from Intensive Care Unit: report from a stakeholders' conference.** *Crit Care Med.* 2012; **40**(2): 502–509.
PubMed Abstract | Publisher Full Text

2. Reay H, Arulkumaran N, Brett SJ, *et al.*: **Priorities for future intensive care research in the UK: results of a James Lind Alliance priority setting partnership.** *JICS.* 2014; **15**(4): 288–296.
Publisher Full Text

3. NICE: **Rehabilitation after critical illness**. NICE Clinical Guidelines: 83. National Institute for Health and Care Excellence, London, UK, 2009.
Reference Source

4. Connolly B, Milton-Cole R, Adams C, *et al.*: **Recovery, rehabilitation and follow-up services following critical illness: an updated UK national cross-sectional survey and progress report.** *BMJ Open.* 2021; **11**(10): e052214.
PubMed Abstract | Publisher Full Text | Free Full Text

5. Connolly B, Denehy L: **Hindsight and moving the needle forwards on rehabilitation trial design.** *Thorax.* 2018; **73**(3): 203–205.
PubMed Abstract | Publisher Full Text

6. Vasilopoulou M, Papaioannou AI, Kaltsakas G, *et al.*: **Home-based maintenance tele-rehabilitation reduces the risk for acute exacerbations of COPD, hospitalisations and emergency department visits.** *Eur Respir J.* 2017; **49**(5): 1602129.
PubMed Abstract | Publisher Full Text

7. Nakayama A, Takayama N, Kobayashi M, *et al.*: **Remote cardiac rehabilitation is a good alternative of outpatient cardiac rehabilitation in the COVID-19 era.** *Environ Health Prev Med.* 2020; **25**(1): 48.
PubMed Abstract | Publisher Full Text | Free Full Text

8. Light K, Bishop M, Wright T: **Telephone calls make a difference in home balance training outcomes: a randomized trial.** *J Geriatr Phys Ther.* 2016; **39**(3): 97–101.
PubMed Abstract | Publisher Full Text

9. McGregor G, Sandhu H, Bruce J, *et al.*: **Clinical effectiveness of an online supervised group physical and mental health rehabilitation programme for adults with post-COVID-19 condition (REGAIN study): multicentre Randomised Controlled Trial.** *BMJ.* Erratum in: BMJ. 2024 May 1;385:q988. 2024; **384**: e076506.
PubMed Abstract | Publisher Full Text | Free Full Text

10. O'Neill B, Bradley JM, Connolly B, *et al.*: **Remote multicomponent rehabilitation compared to standard care for survivors of critical illness after hospital discharge (iRehab): a protocol for a randomised controlled assessor-blind clinical and cost-effectiveness trial [version 1; peer review: 2 approved].** *NIHR Open Res.* 2025; **5**: 29.
PubMed Abstract | Publisher Full Text | Free Full Text

11. Hoffmann TC, Glasziou PP, Boutron I, *et al.*: **Better reporting of interventions: Template for Intervention Description and Replication (TIDieR) checklist and guide.** *BMJ.* 2014; **348**: g1687.
PubMed Abstract | Publisher Full Text

12. Skivington K, Matthews L, Simpson SA, *et al.*: **A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance.** *BMJ.* 2021; **374**: n2061.
PubMed Abstract | Publisher Full Text | Free Full Text

13. Leventhal H, Phillips LA, Burns E: **The Common-Sense Model of Self-Regulation (CSM): a dynamic framework for understanding illness self-management.** *J Behav Med.* 2016; **39**(6): 935–946.
PubMed Abstract | Publisher Full Text

14. Hagger MS, Orbell S: **The common sense model of illness self-regulation: a conceptual review and proposed extended model.** *Health Psychol Rev.* 2022; **16**(3): 347–377.
PubMed Abstract | Publisher Full Text

15. Low J, Davis S, Drake R, *et al.*: **The role of acceptance in rehabilitation in life-threatening illness.** *J Pain Symptom Manage.* 2012; **43**(1): 20–28.
PubMed Abstract | Publisher Full Text

16. Hagger MS, Luszczynska A: **Implementation intention and action planning interventions in health contexts: State of the research and proposals for the way forward.** *Appl Psychol Health Well Being.* 2014; **6**(1): 1–47.
PubMed Abstract | Publisher Full Text

17. Lenferink A, Brusse-Keizer M, van der Valk PD, *et al.*: **Self management interventions including action plans for exacerbations versus usual care in patients with Chronic Obstructive Pulmonary Disease.** *Cochrane Database Syst Rev.* 2017; **8**(8): CD011682.
PubMed Abstract | Publisher Full Text | Free Full Text

18. van Grootel J, Bor P, Netjes JA, *et al.*: **Improving physical activity in hospitalized patients: the preliminary effectiveness of a goal-directed movement intervention.** *Clin Rehabil.* 2023; **37**(11): 1501–1509.
PubMed Abstract | Publisher Full Text | Free Full Text

19. Apps C, Brooks K, Terblanche E, *et al.*: **Development of a menu of recovery goals to facilitate goal setting after critical illness.** *Intensive Crit Care Nurs.* 2023; **79**: 103482.
PubMed Abstract | Publisher Full Text

20. Brodsky M, Huang M, Shanholtz C, *et al.*: **Recovery from dysphagia symptoms after oral endotracheal intubation in ARDS survivors. A 5-year longitudinal study.** *Ann Am Thorac Soc.* 2017; **14**(3): 376–83.
PubMed Abstract | Publisher Full Text | Free Full Text

21. Marciniuk DD, Goodridge D, Hernandez P, *et al.*: **Managing dyspnea in patients with advanced Chronic Obstructive Pulmonary Disease: a**

Canadian Thoracic Society clinical practice guideline. *Can Respir J.* 2011; **18**(2): 69–78.
PubMed Abstract | Publisher Full Text | Free Full Text

22. Neufeld KJ, Leoutsakos JMS, Yan H, *et al.*: **Fatigue symptoms during the first year Following ARDS.** *Chest.* 2020; **158**(3): 999–1007.
PubMed Abstract | Publisher Full Text | Free Full Text

23. Merriweather JL, Griffith DM, Walsh TS: **Appetite during the recovery phase of critical illness: a cohort study.** *Eur J Clin Nutr.* 2018; **72**(7): 986–992.
PubMed Abstract | Publisher Full Text

24. Krewulak KD, Stelfox HT, Leigh JP, *et al.*: **Incidence and prevalence of delirium subtypes in an adult ICU: a systematic review and meta-analysis.** *Crit Care Med.* 2018; **46**(12): 2029–2035.
PubMed Abstract | Publisher Full Text

25. Nikayin S, Rabiee A, Hashem MD, *et al.*: **Anxiety symptoms in survivors of critical illness: a systematic review and meta-analysis.** *Gen Hosp Psychiatry.* 2016; **43**: 23–29.
PubMed Abstract | Publisher Full Text | Free Full Text

26. Davydow DS, Gifford JM, Desai SV, *et al.*: **Depression in general Intensive Care Unit survivors: a systematic review.** *Intensive Care Med.* 2009; **35**(5): 796–809.
PubMed Abstract | Publisher Full Text | Free Full Text

27. Ferguson K, Bradley JM, McAuley DF, *et al.*: **Patients' perceptions of an exercise program delivered following discharge from hospital after critical illness (the Revive Trial).** *J Intensive Care Med.* 2019; **34**(11–12): 978–84.
PubMed Abstract | Publisher Full Text

28. O'Neill B, Green N, Blackwood B, *et al.*: **Recovery following discharge from intensive care: what do patients think is helpful and what services are missing?** *PLoS One.* 2024; **19**(3): e0297012.
PubMed Abstract | Publisher Full Text | Free Full Text

29. King J, O'Neill B, Ramsay P, *et al.*: **Identifying patients' support needs following critical illness: a scoping review of the qualitative literature.** *Crit Care.* 2019; **23**(1): 187.
PubMed Abstract | Publisher Full Text | Free Full Text

30. Sakhaei S, Sadagheyani HE, Zinalpoor S, *et al.*: **The impact of pursed-lips breathing maneuver on cardiac, respiratory, and oxygenation parameters in COPD patients.** *Open Access Maced J Med Sci.* 2018; **6**(10): 1851–1856.
PubMed Abstract | Publisher Full Text | Free Full Text

31. Dashti HS, Mogensen KM: **Recommending small, frequent meals in the clinical care of adults: a review of the evidence and important considerations.** *Nutr Clin Pract.* 2017; **32**(3): 365–377.
PubMed Abstract | Publisher Full Text

32. Pohlenz-Saw JAE, Merriweather JL, Wandrag L: **(Mal)nutrition in critical illness and beyond: a narrative review.** *Anaesthesia.* 2023; **78**(6): 770–778.
PubMed Abstract | Publisher Full Text

33. Pfoh ER, Wozniak AW, Colantuoni E, *et al.*: **Physical declines occurring after hospital discharge in ARDS survivors: a 5-year longitudinal study.** *Intensive Care Med.* 2016; **42**(10): 1557–1566.
PubMed Abstract | Publisher Full Text

34. Puhan MA, Gimeno-Santos E, Cates CJ, *et al.*: **Pulmonary rehabilitation following exacerbations of Chronic Obstructive Pulmonary Disease.** *Cochrane Database Syst Rev.* 2016; **12**(12): CD005305.
PubMed Abstract | Publisher Full Text | Free Full Text

35. Larun L, Brurberg KG, Odgaard-Jensen J, *et al.*: **Exercise therapy for chronic fatigue syndrome.** *Cochrane Database Syst Rev.* 2017; **4**(4): CD003200.
PubMed Abstract | Publisher Full Text | Free Full Text

36. Long L, Mordi IR, Bridges C, *et al.*: **Exercise-based cardiac rehabilitation for adults with heart failure.** *Cochrane Database Syst Rev.* 2019; **1**(1): CD003331.
PubMed Abstract | Publisher Full Text | Free Full Text

37. O'Neill B, O'Shea O, McDonough S, *et al.*: **Clinician-facilitated physical activity intervention versus pulmonary rehabilitation for improving physical activity in COPD: a feasibility study.** *COPD.* 2018; **15**(3): 254–264.
PubMed Abstract | Publisher Full Text

38. McDowell K, O'Neill B, Blackwood B, *et al.*: **Effectiveness of an exercise programme on physical function in patients discharged from hospital following critical illness: a Randomised Controlled Trial (the REVIVE trial).** *Thorax.* 2017; **72**(7): 594–595.
PubMed Abstract | Publisher Full Text

39. Tew GA, Bedford R, Carr E, *et al.*: **Community-based prehabilitation before elective major surgery: the PREP-WELL quality improvement project.** *BMJ Open Qual.* 2020; **9**(1): e000898.
PubMed Abstract | Publisher Full Text | Free Full Text

40. Nakayama A, Takayama N, Kobayashi M, *et al.*: **Remote cardiac rehabilitation is a good alternative of outpatient cardiac rehabilitation in the COVID-19 era.** *Environ Health Prev Med.* 2020; **25**(1): 48.
PubMed Abstract | Publisher Full Text | Free Full Text

41. Dekker-van Weering M, Jansen-Kosterink S, Frazer S, *et al.*: **User experience, actual use, and effectiveness of an information communication technology-supported home exercise program for pre-frail older adults.** *Front Med (Lausanne).* 2017; **4**: 208.
PubMed Abstract | Publisher Full Text | Free Full Text

42. NSW Government Health: **Delivering pulmonary rehabilitation via telehealth during COVID-19.** Sydney, NSW: NSW Health, 2020; [Accessed 01 February 2024].
Reference Source

43. Connolly SB, Kotseva K, Jennings C, *et al.*: **Outcomes of an integrated community-based nurse-led Cardiovascular Disease prevention programme.** *Heart.* 2017; **103**(11): 840–847.
PubMed Abstract | Publisher Full Text | Free Full Text

44. A-Tjak JGL, Davis ML, Morina N, *et al.*: **A meta-analysis of the efficacy of Acceptance and Commitment Therapy for clinically relevant mental and physical health problems.** *Psychother Psychosom.* 2015; **84**(1): 30–36.
PubMed Abstract | Publisher Full Text

45. Graham CD, Gouick J, Krahé C, *et al.*: **A systematic review of the use of Acceptance and Commitment Therapy (ACT) in chronic disease and long-term conditions.** *Clin Psychol Rev.* 2016; **46**: 46–58.
PubMed Abstract | Publisher Full Text

46. Hann KEJ, McCracken LM: **A systematic review of randomized controlled trials of Acceptance and Commitment Therapy for adults with chronic pain: outcome domains, design quality, and efficacy.** *J Contextual Behav Sci.* 2014; **3**(4): 217–227.
Publisher Full Text

47. Harris R: **Embracing your demons: an overview of Acceptance and Commitment Therapy.** *Psychother Aust.* 2006; **12**(4): 2–8.
Reference Source

48. Dochat C, Wooldridge JS, Herbert MS, *et al.*: **Single-session Acceptance and Commitment Therapy (ACT) interventions for patients with chronic health conditions: a systematic review and meta-analysis.** *J Contextual Behav Sci.* 2021; **20**: 52–69.
PubMed Abstract | Publisher Full Text | Free Full Text

49. Zhenggang B, Shiga L, Luyao Z, *et al.*: **Acceptance and Commitment Therapy (ACT) to reduce depression: a systematic review and meta-analysis.** *J Affect Disord.* 2020; **260**: 728–737.
PubMed Abstract | Publisher Full Text

50. ICU Steps: **Delerium and intensive care**. [Last accessed 20.04.2024].
Reference Source

51. McPeake J, Iwashyna TJ, Boehm LM, *et al.*: **Benefits of peer support for Intensive Care Unit survivors: sharing experiences, care debriefing, and altruism.** *Am J Crit Care.* 2021; **30**(2): 145–149.
PubMed Abstract | Publisher Full Text | Free Full Text

52. Haines KJ, Beesley SJ, Hopkins RO, *et al.*: **Peer support in critical care: a systematic review.** *Crit Care Med.* 2018; **46**(9): 1522–1531.
PubMed Abstract | Publisher Full Text

53. **Drivel defense index**. [last accessed 16th Jan 2025].
Reference Source

54. Ho FYY, Yeung WF, Ng THY, *et al.*: **The efficacy and cost-effectiveness of stepped care prevention and treatment for depressive and/or anxiety disorders: a systematic review and meta-analysis.** *Sci Rep.* 2016; **6**: 29281.
PubMed Abstract | Publisher Full Text | Free Full Text

55. Wight D, Wimbush E, Jepson R, *et al.*: **Six steps in Quality Intervention Development (6SQuID).** *J Epidemiol Community Health.* 2016; **70**(5): 520–5.
PubMed Abstract | Publisher Full Text | Free Full Text

56. Fernandez ME, Ten Hoor GA, van Lieshout S, *et al.*: **Implementation mapping: using intervention mapping to develop implementation strategies.** *Front Public Health.* 2019; **7**: 158.
PubMed Abstract | Publisher Full Text | Free Full Text

57. O'Cathain A, Croot L, Sworn K, *et al.*: **Taxonomy of approaches to developing interventions to improve health: a systematic methods overview.** *Pilot Feasibility Stud.* 2019; **5**: 41.
PubMed Abstract | Publisher Full Text | Free Full Text

58. Yardley L, Morrison L, Bradbury K, *et al.*: **The person-based approach to intervention development: application to digital health-related behavior change interventions.** *J Med Internet Res.* 2015; **17**(1): e30.
PubMed Abstract | Publisher Full Text | Free Full Text

59. Borrelli B: **The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trails.** *J Public Health Dent.* 2011; **71**(s1): S52–S63.
PubMed Abstract | Publisher Full Text | Free Full Text

60. Bradley JM, Hutchings M, Arden MA, *et al.*: **A RCT to explore the effectiveness of supporting adherence to nebuliser medication in adults with cystic fibrosis: fidelity assessment of study interventions.** *BMC Pulm Med.* 2024; **24**(1): 148.
PubMed Abstract | Publisher Full Text | Free Full Text

61. Slade SC, Dionne CE, Underwood M, *et al.*: **Consensus on Exercise Reporting Template (CERT): explanation and elaboration statement.** *Br J Sports Med.* 2016; **50**(23): 1428–1437.
PubMed Abstract | Publisher Full Text

62. Khan BA, Perkins AJ, Khan SH, *et al.*: **Mobile critical care recovery program for survivors of acute respiratory failure: a randomized clinical trial.** *JAMA Netw Open.* 2024; **7**(1): e2353158.
PubMed Abstract | Publisher Full Text | Free Full Text

63. Begjani J, Hosseini ASS, Saneifard H, *et al.*: **Social learning-based health literacy promotion on the self efficacy and social anxiety of adolescents with type 1 diabetes.** *Clin Diabetes Endocrinol.* 2024; **10**(1): 14.
PubMed Abstract | Publisher Full Text | Free Full Text

64. Whyte J, Barrett AM: **Advancing the evidence base of rehabilitation treatments: a developmental approach.** *Arch Phys Med Rehabil.* 2012; **93**(8 Suppl): S101–10.
PubMed Abstract | Publisher Full Text | Free Full Text

65. Michie S, van Stralen MM, West R: **The behaviour change wheel: a new method for characterising and designing behaviour change interventions.** *Implement Sci.* 2011; **6**: 42.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

66. Broanbent E, Wilkes C, Koschwanez H, *et al.*: **A systematic review and meta-analysis of the brief illness perception questionnaire.** *Psychol Health.* 2015; **30**(11): 1361–1385.
PubMed Abstract | **Publisher Full Text**

67. Sawyer AT, Harris SL, Keonig HG: **Illness perception and high readmission health outcomes.** *Health Psychol Open.* 2019; **6**(1): 2055102919844504.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

68. Hayes SC, Strosahl KD, Wilson KG: **Acceptance and commitment therapy: the process and practice of mindful change**. Guilford press, 2011.
Reference Source

69. Polk KL, Schoendorff B: **The ACT matrix: a new approach to building psychological flexibility across settings and populations**. Context Press/New Harbinger Publications, 2014.
Reference Source

70. Merbitz NH, Westie K, Dammeyer JA, *et al.*: **After critical care: challenges in the transition to inpatient rehabilitation.** *Rehabil Psychol.* 2016; **61**(2): 186–200.
PubMed Abstract | **Publisher Full Text**

71. Clarke R, Schofield H, Tantam K: **Lessons from a review of physiotherapy and psychological rehabilitation received during ICU stay and beyond to inform the development of an ICU follow clinic.** *J Intensive Care Soc.* 2020; **23**(2): 103–108.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

72. Scott P, Thomson P, Shepherd A: **Families of patients in ICU: a scoping review of their needs and satisfaction with care.** *Nurs Open.* 2019; **6**(3): 698–712.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

73. **NHS England social prescribing: reference guide and technical annex for primary care networks**.
Reference Source

Open Peer Review

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Version 2

Reviewer Report 20 October 2025

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?

Porkodi Arjunan
King Faisal University, Al Hofuf, Saudi Arabia

1. **Participants – ICU population**
   Please clarify whether the study intends to include all post-ICU The authors described the participants are people who have had an admission to the intensive care unit and are within 0–12 weeks of discharge home. Justify the reason for taking all the patients admitted in ICU and also 12 weeks after discharge almost the patients recovered from the illness, then what is the purpose of implementing rehabilitation. The rehabilitation should start from the time of admission to the hospital.
2. **Exercise and physical activity- weekly live session**
   How is it possible to have live session one on one for exercise, in that case how many rehabilitations specialist will be needed to manage the exercise session. All ICU Patients may not require exercise/ rehabilitation. Justify the reason and feasibility

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: I have expertise in the area of heart failure and Cardiac rehabilitation, and ICU

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 22 Oct 2025

Brenda O'Neill

Thank you for your further review and comments which we hope we have fully addressed below.

1. Participants – ICU population

Please clarify whether the study intends to include all post-ICU The authors described the participants are people who have had an admission to the intensive care unit and are within 0–12 weeks of discharge home. Justify the reason for taking all the patients admitted in ICU and also 12 weeks after discharge almost the patients recovered from the illness, then what is the purpose of implementing rehabilitation. The rehabilitation should start from the time of admission to the hospital.
Response – Guidelines recommend rehabilitation at each phase of recovery after critical illness: in ICU, on hospital wards and after hospital discharge. Most research and evidence to date has focused on rehabilitation starting/delivered in ICU and we agree with the reviewer that rehabilitation should start at the time of admission to the hospital. However, there is a dearth of research supporting rehabilitation for people (who had an ICU admission) once they have been discharged home from hospital. The rehabilitation proposed in the trial provided will not interfere with usual care provided during the ICU or hospital stay; it is targeting these patients in the post discharge phase.

It is not correct that 12 weeks after discharge patients have recovered. The consequences of critical illness are substantial, sometimes referred to as Post Intensive Care Syndrome (PICS). PICS encompasses physical deconditioning, respiratory and swallowing problems, reduced activities of daily living, cognitive and mental health impairments, fatigue, and poor health-related quality of life (HRQoL)[1–7]. Post hospital discharge, rehabilitation aims to support patients to manage these symptoms/problems but rehabilitation at this stage of recovery is not widely available[8] .

The study that we are testing specifically aims to explore whether the rehabilitation intervention we developed is effective for patients who had an ICU admission and have been discharged home (regardless of the rehabilitation they may have received prior to hospital discharge)[9].

The intervention is intended to start within 12 weeks of discharge from the hospital to facilitate positive readjustment once a patient has returned to life at home after critical illness. The impact of timing post discharge interventions is unknown (early versus later in the recovery trajectory). Patients' needs in the first year after ICU span across all the stages of the recovery trajectory following discharge home[10-12]. Patients have low confidence to self-manage when they are discharged home after ICU and this only improves marginally over time in the first year after hospital discharge[11,13]. They need support and help with recovery[10,12]. We had wanted to provide an opportunity for delivery of support and rehabilitation in the early discharge phase as this has been identified by patients as a period of high adjustment and when patients have multiple physical and mental well-being problems present[14,15] and we had previously shown it was feasible to recruit and deliver exercise during this phase[15]. The optimal timing for intervention delivery is unknown and will be a topic for future research.

1. Dinglas V, Friedman L, Colantuoni E, et al. Muscle Weakness & 5-Year Survival in ARDS. Critical Care Medicine 2017;45(3):446-453.
2. Hopkins R, Suchyta M, Kamdar B, et al. Instrumental Activities of Daily Living after Critical Illness: A Systematic Review. Annals of the ATS 2017;14(8):1332-43.
3. Pandharipande PP, Girard TD, Jackson JC, et al. Long-Term Cognitive Impairment after

Critical Illness. N Engl J Med 2013;369(14):1306-16.
4. Brodsky M, Huang M, Shanholtz C, et al. Recovery from Dysphagia Symptoms after Oral Endotracheal Intubation in ARDS Survivors. A 5-Year Longitudinal Study. Annals of the ATS 2017;14(3):376-83.
5. Pfoh E, Wozniak A, Colantuoni E, et al. Physical declines occurring after hospital discharge in ARDS survivors: a 5-year longitudinal study. Intensive Care Med 2016;42(10):1557-66.
6. Oeyen SG, Vandijck DM, Benoit DD, et al. QOL after intensive care: a systematic review. Crit Care Med 2010;38(12):2386-400.
7. Neufeld KJ, Leoutsakos J-MS, Yan H, et al. Fatigue Symptoms during the First Year after ARDS. Chest 2020;158(3):999-1007
8. Connolly B, Milton-Cole R, Adams C on behalf of The Faculty of Intensive Care Medicine Life After Critical Illness Working Group, et al. Recovery, rehabilitation and follow-up services following critical illness: an updated UK national cross-sectional survey and progress report. BMJ Open 2021;11:e052214. doi: 10.1136/bmjopen-2021-052214
9. O'Neill B, Bradley JM, Connolly B, et al.: Remote multicomponent rehabilitation compared to standard care for survivors of critical illness after hospital discharge (iRehab): a protocol for a randomised controlled assessor-blind clinical and cost-effectiveness trial [version 1; peer review: 2 approved]. NIHR Open Res. 2025; 5: 29.
10. Goddard S, Gunn H, Kent B, Dennett, R. The Experience of Physical Recovery and Physical Rehabilitation Following Hospital Discharge for Intensive Care Survivors—A Qualitative Systematic Review. Nurs Rep 2024;14:148-163.
11. King J, O'Neill B, Ramsay P, et al. Identifying patients' support needs following critical illness: a scoping review of the qualitative literature. Crit Care 2019;23(1):187.
12. O'Neill B, Green N, Blackwood B, et al. Recovery following discharge from intensive care: What do patients think is helpful and what services are missing? PLoS One 2024;19(3):e0297012.
13. O'Neill B, Linden MA, Ramsay P, et al. Patient activation and support needs in patients after ICU discharge: A UK survey of critical illness survivors. J Intensive Care Soc 2025;26(1):38-46
14. Iwashyna TJ, Cooke CR, Wunsch H, Kahn JM. Population burden of long-term survivorship after severe sepsis in older Americans. J Am Geriatr Soc. 2012 Jun;60(6):1070-7. doi: 10.1111/j.1532-5415.2012.03989.x. Epub 2012 May 29. PMID: 22642542; PMCID: PMC3374893.
15. Ferguson K, Bradley JM, McAuley DF, Blackwood B, O'Neill B. Patients' Perceptions of an Exercise Program Delivered Following Discharge From Hospital After Critical Illness (the Revive Trial). J Intensive Care Med 2019;34(11-12):978-84

2. Exercise and physical activity- weekly live session
How is it possible to have live session one on one for exercise, in that case how many rehabilitations specialist will be needed to manage the exercise session. All ICU Patients may not require exercise/ rehabilitation. Justify the reason and feasibility.

Response - This is a patient centred multicomponent intervention and the components are

provided based on patients symptoms, problems and treatment goals.
The intervention is delivered remotely by a central team based in Belfast and there are a team of 3 full time equivalent staff. One iRehab specialist is assigned to one patient to provide their intervention across the whole 6 week programme.

The amount of exercise that best suits each patient is important and for each patient readiness, need and risk to exercise is explored on an individual basis by considering information from the recruitment site and trial database about for example, patients' diagnosis and comorbidities, contra-indications, current exercise capacity, as well as the intervention manual which the trained iRehab specialist follows to ensure safety. For example, the iRehab specialist will assess the need for a family member to be nearby, and the ability to undertake lower intensity exercise versus higher intensity exercise.

The iRehab specialists also offer patients the opportunity to attend a weekly live group exercise sessions and the iRehab specialists deliver these in pairs to the group of patients who attend (not all patients will tkat this opportunity). Again, this delivery is remote via Microsoft teams or BEAM and Zoom.

Competing Interests: No competing interests were disclosed.

Reviewer Report 10 October 2025

https://doi.org/10.3310/nihropenres.15365.r37565

Andreas Xyrichis
King's College London, London, England, UK

Thank you. I have no further comments.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Health services research

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 17 September 2025

https://doi.org/10.3310/nihropenres.15251.r36827

Andreas Xyrichis
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This manuscript presents a comprehensive account of developing the iRehab intervention for post-critical illness rehabilitation. The work addresses a significant clinical need and demonstrates rigorous adherence to established frameworks for complex intervention development.

There is much to commend about this article:
1. Methodological rigour and framework adherence: The authors demonstrate commendable adherence to the MRC framework for complex intervention development, systematically addressing each core element (a-f). The integration of multiple evidence sources—existing literature, psychological theory, patient experiences, and clinical expertise—reflects thorough intervention development methodology. The use of TIDieR reporting guidelines enhances transparency and supports replication efforts.

2. Theoretical foundation and integration: The selection of Leventhal's Common-Sense Model provides a coherent theoretical foundation for supporting patient self-regulation following critical illness. The integration with Acceptance and Commitment Therapy principles for psychological wellbeing creates a complementary framework that addresses both cognitive and behavioural aspects of recovery. This dual theoretical approach appropriately reflects the complexity of post-ICU rehabilitation needs.

3. Patient-centred development approach: The extensive patient and public involvement represents a strength of this work. The formation of a Patient Advisory Group with ongoing involvement throughout development, trial conduct, and dissemination planning demonstrates genuine co-production rather than tokenistic consultation. The patient partners' contribution to the plain language summary exemplifies meaningful collaboration and enhances accessibility.

4. Intervention design and flexibility: The four-component structure (symptom management, exercise/physical activity, psychological support, peer support) addresses the multifaceted nature of post-critical illness syndrome comprehensively. The two-level resource system (Level 1 standardised, Level 2 specialist-guided) strikes an appropriate balance between standardisation for research purposes and individualisation for clinical effectiveness. This graduated approach reflects real-world clinical decision-making processes.

5. Remote delivery innovation: The adaptation for remote delivery demonstrates forward-thinking design, particularly relevant given recent healthcare delivery changes. The flexibility to deliver via video or telephone, supported by posted materials, addresses potential technology barriers while maintaining intervention accessibility. The consideration of practical implementation barriers (technology access, family support) shows thoughtful intervention design.

6. Logic model and outcome alignment: Table 3 provides a clear logic model linking intervention inputs through to anticipated impacts. The alignment between intervention components and proposed outcome measures (EQ-5D-5L, physical function tests, illness perception measures) demonstrates coherent intervention theory. The inclusion of moderating factors and external considerations shows sophisticated understanding of implementation contexts.

7. Quality assurance and fidelity planning: The detailed training requirements for iRehab specialists, standardised manual development, and planned process evaluation demonstrate commitment to intervention fidelity. The multiprofessional expert review and iterative refinement process enhances intervention credibility and implementation readiness.

Minor Suggestions
1. Consider briefly discussing how the intervention might be adapted for different healthcare systems beyond the UK NHS.
2. The logic model could benefit from explicit mention of cost-effectiveness pathways given the economic evaluation component.

Is the rationale for developing the new method (or application) clearly explained?
Yes

Is the description of the method technically sound?
Yes

Are sufficient details provided to allow replication of the method development and its use by others?
Yes

If any results are presented, are all the source data underlying the results available to ensure full reproducibility?
No source data required

Are the conclusions about the method and its performance adequately supported by the findings presented in the article?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Health services research

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 26 Sep 2025

Brenda O'Neill

Thank you for your review of our manuscript. We really appreciate your helpful

comments and suggested edits

1. Consider briefly discussing how the intervention might be adapted for different healthcare systems beyond the UK NHS

Response- We have considered this and added a suggestion to the discussion. Please see discussion section, page 11, after paragraph 2

"If the intervention is effective the trial manuals, resources and training package could be adapted for different healthcare systems beyond the UK NHS by considering for example, translations and cultural adaptations, and using a similar centralised staffing model for intervention delivery."

2. The logic model could benefit from explicit mention of cost-effectiveness pathways given the economic evaluation component.

Response- Thank you: we could consider this although it would be challenging as it would bring much additional detail to the current logic model. The trial plans a cost analysis that will include economic modelling. We will suggest to the trial Health Economists on the team to consider the development of a separate logic model to more fully propose the relationships and interactions between the intervention costs and trial outcomes.

Competing Interests: No competing interests were disclosed.

Reviewer Report 05 September 2025

https://doi.org/10.3310/nihropenres.15251.r36828

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David M Griffith
[1] University of Edinburgh, Edinburgh, UK
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Thank you for the opportunity to review this excellent paper which describes the process of development of a the iRehab intervention. The manuscript is well written, and the reporting and development of the intervention follows recognised guidance. What is particularly impressive is the active participation of patients and members of the public in the development of the intervention, the ongoing conduct of the trial, and in the drafting and reporting of this manuscript. The resulting intervention is indeed patient-centred I would expect it to be well received by patients as a result.

My comments relate to the alignment of the trial intervention with the trial outcome measures, given this has been a limitation of many previous post-ICU studies. It is not clear whether the trial outcome measures were considered during the development phase and there is no reflection in the discussion about how well the outcome measures will capture the success of the intervention.

Specifically:

1. The manuscript does not specifically mention the primary (or secondary) outcome measures used in iRehab (EQ-5DL) could the authors include this information in the manuscript?
2. How were the trial outcomes considered in the development of the intervention?
3. Could the authors reflect on the alignment between the intervention and the iRehab primary outcome measure.
4. Pain is a common issue in ICU survivors. Given that pain/discomfort is one of the 5 dimensions of EQ-5D-5L, could the authors mention specifically how the intervention will address pain issues in the post-ICU period.

Is the rationale for developing the new method (or application) clearly explained?

Yes

Is the description of the method technically sound?

Yes

Are sufficient details provided to allow replication of the method development and its use by others?

Yes

If any results are presented, are all the source data underlying the results available to ensure full reproducibility?

No source data required

Are the conclusions about the method and its performance adequately supported by the findings presented in the article?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Critical care recovery. Critical Care. Post-ICU weakness.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 26 Sep 2025

Brenda O'Neill

Thank you for reviewing our manuscript and the helpful comments and edits which have improved our reporting. Please find our responses to your comments below.

1. The manuscript does not specifically mention the primary (or secondary) outcome measures used in iRehab (EQ-5DL) could the authors include this information in the manuscript?

Response - The logic model presented in Table 3 proposes how the intervention within the iRehab trial could change the trial outcome measures - see column 'What changes do we expect to see'.
We refer to the logic model in the discussion section but for better visibility we have added the following amendment
See discussion, Page 10, paragraph 1
"*A logic model was developed to propose how the intervention could lead to its effects and under what conditions during the iRehab trial (Table 3).*"

amended to
"A logic model was developed to propose how the intervention could lead to its effects and under what conditions during the iRehab trial (Table 3). If the intervention is effective the expectation is that improvements at 8 weeks will be observed in health-related quality of life per the EQ-5D-5L; also measures of leg strength/exercise capacity (30second sit to stand test), illness perception (Brief Illness Perception Questionnaire), fatigue (FACIT-F), anxiety and depression (HADS), patient satisfaction/acceptability (TFAQ).

2. How were the trial outcomes considered in the development of the intervention?

Response - The trial outcomes were considered in the context of the proposed causal pathway of the intervention, literature identifying post ICU sequalae, and relevant core outcome sets (Table 3 and references 44, 45, 48).

The objective of the intervention is "To improve the health-related quality of life, physical function, fatigue, mood, and other health related outcomes after critical illness." As the intervention is multi-component, underpinned by theory and research, and tailored to patients' needs it is anticipated it will contribute to several dimensions that underpin health-related quality of life.

The core outcome set for long-term outcomes following acute respiratory failure (ref 44) indicates EQ-5D-5L is the preferred option for measuring health-related quality of life. with SF36 a secondary option. Recent reviews (ref 46, 47) have concluded the EQ-5D-5L is as good as other health related QOL outcome measures (e.g. SF36), and responsive to multicomponent rehabilitation in patients after critical illness (48).

Furthermore, recognising that HRQoL has multiple components and means different things to different people it was important to include secondary outcomes (such as leg strength/endurance, fatigue, mood) that link to common problems identified after critical illness.

3. Could the authors reflect on the alignment between the intervention and the iRehab primary outcome measure.

Response - For the iRehab trial, the primary outcome is health-related quality of life,

measured using the EQ-5D-5L at eight weeks post-randomisation. Health-related quality of life is multidimensional, encompassing components of physical, psychological, emotional, and social wellbeing. The EQ-5D-5L is the recommended measure for assessing quality of life in core outcome sets for longer-term outcomes following respiratory failure and physical rehabilitation in critical illness (44,45). S ystematic reviews confirm the EQ-5D-5L to be similarly robust compared with other longer measures, such as the SF-36 (46,47). The scale measures the extent of impairment in mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, ranging from no problems to severe problems. These domains, and the visual analogue scale (VAS 0-100mm) capturing health utility, are widely used for health economic evaluation. The scale was responsive to change in a study assessing multicomponent rehabilitation in post-critical illness patients (48), and has been validated for telephone completion. Importantly, our patient and public partners endorsed quality of life as an important outcome to reflect recovery after critical illness.

Additional advantages of the EQ-5D-5L are that it is concise, short, suitable for remote completion, and supports a health economic evaluation.

4. Pain is a common issue in ICU survivors. Given that pain/discomfort is one of the 5dimensions of EQ-5D-5L, could the authors mention specifically how the intervention will address pain issues in the post-ICU period.

Response - The intervention includes the opportunity for participants to discuss any problems/symptoms they have since going home from hospital with their iRehab specialists; a range of resources are available to help. If pain is identified as a problem/symptom this could be addressed by the patient receiving advice and strategies from a specific leaflet about "pain after critical illness;" and they could be signposted to see their general practitioner if they need pharmacological input or an alternative onward referral.
Because there is some overlap between pain and other symptoms e.g. sleep (poor sleep due to pain), mental health (higher perception of pain when anxious) and higher pain levels due to muscle weakness/reduced function, the patient might also receive strategies targeted to improving these e.g. acceptance and commitment therapy and mindfulness, tips for better sleep, modifications to enable a suitable amount of exercise; and adaption of weekly goals to be more achievable within pain boundaries.

To help link the dimension of pain to the intervention we have included pain as an example symptom in Table 2, Column 3 "Content"

Line 1

- **"Participants identify symptoms of relevance to them in their recovery e.g. difficulty swallowing, breathlessness**

amended to

- **"Participants identify symptoms of relevance to them in their recovery e.g. difficulty swallowing, breathlessness, pain**

Competing Interests: No competing interests were disclosed.

Reviewer Report 05 September 2025

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Porkodi Arjunan
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This manuscript addresses an important and timely topic in post–intensive care rehabilitation. The study has potential significance; however, the current version requires substantial clarification of participant selection, the definition and scope of the iRehab specialist, standardization of the intervention across settings, and patient safety procedures.

Specific Comments

1. **Participants – ICU population**
   Please clarify whether the study intends to include all post-ICU patients across subspecialties (e.g., cardiothoracic, neuro, transplant, burns) or focus on specific ICU populations. Given the heterogeneity in recovery needs, justification is required for the chosen population.
2. **Definition of the iRehab specialist**
   The role of the "iRehab specialist" is not clearly defined. It is unclear whether this refers to a single individual or a multiprofessional team. Please clarify the team composition, professional background, and responsibilities. Additionally, explain whether the iRehab specialist will strictly follow the primary physician's plan or develop an independent rehabilitation plan, and how multiprofessional input will be integrated.
3. **Duration of post-ICU management**
   The proposal to provide six weeks of uniform post-ICU management for all patients needs justification. Not all post-ICU patients may require this duration of follow-up. Please explain the rationale for a uniform 6-week intervention and how variation in patient needs will be addressed.
4. **Exercise intervention feasibility**
   The manuscript should clarify how the program will apply to patients unable to participate actively in exercise. In cases where patients require only passive movements, explain how the intervention remains applicable and beneficial
5. **Safety considerations during exercise**
   Please describe how complications or adverse events arising during exercise sessions will be identified and managed. A safety monitoring plan is essential for patient protection.
6. **Participant timeframe (0–12 weeks post-discharge)**

The recruitment timeframe of 0–12 weeks post-discharge appears broad. By 12 weeks, many patients may already have regained near-normal function. Please justify this wide window and consider narrowing the inclusion timeframe.

7. **Intervention standardization**
As hospital policies and discharge practices differ, it is important to clarify how the intervention will be standardized across centers. Please describe how consistency will be ensured in delivering the iRehab program despite institutional differences.

Is the rationale for developing the new method (or application) clearly explained?
Yes

Is the description of the method technically sound?
Yes

Are sufficient details provided to allow replication of the method development and its use by others?
Partly

If any results are presented, are all the source data underlying the results available to ensure full reproducibility?
No source data required

Are the conclusions about the method and its performance adequately supported by the findings presented in the article?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: I have expertise in the area of heart failure and Cardiac rehabilitation, and ICU

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 26 Sep 2025

Brenda O'Neill

Thank you for your detailed review and the helpful comments and suggestions which have improved our reporting. Please find our response to your comments below.

1. **Participants – ICU population**

Please clarify whether the study intends to include all post-ICU patients across subspecialties (e.g., cardiothoracic, neuro, transplant, burns) or focus on specific ICU populations. Given the heterogeneity in recovery needs, justification is required for the chosen population.

Response - The study intends to include people who received invasive mechanical ventilation for 48 hours or longer during an ICU admission. The inclusion criteria were selected based on evidence for poor recovery in these patients.. Full details of the inclusion and exclusion are available in the study protocol [ref 10, https://openresearch.nihr.ac.uk/articles/5-29]

All eligible patients will be included in the trial, regardless of subspecialty unless an established rehabilitation pathway exists for their management in local practice. In this case, patients would not be included and would access that particular care pathway.
The reference to the paper detailing the iRehab trial protocol has now additionally been included in the manuscript conclusion so that readers can access the iRehab trial inclusion criteria and additional deails.
see Conclusion/page 11
“This paper reports the development of a rehabilitation program that is currently under evaluation within a rigorous clinical trial framework (10)……..”

2. Definition of the iRehab specialist
The role of the “iRehab specialist” is not clearly defined. It is unclear whether this refers to a single individual or a multiprofessional team. Please clarify the team composition, professional background, and responsibilities. Additionally, explain whether the iRehab specialist will strictly follow the primary physician’s plan or develop an independent rehabilitation plan, and how multiprofessional input will be integrated.
Response - One iRehab specialist is assigned to one patient to provide their intervention across the whole 6 week programme The team of trained iRehab specialists deliver the group sessions in pairs.
Rather than a physician-planned intervention the iRehab specialists will develop a patientcentred rehabilitation plan following the instructions from the iRehab intervention manual and training .

The text has been edited to clarify this

see p 7 “(iii) Constructing the intervention
The intervention was developed to embed progressive intervention strategies capable of being delivered by a trained intervention team from a broad range of backgrounds. A multiprofessional group, each with specific expertise, is expected to support and guide iRehab specialists in the management of patient symptoms and problems as required. iRehab specialists utilize resources ……..”

amended to

see p 7 “(iii) Constructing the intervention
The intervention was developed to embed progressive intervention strategies capable of being delivered by a trained intervention team from a broad range of backgrounds. “One iRehab specialist is assigned to one patient and provides their intervention across the 6 week programme” A multiprofessional group, each with specific expertise, will support and guide iRehab specialists in the management of patient symptoms and problems as required. iRehab specialists utilize resources ……..”

For information the iRehab intervention specialists are a team of trained professionals with experience of working with critical care patients and/or delivering rehabilitation to clinical populations. Key criteria for these roles include a graduate qualification in a relevant subject e.g. Physiotherapy, Occupational Therapy, Sport and Exercise Science, Nursing. iRehab intervention specialists are supported by regular meetings with a multiprofessional team to review intervention delivery and address any specific participant queries. This multiprofessional team has extensive expertise in the management of patients after critical illness.

3. Duration of post-ICU management
The proposal to provide six weeks of uniform post-ICU management for all patients needs justification. Not all post-ICU patients may require this duration of follow-up. Please explain the rationale for a uniform 6-week intervention and how variation in patient needs will be addressed.

Response- The 6 week approach was based on literature and programmes in other populations such as cardiac and pulmonary rehabilitation, as well as data from our preliminary exercise-based study in this population (references 26, 37).

Variation in patient needs are addressed through the range of components that make up the intervention outlined in Table 2.

The duration of the programme that best suits patients is important. Therefore, we will gather data on whether participants complete all sessions (adherence) and this will give insight into whether patients discontinue the intervention before the 6 week period or not (reporting per TIDIER in the results manuscript).

4. Exercise intervention feasibility
The manuscript should clarify how the program will apply to patients unable to participate actively in exercise. In cases where patients require only passive movements, explain how the intervention remains applicable and beneficial

Response- It is extremely unlikely that a patient who meets the study criteria and is discharged home from hospital would require only passive movements given the trial inclusion /exclusion criteria. The inclusion criteria include being discharged from hospital and able to participate in the intervention and with trial procedures e.g. using equipment such as computer or telephone, and exclusion criteria include having no ‘contra-indications to exercise’ and not being ‘discharged to a care home with/without nursing care’.

5. Safety considerations during exercise
Please describe how complications or adverse events arising during exercise sessions will be identified and managed. A safety monitoring plan is essential for patient protection.

Response- Exclusion criteria for trial recruitment include having no “Contra-indication to exercise” and these are based on the American College of Sports Medicine [2017]. Training specific to this criterion is provided to recruiting staff during the Site Initiation Visit (SIV) and

iRehab specialists and responses to common queries are included in their trial manuals and a Frequently Asked Questions (FAQ) document on the trial website. Staff are also advised and encouraged to discuss any concerns or queries about contra-indication to exercise with the PI and the iRehab study team.

For each patient, readiness and risk to exercise is explored on an individual basis by considering information from the recruitment site and trial database about for example, patients' diagnosis and comorbidities, as well as the intervention manual which the trained iRehab specialist follows to ensure safety. For example, the iRehab specialist will assess resting oxygen saturation, or the need for a family member to be nearby, ability to undertake lower intensity exercise versus higher intensity exercise.

During the iRehab trial, Adverse Events (AEs) and Serious Adverse Events SAEs will be assessed and reported in keeping with regulatory requirements. All staff follow the trial protocol and training to identify and manage AEs or SAEs. We have defined escalation plans for participants who experience a fall or are at risk of mental health crisis. The iRehab specialists delivering the intervention are also trained to optimise safety for undertaking exercise.

6. Participant timeframe (0–12 weeks post-discharge)
The recruitment timeframe of 0–12 weeks post-discharge appears broad. By 12 weeks, many patients may already have regained near-normal function. Please justify this wide window and consider narrowing the inclusion timeframe.

Response- This is an important point. Research shows that people experience variable symptoms after discharge home following ICU and recovery trajectories are unpredictable with morbidity reported even years after ICU discharge (described in the iRehab trial protocol paragraph 1 and references 2-11 https://openresearch.nihr.ac.uk/articles/5-29). The optimal timing of intervention delivery is unknown (early versus later in the recovery trajectory) and we wanted to provide an opportunity for delivery of rehabilitation in the early discharge phase as this has been identified by patients as a period of high adjustment and when patients have multiple physical and mental well-being problems present (de silve et al 2024, Ferguson et al 2019, Iwashyna et al 2012); our patient partners also agreed this timing and we had previously shown it was feasible to recruit and deliver rehabilitation during this phase (McDowell et al 2017).

During the trial we will gather data about the number of weeks between participants being discharged from hospital and when they are recruited and this will give insight into whether a wide or narrow window is optimal (we will report this in the trial results manuscript).

7. Intervention standardization
As hospital policies and discharge practices differ, it is important to clarify how the intervention will be standardized across centers. Please describe how consistency will be ensured in delivering the iRehab program despite institutional differences.

Response- The trial protocol (reference 10) clarifies this: standard NHS care is the comparator group. The standard care and post ICU pathways at each site are identified to

enable the team to ensure separation of trial arms. Sites are also actively monitored during the trail to gauge any changes that may necessitate reconsidering site eligibility. Sites delivering a similar intervention to the iRehab intervention are excluded.

During the trial the iRehab intervention is delivered only by a centralised team of trained and certified iRehab specialists, that are independent of the recruitment sites/centres. To minimise performance bias in intervention delivery, the core components are protocolised to guide overarching delivery, whilst still enabling flexibility in how components are applied to individual participants. Active monitoring and early feedback by the independent process evaluation team will be implemented to ensure intervention fidelity; this is identified in the trial protocol [reference 10]

Competing Interests: No competing interests were disclosed.