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Patient and carer experience of hospital based rehabilitation from Intensive Care to hospital discharge: mixed methods process evaluation of the RECOVER randomised clinical trial

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Title: PATIENT AND CARER EXPERIENCE OF HOSPITAL BASED REHABILITATION FROM INTENSIVE CARE TO HOSPITAL DISCHARGE: MIXED METHODS PROCESS EVALUATION OF THE RECOVER RANDOMISED CLINICAL TRIAL

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Keywords: adult intensive and critical care, rehabilitation medicine, quality in healthcare, organisation of health services, qualitative research.

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ABSTRACT

Objectives: To explore and compare patient/carer experiences of rehabilitation in the intervention and usual care arms of the RECOVER trial (ISRCTN09412438); a randomised controlled trial of a complex intervention of post-Intensive Care Unit (ICU) acute hospital-based rehabilitation following critical illness.

Design: Mixed methods process evaluation including comparison of patients' and carers' experience of usual care versus the complex intervention. We integrated and compared quantitative data from a Patient Experience Questionnaire (PEQ) with qualitative data from focus groups with patients and carers.

Setting: Two University-affiliated hospitals in Scotland.

Participants: 240 patients discharged from ICU who required ≥ 48 hours of mechanical ventilation were randomised into the trial (120 per trial arm). Exclusion criteria comprised: primary neurologic diagnosis, palliative care, current/planned home ventilation, age <18 years. 182 patients completed the PEQ at 3 months post-randomisation. 22 participants (14 patients: 8 carers) took part in focus groups (2 per trial group) at >3 months post-randomisation.

Interventions: A complex intervention of post-ICU acute hospital rehabilitation, comprising enhanced physiotherapy, nutritional care and information provision, case-managed by dedicated Rehabilitation Assistants (RAs) working within existing ward-based clinical teams, delivered between ICU discharge and hospital discharge. Comparator was usual care.

Outcome measures: A novel PEQ capturing patient-reported aspects of quality care

Results: The PEQ revealed statistically significant between-group differences across 4 key intervention components: physiotherapy (p 0.039), nutritional care (p 0.038), case-management (0.045) and information provision (<0.001); suggesting greater patient satisfaction in the intervention group. Focus group data strongly supported and helped explain these findings. Specifically, case-management by dedicated RAs facilitated greater access to physiotherapy, nutritional care and information that cut across disciplinary boundaries and staffing constraints. Patients highly valued its *individualisation* according to their needs, abilities and preferences.

Conclusions: Case-management by dedicated RAs improves patients' experiences of post-ICU hospital-based rehabilitation, and increases perceived quality of care.

Trial registration: ISRCTN 09412438 DOI 10.1186/ISRCTN09412438

Strengths and limitations

Strengths:

- Our trial is among the very few critical care complex interventional trials to incorporate the Medical Research Council's (MRC) recommendations for outcomes *and* process evaluation into its evaluation strategy

- Our trial is among the very few such trials to critically explore patient experience, using both a novel patient experience questionnaire and qualitative methods
- Exploring patient experience helped identify the perceived value of each interventional component and the means to *individualise* post-ICU rehabilitation in accordance with NICE guidance

Limitations:

- The patient experience questionnaire has yet to be psychometrically validated
- Sample size was small in our comparative focus group interviews

INTRODUCTION

Intensive Care (ICU) survivors commonly experience physical, psychological and cognitive impairment, recently termed “the post-intensive care syndrome”[1]. National Institute for Health and Care Excellence (NICE) recommends regular assessment and individualised rehabilitation for these patients[2], but optimum rehabilitation components and service delivery models are uncertain. Several trials have evaluated rehabilitation interventions conducted or initiated during the ICU stay[3-6] the acute hospital stay[7], and after hospital discharge[8-11]. Systematic reviews suggest that early ICU-based interventions may be effective[12-15], but interventions starting post-ICU discharge, including the RECOVER study[16], have failed to demonstrate clinical efficacy using recommended outcome-based approaches[17].

Recognising the limitations of outcomes evaluations of complex interventions alone, the Medical Research Council (MRC) recommends, in addition, the *process* evaluation of complex interventions[18]. This is intended to describe the fidelity and quality of implementation, clarify causal mechanisms, and identify contextual influences that may influence outcomes[18]. Specific recommendations from subsequent guidance include: exploring patients’ experiences of the intervention, and the use of qualitative approaches to explain quantitative findings[19]. With the exception of a single study[20], however, previous trials of rehabilitation interventions in this patient group have failed to describe patient experience of the intervention, therefore preventing detailed understanding of potentially beneficial components and/or treatments.

We recently reported the quantitative outcomes of a randomised controlled trial (RCT) of increased hospital-based physical rehabilitation and information provision following ICU discharge (RECOVER trial; ISRCTN09412438[16]). The intervention involved a dedicated rehabilitation assistant (RA) working within existing ward-based clinical teams to increase the frequency and intensity of physiotherapy and nutritional care, together with individualised critical illness-related information provision, from ICU to hospital discharge. The comparator was current usual care. We found no between-group differences across quantitative measures of physical function (Rivermead Mobility Index[21]; hand-grip strength; the timed-up-and-go test[22]; health-related quality of life (HRQoL; SF-12[23]); self-reported symptoms (fatigue, pain, appetite, joint stiffness, breathlessness using visual analogue scales (VAS)), or rates of anxiety, depression, and post-traumatic stress using the Hospital Anxiety and Depression Scale[24] and Davidson's Trauma scale respectively[25] at 3, 6, or 12 months post-randomisation.

However, a patient experience questionnaire (PEQ) administered at 3 months post-randomisation indicated that patient satisfaction scores were higher among the intervention group across four key intervention components. In this paper, we report the findings of a pre-planned, mixed methods process evaluation, comprising the triangulation of PEQ data with qualitative data from comparative focus group interviews with patients/carers. Our aim was to better understand and compare patients' experiences of rehabilitation in the trial, and specifically to explore effects on perceived quality of care that were unlikely to be captured with traditional quantitative outcome measures.

METHODS

We conducted a mixed methods analysis of population-level quantitative data from the PEQ (n=182 respondents) and qualitative analysis of comparative focus groups (n=22 participants), as part of a pre-planned process evaluation of the trial.

Trial overview

RECOVER was a parallel group, complex intervention RCT with blinded outcome assessment, undertaken in two University-affiliated hospitals in Edinburgh, Scotland[16]. The intervention development, trial protocol, and quantitative trial outcomes have been published previously[26-29]. A summary of trial design, content, and key differences in rehabilitation treatment are shown in figure 1.

In accordance with MRC guidance on the process evaluation of complex interventions[19], we conducted focus groups with patient participants and family members from both trial arms in order to explore and compare experiences of rehabilitation. We planned an a priori mixed methods process evaluation of the intervention, by integrating the quantitative PEQ data with the qualitative focus group data, in order to maximise understanding of the individual effects of the intervention's key components.

Patient Experience Questionnaire (PEQ)

The PEQ was designed based on pre-trial qualitative research (Doctoral thesis) among survivors of prolonged mechanical ventilation (n=20), which identified nine domains of post-ICU acute hospital care and rehabilitation that concerned participants most[30]. Based on expert advice, these were incorporated within a VAS including anchor points (excellent (0) to poor (20)) and anchor quotes derived from the data[29] to help patients report their experiences (figure 2). Developing the PEQ on the basis of patients' accounts was intended to maximise the questionnaire's sensitivity to issues that patients previously reported as important markers of quality of care[31]. Questionnaires were completed at 3 months post-randomisation, at the time of primary outcome assessment, with research staff blinded from group allocation.

Scores for each question were compared between the usual care and intervention groups using Mann-Whitney tests and median differences (with 95% confidence intervals). We calculated P values to assess the significance of any differences between the groups, using P<0.05 as statistically significant. In order to examine the consistency of patient experience between the trial groups, we also explored the variability and dispersion of responses by comparing the interquartile ranges (IQR) between groups.

Comparative focus groups with patients and family members

Qualitative approaches can be useful in understanding the clinical context in which complex interventions take place, in identifying unexpected causal mechanisms or effects, identifying evolving changes in trial implementation and exploring "what works, for whom, under what circumstances"[19 32]. Focus group interviews are increasingly used to explore experiences of healthcare. Typically comprising 6-12 participants, they are an efficient means of capturing multiple participants' perspectives. Group dynamics can be particularly helpful in eliciting the views of patients or patient groups who might otherwise be too "grateful" or reluctant to "complain", and in identifying potential solutions to shared concerns[33 34]. We specifically wanted to explore and compare participants' experiences of usual care versus the complex intervention.

We conducted two comparative focus groups with patients and family members in each trial arm (n=4 focus groups). The main trial was approved by the Scotland A Research Ethics Committee (10/MRE00/18) and additional written consent was provided by focus group participants. An experienced qualitative researcher (PR) developed topic guides for each group, based on pre-trial work[24, 25, 29] and the published taxonomy of intervention[26] (see electronic supplementary material). Participants were given significant freedom to discuss other issues of concern. The focus groups took place after the primary outcome data (including the PEQ) had been collected after 3 months post-randomisation, to minimise bias. Participant characteristics are summarised in table 1.

Table 1: Characteristics of the focus group participants. All values median (1st, 3rd quartile) unless stated. Demographic data were not available for carers.

Focus groups	**Usual care group**	**Intervention group**
Numbers and composition	Group 1: 7 participants (4 patients; 3 carers) Group 2: 5 participants (3 patients; 2 carers)	Group 1: 6 participants (4 patients; 2 carers) Group 2: 4 participants (3 patients; 1 carer)
Patient age	70 (63,78)	55 (36, 69)
Proportion male (%)	66	50
APACHE II score	23 (17, 26)	18 (15, 21)
Length of ventilation (days)	11 (5,19)	5 (4, 18)
ICU length of stay (days)	12 (4,16)	7 (5, 10)
Length of hospital stay (days)	9 (6,18)	13 (12,80)

Focus group discussions were recorded using a digital voice recorder and transcribed verbatim. Data were managed and analysed using qualitative data analysis software (NVIVO 10). PR developed an *a priori* analytical framework, based around key components of the intervention, which mapped onto the dimensions of the PEQ. We used thematic analysis to collate data that was relevant to each intervention component, identifying broad patterns of experience therein[35]. In order to minimise bias, the primary analysis was undertaken by an experienced independent qualitative researcher. A confirmatory analysis was subsequently undertaken by PR. All quantitative trial data were unavailable to the qualitative researchers during analysis.

Integration of qualitative and quantitative data

We adopted a sequential explanatory model to data collection and analysis[36]; namely the administration and analysis of the quantitative measure (PEQ) across the trial population, followed by the conduct and analysis of qualitative focus group interviews, each having equal importance in terms of explanatory power. To integrate data sources, we grouped the nine PEQ dimensions into four areas that represented the key components of the complex intervention (table 2), reporting the median response values, inter-group differences, and the dispersion of responses within the PEQ for each group. We then used data from the focus group interviews to help explain our findings and enhance our understanding of patients' experiences of these key components. Illustrative quotes are provided.

Table 2: The four rehabilitation components explored in the study, together with the PEQ domains included in the triangulation with focus group data.

Aspect of rehabilitation explored in focus groups	**Domains of patient experience questionnaire included**
Physiotherapy	"Exercises to get you moving/back on your feet"
Nutritional care	"Help with eating and nutrition"
Case management	"Transfer from ICU to the ward" "Ward staff's understanding of your time in intensive care" "Help, support and advice with being independent" "Being involved in decisions about your care" "Organisation and coordination of care"
Information provision	"Information about what happened in intensive care" "Knowing what to expect after you got home"

RESULTS

The quantitative responses to the PEQ are summarised in table 3, illustrating the distribution of responses within each trial group, and the differences between the intervention and usual care groups. The integration of the quantitative and qualitative data is presented below according to the four pre-defined intervention components.

Table 3: Summary of quantitative data responses to the nine domains in the patient satisfaction questionnaire administered at 3 months post-intervention, when the primary outcome assessment took place. *P values are with the Wilcoxon Mann-Whitney test; as this test is not a median test but a Rank Sum test the point estimates are not the difference between the two medians. U, usual care group; I, intervention group.

Intervention component	PEQ domain	Trial Group	Respondents	Median (cm)	1^{st}, 3^{rd} quartile (cm)	Inter-quartile distance (cm)	Median difference (95% CI) (cm)	P value
Physiotherapy	Exercises to get you moving/back on your feet	U I	83 95	6.1 5.0	1.2, 10.3 1.1, 7.9	9.1 6.8	1.40 (0.00 to 4.00)	0.039*
Nutritional care	Help with eating and nutrition	U I	87 95	9.9 5.4	4.8, 14.5 2.3, 10.0	9.7 7.7	1.60 (0.00 to 3.80)	0.038*
Case management	Transfer from ICU to the ward	U I	73 67	5.7 5.2	1.7, 14.9 4.8, 10.0	13.2 5.2	0.20 (-0.90 to 2.80)	0.481
	Ward staff's understanding of your time in intensive care	U I	78 87	5.1 5.1	1.1, 10.2 1.9, 8.0	9.1 6.1	0.00 (-1.10 to 1.20)	0.850
	Help, support and advice with being independent	U I	81 95	5.5 5.3	1.2, 10.1 2.6, 10.0	8.9 7.4	0.10 (-1.10 to 1.40)	0.787
	Being involved in decisions about your care	U I	81 91	10.0 7.3	5.0, 15.0 4.8, 14.3	10.0 9.5	0.70 (-0.40 to 3.30)	0.226
	Organisation and coordination of care	U I	83 96	7.1 5.3	4.8, 12.0 2.2, 10.0	7.2 7.8	1.30 (0.00 to 3.50)	0.045*
Information provision	Information about what happened in Intensive Care	U I	68 83	10.2 3.6	5.0, 16.9 1.0, 10.0	11.9 9.0	4.90 (2.80 to 8.00)	<0.001*
	Knowing what to expect after you got home	U I	81 89	10.0 7.2	5.0, 15.0 2.6, 14.9	10.0 12.3	0.50 (-0.40 to 3.30)	0.308

Physiotherapy: PEQ data indicated general satisfaction across both groups (intervention group median 5.0cm versus 6.1cm in the usual care group), but scores were better for intervention group patients, reaching statistical significance (P=0.039). Intervention group participants gave more consistently satisfied responses (interquartile range (IQR): intervention group 6.8cm versus 9.1cm in the usual care group). In focus groups, physiotherapy emerged as one of the most important aspects of rehabilitation for all:

> *"…the biggest saviour in the whole thing has probably been the physio… physio is the main thing."* (usual care participant)

Experiences of physiotherapy varied widely in the usual care group, however, and participants frequently remarked upon resource constraints (lack of staffing) and its perceived impact upon recovery.

> *"…He (husband) wanted out of bed and he wanted to make a recovery, but if you've no(t) got the bodies (staff) there to help…"* (usual care participant's wife)

In contrast, intervention participants valued the frequency and consistency of physiotherapy provided by RAs.

> *"I had two (physio) sessions-a morning and an afternoon…"* (intervention participant)

Intervention participants highly valued the timing and delivery of physiotherapy according to their individual abilities, needs and preferences, facilitating greater involvement in the rehabilitation process.

> *"…if there was anything that I felt that I couldn't do, or it was too much, I was just to rest get my breath if need be, and just tell them (RAs) when I was ready…and every time they would say "What would you like to do today?" and in the end I could pick what I wanted"* (intervention participant)

Explanation, support and encouragement to perform exercises unsupervised was also highly valued.

"…If you're left with a sheet of paper to say, do these exercises on a daily basis, I am not likely to be motivated, but if somebody is…physically there, saying "Do these, let's do it together", it's very different" (intervention participant)

Overall, the RA's provided continuity and consistency of care in accordance with intervention group participants' individual needs, abilities and preferences.

Nutritional care: Responses to the PEQ revealed greater satisfaction in the intervention group (median response 5.4cm versus 9.9cm in the usual care group; reaching statistical significance P=0.038). Intervention participants were also more consistently satisfied (IQR 7.7cm versus 9.7cm). In the focus groups, nutritional care was universally perceived as important to recovery, but experiences varied widely among the usual care group.

> *"…she (dietitian) checked what I was eating…She said you could do with a wee (little) bit more of such and such, so she arranged to have that wee bowl of fruit or something"* (usual care participant)

Several participants, however, felt that nursing staff were too busy to physically help them eat or deliver prescribed supplements.

> *"Nobody was interested. I was actually taking him (husband) in flasks of porridge to try and encourage him to eat…I was actually spoon feeding him…he was so weak, it was like there was nobody there to do this"* (usual care patient's wife)

Intervention participants, in contrast, valued the RAs' physical assistance with eating (including nutritional supplements) and support to achieve prescribed nutritional targets, using individualised feedback. Also valued was their advocacy in relaying dietary concerns to relevant ward-based clinicians.

> *"I managed to say, " (RA), I can't manage this (high protein supplement)". Can you speak to (the ward-based Dietitian) about it? And we did work out something and it worked, because I…asked (RA) to represent me, because with (ward-based Dietitian), I couldn't get through"*

One intervention participant particularly valued the RA's support in accompanying her to the hospital canteen.

> *"……I was really grateful to (RA). She would spare the time to take me downstairs (to the hospital canteen) and bring me back up during lunch to just try and encourage me to eat"*

Overall, the RAs appeared to more consistently operationalise dietetic recommendations, individualising care according to patients' needs and preferences.

Case management: Median PEQ responses to the questions "transfer from ICU to the ward", "ward staff's understanding of your time in intensive care" and "help, support and advice with being independent" were similar between the groups with values between 5-6cm ("very good"). However, for all these domains the IQR values were wider for the usual care group, notably for the "transfer from ICU to the ward" (13.2cm versus 5.2cm), suggesting wider variation in experience. Responses to "being involved in decisions about your care" were less positive (usual care 10.0cm versus 7.3cm in the intervention group) with wide variation in responses for both groups. The most direct question about case management, "organisation and coordination of care", indicated better experience among intervention patients (5.3cm versus 7.2cm; reaching statistical significance P=0.045).

In the focus groups, clear differences emerged between the groups. Both described a perceived deterioration in the quality of care following transfer to the general wards, which was attributed to staff shortages, high workload, and the dependency of other patients.

> *"You know the NHS is short staffed, you know that with their resources….but I mean you're giving them all this care in Intensive Care, and after that, it's like you're thrown to the dogs"* (usual care participant's wife)

Experiences across both groups were very variable, and seemed dependent on the discharge destination (specific ward). The experience of usual care participants appeared less consistent; several appeared to "slip through the net", for example, in terms of pre-discharge assessment and provision of aids and adaptations for community living.

> *"Was somebody supposed to come down and assess ....her needs? If she needed anything adapted…needed any kind of equipment or stuff like that? That never happened"* (usual care patient's son)

Usual care participants frequently described the "push" for hospital discharge, a general lack of involvement in decision-making, and communication that was often ambiguous, contradictory and "last minute".

> *"… I think for… basically knocking on Death's door, I think the length of time between coming out of Intensive Care and going home is far, far too short. They are in a rush to…get people out"* (usual care patient's son)

Usual care participants were also critical of a lack of post-discharge follow-up.

> *"I thought we might have been asked to come back for a check-up after so many weeks… I've never heard anything about anything like that"* (usual care patient)

Intervention participants, in contrast, valued the RA's assistance across multiple roles, including assistance with eating, washing and dressing, coordination of relevant assessments and referrals, and communication of discharge plans. Intervention group participants attributed this support to consistency and continuity of care.

> *"…having one person assigned to you, I thought that was marvellous, you know? There was always that one person that you knew you would see almost, probably every day…and if you had any worries you could talk to that one person and your worries got to the right source...the source that would do something about it"* (intervention patient)

Other examples included the coordination of post-discharge support

> *"…I felt I was very lucky because the day of my discharge, (the RA) had managed to gather all the things I needed, had managed to secure all the telephone numbers that I might need…I didn't have any qualms about going home…"* (intervention participant)

Information provision: Responses to *"information about what happened in intensive care"* showed the largest between-group differences, with intervention patients reporting the greatest and usual care patients the lowest satisfaction across all PEQ domains (10.2cm versus 3.6cm; reaching statistical significance $P<0.001$). In contrast, group responses were similar to *"knowing what to expect after you got home"*, with poorer median values than for many domains (intervention group 7.2cm versus 10.0cm in the usual care group) and wide variation in satisfaction for both groups. These data suggest the intervention improved information provision relating to the critical illness episode, but persisting unmet informational need following hospital discharge.

Focus group data strongly supported these findings. Amnesia, strange dreams and delusional memories were prevalent for all patients, and limited recall of the ICU admission and early post-discharge period was frequently described. Usual care participants frequently felt ill-informed about the circumstances and chronology of events surrounding their ICU admission and relied almost exclusively upon family members for information. This contributed to anxiety around potential recurrence, ill-explained critical illness-related morbidity, the protraction and limits of the recovery process, and the long-term implications of critical illness. Several usual care participants attributed greater anxiety to acquiring information from independent sources, such as the internet.

> *"I still don't know why I ended up in there (ICU). Well, I know why, but I don't know why I got what I got…I worry a lot more about my health than I ever did before, because I've got no idea what started it. I think that's the biggest problem. I went on the internet and looked up…the septic shock thing and what that entailed…and I wish to God that I hadn't … ….because I felt like I'd just been knocked back about six steps…."* (usual care participant)

When asked, many agreed that a clear outline of "what happened" would have been helpful.

> *"I think it would have helped me…definitely, just to fill in all the blanks. I would like to know what happened with this and what happened with that and…but I never got anything like that"* (usual care participant)

In marked contrast, intervention participants valued the structured, individualised information they received. The discussion with an ICU physician was generally valued for the opportunity to "fill in the blanks", especially reasons for ICU admission and the clinical course. Some focus group participants declined, however, describing their ICU experience as too "raw" in the early post-ICU period.

> *"I think them coming to see you helps to fill that void, you know, because being in Intensive Care, it's almost like you've lost a number of days without knowing what's happening…(the ICU Consultant) managed to explain the facts and…what you went through…why you ended up in Intensive Care. It really did help…me to put things in chronological order"* (intervention participant)

The individualised lay summary of the ICU admission was valued for its easily understandable explanation, although the terminology used and its occasional receipt by post (after hospital discharge) sometimes caused anxiety, highlighting the value of face-to-face clarification, reassurance and the opportunity to ask questions.

> *"…mine was good…but I got a wee (little) bit of a fright…although I knew I was on the breathing machine, I didn't know that it was…called a life support machine and see when I seen it written down..!* (intervention participant)

When participants accepted the offer of an ICU visit prior to hospital discharge, it was generally valued as an opportunity to make sense of the critical illness episode. However, timing was important, with several focus group participants reporting that their experiences were still "too raw". Finally, the therapeutic relationship with the RA appeared to facilitate the sensitive timing and presentation of information in accordance with patients' needs, emotional status and ability to retain information.

DISCUSSION

This mixed methods process evaluation provides valuable insights into patient/carer experiences in a complex intervention trial of post-ICU acute hospital rehabilitation. There was substantial concordance between cohort-level questionnaire data and the detailed accounts of focus group participants. Evidence of greater satisfaction with physiotherapy, nutritional care, information provision and coordination of care emerged from both data sources, suggesting that a case-management approach, delivered by a dedicated RA, improved patient experience of post-ICU acute hospital rehabilitation. Focus group data revealed the high value intervention participants placed on the *individualisation* of their care, according to their needs, abilities and preferences.

Despite evidence of greater satisfaction in the intervention group, we found no statistically or clinically significant between-group differences across functional, physical, psychological and HRQoL outcomes between hospital discharge and 12 months follow-up in the trial[16]. The discordance between these "biomedical" outcomes and greater reported patient satisfaction is striking. It is possible that biomedical outcomes are resistant to modification at this stage of recovery[37] or that they fail to measure "what matters" to patients during acute hospital-based recovery[37 38].

Qualitative studies among other hospitalised patient groups have shown the high value that patients place on the therapeutic or collaborative relationship with rehabilitation staff, flexibility around the timing, content and delivery of rehabilitation, and its individualisation according to needs and preferences[39-41]. These issues underpinned the development of the RECOVER intervention, and the PEQ was specifically developed to capture them. Our data provide strong evidence for important effects on these person-centred outcomes.

A key finding was the value participants placed on information. The "need to know" has long been reported in the critical care literature[42], underpinning various strategies such as ICU discharge summaries[43], patient diaries[44-46], follow-up clinics[47 48], and return visits to the ICU[49]. Our comprehensive, individualised approach was documentary (rehabilitation manual; individualised lay summary), didactic (discussion with

ICU physician and the RAs), and experiential (offer of a return visit to the ICU). Both qualitative and quantitative data provided strong evidence for the benefit of information, and focus group data uncovered preferences for its timing, content (including terminology) and delivery. These findings support the need for individualised information in routine post-ICU care.

A particular strength of our process evaluation was consideration of the clinical context in which the intervention took place, and participants' response to and interaction with the intervention. These are recommended when evaluating how or why complex healthcare interventions may (or may not) work[19]. Our data provide empirical evidence that enhanced access to physiotherapy, nutritional care, and information are important to patients during recovery, but highlight a range of preferences and the need for individualised content, delivery and timing. Case management by a dedicated RA was a key "active ingredient" that facilitated these preferences and seemed to increase engagement in the rehabilitation process, resulting in greater overall perceived benefit.

Our findings are relevant to future trial design in this patient population. Specifically, trial interventions that use *individual* adaptation versus standardised or fixed interventions require different approaches to both process and effectiveness evaluation[50 51]. We standardised the *process* and *function* of the intervention (i.e. individualisation and patient engagement in the rehabilitation process, respectively) but not the *content*, capturing actual differences in treatments received in the process evaluation. This approach is particularly recommended when the "real world" or clinical context is complex[19]. With this perspective, the internal validity of a trial should be defined functionally as well as compositionally[32 50]. Our data indicate that concordance between biomedical and person-centred outcomes should not be assumed[37], highlighting the importance of specific standardised measures (few currently exist) and the use of qualitative approaches to capture the latter.

Importantly, cost-effectiveness analysis of the RECOVER trial found no incremental cost-effectiveness over the 12 months post-randomisation, and no difference in Quality Adjusted Life Years between the groups[16]. It is increasingly recognised that HRQoL trajectories are difficult to modify following critical illness, in part because pre-existing comorbidity dominates reported HRQoL during recovery[52-55]. Quality of care, patient satisfaction, and "person-centeredness" are excluded from cost-effectiveness analysis. The use of service models based on multi-skilled RAs providing individualised case management is potentially cost-neutral or even cost-saving compared to existing models that require multiple specialists from different disciplines. Our data provide strong evidence that this approach delivers higher quality care from patients' and carers' perspectives and may well justify service re-design. Our model of care has been adopted into routine clinical practice at the main study hospital.

In conclusion, we have shown that physiotherapy, nutritional care, and information are highly valued by patients during post-ICU acute hospital rehabilitation. A rehabilitation strategy coordinated by a dedicated multi-skilled RA improved patients' satisfaction with and perceived quality of care, cutting across traditional disciplinary boundaries, ward-level resource constraints and circumventing communication failures. The focus on individualised, coordinated care according to patient ability and preference was highly valued.

Contributors: The following is taken from the submitted manuscript. The initials refer to the listed co-authors: TW, LS, PR, JM and GH designed the trial and completed pilot and feasibility work. Specialist clinical input to trial conduct was provided by TW and DG (critical care perspective), LS (physiotherapy/rehabilitation), PR and JR (nursing) and JM (dietetics). Statistical advice was provided by Professor Gordon D Murray and Professor Stephanie C Lewis (both at the University of Edinburgh). The Patient Experience Questionnaire was developed by PR. The qualitative focus group interviews were designed by PR and GH and conducted and analysed by PR. All co-authors contributed to the mixed methods integration and analysis.

There are no competing interests.

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Additional unpublished data may be requested by contacting the lead author.

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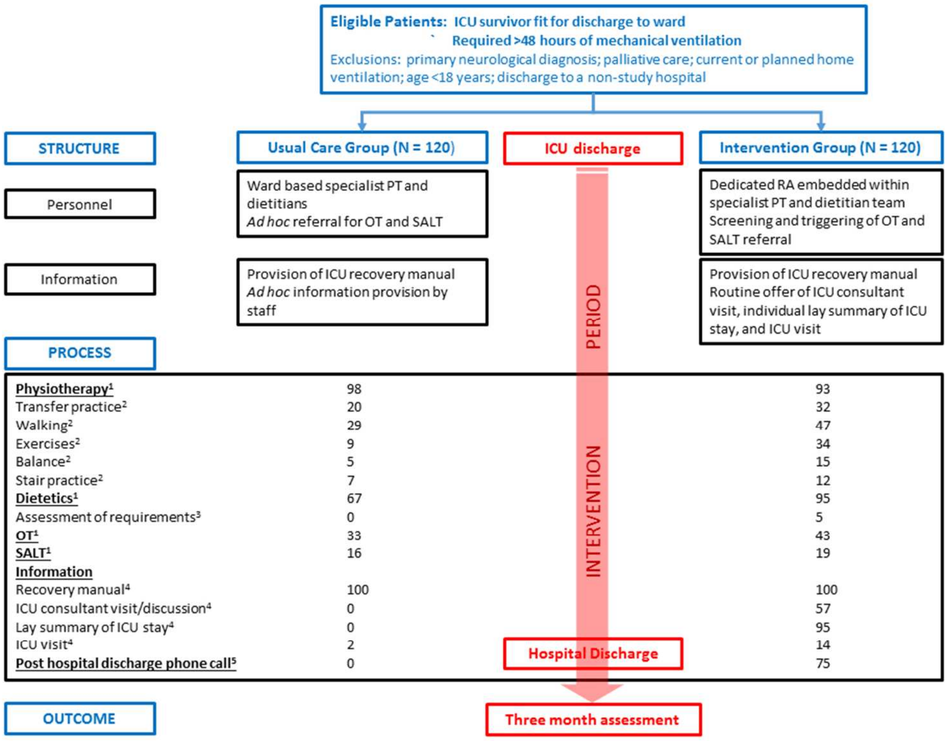
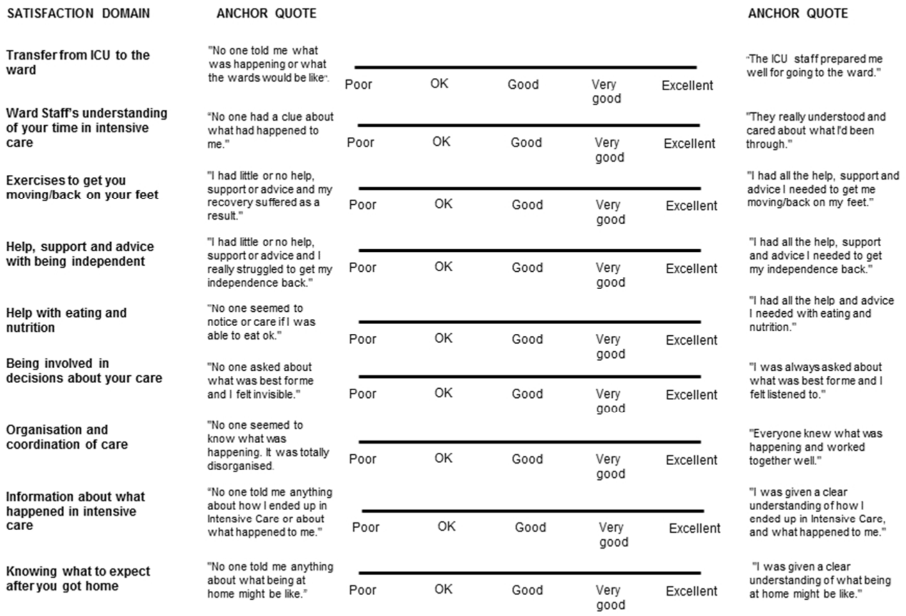


Physiotherapy[1]	98	93
Transfer practice[2]	20	32
Walking[2]	29	47
Exercises[2]	9	34
Balance[2]	5	15
Stair practice[2]	7	12
Dietetics[1]	67	95
Assessment of requirements[3]	0	5
OT[1]	33	43
SALT[1]	16	19
Information		
Recovery manual[4]	100	100
ICU consultant visit/discussion[4]	0	57
Lay summary of ICU stay[4]	0	95
ICU visit[4]	2	14
Post hospital discharge phone call[5]	0	75



SATISFACTION DOMAIN	ANCHOR QUOTE						ANCHOR QUOTE
Transfer from ICU to the ward	"No one told me what was happening or what the wards would be like".	Poor	OK	Good	Very good	Excellent	"The ICU staff prepared me well for going to the ward."
Ward Staff's understanding of your time in intensive care	"No one had a clue about what had happened to me."	Poor	OK	Good	Very good	Excellent	"They really understood and cared about what I'd been through."
Exercises to get you moving/back on your feet	"I had little or no help, support or advice and my recovery suffered as a result."	Poor	OK	Good	Very good	Excellent	"I had all the help, support and advice I needed to get me moving/back on my feet."
Help, support and advice with being independent	"I had little or no help, support or advice and I really struggled to get my independence back."	Poor	OK	Good	Very good	Excellent	"I had all the help, support and advice I needed to get my independence back."
Help with eating and nutrition	"No one seemed to notice or care if I was able to eat ok."	Poor	OK	Good	Very good	Excellent	"I had all the help and advice I needed with eating and nutrition."
Being involved in decisions about your care	"No one asked about what was best for me and I felt invisible."	Poor	OK	Good	Very good	Excellent	"I was always asked about what was best for me and I felt listened to."
Organisation and coordination of care	"No one seemed to know what was happening. It was totally disorganised.	Poor	OK	Good	Very good	Excellent	"Everyone knew what was happening and worked together well."
Information about what happened in intensive care	"No one told me anything about how I ended up in Intensive Care or about what happened to me."	Poor	OK	Good	Very good	Excellent	"I was given a clear understanding of how I ended up in Intensive Care, and what happened to me."
Knowing what to expect after you got home	"No one told me anything about what being at home might be like."	Poor	OK	Good	Very good	Excellent	"I was given a clear understanding of what being at home might be like."

Patient and family focus group interview guide: Usual Care Group

	Examples of general questions	Examples of prompts and prompts
Physiotherapy	I'd like to ask now about the kind of help people got to help you get back on your feet and ready for hospital discharge…	• How important was physiotherapy to your (or your relative's) overall recovery? • Did you have any hopes or expectations on the physiotherapy you (or your relative) might receive on the wards? • How would you describe the physiotherapy you (or your relative) received? • Did you feel that you/they had enough physiotherapy? • How effective was physiotherapy in terms of progressing your/their recovery? • How confident did you feel about progressing your/their recovery after you/they got home?
Nutritional support	People often lose a lot of weight and muscle whilst they're very ill in ICU…	• How important was eating/nutrition to you (or your relative's) overall recovery? • What kind of help did you/they get with that? • Did you get the kind of help you felt you/they needed with eating and nutrition? • How confident did you feel about eating/nutritional issues after you/they got home?
Case management	I'd like to ask more generally about your care on the wards…	• To what extent do you think that the staff understood what you (or your relative) had been through in Intensive Care? • Did you feel that you/they got as much help as you/they needed with things like washing, getting dressed, etc? • In what ways did that affect your/their care and your/their recovery? • How involved were you in decisions about your getting home? • Did you know what kinds of arrangements were being made on your/their behalf? • Did you feel as involved as you wanted to be in those kinds of arrangements? • If you/they were told that you/they would receive support or equipment after you got home, did that actually happen? • If not, what were you able to do about that? • What would have been helpful for you?
Information provision	How much did you know or understand about what brought you into Intensive Care and what happened while you were there?	• It's very common not to remember much…or to have very "jumbled" picture of what happened. Your family may very well have filled in some of the blanks for you… • How important was that information to you when you were on the ward? • Would it have been useful for someone (perhaps a doctor or a nurse) go through exactly what happened, and to be able to ask questions? • Would some written information have been useful? • When would it be best to receive that kind of information (if you wanted it)? • Do you think visiting the ICU before you went home might have been useful?

Patient and family focus group interview guide: Intervention Group

	Examples of general questions	Examples of prompts and prompts
Physiotherapy	I'd like to ask now about the help you/your relative got to help you/them get back on your/their feet. You/they were offered extra help from (RAs) as part of the study…	• How important was physiotherapy to your (or your relative's) overall recovery? • Did you have any hopes or expectations on the physiotherapy you (or your relative) might receive on the wards? • How would you describe the physiotherapy you/they received on the wards? • Did you/they feel that you/they had enough physiotherapy? • Tell me more about the extra help you received from the Rehabilitation Assistants (names)? • What kinds of things were most helpful to you? • Was there anything that could have been done differently or better? • How confident did you feel about progressing your/their recovery after you/they got home?
Nutritional care	People often lose a lot of weight and muscle whilst they're very ill in ICU…	• How important was eating/nutrition to your (or your relative's) overall recovery? • What kind of help did you get with that from the ward Dietitian? • How helpful was that in progressing your/their recovery? • Tell me more about what the Rehabilitation Assistants (names) did to help you with eating and nutrition? • Was there anything that could have been done differently or better? • How confident did you feel about eating/ nutritional issues after you/they got home?
Case management	I'd like to ask more generally about your care on the wards…	• To what extent do you think the ward staff understood what you (or your relative) had been through in Intensive Care? • Did you feel that you/they got as much help as you/they needed with things like washing, getting dressed, etc. • In what ways did that affect your/their care and recovery? • How involved were you in decisions about your getting home? • Did you know what kinds of arrangements were being made on your behalf? • Did you feel as involved as you wanted to be in those kinds of arrangements? • Tell me about the sorts of things the Rehabilitation Assistants (names) did to help you with these issues? • If you were told that you would receive support or equipment after you got home, did that actually happen? • If not, what were you able to do about it? • What would have been helpful to you?
Information	How much did you know or understand about what brought you into Intensive Care and what happened while you were there?	• You will have been offered a visit from one of the **ICU Consultants** while you were you on the wards, so that they could explain what happened to you… • How useful was that? Was the timing ok? Were you able to ask the questions you wanted to? • You will also have received **a letter** describing what happened to you in easily understandable language • How useful was that? In what way? Some of you may have received the letter after you got home…how was that for you

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:
Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

YOU MUST PROVIDE A RESPONSE FOR ALL ITEMS. ENTER N/A IF NOT APPLICABLE

No. Item	**Guide questions/description**	**Reported on Page #**
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	Lead author, page 6
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	PhD
3. Occupation	What was their occupation at the time of the study?	Researcher, page 6
4. Gender	Was the researcher male or female?	Not explicitly reported
5. Experience and training	What experience or training did the researcher have?	PhD, page 6
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	Yes, subset of RECOVER participants, page 6
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	N/A
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Not reported
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	MRC guidance on evaluating complex interventions, page 4
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Convenience.

11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Face to face (subset of RECOVER participants)
12. Sample size	How many participants were in the study?	182 completed questionnaire. 22 participated in focus groups. Page 1
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Not reported
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Not reported
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	No
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Table, page 6
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Electronic supplementary material
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	No
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Audio, page 6
20. Field notes	Were field notes made during and/or after the inter view or focus group?	Not reported
21. Duration	What was the duration of the inter views or focus group?	Not reported
22. Data saturation	Was data saturation discussed?	Not reported
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	2, pages 6 and 7
25. Description of the coding tree	Did authors provide a description of the coding tree?	Based on components of the intervention: pages 6 and 7
26. Derivation of themes	Were themes identified in advance or derived from the data?	Based on components of the intervention: pages 6 and 7
27. Software	What software, if applicable, was used to manage the data?	NVivo, page 6
28. Participant checking	Did participants provide feedback on the findings?	No
Reporting		

29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Yes, page 10
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	No

Once you have completed this checklist, please save a copy and upload it as part of your submission. When requested to do so as part of the upload process, please select the file type: *Checklist*. You will NOT be able to proceed with submission unless the checklist has been uploaded. Please DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

BMJ Open

Patient and carer experience of hospital based rehabilitation from Intensive Care to hospital discharge: mixed methods process evaluation of the RECOVER randomised clinical trial

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Title: PATIENT AND CARER EXPERIENCE OF HOSPITAL BASED REHABILITATION FROM INTENSIVE CARE TO HOSPITAL DISCHARGE: MIXED METHODS PROCESS EVALUATION OF THE RECOVER RANDOMISED CLINICAL TRIAL

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Keywords: adult intensive and critical care, rehabilitation medicine, quality in healthcare, organisation of health services, qualitative research.

Word count: 3980

ABSTRACT

Objectives: To explore and compare patient/carer experiences of rehabilitation in the intervention and usual care arms of the RECOVER trial (ISRCTN09412438); a randomised controlled trial of a complex intervention of post-Intensive Care Unit (ICU) acute hospital-based rehabilitation following critical illness.

Design: Mixed methods process evaluation including comparison of patients' and carers' experience of usual care versus the complex intervention. We integrated and compared quantitative data from a Patient Experience Questionnaire (PEQ) with qualitative data from focus groups with patients and carers.

Setting: Two University-affiliated hospitals in Scotland.

Participants: 240 patients discharged from ICU who required ≥ 48 hours of mechanical ventilation were randomised into the trial (120 per trial arm). Exclusion criteria comprised: primary neurologic diagnosis, palliative care, current/planned home ventilation, age <18 years. 182 patients completed the PEQ at 3 months post-randomisation. 22 participants (14 patients: 8 carers) took part in focus groups (2 per trial group) at >3 months post-randomisation.

Interventions: A complex intervention of post-ICU acute hospital rehabilitation, comprising enhanced physiotherapy, nutritional care and information provision, case-managed by dedicated Rehabilitation Assistants (RAs) working within existing ward-based clinical teams, delivered between ICU discharge and hospital discharge. Comparator was usual care.

Outcome measures: A novel PEQ capturing patient-reported aspects of quality care

Results: The PEQ revealed statistically significant between-group differences across 4 key intervention components: physiotherapy (p 0.039), nutritional care (p 0.038), case-management (0.045) and information provision (<0.001); suggesting greater patient satisfaction in the intervention group. Focus group data strongly supported and helped explain these findings. Specifically, case-management by dedicated RAs facilitated greater access to physiotherapy, nutritional care and information that cut across disciplinary boundaries and staffing constraints. Patients highly valued its *individualisation* according to their needs, abilities and preferences.

Conclusions: Case-management by dedicated RAs improves patients' experiences of post-ICU hospital-based rehabilitation, and increases perceived quality of care.

Trial registration: ISRCTN 09412438 DOI 10.1186/ISRCTN09412438

Strengths and limitations

Strengths:

- Our trial is among the very few critical care complex interventional trials to incorporate the Medical Research Council's (MRC) recommendations for outcomes *and* process evaluation into its evaluation strategy

- Our trial is among the very few such trials to critically explore patient experience, using both a novel patient experience questionnaire and qualitative methods
- Exploring patient experience helped identify the perceived value of each interventional component and the means to *individualise* post-ICU rehabilitation in accordance with NICE guidance

Limitations:

- The patient experience questionnaire has yet to be psychometrically validated
- Sample size was small in our comparative focus group interviews

INTRODUCTION

Intensive Care (ICU) survivors commonly experience physical, psychological and cognitive impairment, recently termed "the post-intensive care syndrome"[1]. National Institute for Health and Care Excellence (NICE) recommends regular assessment and individualised rehabilitation for these patients[2], but optimum rehabilitation components and service delivery models are uncertain. Several trials have evaluated rehabilitation interventions conducted or initiated during the ICU stay[3-7] the acute hospital stay[8], and after hospital discharge[9-12]. Systematic reviews suggest that early ICU-based interventions may be effective[13-16], but interventions starting post-ICU discharge, including the RECOVER study[17], have failed to demonstrate clinical efficacy using recommended quantitative outcome-based approaches[18].

Recognising the limitations of outcomes evaluations of complex interventions alone, the Medical Research Council (MRC) recommends, in addition, the *process* evaluation of complex interventions[19]. This is intended to describe the fidelity and quality of implementation, clarify causal mechanisms, and identify contextual influences that may influence outcomes[19]. Specific recommendations from subsequent guidance include: exploring patients' experiences of the intervention, and the use of qualitative approaches to explain quantitative findings[20]. With the exception of a single study[21], however, previous trials of rehabilitation interventions in this patient group have failed to describe patient experience of the intervention, therefore preventing detailed understanding of potentially beneficial components and/or treatments.

We recently reported the quantitative outcomes of a randomised controlled trial (RCT) of increased hospital-based physical rehabilitation and information provision following ICU discharge (RECOVER trial; ISRCTN09412438[17]). The intervention involved a dedicated rehabilitation assistant (RA) working within existing ward-based clinical teams to increase the frequency and intensity of physiotherapy and nutritional care, together with individualised critical illness-related information provision, from ICU to hospital discharge. The comparator was current usual care (see figure 1, supplementary files for a summary of trial design and content). We found no between-group differences across quantitative measures of physical function (Rivermead Mobility Index[22]; hand-grip strength; the timed-up-and-go test[23]; health-related quality of life (HRQoL; SF-12[24]); self-reported symptoms (fatigue, pain, appetite, joint stiffness, breathlessness using visual analogue scales (VAS)), or rates of anxiety, depression, and post-traumatic stress using the Hospital Anxiety and Depression Scale[25] and Davidson's Trauma scale respectively[26] at 3, 6, or 12 months post-randomisation.

However, a patient experience questionnaire (PEQ) administered at 3 months post-randomisation indicated that patient satisfaction scores were higher among the intervention group across four key intervention components. In this paper, we report the findings of a pre-planned, mixed methods process evaluation, comprising the triangulation of PEQ data with qualitative data from comparative focus group interviews with patients/carers. Our aim was to better understand and compare patients' experiences of rehabilitation in the trial, and specifically to explore effects on perceived quality of care that were unlikely to be captured with traditional quantitative outcome measures.

METHODS

We conducted a mixed methods analysis of population-level quantitative data from the PEQ (n=182 respondents) and qualitative analysis of comparative focus groups (n=22 participants), as part of a pre-planned process evaluation of the trial.

Trial overview

RECOVER was a parallel group, complex intervention RCT with blinded outcome assessment, undertaken in two University-affiliated hospitals in Edinburgh, Scotland[17]. The intervention development, trial protocol, and quantitative trial outcomes have been published previously[27-30]. A summary of trial design, content, and key differences in rehabilitation treatment are shown in figure 1.

In accordance with MRC guidance on the process evaluation of complex interventions[20], we conducted focus groups with patient participants and family members from both trial arms in order to explore and compare experiences of rehabilitation. We planned an a priori mixed methods process evaluation of the intervention, by integrating the quantitative PEQ data with the qualitative focus group data, in order to maximise understanding of the individual effects of the intervention's key components.

Patient Experience Questionnaire (PEQ)

The PEQ was designed based on pre-trial qualitative research (Doctoral thesis) among survivors of prolonged mechanical ventilation (n=20), which identified nine domains of post-ICU acute hospital care and rehabilitation that concerned participants most[31]. Based on advice from an expert in questionnaire development, these were incorporated within a VAS including anchor points (excellent (0) to poor (20)) and anchor quotes derived from the data[29] to help patients report their experiences (see figure 2, supplementary files for the PEQ). We explored the face and content validity of the questionnaire by asking a small number of recovering patients to describe the extent to which the PEQ reflected their experiences of ward care. Developing the PEQ on the basis of patients' accounts was intended to maximise the questionnaire's sensitivity to issues that patients previously reported as important markers of quality care[32]. Questionnaires were completed at 3 months post-randomisation, at the time of primary outcome assessment, with research staff blinded from group allocation.

Scores for each question were compared between the usual care and intervention groups using Mann-Whitney tests and median differences (with 95% confidence intervals). We calculated P values to assess the significance of any differences between the groups, using $P<0.05$ as statistically significant. In order to examine the consistency of patient experience between the trial groups, we also explored the variability and dispersion of responses by comparing the interquartile ranges (IQR) between groups.

Comparative focus groups with patients and family members

Qualitative approaches can be useful in understanding the clinical context in which complex interventions take place, in identifying unexpected causal mechanisms or effects, identifying evolving changes in trial implementation and exploring "what works, for whom, under what circumstances"[20 33]. Focus group interviews are increasingly used to explore experiences of healthcare. Typically comprising 6-12 participants, they are an efficient means of capturing multiple participants' perspectives. Group dynamics can be particularly helpful in eliciting the views of patients or patient groups who might otherwise be too "grateful" or reluctant to "complain", and in identifying potential solutions to shared concerns[34 35]. We specifically wanted to explore and compare participants' experiences of usual care versus the complex intervention.

We conducted two comparative focus groups with patients and family members in each trial arm (n=4 focus groups). The main trial was approved by the Scotland A Research Ethics Committee (10/MRE00/18) and additional written consent was provided by focus group participants. An experienced qualitative researcher (PR) developed topic guides for each trial group, based on pre-trial work[24, 25, 29] and the published taxonomy of intervention[26] (see tables 1 and 2, supplementary files for indicative topic guides for each group). Participants were given significant freedom to discuss other experiences of care, both positive and negative. The focus groups took place after the primary outcome data (including the PEQ) had been collected after 3 months post-randomisation, to minimise bias. Participant characteristics are summarised in table 1.

Table 1: Characteristics of the focus group participants. Demographic data were not available for carers.

Focus groups	**Usual care group**	**Intervention group**
Numbers and composition	Group 1: 7 participants (4 patients; 3 carers) Group 2: 5 participants (3 patients; 2 carers)	Group 1: 6 participants (4 patients; 2 carers) Group 2: 4 participants (3 patients; 1 carer)
Patient age	70 (63,78)	55 (36, 69)
Proportion male (%)	66	50
APACHE II score	23 (17, 26)	18 (15, 21)
Length of ventilation (days)	11 (5,19)	5 (4, 18)
ICU length of stay (days)	12 (4,16)	7 (5, 10)
Length of hospital stay (days)	9 (6,18)	13 (12,80)

All values median (1st, 3rd quartile) unless stated.

Focus group discussions were recorded using a digital voice recorder and transcribed verbatim. Data were managed and analysed using qualitative data analysis software (NVIVO 10). PR developed an *a priori* analytical framework, based around the 4 key components of the intervention, which mapped onto the dimensions of the PEQ. We used thematic analysis to collate qualitative data that was relevant to each intervention component, identifying broad patterns of experience therein[36]. In order to minimise bias, the primary analysis was undertaken by an experienced independent qualitative researcher. A confirmatory analysis was undertaken by PR. All quantitative trial data were unavailable to the qualitative researchers during analysis.

Integration of qualitative and quantitative data

We adopted a sequential explanatory model to data collection and analysis[37]; namely the administration and analysis of the quantitative measure (PEQ) across the trial population, followed by the conduct and analysis of qualitative focus group interviews, each having equal importance in terms of explanatory power. To integrate data sources, we grouped the nine PEQ dimensions into four areas that represented the key components of the complex intervention (table 2), reporting the median response values, inter-group differences, and the dispersion of responses within the PEQ for each group. We then used data from the focus group interviews to help explain our findings and enhance our understanding of patients' experiences of these key components. Illustrative quotes are provided.

Table 2: The four rehabilitation components explored in the study, together with the PEQ domains included in the triangulation with focus group data.

Aspect of rehabilitation explored in focus groups	**Domains of patient experience questionnaire included**
Physiotherapy	"Exercises to get you moving/back on your feet"
Nutritional care	"Help with eating and nutrition"
Case management	"Transfer from ICU to the ward" "Ward staff's understanding of your time in intensive care"

	“Help, support and advice with being independent” “Being involved in decisions about your care” “Organisation and coordination of care”
Information provision	“Information about what happened in intensive care” “Knowing what to expect after you got home”

RESULTS

The quantitative responses to the PEQ are summarised in table 3, illustrating the distribution of responses within each trial group, and the differences between the intervention and usual care groups. The integration of the quantitative and qualitative data is presented below according to the four pre-defined intervention components.

Table 3: Summary of quantitative data responses to the nine domains in the patient satisfaction questionnaire administered at 3 months post-intervention, when the primary outcome assessment took place.

Intervention component	PEQ domain	Trial Group	Respondents	Median score[1] (cm)	1st, 3rd quartile (cm)	Inter-quartile distance (cm)	Median difference (95% CI) (cm)	P value
Physiotherapy	Exercises to get you moving/back on your feet	U I	83 95	6.1 5.0	1.2, 10.3 1.1, 7.9	9.1 6.8	1.40 (0.00 to 4.00)	0.039*
Nutritional care	Help with eating and nutrition	U I	87 95	9.9 5.4	4.8, 14.5 2.3, 10.0	9.7 7.7	1.60 (0.00 to 3.80)	0.038*
Case management	Transfer from ICU to the ward	U I	73 67	5.7 5.2	1.7, 14.9 4.8, 10.0	13.2 5.2	0.20 (-0.90 to 2.80)	0.481
	Ward staff's understanding of your time in intensive care	U I	78 87	5.1 5.1	1.1, 10.2 1.9, 8.0	9.1 6.1	0.00 (-1.10 to 1.20)	0.850
	Help, support and advice with being independent	U I	81 95	5.5 5.3	1.2, 10.1 2.6, 10.0	8.9 7.4	0.10 (-1.10 to 1.40)	0.787
	Being involved in decisions about your care	U I	81 91	10.0 7.3	5.0, 15.0 4.8, 14.3	10.0 9.5	0.70 (-0.40 to 3.30)	0.226
	Organisation and coordination of care	U I	83 96	7.1 5.3	4.8, 12.0 2.2, 10.0	7.2 7.8	1.30 (0.00 to 3.50)	0.045*
Information provision	Information about what happened in Intensive Care	U I	68 83	10.2 3.6	5.0, 16.9 1.0, 10.0	11.9 9.0	4.90 (2.80 to 8.00)	<0.001*
	Knowing what to expect after you got home	U I	81 89	10.0 7.2	5.0, 15.0 2.6, 14.9	10.0 12.3	0.50 (-0.40 to 3.30)	0.308

*P values are with the Wilcoxon Mann-Whitney test; as this test is not a median test but a Rank Sum test, the point estimates are not the difference between the two medians. U, usual care group; I, intervention group.

1 VAS scores: excellent (0), very good (5), good (10), ok (15) and poor (20)

Physiotherapy: PEQ data indicated general satisfaction across both groups (intervention group median 5.0cm versus 6.1cm in the usual care group), but scores were better for intervention group patients (P=0.039). Intervention group participants gave more consistently satisfied responses (interquartile range (IQR): intervention group 6.8cm versus 9.1cm in the usual care group). In focus groups, physiotherapy emerged as one of the most important aspects of rehabilitation for all:

> *"…the biggest saviour in the whole thing has probably been the physio… physio is the main thing."* (usual care participant 1)

Experiences of physiotherapy varied widely in the usual care group, however, and participants frequently remarked upon resource constraints (lack of staffing) and its perceived impact upon recovery.

> *"…He (husband) wanted out of bed and he wanted to make a recovery, but if you've no(t) got the bodies (staff) there to help…"* (usual care participant's wife 2)

In contrast, intervention participants valued the frequency and consistency of physiotherapy provided by RAs.

> *"I had two (physio) sessions-a morning and an afternoon…"* (intervention participant 3)

Intervention participants highly valued the timing and delivery of physiotherapy according to their individual abilities, needs and preferences, facilitating greater involvement in the rehabilitation process.

> *"…if there was anything that I felt that I couldn't do, or it was too much, I was just to rest get my breath if need be, and just tell them (RAs) when I was ready…and every time they would say "What would you like to do today?" and in the end I could pick what I wanted"* (intervention participant 4)

Explanation, support and encouragement to perform exercises unsupervised was also highly valued.

> *"…If you're left with a sheet of paper to say, do these exercises on a daily basis, I am not likely to be motivated, but if somebody is…physically there, saying "Do these, let's do it together", it's very different"* (intervention participant 3)

Overall, the RA's provided continuity and consistency of care in accordance with intervention group participants' individual needs, abilities and preferences.

Nutritional care: Responses to the PEQ revealed greater satisfaction in the intervention group (median response 5.4cm versus 9.9cm in the usual care group (P=0.038)). Intervention participants were also more consistently satisfied (IQR 7.7cm versus 9.7cm). In the focus groups, nutritional care was universally perceived as important to recovery, but experiences varied widely among the usual care group.

> *"she (dietitian) checked what I was eating…She said you could do with a wee (little) bit more of such and such, so she arranged to have that wee bowl of fruit or something"* (usual care participant 5)

Several participants, however, felt that nursing staff were too busy to physically help them eat or deliver prescribed supplements.

> *"Nobody was interested. I was actually taking him (husband) in flasks of porridge to try and encourage him to eat…I was actually spoon feeding him…he was so weak, it was like there was nobody there to do this"* (usual care patient's wife 2)

Intervention participants, in contrast, valued the RAs' physical assistance with eating (including nutritional supplements) and support to achieve prescribed nutritional targets, using individualised feedback. Also valued was their advocacy in relaying dietary concerns to relevant ward-based clinicians.

> *"I managed to say, " (RA), I can't manage this (high protein supplement)". Can you speak to (the ward-based Dietitian) about it? And we did work out something and it worked, because I…asked (RA) to represent me, because with (ward-based Dietitian), I couldn't get through"* (intervention participant 6)

One intervention participant particularly valued the RA's support in accompanying her to the hospital canteen.

> *"……I was really grateful to (RA). She would spare the time to take me downstairs (to the hospital canteen) and bring me back up during lunch to just try and encourage me to eat"* (intervention participant 6)

Overall, the RAs appeared to more consistently operationalise dietetic recommendations, individualising care according to patients' needs and preferences.

Case management: Median PEQ responses to the questions "transfer from ICU to the ward", "ward staff's understanding of your time in intensive care" and "help, support and advice with being independent" were similar between the groups with values between 5-6cm ("very good"). However, for all these domains the IQR values were wider for the usual care group, notably for the "transfer from ICU to the ward" (13.2cm versus 5.2cm), suggesting wider variation in experience. Responses to "being involved in decisions about your care" were less positive (usual care 10.0cm versus 7.3cm in the intervention group) with wide variation in responses for both groups. The most direct question about case management, "organisation and coordination of care", indicated better experience among intervention patients (5.3cm versus 7.2cm; P=0.045).

In the focus groups, clear differences emerged between the groups. Both described a perceived deterioration in the quality of care following transfer to the general wards, which was attributed to staff shortages, high workload, and the dependency of other patients.

> *"You know the NHS is short staffed, you know that with their resources….but I mean you're giving them all this care in Intensive Care, and after that, it's like you're thrown to the dogs"* (usual care participant's wife 2)

Experiences across both groups were very variable, and seemed dependent on the discharge destination (specific ward). The experience of usual care participants appeared less consistent; several appeared to "slip through the net", for example, in terms of pre-discharge assessment and provision of aids and adaptations for community living.

> *"Was somebody supposed to come down and assess ....her needs? If she needed anything adapted…needed any kind of equipment or stuff like that? That never happened"* (usual care patient's son, 7)

Usual care participants frequently described the "push" for hospital discharge, a general lack of involvement in decision-making, and communication that was often ambiguous, contradictory and "last minute".

> *"… I think for… basically knocking on Death's door, I think the length of time between coming out of Intensive Care and going home is far, far too short. They are in a rush to…get people out"* (usual care patient's son, 7)

Usual care participants were also critical of a lack of post-discharge follow-up.

> *"I thought we might have been asked to come back for a check-up after so many weeks… I've never heard anything about anything like that"* (usual care patient 8)

Intervention participants, in contrast, valued the RA's assistance across multiple roles, including assistance with eating, washing and dressing, coordination of relevant assessments and referrals, and communication of discharge plans. Intervention group participants attributed this support to consistency and continuity of care.

> *"…having one person assigned to you, I thought that was marvellous, you know? There was always that one person that you knew you would see almost, probably every day…and if you had any worries you could talk to that one person and your worries got to the right source...the source that would do something about it"* (intervention patient 3)

Other examples included the coordination of post-discharge support

> *"…I felt I was very lucky because the day of my discharge, (the RA) had managed to gather all the things I needed, had managed to secure all the telephone numbers that I might need…I didn't have any qualms about going home…"* (intervention participant 6)

Information provision: Responses to *"information about what happened in intensive care"* showed the largest between-group differences, with intervention patients reporting the greatest and usual care patients the lowest satisfaction across all PEQ domains (10.2cm versus 3.6cm; P<0.001). In contrast, group responses were similar to *"knowing what to expect after you got home"*, with poorer median values than for many domains (intervention group 7.2cm versus 10.0cm in the usual care group) and wide variation in satisfaction for both groups. These data suggest the intervention improved information provision relating to the critical illness episode, but persisting unmet informational need following hospital discharge.

Focus group data strongly supported these findings. Amnesia, strange dreams and delusional memories were prevalent for all patients, and limited recall of the ICU admission and early post-discharge period was frequently described. Usual care participants frequently felt ill-informed about the circumstances and chronology of events surrounding their ICU admission and relied almost exclusively upon family members for information. This contributed to anxiety around potential recurrence, ill-explained critical illness-related morbidity, the protraction and limits of the recovery process, and the long-term implications of critical illness. Several usual care participants attributed greater anxiety to acquiring information from independent sources, such as the internet.

> *"I still don't know why I ended up in there (ICU). Well, I know why, but I don't know why I got what I got…I worry a lot more about my health than I ever did before, because I've got no idea what started it. I think that's the biggest problem. I went on the internet and looked up…the septic shock thing and what that entailed…and I wish to God that I hadn't … ….because I felt like I'd just been knocked back about six steps…."* (usual care participant 8)

When asked, many agreed that a clear outline of "what happened" would have been helpful.

> *"I think it would have helped me…definitely, just to fill in all the blanks. I would like to know what happened with this and what happened with that and…but I never got anything like that"* (usual care participant 9)

In marked contrast, intervention participants valued the structured, individualised information they received. The discussion with an ICU physician was generally valued for the opportunity to "fill in the blanks", especially reasons for ICU admission and the clinical course. Some focus group participants declined, however, describing their ICU experience as too "raw" in the early post-ICU period.

> *"I think them coming to see you helps to fill that void, you know, because being in Intensive Care, it's almost like you've lost a number of days without knowing what's happening…(the ICU Consultant) managed to explain the facts and…what you went through…why you ended up in Intensive Care. It really did help…me to put things in chronological order"* (intervention participant 10)

The individualised lay summary of the ICU admission was valued for its easily understandable explanation, although the terminology used and its occasional receipt by post (after hospital discharge) sometimes caused anxiety, highlighting the value of face-to-face clarification, reassurance and the opportunity to ask questions.

> *"…mine was good…but I got a wee (little) bit of a fright…although I knew I was on the breathing machine, I didn't know that it was…called a life support machine and see when I seen it written down..!* (intervention participant 11)

When participants accepted the offer of an ICU visit prior to hospital discharge, it was generally valued as an opportunity to make sense of the critical illness episode. However, timing was important, with several focus group participants reporting that their experiences were still "too raw". Finally, the therapeutic relationship with the RA appeared to facilitate the sensitive timing and presentation of information in accordance with patients' needs, emotional status and ability to retain information.

DISCUSSION

This mixed methods process evaluation provides valuable insights into patient/carer experiences in a complex intervention trial of post-ICU acute hospital rehabilitation. There was substantial concordance between cohort-level questionnaire data and the detailed accounts of focus group participants. Evidence of greater satisfaction with physiotherapy, nutritional care, information provision and coordination of care emerged from both data sources, suggesting that a case-management approach, delivered by a dedicated RA, improved patient experience of post-ICU acute hospital rehabilitation. Further, focus group data revealed the high value intervention participants placed on the *individualisation* of their care, according to their needs, abilities and preferences.

Despite evidence of greater satisfaction in the intervention group, we found no statistically or clinically significant between-group differences across functional, physical, psychological and HRQoL outcomes between hospital discharge and 12 months follow-up in the trial[17]. The discordance between these "biomedical" outcomes and greater reported patient satisfaction is striking. It is possible that biomedical outcomes are resistant to modification at this stage of recovery[38]**, or** that they fail to measure "what matters" to patients during acute hospital-based recovery[38 39]. The performance of outcome measures also depends on their appropriate selection, their psychometric properties in the population of interest and the timing of data collection in accordance with the delivery of the intervention.

We note with interest that only one previous study of a post-ICU critical rehabilitation intervention employed qualitative approaches in its evaluation[21]. The authors demonstrated that intervention participants not only experienced improvements in objective measures of fitness, but also an increased sense of motivation, wellbeing, achievement and social participation. Future such studies would be well advised to incorporate qualitative approaches and process evaluations into trial design, in order to explore patients' experiences of the intervention (including unanticipated benefits and drawbacks) that may not be accessible by existing questionnaires.

Qualitative studies among other hospitalised patient groups have shown the high value that patients place on the therapeutic or collaborative relationship with rehabilitation staff, flexibility around the timing, content and delivery of rehabilitation, and its individualisation according to needs and preferences[40-42]. These issues underpinned the development of the RECOVER intervention, and the PEQ was specifically developed to capture them. Our data provide strong evidence for important effects on these person-centred outcomes. Our evaluation demonstrates the added value that qualitative research can add in randomised controlled trials; particularly in the design and conduct of a trial, improving its internal and external validity, facilitating replicability, interpretation and generalisability of findings[43] and here, in exploring the value of individual components of a complex intervention.

A key finding was the value participants placed on information. The “need to know” has long been reported in the critical care literature[44], underpinning various strategies such as ICU discharge summaries[45], patient diaries[46-48], follow-up clinics[49 50], and return visits to the ICU[51]. Our comprehensive, individualised approach was documentary (rehabilitation manual; individualised lay summary), didactic (discussion with ICU physician and the RAs), and experiential (offer of a return visit to the ICU). Both qualitative and quantitative data provided strong evidence for the benefit of information, and focus group data uncovered preferences for its timing, content (including terminology) and delivery. These findings support the need for individualised information in routine post-ICU care.

A particular strength of our process evaluation was consideration of the clinical context in which the intervention took place, and participants’ response to and interaction with the intervention. These are recommended when evaluating how or why complex healthcare interventions may (or may not) work[20]. Our data provide empirical evidence that enhanced access to physiotherapy, nutritional care, and information are important to patients during recovery, but highlight a range of preferences and the need for individualised content, delivery and timing. Case management by a dedicated RA was a key “active ingredient” that facilitated these preferences and seemed to increase engagement in the rehabilitation process, resulting in greater overall perceived benefit. A potential limitation of our findings is the marked differences between the focus group's patient participants in terms of patient age, duration of mechanical ventilation and ICU length of stay.

Our findings are relevant to future trial design in this patient population. Specifically, trial interventions that use *individual* adaptation versus standardised or fixed interventions require different approaches to both process and effectiveness evaluation[52 53]. We standardised the *process* and *function* of the intervention (i.e. individualisation and patient engagement in the rehabilitation process, respectively) but not the *content*, capturing actual differences in treatments received in the process evaluation. This approach is particularly recommended when the "real world" or clinical context is complex[20]. With this perspective, the internal validity of a trial should be defined functionally as well as compositionally[33 52]. Our data indicate that concordance between biomedical and person-centred outcomes should not be assumed[37], highlighting the importance of specific standardised measures (few currently exist) and the use of qualitative approaches to capture the latter.

Importantly, cost-effectiveness analysis of the RECOVER trial found no incremental cost-effectiveness over the 12 months post-randomisation, and no difference in Quality Adjusted Life Years between the groups[17]. It is increasingly recognised that HRQoL trajectories are difficult to modify following critical illness, in part because pre-existing comorbidity dominates reported HRQoL during recovery[54-57]. Quality of care, patient satisfaction, and "person-centeredness" are excluded from cost-effectiveness analysis. The use of service models based on multi-skilled RAs providing individualised case management is potentially cost-neutral or even cost-saving compared to existing models that require multiple specialists from different disciplines. Our data provide strong evidence that this approach delivers higher quality care from patients' and carers' perspectives and may well justify service re-design. Our model of care has been adopted into routine clinical practice at the main study hospital.

In conclusion, we have shown that physiotherapy, nutritional care, and information are highly valued by patients during post-ICU acute hospital rehabilitation. A rehabilitation strategy coordinated by a dedicated multi-skilled RA improved patients' satisfaction with and perceived quality of care, cutting across traditional disciplinary boundaries, ward-level resource constraints and circumventing communication failures. The focus on individualised, coordinated care according to patient ability and preference was highly valued.

Contributors: The following is taken from the submitted manuscript. The initials refer to the listed co-authors: TW, LS, PR, JM and GH designed the trial and completed pilot and feasibility work. Specialist clinical input to trial conduct was provided by TW and DG (critical care perspective), LS (physiotherapy/rehabilitation), PR and JR (nursing) and JM (dietetics). Statistical advice was provided by Professor Gordon D Murray and Professor Stephanie C Lewis (both at the University of Edinburgh). The Patient Experience Questionnaire was developed by PR, with expert methodological advice provided by Professor Andrew Thompson at the University of Edinburgh. The qualitative focus group interviews were designed by PR and GH and conducted and analysed by PR. All co-authors contributed to the mixed methods integration and analysis.

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Additional unpublished data may be requested by contacting the lead author.

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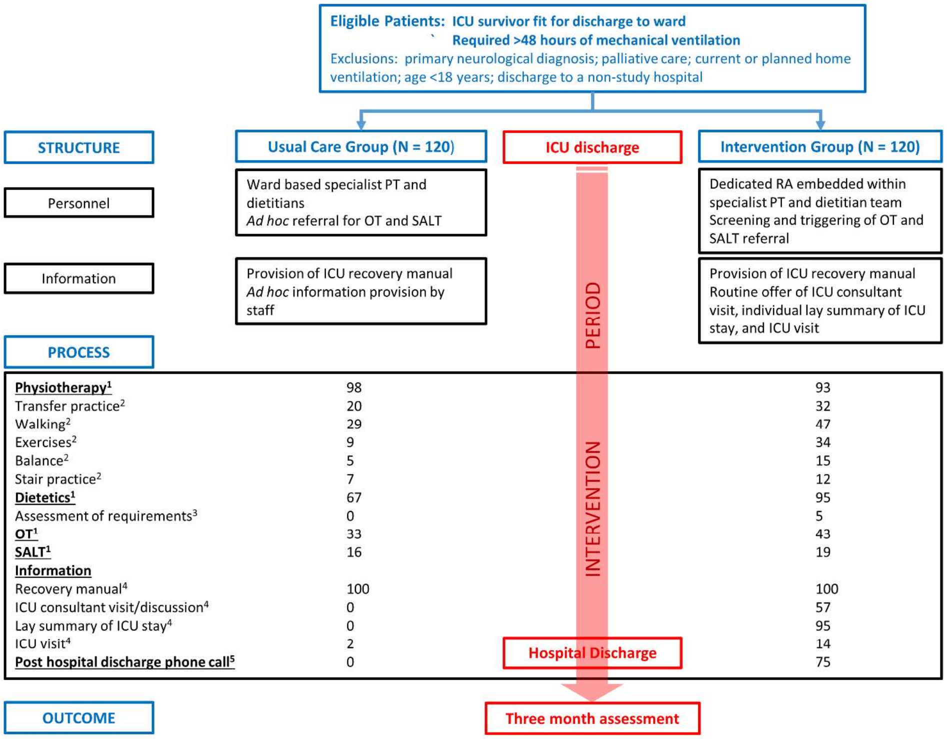

	Usual Care Group	Intervention Group
Physiotherapy[1]	98	93
Transfer practice[2]	20	32
Walking[2]	29	47
Exercises[2]	9	34
Balance[2]	5	15
Stair practice[2]	7	12
Dietetics[1]	67	95
Assessment of requirements[3]	0	5
OT[1]	33	43
SALT[1]	16	19
Information		
Recovery manual[4]	100	100
ICU consultant visit/discussion[4]	0	57
Lay summary of ICU stay[4]	0	95
ICU visit[4]	2	14
Post hospital discharge phone call[5]	0	75

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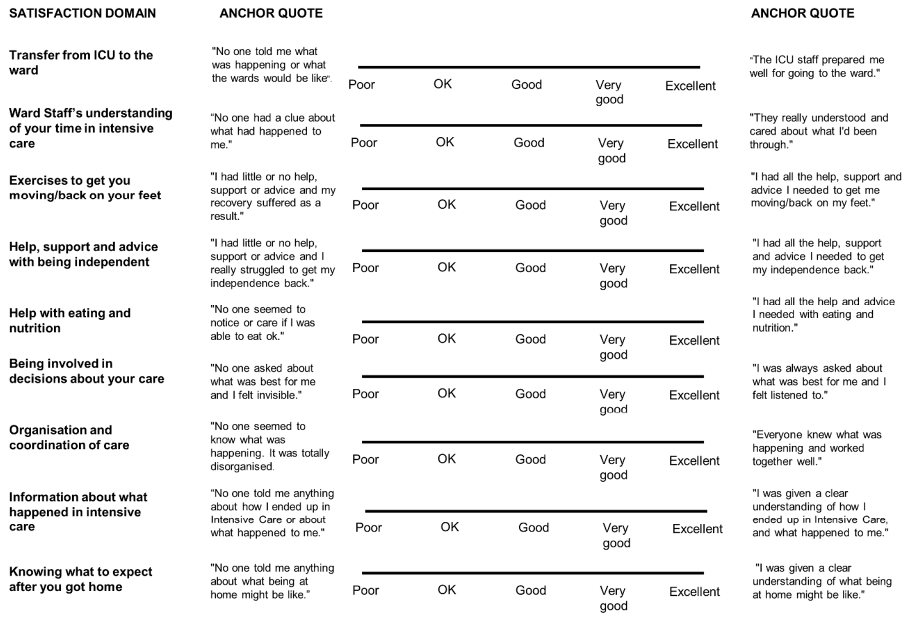

SATISFACTION DOMAIN	ANCHOR QUOTE						ANCHOR QUOTE
Transfer from ICU to the ward	"No one told me what was happening or what the wards would be like".	Poor	OK	Good	Very good	Excellent	"The ICU staff prepared me well for going to the ward."
Ward Staff's understanding of your time in intensive care	"No one had a clue about what had happened to me."	Poor	OK	Good	Very good	Excellent	"They really understood and cared about what I'd been through."
Exercises to get you moving/back on your feet	"I had little or no help, support or advice and my recovery suffered as a result."	Poor	OK	Good	Very good	Excellent	"I had all the help, support and advice I needed to get me moving/back on my feet."
Help, support and advice with being independent	"I had little or no help, support or advice and I really struggled to get my independence back."	Poor	OK	Good	Very good	Excellent	"I had all the help, support and advice I needed to get my independence back."
Help with eating and nutrition	"No one seemed to notice or care if I was able to eat ok."	Poor	OK	Good	Very good	Excellent	"I had all the help and advice I needed with eating and nutrition."
Being involved in decisions about your care	"No one asked about what was best for me and I felt invisible."	Poor	OK	Good	Very good	Excellent	"I was always asked about what was best for me and I felt listened to."
Organisation and coordination of care	"No one seemed to know what was happening. It was totally disorganised.	Poor	OK	Good	Very good	Excellent	"Everyone knew what was happening and worked together well."
Information about what happened in intensive care	"No one told me anything about how I ended up in Intensive Care or about what happened to me."	Poor	OK	Good	Very good	Excellent	"I was given a clear understanding of how I ended up in Intensive Care, and what happened to me."
Knowing what to expect after you got home	"No one told me anything about what being at home might be like."	Poor	OK	Good	Very good	Excellent	"I was given a clear understanding of what being at home might be like."

254x190mm (300 x 300 DPI)

Patient and family focus group interview guide: Usual Care Group

	Examples of general questions	Examples of prompts and prompts
Physiotherapy	I'd like to ask now about the kind of help people got to help you get back on your feet and ready for hospital discharge…	• How important was physiotherapy to your (or your relative's) overall recovery? • Did you have any hopes or expectations on the physiotherapy you (or your relative) might receive on the wards? • How would you describe the physiotherapy you (or your relative) received? • Did you feel that you/they had enough physiotherapy? • How effective was physiotherapy in terms of progressing your/their recovery? • How confident did you feel about progressing your/their recovery after you/they got home?
Nutritional support	People often lose a lot of weight and muscle whilst they're very ill in ICU…	• How important was eating/nutrition to you (or your relative's) overall recovery? • What kind of help did you/they get with that? • Did you get the kind of help you felt you/they needed with eating and nutrition? • How confident did you feel about eating/nutritional issues after you/they got home?
Case management	I'd like to ask more generally about your care on the wards…	• To what extent do you think that the staff understood what you (or your relative) had been through in Intensive Care? • Did you feel that you/they got as much help as you/they needed with things like washing, getting dressed, etc? • In what ways did that affect your/their care and your/their recovery? • How involved were you in decisions about your getting home? • Did you know what kinds of arrangements were being made on your/their behalf? • Did you feel as involved as you wanted to be in those kinds of arrangements? • If you/they were told that you/they would receive support or equipment after you got home, did that actually happen? • If not, what were you able to do about that? • What would have been helpful for you?
Information provision	How much did you know or understand about what brought you into Intensive Care and what happened while you were there?	• It's very common not to remember much…or to have very "jumbled" picture of what happened. Your family may very well have filled in some of the blanks for you… • How important was that information to you when you were on the ward? • Would it have been useful for someone (perhaps a doctor or a nurse) go through exactly what happened, and to be able to ask questions? • Would some written information have been useful? • When would it be best to receive that kind of information (if you wanted it)? • Do you think visiting the ICU before you went home might have been useful?

Patient and family focus group interview guide: Intervention Group

	Examples of general questions	Examples of prompts and prompts
Physiotherapy	I'd like to ask now about the help you/your relative got to help you/them get back on your/their feet. You/they were offered extra help from (RAs) as part of the study…	• How important was physiotherapy to your (or your relative's) overall recovery? • Did you have any hopes or expectations on the physiotherapy you (or your relative) might receive on the wards? • How would you describe the physiotherapy you/they received on the wards? • Did you/they feel that you/they had enough physiotherapy? • Tell me more about the extra help you received from the Rehabilitation Assistants (names)? • What kinds of things were most helpful to you? • Was there anything that could have been done differently or better? • How confident did you feel about progressing your/their recovery after you/they got home?
Nutritional care	People often lose a lot of weight and muscle whilst they're very ill in ICU…	• How important was eating/nutrition to your (or your relative's) overall recovery? • What kind of help did you get with that from the ward Dietitian? • How helpful was that in progressing your/their recovery? • Tell me more about what the Rehabilitation Assistants (names) did to help you with eating and nutrition? • Was there anything that could have been done differently or better? • How confident did you feel about eating/ nutritional issues after you/they got home?
Case management	I'd like to ask more generally about your care on the wards…	• To what extent do you think the ward staff understood what you (or your relative) had been through in Intensive Care? • Did you feel that you/they got as much help as you/they needed with things like washing, getting dressed, etc. • In what ways did that affect your/their care and recovery? • How involved were you in decisions about your getting home? • Did you know what kinds of arrangements were being made on your behalf? • Did you feel as involved as you wanted to be in those kinds of arrangements? • Tell me about the sorts of things the Rehabilitation Assistants (names) did to help you with these issues? • If you were told that you would receive support or equipment after you got home, did that actually happen? • If not, what were you able to do about it? • What would have been helpful to you?
Information	How much did you know or understand about what brought you into Intensive Care and what happened while you were there?	• You will have been offered a visit from one of the **ICU Consultants** while you were you on the wards, so that they could explain what happened to you… • How useful was that? Was the timing ok? Were you able to ask the questions you wanted to? • You will also have received **a letter** describing what happened to you in easily understandable language • How useful was that? In what way? Some of you may have received the letter after you got home…how was that for you

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:
Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

YOU MUST PROVIDE A RESPONSE FOR ALL ITEMS. ENTER N/A IF NOT APPLICABLE

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	Lead author, page 6
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	PhD
3. Occupation	What was their occupation at the time of the study?	Researcher, page 6
4. Gender	Was the researcher male or female?	Not explicitly reported
5. Experience and training	What experience or training did the researcher have?	PhD, page 6
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	Yes, subset of RECOVER participants, page 6
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	N/A
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Not reported
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	MRC guidance on evaluating complex interventions, page 4
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Convenience.

11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Face to face (subset of RECOVER participants)
12. Sample size	How many participants were in the study?	182 completed questionnaire. 22 participated in focus groups. Page 1
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Not reported
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Not reported
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	No
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Table, page 6
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Electronic supplementary material
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	No
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Audio, page 6
20. Field notes	Were field notes made during and/or after the inter view or focus group?	Not reported
21. Duration	What was the duration of the inter views or focus group?	Not reported
22. Data saturation	Was data saturation discussed?	Not reported
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	2, pages 6 and 7
25. Description of the coding tree	Did authors provide a description of the coding tree?	Based on components of the intervention: pages 6 and 7
26. Derivation of themes	Were themes identified in advance or derived from the data?	Based on components of the intervention: pages 6 and 7
27. Software	What software, if applicable, was used to manage the data?	NVivo, page 6
28. Participant checking	Did participants provide feedback on the findings?	No
Reporting		

29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Yes, page 10
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	No

Once you have completed this checklist, please save a copy and upload it as part of your submission. When requested to do so as part of the upload process, please select the file type: *Checklist*. You will NOT be able to proceed with submission unless the checklist has been uploaded. Please DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.