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Citation for published version:

Salisbury, LG, Merriweather, JL & Walsh, TS 2010, 'The Development and Feasibility of a Ward-Based Physiotherapy and Nutritional Rehabilitation Package for People Experiencing Critical Illness', *Clinical Rehabilitation*, vol. 24, no. 6, pp. 489-500. https://doi.org/10.1177/0269215509360639

#### Digital Object Identifier (DOI):

10.1177/0269215509360639

#### Link:

Link to publication record in Edinburgh Research Explorer

#### **Document Version:**

Peer reviewed version

#### Published In:

Clinical Rehabilitation

**Publisher Rights Statement:** 

Salisbury, L. G., Merriweather, J. L., & Walsh, T. S. (2010). The Development and Feasibility of a Ward-Based Physiotherapy and Nutritional Rehabilitation Package for People Experiencing Critical Illness. Clinical Rehabilitation, 24(6), 489-500doi: 10.1177/0269215509360639

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# The development and feasibility of a ward-based physiotherapy and nutritional rehabilitation package for people experiencing critical illness.

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#### <u>Abstract</u>

**Objective**: To investigate ward-based rehabilitation after critical illness and undertake a pilot study exploring the feasibility of delivering enhanced physiotherapy and nutritional rehabilitation.

**Design:** Service evaluation (Part A) and pilot feasibility randomised controlled trial (Part B)

**Setting:** Hospital in-patient wards following discharge from intensive care.

Participants: Part A: 24 people with an intensive care stay of four days or more.

Part B: 16 participants randomised into a control (n=8) or intervention (n=8) group.

Interventions: Part A defined the current 'standard' physiotherapy and nutritional interventions. In part B the control group received this 'standard' service while the intervention group received this 'standard' service plus enhanced rehabilitation.

Main Measures: Part A collected process outcomes of current interventions and outcomes that included calorie and protein intake and the Rivermead Mobility Index. In part B process outcomes determined differences between groups.

Outcomes included those undertaken in part A plus an incremental shuttle test, handgrip dynamometry and visual analogue scales.

**Results:** Part A found low levels of ward-based physiotherapy (walking and transfer practice once per week) and dietetic input (0.8 visits per week). Part B found an increased frequency of both physiotherapy (p=0.002) and dietetic (p=0.001) visits in the intervention group. Physical and nutritional outcomes were suitable for use after critical illness, but no statistically significant differences

were found between groups. Power calculations indicated 100 participants per group would be required for a definitive study.

**Conclusions:** This feasibility pilot work has informed the design of a larger study to evaluate enhanced rehabilitation following critical illness.

#### Introduction

Evidence of significant physical and psychological morbidity after critical illness has been growing over the last decade. Research suggests that these physical and psychological sequelae are associated with reduced health related quality of life and functional ability both in the short and long term.<sup>1-8</sup>

Despite growing recognition of these problems there is currently little formal rehabilitation available for patients after discharge from intensive care. One reason for this is the complex uncoordinated patient journey experienced by most patients. The intensive care unit often exists as a "microsystem" within the hospital with separate staff, budgets and protocols. Following discharge patients are usually discharged to the ongoing medical care of their parent specialities and become widely dispersed across the hospital. The parent specialities are often ill-equipped to manage the complex range of physical and psychological issues present at both medical and nursing/allied health professional level. The patients often "compete" with less disabled or elective cases for limited resource. These problems persist to hospital discharge, following which community support is limited. In this respect patients discharged from general intensive care units may be disadvantaged compared to those following cardiac surgery, stroke, or head injury for whom clear rehabilitation pathways exist.

A report<sup>9</sup> by the Department of Health (United Kingdom) in 2005 'Quality Critical Care' recognised the need to address these issues and suggested that,

"hospitals should develop patient centred rehabilitation services to optimise the recovery of patients discharged from critical care units". A recent NICE guideline 10 supports this standard, but acknowledges the lack of high quality evidence in this area.

Limited research has been undertaken to define or evaluate appropriate rehabilitation after discharge from intensive care for this patient group. Some benefits have been shown from ward visits with clinic follow-up and the provision of a manual or telephone follow up. Ongoing work includes a UK evaluation of follow-up clinics and an Australian evaluation of a home based exercise programme. However, the majority of this work is targeted after discharge from hospital. Little consideration has been given to the evaluation of rehabilitation, in particular physical and nutritional components, delivered to patients while on the hospital wards. This may be of particular importance as high levels of disability have been reported immediately after discharge from intensive care and within the first 3 months.

This two-stage study aimed to undertake the development and pilot feasibility work for an enhanced ward-based physiotherapy and nutritional rehabilitation intervention that would be delivered to patients on the ward, using a generic rehabilitation assistant, following discharge from intensive care. The first part of the study (part A) was a service evaluation to explore current ward physiotherapy and nutritional service provision to patients after intensive care. The second part

(part B) was a feasibility pilot randomised controlled study of an enhanced intervention package delivered by a generic rehabilitation assistant. The following research questions were addressed:

#### Part A

1. What ward-based physiotherapy and nutritional services do patients currently receive after discharge from intensive care?

#### Part B

- 2. Can enhanced ward-based physiotherapy and nutritional rehabilitation, using a generic rehabilitation assistant, be delivered to patients following discharge from intensive care?
- 3. What are the optimal trial methods? Can the interventions be defined and delivered to allow implementation in future trials? What patient-centred outcome measures are feasible for use in this population?

#### Methods

The methods for parts A and B are reported separately.

#### Part A

A service evaluation was undertaken. Routine physical and nutritional clinical data were collected during a 3 month period (June to August 2006) from patients after discharge from a general intensive care unit. Data collection was carried out by the authors and was not blinded. The number and content of ward-based physiotherapy and dietetic visits were recorded. A number of routine clinical measures were collected that included the Rivermead Mobility Index<sup>15</sup>, a scale of fifteen yes/no questions assessing mobility from 'Do you turn over from your back to your side without help' to 'Could you run 10 metres in 4 seconds without limping?'. The timed up and go<sup>16</sup>, a timed test of the ability to rise from a chair, walk three metres, turn around, walk back and sit back down. The 10-metre walk, a simple, easy to use, timed measure of walking ability.<sup>17</sup> Participants were asked to walk a 10-metre distance at their own pace using a walking aid if required. Calorie and protein intake was measured as a percentage of estimated requirements using Schofield<sup>18</sup> and Elia<sup>19</sup> equations respectively.

Patients surviving four days or more in ICU were included if they were discharged to a ward in the hospital. Patients were excluded if they were suicide/overdose attempt, had an underlying illness that had an established inpatient rehabilitation service e.g. head injury, transplant, cardiac, stroke or

referral to palliative care. Data relating to discharge destination was collected. Ethical approval was not required as this was a service evaluation.

#### Part B

#### Study Design

A feasibility pilot randomised controlled trial was undertaken (Figure 1).

Participants were approached for recruitment when discharge planning from the intensive care unit had commenced. Participants were randomised into either the intervention or control group after baseline outcome measures had been collected. A computer generated randomisation list was held by an independent researcher and participants were allocated in the consecutive order following face-to-face or telephone contact with the independent researcher.

#### Insert Figure 1

#### Ethical Approval

Ethical approval was received from Scotland A Research Ethics Committee and allowed the inclusion of participants unable to give informed consent. In these cases consent was sought from the patients nearest relative or welfare guardian. If, and when, the participant became competent to give consent their informed consent was obtained. Consent was obtained by the authors (LS and JM) and in four cases proxy consent was obtained.

#### Patients

Individuals were eligible for inclusion if they had received mechanical ventilation for 4 days or more. They were excluded from the study if their underlying illness already had an established rehabilitation service e.g. stroke, head injury or liver transplant, if they had been referred to palliative care, were a intravenous drug abuser, were participating in other randomised controlled trials or were pregnant.

#### Interventions

All participants continued to receive the 'standard' ward-based physiotherapy and dietetic service as provided at the hospital.

The *Control Group* received the 'standard' physiotherapy and dietetic service only.

The *Intervention Group* received the 'standard' physiotherapy and dietetic service and an 'enhanced' physiotherapy and dietetic rehabilitation package. The content of the 'enhanced' rehabilitation was decided after discussion between the research physiotherapist and dietitian and the appropriate ward-based staff. This enhanced treatment plan was delivered by a generic rehabilitation assistant. The enhanced physical rehabilitation included additional interventions such as supervised passive, active and strengthening exercises, facilitation of additional transfers and mobility practice, balance exercises and advice. The enhanced nutritional rehabilitation included assistance at mealtimes, monitoring of supplement delivery and consumption, and frequent food charts to ensure an adequate oral intake. Patient-centred goal setting was included in the approach. Discipline specific training was provided to ensure the generic rehabilitation assistant was competent to deliver the interventions. Additional detail relating to

the role of the generic rehabilitation assistant, training requirements and their contribution to the enhanced rehabilitation has been published elsewhere<sup>20</sup>. All standard and enhanced interventions were recorded by the generic rehabilitation assistant in detail to allow the interventions to be clearly defined and compared.

#### Measurements

Baseline: Age, gender, illness severity (APACHE II score<sup>21</sup>), ventilation days and ICU length of stay were recorded at study entry.

Outcomes: Patients were assessed 3 months after discharge from intensive care using standard procedures by a research nurse blinded to group allocation. Physical outcome measures comprised the Rivermead Mobility Index<sup>15</sup>, Timed Up and Go<sup>16</sup>, ten-metre walk test<sup>17</sup> and the incremental shuttle walk test<sup>22</sup>. The incremental shuttle walk test is a progressive incremental test over a 10 metre course that stresses the participant gradually until a symptom limited maximum is reached, at which point the test stops. Nutritional outcome measures comprised handgrip dynamometry, as an indication of protein malnutrition<sup>23</sup>, weight, percentage calorie and protein intake compared to estimated requirements (using Schofield<sup>18</sup> and Elia<sup>19</sup> equations respectively) and mid arm muscle circumference as an indicator of muscle mass.<sup>24</sup> In addition, visual analogue scales (VAS) of breathlessness, fatigue, joint stiffness, pain and appetite were collected<sup>25</sup>. The VAS were rated on a scale of zero to 10 where, for example, zero represented no breathlessness and 10 the worst breathlessness imaginable. The same scoring system was used for all VAS.

#### Sample size

This was a pilot study so no formal sample size estimation was done. We aimed to recruit all eligible patients for a six month period, and estimated from local data that 20 patients would be recruited during this period.

#### **Analysis**

In both parts A and B descriptive statistics were used to describe the frequency of the variables recorded over time. To adjust for the variable length of stay between patients, we calculated an average value per week for the numbers of visits and treatments for each patient. For the population we used median (IQR) and ranges to describe the distribution of frequencies in the cohort for part A, and to compare the groups in part B. For part B we undertook a Mann-Whitney U test to compare the frequency of visits and key interventions.

#### Results

Results for part A and part B are presented separately.

#### PART A (Service Evaluation)

In total 24 patients were included in the service evaluation. There were 12 male and 12 female patients and the median (IQR) age was 62.5 (54, 69) years. They had a median (IQR) APACHE II score of 19.5 (15.3, 23.8). Participants stayed in intensive care for a median (IQR) of 18 (7, 36) days and were ventilated for a median (IQR) of 9 (3, 31) days. The median (IQR) length of ward stay was 26 (13, 42) days.

On average the median (IQR) frequency of physiotherapy received by patients was 3.2 (2.4, 4.6) times per week. Provision of weekend physiotherapy only occurred for emergency respiratory problems. Table 1 illustrates the frequency of mobility treatments delivered to patients during their ward stay. On average patients only practiced walking and transfers with the physiotherapists once per week during their ward stay. In addition, the supervised practice of exercises was negligible (0.1 times per week during their ward stay). There was no record of any ongoing mobility or nutritional goal setting or multidisciplinary meetings.

Insert Table 1

Patients typically received a median (IQR) of 0.8 (0.6, 2.2) dietetic visits per week. Although dietetic recommendations were made, e.g. consumption of supplements, additional snacks, recording of oral intake there was no record of any type of follow-up to ensure the recommendations were being followed. Problems were frequently encountered related to untimely removal of enteral feeding tubes.

At admission to the ward on average patients were achieving a median (IQR) of 95% (53-105) and 85% (52-99) intake, of calories and protein respectively, compared to estimated nutritional requirements. The results indicate that the majority of patients were not meeting the energy and protein requirements necessary to maintain weight on admission to the general wards, despite the need to replete body mass in most cases. At discharge from hospital patients were managing to consume on average a median (IQR) of 87% (60-105) and 83% (62-99) of calorie and protein requirements respectively, indicating they were not meeting the necessary requirements to maintain weight or replete body mass. Food record charts were not available for all patients due to noncompletion by ward-based staff and are based on 23 patients at admission to the ward and 13 patients at discharge from hospital.

A high proportion of patients were discharged directly home (62.5%; n=15) and in only one case was community follow-up arranged. The physical and nutritional status of those discharged home was poor. On average patients scored 7 out of

15 on the Rivermead Mobility Index and were slower on timed tests (13 patients able to mobilise independently) in comparison to a normal age matched population.<sup>26</sup> For the timed up and go the patients were undertaking the test in 13.5 (11.8, 21.7) seconds in comparison to eight seconds in a normal population.<sup>26</sup> The ten-metre walk test (metres/sec) was undertaken at an average of 1.2 (0.9, 2.1) metres per second in comparison to 1.6 metres per second in males and 1.4 metres per second in females of 60-69 years of age.<sup>26</sup>

#### Summary

The service evaluation highlighted that physiotherapy and nutritional rehabilitation during the ward phase of recovery after intensive care was limited. Patients were frequently discharged directly home despite poor levels of mobility and nutritional status. The service evaluation highlighted a need for improved services during this phase of recovery and led to the development of the feasibility study to explore whether enhanced rehabilitation could be delivered using a generic rehabilitation assistant.

# Part B (Feasibility Study)

Over a six month recruitment period (27<sup>th</sup> February to 28<sup>th</sup> August 2007) 32 patients were eligible for inclusion. Of these seven were already enrolled in other research trials. Of the 25 remaining patients three were discharged from hospital within a few days before being approached, one patient refused consent, and five were eligible but not approached for logistic reasons, resulting in the recruitment

of 16 participants. These data indicated around five eligible patients per month and ≥50% (16 of 32) recruitment rates were feasible. Consent rates were >90% of approached patients (16 of 17). Eight participants were randomly allocated into each group. Table 2 summarises the demographic details of the two groups.

#### Insert Table 2

Both groups had a larger proportion of male participants. The intervention group were slightly older, had a higher APACHE II score, received more days of ventilation and had longer intensive care unit (ICU) and ward lengths of stay than the control group.

#### Delivery of enhanced physiotherapy and dietetic rehabilitation

The control group received a median (IQR) of 2.6 (1.8, 4.2) physiotherapy and 1.2 (0.6, 2.1) dietetic visits per week. The intervention group received a median (IQR) of 8.2 (7.1, 10.6) physiotherapy visits and 4.9 (3.4, 8.4) dietetic visits per week. A Mann Whitney test between the groups found that the intervention group received statistically significantly more physiotherapy (p = 0.002) and dietetic (p = 0.001) visits than the control group.

#### **Defining the interventions**

Table 3 summarises the physiotherapy treatment interventions that were delivered in each group. The frequency of mobility treatments was significantly

higher in the intervention group (p= 0.002), although respiratory treatments were similar. A range of mobility treatments were administered, but the main differences between the groups were exercises, practicing walking and transfers and advice.

Table 3 indicates that patients in the intervention group received a higher frequency of dietetic visits in comparison to the controls. This was associated with a trend towards greater intake of calories and protein in the intervention group across the in-patient stay. Calorie and protein intakes did range widely within the groups with calorie targets more often achieved than protein targets in both groups.

Insert Table 3

#### **Outcome Measures**

Three month follow up was completed in 11 patients (69%). The 5 missed patients included 3 deaths (2 interventions, 1 control), 1 loss to follow up and 1 non-attendance due to acute confusion. Two participants were only able to complete selected outcome measures at three month follow-up due to limited cognitive ability and lack of space to undertake physical tests (home visit).

The battery of outcome measures undertaken is reported in table 4. They indicate that they are suitable for use in this population although some physical

outcomes were not undertaken due to difficulties with physical ability and the environment. No statistically significant differences were found between groups for any of the outcome measures.

#### Insert table 4

Anthropometric measurements were only completed in three control and four intervention participants, other participants were physically unable to stand to facilitate data collection. At baseline none of the participants in the control group fell under the fifth centile for mid arm muscle circumference. All of the four participants in intervention group fell under the 5<sup>th</sup> centile which is indicative of protein energy malnutrition. At three month follow-up three of the intervention group had shown improvement and were no longer under the fifth centile.

#### **Discussion**

We have shown that patients discharged from intensive care in our hospital receive low levels of physiotherapy, both in terms of rates of treatment and the use of specific mobility treatments. Similarly, the frequency of dietetic assessment was low and systems to monitor implementation of recommendations were lacking. Rates of achieving nutritional goals to maintain or replete body mass were low, especially for protein intake. This was associated with poor mobility and nutritional outcomes. Our pilot feasibility study showed that reorganising care delivery based on a generic rehabilitation assistant supervised

by physiotherapy and dietetic staff could significantly increase the number of physiotherapy and dietetic visits received by each patient during hospital stay. This was associated with statistically significant increased rates of mobility treatments and trends towards improvements in calorie and protein consumption. Our study indicates that it is feasible to test a complex rehabilitation intervention using this approach in this population if an adequate sample size is used to detect meaningful differences in patient-centred outcomes.

The evaluation of complex healthcare interventions is difficult and potentially problematic. These issues have been addressed by the development of the MRC framework for the evaluation of complex interventions<sup>27</sup>, which has recently been revised. This emphasises the need to undertake relevant developmental work to understand the hypotheses underpinning the research questions, define the intervention and the optimum method of measuring it, and determine relevant clinical outcomes. Our study has successfully addressed several of these issues:

Underpinning Hypotheses: Studies in various groups of patients who experienced an episode of critical illness have shown that physical outcomes are poor in both short and longer term follow up. 1,2,4,5,6,8 Most have relied on self-reported health related quality of life tools rather than physical measures or formal assessment of disability. Our data confirm the high level of physical disability over 3 months following intensive care discharge and support the need to explore enhanced rehabilitation strategies. 1,4,8,10 The service evaluation and

control group data confirm the low levels of physiotherapy and dietetic input associated with existing service provision in hospital, and even lower support after hospital discharge. Although this could be specific to local services it is likely that similar levels of support are delivered in many health care facilities. Our data support the conjecture that testing an alternative strategy of delivering rehabilitation is worthwhile, and will expose patients to a different experience.

Defining the intervention: Despite observational studies indicating severe disability in physical and psychological domains following critical illness few interventions have been developed and tested in research. The only randomised ward-based trial in hospital 11 tested the impact of a self-help manual that was delivered in hospital and supported with phone call and clinic visits following discharge. Patients were recruited after one week on the ward but it is unclear when patients used the manual or what compliance rates were. Importantly, the intervention did not include additional support from physiotherapy or dietetic specialists. Despite this, the intervention was associated with a statistically significant improvement in the physical component of the SF-36 HRQoL score at three months. These findings support the rationale for focusing on physical rehabilitation and supplementing physiotherapy and nutritional treatment.

Our pilot data confirm the feasibility of using a generic rehabilitation assistant, and show that this can safely and effectively increase the number of treatments, especially mobility treatments. We observed clinically relevant differences in

patient exposure to physiotherapy between the groups, further indicating this is a valid intervention model. The inclusion of patient-centred goal setting within the approach was highlighted in this pilot as possible and a way to further engage patients in the process of rehabilitation.

The impact of enhanced dietetic visits was more difficult to measure. Our data show that achieving nutritional targets consistently is difficult in this patient group despite increasing frequency of visits. This probably has multiple explanations, including physical barriers to nutrition, organisational issues, and patient issues such as appetite and taste alterations, and psychological factors such as delirium and depression. Dietitians often make nutritional recommendations but delivery is reliant on other health professionals and hospital staff. Factors affecting the achievement of calorie and protein intake need to be identified and strategies developed to allow delivery by a generic rehabilitation assistant. The pilot feasibility study did highlight some areas that could be explored further, such as monitoring supplement consumption and assistance at mealtimes. The use of food diaries linked to a systematic approach to overcoming inadequate intake might further improve achievement of targets. Further research is required to define the relative prevalence of different barriers to adequate nutritional intake and the optimum methods of overcoming them.

A common criticism of complex healthcare intervention studies is that lack of data describing what actually happened makes interpretation of positive or negative

results in trials difficult, and limits the external validity of findings and translation into routine care. We have shown that detailed relevant process information can be collected in patients after discharge from intensive care in both control and intervention groups, which could be used to describe treatments delivered in a larger study.

Relevant clinical outcomes: In order to test the impact of an enhanced rehabilitation intervention it is essential to measure clinically relevant patient-centred outcomes with high rates of follow up in order to minimise bias. In our pilot study we chose a range of outcomes and attempted to measure them at 3 months following randomisation. We achieved follow up for 85% (11 of 13) of surviving patients, which would allow evaluation of the intervention in a larger trial. We also showed that concealment of the follow up nurse from group allocation was possible, which would be an important consideration in a larger trial, because blinding of clinicians delivering the intervention is not possible.

The range of outcomes allowed the benefits and limitations of each to be considered in relation to their possible inclusion in a larger trial. The visual analogue scales were completed by all participants, with the exception of one due to learning difficulties, indicating good rates of follow-up that could be achieved both face to face and by post. The timed up and go test<sup>16</sup>, ten metre walk test<sup>17</sup>, incremental shuttle test<sup>22</sup> and handgrip dynamometry<sup>23</sup> were not collected in one or two cases each due to the limited physical ability of the

participants. These physical tests provide sensitive data but were unable to capture participants with very poor functional ability, and require the physical presence of the patient. In contrast, the Rivermead Mobility Index<sup>15</sup> was able to capture functional ability ranging from confinement in bed to running and was completed by all participants at follow-up. However, the validity of this measure in this patient group is uncertain. Self-completion of food record charts was not always achieved, but provided useful information on food intake for a sub-group of patients.

The NICE guideline<sup>10</sup> highlights the current limited evidence-base surrounding rehabilitation after critical illness. Research recommendations include the need to investigate specific rehabilitation strategies. The NICE guideline recommends considering the use of a self-directed rehabilitation manual for at least 6 weeks after discharge from critical care. Our data indicate that immediately after discharge from intensive care, compliance with a manual may be difficult for many patients, because of high levels of disability, including consciousness disorders such as delirium. Van der Schaaf et al<sup>8</sup> also reported poor functional status immediately after discharge from intensive care. In these patients enhanced supervised rehabilitation strategies may be more effective. Our data indicate that evaluation of this approach is feasible in a concurrent randomised trial, using process and patient centred outcomes to evaluate effectiveness. The Rivermead mobility index<sup>15</sup> is a potential primary outcome measure because of simplicity of administration, high follow up rate, and focus on disability in relation

to physical function. Physical measures of functional and nutritional status are likely to achieve lower follow up rates, and incur greater research costs. One limitation in regards to the outcome measures was the lack of a measure evaluating activities of daily living (ADL's). Future research should consider their inclusion to allow the impact of an intervention on ADL's to be evaluated.

We identified potential confounders to the effectiveness of early rehabilitation strategies, particularly delirium, which is prevalent during and following critical illness and has an independent association with adverse hospital outcomes.<sup>28-30</sup>. Other potential confounders include the degree of disability at ICU discharge and pre-existing chronic illness. Future research should include screening and adjustment for these factors, potentially by stratification at trial entry.

However, caution must be exercised when considering these results. Part A was an audit of the services provided in one hospital with a small sample size and may not be representative of services provided in other hospitals. Part B was a pilot feasibility study, also limited by a small sample size, and only undertaken in one hospital. The feasibility of the implementation of this service model in other hospitals needs to be explored. In both parts A and B the pre-morbid functional ability of the participants was not recorded. This may influence outcome measures after critical illness and should be collected in future studies to assess the effect of pre-morbid functional ability on the intervention. In part B the intervention focused predominantly on physiotherapy and nutritional needs due

to the limited funding available. However, the authors acknowledge that other health professionals are a key part of any rehabilitation intervention and their involvement in future studies would be required. During this pilot study, one participant required occupational and speech and language therapy. The feasibility nature of this study allowed the generic rehabilitation assistant to provide assistance to both these allied health professionals, which was successful. This would indicate it is feasible for this model of service delivery to provide comprehensive rehabilitation across multiple disciplines.

It is difficult to draw definitive conclusions due to the limitations of both the service evaluation and the pilot feasibility study. However, it has been possible to use the data to undertake power calculations and estimate the required sample size for a larger study. Using the Rivermead Mobility Index<sup>15</sup> as the primary outcome and to detect a difference of two points between groups it was found 100 patients per group at 3 months (80% power; 5% significance level) would be required. This could not be achieved in our single centre and further centres would be required in a larger trial.

In conclusion, we have shown that patients currently receive low levels of ward-based physiotherapy and nutritional rehabilitation following discharge from intensive care, despite high levels of physical disability. This study has defined and piloted an enhanced physiotherapy and nutritional rehabilitation package that requires evaluation in a larger trial.

## **Clinical Messages**

- Enhanced physiotherapy and nutritional rehabilitation can be delivered
  using a generic rehabilitation assistant, but clinical and cost-effectiveness
  need to be investigated in a larger study.
- Validation of outcome measures used in intensive care populations is required.

#### **Acknowledgements**

#### REMOVED FOR ANONYMISATION

## **Funding**

This work was supported by a pump-priming grant from the Centre for Integrated Healthcare Research (CIHR\2006\PP\20).

#### References

<sup>1</sup> Griffiths RD, Jones C. Clinical Review. ABC of Intensive Care. Recovery from intensive care. *BMJ* 1999; **319**: 427-429.

<sup>2</sup> Pettila V, Kaarlola A, Makelainen A. Health-related quality of life of multiple organ dysfunction patients one year after intensive care. *Intensive Care Medicine* 2000; **26:** 1473-1479.

<sup>3</sup>Jones C, Griffiths RD, Humphris GH, Skirrow P. Memory, delusions, and the development of acute posttraumatic stress disorder-related symptoms after intensive care. *Critical Care Medicine* 2001; **29:** 573-580.

<sup>4</sup> Herridge MS, Cheung AM, Tansey CM, Matte-Martyn A, Diaz-Granados N, Al Saidi F, Cooper AB, Guest CB, Mazer CD, Mehta S, Stewart TE, Barr A, Cook D, Slutsky AS for the Canadian Critical Care Trials Group. One-Year Outcomes in Survivors of the Acute Respiratory Distress Syndrome. *N Engl J* Med 2003; **348**: 683-693.

<sup>5</sup> Combes A, Costa M-A, Trouillet J-L, Baudot J, Mokhtari M, Gibert C, Chastre J. Morbidity, mortality, and quality-of-life outcomes in patients requiring > 14 days of mechanical ventilation. *Critical Care Medicine* 2003; **31:** 1373-1381.

<sup>6</sup> van der Schaff A, Beelen, A, de Vos, R. Functional outcome in patients with critical illness polyneuropathy. *Disability and Rehabilitation* 2004; **26:** 1189-1197.

<sup>7</sup>Cuthbertson BH, Hull AM, Strachan M, Scott JT. Post-traumatic stress disorder after critical illness requiring general intensive care. *Intensive Care Medicine* 2004; **30**: 450 – 455.

<sup>8</sup> van der Schaff M, Dettling DS, Beelen A, Lucas C, Dongelsmans DA, Nollett F. Poor functional status immediately after discharge from an intensive care unit. *Disability and Rehabilitation* 2008; **30:** 1812-1818.

<sup>9</sup> Department of Health, 2005. Quality Critical Care: Beyond 'Comprehensive Critical Care': A report by the Critical Care Stakeholder Forum.

<sup>10</sup> National Institute for Health and Clinical Excellence (NICE), 2009.
Rehabilitation after Critical Illness.

<sup>11</sup> Jones C, Skirrow P, Griffiths RD, Humphris GH, Ingleby S, Eddleston J, Waldmann C, Gager M. Rehabilitation after critical illness: A randomized, controlled trial. *Critical Care Medicine* 2003; **31**: 2456-2461.

<sup>12</sup> Moran D, Elliott R, McKinley S. The Royal North Shore Hospital ICU nurse initiated telephone follow up service. *Intensive and Critical Care Nursing* 2005; **21**: 47-50.

<sup>13</sup> Cuthbertson BH, Rattray J, Johnston M, Wildsmith JA, Wilson E, Hernendez R, Ramsey C, Hull AM, Norrie J, Campbell M. A Pragmatic Randomised, Controlled Trial of Intensive Care follow up programmes in improving Longer-term outcomes from critical illness. The PRACTICAL study. *BMC Health Serv Res* 2007; **7:** 116.

<sup>14</sup> Elliott D, McKinley S, Alison JA, Aitken LM, King MT. Study protocol: Homebased physical rehabilitation for survivors of a critical illness. *Critical Care* 2006; **10:** R90.

<sup>15</sup> Collen FM, Wade DT, Robb GF, Bradshaw, CM. The Rivermead Mobility Index: a further development of the Rivermead Motor Assessment. *Int Disabil Studies* 199<u>1;</u> **13:** 50-54.

<sup>16</sup>Podsiadlo D, Richardson S. The Timed 'Up and Go': A Test of Basic Functional Mobility for Frail Elderly Persons. *JAGS* 1991; **39:** 142-148.

<sup>17</sup>Wade DT, Wood VA, Heller A, Maggs J, Langton Hewer R. Walking After Stroke. Measurement and Recovery over the First 3 Months. *Scand J Rehab Med* 1987; **19:** 25-30.

<sup>18</sup>Department of Health,1991. Department of Health Dietary reference values for food energy and nutrients for the United Kingdom. HMSO, London.

<sup>19</sup>Elia M. Artificial Nutritional Support. *Medicine International* 1990; **82:** 3392-3396.

<sup>20</sup>Salisbury LG, Merriweather, JL, Walsh TS. Rehabilitation after critical illness: Could a ward-based generic rehabilitation assistant promote recovery? *Nursing in Critical Care* (in press).

<sup>21</sup>Knaus WA, Draper EA, Wagner DP, Zimmerman JE. APACHE II: a severity of disease classification system. *Critical Care Medicine* 1985; **13:** 818-829.

<sup>22</sup>Singh SJ, Morgan MD, Scott S, Walters D, Hardman AE. Development of a shuttle walking test of disability in patients with chronic airways obstruction. *Thorax* 1992; **47**: 1019-24

<sup>23</sup> Griffiths CDM, Clark RG. A comparison of the 'Sheffield' prognostic index with forearm muscle dynamometry in patients from Sheffield undergoing major abdominal and urological surgery. *Clinical Nutrition* 1984; **3:** 147-151

- <sup>24</sup> Lerner A, Heitlinger T, Rossi T. Midarm muscle circumference as an indicator of muscle mass. *The Journal of Pediatrics* 1985; **106:** 168-169.
- <sup>25</sup> Crichton, N. Information Point. Visual Analogue Scale (VAS). *Journal of Clinical Nursing* 2001; **10**: 706.
- <sup>26</sup> Steffen TM, Hacker TA, Mollinger L. Age- and Gender-Related Test
  Performance in Community-Dwelling Elderly People: Six-Minute Walk Test, Berg
  Balance Scale, Timed Up and Go Test and Gait Speeds. *Physical Therapy* 2002;
  82: 128-137.
- <sup>27</sup> Medical Research Council (MRC), 2008. A Framework for development and evaluation of RCTs for Complex Interventions to Improve Health.
- <sup>28</sup> Ely EW, Shintani A, Truman B, Speroff T, Gordon SM, Harrell FE, Inouye SK, Bernard GR, Dittus RS. Delirium as a predictor of mortality in mechanically ventilated patients in the intensive care unit. *JAMA* 2004; **291**: 1753-1762.
- <sup>29</sup> Ely EW, Gautam S, Margolin R, Francis J, May L, Speroff T, Truman B, Dittus R, Bernard GR, Inouye SK. The impact of delirium in the Intensive care unit on hospital length of stay. *Intensive Care Med* 2001; **27:** 1892-1900.

<sup>30</sup> McNicoll L, Pisani MA, Zhang Y, Ely EW, Siegel MD, Inouye SK. Delirium in the intensive care unit: occurrence and clinical course in older patients. *J Am Geriatr Soc* 2003; **51:** 591-598.

# Tables

Table 1 Frequency of mobility treatments

	Frequency (per week) of treatments delivered during ward stay			
	Median (IQR)	Min	Max	
Transfers	1 (0.6 1.7)	0	3.3	
Marching on spot	0 (0, 0)	0	1.2	
Walking	1.3 (0.4, 2.5)	0	3	
Stairs	0 (0, 0.2)	0	1	
Exercises	0.1 (0, 0.8)	0	2.5	

Table 2 Demographic Details of participants

	Control Group (n=8) Median (IQR)	Intervention Group (n=8) Median (IQR)
Gender	6 Male : 2 Female	5 Male : 3 Female
Age (Years)	57.5 (52.8, 70)	67 (44.5, 77.8)
APACHE II score	26 (19.3, 39)	31 (23.3, 42)
Ventilation Days	12.5 (6.8, 22.3)	21.5 (19, 30.3)
Length of ICU stay	16.5 (10.5, 25)	23 (20.5, 33.3)
Length of Ward Stay	15 (11.5, 19.8)	25.5 (21, 32.5)

Table 3 Frequency of Physiotherapy and Dietetic Treatment Techniques.

	Frequency of treatment delivery (per week)					
	Control Group (n = 8)		Intervention Group (n=8)			
	Median (IQR)	Min	Max	Median (IQR)	Min	Max
Frequency of Physiotherapy visits per week**	2.6 (1.8, 4.2)	0	5	8.2 (7.1, 10.6)	2.9	12.7
Frequency of Dietetic visits per week**	1.2 (0.6, 2.1)	0	3	4.9 (3.4, 8.4)	2.3	9.2
Respiratory Treatments	0.7 (0, 2.3)	0	6	0.9 (0.7, 2.1)	0	5.5
Mobility Treatments**	(0, 2.3) 3.3 (3.0, 5.8)	0	7	14.6 (7.2, 18.3)	5.6	20.3
Transfers**	1.0 (0.6, 1.5)	0	1.8	2.2 (1.0, 3.8)	0	6.1
Marching on the spot	0 (0, 0.3)	0	0.5	(0, 0.4)	0	1.3
Walking	1.8 (0, 2.6)	0	3.3	3.9 (0.4, 6.6)	0	7
Stairs	0.2	0	1.1	0.2 (0, 0.8) 3.7	0	2.3
Exercises**	(0, 0.9) 0.2 (0, 1.2)	0	2	3.7 (1.8, 4.9)	0	5.8
Balance Work	0 (0, 0.2)	0	0.4	0 (0, 1.0)	0	1.3
Pedals	0 (0, 0) 0	0	0.8	0 (0, 0.4) 0.5	0	2.3
Advice**	0 (0, 0)	0	0.4	(0.2, 0.9)	0	2.3
Exercise Bike	Not Delivered			0 (0, 0.8)	0	1.3
Massage	Not Delivered			0 (0, 0) 0.5	0	1.8
Passive Range of Movements	Not Delivered			0.5 (0,. 0.9)	0	4.2
	Control n=6			Intervention n=6		
Average Calorie Intake as a Percentage of Estimated Calorie Requirements	102.3 (83.4,153.8)	79.1	161.7	114.6 (66.4, 144.3)	36.9	163.1
Average Weekly Protein Intake as a Percentage of Estimated Protein Requirements	62.8 (50.7, 91.8)	49	103.9	76.7 (48.1, 96.6)	22.7	130.9

<sup>\*\*</sup>Statistically significant difference found between groups using Mann-Whitney U Test

Table 4 Outcome measures at 3 months post intensive care discharge

Outcome Measure		Median (IQR)	Min	Max
Rivermead Mobility Index	Control n=6 Intervention n=5	11 (8, 14.3) 12 (3, 12.5)	8	15 13
Timed Up and Go (seconds)	Control n=5 Intervention n=4	12.8 (9.2, 17.5) 12.5 (8.5, 28.9)	7.4 7	22 42.7
Ten metre walk test (seconds)	Control n=5 Intervention n=4	11 (8.7, 14.2) 11.3 (7.7, 43.2)	7.5 7.5	17 53.3
Incremental Shuttle Test (metres)	Control n=5 Intervention n=4	149 (91, 333) 168 (44.5, 317)	45 10	468 360
Visual Analogue Scale (Breathlessness) (0=none;10=worse)	Control n=5 Intervention n=5	3.5 (2.4, 5.8) 1.2 (0.2, 6.7)	2.2	6.6 9.4
Visual Analogue Scale (Fatigue) (0=none;10=worse)	Control n=5 Intervention n=5	2.5 (2.1, 4.6) 2.1 (0.3, 5.0)	1.9 0	5.0 7.7
Visual Analogue Scale (Joint Stiffness) (0=none;10=worse)	Control n=5 Intervention n=5	1.1 (0.1, 7.2) 4.8 (2.5, 8.0)	0	7.4 9.1
Visual Analogue Scale (Pain) (0=none;10=worse)	Control n=5 Intervention n=5	3.1 (1.5, 7.0) 5.8 (1.7, 7)	0.1 0.9	10 7.5
Visual Analogue Scale (Appetite) (0=none;10=best)	Control n=5 Intervention n=5	4.9 (3.2, 7.4) 8.4 (4.9, 9.2)	2.3	7.8 9.5
Handgrip Dynamometry (Improvement between baseline and 3 months)	Control n=6 Intervention n=4	21.0 (13.8, 25.8) 13.5 (5.5, 47)	-5.0 5.0	28.0 56.0
Calorie Intake as a Percentage of Estimated Calorie Requirements	Control n=4 Intervention n=5	70.0 (63.1, 95.9) 113.4 (71.9, 113.4)	61.8 70.2	103.6 175.5
Protein Intake as a Percentage of Estimated Protein Requirements	Control n=4 Intervention n=5	68.7 (61.9, 93.9) 90.3 (72.7, 126.1)	61.4 55.0	100.7 150.9

No statistically significant difference found between groups using Mann-Whitney U Test

Figure 1 Flow diagram of experimental protocol

