Evaluating the feasibility and effectiveness of a critical care discharge information pack for patients and their families: a pilot cluster randomised controlled trial

Suzanne Bench,1 Tina Day,2 Karina Heelas,3 Philip Hopkins,3 Catherine White,4 Peter Griffiths5

ABSTRACT

Objectives: To evaluate the feasibility and effectiveness of an information pack, based on self-regulation theory, designed to support patients and their families immediately before, during and after discharge from an intensive care unit (ICU).

Design and setting: Prospective assessor-blinded pilot cluster randomised controlled trial (RCT; in conjunction with a questionnaire survey of trial participants’ experience) in 2 ICUs in England.

Participants: Patients (+/- a family member) who had spent at least 72 h in an ICU, declared medically fit for discharge to a general ward.

Randomisation: Cluster randomisation (by day of discharge decision) was used to allocate participants to 1 of 3 study groups.

Intervention: A user-centred critical care discharge information pack (UCCDIP) containing 2 booklets; 1 for the patient (which included a personalised discharge summary) and 1 for the family, given prior to discharge to the ward.

Primary outcome: Psychological well-being measured using Hospital Anxiety and Depression Scores (HADS), assessed at 5±1 days postunit discharge and 28 days/hospital discharge. Statistical significance (p≤0.05) was determined using χ² and Kruskal-Wallis (H).

Results: 158 patients were allocated to: intervention (UCCDIP; n=51), control 1: ad hoc verbal information (n=59), control 2: booklet published by ICUsteps (n=48). There were no statistically significant differences in the primary outcome. The a priori enrolment goal was not reached and attrition was high. Using HADS as a primary outcome measure, an estimated sample size of 286 is required to power a definitive trial.

Conclusions: Findings from this pilot RCT provide important preliminary data regarding the circumstances under which an intervention based on the principles of UCCDIP could be effective, and the sample size required to demonstrate this.

Trial registration number: Current Controlled Trials ISRCTN47262088: results.

INTRODUCTION AND BACKGROUND

Providing information is an important element of effective critical illness rehabilitation care,1,2 yet at the time of discharge from an intensive care unit (ICU) to a general care environment (ward), some patients and relatives report not receiving any information3,4 or receiving ad hoc verbal information, sometimes accompanied by a leaflet or booklet.5

Patient-focused healthcare provision, which promotes shared decision-making, is widely advocated.6-9 Guidelines from the Department of Health in England (p.16) recommend that acutely ill patients should be “encouraged to actively participate in decisions related to their recovery…”10; this, however, requires the provision of appropriate information. To be effective, ICU discharge information needs to take account of the cognitive problems and fatigue apparent in many patients recovering from critical illness.11 Any written information must also
acknowledge the heightened anxiety experienced by both patients and relatives at this time and reflect the differing information needs of both groups at various time points. Our intervention was designed to address all of these elements, in contrast to the interventions described in the few studies which have previously evaluated written ICU discharge information resources.

There is currently little evidence to support best practice with regard to ICU discharge information delivery. Data from the few studies, which have evaluated written resources, suggest that it can improve family members' knowledge and satisfaction and reduce their anxiety during and after ICU discharge. The results of a multicentre UK randomised controlled trial (RCT) also suggest that written information may help lower patients' levels of depression and symptoms of post-traumatic stress disorder (PTSD), when provided as part of a broader rehabilitation strategy. These limited data justify further investigation of the key elements of ICU discharge information that lead to positive health outcomes.

OBJECTIVES
This paper reports a RCT designed to (1) provide an initial evaluation of a user-centred critical care discharge information pack (UCCDIP), (2) inform decisions regarding its further development and evaluation, and (3) estimate the sample size required to power a definitive trial.

METHODS
Design
We designed an external pilot pragmatic RCT (figure 1) to provide initial data regarding the feasibility and effectiveness of UCCDIP. In accordance with the definition of an external pilot, an assessment of the primary outcome was included. To reduce the chance of between-group contamination, the design also incorporated cluster randomisation, where groups of participants (as opposed to individuals) were allocated to study arms. During the trial, a questionnaire survey was conducted to determine the experiences of trial participants and nursing staff.

In line with best practice, a former patient and Trustee of ICUsteps (an ICU patient and relative support charity) was included on the project team. Recruitment took place between 8 August 2011 and 4 May 2012, and informed patient consent was obtained prior to data collection. The trial was registered on The International Standard Randomized Controlled Trial Number (ISRCTN) database (ISRCTN47262088) 5 months after recruitment of the first patient. This delay was due to an administrative problem between trial
registry and the funding body. The full trial protocol is available in online supplementary file 1.

Setting and participants
The study took place in two ICUs (medical n=14 beds and surgical n=18 beds) within a single teaching hospital in central London, England; providing care for a mixed medical, surgical and trauma patient population, requiring level 2 (high dependency) or level 3 (intensive) care. Both units functioned as one department; staff rotated between units and patients were allocated to a bed based on availability; regardless of whether they required medical or surgical care. Patients over 18 years were considered for inclusion into a cluster if they had spent at least 72 h in the ICU (table 1). The intention was to recruit all eligible patients, declared medically fit for discharge to a general ward Monday to Friday (08:00–20:00) and a nominated relative. Inclusion criteria were based on best practice guidelines surrounding ICU discharge, with an aim to avoid including overnight stay elective surgical patients whose discharge had been delayed due to the unavailability of a ward bed.

All participants (patients and relatives) were recruited while the patient was in ICU. Potential patient participants were consented the day prior to a formal discharge decision wherever possible. For patients unable to provide informed written consent at the point of ICU discharge, personal consultee declarations, usually from the patient’s next of kin, were sought. Informed consent from the patient was then obtained prior to data collection on the ward. The relatives of all recruited participants in the intervention group having a placebo effect, in addition to the ‘ad hoc’ information provided by a variety of healthcare professionals. No guidance was given for this and the quality and quantity of information delivered was totally dependent on each staff member’s usual practice. To minimise the risks of additional attention, given to participants in the intervention group having a placebo effect, in addition to the ‘ad hoc’ information given to all participants, a second ‘attention control’ group received alternative written information in the form of a booklet produced by the ICUsteps charity. In contrast to UCCDIP, the information in the ICUsteps booklet covered the whole trajectory of critical illness from ICU admission to after hospital discharge. In addition, the ICUsteps booklet did not offer opportunities for participants to reflect on their experience or feelings, or prompt them to consider their individual information needs.

Table 1 Inclusion/exclusion criteria for individual participants

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult patients (&gt;18 years)</td>
<td>Patients for whom active treatment had been withdrawn</td>
</tr>
<tr>
<td>Adult family members of eligible patients (&gt;18 years)</td>
<td>Inability to verbally communicate in or read English</td>
</tr>
<tr>
<td>Elective or emergency admissions in the ICU ≥72 h</td>
<td>Involvement in a phase I focus group study</td>
</tr>
<tr>
<td>Patients identified for discharge to a general ward setting within the hospital</td>
<td>ICU, intensive care unit.</td>
</tr>
<tr>
<td>Elective discharges between 08:00 and 20:00 Monday to Friday</td>
<td></td>
</tr>
</tbody>
</table>

Intervention
drawing on self-regulation theory (SRT), our intervention (UCCDIP) was developed using data from a previous focus group study. UCCDIP consists of two booklets, one for the patient and one for the relatives (see online supplementary file 2). The front page of the patient booklet includes an individualised patient discharge summary, written by ICU bedside nurses; trained to use a template designed by the project team (CW, PH). The pack also contains information aimed at preparing the patient/family for ICU discharge and the transition to the ward. It encourages active participation by offering space for expression of individual questions and concerns. It also includes diary pages for both the patient and family to record their thoughts and feelings during the in-hospital recovery period, if they wish. In accordance with SRT, UCCDIP was designed as an information resource, to help users develop revised illness perceptions, more consistent with effective coping.

The intervention is further described in Bench et al. Participants in all three study arms received usual care, which consisted ‘ad hoc’ verbal ICU discharge information provided by a variety of healthcare professionals. No guidance was given for this and the quality and quantity of information delivered was totally dependent on each staff member’s usual practice. To minimise the risks of additional attention, given to participants in the intervention group having a placebo effect, in addition to the ‘ad hoc’ information given to all participants, a second ‘attention control’ group received alternative written information in the form of a booklet produced by the ICUsteps charity. In contrast to UCCDIP, the information in the ICUsteps booklet covered the whole trajectory of critical illness from ICU admission to after hospital discharge. In addition, the ICUsteps booklet did not offer opportunities for participants to reflect on their experience or feelings, or prompt them to consider their individual information needs.

Intervention delivery
Immediately after recruitment, patient participants in all clusters were given an identical looking folder containing a covering letter, study information and, where applicable, written discharge information (either UCCDIP or the ICUsteps booklet). These folders accompanied patients when they were discharged to the ward.

For participants randomised to a cluster receiving the intervention, the bedside ICU nurse orientated the patient to the contents of the UCCDIP and the research nurse (KH) checked that the patient discharge summary was completed according to agreed guidelines.
The bedside nurse did not go through the written booklet given to the participant allocated to receive the ICUsteps booklet.

Recruited relatives were allocated to the same study group as the patient, but it was left up to the patient to pass the information on to their family. Although UCCDIP contained an information book specifically for relatives, they were not included in the discussion between the bedside nurse and the patient, unless they happened to be present on the unit at the time.

### Outcomes

The primary outcome was individual patients’ sense of psychological well-being (specifically anxiety and depression), measured using the internationally validated Hospital Anxiety and Depression Score (HADS) tool\(^2\) with a threshold ≥8 used to identify possible clinical cases of anxiety and/or depression.\(^2\) Secondary outcomes included individual patients’ perceptions of coping, measured using the Brief Coping Orientations to Problems Experienced (BCOPE) tool\(^5\) and relatives’ sense of psychological well-being (anxiety, depression and coping assessed using HADS and BCOPE). In addition, patients’ perceptions of their ability for self-care were measured using the Patient Enablement Instrument (PEI).\(^3\) A locally designed questionnaire survey described the discharge experiences of all recruited patients and their relatives. The views of the ICU and ward nursing staff about UCCDIP were also explored using the questionnaire survey and have been previously published.\(^3\) Face and content validity of the questionnaire were reviewed by the patient advisory group, but no pilot was undertaken prior to its use. Table 2 details the instruments and measures used to assess both primary and secondary outcomes.

To assess the effects of the intervention on early in-hospital psychological well-being, outcome data from patient and relative participants were collected on the ward on two occasions after ICU discharge: 1 week (defined as 5±1 day) and at hospital discharge or 28 days, whichever was sooner. The questionnaire survey was completed prior to a patient’s hospital discharge (participants) or at the end of the trial period (nurses) (table 2).

Data were collected by one researcher (SB), with back-up provided (TD). To maximise the chance of retrieving a full data set, researchers facilitated completion of forms (by reading questions and writing responses) for some of the less able patients. Relatives were asked to complete forms on the ward or at home, and to return them directly to the research team (by email or post) or to leave them for collection at the patient’s bedside.

Demographic information, length of ICU stay, ICU readmissions, medical history, Acute Physiology and Chronic Health Evaluation (APACHE) II scores,\(^3\) therapies received and complications pertinent to the critical illness period were retrieved from local databases and medical notes immediately after each patient participant was recruited. At this point, participating relatives were also asked to complete a form detailing their demographics, previous experiences of critical illness and relevant medical history (such as anxiety and/or depression). The number of unit discharges per day during the trial period and other feasibility data, such as comments received from staff and challenges associated with intervention delivery, were also recorded by the research nurse. All completed discharge summaries were photocopied and retained.

### Sample

Based on data from a previous RCT by Gammon and Mulholland,\(^3\) which examined the effect of information giving on the HADS of a sample of perioperative patients, the sample size calculation for the present trial was carried out using G*Power V.3.1.2. To detect a moderate effect size of 0.6 (mean difference of 3 units, SD 5) with a power of 80% and \(\alpha\) set at 0.05, a minimum of

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**Table 2** Data collection instruments and measures

<table>
<thead>
<tr>
<th>Participant</th>
<th>Outcome</th>
<th>Instrument</th>
<th>Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>Anxiety and depression</td>
<td>HADS</td>
<td>1. On ward, 5 (±1) days post-ICU discharge</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2. Hospital discharge or 28 days</td>
</tr>
<tr>
<td>Patient</td>
<td>Perceptions of coping</td>
<td>BCOPE</td>
<td>1. On ward, 5 (±1) days post-ICU discharge</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2. Hospital discharge or 28 days</td>
</tr>
<tr>
<td>Patient</td>
<td>Perceptions of self-care ability</td>
<td>PEI</td>
<td>1. On ward, 5 (±1) days post-ICU discharge</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2. Hospital discharge or 28 days</td>
</tr>
<tr>
<td>Patient</td>
<td>Discharge experience</td>
<td>Questionnaire</td>
<td>Prior to hospital discharge</td>
</tr>
<tr>
<td>Relative</td>
<td>Anxiety and depression</td>
<td>HADS</td>
<td>1. On ward, 5 (±1) days postpatient’s ICU discharge</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2. Patients’ hospital discharge or 28 days</td>
</tr>
<tr>
<td>Relative</td>
<td>Perceptions of coping</td>
<td>BCOPE</td>
<td>1. On ward, 5 (±1) days postpatient’s ICU discharge</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2. Patients’ hospital discharge or 28 days</td>
</tr>
<tr>
<td>Relative</td>
<td>Discharge experience</td>
<td>Questionnaire</td>
<td>Prior to patient’s hospital discharge</td>
</tr>
<tr>
<td>ICU and ward nurses</td>
<td>Views about UCCDIP</td>
<td>Questionnaire</td>
<td>End of trial period</td>
</tr>
</tbody>
</table>

BCOPE, Brief Coping Orientations to Problems Experienced; HADS, Hospital Anxiety and Depression Scale; ICU, intensive care unit; PEI, Patient Enablement Instrument; UCCDIP, user-centred critical care discharge information pack.
45 participants in each group were required. To account for attrition and the likely variation in ICU discharges in each cluster (discharge day), our accrual target was 50 participants in each of three study arms.

Sample size was not based on an intraclass correlation (ICC) calculation, as insufficient information was available to determine the real extent of any homogeneity between clusters. As only those discharged on weekdays were recruited, it was anticipated that every day would produce a fairly similar and randomly determined clinical case load (local data 2010/2011), thus limiting the likelihood of homogeneity (eg, similar diagnoses) within and heterogeneity (eg, care led by different medical teams) between clusters. The intervention for each cluster was also preallocated on a random basis, thus minimising (although not eradicating) the chance of clusters being homogeneous.

There was no opportunity to influence cluster size, and so to maximise the chance of recruiting the required number of participants, data collection was planned to continue for at least 132 days, providing 44 potential clusters in each of the three study arms, significantly greater than the minimum of five recommended by the UK Medical Research Council.35

Randomisation
As described by Hayes and Moulton,36 this trial used cluster randomisation for pragmatic reasons, with an aim to reduce the risk of cross-contamination between study arms. All patient participants (and their relative where applicable) discharged from either ICU on a particular day (a cluster) were allocated to one of the three study groups (figure 1). Particular days of the week were not allocated to specific arms; instead each day was randomly allocated to a study arm and treated as a distinct cluster, based on the allocation schedule.

To ensure that the sequence of allocation was not predictable, the day on which the intervention, control and attention control was used was randomly assigned using a computer-generated random sequence, prepared by a statistician. This involved simple randomisation with no blocking or stratification for defined variables.

The allocation schedule was prepared by persons independent of the trial and concealed by being wrapped in a blank piece of paper and placed inside sequentially numbered, sealed envelopes. These envelopes were signed across the seal and opened by the research nurse (KH), in the presence of another member of the research team, only after a recruited patient was identified for discharge to the ward on a particular day. The clinical ICU staff only became aware of which study group the patient was allocated to when the bedside nurse was provided with a study pack to give to the patient. Allocation concealment for the whole cluster was revealed after the first envelope was opened on any day.

Blinding
It was not possible to achieve full blinding during this trial as intervention delivery required input by healthcare staff and trial participants. Those collecting and analysing data were, however, blinded by the use of codes, which were not broken until after data analysis. Blinding was compromised if participants revealed their information pack to the data collector. In most instances, however, as all participants received a folder, identical on the outside, data collectors (SB/TD) remained blinded to the allocation.

Statistical methods
Data analysis was based on an ‘intention-to-treat’ strategy37 and statistical significance was set at p≤0.05. Average values for sample characteristics, HADS, BCOPE, PEI scores and questionnaire responses in each of the study groups were compared using χ2 for categorical data and Kruskal-Wallis (H) for data of at least ordinal level. In addition, Friedman’s test (χ2r) was used to explore associations between the different types of coping. Difference in HADS (the primary outcome) between the three study groups was also tested using the Statistical Analysis System (SAS) V9.3 (SAS Institute Inc, Cary, North Carolina, USA), Generalised Mixed Models procedure (GLIMMIX) that adjusted for clustering (by fitting a random intercepts model) and recruitment weekday. At time point 2, it was not possible to fit random intercepts because the G-side matrix was always not positive definite. We followed the CONSORT guidance and did not conduct baseline statistical comparisons between study groups.38

This paper reports outcome data from the patient participants only, with reference to the demographics and attrition data collected from the sample of relatives.

RESULTS
Two hundred and twenty-one (18%) of the 1240 screened patients met the inclusion criteria and 158 of these were recruited in 100 clusters, each containing 1–5 patients (table 3). The distribution by cluster size was as follows: one patient (n=66), two patients (n=21), three

<table>
<thead>
<tr>
<th>Table 3</th>
<th>ICU patients discharged and recruited per weekday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruitment day</td>
<td>Clusters, n (%)</td>
</tr>
<tr>
<td>Monday</td>
<td>31 (31)</td>
</tr>
<tr>
<td>Tuesday</td>
<td>20 (20)</td>
</tr>
<tr>
<td>Wednesday</td>
<td>10 (10)</td>
</tr>
<tr>
<td>Thursday</td>
<td>16 (16)</td>
</tr>
<tr>
<td>Friday</td>
<td>23 (23)</td>
</tr>
<tr>
<td>Totals</td>
<td>100 (100)</td>
</tr>
</tbody>
</table>

ICU, intensive care unit.
patients (n=6), four patients (n=3) and five patients (n=4). Fifty-one (32%) patient participants were allocated to the intervention group (UCCDIP), 59 (37%) to control group 1 (ad hoc verbal information) and 48 (30%) to control group 2 (ICUsteps booklet; figure 1). Eighty relatives of the recruited patient participants also agreed to take part.

Sample demographics
The mean age of patients was 60 (SD 16.04) years (table 4). Participants were predominantly white British/Irish (n=115, 73%) and 82 (52%) were male. Median length of ICU stay was 6 days (range 371). Severity of illness on admission (measured by the APACHE II score) ranged from 4 to 34 (median 17) and on discharge to a ward between 0 and 21 (median 9). Ninety-eight (62%) participants received at least 1 day of level 3 (ICU) care. Twenty-nine (18%) had a history of anxiety and/or depression with or without anxiety. The mean age of patients was 60 (SD 16.04) years (table 4). Participants were predominantly white British/Irish (n=115, 73%) and 82 (52%) were male. Median length of ICU stay was 6 days (range 371). Severity of illness on admission (measured by the APACHE II score) ranged from 4 to 34 (median 17) and on discharge to a ward between 0 and 21 (median 9). Ninety-eight (62%) participants received at least 1 day of level 3 (ICU) care. Twenty-nine (18%) had a history of anxiety and/or depression with or without anxiety. The mean age of patients was 60 (SD 16.04) years (table 4). Participants were predominantly white British/Irish (n=115, 73%) and 82 (52%) were male. Median length of ICU stay was 6 days (range 371). Severity of illness on admission (measured by the APACHE II score) ranged from 4 to 34 (median 17) and on discharge to a ward between 0 and 21 (median 9). Ninety-eight (62%) participants received at least 1 day of level 3 (ICU) care. Twenty-nine (18%) had a history of anxiety and/or depression with or without anxiety. The mean age of patients was 60 (SD 16.04) years (table 4). Participants were predominantly white British/Irish (n=115, 73%) and 82 (52%) were male. Median length of ICU stay was 6 days (range 371). Severity of illness on admission (measured by the APACHE II score) ranged from 4 to 34 (median 17) and on discharge to a ward between 0 and 21 (median 9). Ninety-eight (62%) participants received at least 1 day of level 3 (ICU) care. Twenty-nine (18%) had a history of anxiety and/or depression with or without anxiety. The mean age of patients was 60 (SD 16.04) years (table 4). Participants were predominantly white British/Irish (n=115, 73%) and 82 (52%) were male. Median length of ICU stay was 6 days (range 371). Severity of illness on admission (measured by the APACHE II score) ranged from 4 to 34 (median 17) and on discharge to a ward between 0 and 21 (median 9). Ninety-eight (62%) participants received at least 1 day of level 3 (ICU) care. Twenty-nine (18%) had a history of anxiety and/or depression with or without anxiety.

APACHE II scores on both admission and discharge and received more days of level 3 care. They also had higher illness on admission (measured by the APACHE II score) ranged from 4 to 34 (median 17) and on discharge to a ward between 0 and 21 (median 9). Ninety-eight (62%) participants received at least 1 day of level 3 (ICU) care. Twenty-nine (18%) had a history of anxiety and/or depression with or without anxiety. The mean age of patients was 60 (SD 16.04) years (table 4). Participants were predominantly white British/Irish (n=115, 73%) and 82 (52%) were male. Median length of ICU stay was 6 days (range 371). Severity of illness on admission (measured by the APACHE II score) ranged from 4 to 34 (median 17) and on discharge to a ward between 0 and 21 (median 9). Ninety-eight (62%) participants received at least 1 day of level 3 (ICU) care. Twenty-nine (18%) had a history of anxiety and/or depression with or without anxiety. The mean age of patients was 60 (SD 16.04) years (table 4). Participants were predominantly white British/Irish (n=115, 73%) and 82 (52%) were male. Median length of ICU stay was 6 days (range 371). Severity of illness on admission (measured by the APACHE II score) ranged from 4 to 34 (median 17) and on discharge to a ward between 0 and 21 (median 9). Ninety-eight (62%) participants received at least 1 day of level 3 (ICU) care. Twenty-nine (18%) had a history of anxiety and/or depression with or without anxiety. The mean age of patients was 60 (SD 16.04) years (table 4). Participants were predominantly white British/Irish (n=115, 73%) and 82 (52%) were male. Median length of ICU stay was 6 days (range 371). Severity of illness on admission (measured by the APACHE II score) ranged from 4 to 34 (median 17) and on discharge to a ward between 0 and 21 (median 9). Ninety-eight (62%) participants received at least 1 day of level 3 (ICU) care. Twenty-nine (18%) had a history of anxiety and/or depression with or without anxiety. The mean age of patients was 60 (SD 16.04) years (table 4). Participants were predominantly white British/Irish (n=115, 73%) and 82 (52%) were male. Median length of ICU stay was 6 days (range 371). Severity of illness on admission (measured by the APACHE II score) ranged from 4 to 34 (median 17) and on discharge to a ward between 0 and 21 (median 9). Ninety-eight (62%) participants received at least 1 day of level 3 (ICU) care. Twenty-nine (18%) had a history of anxiety and/or depression with or without anxiety.

of the other two groups, even when outliers with a ICU stay of >100 days were removed (n=2). None of these differences were statistically significant.

Participant follow-up
One hundred and one (64%) patient participants provided primary outcome data at time point 1 (5±1 day post-ICU discharge). Fifty-four (34%) were still in hospital and eligible for data collection at time point 2 (28 days or hospital discharge and at least 7 days after their first data collection point). Of these, 38 (70%) provided some data. A total of 48 (60%) patients’ relatives provided at least one set of outcome data.

Twenty-seven (17%) patients and 32 (40%) relatives were lost to any follow-up. By time point 1 (5±1 day), 17 (11%) of the patient sample had already been discharged or transferred from the hospital, and in a further 15 (10%) cases, the patient was either too unwell or unwilling to provide data. In the case of patients’ relatives, the most significant follow-up problem was due to a failure to return data collection forms within the protocol timeframe (n=29, 36%).

Hospital anxiety and depression
One week postdischarge (time point 1), median HADS for patients was 7 for anxiety (HADS-A) and 6 for depression (HADS-D). There were no significant differences (p≥0.05) between study groups (table 5). There was, however, a wide range in individual HADS, with almost half the total patient sample (44%) reaching or exceeding the trigger for disorder (≥8). At time point 1, where it was possible to fit a random intercepts model, the estimated ICCs were all low (HADS-A 0.14, HADS-D 0.00, total HADS 0.07).

Coping and enablement
No significant differences between groups (p≥0.05) for emotion-focused, problem-focused and dysfunctional

### Table 4 Sample characteristics (patients)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
<th>ICUSteps</th>
<th>UCCDIP</th>
<th>Verbal</th>
<th>Total</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>Mean±SD</td>
<td>59±15.26</td>
<td>60±15.19</td>
<td>61±17.48</td>
<td>60±16.04</td>
<td>0.72</td>
</tr>
<tr>
<td>Ethnicity (white British)</td>
<td>n (%)</td>
<td>34 (71)</td>
<td>40 (78)</td>
<td>41 (69)</td>
<td>115 (73)</td>
<td>0.54</td>
</tr>
<tr>
<td>Gender (male)</td>
<td>n (%)</td>
<td>25 (52)</td>
<td>26 (51)</td>
<td>31 (53)</td>
<td>82 (52)</td>
<td>0.99</td>
</tr>
<tr>
<td>Medical/Surgical ICU</td>
<td>Medical, n (%)</td>
<td>28 (58)</td>
<td>28 (55)</td>
<td>26 (44)</td>
<td>82 (52)</td>
<td>0.30</td>
</tr>
<tr>
<td>Admission type (emergency)</td>
<td>n (%)</td>
<td>38 (79)</td>
<td>40 (78)</td>
<td>44 (75)</td>
<td>122 (77)</td>
<td>0.83</td>
</tr>
<tr>
<td>APACHE II score</td>
<td>ICU admission</td>
<td>17 (24)</td>
<td>18.0 (30)</td>
<td>16.0 (29)</td>
<td>17.0 (30)</td>
<td>0.41</td>
</tr>
<tr>
<td>Length of stay</td>
<td>ICU discharge</td>
<td>Median (range)</td>
<td>8.0 (20)</td>
<td>9.5 (20)</td>
<td>9.0 (21)</td>
<td>9.0 (21)</td>
</tr>
<tr>
<td></td>
<td>ICU days</td>
<td>Median (range)</td>
<td>6.0 (62)</td>
<td>7.0 (104)</td>
<td>6.0 (371)</td>
<td>6.0 (371)</td>
</tr>
<tr>
<td></td>
<td>Hospital days</td>
<td>Median (range)</td>
<td>16.0 (132)</td>
<td>21.5 (220)</td>
<td>22.0 (166)</td>
<td>21.0 (221)</td>
</tr>
<tr>
<td>Level 3 critical illness</td>
<td>n (%)</td>
<td>29 (60)</td>
<td>35 (69)</td>
<td>34 (58)</td>
<td>98 (62)</td>
<td>0.58</td>
</tr>
<tr>
<td>Total number of participants</td>
<td>n (%)</td>
<td>48 (100)</td>
<td>51 (100)</td>
<td>59 (100)</td>
<td>158 (100)</td>
<td>NA</td>
</tr>
</tbody>
</table>

APACHE, Acute Physiology and Chronic Health Evaluation; ICU, intensive care unit; NA, not available; UCCDIP, user-centred critical care discharge information pack.
coping categories or PEI scores were identified at either time point. Over time, the median PEI score for the total patient sample did, however, drop from 12 to 10, indicating that patients felt less enabled the longer they stayed in hospital.

Questionnaire findings

Patient participants in the ad hoc verbal information control group reported significantly more chance of worrying a lot ($\chi^2=11.16$ (df 2), $p=0.03$) than those in either other study group. However, after using GLIMMIX to adjust for clustering, the effect of the intervention on ‘worry about leaving the Critical Care Unit (CCU)’ was not statistically significant ($F (2,39)=0.23$, $p=0.80$). There were no other statistically significant differences in reported feelings or experiences between study groups. However, more participants from the medical as opposed to surgical unit reported that their written information had helped their recovery on the ward, with a result approaching statistical significance ($\chi^2=3.69$ (df 2), $p=0.06$).

Adverse effects

One patient asked to be withdrawn from the trial after data collection point 1 as she felt that completion of the HADS had triggered deterioration in her mental health status. A note was made in her medical file, and she was referred to her primary medical team. There were no other reports of any adverse effects.

The impact of protocol violations

Twenty-five (16%) patients and 10 (13%) of the patients’ relatives had data collected outside of the time period stated by the protocol for time point 1. At time point 2, the mean time from ICU discharge to data collection was $23\pm6$ days for patients and $25\pm8.36$ days for the relatives.

Including these data produced no change in HADS or PEI outcomes compared with the analysis, which excluded them. At the first follow-up point, however, some significant differences in the scores given for individual questions in the emotion and problem-focused coping categories of the BCOPE were identified. UCCDIP sample data reflect significantly less use of religion (question 12; $p=0.01$), active coping (question 2; $p=0.04$) and planning (question 9; $p=0.01$) strategies, than those participants in either of the other two study groups. Analysis of the composite scores for each coping category (emotion, problem and dysfunctional) also revealed that those in the UCCDIP group used significantly fewer problem-focused coping strategies ($H=6.49$, $p=0.04$).

DISCUSSION

Despite some limited data from previous research, which suggest that written resources may lower levels of patients’ anxiety, depression and symptoms of PTSD,
the health benefits of providing written ICU discharge information remain inconclusive. Our trial did not find sufficient evidence to determine whether UCCDIP improves patients’ or relatives’ health outcomes or experiences (anxiety, depression, coping, patient enable-
ment) compared with the ICUsteps booklet and/or the delivery of ad hoc verbal information. However, our
survey data suggest that those who receive written information may feel less worried about going to a ward than those who receive ad hoc verbal information alone.

The UK Medical Research Council point out that eval-
uations of draft complex interventions are frequently
undermined by numerous practical and methodological
problems, and recommend a period of feasibility testing
and piloting prior to full scale evaluation. Using these
design principles, data collected during our RCT has
identified some important future considerations.

Deciding the optimal time to provide ICU discharge
information is an important issue for future practice,
particularly considering that recovery rates for physical
and emotional recovery may differ. We gave our inter-
vention to patients immediately prior to their discharge
from the ICU. However, the survey data that we collected
alongside the trial indicate that many felt unable to
engage with the information at this point or during the
early days on the ward, and that some of the patients
allocated to UCCDIP or the ICUsteps booklet were unaware of having received any written material. Retention of information is a common problem for ICU
patients. Having a family member present when
UCCDIP was discussed with the patient may have increased participants’ awareness of and engagement
with the intervention. Where possible, such practice is
encouraged, particularly if a patient’s cognitive function is compromised.

The intention of this trial was to determine the effect of adding UCCDIP into the usual care provided during discharge; thus, after discharge to the ward, no specific
instructions were given to ward nurses or other health-
care staff about their role in facilitating its use.
Knowledge of the intervention, obtained due to contam-
ation of the allocation concealment after recruitment
of the first patient on any day may, however, have influ-
enced staff members’ verbal information delivery, both
its quality and quantity. In addition, follow-up personnel,
such as discharge coordinators and critical care out-
reach nurses, have been shown to aid patients’ and rela-
tives’ interaction with written information. Not
providing this support as part of the intervention in this
trial may account for some of the problems with engage-
ment that we encountered, particularly for those with
English as a second language, poor literacy and/or cog-
nitive impairment. It may also have contributed to the
excessive loss to follow-up we experienced, which in turn
may have influenced our outcome data. We did not
collect data on these participant characteristics and thus
are unable to validate these assumptions. These issues
are further discussed in Day et al.

UCCDIP is a multicomponent intervention, which
includes an individualised patient discharge summary
written by ICU nurses. Survey data (reported in Bench
et al) suggest that this element of UCCDIP was of par-
ticular value to the patients, relatives and ward nurses
who took part in our study. In the protocols for the
Scottish RECOVER and RELINQUISH trials, discharge
summaries, similar to those used in the present
trial, but written by doctors are also included as part of
the intervention. In addition, ‘lay summaries’ are now
being written by physiotherapists in some parts of the
UK (personal communication from Williams N, Edinburgh Critical Care Research Group 6th annual
meeting; 26 June 2013). Healthcare professionals’ inter-
est in using patient discharge summaries is also evident
by the number of ‘discharge summary training packs’
designed by our project team, being downloaded from
the ICUsteps website. Based on these findings, we rec-
ommend that reflective opportunities, such as diaries,
are included as part of all individualised rehabilitation
programmes.

Our results suggest that medical as opposed to surgical
patients may value interventions such as UCCDIP more;
perhaps because this group have an increased tendency
for psychological problems such as PTSD. Elective sur-
geical patients may also be better prepared for an ICU
admission and their stay is generally expected to be
shorter. In our trial, it must be acknowledged, however,
that most admissions to the surgical ICU were
unplanned. Further, admission to the medical or surgical
unit was not always reflective of a patient’s condition
as beds were used flexibly to meet demand. Despite this
limitation, defining subpopulations of critical care (eg,
medical vs surgical, ventilated vs non-ventilated) that
may benefit most from such an intervention remains an
important future consideration, particularly where
resources are limited.

Future research
Evaluating any complex intervention is practically and
methodologically difficult. UCCDIP contains a
number of different components, making it difficult to
isolate those aspects likely to be most effective. Although
findings from the questionnaire survey suggest that the
patient discharge summary was considered valuable,
future research is required to examine its effectiveness
as a stand-alone intervention.

In this trial, the patients and relatives in all clusters
received ad hoc verbal information as part of usual care
practice. Ad hoc information delivery can be inconsis-
tent and its quality can differ between healthcare profes-
sionals. As in other studies, it was unclear who was
delivering the ‘ad hoc’ verbal information during our
trial, what was being said or whether it was actually pro-
vided at all. Although challenging, attention to qualify-
ing and quantifying these data is a recommendation for
further research.
The high prevalence of anxiety and depression experienced by patients and their families in our study suggests that a higher threshold (≥11) on the HADS tool, as used by other researchers, is required to differentiate the effects of interventions such as UCCDIP on participants. The relationship between emotional status, cognitive appraisal and coping behaviours is complex and individualised. Outcome assessment measures, more closely aligned with the theoretical basis of the intervention (in this case SRT) may, therefore, be better suited to evaluate information interventions in recovering critically ill patients. Development of a validated tool to provide more rigorous data to support the positive views of UCCDIP reported in the locally designed questionnaire survey is also required.

Our data collection points were specifically chosen to identify any early effects of the intervention on psychological well-being that might influence ongoing recovery. However, the effects of our intervention on patients’ and relatives’ perceived anxiety, depression, coping and enablement may not have been visible during the early stages of recovery. A longer follow-up period would enable both the early and ongoing impact of different methods of ICU discharge information to be better explored. The common problem of delayed discharge from ICU should also be considered. Delays can have both positive (physically stronger) and negative effects (increased dependency) on psychological well-being at the point of ICU discharge, and thus may have important implications for evaluating information provision.

It is widely acknowledged that in complex intervention studies such as this, the risk of follow-up bias is high. Reasons for low follow-up in this study were multifactorial, but key reasons included patients being discharged from hospital earlier than anticipated and relatives failing to return data collection forms. These factors need to be considered in the design of future trials. Including relatives in the evaluation of any critical illness rehabilitation intervention is important, as the family unit often provides substantial support to the patient and close relatives can also be affected by the patient’s critical illness. Our experience suggests, however, that once a patient leaves ICU, it is very difficult to maintain communication with relatives and that their commitment to completing study requirements is reduced. Alternate methods of data collection, such as individual telephone interviews, may help reduce the level of attrition we experienced in this study.

In line with best practice recommendations, one of the purposes of this pilot RCT was to inform the power calculation for future work. Mean HADS-A and HADS-D was 7 (SD 5) in the patient sample. Based on a power of 95% and 0.05% level of significance, to achieve an effect size of 0.4 (difference of 2), a total sample of 286 (143 in each of two groups) would be required for a definitive trial. The different numbers of participants recruited on each weekday (table 1) should also be accounted for. The recruitment rates we observed suggest that this would require a multicentre study to achieve. Given our attrition, it is difficult to judge if such a study would represent value for money although possible benefits for patients include an improved understanding of their critical illness experience, use of more positive coping strategies and improved psychological well-being during the rehabilitation period. Considering the feasibility challenges we experienced and have previously described, future research could focus on assessing patients’ and relatives’ perceived usefulness of written information resources and the extent to which specific information deemed important is successfully transmitted and retained.

**Limitations**

This was a single-centre pilot trial, with a short follow-up period and a high rate of attrition (particularly in the sample of relatives). Only recruiting patients discharged during weekdays and daytime hours may have led to a selection bias, as poorer outcomes are associated with night-time and weekend discharges. Other potential biases may also have influenced our results. There were some pretest differences between study groups which might have attenuated any potential benefits. HADS were skewed and the sample was small at time point 2. This should be borne in mind when interpreting the statistical model; however, the results were consistent whichever approach was used. There was also a failure to maintain allocation concealment after recruitment of the first patient in each cluster and a possible Hawthorne effect, where staff may have provided verbal information differently from normal because they were aware of the nature of the study.

Results must therefore be viewed with caution and may not be generalisable to the wider critical care population. The study has, however, provided important data, which can inform future trials evaluating interventions like UCCDIP, enabling processes to be streamlined and a sample size based on a more accurate power calculation to be used.

**CONCLUSION**

This single-centre pragmatic pilot RCT used cluster randomisation to undertake an initial evaluation of UCCDIP, a discharge information pack designed by the project team. We were unable to prove the effectiveness of UCCDIP, supporting the view that information giving to those recovering from critical illness is a complex intervention. This research has, however, provided important preliminary data regarding how, when and for whom an intervention based on the principles of UCCDIP could be most effective and what it would look like.

To increase the likelihood of similar interventions improving health outcomes, key considerations for future work are: (1) medical as opposed to surgical
critical care patients may be more likely to benefit from such interventions; (2) after discharge to the ward, patients need further input and support to help them engage fully with written information resources; (3) data collection time points should reflect the potential effects on both early and later recovery; and (4) outcome measures should be used for future evaluations.

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Contributors SB conceived, designed and coordinated the study as part of a PhD, collected and analysed the data and drafted the manuscript. PG was principal investigator, supervised SB and provided critical comment on the drafted manuscript. TD participated in the design and coordination of the study, was second supervisor to SB, assisted with data collection and provided critical comment on the drafted manuscript. KH recruited and consented trial participants, collated baseline data, assisted with intervention delivery and provided critical comment on the drafted manuscript. PH participated in the design and local coordination of the study, co-drafted guidelines for the patient discharge summary and provided critical comment on the drafted manuscript. CW was the service user representative for the project, participated in the design of the study, co-drafted guidelines for the patient discharge summary and assisted with their analysis, and provided critical comment on the drafted manuscript. All authors read and approved the final manuscript.

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Evaluating the feasibility and effectiveness of a critical care discharge information pack for patients and their families: a pilot cluster randomised controlled trial

Suzanne Bench, Tina Day, Karina Heelas, Philip Hopkins, Catherine White and Peter Griffiths

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