King's College Hospital NHS
NHS Foundation Trust

KING'S College LONDON

Study Protocol

Title

A user centred critical care discharge information pack (UCCDIP) for adult critical care patients and their families at the point of discharge from critical care to the ward; a pilot study evaluating feasibility and effectiveness.

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Summary

This study will explore the effectiveness of a user centred critical care discharge information pack (UCCDIP), developed with user involvement, as compared with usual care using a single centre prospective cluster Randomized Controlled Trial (RCT). The primary outcome measure will be sense of psychological well being during early critical illness recovery. Secondary outcome measures will include length of hospital stay, critical care readmission rates, feasibility and user experience.

Background information

Discharge from any critical care facility (High Dependency, Intensive Care or combined facility; as defined by Department of Health, 2000) to a general ward is a difficult time for patients, relatives and healthcare staff. A number of physiological and psycho-social problems, including weakness, feelings of helplessness, anxiety and depression have been identified as compromising critical illness recovery (NICE, 2007; Bench and Day, 2010). These are compounded by the move to a general ward setting. Previous research has indicated that in contrast to the critical care unit where patients feel safe, ward care is seen to be unpredictable and difficult to understand from the patients' perspective (Chaboyer et al, 2005), leading to relocation stress/anxiety (McKinney and Melby, 2002).

Review of relevant literature and justification for study

McKinney and Melby (2002) argue that it is necessary to think creatively about interventions which might enhance the discharge and rehabilitation process. Guidelines for the acutely ill patient in hospital from the National Institute of Health and Clinical Excellence (NICE) recommend that "*patients should be offered information about their condition and encouraged to actively participate in decisions related to their recovery...tailored to individual circumstances*" (NICE, 2007: 16; recommendation 1.2.2.16). This recommendation is based on a review of existing

evidence of patients' experience of care during this transition period, and supports the development of patient focused interventions as stated by Coulter and Ellis that "*recognise the role of participants in the process of securing appropriate, effective, safe and responsive healthcare*" (Coulter and Ellis, 2006: page 7). The importance of providing appropriate, timely and accurate information during critical illness recovery is further endorsed by NICE (2009) in their guidelines for the rehabilitation of patients after critical illness.

Producing health information based on specific research into what patients have identified as being required is of utmost importance in the development of effective interventions (INVOLVE, 2004; Coulter and Ellis, 2006). There is, however, little evidence in the literature of user involvement in the design or evaluation of information strategies for this population group, despite information giving meeting the criteria for being a complex intervention as defined by Campbell et al (2007).

The use of more active information strategies, defined as those requiring user participation, tailored to individual need, builds upon successful approaches to self care developed in community settings (Griffiths, 2005). If feasible within the critical care population, information strategies which encourage self management could enhance perceptions of control and lead to improved psychological and physical recovery. Despite their vulnerability, evidence suggests that some patients are capable of and desire more input and control over their information needs. It is on this premise that the intervention to be evaluated in this study has been developed.

Limited published work has evaluated critical care discharge information strategies, and most previous work has been inconclusive (for example Paul et al, 2004). This may in part be due to a lack of user involvement in decisions related to both information content and delivery methods, and its generalised nature. Jones et al (2003) demonstrated in their RCT that the use of a self help rehabilitation manual was effective in reducing depression in critically ill patients, providing some evidence to support a more participatory approach. Further, Mitchell and Courtney (2004) demonstrated a reduction in families levels of uncertainty with a more individualised information strategy. Systematic reviews from other patient populations also support

the development of information personalized to the individual. For example, a Cochrane review by McDonald et al (2004) examined nine studies to determine whether preoperative education improved postoperative outcomes in patients undergoing hip or knee replacement surgery, concluding that there was some evidence of beneficial effects when preoperative education was tailored according to anxiety and individual need. Such strategies could help patients' regain the sense of empowerment potentially lost during their critical care stay, reducing the psycho-social and physiological complications which prolong recovery from critical illness. Evidence from the review of patient focused interventions by the Health Foundation (Coulter and Ellis, 2006) provides support for this, stating that self management education is about empowering patients to take active control of their illness, including the management of the emotional impact of their illness (Coulter and Ellis, 2006).

A study by Garrod et al (2006) further supports the importance of a focus on psycho-social well-being during rehabilitation. In their study with chronic respiratory patients, those with depression were found to be significantly more likely to drop out of a pulmonary rehabilitation programme than those without depressive symptoms (odds ratio 8.7; confidence interval 2.8-27.1). Evidence such as this, despite being conducted on a chronic respiratory patient population, strongly supports the development of interventions, which improve psycho-social well-being during early critical illness rehabilitation, and suggests that altering psycho-social well-being could impact on physical rehabilitation targets.

Discharge from critical care is a time which presents potential patient safety issues as defined by the National Patient Safety Agency (NPSA, 2004), a view reflected in a number of recent critical care policy documents (DH, 2000; DH, 2005; NICE, 2007; NICE, 2009). Although the association between psychological well being and other outcomes such as length of stay and patient safety has yet to be established with critical care patients, this RCT, which will be conducted in a real clinical environment, has the potential to provide data that could begin to establish the existence of any such links.

Hypothesis

A user centred critical care discharge information pack (UCCDIP) developed with service users, for adult critical care patients and their families, in comparison to usual care, will:

1. Improve the psychological and physical well-being of patients leaving critical care
2. Improve the psychological well-being of relatives when their loved one leaves critical care
3. Improve the critical care discharge experience for patients and relatives
4. Be considered feasible from the perspective of patients, relatives and critical care and ward nurses

Method

This study is the second of two studies focused on the development and evaluation of more effective critical care discharge information strategies, using the Medical Research Council (MRC) framework (MRC 2008) for the development and evaluation of complex interventions as a guide.

A single centre prospective cluster (patients discharged on a single day) RCT will compare outcomes for an intervention group (of patients and relatives) who will receive the user centred critical care discharge information pack (UCCDIP), with a control group who will receive the currently used information strategy (informal ad-hoc verbal information from health care staff). In order to eliminate any effects imposed by an increase in attention alone, a third 'attention control' group will receive the same amount of provider attention and a standard discharge information booklet without the user centred elements. User experience and feasibility data will be collected from patients, relatives and nurses using questionnaires at the end of the trial period. Following the MRC (2008) framework this single centre study will enable initial evaluation of the proposed complex intervention.

The intervention

The intervention to be evaluated is a user centred critical care discharge information pack (UCCDIP), developed using focus groups, a meta-synthesis of the user experience of critical care discharge (Bench and Day 2010) and a review of currently available discharge information strategies (Bench et al 2011). The pack includes the following:

- Patient discharge summary

A "lay" summary of what has happened to the patient since admission, and their current health status completed by critical care bedside nurses.

- Core information on the discharge process and the early days on the ward.

Information about the discharge process, ward organisation and common physical and psychological concerns of critical care patients and their families. Possible self help strategies will also be detailed.

- A self-assessment tool for identification of individual information needs.

Patients and their family members (as appropriate) will use the tool to identify their own information needs at the point of critical care discharge using written prompts. This tool will have separate parts for the patient and the family to complete. Critical care bedside nurses and ward nurses will assist completion where necessary.

- Personalized information

The patient, family and/or health care professionals will document information focused on the identified needs.

- Personal diary

An opportunity for patients and family members to maintain a reflective account of personal feelings, concerns and early rehabilitation experience.

- Support resources

A list of possible information sources, support services and contact details, including health care professionals, internet support sites, and relevant charities and support forums.

The pack is intended to be flexible, and to support and encourage assisted independence. It recognises the different information needs of patients and family members, acknowledges the physical and psychological vulnerability of both the patient and the family member at this point in time, and acknowledges the patients' need to understand what they have been through and have evidence of the progress they have made. The individualised and flexible nature of this information pack makes it suitable for use across a variety of different age groups, levels of illness severity, and for discharge to a range of different in-hospital destinations.

The pack will be given to the patient (and/or family member as appropriate) by the critical care bedside nurse when the decision to discharge to a ward has been made. Ward nurses will then be involved in providing ongoing information support after discharge to the ward (using the new information pack where relevant).

Outcome measures

The primary outcome measure will be sense of psychological well being, measured using the Hospital Anxiety and Depression Scale (HADS) score (Zigmond and Snaith, 1983). Patient perceptions of coping, self-efficacy and sense of empowerment will also be measured in order to determine the factors (upon which the intervention is focused) that might impact on psycho-social wellbeing. Other secondary outcome measures will include length of hospital stay and rates of readmission to critical care in order to provide some insight into whether improvement in psycho-social well being impacts on physical health outcomes. In addition, feasibility from the perspective of patients, family members, critical care and ward nurses will be assessed providing some evidence as to whether the intervention, if effective, is likely to be utilised in real world clinical practice. Finally, the patient and relative experience will be explored in order to allow identification of

previously unknown and/or unconsidered issues of relevance as to whether the intervention is likely to be effective.

Data collection tools

Psychological well-being will be assessed using HADS for both patients and identified family members. HADS is a self-assessment screening tool, designed to detect depression and anxiety (Zigmond and Snaith, 1983), which has been extensively validated (Bjelland et al, 2002). A total score >8 for either depression or anxiety indicates the presence of disorder. In addition, coping, self-efficacy and empowerment assessment tools will be used to further assess psychological well-being.

Questionnaires will be used to assess patients' and relatives' perception of their discharge experience and to determine the feasibility of the intervention from the perpsective of patients, relatives and ward/critical care nurses. Questionnaire items reflect key themes identified from a previous focus group study. User groups (consisting of participants from a phase I focus group study and two user support groups) will be used to test the validity and reliability of questionnaires prior to use.

Hospital databases and medical records will provide access to information related to patient and family demographics, relevant past medical history (including a history of depression or anxiety), admitting diagnosis, patient illness severity, length of critical care stay, therapies received, discharge destination and complications pertinent to the critical illness period.

Sample

The sample will be drawn from a single NHS Trust in Central London. Calculation of sample size is based on the primary outcome measure (sense of psychological well being) using the HADS score. There is currently very little information available to enable precise calculation of the required sample size to determine an effect. In a previous RCT by Gammon et al (1996) examining the effect

of information giving in peri-operative patients using HADS as a primary outcome measure, the mean post intervention score was 4.2 for the intervention group (n=41) and 6.8 (range 0-15) for the control group (n=41) (a difference of about 3 points).

Based on the information available to date, using a power of 80%, a minimum of 45 participants in each group are required in order to detect a difference of 3 points on the HADS score in the intervention group (assuming SD=5). This study aims to recruit 200 patients, with a minimum of 50 patients in each group. The same number of data collection days will be employed for each arm of the study. Data collection will continue until a minimum of n=50 is achieved in all groups. Although the number of critical care discharges vary from day to day leading to a potential difference in the final number of participants in each group, randomisation is likely to ensure that overall numbers are not unduly unbalanced between groups. If groups are unbalanced in size we will ensure that we recruit sufficient individuals so that assumptions of the statistical tests to be used remain robust. As long as the minimum number (n=50) are recruited into each group, analysis of outcomes will not be affected. Records of the daily discharge numbers during the trial period will, however, be used during analysis in order to identify any potential influences on results.

Attrition is likely due to a number of factors including death, lack of opportunity to collect all data or participant drop out. Attrition rates will be assessed as data collection progresses, allowing for necessary adjustments in sample size. With an average of one hundred overall unit discharges per month, and by using an over recruitment strategy, a six month intervention period should enable enrolment of at least the minimum number required.

Inclusion criteria

- Adult patients and family members (>18 years)
- Elective or emergency admissions who have been in critical care for at least 72 hours
- Critical Care patients identified for discharge to a general ward setting

- Elective discharges between 08.00-20.00hrs Monday to Friday

Exclusion criteria

- Patients for whom active treatment has been withdrawn
- Inability to verbally communicate in or read English
- Involvement in the phase I focus group study

All critical care and ward nurses (from wards who have received patients discharged from critical care during the study period) will also be invited to participate in part of the study, in order to determine the feasibility of the intervention in real world practice.

Implementation

Preparation

A series of staff training and information sessions will be provided, and all critical care nurses will be encouraged to attend. Details of the intervention and the attention control will be given and instructions provided as to how they should be utilised. A research assistant will be present throughout the recruitment and intervention period to provide ongoing support and instruction.

Randomisation and recruitment

The statistician will provide a computer generated list of random numbers, which will be used to determine the days on which the intervention, control or 'attention control' methods will be used. A clerical assistant will make up three separate types of sealed information packs labelled with the dates that each is to be used. These packs will be left in the clinical area and their distribution co-ordinated by the research assistant.

The research assistant will screen patients due for discharge from critical care on a daily basis by liaison with the nurse in charge. Those who meet the inclusion criteria will be invited to participate and provided with a participant information form and verbal study information (this will be carried out either by phone or during visiting for

family members). Only one identified family member from each patient will be recruited into the study.

Consent

No less than 4 hours after receipt of the participant information sheet, the research assistant will seek patient consent. Only after consent has been obtained will they be recruited into the study. Capacity to provide informed consent will be determined by the research assistant (who holds a professional healthcare registration) using the MacArthur Competence Assessment tool for clinical research (MacCAT-CR) (Appelbaum and Grisso, 2001). If patients are unable to provide informed consent prior to critical care discharge, advice will be sought from a personal consultee. If a personal consultee is not available, a member of care staff unconnected to the project, who is most likely to know what the individual might have chosen had they retained capacity, will act as the nominated consultee in the event of no personal consultee being available (Code 9 of Mental Capacity Act). Assessment of capacity and consent will be repeated prior to data collection. Any data already collected from those who refuse consent at this point will be discarded.

Delivery of intervention

Recruited participants (patients and relatives) will be clustered by day of patient discharge, with all those identified for discharge on the same day (and their relative) allocated to receive either the intervention (UCCDIP), control (usual information strategy) or 'attention control' (discharge booklet) information delivery method. The research assistant will ensure the appropriate information pack is selected and will assist bedside nurses to use it correctly. The research assistant will also record the number of discharges from the unit on each weekday during the trial period, and any potential cross contamination.

Data collection

The data collector will assist recruited patients and family members to complete the HADS, coping, self efficacy and empowerment assessments after one week on the general ward, and again at one month or on discharge from hospital, whichever is sooner. User experience questionnaire data will also be collected from participants at

the one month/hospital discharge point. The data collector will be blinded to the group into which participants have been randomised. At the end of the trial period, feasibility questionnaires will be placed in the post trays of all nursing staff in critical care and on wards where patients participating in the study have been discharged. A box for posting completed questionnaires will be provided in each area.

The research assistant will access databases and patient notes in order to record relevant retrospective and prospective information throughout the trial period as detailed above.

Withdrawal

All recruited participants who withdraw will be followed up (where possible), and with their consent, reasons for withdrawal and any data collected up to the point of withdrawal will be included in the final analysis.

Data analysis

Objectives 1 and 2:

Groups will be compared in terms of HADS, length of hospital stay after critical care discharge and other similar measures. Techniques used will include Analysis of Variance (ANOVA) with co-variates as necessary, and with possible transformation of the data, for example ranking. For binary measures such as readmission to critical care rates, logistic regression will be considered. A number of concomitant variables, from both patient and relative data, will be drawn from the hospital database, patients' medical records and relative questionnaires and will inform the above analyses.

The goal will be to determine what effects (if any) the intervention has had, and how consistent any effects have been. This data will then inform the power calculation to determine the necessary sample size for a phase III trial. Maintenance of time records will enable checking for any drift over time induced by any of the interventions.

Different group sizes will NOT 'skew' the results. Except in laboratory studies (and not always then) equal sample size is impossible; such a requirement would invalidate most research. We will be comparing averages or typical values and all tests standardise against varying sample size. Sample size does affect the power (or sensitivity) of the test, it is not so much the total sample size that matters but the minimum. We have included in our method a strategy of collecting data until each group has at least 50 to ensure that we will have sufficient power. It is preferable (in terms of effort) and fortunately unlikely that the larger group will be much larger than 50. While equal sample sizes are desirable they are not necessary; the tests will continue to correctly assess the p-value

Records of the daily discharge numbers during the trial period will be used during analysis in order to identify any potential influences on results, and the notes kept by the research assistant detailing any potential cross contamination will also be collated and reported.

Objectives 3 and 4:

Categorical variables, from the feasibility and experience questionnaires, will be examined using cross-tabulation and chi-square, and if necessary log-linear modelling. Qualitative data from the free text section of questionnaires will be collated, coded, categorised and key themes identified. Nvivo7 will be used to assist this process.

Dissemination

A lay summary of study findings will be prepared and sent to all participants before their personal details are destroyed. Information about and consent for this is included in the participant information sheet and on the consent/assent forms.

Findings from this study will be used to refine and amend the intervention being studied before further evaluation using a larger multi-site phase III trial takes place. It will also provide data, which will inform the power calculation to determine the necessary sample size for a phase III trial. This should ensure that such a complex intervention is more likely to be effective at this point.

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