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Evaluation of a critical care discharge information pack

Submission date	Recruitment status	[ ] Prospectively registered
20/10/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/10/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/11/2015	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Discharge from critical care (intensive/high dependency care) can cause high levels of anxiety in patients and their family members. Effective information can help reduce this anxiety, but the best way to provide this is currently unclear. This study investigates whether a discharge information pack called UCCDIP can, in comparison to ad-hoc verbal information and/or a standard discharge information booklet, improve the critical care discharge experience and reduce levels of anxiety and depression on the ward.
UCCDIP (User Centred Critical Care Discharge Information Pack) consists of:
1. A 'lay' patient discharge summary
2. Separate sections for core patient and relative information
3. Prompts for patients/families to identify and record individual needs and questions
4. Opportunities for reflection
5. A list of support resources

Who can participate?
Adult patients 18 years and over (and a nominated family member) who have spent over72 hours in a critical care unit and are ready for discharge to a general ward can participate if:
1. They are able to speak, read and understand English.
2. They are for discharge to a ward within King's College Hospital
3. They are medically discharged from critical care Monday-Friday between 08.00-22.00hrs
All those taking part are required to provide informed written consent

What does the study involve?
Verbal or written information about going to the ward will be given by the bedside nurse in critical care. One week after discharge to a ward and again at hospital discharge, patients and family members will be asked to complete questionnaires, which assess their levels of anxiety, depression and coping, and ask about their discharge experience.

What are the possible benefits and risks of participating?
There are no known risks to participants. All participants will receive some form of information about discharge to a general ward, which may reduce their anxiety. Those in the intervention group will additionally receive personalised information, which is expected to enhance recovery.

Where is the study run from?
This is a single centre study taking part at King's College Hospital NHS Foundation Trust, London.

When is the study starting and how long is it expected to run for?
This study started recruiting on 8th August 2011. Recruitment will continue for 6 months or until at least 150 patients have participated.

Who is funding the study?
National Institute of Healthcare Research (NIHR) Research for Patient Benefit (RfPB).

Who is the main contact?
Suzanne Bench (study co-ordinator)
suzanne.bench@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Suzanne Bench

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10091

Study information

Scientific 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: an evaluation of feasibility and effectiveness.

Acronym
UCCDIP

Study objectives
This single centre pragmatic cluster randomised controlled trial (RCT) evaluates the feasibility and effectiveness of a 'user centred critical care discharge information pack' (UCCDIP) designed to help patients better understand their experience and progress, enhance coping and improve psychological well-being of both patients and relatives in the early recovery period.

On 09/05/2012 the overall trial end date was changed from 29/02/2012 to 19/11/2012.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Committee London - Queens Square, 23/12/2010, ref: 10/H0716/75

Study design
Prevention, process of care, interventional, randomised trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Generic Health Relevance, Disease: Critical Care

Interventions
1. Intervention group: receive UCCDIP prior to discharge from critical care, delivered by bedside nurse
2. Control group: receive ad-hoc verbal information from the bedside nurse about discharge to the ward
3. Attention control group: receive an information booklet produced by icuSteps, which includes

information about discharge to the ward and ongoing recovery, given to them by the bedside nurse.
All participants will be followed up until hospital discharge.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Patient hospital anxiety and depression measured one week after critical care discharge and hospital discharge or after 28 days

Secondary outcome measures
1. Feasibility measured after end of trial period
2. Patient and relative coping measured one week post critical care discharge and hospital discharge or after 28 days
3. Patient enablement measured one week post critical care discharge and hospital discharge or after 28 days
4. Relative anxiety and depression measured one week after patient critical care discharge and hospital discharge or after 28 days
5. User experience measured at hospital discharge

Overall study start date
08/08/2011

Completion date
19/11/2012

Eligibility

Key inclusion criteria
1. Adult patients and family members/carers, more than 18 years of age
2. Elective or emergency admissions who have been in critical care (intensive or high dependency care) for at least 72 hours
3. Critical care patients identified for discharge to a general ward setting
4. Elective discharges between the hours of 0800-2200
5. 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
6. Male and female participants

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 200; UK Sample Size: 200; Description: Three groups, each with a minimum of 50 participants

Key exclusion criteria
1. Patients for whom active treatment has been withdrawn
2. Inability to communicate verbally in or read English
3. Involvement in the phase I focus group study

Date of first enrolment
08/08/2011

Date of final enrolment
08/02/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Florence Nightingale School of Nursing and Midwifery
London
United Kingdom
SE1 8WA

Sponsor information

Organisation
King's College London (UK)

Sponsor details
The Florence Nightingale School of Nursing and Midwifery
James Clerk Maxwell Building
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England
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Sponsor type
University/education

Website
http://www.kcl.ac.uk/nursing/index.aspx

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) UK PB-PG-0110-21026

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	27/11/2015	Yes	No