

Education to increase self efficacy for inpatients having rehabilitation after monophasic neurological disability

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Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/04/2015	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0259174356

Study information

Scientific Title

Education to increase self efficacy for inpatients having rehabilitation after monophasic neurological disability

Study objectives

It has been shown that success in rehabilitation is influenced by patient motivation and level of participation in therapy sessions. Self-efficacy refers to ones belief that one can achieve a particular task. The higher the patients self-efficacy, the greater the amount of effort he/she will dedicate to adopting and maintaining health behaviour changes and treatment programmes. We therefore hypothesise that an intervention which enhances a patients self-efficacy in their ability to achieve the goals chosen on the neurological rehabilitation unit would improve participation and outcome in rehabilitation. Our previous work with patients and staff suggest that patient (and carer) education would increase self efficacy, and two popular forms of education in our survey were a group educational session and a video showing the course and progress of previous patients. We plan to assess the impact of these interventions on self efficacy and other variables, for inpatients having rehabilitation following monophasic neurological disability.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Nervous System Diseases: Monophasic neurological disability

Interventions

Data Collected (includes standard non-research data already collected):

1. Demographic details including educational qualifications

2. Age on leaving full time education
3. Diagnoses
4. FIM at admission and discharge

Randomisation:

Patients will be randomly allocated to one of two groups:

1. Education session, NRU video
2. Educational talk, general video

Concealed randomisation will be achieved using sealed, numbered, opaque envelopes kept in a locked separate location by an independent research assistant who carries out the randomisation and conveys patient allocation information to the trialist. All patients will receive usual practice care from the date of admission to the NRU until they have been randomised to a study group.

Interventions: all patients receive a copy of the NRU patient information manual.

Patients and carers randomised to the education session will be invited to attend a group education session run by a physician (CAY), a medical student, and an ex-patient volunteer (hence termed co-researcher), within 2 weeks of admission.

The education session covers:

1. Definition of rehabilitation and the aims of the unit, its staff and ward routines
2. Stages of rehabilitation

Patients and carers in the control group will be invited to attend a group educational talk run by a physician (SpR) and a medical student within 2 weeks of admission.

The control educational talk covers:-

1. Traumatic brain injury epidemiology, common causes, types, common disabilities, prevention
2. Stroke epidemiology, risk factors, types, common disabilities, prevention

Patients and carers randomised to the NRU video or control video will be invited to watch these respective videos within 3 weeks of admission.

The NRU video shows interviews with volunteer ex-inpatients from the NRU, describing their experience of rehabilitation.

The control video is a documentary of recovery from head injury produced for television of equivalent length to the NRU video.

#1-5 are patient-completed questionnaires (completed monthly), #6 involves a brief interview (weekly), #7 is part of standard ward data monitoring, and #8-9 are staff questionnaires. #6, 8 & 9 would be collected each week by medical students involved in the study.

Patient co-researchers, patient involvement in research design and any patient risk.

This research includes collaboration with disabled people who have been previous inpatients in the NRU.

A patient co-researcher will assist with the education session, contributing their experience of NRU routines, stages of rehabilitation etc. They will not be expected to describe their own medical history or convey any personal information.

Patient volunteers are interviewed and filmed to produce a video. No footage from their hospital admission will be shown. Their medical information will be included at their discretion to illustrate their story as they wish to tell it. No names or identifiable information will be included. Carers will participate if they and the patient chooses.

It should be noted that several of our patients have been interviewed by national or local press by choice.

Co-researchers will be invited to participate following discussion between their consultant (CAY), the NRU psychologist and the key worker, if they recover without significant cognitive or psychological morbidity and are able to communicate verbally. To avoid any charge of obligation to participate between patient and consultant, any co-researcher, or individual who declines to be a co-researcher, will be offered transfer for follow up care to Dr Pinder, consultant in rehabilitation medicine, whom they will already have met on the NRU. In fact, our preliminary work described below shows that patients are spontaneously suggesting involvement in patient education or production of a video.

In designing this study we have drawn on a) qualitative interviews with patients, staff and carers [EC127.02; EC04/Q1501/77] & b) requests and suggestions made by patients and carers out with research studies.

The inconvenience and risks to participants are time spent and boredom attending the educational sessions and watching the videos.

All participants will receive feedback of the study results at the close of the project.

Timetable

Months 1-5: pilot

Months 6-20: data collection

Months 21-24: analysis

There will be an interim analysis at M12.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Liverpool self-efficacy scale
2. General self efficacy measure
3. Hospital anxiety and depression scale
4. Patient and carer feedback questionnaire
5. VAS scales on confidence and recovery
6. Interviews on structured day, participation and goal setting, health promotion, use of games room/computer room/groups
7. Goals achieved and variance
8. Participation in therapy
9. Practice with nursing staff

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/02/2006

Completion date

01/02/2008

Eligibility

Key inclusion criteria

1. Adult patients with any monophasic disabling neurological condition admitted to the NRU, and their carer(s) or next of kin providing the patient wishes
2. Informed consent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Not provided at time of registration

Key exclusion criteria

1. Receptive aphasia (shortened form of FAST)
2. Cognitive impairment (MMSE)
3. Unable to understand English
4. Corrected visual acuity 6/36 or worse

Date of first enrolment

01/02/2006

Date of final enrolment

01/02/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

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Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

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Sponsor type

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Funder(s)

Funder type

Government

Funder Name

The Walton Centre for Neurology and Neurosurgery NHS Trust (UK)

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