PERFECTED CRCT: Care of patients experiencing hip fracture & confusion

[X] Prospectively registered Submission date Recruitment status 05/09/2016 No longer recruiting [X] Protocol [] Statistical analysis plan Registration date Overall study status 05/09/2016 Completed [X] Results [] Individual participant data **Last Edited** Condition category 28/02/2025 Mental and Behavioural Disorders

Plain English summary of protocol

Plain English summary under review

Study website

http://www.perfected.ac.uk/

Contact information

Type(s)

Scientific

Contact name

Dr Simon Hammond

Contact details

Norwich Medical School University of East Anglia Norwich Research Park Norwich United Kingdom NR4 7TJ +44 (0)1603 591460 s.hammond@uea.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

31290

Study information

Scientific Title

Enhancing recovery of patients admitted to acute settings with hip fracture who are identified as experiencing confusion: a multi-centre, cluster-randomised controlled, feasibility trial of the PERFECTED Enhanced Recovery (PERFECT-ER) care versus standard acute care

Acronym

PERFECTED CRCT

Study objectives

The aim of this study is to investigate the feasibility of conducting a large scale trial to evaluate the reliability, effectiveness and cost of delivering care via the processes and initiatives set out by the PERFECT-ER intervention.

Ethics approval required

Old ethics approval format

Ethics approval(s)

04/07/2016, ref: 16/LO/0621

Study design

Randomised; Interventional; Design type: Process of Care, Education or Self-Management, Management of Care, Rehabilitation

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

Specialty: Ageing, Primary sub-specialty: Ageing; UKCRC code/ Disease: Neurological/ Other degenerative diseases of the nervous system

Interventions

Ten hospitals from five regions will be assigned either active or control status (five hospitals per arm). Each region will have two hospitals, one active and one control. Active arm study hospitals

will implement the PERFECT-ER intervention on a single acute trauma ward. Control arm study hospitals will select a single acute trauma ward and deliver treatment as usual in that setting.

Intervention Type

Other

Primary outcome measure

Feasibility outcomes:

- 1. Recruitment rate
- 2. Retention rate

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/11/2016

Completion date

31/07/2018

Eligibility

Key inclusion criteria

- 1. Patient must have had a confirmed proximal hip fracture requiring an operation and be aged 60 or older at time of operation
- 2. Patient has a pre-op AMTS of 8 or below (including those with 0 because of an inability to answer questions)
- 3. Patient must have a 'suitable informant' (e.g. relative, unpaid or paid carer, care home manager) who has a minimum of once a week face-to-face contact with the patient and is able, and consents to, provide information on proxy measures
- 4. Patient and a 'suitable informant' must be recruited into the trial within 5 days of the hip fracture operation
- 5. Patient must spend a minimum of 5 days on the study ward

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 800; UK Sample Size: 800

Total final enrolment

282

Key exclusion criteria

- 1. Decision taken not to have hip surgery
- 2. Patient not expected to survive beyond 4 weeks and therefore it is unlikely that follow-up data will be collected

Date of first enrolment 01/11/2016

Date of final enrolment 31/01/2018

Locations

Countries of recruitment

England

Scotland

United Kingdom

Study participating centre Norfolk and Norwich University Hospital

Colney Lane Norwich United Kingdom NR4 7UY

Study participating centre Ipswich Hospital

Heath Road Ipswich United Kingdom IP4 5PD

Study participating centre Royal Infirmary of Edinburgh

51 Little France Crescent Edinburgh United Kingdom EH16 4SA

Study participating centre Victoria Hospital Hayfield Road

Kirkcaldy United Kingdom KY2 5AH

Study participating centre Royal Derby Hospital Uttoxeter Road

Derby United Kingdom DE22 3NE

Study participating centre Princess Royal University Hospital

Farnborough Common Orpington United Kingdom BR6 8ND

Study participating centre King's College Hospital

Denmark Hill London United Kingdom SE5 9RS

Study participating centre Pinderfields Hospital

Aberford Road Wakefield United Kingdom WF1 4DG

Study participating centre The York Hospital

Wigginton Road York United Kingdom YO31 8HE

Study participating centre Leicester Royal Infirmary

Infirmary Square Leicester United Kingdom LE1 5WW

Sponsor information

Organisation

University of East Anglia

Sponsor details

Norwich Research Park Norwich England United Kingdom NR4 7TJ

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/026k5mg93

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

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

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	04/12/2017		Yes	No
Results article		28/02/2022	28/10/2022	Yes	No
Other publications	Process evaluation	03/02/2023	06/02/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 4.0	03/05/2017	03/12/2024	No	Yes