

Acute medical unit comprehensive geriatric assessment intervention study

Submission date 27/07/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/07/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/05/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

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
8368

Study information

Scientific Title

Acute medical unit comprehensive geriatric assessment intervention study: a multicentre randomised interventional process of care trial

Acronym

AMIGOS

Study objectives

Most hospitals have an acute medical unit (AMU), a central admissions ward designed to look after unwell patients 24 hours per day, 365 days per year. Many older people attend AMUs, but are not admitted to the main hospital wards and so return home within a day or two. Many people sent home have ongoing issues, and some return to hospital or even die in the year following their original attendance. This may be partly due to a lack of comprehensive coordinated care. This research is part of a programme of research to develop and evaluate comprehensive, coordinated care for such people.

We will do this by recruiting approximately 600 patients aged 70 years or over attending and discharged from AMUs in Nottingham and Leicester; they will all be at high risk of adverse outcomes. We will collect baseline information about their health, disability and mental health. Participants will then be allocated to either the intervention (specialist geriatric care) or the usual care group. The decision as to which group participants go into is worked out by chance, just like tossing a coin (randomisation). This is a common technique used in studies of this type.

Those in the usual care group will go home, and will have access to GPs, community therapy teams etc. Those receiving specialist geriatric care will also be assessed and followed up in the community by a geriatrician. The geriatric assessment will focus on common problems, such as falls, incontinence, medication and for some, end of life issues. We will then measure participants' health and use of resources three months later. We will also measure the levels of strain and quality of life of the carers of these patients, at baseline and at follow up. The results of this study will help us better design services for older people.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Nottingham Research Ethics Committee 1, 20/04/2010, ref: 10/H0403/1

Study design

Multicentre randomised interventional process of care trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

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

Topic: Mental Health Research Network; Subtopic: All Diagnoses; Disease: Not Applicable

Interventions

Comprehensive Geriatric Assessment:

Once consent and the baseline data and beside measurements have been collected, the participants will be allocated to the intervention or the control arm (usual care), using an internet based randomisation procedure. Those allocated to usual care will go home as planned. Those allocated to the interface geriatrician will be reviewed by a geriatrician prior to being discharged. The geriatrician will reassess their clinical care, focusing on geriatric syndromes, such as polypharmacy (multiple medications).

Follow-up length: 3 months

Study entry: single randomisation only

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Number of days spent at home over 90 days of follow up, defined as 90 days or the number of days from discharge until death, minus the number of days spent in residential intermediate care units, days in hospital due to unplanned readmission (community hospital, psychiatric hospital or other acute hospital), or the number of days spent in a new care home placement.

These outcomes will be ascertained from a variety of existing databases, including primary care, social care and secondary care systems. The validity of this approach will be tested in the pilot phase, comparing self reported days at home against those recorded in the various databases.

Secondary outcome measures

Outcomes will be collected at 90 days and will include an array of validated outcomes, which will be ascertained by examination of the above databases, by postal questionnaire or by individual interviews if required:

1. Death
2. Institutionalisation
3. Hospital use (Emergency Department, AMU admissions, clinics)
4. Personal Activities of Daily Living (Barthel ADL Index)
5. Self reported falls over previous 90 days
6. Medication audit against STOPP/START criteria at 90 days
7. Psychological wellbeing (General Health Questionnaire [GHQ12])
8. Quality of life (EuroQoL EQ5D) and ICECAP

- 9. Resource use
- 10. Carer strain: Caregiver Strain Index
- 11. Carer generic quality of life: EuroQol EQ5D
- 12. Carer specific quality of life: CQLIR

Overall study start date

15/06/2010

Completion date

31/01/2013

Eligibility

Key inclusion criteria

Patient participant:

1. Attending and being discharged from the Acute Medical Unit at Queen's Medical Centre, Nottingham or Leicester Royal Infirmary, Leicester
2. Aged 70 years or over, either sex
3. Identified as being at high risk of adverse outcomes using the Identification of Seniors At Risk (ISAR) score

When the decision to discharge the patient has been made, usually by duty consultant, the Multidisciplinary Team responsible for making the discharge arrangements will identify all those who are 70 years old or over who score positive on the ISAR score and are living within the usual catchment area of the hospital and indicate them to the study researcher. Patients with potential exceptional reasons for non-recruitment will be discussed with the researcher. These methods have worked successfully in a related cohort study run on the unit in Nottingham already.

Carer participant:

4. Identified as carer of a patient participant; any carer present with the patient participant will be invited to be a carer participant for the study. If a carer participant is not present on the AMU but known to exist, an invitation and information sheet, consent form and questionnaire will be given to the patient participant.

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

Planned sample size: 600

Key exclusion criteria

1. Patient without capacity where there is no consultee available
2. Any exceptional reason cited by the AMU should not be recruited (e.g. dangerous)
3. Patient not resident in normal hospital catchment area

Date of first enrolment

15/06/2010

Date of final enrolment

31/01/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Queens Medical Centre

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

University of Nottingham (UK)

Sponsor details

Kings Meadow Campus

Lenton Lane

Nottingham

England

United Kingdom

NG7 2NR

Sponsor type

University/education

Website

<http://www.nottingham.ac.uk/>

ROR

<https://ror.org/01ee9ar58>

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Programme Grant for Applied Research (PGfAR) (ref: RP-PG-0407-10147)

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?
Protocol article	protocol	24/08/2011		Yes	No
Results article	results	08/10/2013		Yes	No
Results article	results	01/05/2015		Yes	No
Results article	economic evaluation results	05/05/2015		Yes	No