ISRCTN21800480 https://doi.org/10.1186/ISRCTN21800480

# Acute medical unit comprehensive geriatric assessment intervention study

**Submission date**
27/07/2010

**Recruitment status**
No longer recruiting

**Registration date**
27/07/2010

**Overall study status**
Completed

**Last Edited**
15/05/2015

**Condition category**
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof John Gladman

**Contact details**
Division of Rehabilitation and Ageing
Medical School
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH
-
john.gladman@nottingham.ac.uk

## Additional identifiers

**Protocol serial number**
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

## Study type(s)
Treatment

## 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(s)
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.

### Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Senior

### Sex
All

### 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
United Kingdom

England

**Study participating centre**
**Queens Medical Centre**
Nottingham
United Kingdom
NG7 2UH

# Sponsor information

**Organisation**
University of Nottingham (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

## 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 | 08/10/2013 | | Yes | No |
| Results article | results | 01/05/2015 | | Yes | No |
| Results article | economic evaluation results | 05/05/2015 | | Yes | No |
| Protocol article | protocol | 24/08/2011 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |