The CareFile Project: An assessment of the impact of individualised information booklets in patients post stroke

Submission date	Recruitment status No longer recruiting	Prospectively registered		
11/09/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
17/11/2005	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
15/07/2010	Circulatory System			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Deborah Lowe

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

- 1. Potential to improve stroke knowledge following the implementation of an individualised information booklet
- 2. Assessment of new information tool and stroke knowledge assessment tool

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval was obtained from the local Research Ethics Committee

Study design

Randomised controlled feasibility trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Stroke

Interventions

Individualised information booklets.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Knowledge of stroke risk factors and secondary prevention.

Secondary outcome measures

- 1. Satisfaction with information given
- 2. Utilisation of CareFile
- 3. Blood pressure targets

Overall study start date

01/04/2000

Completion date

01/03/2001

Eligibility

Key inclusion criteria

- 1. Confirmed stroke
- 2. All ages
- 3. Either sex
- 4. Patients who are discharged home and who can self complete a questionnaire, or who have a named carer who can do so

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

100

Key exclusion criteria

- 1. Patients with pre-existing cognitive impairment
- 2. Patients who are discharged to institutionalised care
- 3. Patients who are discharged home and who cannot complete questionnaires and have no other named carer who can do so

Date of first enrolment

01/04/2000

Date of final enrolment

01/03/2001

Locations

Countries of recruitment

England

United Kingdom

Study participating centre c/o Stroke Research Office

Liverpool United Kingdom L7 7AL

Sponsor information

Organisation

University Hospital Aintree Research and Development (UK)

Sponsor details

University Hospital Aintree Longmoor Lane Liverpool England United Kingdom L7 7AL

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/008j59125

Funder(s)

Funder type

Industry

Funder Name

Aintree Trust (UK) - Research and Development

Funder Name

Bristol-Myers Squibb (UK) - Research Grant

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	01/01/2007		Yes	No