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Individual Risk Awareness Intervention in Stroke

Submission date 05/08/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 13/10/2010	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 30/09/2016	**Condition category** Circulatory System	[ ] Individual participant data [ ] 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
SLAJ2002

Study information

Scientific Title
To improve adherence to secondary prevention strategies in a high risk stroke population: a randomised controlled trial

Acronym
IRAIS

Study objectives
Improving patients perception of their risk of secondary stroke and heart disease at the time of their first event may improve the likelihood of adherence to secondary prevention strategies such as medication taking and lifestyle modification.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East London Research Ethics Committee, 09/04/2010

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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
Stroke

Interventions
Total participation in the trial for both arms is 3 months or until they have been seen in follow-up once. Both arms will complete a questionnaire collecting demographic information, physiological factors and questions relating to awareness of risk and personal stroke knowledge. The intervention arm receives a 1:1 session for approximately 20 minutes which includes a personalised risk score % for secondary stroke. The control arm receives usual routine practice which involves a 1:1 session with a clinical nurse specialist providing information on stroke.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Another stroke event in 3 months
2. Evidence of adherence to secondary prevention lifestyle modifications at 3 month follow-up through patient self reporting and physiological testing in the intervention arm compared to the control arm of the randomised controlled trial

Secondary outcome measures
Risk score reduction through lifestyle modification at 3 month follow-up

Overall study start date
01/05/2010

Completion date
01/06/2010

Eligibility

Key inclusion criteria
1. Diagnosis of any stroke
2. Aged 18+ years, either sex
3. Cognitively intact in order to understand future consequences of actions to reduce risk
4. Discharge Stroke Scale score of up to and over 40

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
238

Key exclusion criteria
Patients unlikely to survive or be able to attend for the 3 month follow-up consultation

Date of first enrolment
01/05/2010

Date of final enrolment
01/06/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Charing Cross Hospital
London
United Kingdom
W6 8RF

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
c/o Ms Michelle Quaye
Research Governance Manager
London
England
United Kingdom
W6 8RF

Sponsor type
University/education

Website
http://www3.imperial.ac.uk/

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

Imperial College Healthcare NHS Trust (UK) - Hammersmith Hospitals Trustees Research Committee Award

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