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# Decision Analysis in Routine Treatment II: a randomised controlled trial (efficacy study) of a decision aid to support shared decision making for patients with atrial fibrillation

**Submission date**
06/11/2002

**Recruitment status**
No longer recruiting

**Registration date**
06/11/2002

**Overall study status**
Completed

**Last Edited**
27/11/2012

**Condition category**
Circulatory System

[_] Prospectively registered
[_] 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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

### ClinicalTrials.gov number

### Secondary identifying numbers
065131

# Study information

### Scientific Title

### Acronym
DARTS II

### Study objectives
To determine the efficacy of implicit and explicit decision support tools in reducing decision conflict under ideal circumstances.

To support design of a subsequent multi-centre pragmatic randomised controlled trial.

The initial study design was a three arm open randomised controlled trial comparing explicit and implicit decision support tools with paper based guidelines. The explicit arm was discontinued in October 2003.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Multicentre, randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Other

### Study type(s)
Not Specified

### Participant information sheet

### Health condition(s) or problem(s) studied
Atrial fibrillation

### Interventions

Patients randomised to one of three interventions:
1. Explicit DARTS tool - full shared decision making tool
2. Implicit DARTS tool - shortened version of shared decision making tool
3. Evidence based guidelines group - control arm

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
The primary outcome measure is the decision conflict scale. Prior to clinic attendance patients will complete scales on decision conflict, their choice predisposition, knowledge, decision making preference, general anxiety and risk factors/demographic information.

Immediately following the clinic, patients will complete scales on decision conflict, knowledge, decision making role experienced, and anxiety.

At three months, patients will be sent follow-up postal questionnaires including the decision conflict scale, decision making preference scale and the knowledge scale.

### Secondary outcome measures
No secondary outcome measures

### Overall study start date
01/11/2001

### Completion date
30/11/2004

## Eligibility

### Key inclusion criteria
Patients aged over 60 with non-valvular atrial fibrillation on aspirin, warfarin or no anti-thrombotic treatment

### Participant type(s)
Patient

### Age group
Senior

### Sex
Both

### Target number of participants
109

### Key exclusion criteria

1. Acute onset requiring cardiological referral for consideration of cardioversion
2. Had a previous stroke or Transient Ischaemic Attack (TIA)
3. Have absolute contraindications to warfarin
4. Suffer from dementia or cognitive impairment sufficient to hinder shared decision making

### Date of first enrolment
01/11/2001

### Date of final enrolment
30/11/2004

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
### School of Population and Health Sciences
Newcastle upon Tyne
United Kingdom
NE2 4HH

## Sponsor information

### Organisation
Newcastle upon Tyne Hospitals NHS Trust (UK)

### Sponsor details
Research and Development Department
Room 3, The Bridge, Peacock Hall
Royal Victoria Infirmary
Queen Victoria Road
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### Sponsor type
Hospital/treatment centre

### Website

http://www.newcastle-hospitals.org.uk/

**ROR**
https://ror.org/05p40t847

# Funder(s)

**Funder type**
Charity

**Funder Name**
The Wellcome Trust (UK) (grant ref: 065131)

# 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 | 01/06/2007 | | Yes | No |
| Results article | Results of qualitative process evaluation | 01/06/2007 | | Yes | No |