

# Randomised controlled trial (RCT) of dietary intervention to sustain sinus rhythm in patients following initiation of treatment for atrial fibrillation or flutter

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<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 26/10/2018	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

RHC11281

# Study information

## Scientific Title

Randomised controlled trial (RCT) of dietary intervention to sustain sinus rhythm in patients following initiation of treatment for atrial fibrillation or flutter

## Study objectives

Effectiveness of policy of providing dietary instruction to eat oil rich fish to maintain sinus rhythm.

To increase sustained sinus rhythm following cardioconversion in patients to be cardioverted for atrial fibrillation or flutter.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

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

Atrial fibrillation and flutter

## Interventions

1. Addition of fish oil to the diet
2. Maintenance of normal diet

## Intervention Type

Other

## Phase

Not Specified

**Primary outcome measure**

The primary outcome measure will be the number of patients in sustained sinus rhythm for a period of 12 months.

**Secondary outcome measures**

1. Mortality associated with coronary heart disease
2. All mortality
3. Coronary heart disease related morbidity & number of strokes
4. Quality of life assessment
5. Suitability of dietary instructions
6. The patients perception of any change in weekly shopping bills
7. An economic analysis through consultation with a Health Economist.

**Overall study start date**

01/07/1998

**Completion date**

01/07/2002

**Eligibility****Key inclusion criteria**

Inpatients and outpatients aged 18 years and above, recently diagnosed as having atrial fibrillation or flutter, as determined by electrocardiogram (ECG).

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Not provided at time of registration

**Key exclusion criteria**

Does not match inclusion criteria

**Date of first enrolment**

01/07/1998

**Date of final enrolment**

01/07/2002

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

**Wigan & Bolton Health Authority**

Wigan

United Kingdom

WN1 1AH

# Sponsor information

## Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

## Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

## Sponsor type

Government

## Website

<http://www.doh.gov.uk>

# Funder(s)

## Funder type

Government

## Funder Name

NHS Executive North West (UK)

# 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?
<a href="#">Protocol article</a>	protocol	01/01/2005		Yes	No