# A pragmatic randomised controlled trial of the Welsh National Exercise Referral Scheme

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>		
18/05/2010	No longer recruiting	[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
28/05/2010	Completed	[X] Results		
<b>Last Edited</b> 15/09/2014	Condition category Circulatory System	[] Individual participant data		

### Plain English summary of protocol

Not provided at time of registration

# **Contact information**

## Type(s)

Scientific

#### Contact name

Dr Simon Murphy

#### Contact details

Cardiff Institute of Society and Health School of Social Sciences Cardiff University Cardiff United Kingdom CF10 3BD

## Additional identifiers

Protocol serial number 146/2005

# Study information

#### Scientific Title

A randomised controlled trial of the effectiveness of an exercise referral scheme in increasing physical activity in inactive men and women aged 16+ with coronary heart disease risk factors and / or mild to moderate depression, anxiety or stress

#### **Study objectives**

Is a national exercise referral scheme more effective in increasing on physical activity and improving mental health in inactive men and women aged 16+ with coronary heart disease risk factors and / or mild to moderate depression, anxiety or stress compared to the provision of an information leaflet and normal care at 12 months follow up?

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

The Thames Valley Multi-centre Research Ethics Committee (MREC), 08/02/2007, ref: 06/MRE12/85

#### Study design

Single centre pragmatic randomised controlled trial with blind assignment to intervention (exercise referral) or control trial arm (normal care and leaflet) and masked intervention delivery

#### Primary study design

Interventional

#### Study type(s)

Treatment

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

Coronary heart disease risk factors and / or mild to moderate depression, anxiety or stress

#### **Interventions**

A 16 week intervention consisting of an initial and exit consultation with an exercise profession and access to weekly one to one discounted exercise instruction and/or group exercise classes for the period.

Participants in the control group receive a leaflet and normal care.

## Intervention Type

Other

#### Phase

Not Applicable

## Primary outcome(s)

Total minutes of weekly activity using the seven day physical activity recall questionnaire (7-DAY PAR)

## Key secondary outcome(s))

The Hospital Anxiety and Depression Scale (HADS) to assess depression and anxiety, measured at 12 months

#### Completion date

31/10/2008

# **Eligibility**

#### Key inclusion criteria

Sedentary male and females aged 16+ with coronary heart disease risk factors and / or mild to moderate depression, anxiety or stress

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### Key exclusion criteria

- 1. Unstable angina
- 2. Blood pressure 180/100 (in either) or above and/or uncontrolled or poorly controlled hypertension
- 3. Cardio myopathy
- 4. Uncontrolled tachycardia
- 5. Cardiac arrhythmia
- 6. Valvular heart disease
- 7. Congenital heart disease
- 8. Unexplained dizzy spells
- 9. Excessive or unexplained breathlessness on exertion
- 10. Uncontrolled or poorly controlled diabetes
- 11. Uncontrolled or poorly controlled epilepsy
- 12. History of falls or dizzy spells in the last 12 months
- 13. Uncontrolled or poorly controlled asthma (severe COPD)
- 14. First 12 weeks of pregnancy
- 15. Awaiting medical investigation
- 16. Aneurysms
- 17. Cerebro-vascular disease
- 18. Unstable/newly diagnosed angina (within 6 months)
- 19. Established coronary heart disease (including myocardial infarction)
- 20. Any other uncontrolled condition

#### Date of first enrolment

01/07/2007

#### Date of final enrolment

31/10/2008

# Locations

#### Countries of recruitment

**United Kingdom** 

Wales

Study participating centre
Cardiff Institute of Society and Health
Cardiff
United Kingdom
CF10 3BD

# Sponsor information

#### Organisation

Welsh Assembly Government (UK)

#### **ROR**

https://ror.org/000wh6t45

# Funder(s)

## Funder type

Government

#### **Funder Name**

Welsh Assembly Government (UK) (tender contract number: 146/2005)

# **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 adde	d Peer reviewed	? Patient-facing?
Results article	results	01/08/2012	Yes	No
Results article	results	29/10/2013	Yes	No

secondary analysis results

Results article		27/08/2014	Yes	No
<u>Protocol article</u>	protocol	18/06/2010	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025 No	Yes