

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

Submission date 18/05/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 28/05/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 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

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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

Primary study design

Interventional

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

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 added	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
Protocol article	protocol	18/06/2010	Yes	No