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

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

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet.

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

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

Overall study start date
01/07/2007

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

Age group
Adult

Sex
Both

Target number of participants
2,104

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)

Sponsor details
Social Research Division (Yr Is-Adran Ymchwil Gymdeithasol)
Department of the First Minister and Cabinet (Adran y Prif Weinidog ar Cabinet)
Welsh Assembly Government (Llywodraeth Cynulliad Cymru)
Cardiff
United Kingdom
CF10 3NQ

Sponsor type
Government

ROR
https://ror.org/000wh6t45

Funder(s)

Funder type
Government

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

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?
Protocol article	protocol	18/06/2010		Yes	No
Results article	results	01/08/2012		Yes	No
Results article	results	29/10/2013		Yes	No
Results article	secondary analysis results	27/08/2014		Yes	No