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The development and preliminary testing of a self-determination centred exercise consultation training program

Submission date	Recruitment status	[_] Prospectively registered
02/08/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/09/2014	Signs and Symptoms	

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

Version 2

Study information

Scientific Title

Acronym
EMPOWER

Study objectives
1. To determine the effect of the present Exercise on Prescription (EoP) scheme operating in Birmingham on participants' self-reported Physical Activity (PA), associated health behaviours, physical health, and well-being/quality of life at three months and a six-month follow-up
2. To develop a Self Determination Theory-based (SDT) training program for Birmingham health and fitness advisors
3. To determine the effect of the SDT-based (EoP) scheme on participants' self-reported Physical Activity (PA) associated health behaviours, physical health, and well-being/quality of life at three months and a six-month follow-up
4. To compare the effect (at three and six months) of an exercise consultation delivered by SDT-trained health and fitness advisors with an exercise consultation provided by currently trained health and fitness advisors in Birmingham on participants' self-reported physical activity, associated health behaviours, physical health, and well-being/quality of life
5. To examine in an exploratory manner, potential differential effects of the EoP scheme where taught by SDT trained versus control health and fitness advisors as a function of the gender/age, ethnicity, and socio-economic status of the participant

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Birmingham School of Sport and Exercise Sciences Ethics Sub-Committee, 25/07/2007, ref: LE 07/22

Study design
Pragmatic cluster randomised control trial of standard exercise on prescription with a self-determination theory-based exercise on prescription

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
General population under 65 that are sedentary with risk factors, for example CHD, diabetes, high blood pressure, mild depression.

Interventions
The intervention spans a three month period during which a health and fitness advisor has one-to-one contact in person (at leisure centres) or via telephone with the participant four times. The advisors will be informed of the principles of self-determination theory and trained to employ particular strategies targeting the promotion of self-determined motivation for behavioural change in the participant.

Following the baseline assessment of the primary and secondary outcomes, the initial consultation will comprise a one hour one-to-one person centred interview and, consistent with the EoP scheme, have the option of a fitness appraisal. At this time, participants will also be given a booklet designed to encourage self-management of physical activity initiation. At one month, the next contact (15 - 20 minutes) will be conducted via telephone or face-to-face. The discussion will be reinforcing successful physical activity engagement attempts and providing strategies for enhancing exercise efficacy. At two months, a brief (5 minute) phone call or face-to-face contact by the advisor will be made to offer encouragement regarding attempts to be physically active. At three months, primary and secondary outcomes will be re-assessed and a final face-to-face "booster" consultation (20 - 30 minutes) will take place focused on recognising and reinforcing the internalisation of the participant's physical activity involvement. Again, the option of a fitness appraisal will be made available. A supplemental self-management booklet centred on the monitoring and maintenance of physical activity will also be provided at this time.

Participants in the control group will be provided with the standard EoP program.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Self-reported physical activity using the 7-day Physical Activity Recall (PAR), a structured interview that has been extensively validated against objective measures. Both estimated overall energy expenditure and time spent in vigorous and moderate intensity physical activity will be calculated for all participants at three time points (baseline, 3 months and 6 months).

Secondary outcome measures
1. Associated health behaviours: smoking, alcohol consumption, fruit/vegetable intake with brief self-report measures
2. Physical health outcomes: Body Mass Index (BMI), Blood Pressure (BP)
3. Health related quality of life using the Dartmouth Co-op Charts
4. Anxiety and depression measured by the Hospital Anxiety and Depression Scale
5. Vitality using the Subjective Vitality Scale (Ryan and Frederick)
6. Intention to increase physical activity, at baseline and three months only
7. Motivation and processes of change: perceptions of autonomy support from the Advisor, perceived efficacy, autonomy, social connectedness with respect to physical activity, and

motivational regulations for exercise using validated scales (the Behavioural Regulation in Exercise Questionnaire [BREQ-2], the Health care Climate Questionnaire, Wilsons Need Questionnaire)

All secondary outcomes measured at baseline, three months and six months (apart from point 6 above, measured at baseline and three months only).

Overall study start date
01/09/2007

Completion date
31/03/2009

Eligibility

Key inclusion criteria
1. General population under 65 that are sedentary with risk factors, for example Coronary Heart Disease (CHD), diabetes, high blood pressure, mild depression
2. Referred by General Practitioners (GPs) to the Birmingham Exercise on Prescription Scheme

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
500

Key exclusion criteria
1. Angina pectoris
2. Moderate to high (or unstable) hypertension: 160/102 mmHg or above
3. Poorly controlled insulin-dependant diabetes
4. History of myocardial infarction within the last six months unless the patient has completed Stage III cardiac rehabilitation
5. Established cerebro-vascular disease
6. Severe chronic obstructive airways disease
7. Uncontrolled asthma

Date of first enrolment
01/09/2007

Date of final enrolment
31/03/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Sport and Exercise Sciences
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
South Birmingham Primary Care Trust (UK)

Sponsor details
c/o Susan Stokes
Assistant Director of Public Health
Moseley Hall Hospital
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England
United Kingdom
B13 8JL

Sponsor type
Hospital/treatment centre

Website
http://www.southbirminghampct.nhs.uk/

Funder(s)

Funder type
Government

Funder Name
Heart of Birmingham Teaching Primary Care Trust (UK)

Funder Name
Birmingham East and North Primary Care Trust (UK)

Funder Name
South Birmingham Primary Care Trust (UK)

Funder Name
Birmingham City Council (UK)

Funder Name
Birmingham Health and Wellbeing Partnership (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?
Protocol article	protocol	08/06/2009		Yes	No
Results article	results	29/01/2014		Yes	No