

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

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|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>02/08/2007   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>12/09/2007 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>29/09/2014       | <b>Condition category</b><br>Signs and Symptoms   | <input type="checkbox"/> 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**  
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

## **Primary study design**

Interventional

## **Study design**

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

## **Study type(s)**

Quality of life

## **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(s)**

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).

## **Key secondary outcome(s)**

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).

## **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

School of Sport and Exercise Sciences

Birmingham

United Kingdom

B15 2TT

**Sponsor information**

**Organisation**

South Birmingham Primary Care Trust (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****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="#">Results article</a>  | results  | 29/01/2014   |            | Yes            | No              |
| <a href="#">Protocol article</a> | protocol | 08/06/2009   |            | Yes            | No              |

