

# Pilot study to assess the feasibility of running a randomised controlled trial to evaluate the effectiveness of physical activity promotion in general practice in increasing levels of exercise and reducing mental health problems among adolescents

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Stopped	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/09/2011	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Ms Fiona Brooks

### Contact details

CRIPACC

University of Hertfordshire

Hatfield, Herts

United Kingdom

AL10 9AB

+44 (0)1707 285992

f.m.brooks@herts.ac.uk

## Additional identifiers

EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N0096112100

## **Study information**

**Scientific Title**

**Study objectives**

Pilot to assess the feasibility of running a large-scale trial to evaluate the effectiveness of nurse-led consultations in promoting adolescent physical activity.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics approval was received from the local medical ethics committee before trial recruitment began.

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Not Specified

**Participant information sheet**

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

Mental and Behavioural Disorders

**Interventions**

Teenagers will be invited to complete questionnaires about their exercise and other health related behaviours. Those who report that they do not exercise regularly will be randomised to one of two groups.

The intervention group will be invited to a consultation with their practice nurse to discuss exercise and related lifestyle. The nurse will record physical health measures and encourage the

teenager to develop a detailed written plan to achieve self-selected physical activity goals. Vouchers will be provided to encourage increased use of local sports centres. The nurse will also provide telephone support.

Control teenagers will receive usual care.

After 4 months both intervention and control group teenagers will be invited to complete a follow-up questionnaire and attend a brief health-check with their practice nurse. Non-attenders will be sent a final follow-up questionnaire at home.

Added 5 September 2008: trial stopped due to poor recruitment.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

Group comparison in terms of:

1. Frequency of exercise
2. Stage of change for exercise
3. Change in mental health scores (CES-DC)
4. Physical health measures (body mass index [BMI], peak flow, blood pressure)

### **Secondary outcome measures**

Not provided at time of registration

### **Overall study start date**

01/08/2002

### **Completion date**

31/10/2004

## **Eligibility**

### **Key inclusion criteria**

Patients aged 13-17, 1400 in total registered at three general practices in Hertfordshire.

### **Participant type(s)**

Patient

### **Age group**

Child

### **Lower age limit**

13 Years

### **Upper age limit**

17 Years

**Sex**

Not Specified

**Target number of participants**

1400

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/08/2002

**Date of final enrolment**

31/10/2004

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre****CRIPACC**

Hatfield, Herts

United Kingdom

AL10 9AB

## **Sponsor information**

**Organisation**

Department of Health (UK)

**Sponsor details**

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

**Sponsor type**

Government

**Website**

<http://www.doh.gov.uk>

# Funder(s)

## Funder type

Government

## Funder Name

HertNet / CRIPACC (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