ISRCTN61323766 https://doi.org/10.1186/ISRCTN61323766

Trial of efficacy of a family-based programme to increase physical activity among individuals at high risk of diabetes

Submission date	Recruitment status	[X] Prospectively registered
10/01/2001	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/01/2001	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/09/2015	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Simon Griffin

Contact details
MRC Epidemiology Unit
Institute of Metabolic Science, Box 285
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ
+44 (0)1223 330315
Simon.Griffin@mrc-epid.cam.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G0000753

Study information

Scientific Title
Trial of efficacy of a family-based programme to increase physical activity among individuals at high risk of diabetes

Acronym
ProActive

Study objectives
1. Behaviour change: to estimate the extent to which an innovative approach to increasing physical activity can achieve clinically important changes in a high risk group
2. Disease impact: to model the potential for this behaviour change to reduce the incidence of obesity and diabetes in later life
3. Dose finding: to estimate the effect of delivery of the intervention at two levels of intensity on acceptability, efficacy and costs

Please note that as of 18/03/2009 this record was updated; all updates can be found under the relevant field with the above updated date. Please also note that at this time, details of the follow-up study 'ProActive: follow-up study' were added to this record. All details of this follow-up study can be found in the relevant section under the sub-heading 'ProActive: follow-up study'. The ProActive: follow-up study has the following trial dates:
Overall trial start date: 01/04/2009
Overall trial end date: 01/10/2011

ProActive: follow-up study -
We aim to follow-up ProActive trial participants and to quantify changes in objectively measured physical activity and its clinical and psychological correlates over time. Specific objectives include:

1. Assessment of changes in physical activity and its consequences:
1.1. To determine the efficacy of the ProActive intervention programme on objectively measured physical activity and its clinical and psychological correlates five years post-randomisation
1.2. To examine to what extent observed increases in objectively measured physical activity at one year in the ProActive cohort were sustained
1.3. To conduct a cohort analysis to examine whether feasible changes in objectively measured physical activity are associated with clinically important changes in metabolic risk factors

2. Assessment of the determinants of physical activity and self-rated health:
2.1. To characterise individuals who maintained, increased and decreased their levels of physical activity by quantifying the association between determinants and change in physical activity over time. We will examine individual and environmental determinants of physical activity:
2.1.1. Individual determinants: biological, behavioural, demographic, psychological
2.1.2. Environmental determinants: both objective and perceived environmental data
2.2. To examine which psychological variables (e.g. intention, perceived behavioural control, satisfaction) predict long-term change in physical activity in the whole cohort and whether predictors differ across the three trial arms
2.3. To similarly identify predictors and outcomes of self-rated health in a cohort of healthy

adults in order to better understand the mechanisms by which self-rated health is created and how it influences outcomes

3. Adding meaning to the trial and cohort study findings:
3.1. To elicit participants' perceptions of self-rated health and explore the reasons for the effect of the intervention on self-rated health
3.2. To analyse individuals' reflections on participating in the ProActive study, their understandings of the specific intervention they received, and their personal reports of the impact these aspects had on them
3.3. To elicit and analyse personal accounts of activity change, and explore the extent to which this is interpreted as a result of the original intervention, of some other aspect of trial involvement, or because of other influences related to their social or physical environment
3.4. To understand better the barriers and facilitators of long term changes in physical activity, and their relationship with self-rated health and perceptions of disease risk through exploring participants' own perceptions and meanings

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Eastern MREC, 31/10/2002, ref: 02/5/53
2. ProActive: follow-up study - Cambridgeshire 2 REC, 23/01/2009, ref: 09/H0308/3

Study design
Randomised controlled trial and long-term follow-up

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 the contact details below to request a patient information sheet

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

Interventions
Three levels of facilitating physical activity:
1. Face to face of a programme to support motivation, action
2. Telephone delivery and maintenance
3. Comparison group (brief advice by leaflet)

Interventions 1 and 2 are delivered by a facilitator trained in evidence-based methods from psychology.

Added 18/03/2009:
The intervention lasted 12 months; 5 months of intensive intervention followed by 7 months of follow-up.

Co-sponsor as of March 2009 (along with University of Cambridge - see sponsor section below):
MRC Epidemiology Unit (UK)
Institute of Metabolic Science, Box 285
Addenbrooke's Hospital
Hills Road
Cambridge CB2 0QQ
United Kingdom
Website: http://www.mrc-epid.cam.ac.uk/

Initial sponsor at time of registration until March 2009:
CamStrad (Cambridgeshire Support Team - Research & Development) (UK)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
An objective measure of physical activity (PAL), daytime energy expenditure and its ration to basal metabolic rate. Psychological and physiological correlates of this behaviour and costs to the NHS will also be measured.

ProActive: follow-up study -
Physical activity measured as the daytime physical activity ratio (dayPAR). This is the ratio of daytime energy expenditure to resting energy expenditure measured using heart rate monitoring with individual calibration for the heart rate-energy expenditure relationship. The method has been extensively validated:
1. Oxygen uptake (ml O2/kg/body weight) will be measured by indirect calorimetry during a submaximal graded treadmill exercise test
2. Maximal cardiorespiratory fitness (VO2max) will be estimated using predicted maximal heart rate (i.e. 220 minus age)
3. Activity energy expenditure (AEE) will be individually calculated from heart rate monitoring as the amount of energy expended above that during a standardised reference activity (i.e. treadmill walking at 3.2 km.h-1)
4. Time (% of monitored time per day) spent above 1.75 resting heart rate will be individually calculated as an indicator of moderate intensity PA

Physical activity will also be measured by the EPAQ2 questionnaire covering work, recreation and domestic activity over the previous month and year.

Secondary outcome measures
Added 18/03/2009:
Measured at baseline and at 1 year:

1. Maximal cardiorespiratory fitness (VO2max)
2. Self-reported physical activity
3. Weight
4. Height
5. Body fat percentage
6. Blood pressure
7. Glycosylated haemoglobin
8. Fasting plasma glucose, lipids and insulin
9. 36-item short form health survey (SF-36) (wellbeing)
10. Worry about diabetes and perceived risk of diabetes
11. Psychological outcomes including beliefs about increasing physical activity (e.g. attitude, subjective norm, intention, perceived behavioural control), based on the Theory of Planned Behaviour

All self-reported questionnaires (except the SF-36) were also collected at 6 months. At 6 months and 1 year participants were asked about the acceptability of the programme and it's delivery.

ProActive: follow-up study -
1. Physiological correlates of activity:
1.1. Weight measured on standard scales calibrated at three monthly intervals
1.2. Body fat percentage measured by bio-electrical impedance (Bodystat, Isle of Man, UK)
1.3. Systolic/diastolic blood pressure, measured using an automatic sphygmomanometer (Accutorr, UK)
2. An electrocardiogram (ECG) will be performed
3. Biochemical correlates, including fasting plasma glucose, insulin, glycosylated haemoglobin, and lipids measured in one laboratory with established quality assurance systems
4. Psychological outcomes, including beliefs about increasing physical activity over the coming 12 months (e.g. attitude, subjective norm, intention, perceived behavioural control), based on the Theory of Planned Behaviour
5. Self-report measures of well-being and quality of life, including subjective health and energy (SF-36)

A follow-up qualitative component - a two-stage interview procedure - will also be performed at follow-up

Overall study start date
01/04/2001

Completion date
31/03/2005

Eligibility

Key inclusion criteria
Offspring of patients with Type 2 diabetes reporting a sedentary lifestyle.

ProActive: follow-up study -
Existing participants we are able to contact who are willing and able to attend for follow-up measures.

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
365 (ProActive: follow-up study - 353)

Key exclusion criteria
1. Age greater than 30 years, less than 50 years
2. Known diabetes
3. Physical or psychiatric illness limiting programme involvement

ProActive: follow-up study -
Participants who are unable to be contacted, or unable or unwilling to attend for follow-up measures.

Date of first enrolment
01/04/2001

Date of final enrolment
31/03/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
University of Cambridge (UK)

Sponsor details

Research Services Division
16 Mill Lane
Cambridge
England
United Kingdom
CB2 1SB

Sponsor type
University/education

Website
http://www.rsd.cam.ac.uk/

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) (ref: G0000753)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
National Institute for Health Research (NIHR) (UK) - School for Primary Care Research

Funder Name
Medical Research Council (MRC) Epidemiology Unit (UK) Programme funding

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	18/10/2004		Yes	No
Results article	results	05/01/2008		Yes	No
Results article	results	17/03/2009		Yes	No
Results article	results	30/04/2010		Yes	No
Results article	results	01/07/2011		Yes	No
Results article	results	01/02/2014		Yes	No
Results article	results	01/01/2015		Yes	No