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Effects of the barrier-belief counseling approach.

Submission date	Recruitment status	[_] Prospectively registered
10/02/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/07/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/01/2020	Other	

Plain English summary of protocol

Background and study aims
Physical inactivity is a worldwide growing problem with one out of five adults not doing enough exercise. It is a risk factor for chronic diseases such as diabetes and cardiovascular diseases, being overweight and several cancers. Regular physical activity (PA) has a number of fitness and health related benefits and is associated with an estimated 30% reduction in risk for all-cause mortality (death) among adults. Regular, moderately intense exercise is important for a person's physical and mental well-being, and the prevention and management of many chronic diseases. When people start doing PA, they often stop and become inactive again, even when they take part in PA programmes (or interventions). Many people become inactive again when intervention support is no longer provided. However, only sustained PA has an beneficial effect on health and the prevention of illness. It has been suggested that future PA interventions should include behavior maintenance strategies. These strategies should focus on what is most likely to keep people exercising. The barrier-belief approach concentrates on these proven behavior change strategies - change means reach goals, set (different) goals, restructure beliefs, induce acceptance. These are all applied to target the core of problems with starting and maintaining PA. Using well-known theories and strategies, the barrier-beliefs approach composes a way of counseling around the central construct of barrier-beliefs. The aim of this study is to assess how well a tailored BB counseling intervention performs compared with a group education program in general practice. A new perspective of changing behavior will be examined in primary care, called the BB Counseling Approach. The goal of the developing lifestyle intervention is to decrease medical complaints and care intake, to increase PA-behavior in subjects.

Who can participate?
Adults who consult their general practitioner, who are physically inactive.

What does the study involve?
Participants are randomly allocated into one of three groups. Those in group 1 receive BB counseling intervention for a maximum of six months. Each participant decides himself how often they need an appointment with the counselor (with a maximum of 15 appointments during half a year). Those in group 2 receive a group education intervention. It encourages people to change their behavior by helping them to improve their knowledge about healthy

behavior and achieve firm goals. All participants attend 5 group meetings and 2 one-to-one meetings. Those in group 3 are in the control group and do not receive an intervention.

What are the possible benefits and risks of participating?
The risk of injury or complications with this study is minimal. However, it is possible in any experiment that harmful effects may unexpectedly occur. Every precaution will be taken to prevent or minimize the occurrence of adverse events. These precautions include proper subject counselling, allowing only qualified counselors to support the process and administer all measurements. If injury does occur during counselling, the principal researcher will administer appropriate care and refer subjects for proper medical treatment.

Where is the study run from?
1. Institute of Sports Studies, Hanze University of Applied Sciences Groningen (Netherlands)
2. Social Psychology, Faculty of Behavioral and Society Sciences, University of Groningen (Netherlands)
3. Department of Sports Medicine and Orthopedic Surgery, University Medical Center Groningen (Netherlands)

When is the study starting and how long is it expected to run for?
September 2010 to December 2015

Who is funding the study?
Institute of Sports Studies, Hanze University of Applied Sciences, Groningen (Netherlands)

Who is the main contact?
Dr Adrie Bouma

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of the barrier-belief counseling on physical activity in inactive adults.

Acronym
BB Counseling Approach (BBCA)

Study objectives
The barrier-belief counseling approach (BBCA) in the counseling of a physical activity (PA) in inactive adults is more effective than the usual care in primary health care setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Review Committee of the University Medical Centre in Groningen, The Netherlands 01/08 /2010, ref: NL30895.042.10

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
The PA-behavior of inactive adults in primary care will be studied.

Interventions
1. The intervention group
In PA counseling, barrier-beliefs (BBs) are addressed using four different BB behavior change

strategies. The BB counseling aims to develop an individual pattern of PA for the long term that is adapted to the (often limited) motivation of the client, thereby preventing the occurrence of BBs. The client will learn to cope with factors that may inhibit PA in the future. This perspective of counseling barriers focuses mainly on exploring and resolving individual barriers experienced by subjects in the process of changing behavior and releasing guidelines to PA.
1.1. Channel: individual counseling sessions
1.2. Length: maximum 6 months and maximum 15 appointments.
Participants will be tested at 4 moments; T1: a pre-test before starting the intervention; T2: a post-test immediately after completing the intervention; T3: 6 months after T2; T4 6 months after T3.
2. Group education intervention (control group A)
The core of the group education intervention, or the “standard group intervention”, is a directive educational style for eliciting behavioral change by helping subjects to improve their knowledge about healthy behavior and achieve predetermined goals in which norms and guidelines will be leading.
2.1. Channel: group sessions;
2.2. Frequency: 7 moments of contact (5 group meetings and 2 individual meetings). Participants will be tested at 4 moments; T1: a pre-test before starting the intervention; T2: a post-test immediately after completing the intervention; T3: 6 months after T2; T4 6 months after T3.
3. Control group B
This group will receive no intervention, only a pre-test (T1) and 6 months later a post-test (T2).

Intervention Type
Behavioural

Primary outcome measure
1. PA
2. Barrier-beliefs to PA
3. Medical complaints:
3.1. Perceived physical state of the subjects
3.2. Physical complaints
3.3. Psychological complaints

Secondary outcome measures
1. Diet
2. Body composition
3. Quality of life
4. Medical consumption
5. Psychological factors of health behavior

Overall study start date
01/09/2010

Completion date
30/12/2015

Eligibility

Key inclusion criteria
1. The patient has a demand for care in which a medical intervention or referral is not immediately indicated

2. In the opinion of the doctor, a behavioral change towards a healthier lifestyle can affect the decline for health care
3. Subject does not meet the ACSM-guidelines
4. Subject considers to change his behavior within six months
5. Subject voluntary commits to participate in the intervention and to finish it
6. Subject is aged between 18 - 70 years old

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
n=240 (80x intervention group; 80x control group a; 80x control group b)

Total final enrolment
281

Key exclusion criteria
1. Subject has a disease or had recent a disease which unables participation (for instance: heart attack, recent operation, etc)
2. Subject suffers from depression longer than 6 months
3. Subject has chronic pain longer than 6 months
4. Subject is pregnant
5. Subject has difficulties with the Dutch language
6. There is co-morbidity

Date of first enrolment
01/09/2010

Date of final enrolment
01/09/2014

Locations

Countries of recruitment
Netherlands

Study participating centre
Institute of Sports Studies
Hanze University of Applied Sciences Groningen,
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Groningen
Netherlands
9747 AS

Study participating centre
Social Psychology, Faculty of Behavioral and Society Sciences
University of Groningen
Grote Kruisstraat 2/1
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9712 TS

Study participating centre
Department of Sports Medicine and Orthopedic Surgery
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Hanzeplein 1
Groningen
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9713 GZ

Sponsor information

Organisation
University of Groningen

Sponsor details
Social Psychology, Faculty of Behavioral- and Society Sciences
Grote Kruisstraat 2/1
Groningen
Netherlands
9712 TS

Sponsor type
University/education

Website
http://www.rug.nl/

ROR
https://ror.org/012p63287

Organisation
Department of Sports Medicine and Orthopedic Surgery

Sponsor details
University Medical Center Groningen
Hanzeplein 1
Groningen
Netherlands
9713 GZ

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
University/education

Funder Name
Institute of Sports Studies, Hanze University of Applied Sciences, Groningen (Netherlands)

Results and Publications

Publication and dissemination plan
2018 thesis in https://www.rug.nl/research/portal/files/66611682/Complete_thesis.pdf

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2018	24/01/2020	Yes	No