New Perspective of changing behavior: The Circumventing Barrier Approach;A randomized controlled trail to investigate the effectiveness of a subject tailored life style intervention to improve physical activity level and diet for inactive participants in the primary care.

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Primary Objective: The goal of this study is to assess effectiveness of a subject tailored lifestyle intervention compared with a group education program in general practice. A new perspective of changing behavior will be examined in primary care:...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35049

Source
ToetsingOnline

Brief title
New Perspective of Changing Behavior: The Circumventing Barrier Approach

Condition

- Other condition

Synonym
inactive

Health condition

inactieve patiënten

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: counselling, inactive, lifestyle, overweight

Outcome measures

Primary outcome

Primary dependent study parameters at T0, T1, T2 en T3 (assessed at start, 3

months, 6 months, 12 months)

Physical complaints

• First this will be assessed by a self-report of the perceived physical state

of the participants, illness history, type current problems, type of treatment,

number of treatments and the time since last treatment.

• General Health Questionnaire, GHQ (Jackson, 2007) is self report

questionnaire to measure the level of psychological problems. The GHQ-12

consists of 12 items. Respondents specify their level of agreement to a

statement.

• De SCL-90 is a self reported questionnaire measuring physical and

psychological problems. The questionnaire consists of 90 descriptions of

problems in which the respondent has to indicate how much he/she suffers from

that problem last 7 days. Respondent judges, on a 5-point scale 1= a little, 2= some, 3= pretty much, 4=much, 5= very much.

Physical activity

• How many days per week a person spends on physical activities, the amount of time a person spends on the physical activity and the effort of the physical activity is measured with the Short Questionnaire to Asses Health enhancing physical activity (SQUASH; Wendel-Vos et al., 2002) to invent the moving pattern of the subject. For example: walking: * days (days per week), *.. hours and minutes (average time per day), slow/moderate/fast (effort).
• Physician based Assessment and Counseling for Exercise (PACE;), is a method to give individuals a tailored advice about physical activities. With a questionnaire the current moving pattern is invented and the motivation to become active.

Assessed during the interventions

• With the accelerometer ActiGraph the amount and the moments in which te subject is moving. The Actigraph will be worn on the limbs or around the abdomen. The Actigraph only can be read out by the scientist. The subject does not get any information about his physical activities from this accelerometer.
• With a physical activity journal the subject reports his physical activities by describing the kind of activity which he/she practices every day, the endurance of the activity (minutes per day) and the effort of the physical activity (low/medium/high). The journal will be fill in during 1 week before a

appointment.

• With a diet journal the subject reports his diet and moment of intake during

the day. The journal will be filled in during 1 week before a appointment.

• Motivation, attitude, social support, self efficacy and barriers in relation

with healthy behavior and toward behavioral change will be part of the

intervention. In-depth information on experiences, opinions or needs of the

subject are obtained through interviews during the intervention. This

qualitative data is processed by a description of the process by the counselor

within each subject.

Secondary outcome

Secondary study parameters (assessed at T0, T1, T2 en T3)

Body composition

• BMI: measuring body weight / length2

• Fat percentage: bio-impedance measurement

• Obdominal girth (is measured by waist circumference)

Quality of life:

• Firstly, the scale of the EORTC QLQ-C30 (version 3.0) will be used, assessing

*global health status and quality of life, items 29 and 30: *How would you rate

your overall health during the past week?* and *How would you rate your overall

quality of life during the past week?* Answers were given on 7-point scales

ranging from 1 = *very poor* to 7 = *excellent*. Second the Linear Analog Self

Assessment (LASA overall and LASA physical) was used. For *LASA overall*

ratings were made along a line, with on the left site a label *lowest quality*

and on the right site *highest quality*. *LASA physical needed to be expressed

in a percentage (maximum 100 %). The third used instrument was Cantril*s Ladder

(Cantril, 1966). Respondents had to rate their current life satisfaction on a

ladder that ranges from 0 to 10, where 0 reflects worst imaginable life

satisfaction and 10 reflects best imaginable life satisfaction.

Medical consumption

• Frequncy doctor visits / paramedical care: this will be assessed by a

self-report of how many times participant visited a health professional last 2

months.

• Medication: participant is asked what medication he/she is taken at this

moment, how often and which dose.

Independent variables (assessed at T0, T1, T2 en T3)

• Socio-demographic variables will be assessed, such as gender, age, marital

status, education level, socio-economic class and postal code.

Study description

Background summary

Physical symptoms are related to life style. Physical activity has profound
effects on physical complaints and disabilities (Winett, 2001). Transformation
from a sedentary state to a more active lifestyle could pay large dividends to
the individual and to society (Francis, 1996).

Despite of increasing knowledge concerning benefits of physical activity, an increasing number of people are finding it difficult to meet the amount of health beneficial physical activity (WHO, 2004).

The attention for lifestyle counseling within primary care is insufficient (Morey et al., 2008), while research showed that lifestyle counseling is feasible (Sørensen, 2010) and desirable to implement in the primary care (Sargeant et al., 2008, Petrella et al, 2007).

Different methods are used for physical activity promotion such as: lifestyle campaigns, telephone counseling, or oral counseling with or without physical activity. But various studies of this type of interventions have contradictory effects. Reviews show that exercise prescriptions only have a moderate positive (Van Sluijs et al, 2008, 2005, 2004) or no effect on physical activity and diet (Bredahl et al, 2008, Hillsdon et al, 2005) on short term. Moreover, a large percentage of participants stopped being physically active after the intervention, even if they believe in the objective and positive future prospects (Bredahl et al, 2008). Physical activity counseling interventions among primarily sedentary individuals should be partly based on barrier and task self-efficacy (Blanchard, 2007).

Therefore, this study will develop a new perspective of lifestyle counseling in primary care. A method will be developed that aims to change people's behavior by focusing on circumventing barriers to reduce relapse by tailored goal setting (little steps) and releasing guidelines of physical activity.

First assumption is: a person will be better able to sustain a new behavior when a person experiences no barriers in performing the new behavior. The core of this intervention is that a person will be trained to circumvent barriers or seek alternatives and to achieve his/her goals through very small gradual changes. So that a reduced motivation of people not automatically causes decline and people could easily sustain the new behavior.

Second assumption is: Benefits of physical activity can be reached in less than 30 minutes physical activity per day (Francis, 1996, Hamilton et al., 2007, Zderic et al., 2006, Hamilton et al., 2004, Sugiyam et al., 2008, Magliano et al., 2008, Vandelanotte et al., 2009). Performing light intensive activities during the day, a few minutes at a time, is the most effective way of changing health of sedentary individuals (Hamilton et al., 2007, Zderic et al., 2006, Hamilton et al., 2004, Sugiyam et al., 2008, Magliano et al., 2008, Vandelanotte et al., 2009). It will be studied if performing light intensive lifestyle activities during the day reduces physical complaints. Besides, it is of bigger socio-economic importance that many people change a little than few people change much. Therefore guidelines of physical activity will be released. To encourage participants to become active, this intervention will primary focus on lifestyle physical activity in the immediate vicinity of the participant, such as cycling, walking, in transportation to home and work and domestic activities.

Study objective

Primary Objective:
The goal of this study is to assess effectiveness of a subject tailored lifestyle intervention compared with a group education program in general practice. A new perspective of changing behavior will be examined in primary care: the Circumvent Barrier Approach.

The goal of the developing lifestyle intervention is to decrease medical complaints and care intake, to increase the amount of physical activity and to improve diet in subjects.

Goals on short term for subjects:
Becoming active in subjects own environment, reaching for personal goals in a responsible and healthy way and to learn to continue an active and healthy lifestyle (physical activity and diet).

Goals on medium and long term for subjects:
*Improve well being and quality of life and to reduce medical complaints, and medical consumption
*Improve psychological factors such as motivation, attitude, social support, and self efficacy .

Study design

a randomized controlled trail
A subject tailored lifestyle intervention will be developed aiming on: circumvent barriers, releasing guidelines for physical activity, focuses on tailoring and uses a way of non-directive counseling.
In this study the effects are analysed of a subject tailored lifestyle intervention within the primary health care.

The intervention will be compared with an group education program as a control group to examine the difference in tailoring and using guidelines. The effects and the amount of relapse of the subject tailored lifestyle intervention will be compared with the control group on short and long term (at the start, after 3 months, after 6 months and after one year).

Information about physiological, psychological and self-reported values (SES, BMI, fat%, abdominal girth, physical activity, diet, medical complaints, health related quality of live, and behavioral determinants as motivation, attitude, social support, self efficacy and barriers) will be examined as baseline at the start, during and at the end of the intervention. This quantitative data will be gathered through measures, questionnaires and journals.

Questionnaire:

Physician based Assessment and Counseling for Exercise (PACE;), is a method to give individuals a tailored advice about physical activities. With a questionnaire the current moving pattern is invented and the motivation to become active.

Assessed during the interventions:
• With the accelerometer ActiGraph the amount and the moments in which the subject is moving. The Actigraph will be worn on the limbs or around the abdomen. The Actigraph only can be read out by the scientist. The subject does not get any information about his physical activities from this accelerometer.
• With a physical activity journal the subject reports his physical activities by describing the kind of activity which he/she practices every day, the endurance of the activity (minutes per day) and the effort of the physical activity (low/medium/high). The journal will be fill in during 1 week before a appointment.
• With a diet journal the subject reports his diet and moment of intake during the day. The journal will be filled in during 1 week before a appointment.

Intervention

1. Circumvent Barrier Approach
This study examines the effectiveness of a subject tailored lifestyle intervention with a new perspective of changing behavior by circumvent barriers. This perspective of circumvent barriers focuses mainly on exploring and resolving individual barriers experienced by participants in the process of changing behavior.

When a person wants to change behavior, he has to be motivated. The person has to have the intention to change before he will change. Intention requires that a person wants to change, is able to change and is about to change. Starting a changing process and during counseling interventions participants normally are highly motivated to perform the new behavior. High motivation is needed to overcome barriers. During the changing process, barriers will remain but motivation will probably decrease. Because a person will not constantly be extremely motivated to circumvent barriers that he experiences. That makes that a lot of people slip back into old habits when counseling stops.
Therefore, counseling should aim to reduce or circumvent barriers. So few motivation is sufficient to maintain the new behavior resulting that participants are able to sustain the new behavior themselves.
Therefore this study aims on designing a behavioral change by circumvent and circumventing relevant barriers.

Different kinds of barriers can be distinguished.

Type barrier
Explanation
Structural barriers time, money, distance

Situational barriers emotions, social situations linked to situation

Aversive barriers
negative emotions such as: anxiety, shame or linked to myalgia and
injuries
Goal barriers hinders other important goals

Absence barriers absence of:
function of old behavior
positive outcome old behavior
positive outcome new behavior

The circumvent barrier approach consists of adapt the new behavior into
lifestyle by focusing on:
• Circumvent disadvantages
• Circumvent negative perspectives / elevate positive percention
• Elevate self efficacy
• Offering alternatives
• Goalsetting (adapt, smaller, self chosen)
• Translating objectives into various activities
• Flexibel coping

Second assumption is: Benefits of physical activity can be reached in less than
30 minutes physical activity per day (Francis, 1996, Hamilton et al., 2007,
Zderic et al., 2006, Hamilton et al., 2004, Sugiyam et al., 2008, Magliano et
al., 2008, Vandelanotte et al., 2009). Performing light intensive activities
during the day, a few minutes at a time, is the most effective way of changing
health of sedentary individuals (Hamilton et al., 2007, Zderic et al., 2006,
Hamilton et al., 2004, Sugiyam et al., 2008, Magliano et al., 2008,
Vandelanotte et al., 2009). It will be studied if performing light intensive
lifestyle activities during the day reduces physical complaints.

The support continues in a client-centered method. The guidance is
non-directive at guiding change and leaves the participant about whether and
how it is working with its own set targets for change. The counselor takes no
responsibility for the change process while leaving it to the participant.
Method The aim is to achieve certain behavior by influencing behavioral
determinants according to the ASE model (De Vries, 1988), motivate participants
intrinsic according to the Self Determination Theory and Motivatie Theory (Deci
& Ryan, 1985, Deci & Ryan, 2000), to assist stages of behavioral change
according to the trans-theoretical model (Prochaska & DiClemente, 1984) and
using the communication method Motivational Interviewing (Miller&Rollnick,
1991).

Channel: Intensive way of individual counseling in personal interviews.
Frequency: The length of the intervention is maximum 6 months. The subject can
decide himself how frequent he/she needs an appointment with the counselor

(with a maximum of 15 appointments during half a year).

2. Group education intervention (control group)

The core of the group education intervention or the *standard group intervention* is a directive education style for eliciting behavioral change by helping subjects to improve their knowledge about healthy behavior and achieve firm goals. Compared with nondirective counseling, it is more fixed and goal-directed. The group education intervention will be a intervention in which norms and guidelines for goal setting, amount of behavior and eating pattern will be leading. Advising will be done in ACSM guidelines and general diet guidelines (American College of Sports Medicine, 1998, 2009). The subject has to follow and practice the advices, norms and guidelines and practices into his/her own life.

The educational method in this study is developed according to Goal setting Theory (Lock, 1990).
The adviser will focus primary on improving daily activity pattern and on improving diet. The advisor formulates subjects* goals, giving feedback on subject practicing his goals.
Frequency: The group education intervention has 7 moments of contact (5 group meetings and 2 individual meetings)

Week 1. Individual Assessment and intake
Week 2. Group meeting Goalsetting
Week 4. Group meeting Exploring bounderies
Week 8. Group meeting Pushing boundaries
Week 14. Group meeting Set new behavior
Week 22. Group meeting Persist new behavior
Week 24. Individual Assessment

Study burden and risks

Currently there are no known risks arising from participation in the above interventions. There are no harmful effects expected following the interventions.

Counseling intervention, burden:
30 minutes each visit. The total amount of contact time will be maximum 450 minutes. Total endurance of intervention will be 6 months and total endurance of study will be 1 year (inclusive measurements).

Group education intervention, burden:
120 minutes each meeting (group sessions). The total amount of contact time will be maximum 660 minutes. Frequency: The group education intervention has 7 moments of contact (5 group meetings and 2 individual meetings). Total endurance of intervention will be 6 months and total endurance of study will be

1 year (inclusive measurements).

Measurements:
T0 before starting the intervention, T1 after 3 months, T2 after 6 months, T3 after 1 year.

Estimated investment of time for completing the questionnaires: 40 minutes each time

1. Physical activity
• SQUASH.
• PACE

2. Medical complaints
• Self-report
• GHQ-12
• De SCL-90

3. Quality of life:
• EORTC QLQ-C30 (version 3.0) items 29 and 30
• LASA overall and LASA physical
• Cantril*s Ladder

4. Medical consumption
• Frequncy doctor visits / paramedical care.
• Medication: participant is asked what medication he/she is taken at this moment, how often and which dose.

5. Behavior:
• Motivation, attitude, social support, self-efficacy and barriers in relation with healthy behavior and toward behavioral change will be assessed by formulated statements.

Socio-demographic variables will be assessed

Estimated investment of time for measurements: 10 minutes each time
• BMI: measuring body weight / length2
• Fat percentage: bio-impedance measurement
• Obdominal girth (is measured by waist circumference)

* With the accelerometer ActiGraph the amount and the moments in which the subject is moving. The Actigraph has to be worn during the day, on the limbs or around the abdomen, one week before an appointment throughout the day, during 7 days.
* With a physical activity journal the subject reports his physical activities, one week before an appointment throughout the day, during 7 days.
* With a diet journal the subject reports his diet and moment of intake, one

week before an appointment throughout the day, during 7 days.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patient has a request for help where intervention or referral is not immediately identified
2. In the opinion of the doctor, a behavioral change towards a healthier lifestyles 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 take part on the intervention en to finish it
6. Subject has an age between 18 - 70 years

Exclusion criteria

1. Subject has a disease or had recent a disease which barriers 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 has difficulties with the Dutch language
5. There is co morbidity

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-07-2011

Enrollment: 200

Type: Actual

Ethics review

Approved WMO

Date: 30-08-2010

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL30895.042.10