Ik Beweeg: Experiment 1.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28985

Source
NTR

Health condition

Physical inactivity
Obesity

Sponsors and support

Primary sponsor: Open University of the Netherlands
Faculty of Psychology
PO box 2960
6401 DL Heerlen
Source(s) of monetary or material Support: ZonMw
PO box 93 245
2509 AE The Hague

Intervention

Outcome measures

Primary outcome

The main study parameter is the change in physical activity level. PA will be assessed using the validated self-administrated International Physical Activity Questionnaire (IPAQ). Every activity will be assessed in minutes per week, with a further distinction into moderate and heavy intensity. The IPAQ was proven a valid and reliable internationally accepted

questionnaire. We will use the validated computerised Dutch version of the IPAQ.

Secondary outcome

The intervention aims to increase PA by targeting these determinants. We therefore not only measure behavioural outcomes, but also changes in the relevant PA related determinants. We use standard reliable scales and existing questionnaires: stage of Change, intention, intrinsic motivation, the degree that participant's s need for autonomy, competence and relatedness is met, commitment to PA, self-regulation processes: goal setting, strategic planning, action and coping planning, awareness of personal PA level.

To assess the expected differential effects of the interventions for SES, SES will be assessed using education level, income and standard CBS SES methods.

We will ask respondents for their appreciation, usefulness, readability, attractiveness, personal relevance, and understanding of the intervention. These measures are based on our previous CT evaluation studies.

Study description

Background summary

Rationale:

Physical inactivity is responsible for 8000 deaths per year, 6% of all deaths in the Netherlands, while societal and health care costs are huge. Regular physical activity (PA) is related to improved cardiovascular, respiratory, and muscular function, and the reduction of ZonMw priority diseases CVD, Diabetes II, osteoporosis, cancer, and depression. Given that almost half of the Dutch population is insufficiently active, promoting PA among the population is highly important.

Motivational interviewing has proven its efficacy in changing motivation and PA behaviour. However, MI is an intensive, costly counselling technique, able to reach only limited numbers of people. This makes MI inapt for promoting PA among the large Dutch population.

Computer tailoring can be a suitable technique to combine individual counselling with a large scale reach. From previous research we know that MI can be performed through less intensive counselling; MI via telephone has proven effective and recent studies have shown that MI principles can indeed be successfully translated to written CT.

Objective:

Getting insight in how MI elements can best be integrated in computer tailoring in such a way that it is feasible, usable, and that it results in an improvement in intrinsic motivation and physical activity behavior. The main questions is how much structure is needed in online CT to be most effective. Therefore, we will test whether MI elements can best be incorporated using only open-ended questions, only closed questions or using a combination of both.

Study design:

Three group RCT, with measurements at baseline, directly following the intervention and one month post intervention. Three MI applications in CT will be compared: one consisting of open-ended questions only, one consisting of closed questions only, and one consisting of a combination of open-ended and closed questions.

We expect that the combined condition of open-ended and closed questions will lead to the highest levels of participation, evaluation and the most optimal effects on intrinsic motivation and PA behaviour.

Study population:

Participants will be aged between 20 and 65, recruited from a Dutch internet panel.

Interventions:

Three interventions are used. These only differ from each other with respect to the question types they contain: one consists of open-ended questions only, one consists of closed questions only, and one consists of a combination of open-ended and closed questions. All three interventions are aimed at intrinsically stimulating initiation and maintenance of regular physical activity among adults. People can choose themselves whether or not they continue the intervention, and if they want extra information or not, without there being any consequences. The intervention is based on Motivational Interviewing, which is a client-centred, semi-directive counselling approach of engaging intrinsic motivation to change behaviour by developing discrepancy and exploring and resolving ambivalence within the client.

Study parameters/endpoints:

The main study parameter is the change in physical activity level. Besides PA behaviour, PA related determinants like intrinsic motivation, intention and self-efficacy are measured.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Participation in the study will bring no burden or risks. Respondents are only asked to spend some time to complete questionnaires. Since the nature of the intervention is non-directive, participants are as free as possible to make their own decisions.

Study objective

We expect that the combined condition of open and structured will lead to the highest levels of participation, evaluation and the most optimal effects on intrinsic motivation and PA behavior.

Study design

After reading the research information and giving informed consent participants are automatically assigned to one of the three interventions by means of a digital randomizer which is built-in in the website.

After randomization, participants fill out the baseline questionnaire.

After this, subjects proceed to the intervention they were assigned to during the automatic randomization process. The three interventions differ upon the type of questions they contain:

1. Exclusively open ended questions;

2. Exclusively closed questions;

3. A combination of open ended and closed questions.

After completing the intervention, subjects fill out a second questionnaire.

One month later, participants automatically receive an invitation for the follow up questionnaire.

Measurements are collected by asking subjects to fill in questionnaires at baseline, directly following the intervention and 1 month post intervention.

Intervention

After giving informed consent participants are automatically assigned to one of three online computer tailored interventions by means of a digital randomizer which is built-in in the website.

These three interventions only differ from each other with respect to the question types they contain: one consists of open-ended questions only, one consists of closed questions only, and one consists of a combination of open-ended and closed questions.

All three interventions are aimed at intrinsically stimulating initiation and maintenance of regular physical activity among adults. People can choose themselves whether or not they continue the intervention, and if they want extra information or not, without there being any consequences. The intervention is based on Motivational Interviewing, which is a client-centered, semi-directive counselling approach of engaging intrinsic motivation to change behaviour by developing discrepancy and exploring and resolving ambivalence within the client.

In all three interventions subjects proceed through several items among which are questions and exercises. Subjects get computer tailored feedback messages, for example an empathic reflection on a given answer or a short summary in which several answers given by the participant are combined and “interpreted”.

In all three interventions, the following elements are addressed:

1. Awareness of one’s current PA behaviour and how this relates to the health guidelines;

2. Perceived importance of adopting or maintaining regular physical activity. For example subjects who perceive regular PA as unimportant are encouraged to think of reasons why regular physical activity may be important to them. People who already perceive regular PA as being important receive a positive confirmation;

3. Confidence / self efficacy with regard to becoming or remaining physically active;

4. Intention formation and planning.

Contacts

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Eligibility criteria

Inclusion criteria

Participants will be adults, aged between 20 and 65. Participants will be recruited from a Dutch internet panel. Participants can participate in the intervention online, by logging in from their home internet environment. They do not need to travel to a research setting.

Exclusion criteria

Physical impairments which affect the ability to move.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-11-2011
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion Date:	27-09-2011
Application type:	First submission

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
NTR-new	NL2939
NTR-old	NTR3086
CCMO	NL38329.096.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A