

Ik Beweeg. Main Study

No registrations found.

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

Summary

ID

NL-OMON27647

Source

Nationaal Trial Register

Health condition

Obesity
Physical inactivity
Sedentary behavior

Sponsors and support

Primary sponsor: Open University of the Netherlands, Faculty of Psychology

Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

Physical activity behavior, measured through self report with the SQUASH (Short Questionnaire to ASses Health enhancing physical activity).

Secondary outcome

Motivational regulation measured through self-report with the SRQ-E (Exercise Self-Regulation Questionnaire)

Perceived competence, interest, effort, pressure/tension, perceived choice, value (intrinsic motivation inventory)

Appreciation for the intervention (intervention conditions only)

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 the efficacy of a web-based computer-tailored PA intervention, based on MI.

Study design:

Three group RCT, with measurements at baseline, 3, 6 and 12 months.

Study conditions:

- 1) Web-based computer tailored PA intervention based on MI
- 2) Traditional web-based computer-tailored PA intervention

3) Control condition (waiting list)

Study population:

Participants will be aged between 18 and 70, recruited via advertisements in newspapers.

Study parameters/endpoints:

The main study parameter is the change in physical activity level. Besides PA behaviour, PA related determinants like motivational regulation, perceived competence, interest, effort, pressure/tension, perceived choice and value.

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 web-based computer tailored Motivational Interviewing (MI) physical activity (PA) intervention will be more effective in increasing (self-determined motivation towards) PA when compared to the traditional web-based computer-tailored PA intervention.

Study design

Baseline

Follow up 1 at 3 months

Follow up 2 at 6 months

Follow up 3 at 12 months

Intervention

After giving informed consent participants are automatically assigned to one of three study conditions by means of a digital randomizer which is built-in in the website. These research conditions will be described below:

1) Web-based computer-tailored physical activity (PA) intervention, based on motivational interviewing (MI).

Throughout the intervention, several aspects of PA are discussed. Participants receive information about the Dutch PA guidelines and about their own current PA behavior. They are able to request additional information about the effects of regular physical activity in several domains such as physical health, mental health, physical appearance, and social life. The importance of regular PA is discussed through elaborating on the relationship between the participant's personal held values and regular physical activity, and by exploring the possible effects of regular physical activity, on the short and on the long term. Furthermore, attention is paid to the participant's confidence (that he/she could succeed in becoming more physically active) by looking at personal strengths and positive experiences and by elaborating on tips and tricks to make it easier to become more physically active. Finally, participants can formulate their own specific action plan through a structured planning module. During this planning module, they received several tips, for instance about how they could best formulate realistic goals. They also can make their own coping plans (in which they were asked to anticipate on situations in which it would be difficult to become physically active).

The intervention consist of 3 online sessions, over a period of 6 weeks, with an additional follow up booster session (session 4) at three months after the start. Although all sessions will address both the motivation part as well as the planning part, there are differences in the main focus of the different sessions. Basically, the first session will put more emphasis on eliciting change talk and increase self-determined motivation, while the last session will focus more on self-regulation aspects.

2) A more traditional web-based PA intervention. The traditional intervention group receives an intervention that is directed towards influencing the traditional determinants of PA in a more directive and persuasive way.

This intervention will also have 3 online sessions:

- Session 1: main focus on providing feedback on people's current PA and their stage of behavioral change
- Session 2: main focus on providing information on changing attitude, experienced social support, increasing self efficacy
- Session 3: main focus on changing intention and stimulating behavior change.
- Further, a follow up session will occur after three months to recapitulate people's motivation and to address and reward improvement in PA.

3) A waiting list control group, who receives no intervention.

Contacts

Public

Open University of the Netherlands

Postbus 2960
S.A.H. Friederichs
Valkenburgerweg 177
Heerlen 6401 DL
The Netherlands
+31 (0)45 5762197

Scientific

Open University of the Netherlands

Postbus 2960
S.A.H. Friederichs
Valkenburgerweg 177
Heerlen 6401 DL
The Netherlands
+31 (0)45 5762197

Eligibility criteria

Inclusion criteria

Participants will be adults, aged between 18 and 70. Participants will be recruited via advertisements in national newspapers. 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 severely 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):	01-10-2013
Enrollment:	600
Type:	Anticipated

Ethics review

Positive opinion	
Date:	19-08-2013
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	NL3970
NTR-old	NTR4129
CCMO	NL38329.096.11 CCMO
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A