The Active and Healthy Aging Study (Dutch: Actief en Gezond Oud Studie).

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27923

Source
NTR

Brief title
AGO Study

Health condition

Inactive individuals aged 60 to 70 years, without contra-indications to increase their physical activity.
Keywords: glucose metabolism, aging, physical activity, lifestyle intervention, web-based, self-monitoring
Dutch: glucoseregulatie, veroudering, fysieke activiteit, lifestyle-interventie, thuismonitoring

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: netherlands Consortium for Healthy Ageing
Philips Health Care

Intervention

Outcome measures

Primary outcome

Level of daily activity, as measured using independent tri-axial accelerometers. These accelerometers have been validated against energy expenditure measured using VO2-max. We will use this independent measure of activity, because:
A. The DirectLife activity monitor is part of the intervention therefore not independent not suitable as measure of end point;

B. The Genea accelerometer yields more detailed data on physical activity.

Secondary outcome

1. Other metabolic and anthropometric parameters: weight, waist hip ratio, body fat percentage (BIA) and blood pressure will be measured at baseline and at the final visit, and blood sampling for total cholesterol, HDL-cholesterol, triglycerides, fasting glucose, fasting insulin and HbA1c;

2. Well being and perceived health will be assessed by RAND-36 questionnaire prior to the trial and after the trial;

3. Sleep quality will be assessed by the Pittsburg Sleep Quality Index (PSQI).

Study description

Background summary

With an increasingly ageing population, there is a need for lifestyle interventions that can be implemented at a population level to improve health in old age and increase healthy lifespan in the general population. Healthy longevity has been associated with enhanced glucose tolerance and insulin sensitivity, characteristics that can be modified by increasing physical activity. The Philips Directlife program is a web-based lifestyle intervention directed at increasing daily physical activity consisting of 1) an activity monitor, 2) a personal website, and 3) a personal e-coach. Glucose metabolism can be measured with minimal invasive measures and sensitively using a 24-hour glucose sensor (continuous glucose measurement, CGM) placed subcutaneously in the abdomen. This study will test the following hypotheses:

Primary: The DirectLife program is effective in increasing the level of physical activity in an ageing population.

Secondary:

1. The level of physical activity associates with parameters of 24-hour glucose rhythms in an ageing population;

2.An increase in physical activity associates with beneficial changes in 24-hour glucose rhythms as measured with CGM, and with changes in metabolic parameters, anthropometry,

well-being and sleep quality.

We will perform a randomized controlled trial in 316 participants aged 60-70 year with sedentary lifestyle. We will apply the Philips Directlife program as intervention vs. no intervention in the control group. The primary outcome is change in daily physical activity, as measured by independent tri-axial accelerometers. Secondary outcome parameters include parameters measured during 24-hour glucose rhythms, such as mean glucose, standard deviation of the mean, postprandial glucose rhythms etc., and metabolic parameters, well-being and sleep quality. The overview of the study is shown in figure 1. Shortly, participants are recruited from the general population and screened for physical activity level using questionnaire. The study outline comprises two visits to the study center. The primary visit is at t=0 weeks during which baseline anthropometric measurements and well-being are assessed and the CGM sensor applied which is worn for 4 days. The second visit is at t=14 weeks, after which outcome parameters are assessed and CGM applied for the second time to be worn for four days. After t=14 weeks, the control group will get access to the Philips DirectLife program after the study has ended.

Study objective

Internet-based coaching combined with accelorometry of inactive individuals aged 60-70 years is effective in increasing physical activity, and this increase in physical activity associates with enhanced 24-hour glucose regulation.

Study design

T=0: Baseline visit for assessment of physical activity, glucose monitoring, blood sampling and anthropometrics;

T=1 wk to T=13 wk: Intervention or control period;

T = 13 wks: End visit for assessment of PA, glucose monitoring, blood sampling and anthropometrics.

Intervention

The study is an open, randomized controlled intervention trial. Participants will be randomized to DirectLife intervention or control group. The control group will be offered use of DirectLife after the end of the study, i.e. the second "assessment period", such that all participants will receive an equal amount of study visits, and can both benefit from the DirectLife program.

Philips DirectLife has developed a lifestyle activity intervention program, DirectLife, to increase people's daily life physical activity. Based on health behavior change models (Prochaska et al., 1994; Vries and Mudde, 1998), DirectLife takes into account the current

individual activity level, and subsequently provides a personal goal. Very briefly, DirectLife consists of three elements, namely:

1. An activity monitor;

2. A personal website;

3. A personal e-coach, who provides regular updates by e-mail of the physical activity status and gives advice to increase physical activities.

By means of these elements, DirectLife increases awareness about one's own physical activity behavior, gives feedback, and provides support to make sustainable changes in physical activity behavior.

DirectLife has a scientific base. The activity monitor of DirectLife is based on the Tracmor, i.e. a tri-axial accelerometer, which has been reviewed as the most accurate device for the estimation of total daily life energy expenditure (Bonomi et al., 2010; Plasqui et al., 2005; Plasqui and Westerterp, 2007). Moreover, DirectLife combines high-tech with human elements to help people to change to a more active lifestyle (Goris and Holmes, 2008). Participants of the DirectLife program continuously wear an accelerometer throughout the day to measure daily activity. These data are uploaded through the internet. After an initial "assessment period" in which the current level of daily activity is measured, a target is set to increase the level of daily activity during a twelve week web based interactive coaching program. Participants are given a target for daily activity which increases weekly, and data from the accelerometer are used for regularly feedback.

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Eligibility criteria

Inclusion criteria

1. Age 60 to 70 years;

2. Sedentary lifestyle;

3. Motivated to increase physical activity;

4. Familiar with use of and access to personal computer.

Exclusion criteria

1. Physical condition that inhibits increase of physical activity;

2. Diabetes mellitus type I or II;

3. Use of glucose lowering medication.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-11-2011
Enrollment:	232
Type:	Actual

Ethics review

Positive opinion Date:	24-08-2011
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	NL2899
NTR-old	NTR3045
Other	METC LUMC : P10.220
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A