Improving physical activity and metabolic health in an ageing population

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This study will test the following hypotheses:Primary: The DirectLife program is effective in increasing the level of physical activity in an ageing populationSecondary:1. The level of physical activity associates with parameters of 24-hour glucose...

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

Summary

ID

NL-OMON34041

Source
ToetsingOnline

Brief title
Physical activity in healthy ageing

Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Healthy Ageing

Health condition

veroudering

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Netherlands Consortium of Healthy Ageing/ Netherlands Genomic Initiative,Philips

Intervention

Keyword: Ageing, Continuous Glucose Monitoring, Metabolism, Physical Activity

Outcome measures

Primary outcome

Primary end points

• Level of daily activity, as measured using the DirectLife activity monitors,

expressed as activity counts per day (cnts/d).

• We will use continuous glucose monitoring to assess at least the following

parameters of 24-hour glucose rhythms: i) mean glucose level during , ii)

standard deviation of all 24 hour glucose measurements, iii) highest peak after

a meal (including one standardized oral glucose loading), iv) difference

between highest and lowest level, v) nadir glucose.

Secondary outcome

Secondary end points

- 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

- Well being and perceived health will be assessed by Quality of Life (QoL)

SF-36 questionnaire prior to the trial and after the trial

- sleep quality will be assessed by the Pittsburg Sleep Quality Index before

and after the intervention.

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.

Study objective

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/or sleep quality.

Study design

Open, randomized-controlled trial

Intervention

Intervention Group: Philips Directlife Intervention Program, consisting of baseline 1 week assessment period of baseline physical activity, after which 12 weeks of program aimed at increasing daily activity, using an activity monitor, a personal website and a personal e-coach.
The control group will do the 1-week assessment period but will not do the 12-week Directlife intervention program.

Study burden and risks

All study components are minimally or non-invasive. The sensor used in the continuous glucose monitoring system is placed in the abdominal subcutaneous tissue during four days. The sensor is inserted using a needle the size of a regular venipunction and is 1,5 cm long, and is inserted in a 45 degree angle. Once inserted, the needle is removed and a plastic and flexible sensor is left in place, which is 1,3 cm long and 3 mm wide. The outward part of the sensor is only a few centimeters in size, very flexibel and thus comfortable to wear. It is water-proof, and fixated, therefore sports (including swimming) and bathing can be performed as usual. Potential side effects include irritation, infection or bleeding around the place of insertion.
The measurement of glucose rhythms during four days may elude disturbances in glucose metabolism that warrant further diagnostics for glucose intolerance and/or diabetes mellitus.
Venous blood sampling could lead to small hemorrage around the needle insertion location.
Benefits of participation in the current study protocol include a lifestyle intervention directed at increasing physical activity that is free of costs for study participants and may lead to health benefits related to increased physical activity level. All participants, including those initially assigned to the *no intervention* group, will have this benefit.

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

Age between 60-70 years
Low level of physical activity at baseline (as assessed by physical activity questionnaire)
motivation to engage in a more active life style
access to PC and knowledge how to use it

Exclusion criteria

Known diabetes mellitus type I or II
- Severe physical condition that inhibits increase in physical activity
- Use of glucose lowering medication

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):	07-11-2011

Enrollment:	316
Type:	Actual

Ethics review

Approved WMO Date:	05-08-2011
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	13-04-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL34350.058.10

Study results

Date completed:	18-08-2012
Actual enrolment:	235