It's LiFe! Innovative monitoring and personalised feedback as a self-management tool in disease management programmes for people with COPD and/or type 2 diabetes; a randomised controlled trial

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

Summary

ID

NL-OMON39684

Source
ToetsingOnline

Brief title
RCT It's LiFe!

Condition

- Diabetic complications
- Pulmonary vascular disorders

Synonym
Chronic Obstructive Pulmonary Disease (longziekte), type 2 Diabetes (suikerziekte)

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Zon MW

Intervention

Keyword: Accelerometer, Physical activity, Primary care, Self-management

Outcome measures

Primary outcome

Physical activity measured with a physical activity monitor (PAM).

Secondary outcome

Quality of life, general self-efficacy, exercise self-efficacy and health

status.

Study description

Background summary

Physical activity is an important factor for a healthy lifestyle. Although physical activity can delay complications and decrease the burden of the disease in chronically ill persons, their level of activity is often far from optimal. Many interventions have been developed to stimulate physical activity, with disappointing results. New in this field is the use of technology. Human persuasion (for example guidance by a practice nurse) can be enhanced by technological persuasion. Therefore a monitor and feedback tool, consisting of an accelerometer linked to a smart phone and webserver, has been developed and tested.

Study objective

The main objective of this study is to measure the effects of the monitoring and feedback tool embedded in a Self-management Support Program on physical activity. The secondary objective is to measure the effect on self-efficacy, quality of life and health status. In addition a process evaluation will be

conducted.

Study design

A three-armed cluster randomised controlled trial will be conducted with 240 patients from 24 general practices. Randomisation level is the practice. The following conditions will be compared: 1) Tool and Self-management Support Program; 2) Self-management Support Program; 3) Care as usual. Outcome measures will be measured at t0 (before the start of the intervention), t1 (after 4-6 months, directly after the intervention) and t2 (3 months after the end of the intervention).

Intervention

Spread over a period of four to six months patients in condition 1 and 2 have to visit the practice nurse for 3-4 times for physical activity counselling. Specific activity goals will be set that are tailored to the individual patient*s preferences and needs. On top of this, patients in condition 1 will be instructed to use the monitoring and feedback tool in daily life. Patients in condition 3 will not be exposed to any intervention.

Study burden and risks

The burden of the intervention is considered without risks. Only patients with a health status in which the gradual increase of their physical activity level is justified, will be recruited. Furthermore the questionnaires about quality of life, self-efficacy and health status are considered without risk.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

People diagnosed with COPD or diabetes type 2 who are predominantly treated in primary care and are expected to benefit from more physical activity, will be included. Their age should be below 70 and above 40.
Additional inclusion criteria for the diabetes group are a recent (no longer than a year ago) HbA1c concentration of more than 7% / more than 53 mmol/mol and a body mass index of more than 25kg/m2.
For the COPD group the following additional inclusion criteria apply: a clinical diagnosis of COPD according to the GOLD-criteria stage 1, 2 and 3 (post bronchodilator FEV1/IVC <= 70% and FEV1 between 30 and 80% of the predicted value); at least six weeks respiratory stable and on a stable drug regimen.

Exclusion criteria

Patients with complex coexisting medical conditions with a low survival rate, severe psychiatric illness or chronic disorders or diseases that seriously influence the ability to be physically active (e.g. amputation, paralysis, claudication intermittens) and those being primarily treated by a medical specialist or participating in another physical activity intervention as well as patients with insufficient mastery of the Dutch language will be excluded.
Furthermore, patients who do not own a computer with internet connection at home and therefore can*t receive a mail will be excluded. Since the practice nurses select patients from the medical information system, they will decide which patients will be approached.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-03-2013
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO

Date:	19-02-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	21-05-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	12-08-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	11-06-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
Other	NL42580..068.12
CCMO	NL42580.068.12