Efficacy of a physical activity coaching system for patients with COPD

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Primary objective: To study physical activity of COPD patients before, during, and after pulmonary rehabilitation. To evaluate whether and to what extent our designed physical activity coaching system can support the maintainance of physical...

Ethical review	Approved WMO
Status	Completed
Health condition type	Congenital respiratory tract disorders
Study type	Interventional

Summary

ID

NL-OMON47200

Source
ToetsingOnline

Brief title
Efficacy of a physical activity coaching system for patients with COPD

Condition

- Congenital respiratory tract disorders

Synonym
chronic obstructive pulmonary disease

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: Philips Research

Intervention

Keyword: COPD, physical activity coaching, physical activity monitoring, pulmonary rehabilitation

Outcome measures

Primary outcome

The primary endpoint of the study is physical activity data measured by the

activity monitor.

Secondary outcome

The secondary endpoint of the study is the patients' psychology, quality of

life, and personality, measured by several questionnaires:

- 4x Symptoms/Exacerb., COPD Assessment Test, CAT (Mackay et al., 2012)

Measured at start of rehab, at the end of rehab, and at the end of the study:

- 3x Exercise Self Efficacy Scale, (Kroll et al. 2007)

- 3x Responses to physical activity, PAAS (Physical Activity Affect Scale, Lox,

Tuholski, Wasley and Treasure, 2000)

- 3x COPD Self-efficacy, CSES (Wigal, Creer, et al., 1991)

- 3x Motivation/self-efficacy for ADL/leisure activities (IPAQ-SF)

- 5x Breathlessness during daily activities (functional status), London Chest

Activity of Daily Living, LCADL (Garrod et al, 2000)

- 3x St George*s Respiratory Questionnaire Dutch for Netherlands (SGRQ; Jones,

Quirk, & Baveystock, 1991).

- 3x Anxiety and depression (HADS; Zigmond & Snaith, 1983)

- 3x Motivation for PA, Treatment Self Regulation Questionnaire - Physical activity (TSRQ-PA, Williams, Grow, et al., 1996; Levesque et al., 2007)
- 3x Dyspnoea general, Medical Research Council (part of BODE index), MRC (Bestall, Paul, Garrod et al., 1999)

Measured at the start of rehab:
- 1x Perceived health status, Medical Outcomes Study 36 (1 item selection), MOS-36 (Ware & Sherbourne, 1992)
- 1x Health literacy, Short Test of Functional Health Literacy, STOHFLA (Chew, Bradley, Boyko et al., 2004)
- 1x via CIRO Assessment: Nederlandse Persoonlijkheids Vragenlijst, NPV (Barelds, Luteijn, van Dijk, & Starren, 2007)
- 1x via CIRO Assessment: Utrechts Coping List, UCL (Schreurs, van de Willige, Brosschot, Tellegen, & Graus, 1993)

Measured at the end of rehab:
- 1x Some questions about personality-based activity orientation & some questions about prefernces for physical activities and social context
- 1x Social Support for Exercise, SSE (Sallis et al., 1987)

Measured at the end of the study:
- 1x Social Support for Exercise, SSE (Sallis et al., 1987)
- 8x Some (3) questions about mood (*how do you feel?*). These are asked weekly.
- 1x (interviewed) Some questions about usability, experiences, and acceptance

Overview questionnaires and control variables to be received from CIRO+ center

(these are in bold; see protocol):

Start study Start rehabilitation End rehabilitation End study

ESES X X X

PAAS X X X

CSES X X X

IPAQ-SF X X X

SGRQ X X X X

HADS X X X X

TRSQ-PA X X X

MOS-36 X

STOHFLA X

NPV X

UCL X

some questions about prefernces etc X

SSE X X

Mood questions 8x

Exit interview X

CAT X X X X

Age X

Gender X

BMI X X

Smoking status X X

Comorbidities X

Number of hospitalizations last year X

Number of exacerbations last year X

6MWDT x (2x) X

LTOT use X

Rehab setting X

CWRT X X

Spirometry X X

Body box X

DLCO X

mMRC X X X X

Fat-free mass X X

1RM leg press X X

1RM leg extention X X

Study description

Background summary

In order to gain a good understanding of the research that has been done in the area of Pysical Activity (PA) promotion for older COPD patients and to identify the most appropriate literature for our purposes, literature scans were done with keywords that contained in any order of combination: physical activity, exercise, COPD, pulmonary rehabilitation, behavior change, quality of life. The clinical literature revealed the benefits of physical activity and exercise on a whole range of aspects ranging from *generally feeling better* to *increased exercise tolerance in patients suffering from COPD*. However, only a handful of papers discussed actually the promotion of physical activity, the determinants of PA initiation and maintenance for COPD. In fact, the scans revealed a gross lack of research on the topic for this particular patient group.

Then a systematic literature study was done on the non-physical determinants of PA in the older adult population * as papers related to COPD were scant, we looked for populations with characteristic similar to COPD patients. With that in mind, we found especially the literature with older populations possibly suffering from other chronic conditions (like heart failure) to be most relevant and applicable. We found that self-efficacy; personal barriers, intrinsic and identified regulation, intention, attitudes and social support were among the stronger determinants.
What was unexplored were the less cognitive and rational determinants and aspects of PA and exercise for the older population. The literature scans showed that especially the papers around and after 2000, the state-of-the-art research on PA promotion in general (so chronically ill population, but also relatively healthy populations that could benefit from physical activity like kids in high school), showed an increased interest in the social and more emotive aspects/determinants of physical activity, and in the direct environmental factors. With the rise of truly patient centered designs, and the notion of chaotic behavior change, newer intervention design methods are being developed and explored.
Last year (2013) a pilot study wherein physical activity and well-being in 30 COPD patients (during 8-week rehabilitation and 4 weeks thereafter= 12 weeks in total) was investigated for gaining insight into this population was performed. Thereafter, we assessed the first software version of our coaching system in 15 COPD patients (at rehabilitation but also at home).This user trial (ICBE 2012-0362 Physical Activity Coaching system for COPD) lasted for two weeks (in every patient) and assessed the use and opinion of the patients about the system. This version only gave patients insight about their physical activity; patients did not receive coaching yet.
Now we are incorporating the information we have collected by the user trial in our coaching software and we want to study the efficacy of our second version of the coaching software (including real coaching on the physical activity of COPD patients) in 45 patients, compared to 45 patients without receiving coaching (not receiving insight into their physical activities).

Study objective

Primary objective:

To study physical activity of COPD patients before, during, and after pulmonary rehabilitation. To evaluate whether and to what extent our designed physical activity coaching system can support the maintainance of physical activity of COPD patients at home after pulmonary rehabilitation, compared to a control group without physical activity coaching (nor receiving insight into their physical activities during the whole study).

Secondary objective(s):

To evaluate the use and acceptance of COPD patients to use an electronic physical activity coaching program at home. We try to get a good insight into how patients use the second prototype of the coaching system * navigation, understanding of content, interaction, learnability etc.

Also we want to evaluate quality of life before, during, and after pulmonary rehabilitationby several questionnaires (e.g. anxiety, depression, self efficacy responses to physical activity, motivation, personality, mood). At the end of the study we want to measure possible other explanatory factors for differences in physical activity, such as commonly used transport, having a dog, home settings (how do you live?), and exacerbation history. This will be done via an exit interview, as performed by the Philips Researcher.

Study design

We intend to collect data about the physical activity of COPD patients before, during, and after pulmonary rehabilitation. We want to evaluate if our designed physical activity coaching system can support the maintenance of physical activity of COPD patients at home after pulmonary rehabilitation, compared to a control group without physical activity coaching. We will use Philips activity monitors and questionnaires.
It is planned to test the coaching system in a 2 arm study. Both groups include 45 COPD patients.
The experimental group receives (after pulmonary rehab) physical activity coaching. This group is compared to a control group, who doesn*t receive the coaching part, but only wears the Philips activity monitor, and uploads his/her data weekly.

The study is not blind, because participants may know in which group they are (there are clear and open differences between the groups). However, patients are included separately, and may not be aware of the existence of the other two groups. (Double)-blindness is not important for this investigation, whereas we expect little to no placebo effects in physical activity.

Patients are randomly allocated to the groups during rehabilitation, to avoid group bias. All subjects receive a Philips sensor which they wear before pulmonary rehabilitation (4 weeks), during pulmonary rehabilitation(8-16 weeks), and 8 weeks after pulmonary rehabilitation. Half of the subjects receive (after pulmonary rehab) physical activity coaching.

To have in 2 arms physical activity data from 38 subjects for analysis and assuming that a part of the subjects do not finalize pulmonary rehabilitation or do not use the physical activity monitor or coaching system at home, it is planned to start with 45 people in each arm.

Patients are identified for inclusion during baseline assessment a visit at CIRO+. After consent is signed by the patients, patients will receive a Philips

physical activity sensor to measure their baseline activity level before joining rehabilitation. Patients will fill in questionnaires on four occasions: When the Philips sensor is supplied, at the start of pulmonary rehabilitation, at the end of pulmonary rehabilitation, and at the end of the study (at home).During the 8-16 weeks of rehabilitation, the patients will use the Philips sensor, besides filling in some questionnaires (at start and end of rehabilitation).

At home, half of the patients will next to the physical activity sensor receive the Philips coaching system. Patients will use the system 8 weeks at home after rehabilitation. At the end of these 8 weeks, patients will fill in some questionnaires for the last time.
After 8 weeks at home the sensors, questionnaires, and coaching system will be collected from the patient; done by the Philips Researcher.

Intervention

At home, half of the patients (45 max) will, besides the physical activity sensor, receive the Philips coaching system. Patients will use the system for 8 weeks at home after rehabilitation.
The other (control) group will not have an intervention, but will only upload his/her PA data weekly.

Study burden and risks

We identified several risks related to: electrical safety, heat radiation, interference with other devices, skin irritations, and falling. However, the device used in this study is CE marked, battery operated, and used within intended use, so these effects are not likely to occur and the risk is considered negligible.

For the coaching programme we identified a risk that coaching possibly stimulates COPD patient to be active beyond what he/she can physically tolerate. The risk for this is indicated as extremely small by clinical experts. Also expected harm in this case will not be severe this is also confirmed clinical experts. Also we implement and additional mitigation for this risk by setting the target activity threshold together with clinical experts.
Also patients may feel anxiety or pressure by the fact that they are being monitored. We mitigate this risk by providing proper information to the patient. Also it is explained in the informed consent that although we are monitoring, there will be no judgement made based on the collected measurements.

Contacts

Public
Philips Research

High Tech Campus 36
Eindhoven 5656AE
NL
Scientific
Philips Research

High Tech Campus 36
Eindhoven 5656AE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Age > 45
* Clinical diagnosis of COPD according to Global Initiative for Chronic Obstructive Lung Disease (GOLD)1 referred for pulmonary rehabilitation;
* Physically and mentally capable to cooperate
* Sufficient understanding of the Dutch language
* Clinical stability concerning pulmonary infections or acute exacerbations within last four weeks;
* Absence of recent Myocardial Infarction (within last 3 months), unstable angina, other significant cardiac problems, SBP > 180 mmHg, DBP > 100 mmHg or tachycardia;
* Absence of significant orthopaedic, neurological, cognitive and/or psychiatric impairment restricting mobility;
* Internet access at home.

Exclusion criteria

* Subjects who do not meet the above mentioned inclusion criteria
* Subjects who are not primarily diagnosed with COPD
* Subjects unwilling or unable to sign the informed consent form (if applicable)
* Subjects with any significant disorder or disease other than COPD expected to significantly interfere with the study
* Subjects with orthopaedic, neurological or other complaints that significantly impair normal biome-chanical movement patterns, as judged by the investigator;
* Subjects with respiratory diseases other than COPD (e.g. asthma);
* Subjects with COPD exacerbations within 4 weeks prior to Visit 1;
* Subjects with cognitive impairment

Study design

Design

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

Primary purpose: Other

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	20-07-2015
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	30-06-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	15-07-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-02-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-02-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 28407
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL52206.100.15
OMON	NL-OMON28407