Pilot: Feasibility of a partially supervised conditioning program in patients with CF: ACTIVATE- CF.

Published: 15-06-2016
Last updated: 14-04-2024

The primary aim of this pilot study is to evaluate the feasibility of the study protocol. The ACTIVATE-CF protocol will be judged feasible when at least 75% of the included patients can comply to the study protocol (with regard to both the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders congenital
Study type	Interventional

Summary

ID

NL-OMON45217

Source
ToetsingOnline

Brief title
Pilot: Activate-CF.

Condition

- Respiratory disorders congenital

Synonym
cystic fibrosis, mucoviscidosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Nederlandse Cystic Fibrosis Stichting

Intervention

Keyword: conditioning program, Cystic Fibrosis, FEV1, partial supervision

Outcome measures

Primary outcome

The primary aim of this pilot study is to evaluate the feasibility of the study protocol. The ACTIVATE-CF protocol will be judged feasible when at least 75% of the included patients can comply to the study protocol (with regard to both the intervention and the control group).

Moreover, at least 75% of the intervention group has to succeed to increase their physical activity levels, so that they engage in a minimum of 3 hours of at least moderate activity per week.

Secondary outcome

Secondary outcomes of this study will be:

- Difference between reported quality of life (CFR-Q scores) from baseline to 6 months in the intervention group compared to controls

- Difference between the changes in FEV1 (in% predicted) from baseline to 6 months in the intervention group compared to controls.

- FVC (% predicted) and RV/TLC (%)

- Differences between the changes in reported physical activity (with the HAES questionnaire) from baseline to 6 months in the intervention group compared to controls.

- Difference between reported fatigue (CIS-20 and only for the pediatric subjects, PedsQL fatigue scores) from baseline to 6 months in the intervention group compared to controls

- Differences between reported levels of stress, anxiety and depression (DASS scores) from baseline to 6 months in the intervention group compared to controls.

- Difference between VO2peak (%predicted) from baseline to 6 months in the intervention group compared to the controls

- Difference between maximal aerobic power (Wmax, %predicted) from baseline to 6 months in the intervention group compared to the controls

We further intend to assess the persistence of behavioral changes and benefits from the intervention once the supervision is largely withdrawn.

Study description

Background summary

Physical activity and exercise have become an accepted and valued component of Cystic Fibrosis. Regular physical activity and exercise can slow the rate of decline of pulmonary function, improve physical fitness, and enhance quality of life. However, motivating people to be more active is challenging.
Supervised exercise programs are expensive and labor intensive, and adherence falls off significantly once supervision ends. Unsupervised or partially supervised programs are less costly and more flexible, but compliance can be more problematic.

Study objective

The primary aim of this pilot study is to evaluate the feasibility of the study protocol. The ACTIVATE-CF protocol will be judged feasible when at least 75% of the included patients can comply to the study protocol (with regard to both the intervention and the control group). Moreover, at least 75% of the intervention group, has to succeed to increase their physical activity levels.

Study design

In this feasibilty study, a monocenter, randomized controlled trial protocol

with a parallel group design, will be tested. The intervention will have a partially supervised phase lasting 6 months, followed by a phase were supervision is largely withdrawn (i.e., the intervention group will continue to have access to some items of the intervention but will not receive counselling or additional motivation by members of their centre*s team). After the 6-months study period, key components of the intervention (pedometers, web-based log, counselling) will be offered to the controls. Thus, the controls are not obliged to follow the 'active' intervention and the data of this 'active' periode will not be included for the data process. No cross over design is adressed.

Intervention

A total of 20 patients with CF, of at least 12 years of age, with a FEV1 *35% predicted will be randomised. Following baseline assessment patients will be randomized into an intervention and a control group. Thereafter, they will be seen every 3 months for assessments for one year (4 follow-up visits). Along with individual counseling to increase vigorous physical activity by at least 3 hours per week on each clinic visit, the intervention group will document daily exercise and inactivity time and will receive a step counter and they will record their progress with a web-based program. They will also receive monthly phone calls from the study staff during the first 6 months of the study. After 6 months, they will continue with the step counter and web-based program for a further 6 months. The control group will receive standard care and keep their activity level constant during the study period. After 6 months, they will receive the intervention (not obligatory).

Study burden and risks

As the participants already visit the centre/clinic for their regularly CF checkups/ clinical visit as well and the same tests are be performed during these visits, the participants only experience burden due to the questionnaires, the additional exercise test and the activity interview.

As regard to the intervention, the intervention group will spend minimally 3 hours per week more to (moderate/vigorous) physical activities. Logically, physical activity is associated with risk to injury, but the physical therapist/ exercise physiologist will attempt to keep this risk as low as possible by providing appropriate advice and exercises/activities.

Contacts

Public
Universitair Medisch Centrum Utrecht

Lundlaan 6
Utrecht 3584AB
NL
Scientific
Universitair Medisch Centrum Utrecht

Lundlaan 6
Utrecht 3584AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* CF based on either two CF-causing mutations and/or a sweat chloride concentration during two tests of >60 mmol/l.
* Age * 12 years
* FEV1 * 35% predicted (based on the equations published by Stanojevic et al. 2008)
* Access to the internet

Exclusion criteria

* Participation in another clinical trial up to 4 weeks prior to the first baseline visit
* Pregnancy/Breastfeeding
* Status post lung transplantation
* Inability to exercise
* More than 4 hours of reported strenuous physical activities per week currently or up to 3 months prior to baseline measurements and not already planned within the coming 6 months.

* Unstable condition affecting pulmonary function or exercise participation (i.e., major hemoptysis or pneumothorax within the last 3 months, acute exacerbation and ivantibiotics during the last 4 weeks, unstable allergic bronchopulmonary aspergillosis,
planned surgery, listed for lung transplantation, major musculoskeletal injuries such as fractures or sprains during the last 2 months, others according to the impression of the doctor)
* Cardiac arrhythmias with exercise
* Requiring additional oxygen with exercise
* Recent diagnosis of diabetes 3 months prior to or at screening
* Recent changes in medication 1 month or less prior to screening (systemic steroids, ibuprofen, inhaled antibiotics, mannitol, DNAse, hypertonic saline)
* At least one G551D mutation and not on ivacaftor (VX770) yet but planned start or planned stop of ivacaftor during the trial
* Colonization with Burkholderia cenocepacia

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-10-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	15-06-2016
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	09-03-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-07-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	03-07-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL51804.041.15