Davos@home: eHealth support of patients with severe asthma after AACT (Alpine Altitude Climate Therapy)

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The objective of this study is to assess the clinical effectiveness of the PatientCoach mHealth app with and without home monitoring devices on sustained asthma control after AACT, in patients with severe or uncontrolled asthma.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON54107

Source
ToetsingOnline

Brief title
Davos@home

Condition

- Bronchial disorders (excl neoplasms)

Synonym
severe asthma

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Vereniging Nederland Davos;Stichting Astmabestrijding

Intervention

Keyword: eHealth, monitoring, self-management, severe asthma

Outcome measures

Primary outcome

Primary outcome is the time to first exacerbation.

Secondary outcome

Secondary outcomes are total exacerbation rate, asthma control, asthma-related

quality of life, fatigue, depression, health care utilisation, work

productivity and activity impairment, and technology acceptance.

Study description

Background summary

Alpine Altitude Climate Treatment (AACT) is used as add-on treatment in severe uncontrolled asthma. However, upon returning home relapses regularly occur. Previously, research showed that eHealth support improves long-term outcomes. The use of home monitoring devices may further sustain long-term asthma control.

Study objective

The objective of this study is to assess the clinical effectiveness of the PatientCoach mHealth app with and without home monitoring devices on sustained asthma control after AACT, in patients with severe or uncontrolled asthma.

Study design

A pragmatic randomized trial with a follow-up of 12 months

Intervention

The use of PatientCoach including home monitoring devices (home spirometer, Fitbit activity meter, FeNO device)

Study burden and risks

Participants will be provided with an mHealth support app designed as an add-on to regular care. Therefore no standard care is withheld. Risks for using the app or the home monitoring devices are negligible. A burden is that participants are regularly asked to fill in questionnaires. Participants in the home monitoring group are also asked to use their home monitoring devices and to copy these values into the app.

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

Adult patients with severe asthma who are referred to AACT in the Dutch Asthma

Center Davos. To be eligible for AACT, patients need to have uncontrolled asthma despite using high doses of inhaled corticosteroids combined with long-acting bronchodilators for more than 1 year. They have also experienced at least two severe exacerbations requiring a course of oral corticosteroids during the past year, or received maintenance oral corticosteroid therapy. There are no additional eligibility criteria specifically for this study.

Exclusion criteria

Not in possession of a smartphone.
Not being able to read or write.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-01-2022
Enrollment:	126
Type:	Actual

Ethics review

Approved WMO

Date:	11-08-2021
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	28-12-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	10-03-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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: 27453
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL75682.058.20
Other	NTR NL9273