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

Published: 11-08-2021 Last updated: 19-07-2024

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

1 - Davos@home: eHealth support of patients with severe asthma after AACT (Alpine Al ... 1-06-2025

## 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**

#### **Public**

Leids Universitair Medisch Centrum

Albinusdreef 2 J10-S Leiden 2333 ZA NL

## **Scientific**

Leids Universitair Medisch Centrum

Albinusdreef 2 J10-S Leiden 2333 ZA NL

# **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

3 - Davos@home: eHealth support of patients with severe asthma after AACT (Alpine Al ... 1-06-2025

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