# Development and testing of an adolescent adherence patient tool for asthma.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

# **Summary**

### ID

NL-OMON27972

**Source** Nationaal Trial Register

Brief title ADAPT-asthma study

#### **Health condition**

Asthma; Adherence; Adolescents; eHealth; Intervention; Medication; mHealth; Pharmacy

### **Sponsors and support**

**Primary sponsor:** Pharmacoepidemiology and Clinical Pharmacology, Utrecht Pharmacy Practice Network for Education and Research (UPPER), Utrecht Institute for Pharmaceutical Sciences, Utrecht University. Netherlands Organization for Health Research and Development (ZonMw). Umenz Benelux BV.

Source(s) of monetary or material Support: ZonMw Umenz Benelux BV

### Intervention

### **Outcome measures**

#### **Primary outcome**

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To evaluate the effectiveness of the ADAPT intervention on self-reported medication adherence

#### Secondary outcome

To evaluate the effectiveness of the ADAPT intervention on self-reported:

- Asthma control
- Asthma-related quality of life
- Medication beliefs
- Illness perceptions
- Patient and pharmacist satisfaction

# **Study description**

#### **Background summary**

Adherence rates among asthma patients are generally low and decrease during adolescence, resulting in poorly controlled asthma. The aim of this study was to evaluate the effectiveness of the ADolescent Adherence Patient Tool (ADAPT), an interactive mobile health (mHealth) intervention, in supporting self-management and improving inhaled corticosteroid adherence in adolescents with asthma.

We conducted a cluster randomized controlled trial in 66 Dutch community pharmacies. Asthma patients aged 12-18 years were invited to participate, based on medication refill records. The main study outcome was self-reported medication adherence, measured with the Medication Adherence Report Scale (MARS). Secondary outcomes were asthma, control quality of life, illness perceptions, and medication belief. Outcomes were measured at start (t=0 months) and at the end of follow-up (t=6 months). Mixed-effects models were used to analyze the effect.

In total, 234 adolescents (147 in the control group and 87 in the intervention group) completed the study; mean age 15.1±1.9 years and 52.6% females. Adherence rates of patients with low baseline adherence (MARS scores  $\leq$ 19; n=76) increased with 1.42 points in the intervention group (n=26). Adherence rates of patients in the control group (n=50) decreased with 0.70 points. Thus there was a positive effect of the intervention on medication adherence (MARS +2.12, p=0.04). This effect was stronger (MARS +2.52, p=0.02) in poor adherent adolescents with uncontrolled asthma (n=74). No effect of the intervention, and medication beliefs.

Most patients (78%) would recommend the ADAPT intervention to others, and thought that the pharmacy was the right place for mHealth aiming to support adherence (63%). The possibility to monitor asthma symptoms was highly appreciated by patients and pharmacists. Pharmacists were satisfied with ADAPT intervention (96%), and using the intervention was

not time consuming (91%). The ADAPT intervention promoted contact with patients (74%) and facilitated the healthcare providing role of pharmacists (83%).

The ADAPT intervention increases adherence in adolescents with asthma having with poor adherence rates. Both pharmacists and patients were positive about the ADAPT intervention. Healthcare providers could consider a tailored mHealth approach to improve the asthma treatment. This study emphasizes opportunities for mHealth in improving the quality of care, which supports the need for further implementation in clinical practice.

#### Study objective

A mHealth intervention will be effective in improving adherence and asthma outcomes in adolescents with asthma

#### Study design

Patients in the intervention group use the smartphone application and will be followed by their pharmacist through a management system for 6 months. To determine the effect of the ADAPT intervention a questionnaire is used to measure the primary and secondary parameters at baseline (t=0) and after 6 months at the end of the follow-up (t=6).

#### Intervention

The ADAPT (ADolescent Adherence Patient Tool) intervention consisted of a smartphone application for patients, which was securely connected to a desktop application of community pharmacists.

# Contacts

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# **Eligibility criteria**

### **Inclusion criteria**

Adolescent patients using inhaled corticosteroids (ICS) registered in one of the pharmacies in the UPPER-network

- Age between 12-18 years

- Use of ICS: filling of at least 2 prescriptions for ICS or ICS/LABA combination during the previous 12 months

- Diagnosis of (persistent) asthma (verified by GP)
- Having a smartphone

### **Exclusion criteria**

- Patients who use ICS for indications other than asthma
- Patients who have insufficient understanding of the Dutch language
- Patients who are not able to take care for themselves (e.g. living in an institution)

# Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2015
Enrollment:	360
Туре:	Actual

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### **IPD** sharing statement

Plan to share IPD: No

# **Ethics review**

Positive opinion Date: Application type:

17-02-2015 First submission

# **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

RegisterIDNTR-newNL4957NTR-oldNTR5061OtherZonMw and METC UMC Utrecht : ZonMw: 836031002; METC: 14-592/M and<br/>NL50997.041.14

# **Study results**

#### Summary results

- Kosse RC, Bouvy ML, de Vries TW, Kaptein AA, Geers HC, van Dijk L, Koster ES. mHealth intervention to support asthma self-management in adolescents: the ADAPT study. Patient Prefer Adherence 2017;11:571-577.

https://www.dovepress.com/mhealth-intervention-to-support-asthma-self-management-in-ado lescents--peer-reviewed-article-PPA

- Kosse RC, Bouvy ML, Belitser SV, de Vries TW, van der Wal PS, Koster ES. Effective

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engagement of adolescent asthma patients with mHealth supporting medication adherence. JMIR mHealth and uHealth 2019. https://preprints.jmir.org/preprint/12411 - Kosse RC, Bouvy ML, de Vries TW, Koster ES. Evaluation of a mobile health intervention to support asthma self-management and adherence in the pharmacy. Int J Clin Pharm 2019.