Abstract Presentations

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Breathing and feeling well through universal access to right care
ACCEPTANCE
Effectiveness and acceptability of a smart inhaler asthma self-management programme: a cluster RCT study protocol

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All other authors declare that they have no competing interests.
Asthma & medication adherence

- Decreased quality of life
- Increased health utilization
- Increased costs

- Illness perception
- Health-related quality of life

- Demographics
- Asthma control

- Medication beliefs

References:

Horne et al. Psychology and Health, 2002;17:1,17-32
Jentzsch et al. Respiratory Medicine. 2012;106:338-343
Dima et al. Eur Respir J 2015; 45: 994-1018
eHealth and electronic monitoring devices

Self-management-based eHealth interventions

- Tailored
- Monitoring from distance
- Outside office hours

Electronic monitoring devices

- Detect inhaler use, audiovisual reminders and feedback
- Increase medication adherence
- Potentially benefit clinical outcomes

Evidence on **long-term benefits** and **acceptability** is scarce.
Smart inhaler

Electronic Monitoring Device attached to inhaler
- Register actuation

Data on medication use
- Record date, time
- Individualized reminders
- Keeping track of symptoms and triggers over time

Health care professional Access to patient data
- Assess medication adherence
- Understand inhaler use

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<tr>
<th>PRIMARY OBJECTIVE</th>
<th>SECONDARY OBJECTIVES</th>
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<td>To evaluate the effect of the smart inhaler programme (Turbu+™) on medication adherence compared to control over 12 months in partially controlled and uncontrolled patients</td>
<td>To evaluate the effect of the smart inhaler programme on asthma control and on other clinical outcomes</td>
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<td>To evaluate who would benefit most based on patient characteristics i.e. beliefs about medicine, illness perception, eHealth literacy</td>
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<td>To evaluate usability and acceptability from a patients and health care professional perspective</td>
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<td>To collect health utilization data to inform cost-effectiveness analysis</td>
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Study design

**Intervention (‘smart inhaler’)**
- Turbu+™ add-on device
- Turbu+™ Insights application
  - View adherence data
  - Reminders & motivational messages
  - Symptom tracking feature
- Turbu+™ healthcare portal
  - View adherence data

**Control (‘silent monitoring’)**
- Turbu+™ add-on device
- No access to adherence data by patient and health care professional

+ usual care according to the Dutch asthma guidelines
Study design

General practices → General practitioner → Asthma patients; ACQ ≥0.75

Run-in (6 weeks) → Randomisation if adherence <80%

Visit T-1 → INTERVENTION

Intervention period (12 months)

Visit T0 → Visit T-1

Visit T6 → Visit T12

Visit T9

LEGEND

Symbicort Maintenance + electronic monitoring device and Turbu+™ App

Symbicort Maintenance + ‘silent’ electronic monitoring device
Study population

Multi-center trial

Clusters
61 general practices
(± 4 patients/cluster)

Participants
242 patients (121 per arm)

Key inclusion
- Doctor-diagnosed asthma, partially controlled or uncontrolled (ACQ ≥ 0.75)
- ≥ 18 years old
- Use of Symbicort® Turbuhaler® ≥ 8 weeks at inclusion
- Being ‘non-adherent’ (< 80%)

Key exclusion
- Use of maintenance and reliever regimen
- Change in ICS dose or exacerbation <4 weeks prior to inclusion
- Current use of anti-IL5 or anti-IgE
- COPD, IRD, bronchiectasis

Clusters & Participants

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### Study outcomes

#### Primary outcome

**Difference in medication adherence between the smart inhaler group and the control group over twelve months**

#### Secondary outcomes

- Asthma control (ACQ)
- Quality of life (mini-AQLQ)
- Exacerbations
- Medication adherence
- Reliever use (pharmacist + SABA EMD)
- Usability (SUS) and acceptability (TAQ)

#### Other outcomes

- Medication beliefs (BMQ)
- Illness perception (IPQ)
- eHealth literacy (eHLQ)
- Attitude and self-efficacy (KASE-AQ)
- Total costs (health care utilization and work absence (WPAI))

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**Results expected: June 2022**

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Thank you for your attention!

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