

Research Ideas on Respiratory Conditions and Tobacco Dependency Abstract

Abstract ID = 11635

Presented by Susanne van de Hei on Saturday 13 June 2020

Effectiveness and acceptability of a smart inhaler asthma self-management programme: a cluster RCT study protocol

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Research question: This study aims to investigate the effectiveness of a smart inhaler asthma self-management program on medication adherence and clinical outcomes, to investigate who would benefit most based on patient characteristics, and to evaluate its acceptability.

Background: Self-management-based eHealth interventions are promising in increasing medication adherence and maintaining asthma control. However, evidence on long-term benefits and acceptability is scarce. This study will provide insight in the long-term benefits of a smart inhaler program on medication adherence and clinical outcomes in a real-world clinical setting and inform future studies on use and acceptance of eHealth self-management interventions.

Methodology: An open-label cluster randomized controlled trial of 12 months will be conducted in general practices in the Netherlands. Practices will be randomly assigned to intervention or control. The intervention consists of 1) an electronic monitoring device (EMD) attached to the patients' inhaler that measures medication use, 2) a smartphone application to set medication reminders, receive motivational messages and track asthma symptoms, and 3) a portal for healthcare professionals to view data on medication use. The control group will receive an EMD for measuring medication adherence objectively that can only be viewed by the researchers. Eligible patients are adults with partially controlled or uncontrolled asthma with evidence of non-adherence. The primary outcome is change in medication adherence over time. Other outcomes include asthma control, quality of life, SABA use, exacerbations, medication beliefs, eHealth literacy, acceptance and cost-effectiveness.

Questions to discuss:

- Recruitment strategies
- Measures of adherence

Declaration of Interest

This study is funded by AstraZeneca. All authors declare that they have no competing interests.

References and Clinical Trial Registry Information

Dutch trial register: NL7854