OUTER SPACE-2: a randomised study on inhaler treatment adherence using a smart spacer in adults with asthma

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Primary objective:To assess the overall feasibility of undertaking a definitive randomized controlled trial on the effects of tailored inhaler education by the GP/nurse supported by a smart spacer, in primary care treated adults with asthma....

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

Summary

ID

NL-OMON49894

Source
ToetsingOnline

Brief title
OUTERSPACE-2

Condition

- Bronchial disorders (excl neoplasms)

Synonym
asthma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Trudell Medical

Intervention

Keyword: asthma, ehealth, medication adherence, spacer

Outcome measures

Primary outcome

Primary objective:

To assess the overall feasibility of undertaking a definitive randomized controlled trial on the effects of tailored inhaler education by the GP/nurse supported by a smart spacer, in primary care treated adults with asthma.

Secondary outcome

Secondary objectives:

1) determine patient recruitment speed, participation rate (proportion of eligible patients), drop-out rate and inform sample size calculation for a definitive trial.

2) assess patient and healthcare provider satisfaction with the workflow (System Usability Scale [SUS]).

3) explore the distribution of medication adherence patterns (persistence and inhaler technique) and clinical outcomes (lung function, FeNO, Asthma Control Questionnaire [ACQ], Test for Adherence to Inhalers [TAI], and Work Productivity and Activity Impairment questionnaire [WPAI], SABA use, oral steroid bursts)

Study description

Background summary

In the Netherlands, around 586,200 people have asthma.1,2 Globally, asthma is a main cause of disability, health care services utilization, and quality of life impairment.3,4 Asthma management aims to achieve good symptom control, minimize exacerbations, reduce side effects and as a result prevent the progression of obstructive lung damage.5

Although the majority of asthma patients can be effectively controlled with the available medications, a substantial subset remains uncontrolled despite being offered the optimal therapy.5,6 Poor adherence to treatment is one of the commonest causes of poor control and is widely reported in patients with all severit ies of asthma.7,8 Achieving adherence can significantly reduce the disease burden. Yet, the key challenge that physicians, pharmacists and nurses are facing is helping patients with asthma finding a way to ensure good adherence.9 Whilst elements of adherence, such as moment of inhalation, have been studied10, studies of adherence to treatment between clinic visits including the vital domain of how devices are used are limited.11

Effective treatment of many respiratory illnesses requires drug delivery to the airways and lungs. The devices which are used to achieve this include nebulisers, dry powder inhalers (DPIs) and pressurised metered dose inhalers (pMDIs). The latter are most commonly used in combination with spacers (or valved holding chambers) as recommended in the Dutch primary care NHG guidelines. There are several reasons behind the preference for pMDI and spacer use12, including: (i) they are usually the cheapest option, (ii) DPIs are unsuitable for people that cannot generate sufficient inspiratory flow. However, many patients persist with critical errors in inhaler technique, leading to poorer disease control and poorer outcomes.13 A Cochrane Review of interventions to improve inhaler technique for people with asthma in 2017 concluded that *Guidelines consistently recommend that clinicians check regularly the inhaler technique of their patients; what is not clear is how clinicians can most effectively intervene if they find a patient*s technique to be inadequate, and whether such interventions will have a discernible impact on clinical outcomes*.14

Complete adherence for inhaled medications has two components: i. *implementation and persistence* and ii. inhaler technique.15 Implementation and persistence in this context is intended to describe the extent to which an individual uses the medication at the directed times for a chronic period. This can be measured using patient diaries, which are prone to reporting error or more accurately using electronic inhaler monitors. Studies with these devices show that persistence with treatment is relatively poor in most settings but this may be improved by educational interventions. A recent UK study showed that average persistence for children with asthma was 49% for those who were monitored but received no reminders and 70% for those who received reminders to take their treatment.16 However, while the number of puffs taken improved, asthma control did not improve, likely due to lack of inhaler technique improvement. Whilst inhaler technique is regularly checked, in mostly primary care clinic visits, this aspect of adherence is much more difficult to monitor remotely.

Most patients with asthma use spacers in combination with pMDIs to assist

optimal drug delivery to the lungs. Until recently their use has been difficult to measure. Understanding if critical errors in administration of inhaled medications are occurring is vital if healthcare professionals are to be able to effectively educate people with asthma.
We aim to assess the feasibility - and explore the effects - of tailored inhaler education by a GP/nurse supported by a CE-marked smart spacer that monitors adherence and inhaler technique, and compare this with usual, generic primary care based asthma management.

Study objective

Primary objective:
To assess the overall feasibility of undertaking a definitive randomized controlled trial on the effects of tailored inhaler education by the GP/nurse supported by a smart spacer, in primary care treated adults with asthma.

Secondary objectives:
1) determine patient recruitment speed, participation rate (proportion of eligible patients), drop-out rate and inform sample size calculation for a definitive trial.
2) assess patient and healthcare provider satisfaction with the workflow (System Usability Scale [SUS]).
3) explore the distribution of medication adherence patterns (persistence and inhaler technique) and clinical outcomes (lung function, FeNO, Asthma Control Questionnaire [ACQ], Test for Adherence to Inhalers [TAI], and Work Productivity and Activity Impairment questionnaire [WPAI], SABA use, oral steroid bursts)

Study design

Single center, randomized controlled feasibility trial of 2 months. Patients will be recruited from 4 GP practices in the Netherlands. Patients (n=40) will use the smarts spacer for 1 month (t=-1). Then they will be randomized in two groups (t=0). The control group will get usual care, the intervention group will get tailored feedback and education on basis of data from the smart spacer. After 1 month (t=1) the study is ended and patients will get again their usual care.
At t=-1. t=0 and t=1 ACQ, WPAI an TAI questionnaires and FeNO test will be assessed. At t=0 and t=1 a lung function will be tested. At t=1 usability will be analyzed by the SUS questionnaire and structured interviews with 5 patients and all caregivers.

Intervention

The investigational treatment is tailored inhaler use education, supported by data generated by a smart spacer. In addition to usual care, patients in the

intervention group receive detailed information about how and when they used their inhaled medications. If errors in medication use are identified, protocolled education by the GP/nurse in line with Dutch guidelines will be provided to help eliminate errors. To overcome inter-nurse bias, and to protocolize the education, the nurses are instructed to use the *TAI Toolkit*.
11

Study burden and risks

The burden and risks associated with participation in this study is very limited. Patients will receive usual care until the intervention. The intervention is tailoring the education. The education itself is usual care, only the choice which education is given is smart spacer data driven. Patients may experience extra burden due to the extra spirometry and the FeNO test, furthermore patients are asked to fill in the questionnaires. The burden of these tests and questionnaires is deemed limited.

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

1) adults >= 18 years;
(2) physician diagnosed asthma treated in primary care;
(3) using any inhaled corticosteroid (ICS) (+/-long-acting beta agonist [LABA] +/- short-acting beta agonist [SABA]) administered by a pressurized Metered Dose Inhaler (pMDI) and a spacer;
(4) willing to sign informed consent.

Exclusion criteria

(1) < 18 years;
(2) exacerbation in the last 3 months (defined as use of antibiotics and/or prednisone short-course and/or admission to a ED or hospital).

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):	23-11-2021
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	03-09-2021
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	18-06-2024
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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

Register	ID
CCMO	NL78361.099.21
Other	UMCG research register 202100390, NTR NL9637