Evaluating the implementation of the RACE-instrument in asthma and COPD patients with inhaled maintenance therapy

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29180

Source
NTR

Brief title
Implementation of the RACE-instrument in asthma and COPD patients

Health condition

Asthma and COPD

Sponsors and support

Primary sponsor: This study is supported by AstraZeneca and the Royal Dutch Pharmacists Association (KNMP) with an unconditional research grant.
Source(s) of monetary or material Support: This study is supported by AstraZeneca and the Royal Dutch Pharmacists Association (KNMP) with an unconditional research grant.

Intervention

Outcome measures

Primary outcome

The primary objective is to evaluate the feasibility and acceptability of the RACE-instrument with complex multidimensional interventions provided in consultations by community pharmacists in asthma and COPD patients with maintenance inhaler therapy.

Secondary outcome

As secondary objective the effectiveness of personal support and tailored care provided with the RACE-instrument and its complex multidimensional interventions by community pharmacists is compared between IG and CG patients regarding number of barriers to self-management with inhaled maintenance therapy, the achievement of personal goals and disease stability.

Study description

Background summary

Rationale:
Suboptimal self-management of inhaled maintenance therapy in asthma and COPD patients is frequently observed in clinical practice and has been associated with poor outcomes. Good insights into the underlying multitude of complex barriers concerning cognitive, affective and practical barriers are lacking and therefore a ‘one-size fits-all approach’ is often applied in clinical practice. To support patients in improving disease control by tailored care from healthcare professionals, the RACE-instrument was developed to measure individual barriers to self-management of inhaled maintenance therapy, disease control and individual treatment goals. Community pharmacists have an important role in providing long-term care for effective self-management as interactions with these patients take place on a regular basis during prescription refills. The RACE-instrument may therefore be applied by community pharmacists in consultations with asthma and COPD patients.

Objective:
The primary objective is to evaluate the feasibility and acceptability of the RACE-instrument with complex multidimensional interventions provided in consultations by community pharmacists in asthma and COPD patients with maintenance inhaler therapy.
As secondary objective the effectiveness of personal support and tailored care provided with the RACE-instrument and its complex multidimensional interventions by community pharmacists is compared between intervention and control group regarding number of barriers to self-management with inhaled maintenance therapy, the achievement of personal goals and disease stability.

Study design:
An exploratory randomized controlled trial (RCT) will be conducted in approximately 40 community pharmacies in the Netherlands. These community pharmacies are divided over two study populations for the inclusion of asthma and COPD patients. Within these study populations, patients are randomized per pharmacy to the control group (CG) or intervention

group (IG). Patients of both groups will be invited to fill in the online questionnaire on the four modules of the RACE-instrument at three consecutive timepoints (baseline, after 4 and 8 weeks). IG patients receive the results from the questionnaire and are requested to make an appointment for consultation with their pharmacist at baseline and after 4 weeks; CG patients receive usual care during the study and their RACE results at 8 weeks with the possibility for a subsequent pharmacist consultation at the end of the study. Prior to study start pharmacists are trained on applying the RACE-instrument with its complex multidimensional interventions, providing personal support. Participating pharmacists and IG patients will be asked to answer an online questionnaire after the three consecutive measurements have taken place; with those willing a semi-structured interview will be held on their experiences with the RACE-instrument in consultations.

Study population:
Patients are eligible for inclusion when ≥ 18 years, using long-acting β2-agonists (LABA) and/or long-acting muscarinic antagonists (LAMA) for COPD inhaled maintenance therapy and inhalation corticosteroids (ICS) for asthma inhaled maintenance therapy according to dispensing data in the pharmacy information systems.

Intervention:
The intervention consists of personal support and tailored care provided by community pharmacists with the RACE-instrument and its complex multidimensional interventions in consultations with asthma patients or COPD patients who use inhaled maintenance therapy.

Main study parameters/endpoints:
Related to the primary objective concerning the feasibility and acceptability of the RACE-instrument with interventions in consultations, the evaluation includes 1) experiences on barriers and facilitators in using this instrument from the perspectives of pharmacists and patients, 2) the recognition of self-management barriers obtained from the RACE-questionnaire by the patient and 3) the agreement on corresponding interventions between the patient and pharmacist.
The effectiveness of the instrument (secondary objective) will be assessed for the following outcomes measured by the RACE-questionnaire at the study end and compared within study populations of asthma or COPD patients between IG and CG: 1) number of barriers to self-management, 2) disease control and 3) the achievement of individual treatment goals measured with goal attainment scaling (GAS). Multivariate regression analysis will be used with adjustment for baseline scores, patient characteristics and patient clustering within pharmacies.

Study objective

When providing personal support and tailored care by community pharmacists with the RACE-instrument and its complex multidimensional interventions in consultations, self-management and treatment outcomes in asthma and COPD patients who use inhaled maintenance therapy can be optimized.

Study design

T0: Patients of both groups will be invited to fill in the RACE-questionnaire at baseline. In addition, IG patients will have a consultation with their pharmacist.
T1: Patients of both groups will be invited to fill in the RACE-questionnaire after 4 weeks. In addition, IG patients will have a second consultation with their pharmacist.
T2: Patients of both groups will be invited to fill in the RACE-questionnaire after 8 weeks.
T3: Within two weeks after T2, participating pharmacists and patients from the intervention group will also be interrogated on their experiences with the RACE-instrument with a questionnaire and with those willing a semi-structured interview will be held.

Intervention

The intervention consists of personal support and tailored care provided by community pharmacists with the RACE-instrument and its complex multidimensional interventions in consultations with asthma patients or COPD patients who use inhaled maintenance therapy.

Contacts

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Eligibility criteria

Inclusion criteria

- ≥ 18 years of age
- Being treated for asthma with ICS maintenance therapy or
- Being treated for COPD with LAMA or LABA
according to dispensing data for these conditions present in the pharmacy information systems.
- Able to answer to online questionnaires

Exclusion criteria

- Concomitant asthma and COPD, suspicions hereof or diagnosed with other significant lung diseases from information present in the pharmacy
- Incapability to speak, write and comprehend the Dutch language
- Presence of any cognitive impairments

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	17-10-2021
Enrollment:	400
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N.A.

Ethics review

Positive opinion

Date:	02-10-2021
Application type:	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

Register	ID
NTR-new	NL9759
Other	METC Leiden Den Haag Delft : N21.111

Study results

Summary results
The data obtained in this trial will be disclosed as an international publication.