On TRACk: a blended intervention incorporating TRaining, prepAration and Counseling to improve inhaler technique and medication adherence in patients with a chronic lung disease

No registrations found.

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

Summary

ID

NL-OMON22618

Source
NTR

Brief title
On TRACk

Health condition

Asthma/COPD

Sponsors and support

Primary sponsor: ZonMw
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

adherence to inhaler medication and inhaler technique

Secondary outcome

disease control, quality of life, hospitalizations, work absence, beliefs about medication, self-efficacy in understanding and using medication, perceived efficacy in interactions

Study description

Background summary

RESEARCH QUESTION: Can on TRACk, a TRain, prepAre, Communicate strategy, improve inhaler medication adherence and inhaler technique of lung patients?
INTERVENTION: On TRACk combines two innovative and proven successful elements: (1) online training of PTs to improve their inhaler medication counseling (both content, including giving a correct inhalation instruction, and patient-centred communication style), (2) preparing technicians and patients for these counseling moments in which inhaler technique is evaluated and medication use is discussed based on topics chosen by patients.

Study objective

On TRACk, a blended intervention that prepares both patients and pharmacy technicians for two inhaler medication consultations and trains technicians in their communication will improve inhaler medication adherence and inhaler technique in patients with asthma/COPD and lead to better health outcomes

Study design

participants fill out questionnaires are t=0, with follow up every three months for a year. Participants in the intervention group will have planned dispence conversations at t=3 and t=9.

Intervention

In step 1, PTs will be trained with the On TRACk training. Hereto they will videotape five planned second dispense conversations and upload these through a secure connection via their personal account to the On TRACk web portal following strict protocols. Two conversations will be selected by the trainer to perform self-reflection and provide personal feedback, both online.

In step 2, trained PTs invite eligible patients who collect inhaler medication for the first time to participate in the study. For patients, participation involves preparing themselves for a planned second dispense conversation in the pharmacy using materials provided via the On TRACk web portal. Patients hereto are given access with personal log in data to the web

portal. Here they will find information about the medication and their illness, and tips and tools to support their self-management. They will select topics for the conversation using a question prompt list (QPL). A QPL is a structured list with questions designed to aid patients' question asking behavior. This information will be send via the portal to the PT so that (s)he can prepare the conversation using the topics selected by the patient.

In step 3, the planned second dispense conversation takes place in the pharmacy consultation room in which all topics are discussed, as well as demonstration and refinement of the inhaler technique. A follow-up conversation will be planned at six months to monitor inhaler technique (including suitability of the device) and medication use.

Contacts

Public
Nivel
Roland te Paske

030 272 9680
Scientific
Nivel
Roland te Paske

030 272 9680

Eligibility criteria

Inclusion criteria

All patients with asthma and/or COPD who collect their maintenance inhaler medication for the first time in the community pharmacy will be asked consecutively to participate in this study by the pharmacy technician. Further inclusion criteria are: (1) aged 16 years or older, (2) understanding the Dutch language.

Exclusion criteria

(1) simultaneous experimental SABA use, (2) cognitive impairment.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2021
Enrollment:	360
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Will individual participant data be available (including data dictionaries)? Yes

What data in particular will be shared? Individual participant data that underlie the results reported in the upcoming articles that will be written based on the trial outcomes, after deidentification. I.E. text, tables figures and appendices.

What other documents will be available? Study protocol, peer reviewed articles with results from the trial (ultimately bundled in a PhD thesis)

When will data be available (start and end dates)? Directly after publishing clinical study reports. Maximum of three years.

With whom? At request, for researchers who will provide a methodologically sound proposal. For what types of analyses? To achieve the aims in the approved proposal.

By what mechanism will data be made available? Proposals should be directed to R.tePaske@nivel.nl, M.Vervloet@nivel.nl or L.vandijk@nivel.nl. To gain access, data requestors will need to sign a data access agreement. Data are available for 3 years at third party website.

Ethics review

Positive opinion

Date:	02-06-2021
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	NL9750
Other	METc VUmc : 2020.358

Study results