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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22618

Bron
NTR

Verkorte titel
On TRACk

Aandoening

Asthma/COPD

Ondersteuning

Primaire sponsor: ZonMw
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

adherence to inhaler medication and inhaler technique

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2021
Aantal proefpersonen:	360
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
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.

Ethische beoordeling

Positief advies

Datum:	02-06-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9750
Ander register	METc VUmc : 2020.358

Resultaten