FRESH AIR: a implementation science research project to improve the prevention, diagnosis and treatment of non-communicable lung diseases in low and middle income countries (LMICs) and other low-resource settings

Gepubliceerd: 29-10-2015 Laatst bijgewerkt: 13-12-2022

Health outcomes for people at risk of or suffering from non-communicable lung diseases in low-resource settings will be improved by developing capacity for implementation of evidence-based interventions for prevention, diagnosis and treatment in...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21656

Bron
NTR

Verkorte titel
FRESH AIR

Aandoening

non-communicable lung diseases, COPD, asthma, Household air pollution, Very brief smoking advice, low-resource settings, implementation research,

Ondersteuning

Primaire sponsor: LUMC, IPCRG, MAKERERE, MHKR, UMP, UoC, ARTEG, ELF, UW, NCSCT, UMCG, UCPH, ECC

Of all beneficiaries, only UCPH will use contributions in kind provided by third parties
Overige ondersteuning: H2020-HCO-2014-2015 European Commission, Grant Agreement, number 680997

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Spirometry study
1. self-reported satisfaction of Spirometry 360 training (12-items post-course survey)
2. frequency spirometry tests performed
3. number of test errors

VBA study:
- % training followed
- pre, post-training knowledge
- self-reported implementation VBA (n of VBA given)
- acceptability
- practibility
- feasibility
-affordability
- knowledge
- % self-reported smoking status
- self-reported changes to clinical practice

Pulmonary rehab study
- incremental shuttle walking test
- sit-to-stand test (number of repetitions and Borg score)
- Biceps curl (weight, number of repetitions and Borg score of perceived exertion
- pull-ups (weight, repetitions and Borg score of perceived exertion
- step-ups (number of repetitions and Borg score of perceived exertion
cycling (resistance and Borg score of perceived exertion)
- biometric data (BMI)
- blood pressure, pulse, pulse oximetry and Borg score of perceived exertion
- CCQ scale (health status)
- MRC dyspnoea scale (health status)
- Biceps curl (weight, number of repetitions and Borg score of perceived exertion

U-5s study
Due to the explorative approach of this sub study no endpoints have been set. The study outcomes are formed by the themes emerging from data analysis and will provide insight in the local concepts, terms, barriers to health care and the clinical and local diagnosis and treatment of respiratory disease

-descriptive data on diagnosis

Cough how long? Days, median (IQR)
Previous episodes of cough? n (%) How many? Median, IQR

Previous episodes of wheeze? n (%) How many? Median, IQR
Fever a problem: n (%)
Temperature felt or measured: n(%)
Temp: degrees celcius, mean (IQR)
Fever how long: n (%)
Respiratory rate counted n(%)
Respiratory rate, mean (SD)
Chest exposed n(%)
Stethoscope used n(%)
Chest indrawing? n(%)
Stridor?, n(%)
Wheezing, n(%)
Cyanosis checked. n(%)
Saturation: mean (IQR), n < 92% (%)

-descriptive data on treatment
Bronchodilator trial? n(% of wheezers)
Effect of bronchodilator trial, n (% of IBD trials)
Treated with antibiotics, ICS, IBD, other n (%)

-descriptive data on outcome of acute respiratory disease
Admitted n (%) (May not be relevant, depending on local health centre possibilities)
Follow up arranged: n(%)
Follow up achieved: n(%)
Child still has cough/difficult breathing/wheeze at follow-up: n(%)

Midwife study:
program evaluation
- self reported level of satisfaction
- self-reported changes in behaviour
-self-reported barriers of implementation

Toelichting onderzoek

Achtergrond van het onderzoek

Around 90% of deaths from COPD and 80% deaths from asthma occur in low and middle-income countries (LMICs). FRESH AIR, acronym for Free Respiratory Evaluation and Smoke-exposure Reduction by primary Health cAre Integrated gRoups, is a three year project that addresses the urgent need to prevent, diagnose and treat non-communicable lung diseases in low and middle income countries (LMICs) and other low-resource settings where the greatest burden of disease occurs. Over the next 3 years FRESH AIR will explore why so many

people in LMICs are dying from chronic lung diseases and what can be done to reduce the burden. A set of implementation science studies will examine the burden of chronic lung diseases, their risk factors, public awareness of these risk factors and how evidence-based approaches to prevention, diagnosis and treatment can be implemented in affordable and appropriate ways.

Doel van het onderzoek

Health outcomes for people at risk of or suffering from non-communicable lung diseases in low-resource settings will be improved by developing capacity for implementation of evidence-based interventions for prevention, diagnosis and treatment in these contexts.

This study will consist out of five sub studies.

The first substudy will focus on the improving of diagnosis and treatment of lung diseases by supporting training and implementation of lung function measurements through delivery of an online spirometry training and feedback program in low-resource settings (will be referred to as spirometry study)

The second study is a development study to examine feasibility and acceptability of very brief advice on smoking (VBA) training for healthcare workers. It main aim is to determine whether the VBA on smoking intervention can be adapted to the healthcare context in the four partner countries; and whether training health and social care workers in delivering the intervention results in a change to their clinical practice. (will be referred to as VBA study)

The third study examines the feasibility and acceptability of a pulmonary rehabilitation intervention. (will be referred to as pulmonary rehab study)
The fifth study is a qualitative, clinical study assessing respiratory symptoms and asthma in children under five years (U-5's) of age in low-resources settings. Thereby aiming to obtain comprehensive knowledge on respiratory health practices in order to strengthen the diagnosis and treatment of respiratory distress in children in primary health care in and thereby reduce respiratory morbidity and mortality. (will be referred to as U'5 study)

The fourth study is aimed at assessing the feasibility and acceptability of a midwife-led health education intervention aimed at reducing exposure to HAP among pregnant women through a train the trainer programme delivered by midwives. This will be a development project and the information that will be generated will inform a larger study that will aim to assess the impact of interventions to reduce biomass exposure among pregnant women on pregnancy outcomes and lung health during infancy. (will be referred to as midwife study)

All studies will be conducted parallel to one another in the health care sector of rural areas in Greece, Kyrgyz Republic, Uganda and Vietnam. With the exception of the midwife study which will only be conducted in the rural areas of Uganda.

Onderzoeksopzet

Spirometry study

- continuous data collection on outcomes 2 and (month 2-5)

- outcome 1, after Spirometry 360 training

VBA study

- pre training, baseline knowledge (T0)

- post training, knowledge (T1)

- post training, program evaluation (T1)

- post training self-report VBA delivery (T2)

- post training, after 4 weeks, smoking status participants (T2)

Pulmonary rehab study:

- baseline (T0)

- beginning of each rehab program session (T1-12)

- Post-rehab program, evaluation (T13)

U-5s study

As it is an observational sub study, no fixed time points have been set. Data will be collected throughout the predefined period of data collection.

Midwife study:

information on acceptability and feasibility of the midwife program and supporting material will be assessed throughout the predefined period of data collection.

- post training, evaluation satisfaction

Onderzoeksproduct en/of interventie

Spirometry study:

A Spirometry 360 online training and feedback program, consisting out of a series of

Spirometry 360 activities. No control intervention will be admitted or implemented.

VBA study:

A Very brief advice training module translated and adapted to the local language, context and need.

Pulmonary rehab study:

A pulmonary rehab training module translated and adapted to the local language, context and needs. The format of the rehabilitation program with supporting materials , patient information resources and web-based information will be based on the outcome of the development study conducted in Uganda and funded by the Medical Research Council (MRC), the Welcome Foundation and the Dept. of Overseas Affairs in the UK (expected end date: February 2016). The Group-based program will consist of 6-week, twice weekly pulmonary rehabilitation programme consisting of physical exercises and health education, led by a physiotherapist and held in health centre.

U-5's study:

No intervention will be held, as it involves an observational sub study

Midwife study:

a health education programme to create and/or increase awareness about lung health and reduction of exposure to biomass smoke in pregnant women and children. The program is drafted and developed with help of the local midwives, paediatric nurses and research team.

Contactpersonen

Publiek

Leiden University Medical Centre(LUMC), department of Public Health & Primary Care

M.J.J. van der Kleij
Leiden
The Netherlands

Wetenschappelijk

Leiden University Medical Centre(LUMC), department of Public Health & Primary Care

M.J.J. van der Kleij
Leiden
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Spirometry study:

The study population will consist out of:

- English speaking family physicians or general practitioners

- paediatricians

- Internal Medicine Physicians

- Nurse Practitioners

- Respiratory Therapists

- Nurses

- Medical Assistants

- Physician Assistants

- Health Educators

VBA study:

The study population will consist out of:

- health care workers: registered at a health care centre (can include HIV or TBC centres) and have the capability, opportunity and motivation to intervene with tobacco smokers

-social care workers: have the capability, opportunity and motivation to intervene with

tobacco smokers and be in regular contact with tobacco smokers

Pulmonary rehab study:
The study population will consist out of patients with:
- A by a study doctor or GP confirmed definite diagnosis of a chronic respiratory disease (including include COPD, interstitial lung disease, bronchiectasis and pulmonary hypertension that will not include reversible airways disease such as asthma)
- A Medical Research Council dyspnoea score grade 2 or higher;
- Previous TB treatment or confirmed COPD diagnosis;

U-5's study:
The population to be studied will be composed using purposive sampling will consist of:
- Caregiver: has a child/children between 12-59 months, with long-term cough who has/have been treated for ARI at the Health Care Centres, hospitals or at the local expert in rural areas or at hospitals one or several times
- healthcare worker: registered level of education and experience. formally registered as employee at the included health care centre
-local expert: identified by the local research members.

Midwife study:
The study population will consist out of:
- midwives: formally registered as employee at a health care centre which have a clear and functional link with community health care workers.
- pregnant women: attending an antenatal clinic
- village health team: a health care worker within the community of the study setting that has been trained to deliver a selected package of preventive, promotion and curative health services within the communities.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Pulmonary rehab study:

exclusion criteria

-unstable cardiovascular disease, locomotor difficulties that preclude exercise.

- Within 4 weeks of an acute exacerbations of their condition;

- Malignant disease such as lung cancer;

- Reversible airways disease such as asthma;

- Unwilling or unable to attend a PR programme;

- Unable to provide informed consent.

U-5's study

exclusion criteria:

-caregiver: the child is diagnosed with tuberculosis or has a medical history of tuberculosis.

specific exclusion criteria for the spirometry study and the midwife study are yet to be determined in collaboration with the local research teams of Uganda, Kyrgyz Republic, Greece and Vietnam.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2015
Aantal proefpersonen:	0
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL5644
NTR-old	NTR5759
Ander register	: H2020 680997

Resultaten

Samenvatting resultaten
van Gemert F, van der Molen T, Jones R, Chavannes N, The impact of asthma and COPD in sub-Saharan Africa, Prim Care Respir J. 2011, 20 (3), 240-8.

van Gemert F, Chavannes N, Nabadda N, Luzige S, Kirenga B, Eggermont C, et al. Impact of chronic respiratory symptoms in a rural area of sub-Saharan Africa: an in-depth qualitative study in the Masindi district of Uganda. Prim Care Respir J 2013 Sep;22(3):300-305.

Verbiest M, Chavannes N, Scharloo M, Kaptein A, Assendelft W, Crone M, Effecting change in primary care management of respiratory conditions: a global scoping exercise and literature review of educational interventions to inform the IPCRG's E-Quality initiative, Prim Care Respir J. 2012, 21 (4), 431-6.

van Gemert F, Kirenga B, Chavannes N, Kamya M, Luzige S, Musinguzi P, Turyagaruka J, Jones R, Tsiligianni I, Williams S et al: Prevalence of chronic obstructive pulmonary disease and associated risk factors in Uganda (FRESH AIR Uganda): a prospective cross-sectional observational study. The Lancet Global health 2015, 3(1):e44-51.

Østergaard MS. Childhood asthma: reasons for diagnostic delay and facilitation of early diagnosis — a qualitative study. Prim Care Respir J. General Practice Airways Group; 2005;14(1):25–30.

Østergaard MS, Nantanda R, Tumwine JK, Aabenhus R. Childhood asthma in low income countries: An invisible killer? Prim Care Respir J. Primary Care Respiratory Society UK;

2012;21(2):214–9.

Nantanda R, Ostergaard MS, Ndeezi G, Tumwine JK. Factors associated with asthma among under-fives in Mulago hospital, Kampala Uganda: a cross sectional study. BMC Pediatr [Internet]. 2013;13(1):141. Available from: http://www.biomedcentral.com/1471-2431/13/141

Mallaina P, Lionis C, Rol H, Imperiali R, Burgess A, Nixon M, Malvestiti FM, Smoking cessation and the risk of cardiovascular disease outcomes predicted from established risk scores: results of the Cardiovascular Risk Assessment among Smokers in Primary Care in Europe (CVASPIRE) study.BMC Public Health. 2013 Apr 18;(13):362