ISRCTN33589847 https://doi.org/10.1186/ISRCTN33589847

Effect of the Zurich resource model teaching module on adherence to self-monitoring and to the written action plan in patients with asthma: a randomised controlled trial

Submission date
19/10/2006

Recruitment status
No longer recruiting

Registration date
20/11/2006

Overall study status
Completed

Last Edited
06/01/2021

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of the Zurich resource model teaching module on adherence to self-monitoring and to the written action plan in patients with asthma: a randomised controlled trial

Study objectives
New methods are needed to improve adherence of asthma patients to a written personal action plan. With this trial we aim to provide evidence about the usefulness of an asthma unspecific educational course to achieve the goal of better adherence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cantonal Ethics Committee of the Canton Zurich, approved on the 18th October 2005 (ref: KEK-StV-Nr:29/05).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Asthma

Interventions
Zurich Resource Model (ZRM) training:
ZRM is thought to motivate the patient and to enable the patient to sense and interpret signs of deterioration more adequately and thereby improves the adherence in following the action plan. The ZRM model is based on findings in neurosciences and psychological theory. The ZRM model integrates treatment strategies from psychological as well as behavioral, body-oriented, and supportive-humanistic methods. ZRM training follows a specific manual and is suitable equally

for work with individuals and with groups, with adolescents and adults. Patients randomised to the ZRM group have a two day ZRM training in an outpatient setting followed by three ZRM refreshers of two hours for a repetition of important concepts after four, ten and 14 weeks.

Control group with usual care:
Usual care means treatment according to asthma guidelines which consists of clinical visits, adequate treatment and education in self-management with instruction in a personal Peak Expiratory Flow (PEF) and symptom based action plan. Patient education will include three main dimensions, knowledge (pathophysiology of the disease, effects and side effects of drugs) skills (inhalation technique and peak flow/symptom monitoring) and behaviour (instruction in the use of a written action plan, self-management). All patients included in the study will get that kind of patient education in a uniform defined way at the Medical Policlinic and Centre for interdisciplinary patient education. Part of the education (knowledge, inhalation technique, use of a peak-flow meter and monitoring) will be delivered in group trainings, while self-management with a personal action plan will be instructed individually.

Assessments will be made after one, three, six and 12 months.

Intervention Type
Behavioural

Primary outcome measure
To assess if patients with not optimally controlled asthma, who are treated according to GINA Guidelines and who participate in a ZRM course better adhere to:
1. Self-monitoring (PEF and symptoms);
2. Self-management according to the written personal action plan; and
3. Preventive strategies for known personal triggers, compared with patients treated according to GINA Guidelines alone.

Secondary outcome measures
To assess whether asthma patients participating in the ZRM training achieve better patient-assessed asthma control (asthma control questionnaire) and motivation and self-efficacy for self-management.

Overall study start date
04/10/2005

Completion date
04/02/2007

Eligibility

Key inclusion criteria
1. Males and females of full legal age (18 years old and elder)
2. Persistent not optimally controlled asthma according to the Global Initiative on Asthma (GINA) guidelines (symptoms during day, or night time symptoms, or limitation in daily activities or sports because of asthma, or need for rescue medication or unscheduled visits due to exacerbations in the last six months)
3. Asthma is defined by history, symptoms and more than 12% reversibility of airflow obstruction after beta2-mimetika inhalation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Psychiatric diagnosis such as major depression, schizophrenia, substance abuse or personality disorders
2. Other lung diseases: Chronic Obstructive Pulmonary Disease (COPD), lung cancer, fibrosis, sarcoidosis
3. Insufficient knowledge of German language to follow Zurich Resource Model (ZRM) course and /or to complete questionnaires

Date of first enrolment
04/10/2005

Date of final enrolment
04/02/2007

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital Zurich
Zurich
Switzerland
8091

Sponsor information

Organisation
AstraZeneca (Switzerland)

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Sponsor type
Industry

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http://www.astrazeneca.ch

ROR
https://ror.org/034rhks82

Funder(s)

Funder type
Industry

Funder Name
AstraZeneca (Switzerland)

Alternative Name(s)
AstraZeneca PLC, Pearl Therapeutics

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results		06/01/2021	Yes	No