

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

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		<input type="checkbox"/> Protocol
Registration date 20/11/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 06/01/2021	Condition category Respiratory	<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

<https://ror.org/034rhks82>

Funder(s)

Funder type

Industry

Funder Name

AstraZeneca (Switzerland)

Alternative Name(s)

AstraZeneca PLC, Pearl Therapeutics, AZ

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

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