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Improving chronic disease care in South Tyrol with a new health tool

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Registration date 23/08/2023	**Overall study status** Ongoing	
Last Edited 24/06/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The aim of this study is to validate German and Italian versions of the ABCC tool and evaluate its effectiveness and cost-effectiveness within the South Tyrolean Primary Care setting. Chronic diseases such as chronic obstructive pulmonary disease (COPD), asthma, type 2 diabetes, and heart failure often coexist and place a significant burden on individuals and health systems. The ABCC tool aims to comprehensively assess and visualize disease burden, stimulate self-management, and encourage shared decision-making.

Who can participate?
Patients 18 years of age or older with COPD, asthma, type 2 diabetes, and heart failure, who receive care from South Tyrolean general practices

What does the study involve?
The ABCC tool will first be translated and validated in German and Italian. Half of the participants will then use the validated ABCC tool for one patient-reported outcome measurement assessment, while the other half will receive usual care. The patients' perception of quality of care is assessed after 18 months, as well as quality of life, self-management behavior, and healthcare utilization. The study will also conduct a cost-effectiveness analysis.

What are the possible benefits and risks of participating?
Participants using the ABCC tool may benefit from enhanced patient-centered care, improved quality of life, and potentially reduced healthcare costs. However, there may be no direct benefits for the control group. Risks are expected to be minimal, as the ABCC tool is a monitoring tool and not a diagnostic or therapeutic intervention.

Where is the study run from?
The Institute of General Practice and Public Health at Claudiana - College of Health Professions in Bolzano (Italy)

When is the study starting and how long is it expected to run for?
January 2024 to April 2027

Who is funding the study?
Autonomous Province of Bolzano, Department of European Integration (Italy)

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Versione no. 2 del 8.7.2023

Study information

Scientific Title
A quasi-experimental study to evaluate the effectiveness and cost-effectiveness of the Assessment of Burden of Chronic Conditions (ABCC) tool in South Tyrolean primary care for patients with COPD, asthma, type 2 diabetes, and heart failure: the ABCC South Tyrol study

Acronym
ABCC-ST

Study objectives

The central hypothesis of this study is that the use of the Assessment of Burden of Chronic Conditions (ABCC) tool, after being translated and validated in German and Italian, will improve patients' perception of the quality of care, enhance self-management behaviors, improve quality of life, and potentially reduce healthcare costs in a South Tyrolean primary care setting for patients with chronic conditions, i.e. COPD, asthma, type 2 diabetes, and heart failure.

Patients who use the ABCC tool will demonstrate greater improvements in these outcomes compared to patients who receive standard care. The ABCC tool will prove to be cost-effective, considering direct medical costs reimbursed by the National Health Service.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/08/2023, Scientific Ethics Committee of the Autonomous Province of Bolzano, Italy (Comitato etico, c/o Comprensorio Sanitario di Bolzano Italia) (Via Lorenz Böhler 15, Bolzano, 39100, Italy; +39 (0)471438272; comitatoetico.bz@sabes.it), ref: 73-2023

Study design
Single-center quasi-experimental interventional trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Perceived quality of care of patients with a diagnosis of chronic obstructive pulmonary disease (COPD), asthma, T2DM, and/or heart failure

Interventions
The intervention for this study is the use of the Assessment of Burden of Chronic Conditions (ABCC) tool, which is a patient-reported outcome measure (PROM). This tool has been specifically designed to facilitate individualized medical decision-making for patients with complex health conditions.

The ABCC tool has four modules:
1. A self-assessment questionnaire for patients to evaluate their perceived burden of disease due to one or more chronic conditions.
2. A visual tool that presents the results of the self-assessment in an intuitive 'balloon diagram'. This allows both patients and healthcare providers to easily understand and discuss the patient's condition.
3. A joint decision-making discussion module, facilitated by the results of the self-assessment and integrated treatment recommendations.
4. A personalized care target-setting module, in which individualized care goals are determined based on the patient's self-assessment and the joint decision-making discussion.

For this study, the ABCC tool will be translated into German and Italian using a forward-backward translation process, and validated by cognitive interviews with a small group of chronically ill individuals. The translated tool will then be used over a duration of 18 months to evaluate its effectiveness in improving patients' perception of their care quality.

For the quasi-experimental study cluster-randomization of general practices (GPs), the method will be stratified randomization based on the GP office size (more than 1000 patients, less than 1000 patients), location (rural, urban), and language of the majority of patients (German/Ladin speaking, Italian speaking).

The validation of the translated ABCC tools will employ other condition-specific tools such as the 'COPD Population Screener™' (COPD-PS™) and the 'Asthma Control Test™' (ACT™) for patients with COPD and asthma respectively. For patients with Type 2 Diabetes Mellitus (T2DM), the 'European Quality of Life 5 Dimensions 5 Level' (EQ-5D-5L) questionnaire will be used, and for patients with heart failure, the 'Kansas City Cardiomyopathy Questionnaire' (KCCQ) will be used.

The study's control group will receive the usual care without the use of the ABCC tool. The primary outcome will be the change in patient's perception of the quality of care after 18 months, compared between the group using the ABCC tool and the control group. Secondary outcomes will include changes in quality of life, self-management behavior, and healthcare utilization.

Intervention Type
Other

Primary outcome(s)
The shift in perceived quality of care over an 18-month period, measured using the Patient Assessment of Chronic Illness Care (PACIC) questionnaire at baseline, 6, 12, and 18 months

Key secondary outcome(s))
1. Shift in perceived quality of care, individually for each chronic condition, measured using the PACIC questionnaire at baseline, 6, 12, and 18 months
2. Perceived quality of care against regular care, both for the entire participant group and individually for each chronic condition, measured using the PACIC questionnaire at 6- and 12-month intervals
3. Universal health-related quality of life, measured using the EQ-5D-5L questionnaire, compared to standard care, both for the entire participant group and for each chronic condition separately at 6, 12, and 18-month intervals
4. Participant activation measured using the Patient Activation Measure (PAM) compared to standard care, both for the entire participant group and individually for each chronic condition, at 6, 12, and 18-month intervals
5. Cost-effectiveness analysis of the ABCC tool compared to usual care, focusing on direct medical costs reimbursed by the National Health Service, after an 18-month period

Completion date
30/04/2027

Eligibility

Key inclusion criteria

1. Patients with a diagnosis of chronic obstructive pulmonary disease (COPD), asthma, T2DM, and /or heart failure
2. Can understand and read German or Italian

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
95 years

Sex
All

Key exclusion criteria
1. Patients with asthma or COPD who have taken prednisone for an exacerbation within 6 weeks prior to the start of the study
2. Patients with T2DM or heart failure who have been hospitalised within 6 weeks prior to the start of the study

Date of first enrolment
01/01/2025

Date of final enrolment
31/05/2025

Locations

Countries of recruitment
Italy

Study participating centre
Institute of General Practice and Public Health, Claudiana College of Health Care Professions
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Sponsor information

Organisation
Landesfachhochschule für Gesundheitsberufe Claudiana

ROR
https://ror.org/051nxta34

Funder(s)

Funder type
Government

Funder Name
Provincia autonoma di Bolzano - Alto Adige

Alternative Name(s)
Provincia Autonoma di Bolzano, Province of Bolzano

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon request at the Secretarial Office, info@am-mg.claudiana.bz.it. The type of data that will be shared includes individual data for patients' baseline characteristics, outcome measures, and study site characteristics. The data will be available for access after the study has been completed and the data has been fully processed and anonymized. Consent from participants was obtained, and all data will be fully anonymized to protect participants' privacy. The data will be fully anonymized, including patients' and GP offices' information, to ensure confidentiality. There are no ethical or legal restrictions on sharing the data as long as proper data anonymization procedures are followed. Additional comments: The research team value data transparency and aim to share the data in a responsible and secure manner to support further research and scientific inquiry.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		20/03/2024	22/03/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes