

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

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<b>Registration date</b> 23/08/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 24/06/2024	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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?  
Christian J. Wiedermann, christian.wiedermann@am-mg.claudiana.bz.it

## Contact information

### Type(s)

Principal Investigator

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

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

## **Secondary study design**

Cluster randomised trial

## **Study setting(s)**

GP practice

## **Study type(s)**

Quality of life

## **Participant information sheet**

Not available in web format, please use the contact details to request a participant information sheet

## **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/Latin 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 measure**

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

## **Secondary outcome measures**

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

**Overall study start date**

01/12/2022

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

95 Years

**Sex**

Both

**Target number of participants**

354

**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

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**Sponsor type**

University/education

**Website**

<http://www.claudiana.bz.it/>

**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

### Publication and dissemination plan

Upon the conclusion of the study, the findings will be broadly disseminated to facilitate transparency and contribute to the advancement of healthcare. Participants will be informed of the study results in a comprehensible manner. For healthcare professionals, the primary dissemination method will be through publication in peer-reviewed academic journals. In addition, results will be shared at relevant medical and scientific conferences, seminars, and through professional networks. The general public will be informed of the study results through accessible summaries disseminated via popular media outlets, the study website, and potentially through public lectures.

Data from the trial will be made available according to current best practices for data sharing, with due respect to participant confidentiality and data protection regulations. Any data sharing arrangements will be guided by relevant ethical and legal considerations.

There are no publication restrictions associated with this study. All publications will adhere to recognized ethical guidelines such as the International Committee of Medical Journal Editors (ICMJE) recommendations for authorship.

**Intention to publish date**  
31/12/2027

### 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](mailto: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?
<a href="#">Protocol article</a>		20/03/2024	22/03/2024	Yes	No