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# Finding out what patients think about the care they receive for osteoarthritis in general practice in South Tyrol, Italy

**Submission date**
19/01/2023

**Recruitment status**
No longer recruiting

**Registration date**
30/01/2023

**Overall study status**
Completed

**Last Edited**
20/12/2023

**Condition category**
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and study aims
Osteoarthritis (OA) is a degenerative condition in which the cartilage in joints wears down, leading to pain, stiffness and difficulty moving the affected joint.
General practice and primary care have become increasingly relevant in the care of patients with OA. This study provides an overview of the quality of care for knee and hip OA after consulting a GP in South Tyrol or Spa treatment in the Gastein Valley.

Who can participate?
The inclusion of participants is based on the GPs' diagnosis of knee or hip OA, irrespective of which diagnostic criteria the GPs use. Patients presenting with unspecified symptoms or diagnoses such as 'knee or hip pain' or 'knee or hip problems' will be considered for recruitment. Inclusion criteria defining OA diagnosis according to NICE are people who are 45 years or older, have activity-related joint pain, and have either no morning joint-related stiffness or morning stiffness that lasts no longer than 30 min.

What does the study involve?
The study requires participants to self-complete a health-related questionnaire that assesses the quality of care experienced in the treatment of osteoarthritis of the knee or hip.

What are the possible benefits and risks of participating?
The survey results can not only improve the quality of care of OA at the level of the public health service but also lead to an increase in the individual quality of OA care of the participant. The study will be conducted in general medical practices and the validated quality of care reported by the patient will be made known to the primary care physician. This contrasts with negligible risks. This study was approved by the Italian Regional Ethical Committee of the Province of Alto Adige.

Where is the study run from?
The study is performed by the Institute of General Practice and Public Health in Bolzano (BZ), Italy and the Institute for Physiology and Pathophysiology of the Paracelsus Medical University

in Salzburg, Austria harbours the Gastein Research Institute which is also a research unit of the Ludwig Boltzmann Institute for Arthritis and Rehabilitation. Study sites are selected general practices in South Tyrol and spa and rehabilitation centers in the Gastein Valley in Salzburg.

When is the study starting and how long is it expected to run for?
October 2022 to May 2025

Who is funding the study?
This research is funded by the 'South Tyrolean Fund for the Promotion of Scientific Research (SFPR) at the South Tyrolean Health Care Service (SABES|ASAA) and the Paracelsus Medical University Salzburg (PMU)'.

Who is the main contact?
Christian J. Wiedermann, M.D., christian.wiedermann@am-mg.claudiana.bz.it

# Contact information

### Type(s)
Principal investigator

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# Additional identifiers

### Protocol serial number
Protocol 20220803

# Study information

### Scientific Title
Patient-reported quality of care for osteoarthritis in general practice in South Tyrol, Italy

### Acronym
QIOAST

### Study objectives
Evidence-based recommendations for the treatment of knee and hip osteoarthritis (OA) are similar internationally. Nevertheless, the clinical practice varies across countries. Instruments for

measuring quality have been developed to improve health care through targeted interventions. However, such instruments for health-related patient-reported outcomes for OA have not yet been validated for the German and Italian languages. To be able to set targeted measures for the improvement of prevention and non-surgical treatment of OA in South Tyrol, Italy as well, the quality of care must be recorded.
Therefore, the aim of the study is to update, translate and validate the OsteoArthritis Quality Indicator (OA-QI) questionnaire version 2, an established and validated questionnaire in Norwegian and English for Germany and Italy. A second aim is to determine the quality of care for OA of the hip and knee in a sample of patients who consult general practice in South Tyrol, Italy and in a selected group of patients with OA in spa treatment for rehabilitation in Salzburg, Austria.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
Approved 19/10/2022, Scientific Ethics Committee of the Autonomous Province of Bolzano, Italy (Comitato etico, c/o Comprensorio Sanitario di Bolzano, Via L. Böhler 15, Bolzano (BZ), 39100 , Italy; +39 471438272; comitatoetico.bz@sabes.it), ref: 103-2022

## Primary study design
Observational

## Study design
Observational cohort study

## Study type(s)
Other

## Health condition(s) or problem(s) studied
Osteoarthritis of knee and hip

## Interventions
Patients in general practice or during a spa stay with rehabilitation treatment, who meet the inclusion criteria and have given informed consent, answer a questionnaire online or in the general practice or in the spa center. The questionnaire consists of items measuring the quality of previous osteoarthritis treatment and other questions that provide information about demographic and disease-related characteristics as well as aspects of quality of life and functional activity. No further measures are included.

The English version of the OA-QI v2 will be cross-culturally adapted and translated into Italian and German following an established forward-backward translation procedure, with independent translations and back translations. In addition, cognitive interviews to assess after-translation content validity from a patient perspective will be conducted in a limited number of participants. Internal validity will be assessed. Construct validity analyses will be performed using predefined hypotheses. To test for clarity of the translated German and Italian G-OA-QI v2 and I-OA-QI v2 questionnaires and their validity, a pilot study is conducted with 25 German-speaking and 25 Italian-speaking knee or hip osteoarthritis patients, respectively.

Patients' health-related reports on the quality of hip and knee OA care will be assessed in a cross-sectional survey using the validated Italian or German version of the updated OA-QI v2

questionnaire, according to the patient's mother tongue. The G-OA-QI v2 and I-OA-QI v2 questionnaires will be tested to assess the quality of OA care in the respective samples of consecutive OA patients participating in general practices in South Tyrol, Italy and in the participating health care and Spa centers of Gastein, Salzburg, Austria.

Subjects in South Tyrol are recruited in general practices of the Department of Basic Medical Services of the South Tyrolean Public Health Services. In Salzburg, subjects visiting the valley of Gastein for spa-treatment, including low-dose radon for a variety of rheumatic diseases, including OA, are recruited.

### Intervention Type
Other

### Primary outcome(s)
Mean total pass rate calculated as a percentage of achieved QI items of the updated, translated and validated G-OA-QI v2 and I-OA-QI v2 for the whole sample as well as for subgroups including type of OA, language, and treatment location, measured at a single time point

### Key secondary outcome(s)
Measured at a single time point:
1. Scores on the individual QI items
2. Demographic and clinical characteristics measured using patient records

### Completion date
31/05/2025

## Eligibility

### Key inclusion criteria
1. Knee or hip OA diagnosis according to NICE
2. Aged 45 years or older
3. Have activity-related joint pain
4. Have either no morning joint-related stiffness or morning stiffness that lasts no longer than 30 min

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
45 Years

### Sex
All

### Key exclusion criteria
1. Malignant illness
2. Rheumatoid or other inflammatory arthritis
3. Severe degeneration of the hip or knee joint (Kellgren and Lawrence Grade IV)
4. Other inflammatory rheumatic diseases
5. Mental or psychiatric disorder
6. Inability to cooperate with the study requirements
7. Involvement in any other studies at the moment

### Date of first enrolment
01/07/2023

### Date of final enrolment
28/02/2024

## Locations

### Countries of recruitment
Austria

Italy

### Study participating centre
**Institute of General Practice and Public Health, Claudiana College of Health Professions**
Lorenz Böhler Street 13
Bolzano - Bozen (BZ)
Italy
39100

### Study participating centre
**Gastein Research Institute, Paracelsus Medical University**
Strubergasse 21
Salzburg
Austria
5020

## Sponsor information

### Organisation
Südtiroler Sanitätsbetrieb

# Funder(s)

### Funder type
Government

### Funder Name
South Tyrolean Fund for the Promotion of Scientific Research (SFPR) at the South Tyrolean Health Care Service (SABES|ASAA) and the Paracelsus Medical University Salzburg (PMU)

# Results and Publications

### Individual participant data (IPD) sharing plan
The data presented in this study will be available upon request from the corresponding author. The data are not publicly available due to language and ethnicity reasons in the politically autonomous state of the Italian region, Trentino – Alto Adige.
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### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | | 10/03/2023 | 02/08/2023 | Yes | No |