

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 30/01/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/12/2023	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name

Prof Christian Josef Wiedermann

ORCID ID

<http://orcid.org/0000-0002-4639-8195>

Contact details

Lorenz Böhler Street 13
Bolzano - Bozen (BZ)
Italy
39100
+39 471067200
christian.wiedermann@am-mg.claudiana.bz.it

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Protocol 20220803

Study information

Scientific Title

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

Study design

Observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

GP practice

Study type(s)

Other

Participant information sheet

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

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 measure

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

Secondary outcome measures

Measured at a single time point:

1. Scores on the individual QI items
2. Demographic and clinical characteristics measured using patient records

Overall study start date

20/10/2022

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

Age group

Adult

Lower age limit

45 Years

Sex

Both

Target number of participants

320 (170 in South Tyrol and 150 in Salzburg)

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

Sponsor details
Thomas-Alva-Edison-Straße 10/D
Bolzano - Bozen (BZ)
Italy
39100
+39 471223 601
gd@sabes.it

Sponsor type
Hospital/treatment centre

Website
<https://www.sabes.it>

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

Publication and dissemination plan

The study results will be submitted to international, open-access, peer-reviewed journals for publication. The validated translation of the OA-QI v2 into Italian and German will result in two papers. The original article on the quality of OA care will be published in a clinical rheumatology journal and is expected to propose specific interventions for quality improvement in both South Tyrol and Salzburg.

Intention to publish date

28/02/2025

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.
christian.wiedermann@am-mg.claudiana.bz.it

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