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Phase 3a and 3b update of the gastric cancer module, EORTC QLQ-STO22

Submission date
11/09/2026

Recruitment status
Recruiting

Registration date
01/10/2026

Overall study status
Ongoing

Last Edited
01/10/2026

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Although the EORTC QLQ-STO22 (QLQ-STO22) is one of the most widely used measures of quality of life for people with stomach (gastric) cancer, it needs to be updated to capture issues related to new and diverse treatment approaches which have been licenced since the beginning of the century when the development of the original QLQ-STO22 started. Updating the QLQ-STO22 will also provide the opportunity to consider the experiences and perspectives of patients and healthcare professionals (HCPs) from countries which were not included in the original development of the QLQ-STO22, and in particular those from East Asia.
The first phase of the update, which identified whether an update was needed, has been completed. It involved collecting and reviewing information on stomach cancer from a systematic review and interviews with 18 HCPs and 104 patients across 10 countries, including four from East Asia and three non-European countries.
The systematic review and interviews with HCPs and patients found no evidence that culturally specific adaptations to the QLQ-STO22 were needed. However, the systematic review and interviews found some quality of life issues were missing including flatulence, eating small amounts and peripheral neuropathy symptoms. In the second phase of the update, the EORTC quality of life group (QLG) recommended removing two non-specific questions (i.e., thinking about illness and worry about the future). Also, the translation team recommended adaptations to the wording of seven items (from 'Did you…?' To 'Have you…?').
An updated version of the QLQ-STO22 including five additional questions (covering the three missing issues) and linguistic changes to the seven questions needs to be pilot tested with a larger group of patients with stomach cancer including those from East Asia. This Phase 3 involves testing the updated QLQ-STO22 for its relevance to patients with stomach cancer, to identify and solve potential problems in its administration, and identify missing or redundant issues. The scale structure of the provisional measure will also be explored. The outcome of this work will be an updated measure of quality of life issues of specific relevance to patients with stomach cancer across different cultures and treated with current protocols.

Who can participate?
People aged at least 18 years of age with stomach cancer stages 1-4, who can understand, speak and read English (or Welsh for patients recruited in Wales), and who are able to give informed consent.

What does the study involve?
When evaluating the impact of an illness, such as cancer and its treatments, one of the most important areas to consider is the effect on people's quality of life quality of life. Quality of life can be affected in a number of ways by cancer and its treatment, and different patients may have different experiences. We have created an updated version of a quality of life questionnaire used specifically for stomach cancer, known as the EORTC QLQ-STO22. We need to test the updated version of our questionnaire and would like you to complete it and comment on it. We would like to speak to people with stomach cancer to find out all the different ways the effects of stomach cancer and its treatment affect people's lives and also to find the best way to measure the effects of stomach cancer on people's lives and whether the updated version of the questionnaire is suitable.
To take part we will ask patients to read a participant information sheet and ask any questions about participating to their friends, healthcare team or the research team. If they decide to take part patients will be asked to give informed consent and then answer some questions about themselves. Patients will be asked to complete some questionnaires, with questions asking about issues relating to their quality of life, and how much they experience each of the issues. The researcher will then ask some questions about the questionnaires; this is important as we are interested in whether the patients have any suggestions for questions, such as whether any should be removed, re-worded, if any questions are missing or not understandable.
The study involves a one-off discussion with a researcher. There will be no follow ups and is likely to take up to 20 minutes, but no longer than 1 hour.

What are the possible benefits and risks of participating?
It is hoped that the information provided to us by patients will help make sure we are measuring what matters most to people with stomach cancer.

Where is the study run from?
University of Southampton (UK)

When is the study starting and how long is it expected to run for?
October 2026 to May 2029

Who is funding the study?
European Organisation for Research and Treatment of Cancer (EORTC) (UK)

Who is the main contact?
Amy Din (study coordinator), A.E.Din@soton.ac.uk

Contact information

Type(s)
Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
373545

Central Portfolio Management System (CPMS)
74804

UK sponsor number
114091

Study information

Scientific Title
Phase 3a and 3b update of the gastric cancer module, European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ) Stomach Cancer 22 items (STO22)

Acronym

EORTC QLQ-STO22

Study objectives
The aims of this project are to:
1. Perform Phase 3a and 3b pre-testing of the revised QLQ-STO22 to identify and solve potential problems in its administration and provide a further opportunity to identify any confusing, unacceptable, missing or redundant issues
2. Carry out a preliminary evaluation of the psychometric properties of the updated QLQ-STO22, and explore the content and structure of the updated draft measure
3. Further examine any cultural differences in the quality of life experiences of patients from East Asia and non-East Asia

The objectives of this project are to:
1. Pre-test and psychometrically validate the updated QLQ-STO22 in patients with gastric cancer
2. Work in collaboration with the EORTC Gastrointestinal Tract Cancer group (GITCG), Asian Clinical Trials Network for Cancer Projects (ATLAS), Japan Clinical Oncology Group Stomach Cancer Study Group (JCOG SCSG) to update the QLQ-STO22 module to ensure its sensitivity and acceptability to new and diverse treatments and relevance to patients from countries within East Asia

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 07/09/2026, The North East - York Research Ethics Committee (REC) (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8096; york.rec@hra.nhs.uk), ref: 26/PR/1192

Primary study design
Observational

Secondary study design
Cross sectional study

Study type(s)

Health condition(s) or problem(s) studied
Gastric adenocarcinoma

Interventions
To fulfil the central objective of establishing a reliable and valid health related quality of life (HRQoL) measurement, the European Organisation for Research and Treatment of Cancer (EORTC) quality of life group (QLG) has developed a four-phase methodological framework to be used to develop domain-specific HRQoL modules in cancer (Bjordal et al. 2021). Updating modules follows the same four-phases; to provide context all four-phases are described below. NB: This study is the third phase in a four-phase validation process.

Firstly, and importantly, validated modules can be used in conjunction with the EORTC quality of life (QoL) core questionnaire (QLQ-C30; general cancer HRQoL measure) to assess HRQoL in specific patient groups.

The purpose of Phase 1a module update is to generate issues and thereby justify whether an update is required. This involves pooling an exhaustive list of relevant QoL issues covering domains of interest to update the content validity. A systematic review was firstly undertaken to identify HRQoL questionnaires used to assess patients with GC (Rowsell et al. 2022). This review also compared the HRQoL measures used across cultures, specifically East Asia, where GC is more prevalent. A total of 267 articles were identified, which included HRQoL questionnaires (n = 24). Some of the HRQoL questionnaires included in identified articles were developed within East Asian countries (n = 8). The articles search captured HRQoL issues including diarrhoea, constipation, reflux, abdominal pain and abdominal fullness or bloating, difficulty swallowing, restricted eating, and weight loss. With respect to psychosocial issues, issues relating to compatibility of some of the Westernised questionnaires within East Asian cultures were highlighted. Hence, for HRQoL measures developed in Western cultures, there are disparities between the linguistic equivalence and acceptability of HRQoL measures. Therefore, HRQoL measures may need adapting to be culturally relevant.

To supplement the issues and domains extracted from the literature review, Phase 1a also involved structured in-depth interviews performed with patients treated for GC within the last 12 months. Patients from both East Asia (n=25) and non-East Asia (n = 36) were recruited to draw cross-cultural comparisons.

Patients were asked to describe their experiences of having GC and receiving treatment. Patients were then shown the QLQ-C30 and the QLQ-STO22, and asked which items they felt were relevant, important, confusing, upsetting, and which they had not experienced. They were also asked if any questions needed re-wording and/or were missing. New issues extracted from Phase 1a formed a list of new issues which were reviewed by Healthcare Professionals (HCPs) in Phase 1b. HCPs were from both East Asia (n = 11) and non-East Asian (n = 7) countries to ensure representation in order to draw cross-cultural comparisons. HCPs were asked about patient experiences of GC and its treatment, and the impact of GC on patients' lives. HCPs were also asked to provide feedback on the relevance, importance and appropriateness of the issues. There was no evidence to suggest any required cultural adaptations with initial support for the use of QLQ-STO22 with patients in East Asia offered.

Given the necessary modifications to the wording of existing items within the QLQ-STO22 as a well as introduction of new questions, a revised module was recommended. In Phase 2, items to cover eating small amounts, neuropathy and flatulence (n = 5) were added, items which covered thinking about illness and worry about future health (n = 2) were removed, and items were also revised (n = 7). Therefore, the GC module preliminary item list now covers 25 items (i.e., provisionally known as the QLQ-STO25), and requires testing before it can be widely used.

Now Phase 2 has been completed, pre-testing of the updated version of the QLQ-STO22 will be undertaken in Phase 3, a cross-sectional, multicentre study; this current protocol outlines the process of Phase 3 in detail. The purpose of Phase 3 is to identify and solve potential problems with the preliminary item list. Phase 3a, will involve structured interviews with patients who currently have GC, with a total of 75-80 patients participating. These patients will be stratified according to treatment type and country of origin (East Asia or Non-East Asia) with a 30:70 split to ensure representation within East Asia (i.e., a minimum of 24 patients from East Asia). NB: no more than 30% of the sample can come from one country.

Patients will be invited to complete the QLQ-C30, the updated version of the QLQ-STO22, and the EORTC WISP (Write In three Symptoms/Problems) addendum instrument (a self-report

additional issues, i.e., symptoms or problems) on one occasion (Rojas-Concha et al. 2024). Patients will be asked to respond to the questionnaires 4-point Likert scale, while encouraged to “Think Aloud” and consider the relevance and importance of each item.

Phase 3a analysis will identify whether items are to be refined, retained, or deleted.

Phase 3b is the preliminary evaluation of the psychometric properties of the near-final version of the QLQ-STO22 update, identifying any necessary modifications prior to evaluating the validity and reliability (Phase 4).

Phase 4 is a confirmatory field-testing phase, which consists of a full-scale international validation of the final GC module, involving a large sample (i.e. >400). As this is an updated version of the QLQ-STO22, comparison compliance and acceptability of the new version with original QLQ-STO22 will be undertaken. The updated version of the QLQ-STO22 will be tested alongside the QLQ-C30. Patients will be given a debriefing questionnaire, asking how long it took them to complete QLQ-STO22 update, and whether any items were problematic. External validation of the updated QLQ-STO22 will be undertaken (e.g., clinical and sociodemographic information). Psychometric analysis will be undertaken to measure the validity and reliability of the module for clinical research and practice.

Intervention Type
Other

Primary outcome(s)
1. Finalised item list for the updated QoL assessment module for gastric cancer, which can be taken forward to a future Phase 4 international validation study. An exploratory assessment of the module’s preliminary psychometric properties, including scale structure, internal consistency, item performance, and the missing data patterns, measured using validated measures: EORTC QLQ-C30, EORTC (Write In three Symptoms/Problems) WISP. Under validation: EORTC QLQ-STO22 (update). Measured at 31/10/2026-31/10/2028

Key secondary outcome(s)

Completion date
31/05/2029

Eligibility

Key inclusion criteria
1. Adults (aged ≥18 years)
2. Histologically confirmed gastric adenocarcinoma with an epicentre located within 2 cm from the gastroesophageal junction
3. Stages I–IV
4. On treatment (chemotherapy, radiotherapy, targeted or immunotherapy or surgery) or within 1 year of finishing treatment or receiving supportive or palliative care
5. Ability to provide informed consent

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Unable to speak the native language of the recruiting centre (i.e., for UK sites this will be either English or Welsh)
2. Inability to complete questionnaires due to language or cognitive limitations.
3. Participated in Phase 1 (or Phase 3a for patients approached for Phase 3b) of the QLQ-STO22 update
4. Patients with a concurrent malignancy
5. Cancer survivors defined as people who have completed treatment with curative intent more than 1 year ago and are now cancer free
6. Patients enrolled in other quality of life studies which might affect the results of the current study, e.g., the update of the EORTC oesophageal cancer - QLQ OES18 and QLQ OG25
7. Patients who have not started active treatment yet

Date of first enrolment
31/10/2026

Date of final enrolment
31/10/2028

Locations

Countries of recruitment
United Kingdom

England

Wales

Belgium

China

Croatia

Ethiopia

Greece

India

Italy

Japan

Jordan

Korea, South

Lithuania

Mongolia

Norway

Singapore

Slovenia

Spain

Viet Nam

Study participating centre
University Hospital Southampton
Southampton University Hospital
Tremona Road
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Study participating centre
Salford Royal Hospital
Stott Lane
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M6 8HD

Study participating centre
South West Wales Cancer Network
41 High Street
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SA1 1LT

Study participating centre
Humanitas Research Hospital
Milan
Italy

Study participating centre
Dept at Institute of Medical Sciences Mongolia
Ulaanbaatar
Mongolia

Study participating centre
Vilnius University Faculty of Medicine
Vilnius
Lithuania

Study participating centre
University Medical Centre Maribor
Maribor
Slovenia

Study participating centre
Tikur Anbessa Specialized Hospital, Addis Ababa University
Addis Ababa
Ethiopia

Study participating centre
Oslo University Hospital
Oslo
Norway

Study participating centre
Fukushima Medial University
Fukushima
Japan

Study participating centre
Medical Oncology Dept Hospital Clinico Universitario de Valencia
Valencia
Spain

Study participating centre
Center for Gastric Cancer
Seoul
Korea, South

Study participating centre
Institute for Gastroenterological Tumors
Zagreb
Croatia

Study participating centre
Advanced Centre for Treatment, Research and Education in Cancer
Mumbai
India

Study participating centre
Tata Memorial Hospital
Mumbai
India

Study participating centre
Shizuoka Cancer Center
Shizuoka
Japan

Study participating centre
Hospital Universitario Vega Baja
Alicante
Spain

Study participating centre

Hippocration General Hospital, University of Athens
Athens
Greece

Study participating centre
National Cancer Center, Hospital Boulevard
Singapore

Study participating centre
Ho Chi Minh City Oncology Hospital
Ho Chi Minh City
Viet Nam

Study participating centre
Insituto Oncologico Veneto
Padura
Italy

Study participating centre
King Hussein Cancer Center, Faculty of Medicine, University of Jordan
Amman
Jordan

Study participating centre
Metropolitan General Hospital
Athens
Greece

Study participating centre
University Hospitals Leuven
Leuven
Belgium

Study participating centre
National Cancer Center
Tokyo
Japan

Study participating centre
The First Affiliated Hospital, Suzhou University
Suzhou
China

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type

Funder Name
European Organisation for Research and Treatment of Cancer

Alternative Name(s)
EORTC

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Belgium

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available