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EUROHELICAN—The First *Helicobacter Pylori* Screen-and-Treat Population-Based Study in Young Adults in Europe

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ABSTRACT

Background: Most gastric cancer cases are attributable to chronic *Helicobacter pylori (H. pylori)* infection and can theoretically be prevented.

Objective: In the EUROHELICAN project, we aimed to assess the feasibility, acceptability, effectiveness, and adverse events of a *Helicobacter pylori* screen-and-treat program in the 30–34-year age group for the first time in Europe.

Design: The study was conducted in the Community Healthcare Center dr. Adolf Drolc Maribor, following the methodology prepared by the National Institute of Public Health. We invited asymptomatic individuals aged 30–34 to be tested for *H. pylori* IgG antibodies; positive results were confirmed by urea breath test (UBT).

Results: 2102 participants accepted the invitation. The response rate was 24.4% (95% CI: 23.2–25.5), which was higher in women—28.1% (95% CI: 26.4–29.8) than in men—20.5% (95% CI: 0.19.0–22.1, $p < 0.001$). The serological prevalence of *H. pylori* infection was 14.2% (95% CI: 12.7–15.9). A confirmatory urea breath test (UBT) was positive in 83.7% of serology-positive patients. The eradication rate of 14-day bismuth-based quadruple therapy (esomeprazole 40 mg BID, amoxicillin 500 mg, metronidazole 400 mg and bismuth oxide 120 mg, all QID) was 94.7% (95% CI: 89.5–97.9). Adverse events (AEs) during treatment were reported more frequently in women (38.8%, 95% CI: 28.1–50.3) than in men (21.5%, 95% CI: 12.3–33.5; $p < 0.05$).

Conclusion: *H. pylori* screening and-treat program in 30–34 age group in Slovenia is feasible; *H. pylori* treatment is very effective with acceptable rate of AEs. Different approaches to raising public awareness are needed to increase participation rates.

Trial Registration: EU PAS number of HMA-EMA RWD Catalog: EUPAS107327, Study ID: 108428; ClinicalTrials.gov ID: NCT06216639, Protocol ID: EUROHELICAN01

1 | Introduction

Infection with the gram-negative bacterium *Helicobacter pylori (H. pylori)* is the most prevalent chronic bacterial infection worldwide, affecting 43% of the world's population [1]. Approximately 20% of infected individuals are at risk of developing *H. pylori*-related diseases, including peptic ulcer disease, *H. pylori*-related dyspepsia, iron-deficient anemia, idiopathic thrombocytopenic purpura, mucosa-associated lymphoid tissue lymphoma, or gastric cancer [2]. The attributable fractions of non-cardia gastric cancer (NCGC) to the infection with *H. pylori* were estimated to be 87% in the low-risk settings for gastric cancer in Australia, Europe and the United States, and 78% in the high-risk setting for gastric cancer in China [3]. In Europe,

Key Summary

- Summarise the established knowledge on this subject
  - *Helicobacter pylori* is a group I carcinogen and a cause of most of non-cardia gastric cancers.
  - With *H. pylori* eradication, especially in younger age groups, gastric cancer can be prevented.
- What are the significant and/or new findings of this study?
  - This study showed, for the first time, that a *H. pylori* screen-and-treat program targeting young adults aged 30–34 in Europe is feasible.
  - Treatment of *H. pylori* infection is highly effective with an acceptable rate of AEs. Various approaches to raise public awareness are needed to increase participation rates.

gastric cancer remains an important public health issue, with the regions of Eastern and Southern Europe, having the highest gastric cancer incidence worldwide, second only to Eastern Asia. The overall 5-year survival rate of gastric cancer remains low in the range of 20%–40% for most countries and drops to 10% in advanced disease stage, but with persisting international disparities [4, 5]. In Slovenia, the crude incidence rate of gastric cancer is 26.8 for men and 16.4 for women [6].

EU4Health-funded project—Accelerating gastric cancer reduction in Europe through *Helicobacter pylori* eradication (EUROHELICAN) was designed to assess the feasibility, acceptance, effectiveness and possible adverse events (AEs) of implementing *H. pylori* screen-and-treat program in an early 30s age group for the first time in Europe.

2 | Methods

2.1 | Study Design

The EUROHELICAN project has 6 work packages (WPs; Figure 1). *H. pylori* screen-and-treat application study represents WP 4. The project was funded 80% by the European Health and Digital Executive Agency (HaDEA) and 20% by the Slovenian Ministry of Health. EUROHELICAN WP4 was conducted in the Community Healthcare Center dr. Adolf Drolc Maribor (CHC Maribor) followed the methodology prepared by the consortium partner the National Institute of Public Health of Slovenia (NIJZ). NIJZ has provided: methodology design; a questionnaire on risk factors in early childhood and study participants' habits regarding alcohol consumption and tobacco use; a description of the target population and representative sampling; training for health care personnel involved in the screen-and-treat program; and invitation methods and invitation materials. The program was free of charge for all participants. NIJZ provided an online IT platform REDCap (Research Electronic Data Capture, Vanderbilt, United States) for entry and quality assurance of collected data. The study received approval from the National Medical Ethics Committee (0120-12/2023/3) and was registered as a non-interventional study in both the EU registry (EU PAS: EUPAS107327; Study ID: 108428) and the U.S. ClinicalTrials.gov registry (NCT06216639; Protocol ID: EUROHELICAN01). The study was designed following the principles of Wilson and Junger for screening [7] and the latest international recommendations for cancer screening programs [8].

The organizational pyramid of EUROHELICAN WP 4 had three levels:

— first level: Steering Committee and Program Council—NIJZ,

— second level; effector level—CHC Maribor

— third level: common activities on raising the public awareness and education of the lay public about the importance of silent *H. pylori* infection for gastric diseases—NIJZ and CHC Maribor.

External evaluators monitored the study: Nantes University Hospital (CHU Nantes) and the International Agency for Research on Cancer (IARC/WHO).

2.2 | Communication and Dissemination Activities

NIJZ led communication and dissemination activities (EUROHELICAN WP 2). The main goal was to disseminate the project's results in both local and international contexts through a diverse range of communication tools, aimed at both the general public and professional audiences. An important objective was to raise awareness of gastric cancer as an important public health issue, with particular focus on the *H. pylori* infections as the leading cause of gastric cancer.

We tried to accomplish our communication and dissemination objectives through different strategies and actions:

- Communication strategy and graphics for the project design.
- Press release and press conference with prepared materials and audio statements at the beginning of inviting participants to the study.
- Promotional material for the participants (lunch bags, leaflets, posters, pens, notebooks).
- Social media campaigns to raise awareness of gastric cancer and encourage participants to take part in the study; paid social media campaigns reached 684,929 people and generated 42,077 clicks.
- Digital campaign on Google Ads that made 3558 impressions.
- Advertisement on the city buses (57,386 screenings).
- Press releases in newspapers and on websites.
- Encouragement of TV and radio stations and other media to use prepared materials and to prepare interviews.
- TV and radio advertising to encourage participants to take part in the study.
- Podcasts on gastric cancer and *H. pylori*.

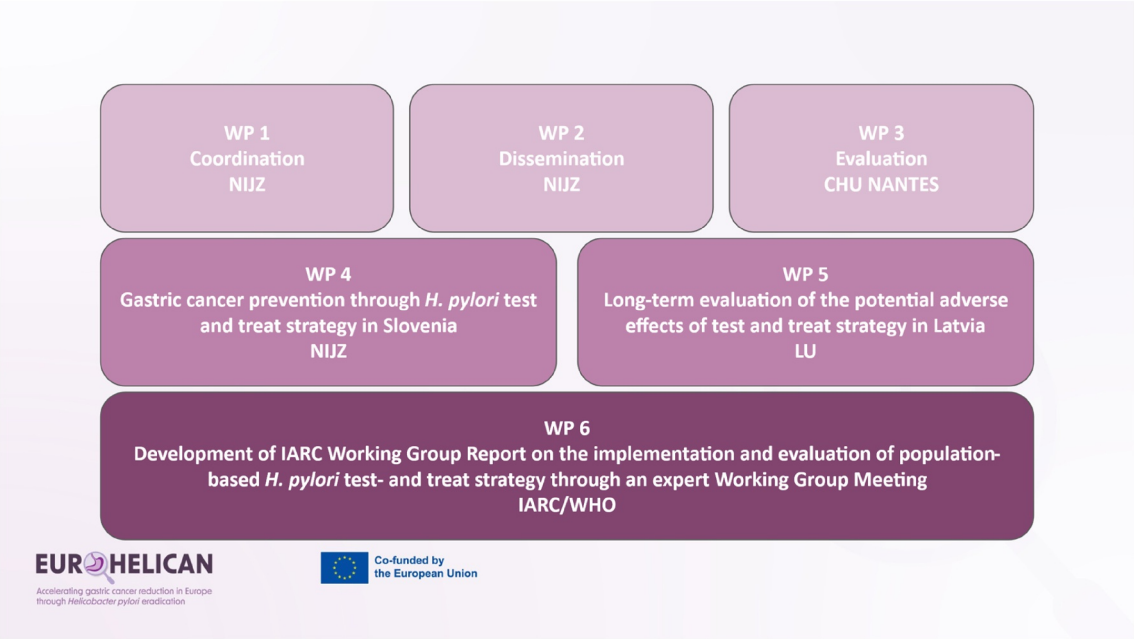

FIGURE 1 | EUROHELICAN study structure.

- Preparation of the webpage for participants and the project's webpage, with additional information and materials available for further dissemination.
- Project presentations at national and international conferences.
- Multiple press statements.

2.3 | Participants

Representative sampling was carried out using the Monte Carlo method. A total of 5491 citizens aged 30–34 from the randomized sample who had a chosen personal physician at CHC Maribor were selected for invitation, with the aim of reaching the target number of 2000 participants. The decision to enroll persons in this age range was based on the finding that younger adults who have not yet developed precancerous gastric lesions would benefit most from *H. pylori* eradication. With the eradication of *H pylori* infection in this age group, we can also prevent vertical transmission within families. Therefore, the proposed screen-and-treat strategy is considered to have positive long-term outcomes for treated patients, not only for the potential development of gastric cancer, but also for other gastric-derived health problems (such as ulcers, dyspepsia, sideropenic anemia, idiopathic thrombocytic purpura, MALT lymphoma) [9].

Because the randomized invitation yielded insufficient enrollment (24.4% response rate; 1338 participants), the study was subsequently opened to non-randomized volunteers from the same age group residing in the wider Maribor region. An overview of the study protocol is presented in Figure 2.

Invitation materials included an invitation letter explaining the study procedures, an informed consent form to be returned together with the attached prepaid envelope, and a participant information leaflet. The leaflet described the association between gastric cancer and *H. pylori* infection, the nature of voluntary participation in the study, the personal data protection regulations, and withdrawal options, and provided a link to the website with additional information about the study. The registered nurses at CHC Maribor made phone contact with the invitees who had not previously responded to the mail invitation. Participants with signed informed consent underwent an interview with a registered nurse regarding potential risk factors for *H. pylori* infection during their childhood.

Participants were excluded after the interview if any of the following conditions were identified:

- Previous treatment of *H. pylori* infection,
- History of partial or total gastric resection due to benign or malignant lesions, or
- Patients with mental or developmental limitations who cannot provide a full-informed consent to participate (based on an assessment from the patient's personal physician team).

2.4 | *H. pylori* Diagnostic Tests

The interview was followed by serological testing. We used locally validated *H. pylori* serology produced by Virion Serion, Friedrich-Bergius-Ring 19, 97076 Würzburg, Germany, with high (> 90%) sensitivity and specificity. The test IgG reference zone was: < 35 E/mL negative, > 50 E/mL positive, and 35–50 E/mL gray zone. Participants with a positive serology (positive and gray zone) were referred to UBT to confirm an active *H. pylori* infection. A mass spectroscope with 75 mg of urea ^{13}C (INFAI GmbH, Hagen, Germany) was used. All participants with positive results of serology were asked to discontinue PPIs 14 days and antibiotics or bismuth 1 month prior to UBT.

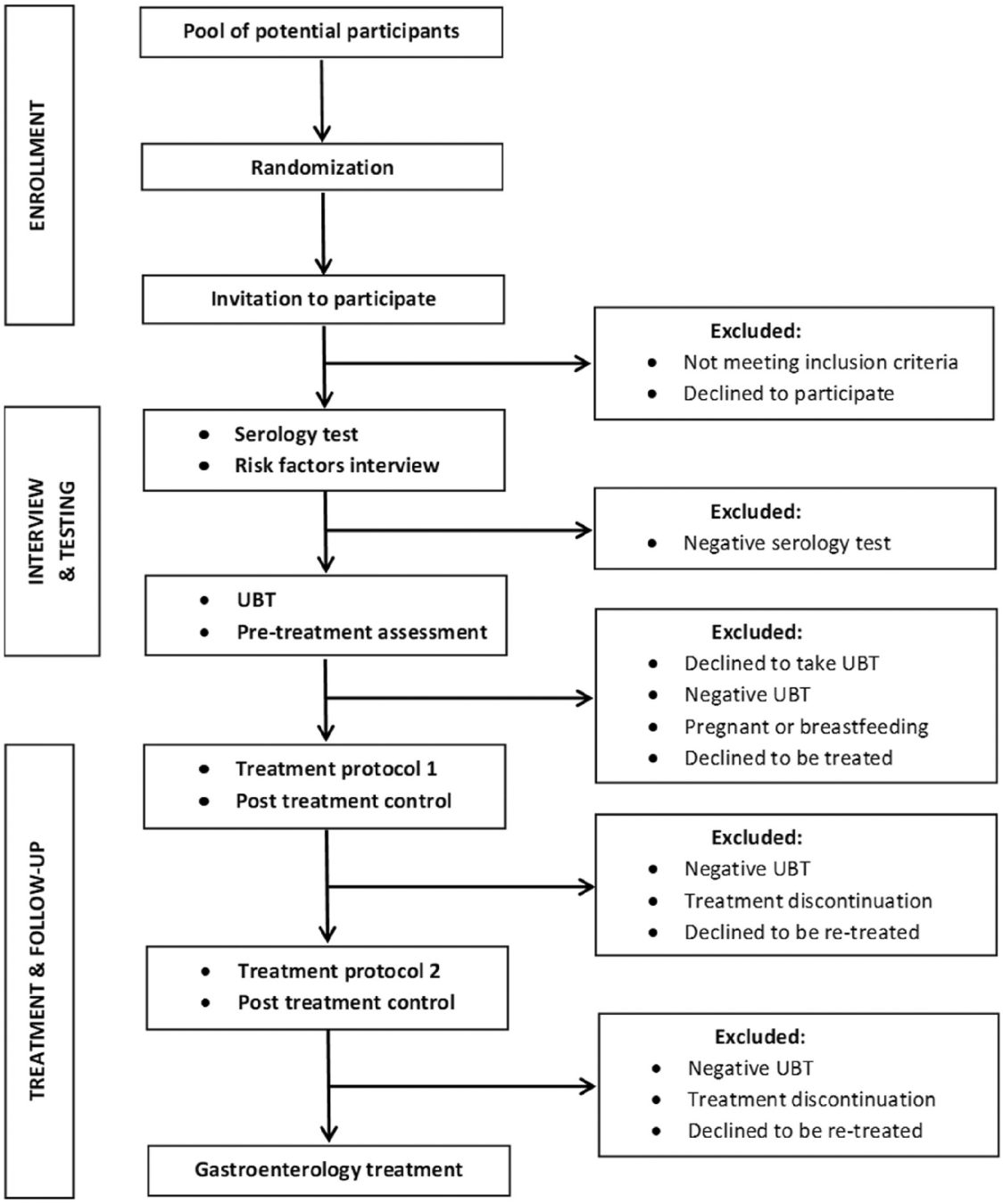

FIGURE 2 | Flow diagram of the proposed screen-and-treat strategy.

Women with a positive UBT were informed about the potential adverse events (AEs) of antibiotic treatment on their fetus or new-born. Pregnant and breastfeeding women had their treatment postponed until after breastfeeding.

2.5 | Treatment

First-line therapy was 14-day Esomeprazole 40 mg BID, Amoxicillin 500 mg, Metronidazole 400 mg, and Bizmut Oxid Krka 120 mg, all QID. In case of Amoxicillin allergy, Clarithromycin 500 mg BID was used.

One month after first-line treatment was completed, patients were referred to a control UBT and to an interview with a registered nurse about potential AEs during the 14-day treatment.

2.6 | Data Management

Clinical and other relevant participant data were collected electronically through direct entry into a predefined input mask or online form. The input mask was developed using REDCap. Medical staff accessed the data-entry tool via a secure, password-protected URL. The record is retrieved using the

Health Insurance Card number (HIC), which serves as a unique identifier and is therefore the most appropriate method of patient identification. In total, 10 electronic forms were completed sequentially in accordance with the study's clinical protocol.

2.7 | Statistical Analysis

Continuous variables are presented as the arithmetic mean and standard deviation. Categorical variables were presented as proportions with 95% confidence intervals (CIs; calculated using normal approximation). Bivariate statistical analyses were performed using the χ^2-test for categorical data. The p-value cut-off for significance was set at < 0.05. All analyses were performed using MS Excel and the IBM SPSS Statistics version 25.

3 | Results

From 5491 individuals aged 30–34 (randomized sample), 1338 participants responded positively (24.4% participation rate, 95% CI: 23.2–25.5). In the second step, the study was then opened to include an additional 764 volunteers from the same age group (non-randomized sample; Table 1). The registered nurse interviewed a total of 2011 persons. The randomized group response rate was higher in women (28.1%, 95% CI: 26.4–29.8) than in men (20.5%, 95% CI: 19.0–22.1) ($p < 0.001$).

The overall prevalence of *H. pylori* infection, as determined by serological testing among 1919 participants from the total sample, was 14.2% (95% CI: 12.7–15.9). The prevalence was 13.6% (95% CI: 11.7–15.7) in the randomized sample and 15.3% (95% CI: 12.7–18.1) in the non-randomized sample, with the difference between the samples not statistically significant ($p = 0.324$). The prevalence was the same in both men and women. A significantly higher prevalence of *H. pylori* infection was observed among immigrants—36.0% (95% CI: 26.1–46.8) and among individuals with lower educational attainment (who concluded at maximum 2- or 3-year vocational school)—33.8% (95% CI: 23.6–45.2; Figure 3). Only 4.6% (89/1919) of the participants tested were born outside Slovenia. Of 32 participants with serology in the gray zone, 21 were tested with UBT. Of those 21 participants, 9 (42.8%) had positive UBT results, thereby increasing the serology's sensitivity by 0.5% (95% CI: 0.2–0.8).

UBT was positive in 180 patients (83.7%) of serology-positive patients. There was no difference among samples, sex groups, socioeconomic groups, or country of birth.

Adherence to treatment, defined as the intake of more than 90% of prescribed tablets, was achieved in 133 (90.4%) of participants from the total sample (95% CI: 84.4–94.7), with no difference between treatment groups. In total, 46 (31.0%) of patients reported at least one AE, more frequently among women (38.8%, 95% CI: 28.1–50.3) than among men (21.5%, 95% CI: 12.3–33.5; $p < 0.05$; Figure 4). Among patients who reported AEs, 59% reported mild and 41% reported moderate severity. The most frequent AEs were weakness, abdominal pain, change in taste, diarrhea and vomiting. There was no serious AE reported as per the applied classification of the severity of adverse events (Common Terminology Criteria for Adverse Events—CTCAE). Nevertheless, two patients discontinued their treatment due to persistent nausea and diarrhea. The overall eradication rate was 139/147 (94.7%; 95% CI: 89.5–97.9).

TABLE 1 | Characteristics of the study population.

		Randomized sample			Non-randomized sample		Total	
Participants		***n***	**%**		***n***	**%**	***n***	**%**
Gender	Men	554	41.4%	($p < 0.001$)	336	44.0%	890	42.3%
	Women	784	58.6%		428	56.0%	1212	57.7%
Year of birth	1983	0	0.0%		1	0.1%	1	0.0%
	1987	0	0.0%		1	0.1%	1	0.0%
	1988	193	14.4%		1	0.1%	194	9.2%
	1989	220	16.4%		58	7.6%	278	13.2%
	1990	221	16.5%		157	20.5%	378	18.0%
	1991	233	17.4%		152	19.9%	385	18.3%
	1992	212	15.8%		149	19.5%	361	17.2%
	1993	195	14.6%		120	15.7%	315	15.0%
	1994	53	4.0%		121	15.8%	174	8.3%
	1995	0	0.0%		4	0.5%	4	0.2%
	1998	1	0.1%		0	0.0%	1	0.0%
	No data	10	0.7%		0	0.0%	10	0.5%
	Total	1338	100%		764	100%	2102	100%

[a]2,102 agreed to participate, 2011 completed questionnaire (first step in the study).

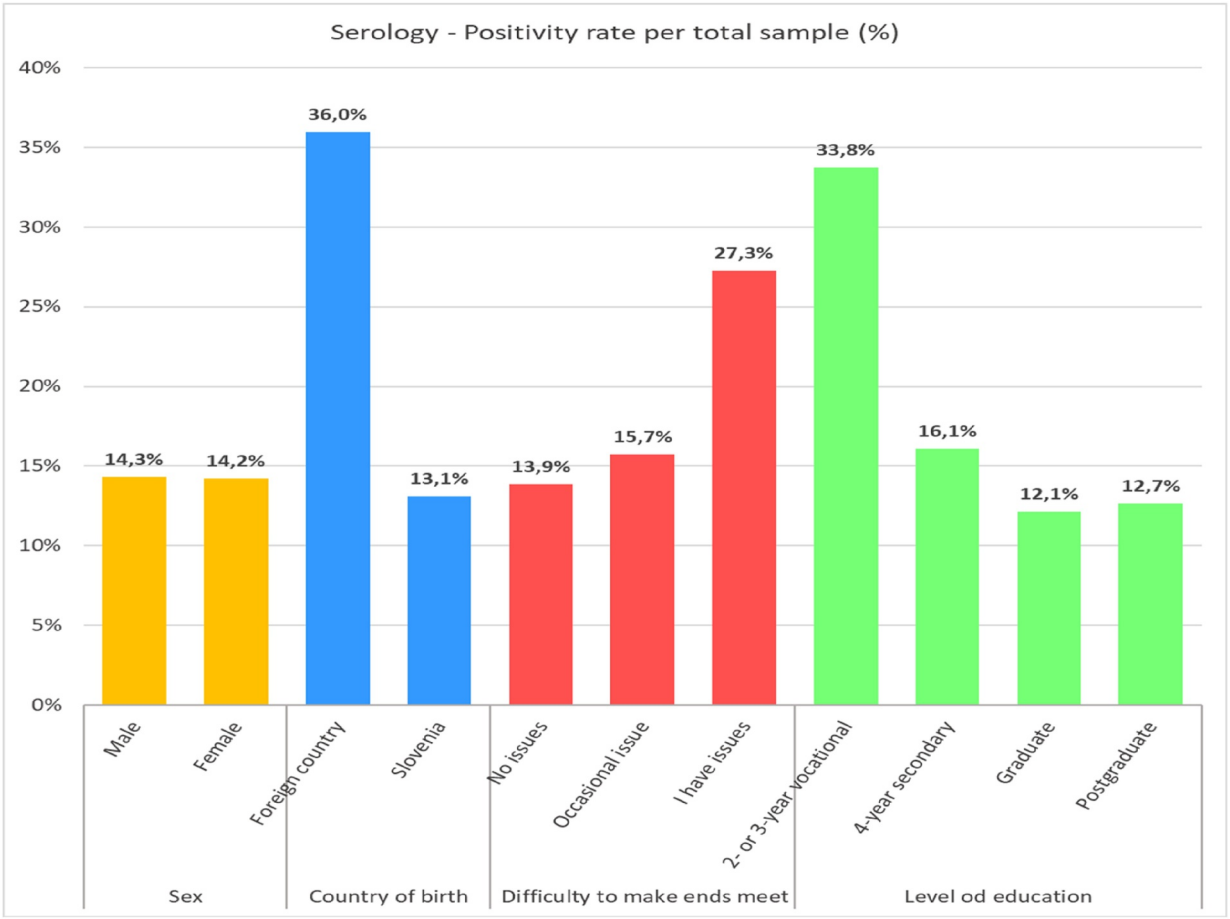

FIGURE 3 | Seropositivity rate by socioeconomic status.

The incidence of gastric cancer in Slovenia starts to rise after the age of 40 years, and cases before that age are extremely rare (6). In our study, patients with symptoms after *H. pylori* treatment or without proven *H. pylori* infection were referred to gastroscopy, and no cancer was found.

The key indicator of compliance in the EUROHELICAN Pilot Study was the dropout rate (Figure 5). The dropout rate was 5.8% (95% CI: 4.8–6.9; 116 participants) among participants who completed the questionnaires but did not attend the laboratory for serology testing. The highest dropout of 21.2% (95% CI: 16.5–26.6; 58 participants) was observed among participants with a positive serology test who were expected to proceed with the confirmatory UBT (two of whom were pregnant). Another high relative dropout rate of −18.3% (95% CI: 13.0–24.8; 33 patients) was observed among participants with a positive UBT result who should start primary infection treatment (among them, 13 pregnant women). Among patients with a positive UBT, 147 (83.3%; 95% CI: 77.1–88.5) initiated eradication therapy.

4 | Discussion

In regions with an intermediate to high incidence of gastric cancer, such as Slovenia, the rollout of a population-based *H. pylori* screen-and-treat program should be considered a public health priority. Pilot projects conducted prior to large-scale implementation are crucial for assessing local preparedness [6].

This study is the first implementation of a screen-and-treat strategy among 30–34-year-old citizens in Europe. The response rate was 24.4%, which was lower than we expected. The majority of individuals infected with *H. pylori* are asymptomatic and should be informed that testing is crucial to determine whether they are infected. The public awareness campaign is therefore of great importance and should be continuous. Additional education for medical care providers on *H. pylori*, gastric carcinogenesis, and their relation to other gastric diseases should be part of the program. On the other hand, we know that older age groups and women respond better to invitations than younger age groups, and that the screen-and-treat response rate in older age groups would probably be higher [10–12].

Some pilot studies have been conducted in high-risk countries, such as the Matsu Islands [13], Japan (through national insurance coverage of *H. pylori* treatment) [14], and Bhutan [15]. They have included the adult population aged 18–75. The population coverage after several rounds of screening ranged from 85.5% to 92% [13, 15].

To further increase participation rates in Slovenia, more efforts should be directed toward education and public awareness. These should involve additional education activities at

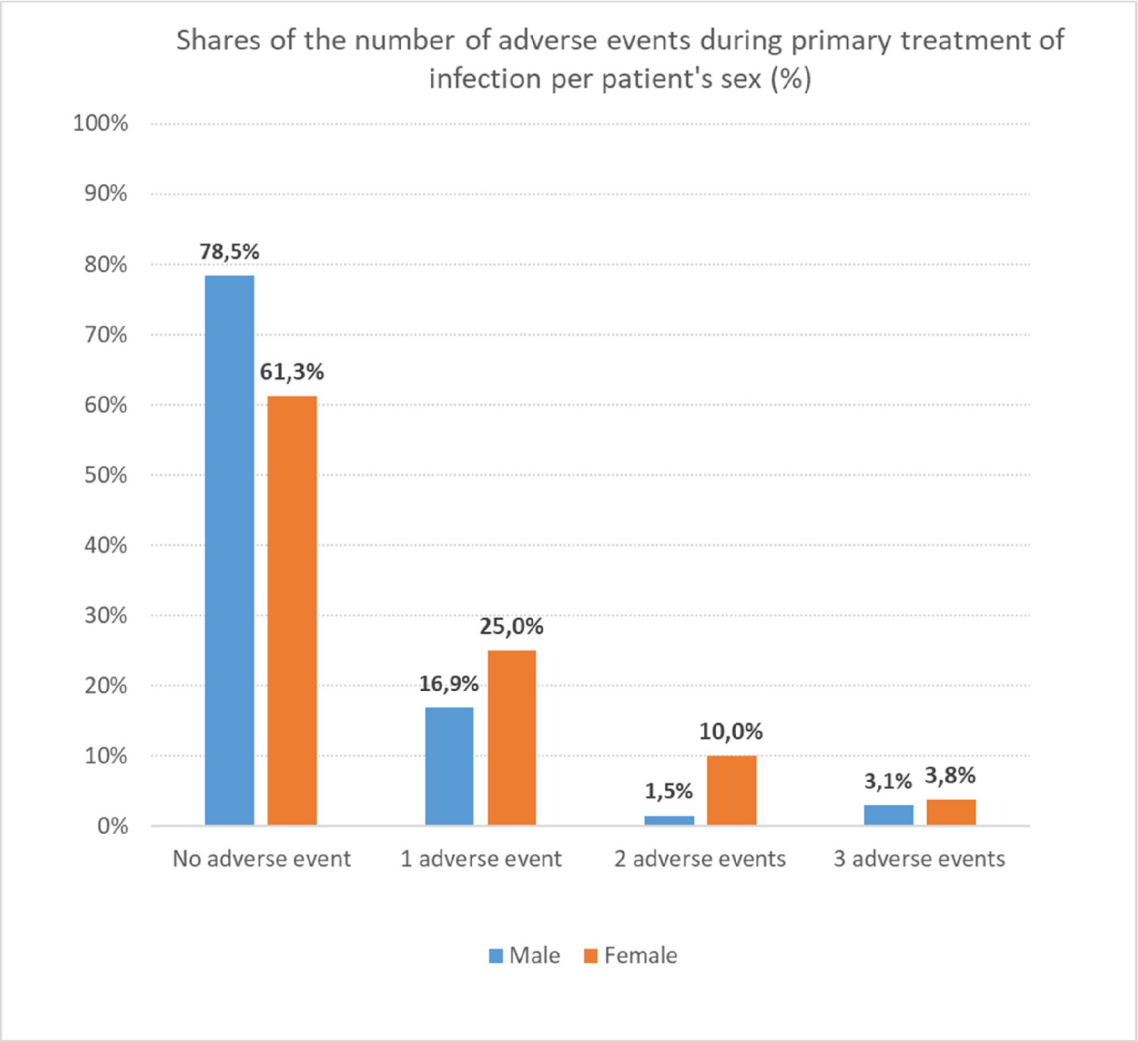

FIGURE 4 | Adverse events of bismuth based quadruple therapy by sex.

universities, community health centers, and private primary care centers (included in the public health care system), as well as campaigns via mass and social media.

The study initially invited a randomized sample of participants, but later included non-randomized volunteers to reach the target participation. People who volunteer for a study can be expected, on average, to be healthier than people who don't volunteer, as they are concerned for their health and are predisposed to follow medical advice. When we compared both groups, there were no significant differences regarding *H. pylori* seropositivity, country of birth, or adherence to the treatment.

The invitation process, as well as further diagnostic tests should be simplified as much as possible. In the Eurohelican study, participants were required to visit CHC Maribor two to four times. The first visit involved an interview and the signing of the informed consent, which was followed by a visit to the laboratory for serology testing. If the serology test was positive, the participants returned for UBT and then for a treatment prescription. It would be easier for young participants if they could complete questionnaires and sign informed consent online and come to the laboratory at a time of their choice. Therefore, only the minority who tested positive would be invited to undergo UBT. This simplified procedure might increase participation rates and reduce dropout rates.

Selecting appropriate population testing methods is crucial and should be tailored to population characteristics and healthcare infrastructure. Participants' preferences with respect to breath, stool, or blood samples can significantly affect their willingness to participate. Participants may feel uncomfortable with providing stool samples [16].

The sensitivity and specificity of serology tests vary widely, typically ranging from 80% to 98%. Because it is not possible to differentiate between current and past infection, serology tests are not recommended as the sole method for diagnosing current *H. pylori* infection. The accuracy of serology tests depends on the choice and number of antigens used [17–19]. Therefore, only locally verified serology tests with sensitivities and specificities of more than 90% should be used as the first test in screen-and-treat programmes, usually followed by the UBT as a confirmatory test. We used a locally validated serological test with high sensitivity and specificity [20]. We decided to treat gray-zone IgG results as positive to increase serology sensitivity. UBT.

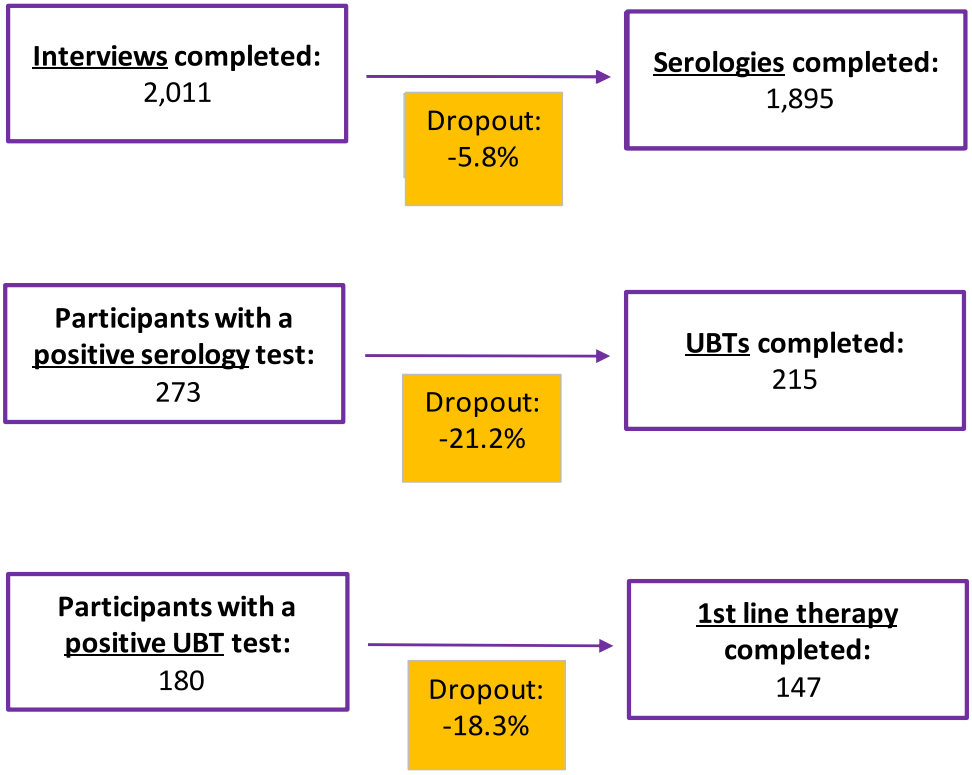

FIGURE 5 | Dropout rate in the EUROHELICAN study.

UBT as a very specific test, was positive in 83.7% of participants with positive serology, which is lower than expected based on previous studies [19, 20]. In our study, the dropout rate between positive serology and UBT (excluding gravidity) was 21.2%. This dropout is hard to explain; it might be related to the need for too many visits to the CHC Maribor (interview, serology, UBT, treatment), which can be difficult for young populations due to lack of time and lifestyle. Both facts, lower confirmation positivity and high dropout rate, deserve further cost-benefit analysis to determine whether UBT should be used as a single test.

The seropositivity rate of 14.2% was somewhat expected, as we know that *H. pylori* seropositivity is low in younger EU populations. Population subgroups at increased risk of *H. pylori*-related diseases include immigrants (36.0% seropositivity rate) and individuals with low educational level (33.8% seropositivity rate). This indicates that these populations are at an increased risk of *H. pylori*-related disease [1, 9] and should be prioritized for screening.

H. pylori is classified as a group I carcinogen, and confirmation of *H. pylori* eradication is of key importance. UBT, as the most accurate non-invasive test, should be used as a confirmatory test. In cases of treatment failure, additional lines of treatment can be prescribed until *H. pylori* infection is successfully eradicated [9, 21].

The first-line treatment regimen in Slovenia is still a 14-day high PPI dose clarithromycin-based triple therapy with an eradication rate of 94%. Bismuth-based 14-day therapy has a 96.6% eradication rate but is not the first-line therapy in Slovenia [22].

The advantage of bismuth-based quadruple therapy is that clarithromycin is not a part of this regimen. In the EUROHELICAN study, bismuth-based quadruple therapy had an eradication rate 94.7% with good compliance and 31.0% rate of mild to moderate AEs. The largest cohort study addressing the tolerance of eradication treatments across different treatment regimens was published by Nyssen et al. (2021), in which 22,492 treatment cases were analyzed, and AEs were recorded in 23% of cases. Classic bismuth-based quadruple therapy was the least well-tolerated, with AEs present in 37%, which is, however, higher compared to the rate of AEs reported in our study [23].

The limitations of the study are low participation rate and relatively high dropout rate. The study population was young and health care questions were not high on their life agenda. Therefore, more public awareness and education is needed to increase the participation rate. The study also highlights the importance of implementing a user-friendly program with minimal required contact with healthcare professionals, which may reduce the dropout rate.

5 | Conclusions

The Eurohelican WP4 study is the first *H. pylori* screen-and-treat study in Europe. Our findings demonstrate that a *H. pylori* screen-and-treat program targeting adults aged 30–34 years is feasible in Europe, and that treatment of *H. pylori* infection is highly effective with an acceptable rate of AEs. The study also highlights the importance of implementing a user-friendly

program design that enables participants to respond to the invitation with minimal required contact with healthcare professionals. Whether to use serology and UBT as a confirmatory test or just UBT remains a matter of debate and requires further analysis. The participation rate needs to be increased, and to achieve that, different public awareness campaigns and additional educational programs for medical workers are needed.

Author Contributions

Bojan Tepes was the scientific coordinator of the EUROHELICAN project, planned and coordinated the project, supervised monitoring and quality control, assisted with the analysis, interpretation, and synthesis of data, wrote the first draft, and approved the submitted manuscript. Tatjana Kofol Bric worked on the preparation of the methodology and study design, supervised the monitoring and quality checks, and critically reviewed the manuscriptdrafts, and approved the final submitted manuscript. Jernej Završnik, Helena Blaun Voner, and Nataa Magua Lorber coordinated the study at CHC Maribor, critically reviewed the manuscript's drafts, and approved the final submitted manuscript. Marcel Kralj and Mitja Oblak assisted with the analysis, interpretation, and synthesis of data, and critically reviewed the manuscript's drafts and approved the submitted manuscript. Jin Young Park critically reviewed the manuscript's drafts and approved the submitted manuscript. Tamara Matyasiak Budnik led the WP 3- external evaluation of the study, critically reviewed the manuscript's drafts, and approved the submitted manuscript.

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Ethics Statement

Ethical approval was granted by the Slovenian National Medical Ethics Committee (0120-12/2023/3).

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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