

How common is irritable bowel syndrome in the Mediterranean island of Malta? A cross-sectional study using Rome IV criteria

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Abstract

Background Irritable bowel syndrome (IBS) is a common disorder of gut–brain interaction that is diagnosed using symptom-based criteria. Prevalence estimates vary according to diagnostic definitions, and data from Southern Europe remain limited. This study aimed to determine the prevalence of IBS in a Maltese adult population using the Rome IV criteria, and to identify associated demographic and clinical factors.

Methods A cross-sectional questionnaire-based study was conducted in community settings. Adults aged ≥ 18 years were recruited using convenience sampling. The questionnaire incorporated Rome IV diagnostic items for IBS, symptom characteristics, dietary behavior, self-reported lactose intolerance, and food intolerance testing. Descriptive statistics, chi-square tests, *t*-tests, and binary logistic regression were used.

Results A total of 1068 participants were included in the analysis (56.5% female; mean age 40.0 $\pm$ 10.9 years). Among participants aged 18–50 years, 13.5% (95% confidence interval [CI] 11.3–15.9%) fulfilled the Rome IV criteria for IBS, corresponding to an overall prevalence of 11.0% (95%CI 9.2–13.0%) in the full cohort. The IBS group was predominantly female (77.8%), with diarrhea-predominant and mixed subtypes being the most frequent. Female sex, unemployment and current smoking were independently associated with meeting the Rome IV criteria for IBS. Participants meeting the Rome IV criteria also had higher odds of self-reported lactose intolerance and of having undergone food intolerance testing. BMI and education were not significantly associated with IBS.

Conclusions IBS is common among Maltese adults, particularly among women. The frequent use of food intolerance testing and high rates of dietary restriction among affected individuals highlight the need for better patient education and evidence-based dietary management strategies.

Keywords Irritable bowel syndrome, Rome IV criteria, prevalence, Malta

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Introduction

Irritable bowel syndrome (IBS) is a chronic disorder of gut–brain interaction characterized by recurrent abdominal pain associated with altered bowel habits, including diarrhea, constipation, or a mixed pattern. Its exact pathophysiology remains unclear, but is probably multifactorial, involving disturbances in gastrointestinal motility, visceral hypersensitivity, immune and microbiota alterations, and psychosocial factors [1–3]. Women are more frequently affected than men, with a 67% higher likelihood of diagnosis [1]. IBS imposes a substantial personal and societal burden, generating significant direct healthcare costs from consultations, investigations and medications, as well as indirect costs from reduced productivity and absenteeism [4,5].

The diagnosis of IBS is symptom-based, with the Rome IV criteria representing the current standard [6]. Developed by the Rome Foundation, these criteria define IBS as recurrent abdominal pain, on average at least 1 day per week in the past 3 months, associated with 2 or more of the following: relation

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to defecation, change in stool frequency, or change in stool form [7-9]. Symptoms should have begun at least 6 months prior to diagnosis. Globally, the pooled prevalence of IBS varies widely, depending on the criteria used: from 3.8% with Rome IV to over 11% with earlier definitions, while rates in women are consistently higher [10,11]. The diagnosis of IBS under the Rome IV criteria is based entirely on symptoms, and clinical red flags that would preclude a positive IBS diagnosis include age ≥ 50 years, recent change in bowel habit, weight loss and iron deficiency anemia [12].

Prevalence also varies considerably across regions and populations, reflecting differences in diagnostic criteria, survey methodology and cultural interpretations of symptoms [10,12,13]. The lowest reported prevalence has been in Southeast Asia (7.0%), while the highest has been in South America (21.0%) [10]. Variability is further influenced by language-specific terms, healthcare-seeking behavior and symptom perception, as well as study settings, whether community-based or clinic-based. These cultural and methodological differences highlight the challenges of establishing accurate global prevalence estimates and the importance of locally relevant epidemiological data.

The primary aim of this study was to determine the prevalence of IBS and the characteristics of IBS symptomatology. The secondary aim was to determine the use of immunoglobulin G (IgG) food intolerance testing among a sample of adults in the Maltese Islands.

Materials and methods

This cross-sectional study was conducted between April 2021 and April 2022. Participants aged ≥ 18 years were recruited via convenience sampling from diverse community and workplace settings. Recruitment sites included public areas, supermarkets, workplaces and university campuses, enabling access to a broad and diverse sample of the Maltese population. However, as convenience sampling was used, the sample may not fully reflect the demographic composition of the general Maltese population, and findings should therefore be interpreted as a sample-based estimate. Participation was voluntary, and informed consent was obtained prior to enrolment. Participants reporting alarm “red flag” symptoms suggestive of organic gastrointestinal disease were advised to seek further medical evaluation through their primary care physician or specialist services. A qualified medical doctor was present at data collection points to address queries and assist respondents.

Data was collected using a self-administered questionnaire. The questionnaire incorporated items from the Rome IV diagnostic questionnaire for functional gastrointestinal disorders, focusing on IBS and its subtypes. The Rome IV criteria require recurrent abdominal pain on average ≥ 1 day/week during the past 3 months, associated with ≥ 2 of the following: relation to defecation, change in stool frequency or stool form, with symptom onset ≥ 6 months prior. Additional items address abdominal bloating, history of IBS or lactose intolerance, and

IgG testing (including cost and subsequent dietary changes). IBS was defined based on self-reported symptoms fulfilling the Rome IV diagnostic criteria. As this was a community-based screening study, no routine biochemical or endoscopic investigations (e.g., fecal calprotectin or colonoscopy) were performed to exclude organic pathology. All participants who completed the IBS questionnaire underwent concurrent point-of-care testing (POCT) for coeliac disease using the Biocard™ Professional anti-tissue transglutaminase IgA test. Verbal consent was obtained before testing, and participants were informed that POCT was a screening tool with recognised limitations. Questionnaire and POCT results were linked using a unique non-identifiable study code. Although participants with positive or inconclusive POCT results completed the questionnaire, their responses were not included in the present IBS analysis to minimise potential misclassification related to undiagnosed coeliac disease. Their coded questionnaire and POCT data were retained for a separate analysis of the coeliac disease screening cohort.

Statistical analysis

Data analysis was performed using IBM SPSS Statistics, version 29.0. Descriptive statistics were generated to summarize participant demographics and other key variables. Associations between categorical variables were assessed using the Pearson chi-square (χ^2) test for independence, while continuous variables, such as height, weight and body mass index (BMI), were compared using independent samples *t*-tests. BMI was calculated from height and weight, and both age and BMI were categorized for the purposes of analysis in order to allow clinically meaningful group comparisons and facilitate interpretation of the findings. Age was categorized into predefined groups (18-24, 25-34, 35-44 and 45-50 years) for subgroup analysis within the 18 to 50-year-old cohort. This age stratification was used to explore potential age-related differences in symptom prevalence within the 18–50-year subgroup, which represented the primary cohort of interest for this part of the study. BMI was categorized according to standard World Health Organization criteria: underweight (<18.5 kg/m²), normal weight (18.5-24.9 kg/m²), overweight (25.0-29.9 kg/m²), and obese (≥ 30 kg/m²). Binary logistic regression was used to identify factors independently associated with meeting Rome IV criteria for IBS with results expressed as odds ratios (ORs) and 95% confidence intervals (CIs). The dependent variable was IBS status (1 = meets Rome IV criteria; 0 = does not meet Rome IV criteria). Independent variables included sex, employment status, smoking status, age group, region, marital status, educational background and BMI classification, all entered as categorical variables. Binary logistic regression analyses evaluating factors associated with self-reported lactose intolerance and food intolerance testing were restricted to participants aged 18–50 years ($n = 868$), as Rome IV IBS status was available only in this subgroup and was included as a predictor in both models. In these models, age was entered as a continuous variable, whereas the remaining

categorical predictors were entered as categorical variables. For the self-reported lactose intolerance model, the underweight BMI category and the unemployed employment category were excluded because of sparse data, which resulted in unstable model estimates. The food intolerance testing model included all candidate predictor variables. Model performance was assessed using overall classification accuracy, Cox and Snell R², Nagelkerke R², and the Hosmer–Lemeshow goodness-of-fit test. Statistical significance was defined as $P < 0.05$. Based on an expected IBS prevalence of approximately 4% using the Rome IV criteria, a 95% confidence level and a $\pm 2\%$ margin of error, the minimum required sample size was 369 participants. The achieved sample size ($n=1068$) substantially exceeded this threshold, providing adequate precision for prevalence estimation and sufficient power for subgroup analyses. Prior to logistic regression, multicollinearity was assessed by calculating Spearman rank correlation coefficients between the dummy-coded predictor variables. Strong correlations were observed only between dummy variables representing different levels of the same categorical predictor, as expected.

This study is reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement. The study was approved by the Faculty Research Ethics Committee (FREC), University of Malta (Reference Number FREC-MDS 1819_085). All participants provided informed consent prior to participation.

Results

Participant characteristics

Of all the participants who completed the questionnaire, 35 had a positive ($n = 17$) or inconclusive ($n = 18$) coeliac disease POCT result and were not included in the present IBS analysis. The final analysed cohort comprised 1,068 adults, of whom 56.5% were female. The mean age was 40.0 ± 10.9 (range 18–71) years. Most participants (90.4%) were Maltese nationals, with the remainder being foreign residents. Demographic indicators, including marital status, educational level, employment status and anthropometric measures (height, weight and BMI), are summarized in Tables 1 and 2. The regional distribution of the full cohort was similar to that of the general population of Malta, with absolute differences ranging from 0.1 to 1.0 percentage points across regions (Supplementary Fig. 1) [14].

Given that the Rome IV diagnostic framework for IBS is typically applied to those aged ≤ 50 years, a subgroup analysis was performed in participants aged 18–50 years ($n=868$; mean age 36.3 ± 8.3 years, 59.2% female). These cohort data are also summarized in Tables 1 and 2.

Prevalence of IBS and associated factors

Among participants aged 18–50 years, 117/868 met the Rome IV criteria for IBS, giving a primary prevalence estimate

Table 1 Demographics of both the total participant cohort and the 18–50 year old subgroup

Characteristic	Total cohort n=1068	18–50-year-old cohort n=868
Marital status		
Single	22.0% (n=235)	24.8% (n=215)
Committed relationship	21.7% (n=232)	25.6% (n=222)
Married	50.8% (n=543)	44.8% (n=389)
Divorced, separated, or widowed	5.4% (n=58)	4.8% (n=42)
Educational background		
Primary school	2.1% (n=22)	1.7% (n=15)
Secondary school	22.9% (n=245)	22.0% (n=191)
College	29.8% (n=318)	27.9% (n=242)
University undergraduate	20.2% (n=216)	21.1% (n=183)
University postgraduate	25.0% (n=267)	27.3% (n=237)
Current employment		
Full-time	91.7% (n=979)	92.3% (n=801)
Part-time	6.1% (n=65)	6.5% (n=56)
Unemployed	2.2% (n=24)	1.3% (n=11)
Smoking status		
Non-smoker	64.4% (n=688)	64.2% (n=557)
Ex-smoker	13.7% (n=146)	13.6% (n=118)
Current smoker	21.9% (n=234)	22.2% (n=193)
Sex		
Female	56.5% (n=603)	59.2% (n=514)

Table 2 Anthropometric characteristics of the total participant cohort and the 18–50-year-old subgroup

Characteristic	Total cohort n=1068	18–50-year-old cohort n=868
Age	40.0 years SD ± 10.9 years	36.3 years SD ± 8.3 years
Height	1.50–1.96 m Mean 1.66 m	1.50–1.96 m Mean 1.66 m
Weight	37.0–130.0 kg Mean 74.8 kg	37.0–130.0 kg Mean 74.0 kg
BMI	15.8–54.3 kg/m ² Mean 27.2 kg/m ²	16.1–54.3 kg/m ² Mean 26.9 kg/m ²

SD, Standard deviation; BMI, body mass index

of 13.5% (95%CI 11.3–15.9%). In the overall cohort, 117/1068 participants met the Rome IV criteria, corresponding to a descriptive overall prevalence of 11.0% (95%CI 9.2–13.0%) (Fig. 1). The IBS group was predominantly female (77.8%) and had a mean age of 34.6 ± 8.7 years.

Statistical analysis

Assessment of multicollinearity showed no evidence of problematic correlations between different predictor variables (Supplementary Table 1). The binary logistic regression model was statistically significant ($\chi^2(23)=56.041$, $P < 0.001$), indicating that the included predictors improved

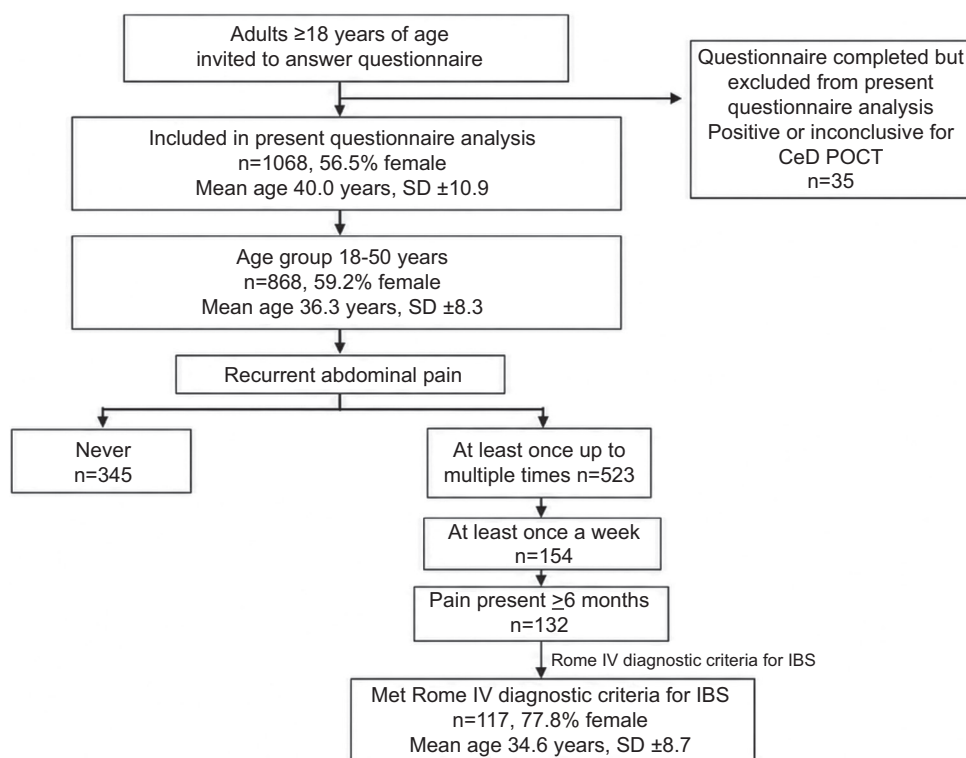


Figure 1 Flowchart showing participant cohort breakdown and subgroup allocation

SD, standard deviation; ♀, female; IBS, irritable bowel syndrome; CeD, coeliac disease; POCT, point-of-care test

prediction of Rome IV IBS status compared with the null model. The model explained 6.3% of the variance according to Cox and Snell R^2 and 11.4% according to Nagelkerke R^2 , suggesting modest explanatory ability. The Hosmer–Lemeshow goodness-of-fit test was non-significant ($\chi^2(8)=13.822$, $P=0.087$), indicating acceptable model fit. Although the overall classification accuracy was 86.5%, this should be interpreted cautiously, given the imbalance between participants meeting and not meeting the Rome IV criteria for IBS.

Among the variables entered into the binary logistic regression model, sex, employment status and smoking status were statistically significant predictors of meeting the Rome IV criteria for IBS. Overall, sex was significantly associated with IBS status ($P<0.001$), with females having higher odds of IBS compared with males (OR 2.69, 95%CI 1.66–4.40; $P<0.001$). Employment status was also significant overall ($P=0.038$); specifically, unemployed participants had higher odds of IBS compared with those in full-time employment (OR 5.03, 95%CI 1.38–18.26; $P=0.014$). Smoking status was significantly associated with IBS overall ($P=0.008$), with current smokers having higher odds of IBS compared with non-smokers (OR 2.12, 95%CI 1.32–3.40; $P=0.002$), while ex-smokers did not differ significantly from non-smokers ($P=0.274$). No significant associations were observed for region, marital status, educational background, age group, or BMI classification (all $P>0.05$) (Table 3).

IBS subtypes

Among the 117 participants meeting the full Rome IV criteria for IBS, the most common subtype was diarrhoea-predominant IBS (IBS-D; 39/117, 33.3%), followed by mixed IBS (IBS-M; 37/117, 31.6%), constipation-predominant IBS (IBS-C; 31/117, 26.5%) and unclassified IBS (IBS-U; 10/117, 8.5%). Among males, 12/26 (46.2%) had IBS-D, 6/26 (23.1%) had IBS-M, 6/26 (23.1%) had IBS-C and 2/26 (7.7%) had IBS-U. Among females, 27/91 (29.7%) had IBS-D, 31/91 (34.1%) had IBS-M, 25/91 (27.5%) had IBS-C and 8/91 (8.8%) had IBS-U. There was no statistically significant association between sex and IBS subtype ($\chi^2(3) = 2.597$, $P = 0.458$).

A similar analysis by age group showed that the most common subtype among younger participants aged 18–24 years was mixed IBS (44.4%), whereas the diarrhea-predominant subtype was more frequent in the 45–50 age group (52.4%). However, the association between age group and IBS stool subtype was not significant ($\chi^2(9)=10.941$, $P=0.280$).

Bloating and food avoidance

Bloating was reported by 80.2% (857/1068) of the total cohort and by 99.1% of participants meeting the Rome IV criteria for IBS. Bloating frequency differed significantly by sex, being more common in females ($\chi^2(9)=107.786$, $P<0.001$), and

Table 4 Binary logistic regression: factors independently associated with self-reported lactose intolerance (n=868). For categorical variables with >2 levels, overall P-values from likelihood-ratio (Score) tests are reported

Variable	B	SE	P-value	OR (95%CI)
Meets Rome IV criteria for IBS	1.316	0.293	<0.001*	3.73 (2.09-6.63)
Marital status	-	-	0.23*	-
Committed Relationship	-0.749	0.340	0.028*	0.47 (0.24-0.92)
Married	-0.723	0.322	0.025*	0.49 (0.26-0.91)
Divorced/separated/widowed	-2.148	4.115	0.042*	0.12 (0.02-0.93)
Sex	-	-	0.961	-
Region	-	-	0.939	-
Educational background	-	-	0.277	-
Smoking status	-	-	0.804	-
Age (years, continuous)	-	-	0.803	-

Reference categories: does not meet Rome IV criteria for IBS, female (sex); Northern region (region); single (marital status); primary and secondary education (educational background); non-smoker (smoking status)
B, regression coefficient; SE, standard error; OR, odds ratio; CI, confidence interval; IBS, irritable bowel syndrome

by age group ($\chi^2(27)=40.573$, $P=0.045$). These findings suggest that while bloating affects all age groups, younger participants may experience more frequent or persistent symptoms. Moreover, Rome IV IBS status ($\chi^2(9)=165.76$, $P<0.001$) was also associated with greater bloating frequency. In contrast, there was no difference in symptoms of bloating between sexes within the IBS subgroup ($\chi^2(9)=14.789$, $P=0.10$). More detailed bloating subgroup distributions are presented in Supplementary Fig. 2.

Overall, 34.4% (367/1,068) of participants reported avoiding certain foods because of gastrointestinal symptoms. Food avoidance was more common among participants meeting the Rome IV criteria for IBS (47.9%, 56/117; Supplementary Fig. 3). Within the IBS subgroup, males were more likely than females to report food avoidance (65.4% vs. 42.9%, $\chi^2(1)=4.113$, $P=0.043$).

Lactose intolerance and food intolerance testing

Self reported lactose intolerance was reported by 8.3% of the total cohort. It was not significantly associated with sex ($P=0.54$) or smoking status ($P=0.45$). However, it differed significantly by marital status ($\chi^2=13.154$, $df=3$, $P=0.004$), with the highest proportion reported among single participants. Among participants meeting the Rome IV criteria for IBS, lactose intolerance was reported by 20.5%.

In binary logistic regression of the 18-50 year old cohort, meeting the Rome IV criteria for IBS was associated with higher odds of reporting lactose intolerance (OR 3.73, 95%CI 2.09-

6.63; $P<0.001$). Marital status was also significantly associated with self-reported lactose intolerance overall ($P=0.023$), while other sociodemographic variables were not significantly associated (Table 4).

Of the 1,068 participants, 126 (11.8%) reported having undergone food intolerance testing. Cost data were available for 82 participants after values recorded as €0 were treated as missing, as these tests are not provided free of charge in Malta. Among participants with valid cost data, the mean reported cost was €133.66 $\pm$ €90.51, with a range of €15–€500. Testing was more commonly reported by females than males (14.6% vs. 8.2%, $\chi^2=10.404$, $df=1$, $P<0.001$). The association with smoking status approached but did not reach statistical significance ($\chi^2=5.838$, $df=2$, $P=0.054$). These sex- and smoking-related differences were not observed within the Rome IV IBS subgroup.

In binary logistic regression of the 18-50 year old cohort, meeting the Rome IV criteria for IBS was associated with higher odds of having undergone food intolerance testing (OR 2.91, 95%CI 1.76-4.81; $P<0.001$). Increasing age was also independently associated with food intolerance testing, with the odds increasing by 3.7% for each additional year of age (OR 1.037, 95% CI 1.006–1.070; $P=0.019$). Female sex was independently associated with higher odds of undergoing food intolerance testing compared with male sex (OR 1.65, 95% CI 1.02–2.67; $P=0.040$). No significant associations were observed for region, smoking status, marital status, educational background, BMI classification or employment status (Table 5).

Discussion

This study provides the first estimate of IBS prevalence in a Maltese adult sample using the Rome IV criteria. The primary prevalence estimate within the 18-50-year age group reached 13.5% (95%CI 11.3-15.9%), while prevalence in the overall study cohort was 11.0% (95%CI 9.2-13.0%, $n=1068$), with a marked female predominance. These estimates are substantially higher than the Rome IV-based population prevalence figures of approximately 3.8-4.1% reported in large international studies [20]. The predominance of diarrhea-predominant (IBS-D) and mixed (IBS-M) subtypes aligns with European data employing the same diagnostic framework [15].

Bloating was commonly reported among participants fulfilling the Rome IV criteria for IBS. The high prevalence in the general cohort mirrors reports from multinational surveys identifying it as one of the most distressing and persistent symptoms [16,17]. However, detailed subgroup findings relating to bloating should be interpreted cautiously, as symptom reporting was based on self-reported questionnaire data and may be subject to recall and selection bias. The significant associations observed between IBS and both current smoking and unemployment may suggest a contribution of lifestyle and psychosocial stressors to symptom expression. However, the association with unemployment should be interpreted cautiously given the small number of unemployed

Table 4 Binary logistic regression: factors independently associated with self-reported lactose intolerance (n = 868). For categorical variables with > 2 levels, overall P values from likelihood-ratio (Score) tests are reported

Variable	B	SE	P-value	OR (95%CI)
Meets Rome IV criteria for IBS	1.316	0.293	<0.001*	3.73 (2.09-6.63)
Marital status	–	–	0.023*	–
Committed relationship	-0.749-0.723-2.148	0.340	0.028*	0.47 (0.24-0.92)
Married		0.322	0.025*	0.49 (0.26-0.91)
Divorced/separated/widowed		4.115	0.042*	0.12 (0.02-0.93)
Sex	–	–	0.961	–
Region	–	–	0.939	–
Educational background	–	–	0.277	–
Smoking status	–	–	0.804	–
Age (years, continuous)	–	–	0.803	–

Reference categories: does not meet Rome IV criteria for IBS, female (sex); Northern region (region); single (marital status); primary and secondary education (educational background); non-smoker (smoking status)

B, regression coefficient; SE, standard error; OR, odds ratio; CI, confidence interval; IBS, irritable bowel syndrome

Table 5 Binary logistic regression: factors independently associated with having undergone food intolerance testing (n = 868). For categorical variables with > 2 levels, overall P values from likelihood-ratio (Score) tests are reported

Variable	B	SE	P-value	OR (95%CI)
Meets Rome IV criteria for IBS	1.068	0.257	<0.001*	2.91 (1.76-4.81)
Sex	–	–	0.040*	–
Male	Reference	–	–	1.00
Female	0.502	0.245	0.040*	1.65 (1.02– 2.67)
Age (years, continuous)	0.037	0.016	0.019*	1.04 (1.01 – 1.07)
Marital status	–	–	0.198	–
Region	–	–	0.817	–
Educational background	–	–	0.110	–
Current employment	–	–	0.640	–
Smoking status	–	–	0.073	–
BMI classification	–	–	0.920	–

Reference categories: does not meet Rome IV criteria for IBS; male (sex); single (marital status); Northern region (region); primary and secondary education (education); full-time employment (employment); non-smoker (smoking status); normal BMI (BMI classification)

B, regression coefficient; SE, standard error; OR, odds ratio; CI, confidence interval; P, probability value; IBS, irritable bowel syndrome; BMI, body mass index

participants, which may have resulted in unstable estimates. The association observed among current smokers, but not ex-smokers, may reflect differences in current lifestyle, stress exposure or symptom perception; however, causality cannot be inferred from this cross-sectional analysis. While bloating affected all age groups in the study, younger participants experienced more frequent or persistent symptoms. These findings support the multifactorial pathophysiology of IBS, where gut-brain axis dysfunction interacts with behavioral and environmental factors [3,6]. The relatively low pseudo-R² values suggest that the variables included in the model had limited explanatory power for Rome IV IBS status, indicating that additional clinical, psychological, dietary, environmental or other unmeasured factors may also contribute to IBS risk.

In binary logistic regression, Rome IV IBS status and marital status were independently associated with self-reported lactose intolerance, while sex, region, education, smoking status and age were not significant predictors. The observed

association with IBS aligns with previous evidence suggesting that individuals with IBS frequently report gastrointestinal symptoms following lactose ingestion. Indeed, lactose is a key fermentable carbohydrate included within the FODMAP group, and its restriction forms a core component of the low-FODMAP dietary approach, which has been shown to improve symptoms in a substantial proportion of IBS patients [18]. The observed association may therefore reflect heightened visceral sensitivity and altered carbohydrate fermentation, rather than true lactase deficiency alone. It is important to distinguish between IBS, lactose intolerance and IgG-based food intolerance testing. IBS is a disorder of gut-brain interaction diagnosed using the symptom-based Rome IV criteria, whereas lactose intolerance refers to symptoms occurring after lactose ingestion, and may be related to lactose malabsorption. In this study, lactose intolerance was self-reported and was not confirmed by hydrogen breath testing or other objective investigations. Therefore, any association between IBS

symptoms and self-reported lactose intolerance should not be interpreted as evidence of confirmed lactase deficiency, as it may reflect symptom overlap or dietary self-attribution. Dietary modification was common, particularly in those meeting the IBS criteria, with almost half reporting food avoidance. The uptake of community-based IgG food intolerance testing, which was reported by over 10% of participants, was notable, given its limited evidence base and the potential for unnecessary dietary restriction. In multivariable analysis, participants meeting Rome IV IBS criteria, females and older participants were more likely to report having undergone food intolerance testing, suggesting that symptom burden and demographic factors may influence healthcare-seeking behaviour and the pursuit of alternative diagnostic investigations. Given the cross-sectional design, the direction of these associations cannot be determined. Reverse causation is plausible, as participants with IBS symptoms may be more likely to attribute symptoms to lactose intolerance, avoid certain foods, or seek IgG-based food intolerance testing. IgG-based food intolerance testing is not a validated diagnostic tool for IBS, lactose intolerance or food intolerance, and positive results may reflect dietary exposure rather than clinically meaningful intolerance. This trend underscores the need for better patient education and access to evidence-based dietary interventions, such as the low FODMAP diet, within primary care and gastroenterology services [19].

Although the prevalence of Rome IV IBS in this Maltese cohort was higher than the pooled worldwide prevalence reported in the literature (13.5% vs. 3.8%) [20], differences in recruitment strategies, symptom perception and healthcare-seeking behaviors may partly explain the variation. Nevertheless, the findings indicate that IBS represents a substantial local health burden.

Strengths of this study include its large sample size, application of the Rome IV criteria, and inclusion of participants from diverse community and workplace settings. However, a key limitation is the use of convenience sampling, which may limit the generalizability of the findings. Individuals with gastrointestinal symptoms or greater health awareness may have been more likely to participate, potentially leading to an overestimation of IBS prevalence. Other limitations include the non-random sampling strategy, and reliance on self-reported data. The exclusion of participants with positive celiac disease screening may also have influenced prevalence estimates. Although this was done to reduce potential misclassification due to undiagnosed celiac disease, it may have introduced bias if excluded participants also fulfilled the symptom-based Rome IV criteria for IBS. Self-reported lactose intolerance was not confirmed using objective testing, and therefore may reflect perceived intolerance or symptom overlap with IBS, rather than true lactose malabsorption. In addition, IgG-based food intolerance testing was self-reported, and this study did not assess the clinical validity of such tests. Thus, the findings are subject to potential recall and selection bias, which may have influenced the symptom reporting and associations observed. Regression estimates for small subgroups, particularly unemployed participants, should be interpreted cautiously, because the small number of participants in these categories may have resulted in unstable OR estimates. Moreover,

prevalence estimates should be interpreted as reflecting the study sample, rather than the general Maltese population. The cross-sectional design does not allow conclusions about temporality or causality. Reverse causation is possible, particularly for associations between IBS symptoms, self-reported lactose intolerance, food avoidance and IgG-based food intolerance testing. The exclusion of individuals over 50 years from the primary analysis limits the interpretation of prevalence across the full adult age range. However, data show that IBS prevalence is lower in the elderly (pooled prevalence 1.9% in 65+ age group vs. 4.9% in 18-39-year age groups, as shown by Sperber *et al* [20]), and individuals ≥ 50 years with new-onset symptoms would still warrant further investigation, including colonoscopy where clinically indicated.

In conclusion, IBS was common in this Maltese adult study sample, particularly among women, and was frequently associated with bloating, dietary changes, and the use of unvalidated food intolerance tests. These findings highlight the need for increased clinical recognition of IBS, targeted public education on evidence-based management, and cautious interpretation of commercial food intolerance testing. Further research is needed to explore modifiable lifestyle and psychosocial factors associated with symptom burden in this population. Future studies using population based and longitudinal designs would be valuable to confirm these sample-based findings, identify causal relationships and evaluate the effectiveness of targeted interventions.

Summary Box

What is already known:

- Irritable bowel syndrome (IBS) is a common disorder of gut-brain interaction diagnosed using the symptom-based Rome IV criteria
- The Rome IV criteria generally yield lower prevalence estimates than earlier diagnostic definitions
- Data on IBS prevalence in Southern Europe and small island populations remain limited

What the new findings are:

- This study provides the first sample-based estimate of IBS prevalence in a Maltese adult sample using the Rome IV criteria
- The primary IBS prevalence estimate was 13.5% among adults aged 18-50 years, while overall cohort prevalence was 11.0%
- Female sex, current smoking and unemployment were independently associated with meeting the Rome IV criteria for IBS
- Participants meeting the Rome IV criteria for IBS had higher odds of reporting lactose intolerance and undergoing food intolerance testing

AQ1 **References**

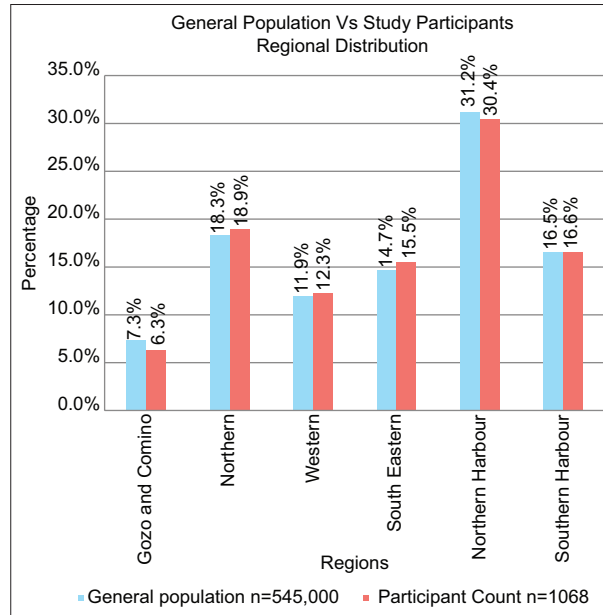
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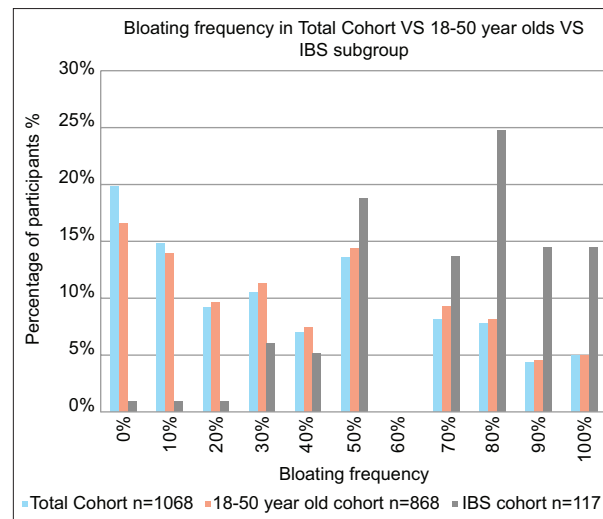
AQ1: The references in the text must follow a sequential numerical order. Therefore, we cannot have reference [13] followed by reference [20] while omitting the references in between.

Please check the manuscript again and send us your corrections regarding both the in-text citations and the reference list at the end of the manuscript, ensuring that they are consistent with each other and follow the correct numerical order.

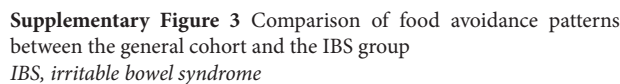
Supplementary material



Supplementary Figure 1 Comparison of the regional distribution of the full study cohort (n=1068) with that of the general population of Malta (National Statistics Office). Absolute differences between the two distributions ranged from 0.1 to 1.0 percentage points across regions



Supplementary Figure 2 Clustered bar chart comparing self-reported bloating frequency among the total cohort (n=1068), the 18-50-year-old subgroup (n=868), and participants meeting the Rome IV criteria for IBS (n=117). Percentages are shown for each response category IBS, irritable bowel syndrome

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