gastrointestinal disorders

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Prevalence of Functional Gastrointestinal Disorders (Rome IV Criteria) among a Cohort of New Zealand Children

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Abstract: Functional gastrointestinal disorders (FGIDs) are characterised by recurring gastrointestinal symptoms that are not secondary to organic disease. FGIDs may cause reduced quality of life, with approximately 22% of children experiencing at least one FGID. This study aimed to assess FGID prevalence among children attending a tertiary care hospital in New Zealand (NZ). Methods: Children aged ≥ four years were prospectively recruited from Christchurch Hospital, NZ. Data were collected on demographics, medical history, gastrointestinal symptoms (Rome IV), and quality of life (EQ-5D-Y). An analysis was carried out using analysis of variance and the chi-squared test of independence. Results: The cohort included 156 children, with a mean age of 9.5 years (SD 3.3), 56% male. According to the Rome IV criteria, 29% experienced at least one FGID, most commonly functional constipation and functional dyspepsia. FGID symptoms were associated with Māori ethnicity ($p = 0.012$) and parental FGID ($p < 0.001$). Quality of life was lower in the FGID group in the domain 'Feeling worried, sad, or unhappy' ($p = 0.002$). Conclusion: the association of FGIDs with worse quality of life, in particular relating to worry and sadness, should highlight the importance of providing support to school age children experiencing FGID symptoms.

Keywords: gastrointestinal symptoms; paediatric; quality of life; functional symptoms

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1. Introduction

Functional gastrointestinal disorders (FGIDs) are characterised by recurring gastrointestinal (GI) symptoms that cannot be attributed to organic disease, structural, or biochemical causes [1]. FGID may be related to a combination of disturbances in gut motility and microbiota, central nervous system processing, visceral hypersensitivity, and altered immune and mucosal function [2].

Children with FGID may present with symptoms such as abdominal pain, nausea, vomiting, regurgitation, diarrhoea, or constipation [1], with these being some of the main reasons for presentation to a primary care physician [3]. FGIDs are strongly associated with interference of children's normal activities, such as school attendance, social activities, and sleep, as well as being associated work absence for their parents [4–6]. In addition, children with FGID experience a reduced quality of life compared to healthy controls [4,7–11] and impaired psychosocial outcomes, such as anxiety and depression, coping, worry, and catastrophising [4,9,12]. FGID during childhood is also associated with increased healthcare utilisation, representing a significant burden to the primary, secondary, and tertiary healthcare systems [4,8,13,14]. Furthermore, up to 25% of children presenting with recurrent abdominal pain subsequently develop irritable bowel syndrome (IBS) as an adult, highlighting the possibility of childhood FGID progressing into adulthood [15].

Specific assessment tools have been developed for the clinical identification of FGIDs in children of all ages, namely the paediatric Rome IV criteria [1,16], symptom-based guidelines developed using scientific evidence, clinical experience, and iterative revisions from previous Rome criteria [17,18]. Rome IV parental reporting tools have also been developed in conjunction that enable data to be collected from a proxy source using a

structured questionnaire to gather information from parents on their child's GI symptoms and activity limitations. The parental report data are then assessed against criteria for the diagnosis of specific FGIDs. There are separate criteria for neonates/toddlers up to the age of four years [16], and for children aged 4–18 years [1]. For neonates and toddlers, these comprise infant regurgitation, infant rumination syndrome, cyclic vomiting syndrome, infant colic, functional diarrhoea, infant dyschezia, and functional constipation [16]. For children aged four and over, the criteria are cyclic vomiting, functional nausea, functional vomiting, rumination syndrome, aerophagia, functional dyspepsia, irritable bowel syndrome, abdominal migraine, abdominal pain not otherwise specified (NOS), functional constipation, and non-retentive faecal incontinence.

According to the Rome IV criteria, the most common FGID experienced by infants is infant regurgitation; for those aged 13–48 months, functional constipation and cyclic vomiting; and for those aged over four years, functional constipation, functional dyspepsia, and irritable bowel syndrome [19]. Various management options are available for FGIDs, these include dietary management, psychosocial input, complementary/alternative medicines, and pharmacological treatments. However, the evidence for their efficacy is mixed [20–27]. It is, therefore, important to develop strategies that may optimise outcomes and improve quality of life [28].

International studies report the prevalence of FGIDs among children according to the Rome IV criteria to range between 6 and 40%, with an overall estimate of 22% [19]. Little is known of the pattern of FGIDs among children in New Zealand, although among adults the prevalence is approximately 30% [29]. It is important to assess the prevalence within local populations to ensure that the diagnostic pathways and appropriate resources are in place that account for the specific epidemiology. The objective of this research was to carry out Rome IV parental report assessments among children attending a tertiary care centre in New Zealand with the aim of establishing local FGID prevalence, as well as to measure the association of FGIDs with independent variables such as quality of life and general well-being.

2. Results

2.1. Demographics and Health Information

One hundred and fifty-six children participated in the study, and they had a mean age of 9.5 years (SD 3.3), and 87 (56%) were male (Table 1). The majority were recruited from inpatient wards (surgical ward: 56 (36%); medical ward: 12 (8%); acute assessment: 38 (24%)) and the remainder from outpatient areas (outpatient clinics: 28 (18%); day ward: 22 (14%)). The reporting parent was female for 133 (85%) of the children. The parents had a mean age of 40.5 years (SD 7.7), and 24 (15%) parents self-reported that they had an FGID, all stating irritable bowel syndrome (IBS). Of the 47 (30%) children who were reported to have a chronic health condition, the most common conditions were asthma 17 (36%), eczema 7 (15%), epilepsy 4 (9%), and diabetes 4 (9%).

2.2. FGID Prevalence, Categories, and Disorders

From the overall cohort, 45 (29%) of the children experienced at least one FGID, with 34 (22%) having one FGID, 3 (2%) two FGIDs, 6 (4%) three FGIDs, and two (1%) four FGIDs. The FGID categories experienced most frequently were functional constipation (12%) and functional dyspepsia (10%), with no patients reporting symptoms that concurred with a diagnosis of aerophagia or non-retentive faecal incontinence (Figure 1). Of those with functional dyspepsia, 13 (8%) had post-prandial distress syndrome, and 3 (2%) had epigastric pain syndrome. When the FGID categories were combined, functional abdominal pain disorders (FAPDs) were the most common (19.9%), followed by functional defaecation disorders (FDDs) (12.2%) and functional nausea and vomiting disorders (FNVDs) (10.9%).

Table 1. Participant demographics and health information as reported by parents.

Variable	Category	Value, N (%)
Child's age, mean (SD)		9.5 y (SD 3.3)
Child's sex	Male	87 (56)
	Female	69 (44)
Ethnicity * (N = 134 (86%))	NZ European	123 (79)
	Māori	23 (15)
	Pacific Islands	16 (10)
	Asian	9 (6)
	MELAA	5 (3)
	Other	2 (1)
Household income (N = 128 (82%))	Up to $50,000	15 (9)
	$50–100,000	40 (25)
	$100–150,000	37 (24)
	$150–200,000	21 (13)
	$200,000+	15 (9)
Parent education	High school	43 (28)
	College	38 (24)
	University	50 (32)
	Post-graduate	25 (16)
Urban/rural living (N = 153 (98%))	Rural	53 (35)
	Urban	100 (65)
Chronic health condition	Yes	47 (30)
Taking prescription drugs	Yes	41 (26)
Allergies	Yes	47 (30)
Parent has FGID (all IBS)	Yes	24 (15)

Data presented for the whole cohort of 156, unless stated otherwise. * Participants could identify as more than one ethnicity, results equal > 100%. MELAA = Middle Eastern/Latin American/African; y = years; N = number; SD = standard deviation; FGID = functional gastrointestinal disorder; IBS = irritable bowel syndrome, $ = New Zealand Dollars

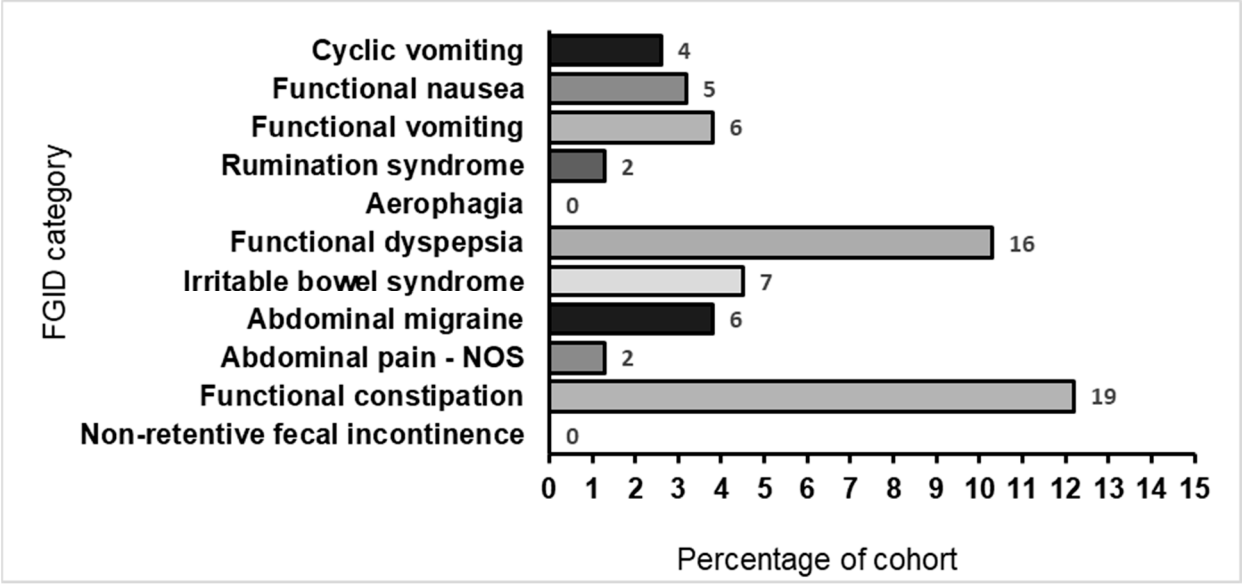

Figure 1. Percentage of children with each FGID category (total: 156 children). The number of children that reported experiencing each FGID is presented at the end of each bar.

2.3. Association of FGID with Independent Variables

When the presence of FGID as a binary variable (yes/no) was tested for association with independent variables, it was shown that identifying as Māori ethnicity and having a parent with FGID were both associated with their child having FGID. When analysis was

stratified by the gender of the parent, it was seen that the associations were not significant for females or males and that the association was for parents overall only (Table 2).

Table 2. Association between presence of any FGID and independent variables in children from New Zealand.

Variable	Category	No FGID	FGID	Mean Difference	*p*-Value
Age		9.4 y (SD 3.2)	10.0 y (SD 3.5)	0.6	0.313
Variable	Category	No FGID	FGID	χ^2 (Phi)	*p*-value
Sex	Male	65 (75)	22 (25)	1.21 (0.09)	0.290
	Female	46 (67)	23 (33)		
Ethnicity	NZ European	91 (74)	32 (26)	2.3 (0.12)	0.137
	Māori	11 (48)	12 (52)	7.2 (0.21)	0.012
	Pacific Islands	14 (88)	2 (12)	2.3 (0.12)	0.155
	Asian	8 (67)	4 (33)	0.1 (0.03	0.745
	MELAA	3 (60)	2 (40)	0.3 (0.05)	0.627
	Other	1 (50)	1 (50)	0.4 (0.05)	0.495
Household income	Up to NZD 50,000	9 (60)	6 (40)	3.0 (0.15)	0.565
	NZD 50–100,000	25 (62)	15 (38)		
	NZD 100–150,000	29 (78)	8 (22)		
	NZD 150–200,000	15 (71)	6 (29)		
	NZD 200,000+	10 (67)	5 (33)		
Parent education	High school	30 (70)	13 (30)	1.2 (0.09)	0.762
	College	26 (68)	12 (32)		
	University	35 (70)	15 (30)		
	Post-graduate	20 (80)	5 (20)		
Urban/rural living	Rural	69 (69)	31 (31)	0.7 (0.07)	0.456
	Urban	40 (75)	13 (25)		
Chronic health condition	No	81 (74)	28 (26)	1.8 (0.11)	0.247
	Yes	30 (64)	17 (36)		
On medications	No	85 (75)	29 (25)	2.7 (0.13)	0.112
	Yes	25 (61)	16 (39)		
Allergies	No	77 (71)	32 (29)	0.05 (0.02)	0.99
	Yes	34 (72)	13 (28)		
Parent (overall) has FGID	No	101 (77)	31 (23)	12.0 (0.28)	<0.001
	Yes	10 (42)	14 (58)		
Mother has FGID	No	4 (80)	1 (20)	2.3 (0.33)	0.311
	Yes	7 (41)	10 (59)		
Father has FGID	No	1 (25)	3 (75)	0.69 (0.24)	0.576
	Yes	4 (50)	4 (50)		

MELAA = Middle Eastern/Latin American/African; y = years; SD = standard deviation; FGID = functional gastrointestinal disorder.

Individual FGIDs were also examined against these variables (Supplementary Materials Table S1), showing that functional constipation was associated with being of Māori heritage (χ^2 8.4 (Phi 0.23), $p = 0.009$) and functional dyspepsia with children having allergies (χ^2 4.8 (Phi 0.18), $p = 0.020$), as well as having a parent with FGID (χ^2 6.7 (Phi 0.21), $p = 0.02$). Children having abdominal migraine was associated with those taking prescription medications (χ^2 5.2 (Phi 0.18), $p = 0.043$), and IBS was associated only with a parent having FGID (all of whom self-reported as being IBS) (χ^2 9.8 (Phi 0.25), $p = 0.011$).

When the FGID syndromes were tested for their association with the same independent variables, it was shown that FNVD had no correlation with any demographic or health factors. Children were more likely to experience FAPD if they were older (mean difference (MD) 1.4 years, $p = 0.045$), taking prescription medications (χ^2 4.7 (Phi 0.17), $p = 0.046$), or had a parent with FGID (χ^2 6.3 (Phi 0.2), $p = 0.029$). FDDs were associated with being of Māori heritage (χ^2 8.4 (Phi 0.23), $p = 0.009$), however, with no children satisfying the criteria for non-retentive faecal incontinence; this result is the same for functional constipation.

2.4. Quality of Life

The ratings given to each EQ-5D-Y category were examined for those reporting limitations with and without an FGID (Figure 2). There was an association found among those with FGID having limitations in the category 'Feeling worried, sad, or unhappy' (χ^2 10.3

(Phi 0.26), $p = 0.002$). Given the previous association between particular FGID and having a parent with FGID (Table 2 and Table S1) this variable was used as a control, with the repeat analysis showing that this association remained (χ^2 7.7 (Phi 0.57), $p = 0.01$), suggesting an underlying relationship with their parent also having an FGID.

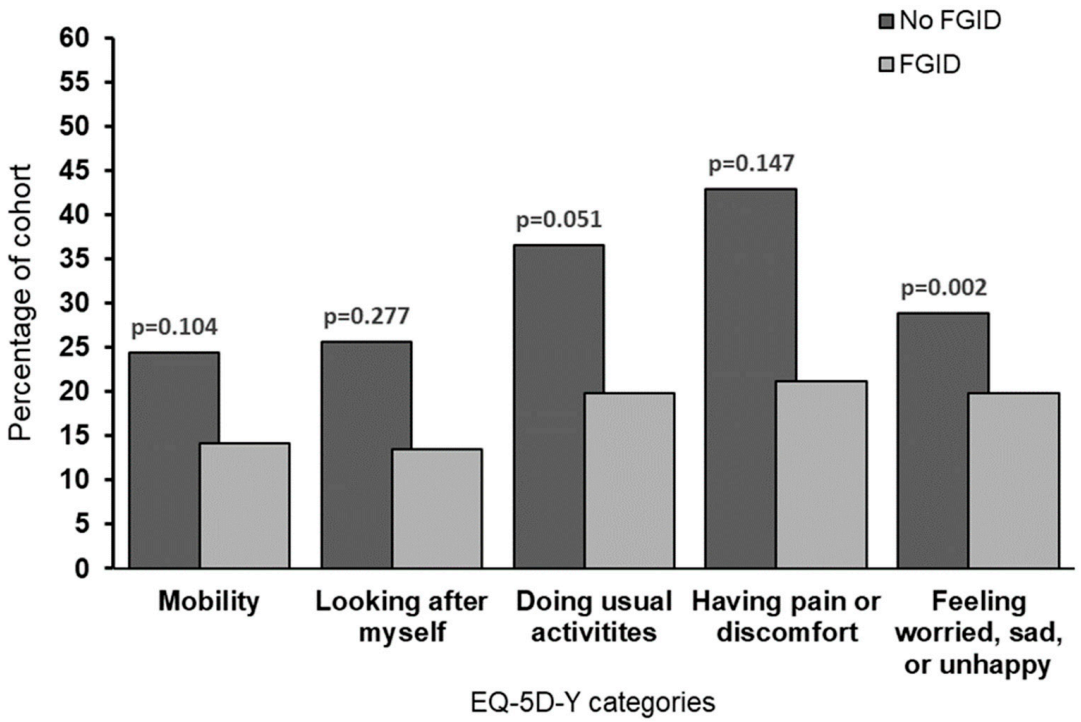

Figure 2. Percentage of the group reporting limitations in the EQ-5D-Y categories grouped by the presence of no FGID/any FGID. *p*-Values for between-group differences (FGID/no FGID) presented at the top of each group-set.

The associations between the EQ-5D-Y categories and specific FGID disorders were also examined. This analysis showed that children with FAPD were compromised in the domains of 'Having pain or discomfort' and 'Feeling sad, worried, or unhappy' when compared to children without these disorders (Table 3). When all analyses were controlled for the parent having FGID, the association was strengthened for children with FAPD in the domains 'Having pain or discomfort' (χ^2 7.7 (0.21), $p = 0.21$) and 'Feeling sad, worried, or unhappy' (χ^2 22.2 (0.3), $p < 0.001$). A relationship between children with FDD and parents having FGID also became evident in the domain of 'Feeling sad, worried, or unhappy' (χ^2 6.7 (0.1), $p = 0.035$).

Table 3. Association between the presence of FGIDs and EQ-5D-Y categories in children.

EQ-5D-Y Category	Functional Nausea and Vomiting Disorder		Functional Abdominal Pain Disorder		Functional Defecation Disorder	
	χ^2 (Phi)	*p*-Value	χ^2 (Phi)	*p*-Value	χ^2 (Phi)	*p*-Value
Mobility	4.4 (0.17)	0.06	1.1 (0.09)	0.37	0.4 (0.05)	0.62
Looking after myself	2.0 (0.1)	0.22	0.01 (0.01)	1.0	0.6 (0.06)	0.46
Doing usual activities	3.8 (0.16)	0.07	2.9 (0.14)	0.12	0.4 (0.05)	0.63
Having pain or discomfort	0.7 (0.07)	0.54	5.1 (0.18)	0.02	0.01 (0.01)	1.0
Feeling Worried, Sad, or Unhappy	1.7 (0.1)	0.24	14.8 (0.31)	<0.001	3.4 (0.15)	0.09

2.5. Overall Health

The overall health VAS section of the EQ-5D-Y showed a mean score of 70.6 (SD 23.1, range 10–100) and median of 80.0 (IQR 50–90), with frequencies indicating the majority scored over 50 out of the maximum of 100, with a score of 100 indicating the 'The best health you can imagine' (Figure 3). The VAS health rating was shown to be worse among children with FGID than those without FGID (MD 12.28, $p = 0.003$). It was also worse for those specifically with FNVD (MD 19.57, $p = 0.004$) and FAPS (MD 14.7, $p = 0.003$) but not FDD (MD 2.6, $p = 0.65$).

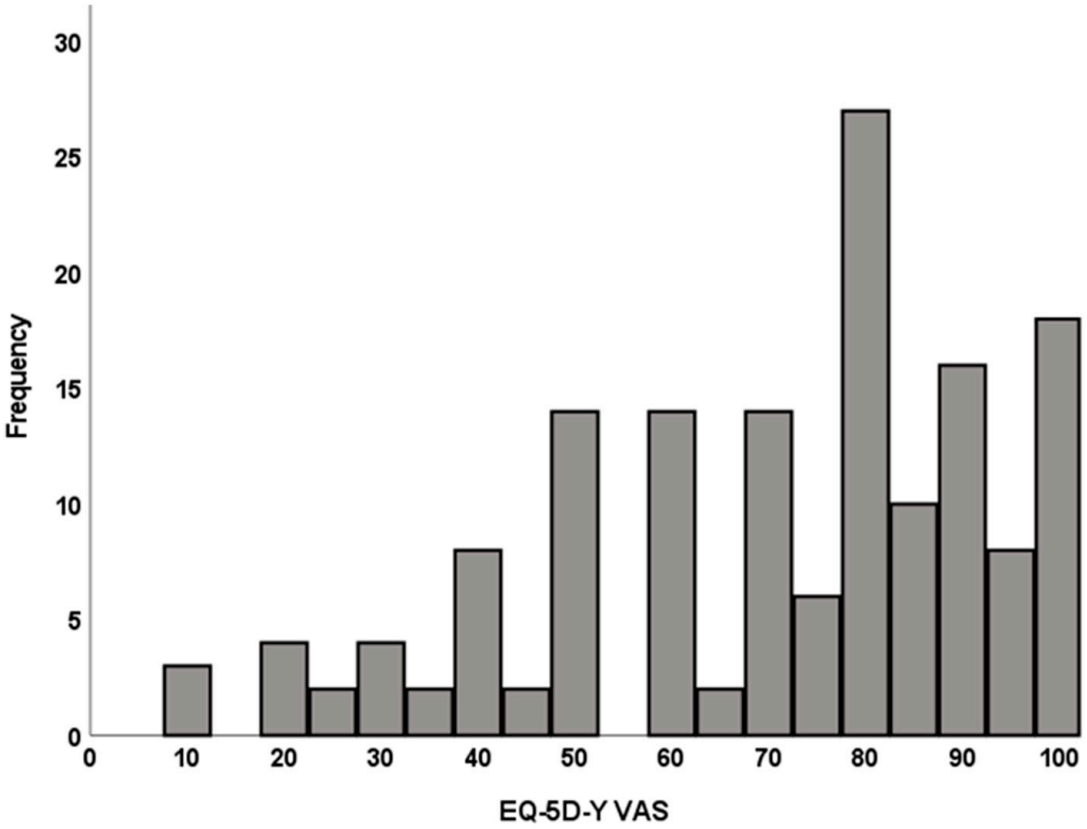

Figure 3. Frequency of the scores given to the EQ-5D-Y VAS scale for the overall health of the children, as reported by their parent.

3. Discussion

The data presented in this study provide an estimate of FGID prevalence among a cohort of children attending a single tertiary care centre in New Zealand. Few demographic or health variables were shown to be associated with children experiencing FGID in this population, although two specific factors were identified: Māori ethnicity and parental FGID. Children with FGID experienced worse quality of life in specific domains, and overall health was compromised for those with FGID, specifically for children with FNVD and FAPD.

The most common FGID categories experienced in this study cohort were the same as in previous works among larger cohorts: functional constipation, functional dyspepsia, and IBS [8,30,31]. However, the cohort of children in this study reported a slightly higher prevalence of FGID (29%) than among the general population reported in a recent systematic review (22%) [19]. This may be explained by the studies in the review predominantly recruiting from schools and not from a healthcare environment as in this research [19]. FGIDs are associated with a number of chronic conditions, such as atopy [32,33], epilepsy [34], familial Mediterranean fever and Henoch–Schönlein purpura [35,36], as well as being a comorbidity of joint hypermobility [37] and obesity [38]. The Rome IV criteria no longer

require exclusion of those with organic disease in recognition of pre-existing conditions also having comorbid FGID [1,17]. However, with 30% of the study cohort having a chronic condition, most frequently atopy and epilepsy, it could be expected that prevalence may be higher in this study cohort. With many children reporting more than one chronic illness, it was not possible to conduct a sensitivity analysis to identify whether these specific chronic conditions were mediating factors for children with FGID.

The independent variable shown to most frequently influence both the presence of FGID, FGID categories, and quality of life in this study was having a parent with an FGID. The relationship between parental FGID and their offspring having an FGID has been shown in a number of studies, specifically for IBS and functional abdominal pain, whereby children exhibit a greater frequency of GI symptoms, miss school more often, and have more frequent healthcare visits than healthy controls [39–41]. Inversely, mothers with IBS express concern about how their condition affects their child, worry about whether their child will also experience IBS, and have high levels of concern for their child's overall health [42]. These coexisting relationships may be linked to social learning, whereby in the presence of a parent somatising FGID children learn how to interpret these symptoms and respond to their own symptom experience, as well as parental reinforcement of illness behaviours [43–45]. The frequency of children presenting with FGID symptoms increases following a parent's experience of illness with associations reported between offspring developing IBS and anxiety [46]. The presence of parental IBS has also been shown to increase the likelihood not only of offspring developing FGID but also of them experiencing mental health disorders via cross-generational transmission [40]. The bidirectional relationship in the gut–brain axis is well known, with GI symptoms being reciprocal with psychosocial outcomes [47,48]. Previous work has shown that parental mental health and anxiety increases the likelihood of FGID in their children [49,50], although the association between parental FGID and influence on offspring quality of life has not been explored.

The association between being of Māori ethnicity and FGID seems moderated by the increased numbers of Māori participants having functional constipation (FC) compared to other ethnic groups. The context of this finding may be related to a number of variables that were not measured as part of this study. The high frequency of FC among children of Māori ethnicity is not unique, as treatment for constipation in children of Māori background has been shown to represent a substantial contribution towards avoidable hospital admissions when compared to non-Māori [51]. However, the reasons for these high rates are infrequently measured but are likely to be multifactorial. Previous reports suggest that the levels of exercise and healthy food intake in Māori children are low [52] while the levels of obesity are high [53]. There is a link between obesity and FGID, specifically FC, with children experiencing both conditions having worse pain and disruption of daily activities [38,54,55]. However, body mass index, activity levels, and food intake were not measured as part of the current study; consequently, any suggested links cannot be substantiated. While the number of Māori participants included in this subgroup analysis was relatively small (23 children (15%)), visual inspection of the difference between those with or without FGID in other ethnic groups (Table 2) provides a descriptive overview of the disparity for Māori participants. Māori people in New Zealand experience known inequalities in health access and engagement [56,57] as a result of cultural, structural, and communication barriers [58]. It is, therefore, of paramount importance that health disparities continue to be identified among this population in order to improve health interventions.

3.1. Strengths

This study provides data on the prevalence of FGID among a cohort of children with/without various chronic conditions. While children with organic diseases known to cause GI symptoms were excluded, this study provides comparative data to previous studies and reviews among the general, healthy population. Specific quality-of-life domains were shown to be compromised in the cohort of children with FGIDs that may be utilised to develop targeted interventions.

3.2. Limitations

The undertaking of this study in a single centre does introduce potential location sampling bias. However, the comprehensive study methodology could be replicated in other centres to establish the generalisability of these results. The use of self-reported FGID among parents as a comparator variable did not enable the formal documentation of parental diagnoses. However, somatic symptoms may manifest equally whether formally diagnosed or otherwise, so they may still exert an influence over their child's outcomes. The small sample size recruited for this study may overestimate the true effect size of the subgroup analyses. The secondary findings were, therefore, considered to be hypothesis generating, not testing, and additional participants will be recruited in future studies to enable sufficiently powered comparisons.

3.3. Conclusions

This cross-sectional study reports the prevalence of FGIDs in a sample of children attending a tertiary care centre in New Zealand and presents data on variables associated with FGIDs, as well as quality of life. The association between children with FGIDs feeling worried, sad, and unhappy should highlight the importance of providing support to school age children experiencing FGID symptoms and promote the utilisation of tools, such as the Rome IV, to rapidly assess and identify those with FGID. The possible association between ethnicity and FGIDs should be further explored in multicentre studies with large sample sizes to allow sufficient comparisons among such important variables. Future work should also concentrate on additional sociodemographic indices, such as deprivation deciles, which may further refine where health promotion endeavours may be beneficial among children in New Zealand.

4. Materials and Methods

4.1. Ethics and Consent

Ethical approval was granted by the University of Otago Human Ethics Committee (Health), NZ (H21/019), and locality approval by the Canterbury District Health Board, Christchurch, NZ (RO#21038). All child participants provided written assent for their parent to provide their demographic and health information, and all parents provided written consent to take part.

4.2. Population

This cross-sectional study was conducted in one tertiary care centre: Christchurch Hospital, Christchurch, New Zealand. Participant inclusion criteria were children aged four years and over with one parent also willing to participate. Exclusion criteria were children with known/existent GI disease, neurodevelopmental disorders, and haematology/oncology conditions.

4.3. Outcome Measures

4.3.1. Demographic Information

Demographic and basic health information was collected on all paediatric participants: age, sex, ethnicity, postcode, parental education, household income, presence of a chronic health problem, prescribed medications, allergies, and medical history. Parents were asked to provide information on their age and sex, as well as to self-report whether they also considered themselves to have an FGID.

4.3.2. FGID Assessment

The FGID assessment was carried out using the Parent-Report form of the Rome IV Diagnostic Questionnaire for Pediatric Gastrointestinal Disorders for Children and Adolescents (Copyright 2016© by Rome Foundation) with permission granted from the Rome Foundation for study-specific use. All questionnaires can be requested from the Rome foundation (http://theromefoundation.org/, accessed on 9 January 2023). The Rome

IV tool asks a series of questions in sections relating to abdominal pain, bowel movements, nausea and vomiting, and other symptoms [1]. The answers given to this assessment can then be utilised to confirm a diagnosis of individual categories of FGID: cyclic vomiting, functional nausea, functional vomiting, rumination syndrome, aerophagia, functional dyspepsia, irritable bowel syndrome, abdominal migraine, abdominal pain not otherwise specified (NOS), functional constipation, and nonretentive faecal incontinence. These categories may then be combined to define those with FGID disorders: functional nausea and vomiting disorders, functional abdominal pain disorders, and functional defecation disorders [1].

4.3.3. Quality of Life

Quality of life was assessed using the EQ-5D-Y™ (proxy version) tool [59], with permission granted from EuroQol for study-specific use. The purpose of the proxy tool is to explore how the parent rates the health of the child, not answering on behalf of the child but rating the child's health as the proxy perceives it. The tool includes questions on mobility, self-care, ability to carry out usual activities, pain or discomfort, feeling worried, sad, or unhappy. It also asks parents to rate their child's health that day on a scale of 1–100, with 100 representing the best health they can imagine.

4.4. Statistics

4.4.1. Sample Size

Previous work has studied FGIDs among children in a community setting, and the prevalence has varied from 23 to 28%; however, the research is limited among children in a hospital setting. It was estimated that the prevalence may be slightly higher at approximately 30% in a population of children attending hospital because of FGIDs being a comorbidity of a number of acute and chronic paediatric conditions. A sample size of 150 was proposed to enable adequate precision (±8%, 95% confidence interval) for the incidence of FGIDs among this cohort.

4.4.2. Analysis

Descriptive data are presented for the number and type of FGIDs experienced by the cohort overall. Between-group comparisons were performed using ANOVA for the linear variables or the Chi-squared (χ^2) test of independence for the ordinal variables. The results of the ANOVA are presented as a mean difference and ordinal variables as the χ^2 value and the Phi effect size, with results closer to 1.0 indicating a stronger effect size. The results in the EQ-5D-Y tool are reduced to binary categories of limitations/no limitations, as per the EuroQol analysis manual [60]. The results are considered significant at the level $p < 0.05$. The analysis was carried out using SPSS v27.0 (IBM Corp, Armonk, NY, USA) [61]

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/gidisord5020021/s1, Table S1: Association between individual FGID categories and independent variables among children in NZ.

Author Contributions: Conceptualisation, A.V.-R. and A.S.D.; methodology, A.V.-R., I.A. and A.S.D.; formal analysis, A.V.-R. and I.A.; investigation, A.V.-R. and I.A.; resources, A.S.D.; data curation, A.V.-R.; writing—original draft preparation, A.V.-R.; writing—review and editing, A.V.-R., I.A. and A.S.D.; supervision, A.V.-R. and A.S.D.; project administration, A.V.-R. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and approved by the of UNIVERSITY OTAGO Human Ethics Committee (Health), NZ (H21/019), and locality approval by the Canterbury District Health Board, Christchurch, NZ (RO#21038).

Informed Consent Statement: Written, informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Data are available upon reasonable request to the corresponding author AVR.

Conflicts of Interest: The authors declare no conflict of interest.

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