

## Delivery of Care for Functional Gastrointestinal Disorders: A Systematic Review

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**Author contributions:**

CB, MAK, MS and AJT devised the concept. CB acquired the systematic search under the supervision of MAK, MS, and AJT. CB wrote the manuscript. MAK, MS, AWOB, AS and AJT provided critical revision of the manuscript for important intellectual content.

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**Keywords:** irritable bowel syndrome, functional gastrointestinal disorders, outpatient specialist care, models of care, delivery of care

## ABSTRACT

**BACKGROUND:** A diverse range of treatments are available for the treatment of functional gastro-intestinal disorders (FGIDs). Individual treatments, including drug therapies, behavioural therapy (“biofeedback”), psychological therapies, and dietary therapies have been well validated in controlled, randomised trials and real-life case series. However, few studies have evaluated models of delivery of care for the whole population of referred patients with a FGID. This review evaluates models of specialist outpatient care for the management of FGIDs.

**METHODS:** A systematic review was performed of full-text articles published until October 2018 in PUBMED/Medline and EMBASE. Studies were included if they evaluated a model of outpatient care in a specialist setting for the treatment of adult patients with a FGID, and included patient-reported outcomes comprising symptoms, quality of life or psychological well-being.

**RESULTS:** Few studies have evaluated the delivery of care for the whole population of referred patients with a FGID, and there was one randomised comparison of different models of care. Two studies that evaluated the outcome of gastroenterologist-only clinics suggested poor long-term results. Two non-comparative case series reported the outcome of multi-disciplinary care, including gastroenterologists and psychological therapists, suggesting improved patient quality of life and psychological well-being.

**CONCLUSIONS:** Despite the high prevalence and cost of treating FGIDs, and the availability of effective treatments, there are few data, and limited randomised comparisons, reporting the outcome of different types of specialist care. The few data available suggest that multi-disciplinary care is superior to gastroenterologist-only care, but this needs to be validated in prospective comparative studies.

FGIDs constitute the commonest disorders treated in gastroenterological practice<sup>1</sup>. They are associated with significant impairment in quality of life<sup>2</sup> and psychological well-being<sup>3</sup>. They account for considerable direct costs to the patient and the healthcare system<sup>4</sup> and secondary costs from impaired workforce productivity and absenteeism<sup>5</sup>.

The limited available evidence on outcomes from current models of care suggest that patients are often dissatisfied with prescribed therapies<sup>6</sup>, seek repeated care, are over-investigated, try numerous therapies often with little benefit<sup>7</sup>, and may undergo surgery that is either unnecessary or of dubious efficacy<sup>8</sup>. Most of these studies report on care provided by specialist gastroenterologists only and focus on drug therapies.

There is a rich body of randomised, controlled trial evidence on the therapeutic value of specific drug treatments and non-drug therapies in the various FGIDs. Pharmacological therapies of proven value include antidepressants<sup>9</sup>, antibiotics<sup>10</sup>, aperients<sup>11</sup> and non-laxative bowel stimulants<sup>12 13 14</sup>. Proven non-drug therapies include dietary<sup>15</sup>, behavioural<sup>16</sup> and psychologically-based therapies<sup>17</sup>.

Despite the evidence that these therapies are also effective in real-world, single-disorder case series<sup>18-20</sup>, there are almost no data on the extent of, and the outcome, of their use when incorporated into routine clinical care.

Prior to the current study we evaluated the outcome of care for patients with a FGID in our specialist gastroenterology clinic, based in a large, university-affiliated general hospital. This clinic is staffed only by gastroenterologists and residents and offers mainly pharmacological therapies. The symptomatic outcome of care was poor in a majority of patients<sup>21</sup>.

A key question in this field therefore remains: what is the best model of specialist care for patients with a FGID? This paper aims to systematically review the outcome of different models of delivery of outpatient care for patients with a FGID. It is not intended to review the specific treatments, but rather models of delivery of care that incorporate these different treatments.

## METHODS

The Preferred Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were used for this review. The protocol of this review was prospectively registered with PROSPERO (CRD42018103584), the international prospective register of systematic reviews.

### **Search Strategy, Study selection and Data Extraction.**

A systematic search of PubMed and EMBASE databases for English-language publications up until October 2018 was conducted. Studies published in abstract form only were excluded. Conference abstracts were not included as they did not provide sufficient information to determine if a study met inclusion criteria. Search terms are shown in table 1. FGIDs included irritable bowel syndrome, functional dyspepsia, functional constipation and faecal incontinence. Search terms addressing models of outpatient care included ambulatory care, healthcare or outcome assessment.

A model of care was defined as the routine application of a patient pathway through a service with defined criteria for patient selection for different treatments. Further the model of care had to define the stages and involvement of clinical staff and treatment modalities. This review included only hospital outpatient care for functional gut disorders, in which clinical care was provided by a gastroenterologist, surgeon, psychologist, psychotherapist, dietician, physiotherapist, nurse or gut-focused hypnotherapist. This

review aimed to assess the value of types or models of hospital outpatient service, not of the individual treatments in isolation. This review therefore only included studies that described the treatment pathway for all patients presenting with a FGID.

The Search and title and abstract review was conducted by CB. Full text articles were reviewed and selected by CB, AWOB, AS, MS and MAK. Any disagreement in selecting papers was resolved by consensus of all authors.

### **Patient Populations**

Studies that comprised adults aged 18 years or older with a FGID, defined by the Rome<sup>22</sup> or Manning criteria<sup>23</sup>, who had attended a specialist outpatient clinic, were included.

Randomised controlled trials, observational, cross-sectional and retrospective studies were included.

### **Outcomes**

Studies which evaluated patient outcomes after attending a specialist clinic were included. These outcomes included symptoms, quality of life and psychological wellbeing. Economic measures were not evaluated due to marked differences between countries in payment and insurance systems.

### **Data analysis**

All studies are described in detail and summarised in Table 2. Due to study heterogeneity a meta-analysis was not performed.

## RESULTS

Of 13089 studies identified, 6003 duplicates were excluded, leaving 7086 studies. After examination of the titles and abstracts, a further 7032 studies were excluded. Of the 56 reports reviewed in detail, 48 were excluded, leaving eight studies included in the final analysis (Figure 1). Fifteen of the 48 excluded studies were retrospective analyses of cohorts which did not include data on patients who did not undertake treatment, or had no controlled comparator; all these reports were in the context of specialist clinics, where it was unclear how patients were selected for that intervention, what proportion of all patients they constituted, which patients declined care, and the outcomes of patients who declined the intervention. The remaining 33 studies were excluded as they were conducted in a primary care setting or did not report patient symptom or condition outcomes.

Studies were categorized according to the model of care, the FGIDs treated, treatment interventions, year of publication and country where research was conducted (Table 2).

### **Models of care**

Models of care were heterogeneous but were categorized into a) gastroenterologist-only outpatient specialist care; b) nurse-led care; c) psychological services integrated into gastroenterology clinic; and d) education about FGID to supplement routine care.

### **Conditions observed**

Four studies included patients with irritable bowel syndrome, two studies included patients with all FGIDs, one study included patients with faecal incontinence, and one study included patients with functional constipation.

## Outcomes

A range of outcome measures were utilised, not allowing for direct comparison between cohorts. Symptom scales included Irritable Bowel Syndrome Symptom Severity Scale (IBS-SSS) <sup>24</sup> or Gastrointestinal Symptom Rating Scale (GSRS) <sup>25</sup>. Quality of life outcomes were measured including the Short Form 36 (SF-36) <sup>26</sup> and the Irritable Bowel Syndrome Quality of Life score (IBS-QOL) <sup>27</sup>.

## Gastroenterologist-only Specialist Clinics

Two studies evaluated the effect of standard outpatient gastroenterologist-only care for FGIDs. Both clinics were in countries where free universal healthcare was available for patients, namely the United Kingdom and Australia. Both clinics were situated in public university-affiliated hospitals.

Canavan et al<sup>28</sup> described a cohort of patients with IBS who were seeing a gastroenterologist for the first time, and then administered a quality of life questionnaire (EuroQoL-5D) before, and three and 12 months after, the initial visit. They showed no significant difference in quality of life after treatment. Symptoms and cost of healthcare were not evaluated. There was a poor survey response rate of 42 percent at 3 months and 17 percent at 12 months.

A study from our centre <sup>21</sup> investigated a clinic staffed only by gastroenterologists. All referrals over a 12-month period to the gastroenterology clinic were examined. All patients with a FGID were asked to complete a survey one year after their clinical care was completed. Symptoms, time absent from work and expectations of the clinical service were evaluated in addition to a medical record review. Seventy three percent of patients underwent endoscopy. Twenty-nine percent of patients had no documented treatment offered and were presumed to have received reassurance and education about their

condition. At one year after the conclusion of treatment a minority of patients reported symptom improvement, while 62 percent felt their symptoms were the same or worse than before treatment. Sixty-four percent of patients were still concerned about their symptoms. Patients who had been referred to a dietician outside of the specialist clinic, and who then undertook a low-FODMAP diet, had a higher rate of symptom improvement than those who were not referred (53% vs 31%,  $p=0.03$ ).

### **Nurse-led care**

Nursing models of care have been evaluated in specific FGIDs both as the sole form of care and as a complement to gastroenterologist care.

Iqbal and colleagues<sup>29</sup> described a specialised hospital clinic where patients with functional chronic constipation were managed by a nurse-led bowel training service in the context of a multi-disciplinary team. The bowel retraining service involved either a specialist nurse or physiotherapist administering a programme which included education, dietary advice, pelvic and abdominal muscle retraining, behavioural therapy relating to toileting, and psychological support. Advice was combined with tailored fibre and aperient supplementation plans tailored to each patient. Patients were seen for up to five sessions at six to eight weekly intervals. Data were collected prospectively. Sixty three percent of patients reported symptom improvement, as measured by the St Marks Satisfaction Scale and 40 percent achieved what was described as a clinically and statistically significant improvement (drop of  $>1$  from baseline) in the Patient Assessment of Constipation Quality of Life Questionnaire (PAC-QoL) scores. The mean PAC-QoL score changed from 2.4 to 1.4 ( $p=0.001$ ), where the score ranges between 0 (best) and 4 (worst). Patients who completed four or more sessions were more likely to report satisfaction at follow up.

Duelund-Jakobson et al<sup>30</sup> evaluated a similar model of care, where a nurse-led service was offered first-line to all patients referred with faecal incontinence. This nurse-led service included the use of “biofeedback”, with or without stool bulking agents, enemas and trans-anal irrigation. All patients who completed the treatment course achieved “satisfaction” with their status of continence on discharge and had a significant reduction in Wexner incontinence scores, from 9 to 4.9 ( $p < 0.001$ ). More than one year after discharge, 73% of patients remained “satisfied” with their symptoms. These positive results were achieved with a mean of one clinic appointment and one telephone follow-up.

Bengtsson et al<sup>31</sup> prospectively evaluated a nurse practitioner providing an assessment and management plan for patients with probable IBS. The Bengtsson study involved a randomised controlled prospective trial model where patients with probable IBS referred to the tertiary hospital were assessed and seen by a nurse practitioner prior to review by the gastroenterologist. Patients randomised to standard care saw the gastroenterologist at the initial appointment. No significant differences in GRSR scores were seen between the groups, however the sample size was small, possibly due to the large number of patients subsequently being diagnosed with a condition other than IBS.

### **Psychological services integrated into gastroenterology clinics**

Kinsinger et al<sup>32</sup> described a specialist clinic which included psychologists integrated into gastroenterological care, offering a range of psycho-therapeutic services. They prospectively collected data for their outpatient service. Nearly half (118 of 259 - 46%) of the patients referred to the psychologist attended. Demographic variables, such as age or gender, or gut condition did not predict attendance. Eighty-seven patients continued with psychological care after their first visit. Disease-specific quality of life surveys suggested the need to avoid foods, dysphoria and anxiety about health were patients’ greatest concerns. Care was predominantly gut-directed hypnotherapy (48%) and cognitive behavioural therapy (44%).

Patients with a functional gut disorder who attended the psychologist had significantly fewer medical procedures after clinic attendance than those who did not see a psychologist or have hypnotherapy. There was no difference in the number of physician office visits during and after these treatments compared to those who had not had these treatments.

Kruimel et al<sup>33</sup> described a prospectively studied cohort of patients with a complex FGID who failed standard treatments and were routinely referred to an integrated joint consultation with a psychiatrist and gastroenterologist. Of 137 referred patients 124 attended their appointment, with 72 completing questionnaires six months after the joint consultation. Of the 77 patients in their hospital catchment area who had access to psychological services, 70 were referred for medications, psychotherapy or both. The predominant medication used was citalopram. Seven patients received psychotherapy only. The commonest psychological therapy was individual psychotherapy with a psychiatrist. There were significant improvements in the 72 patients in psychological wellbeing at 6 and 12 months, as measured by the Hospital Anxiety and Depression Scale (HADS) and State Trait Anxiety Inventory (STAI-DY). There was a significant improvement in quality of life at 6 and 12 months as measured by SF-36, in both psychological and physical domain SF-36 sub-scores. Despite these observed improvements there were no significant reductions in gastrointestinal symptom scores at 12 months. The authors suggested that 80% of this patient population had a co-morbid psychological illness, and that the improvements in quality of life and psychological wellbeing related to the effective management of this psychological co-morbidity.

#### **Education to supplement standard specialist care**

Saito et al<sup>34</sup> prospectively evaluated a cohort of patients who were offered a comprehensive education programme to supplement their gastroenterological care, prior to their first visit with a gastroenterologist. This was compared to patients who did not attend an education

programme. The education programme consisted of a 3-hour session run by a nurse, with dietitians, physical therapists and psychologists discussing the physiology of irritable bowel syndrome as well as self-care aspects of management. There were no significant changes in pain (measured on a visual analogue scale) or quality of life (SF-36) when comparing patients who attended the class and those who did not. The authors concluded that patients who attended the education session were more likely to have overall symptom relief than patients who did not attend (29% vs 7% respectively).

## DISCUSSION

This review has identified that evaluation of the outcome of models of delivery of care for FGIDs is remarkably limited. The studies identified in this review were mainly retrospective; only one<sup>31</sup> was a prospective randomised controlled trial. Very few studies have evaluated standard gastroenterologist-only care, and very few have evaluated other modalities, or integrated diverse models, of care. Where they have been evaluated, gastroenterologist-only delivery of care appears to be of limited value for many patients. The incorporation of psychologically-based therapies or education appears to have been of greater value, but direct comparisons with standard care have not been undertaken. To our knowledge there have been little or no “disease” management programmes applied to FGIDs.

This contrasts with the widespread adoption of effective ‘disease management programmes’ in many other areas of medicine. These programmes aim to coordinate guideline-informed outpatient care for patients with chronic diseases<sup>35</sup>. Heart failure disease management programmes were evaluated in the 1990s and showed significant reductions in hospitalisations, readmission rates, quality of life and cost<sup>36</sup>. Similar programmes in diabetes<sup>37</sup>, chronic obstructive pulmonary disease (COPD) and cirrhosis care have shown similar improved outcomes<sup>38,39</sup>.

Chronic disease management programmes also address hospital readmissions and mortality, although these are not important issues for FGID's. In contrast, in FGID's key parameters are more likely to include symptom relief, patient well-being, patient satisfaction with care, and the volume of investigations and outpatient visits. Talley et al<sup>40</sup> described FGIDs as a public health problem, related to their high prevalence, health care cost (repetitive tests and frequent specialist visits), and patient morbidity. To adequately address this public health problem, innovative models of patient management need to be evaluated, measuring these parameters. Addressing this public health problem would also allow the evaluation of non-hospital and non-specialist care of FGIDs.

There have been many reports of the outcome of non-trial, consecutive patient cohorts receiving individual therapies in specialist settings. These include gut-focused hypnotherapy<sup>20</sup>, a low-FODMAP diet in irritable bowel syndrome<sup>41</sup>, and behavioural treatment ("biofeedback") for constipation<sup>19</sup> and faecal incontinence<sup>18</sup>. However, our systematic review identified only 8 studies in which models of care for all patients with a FGID, from referral, had been evaluated. Of these, several were retrospective or uncontrolled.

There are likely to be multiple factors that account for the lack of published data on outcomes of models of care. In the absence of accepted biomarkers for functional gut disorders, a clinical comparative evaluation of the outcome of care is difficult. New pharmacological studies are often prioritised for publication over non-pharmacological studies<sup>42</sup>. Negative or neutral evaluations of specialist gastroenterological services may also be less likely to be published<sup>43</sup>. The two reports in this review of standard gastroenterologist-only care revealed poor patient outcomes.

There is a wealth of individual study data attesting to the benefit of psychologically-based therapies for FGIDs. Given the high prevalence of psychological co-morbidity in FGID

patients<sup>3</sup>, it might be anticipated that psychological therapies will have an important therapeutic role in these conditions. Kruiemel et al<sup>33</sup> found greater psychological comorbidity in their FGIDs than had been appreciated previously by specialist clinicians. This under-appreciation of psychological co-morbidity in FGIDs has been reported previously<sup>44</sup> and is likely to be widespread. Kinsinger et al<sup>32</sup> showed that integration of psychological services into specialist care is achievable and acceptable to patients; the majority of patients completed four sessions with a psychologist.

Many components of care for FGID's, such as behaviourally-based therapies, can be provided by nurses. The nursing models of care included in this review appeared to provide satisfactory results for patients with FGID's. In the case series reported by Iqbal et al<sup>29</sup> and Duelund-Jakobson et al<sup>30</sup> nurses provided behavioural ("biofeedback") therapy, but in the context of a broader multi-disciplinary unit. Although neither of these studies had comparison cohorts, other randomised controlled trials for behaviourally-based treatment have shown superior outcomes compared to standard care<sup>16</sup>.

This review included only hospital-based clinical care. In a private clinic setting, however, Moore et al<sup>45</sup> examined a "nurse-specialist" led clinic within a private gastroenterologist practice for patients referred with the diagnosis of IBS. A significant reduction in the number, frequency and severity of symptoms was observed after three months. There was no control group in this report.

We suggest that it would be advantageous to co-locate allied health clinicians within hospital outpatient services, alongside gastroenterologists, as part of a multidisciplinary team. This team-based approach to delivery of care can potentially address the variety of syndromes that constitute FGIDs. Including psychology and psychiatry services in a gastroenterological setting may be therapeutically helpful, given that many patients lack insight into the psychological factors that may contribute to their symptoms, are concerned

by possible stigma of receiving separate psychological help, and may interpret referral to an “outside” psychological therapist as rejection (‘handballing’). Integration of psychological services into gastroenterology outpatient clinics may improve the acceptability of psychological therapy if it is presented as part of routine care<sup>46</sup>, but this remains to be tested and proven. Communication between referring the gastroenterologist and allied health professionals is also likely to be enhanced. Other elements which are likely to improve the quality of care include better patient education<sup>34</sup> and communication by treating gastroenterologists<sup>47</sup>. Improving the knowledge, communication and education of gastroenterologists in how they provide consultations for FGIDs is a further consideration that has not been examined in great detail.

In summary this review suggests that gastroenterologist-only clinics, typically with an investigational and pharmacological focus, do not often achieve positive clinical outcomes. More diverse approaches may produce better outcomes. Direct comparisons of these models of care are needed.

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## TABLES

**Table 1.** Criteria used for database searches.

1. Colon, irritable[MeSH Terms]
2. Irritable bowel syndrome[MeSH Terms])
3. Dyspepsia[MeSH Terms])
4. Fecal incontinence[MeSH Terms])
5. Constipation[MeSH Terms]
6. 1 OR 2 OR 3 OR 4 OR 5
7. Outcome Assessment (Health Care)"[Majr])
8. Ambulatory Care[Mesh]
9. Quality Assurance, Health Care[Mesh]
10. Follow-Up Studies[Mesh])
11. Treatment Outcome[Mesh])
12. Referral and Consultation[Mesh]

13. 7 OR 8 OR 9 OR 10 OR 11 OR 12

14. 6 AND 13

**Table 2:** Studies included in systematic review.

<b>AUTHORS</b>	<b>YEAR</b>	<b>COUNTRY</b>	<b>MODEL OF CARE</b>	<b>INTERVENTION</b>	<b>Type of FGID</b>	<b>TYPE OF STUDY</b>	<b>OUTCOMES</b>
Saito et al	2004	USA	Multi-disciplinary Education	Education class. Nurse, dietician, physical therapist and psychologist	IBS	Observational cohort	<ul style="list-style-type: none"> <li>• Bowel Disease Questionnaire</li> <li>• Pain Visual Analog Scale</li> <li>• SF36</li> <li>• Symptom Checklist 90R</li> </ul>
Bengtsson et al	2010	Sweden	Nursing planning and assessment	Nurse assessed and planned care prior	IBS	RCT	<ul style="list-style-type: none"> <li>• Gastrointestinal</li> </ul>

				to initial consultation with gastroenterologist			<p>Symptom Severity Scale</p> <ul style="list-style-type: none"> <li>• Psychological Well Being Index</li> </ul>
Canavan et al	2015	UK	Gastroenterology specialist outpatient clinic	Specialist hospital gastroenterology outpatient clinic	IBS	Prospective Observational Cohort	<ul style="list-style-type: none"> <li>• Euro-QoL 5D</li> </ul>
Duelund-Jakobson et al	2015	Denmark	Nurse-led clinic	Secondary hospital specialist nurse led clinic	Faecal Incontinence	Retrospective	<ul style="list-style-type: none"> <li>• Wexner Incontinence score</li> </ul>
Iqbal et al	2015	UK	Nurse-led clinic	Tertiary specialist hospital nurse led clinic	Chronic constipation	Retrospective	<ul style="list-style-type: none"> <li>• Patient assessment of constipation quality of life</li> <li>• St Marks Patient Satisfaction scale</li> </ul>

Kinsinger et al	2015	USA	Psychologist integrated into Gastroenterology outpatient clinic	Secondary clinic where psychologist within clinic referred patients by Gastroenterologists	IBS and Dyspepsia	Retrospective	<ul style="list-style-type: none"> <li>• Brief Symptom inventory</li> <li>• Irritable Bowel syndrome Quality of Life questionnaire</li> </ul>
Kruimel et al	2015	Netherlands	Joint Psychology and Gastroenterology clinic consultation	Secondary clinic where psychologist and gastroenterologist provided joint consultation	All FGID's	Prospective observational cohort	<ul style="list-style-type: none"> <li>• Gastrointestinal symptom rating scale</li> <li>• Cognitive scale for functional bowel disorders</li> <li>• Hospital anxiety and depression scale</li> <li>• SF-36</li> <li>• State trait anxiety inventory</li> </ul>

Basnayake et al	2018	Australia	Gastroenterology specialist outpatient clinic	Secondary hospital Gastroenterology outpatient clinic	All FGID's	Retrospective cohort	<ul style="list-style-type: none"><li>• Patient self-rating of symptoms</li></ul>
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## FIGURES

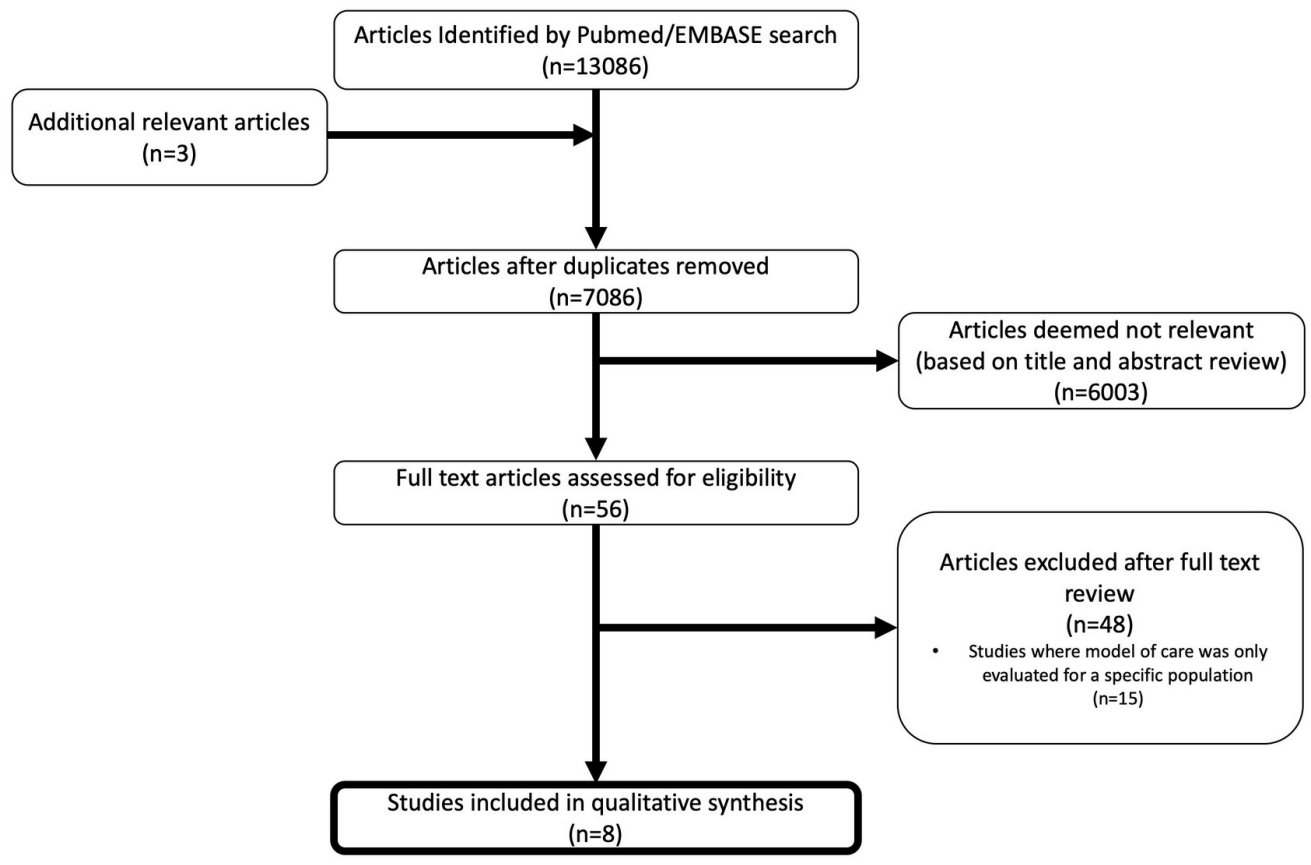
**Figure 1.** PRISMA Flow diagram for search on the delivery care for functional gastro intestinal disorders (FGIDs).

IDENTIFICATION

SCREENING

ELIGIBILITY

INCLUDED



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