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The potential of integrated nurse-led models to improve care for people with functional gastrointestinal disorders: A systematic review
Gastroenterology Nursing, 2020; 43(1):53-64

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This is a non-final version of an article published in final form in ***Gastroenterology Nursing, 2020; 43(1):53-64***

Final version available at: http://dx.doi.org/10.1097/SGA.0000000000000379

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Abstract

Functional gastrointestinal disorders (FGID) such as irritable bowel syndrome (IBS) and functional dyspepsia (FD) are extremely common, debilitating and costly. Although diagnostic guidelines and effective management options exist, management is sub-optimal, with long waiting lists, delayed diagnosis and poor patient outcomes. The aim of this systematic review was to explore and evaluate evidence for existing models of care for functional gastrointestinal disorders. 38 studies pertaining to the diagnosis or management of FGIDs were found, however only 6 investigated a full model of care. Five studies assessed a nurse-led model and one a structured gastroenterologist consultation. Nurse-led models were cheaper to current treatments, and resulted in symptomatic improvement, high patient satisfaction, reduced healthcare usage, and improved psychosocial functioning and quality of life, whilst standard gastroenterological care did not improve pain or quality of life. There is minimal research trialling integrated models of care for the diagnosis and management of functional gastrointestinal disorders. This represents a lost opportunity for timely, effective, healthcare provision to a large patient group. Although low in quality, preliminary data suggest that integrated nurse-led models of care are economically viable and may facilitate timely diagnosis and management, and improve patient outcomes. Further, studies to robustly evaluate the efficacy, safety and acceptability of such models are needed.

INTRODUCTION

Functional gastrointestinal disorders (FGIDs) are common (Chang, Lu, & Chen, 2010; Mountifield, 2010), chronic and complex, with biopsychosocial triggers, shifting symptomatology over time (Halder et al., 2007) and the frequent presence of other unexplained, somatic complaints (Spiegel, Kanwal, Naliboff, & Mayer, 2005). The most common FGIDs are irritable bowel syndrome (IBS) which affects approximately 10% of the population globally (Hulisz, 2004; Talley, 2008a) and functional dyspepsia (FD) with a prevalence of 15% worldwide (El-Serag & Talley, 2004; Talley, 2008a). Symptoms of FGID significantly impair daily life, lead to high healthcare use and costs (Ålander, Svärdsudd, & Agréus, 2008; Kodner & Spreeuwenberg, 2002; Levy et al., 2001b; Longstreth et al., 2003; Talley, Gabriel, Harmsen, Zinsmeister, & Evans, 1995) overuse of investigations (E. C. Linedale, Chur-Hansen, Mikocka-Walus, Gibson, & Andrews, 2016b) and high levels of absenteeism and presenteeism (Talley, 2008b). Although FGIDs are common and significantly impact both the patient and community, they are poorly handled in the healthcare system creating frustration in patients and doctors alike (Knott, Holtmann, Turnbull, & Andrews, 2009).

Recent developments of reliable, accepted diagnostic criteria (Lacy et al., 2016; Stanghellini et al., 2016) and effective evidence-based management options for FGIDs (Enck, Junne, Klosterhalfen, Zipfel, & Martens, 2010; Peters, Muir, & Gibson, 2015) do not appear to have been incorporated into current routine practice. Many primary healthcare providers lack confidence and continue to refer for specialist input (E. Linedale, Mikocka-Walus, Gibson, & Andrews, 2016; Mitchell & Drossman, 1987; Shivaji & Ford, 2014), with capacity restraints resulting in extraordinarily long wait lists. The delay in diagnosis and implementation of effective management options represents a lost opportunity to improve

symptoms, quality of life and workplace productivity, and reduce unnecessary societal expenditure on repeat consultation, unnecessary investigations, and ineffective treatments (Mearin & Lacy, 2012).

Given the chronic nature of FGIDs and the clear interplay of biological, psychological and social factors in triggering symptoms (Douglas A. Drossman, 2016), an integrated model of care (IMoC) is needed. Integrated models of care (IMoC) have been successfully established in other chronic illnesses such as diabetes (*General practice management of type 2 diabetes – 2014–15. Melbourne:* , 2014) and asthma (*Department of Health, Western Australia. Asthma Model of Care. Perth*, 2012), yet have received little attention in FGID.

A model of care is a multidimensional concept that defines the way in which healthcare services are delivered (Queensland Health, 2004). There are several elements of effective care of FGID patients which could be addressed in an IMoC. The provision of a clear diagnosis and patient acceptance of this diagnosis are critical to the successful management of patients with FGIDs. Research has shown that both patient acceptance of functional diagnoses and diagnostic communication from the physician are poor (J. Collins, Farrall, E., Turnbull, D.A., Hetzel, D.J., Holtmann, G., and Andrews, J.M., 2009; Ilnyckyj, Graff, Blanchard, & Bernstein, 2003; E. C. Linedale, Chur-Hansen, Mikocka-Walus, Gibson, & Andrews, 2016a) . Thus, a model of care incorporating the first point of patient contact with the medical system is likely to greatly improve patient outcomes and reduce costs. Other important elements of such a model include diagnostic criteria and the coordinated use of newer treatments with proven efficacy for global symptom relief, including cognitive behavioural therapy, gut-directed hypnotherapy and the low FODMAP diet (Enck et al., 2010; Peters et al., 2015).

Although there are many recommendations as to how FGID should be diagnosed and managed (American College of Gastroenterology Task Force on Irritable Bowel et al., 2009; Astegiano et al., 2008; NICE, 2016), few designs have been tested to date. To inform the development of an IMoC for FGIDs we undertook a systematic review of existing models that have been tested for FGIDs.

METHODS

Types of Studies

The protocol for this quantitative systematic review was registered at PROSPERO International prospective register of systematic reviews 15/01/2016 (PROSPERO 2016:CRD42016033146) and the search conducted in January 2016. No new publications were identified in Jan-Dec 2016.

Inclusion criteria

Primary studies concerning the diagnosis and management of FGID, irritable bowel syndrome (IBS) or functional dyspepsia (diagnosed in primary, secondary or tertiary care) were included. Studies of any quantitative research design published 1995-2016 and reporting patient related outcomes (i.e. quality of life, symptom severity) in an adult population were included. Both full text and abstracts were included.

Exclusion criteria

Studies regarding patients with organic disease, or functional abdominal pain were excluded, as were reviews, opinion pieces, dissertations, or secondary analyses. Qualitative studies, and those reporting cost or health-care use alone were excluded, as were studies trialling a treatment.

Search methodology

Sources

Databases searched were PubMed, Medline, Embase, Web of Science, Cochrane, CINAHL, PsychInfo the ISCRTN registry. Reference lists of all included studies were also searched, experts in the field were contacted to identify additional references, and authors contacted for further information as required.

Search strategy

The search strategy covered three main concepts: functional gastrointestinal disorders, models and care, as indicated in Table 1.

Study selection

A systematic review was conducted according to the 5 steps outlined by Khan, Kunz, Kleijnen, and Antes (2003). The framing question was ‘what models of care have been evaluated for functional gastrointestinal disorders’. In the first phase, titles and abstracts of the search results were screened by the primary researcher (EL) to assess suitability for inclusion. Studies whose suitability was uncertain were also screened by the second reviewer (AMW) and consensus reached on inclusion. Where uncertainty regarding inclusion or disagreement occurred, a third researcher (JMA) was consulted and a joint decision regarding selection was reached. In the second phase, full papers deemed suitable from the initial search were screened by both reviewers (EL, AMW) and checked against a pre-designed relevance checking proforma based on the inclusion/exclusion criteria.

Data extraction

Data including author, year of publication, country of origin, design, model of care, sample size and characteristics, disease type (for example, FGID, irritable bowel syndrome, functional dyspepsia), outcomes measured and results, were extracted by the primary researcher (EL), using a customised extraction table. Extracted data was checked against the original articles by the second reviewer (AMW).

Data synthesis

Due to the limited number of available studies, and heterogeneity in study design and outcomes measured, we provided a narrative synthesis of the findings regarding full models of care (including both diagnosis and management). Studies pertaining to components of a model (such as diagnosis, patient education, or management) were summarised in Figure 1, but not synthesised.

Assessment of quality and risk of bias

Quality assessment of the 7 included studies was conducted (Supplementary Table A) using the Quality Assessment Tool for Quantitative Studies (Effective Public Health Practice Project) (Project, 2007) as recommended by the Cochrane group ("Cochrane Handbook for Systematic Reviews of Interventions "). This scale allows all quantitative study designs to be assessed with one tool. Studies were assessed in 6 domains: selection bias, study design, confounders, blinding, data collection methods, withdrawal and dropouts, intervention integrity and analyses and scored according to the rules (Project, 2007). An overall global rating was given based on the number of weak domain ratings (strong=no weak ratings, moderate=1 weak rating, weak=2 or more weak ratings). Studies were appraised independently by EL and AMW, and an overall rating reached by consensus. All studies regardless of quality rating were included in this review due to the scarcity of research found.

RESULTS

Search results

Out of the 95 full text articles identified, 57 were excluded (Figure 1) for reasons that included: non-primary research (n=14), treatment trial (n=10), duplicate abstract, protocol or secondary analysis of full-text article already included (n=15), not pertaining to FGID (n=4), or IMoC (n=6), assessed outcomes not in inclusion criteria (n=7), data unpublished (n=1). Of the 38 unique primary research studies that pertained to diagnosis or management of FGIDs (Figure 1), only 6 were deemed suitable for inclusion as a full IMoC, including both a diagnostic and management component. A summary of the studies that considered only one of these components of care (i.e. diagnosis OR management) is presented in Supplementary Table B. An overview of these studies is included, as the examined components may be relevant to inform the development of a full IMoC for FGID (Figure 2). A review of individual components is outside the scope of this review.

Nature of studies

Included studies were all low in quality (Table 2). Two studies were published in abstract form only, and full data were unable to be analysed (Buresi et al., 2014; Novak et al., 2014), and one described subjective changes in patient outcomes without reference to baseline or statistical analysis (Dill & Dill, 1995). One study was a randomised controlled trial (Bengtsson, Ulander, Borgdal, & Ohlsson, 2010), 3 observational (Dill & Dill, 1995; Ilnyckyj et al., 2003; Moore, Gagan, & Perry, 2014) and 2 non-randomised controlled designs (Buresi et al., 2014; Novak et al., 2014). Four studies evaluated IBS IMoCs in Sweden (Bengtsson et al., 2010), USA (Dill & Dill, 1995), Canada (Ilnyckyj et al., 2003) and New Zealand (Moore et al., 2014), and 2 studies, in abstract form only, evaluated IMoCs for functional dyspepsia

in Canada (Buresi et al., 2014; Novak et al., 2014). No studies presented an IMoC for FGIDs in general. Due to the small number, studies regarding irritable bowel syndrome and functional dyspepsia are not discussed separately. Five articles assessed some form of a nurse-led care model (Bengtsson et al., 2010; Buresi et al., 2014; Dill & Dill, 1995; Moore et al., 2014; Novak et al., 2014), and one evaluated the performance of a structured gastroenterologist consultation (13).

Summary of full models of care

Nurse-led models

Five studies evaluated a nurse-led model (Bengtsson et al., 2010; Buresi et al., 2014; Dill & Dill, 1995; Moore et al., 2014; Novak et al., 2014). These models differed in the setting, role and timing of nurse management. Roles included the provision of active triage and patient education prior to a consult with a gastroenterologist (Bengtsson et al., 2010; Novak et al., 2014), ongoing holistic management post-diagnosis (Dill & Dill, 1995), screening and treatment trials prior to gastroenterologist consultation (Buresi et al., 2014) and independent nurse diagnosis and management (Moore et al., 2014). Full description of the models and findings are presented in Table 2.

Four of the 5 nurse-led studies measured symptom severity and patient satisfaction. Symptomatic improvement was seen in all (Bengtsson et al., 2010; Dill & Dill, 1995; Moore et al., 2014; Novak et al., 2014). One study reported subjective improvement following the intervention (no baseline comparator) (Dill & Dill, 1995), 2 compared to baseline at 3 (Moore et al., 2014) and 6 months (Novak et al., 2014) follow-up, and 1 compared to control group (mean GOS change -0.6±0.1, $p<0.001$) (Bengtsson et al., 2010). Patient satisfaction was high (Dill & Dill, 1995; Novak et al., 2014) or improved compared to baseline (Moore et al.,

2014), with the exception of the model reported by Bengtsson et al. (2010) where the nurse's role was to implement a care plan prior to consultation with a gastroenterologist. Two studies evaluated healthcare utilisation and showed reduced gastroenterologist visits compared with treatment as usual controls (Bengtsson et al., 2010), and reduced doctor visits following the intervention (Dill & Dill, 1995). Psychosocial health was measured in various forms in 4 studies with overall improvement found in all (Buresi et al., 2014; Dill & Dill, 1995; Moore et al., 2014) except that reported by Bengtsson et al. (2010). Studies that assessed quality of life (Buresi et al., 2014; Moore et al., 2014) and psychosocial functioning (Dill & Dill, 1995) showed improvement, but Moore et al. (2014) found no simultaneous improvement in coping strategies. The cost of a nurse-led model was assessed in two studies and found to be significantly reduced compared to current treatments (Buresi et al., 2014; Dill & Dill, 1995).

Structured gastroenterologist care

Only 1 observational cohort study investigated the value of a structured gastroenterologist consultation (Ilnyckyj et al., 2003). The consultation included establishing a positive diagnosis, investigations as indicated, education and reassurance, and psychological referrals as appropriate. Ambulatory gastroenterology visits returned to and remained at baseline levels for 2 years' post-consultation. However, other ambulatory and psychiatric healthcare utilisation remained unchanged. In addition, quality of life and pain also remained unchanged at 1-year follow up, although a reduction in pain was seen at the 2-year mark.

DISCUSSION

This systematic review demonstrates that, despite FGIDs being highly prevalent, there is a paucity of data examining IMoC for FGIDs. This represents a lost opportunity for effective and efficient provision of care to this large patient group, which can be ill-afforded considering the need for cost constraint and optimal outcomes in healthcare systems worldwide. While a number of studies relate to the management of FGIDs, there is minimal research into IMoC which incorporate both diagnosis and management. This review considers IBS and FD together, as they often co-occur and thus are best treated as one clinical group. Many patients with IBS will subsequently have FD and visa-versa. In general, our healthcare systems function more efficiently when related conditions affecting one large patient group receive a similar (but not rigidly identical) approach. The current approaches to the diagnosis and management for IBS and FD are very similar; namely exclude alarms, offer reassurance, explanation, and recommend lifestyle changes, psychological and/or dietary therapies and medication when needed.

FGIDs are significant and growing public health problem (Talley, 2008b), with up to 40% of the population affected within their lifetime (2), and referrals representing up to 50% of gastroenterology workload (Mitchell & Drossman, 1987; Shivaji & Ford, 2014). There is a high economic cost of FGIDs, with an estimated annual cost of 41 billion dollars (US) for IBS alone, in the UK, Japan, Australia, Sweden, Germany, France, and Canada in 2000 (Fullerton, 1998). These costs are driven by persistent and/or unmanaged symptoms, unnecessary investigations, repeated healthcare visits and workplace impairment (Fortea & Prior, 2013; Talley, 2008a), and represent a significant opportunity for improved healthcare service delivery.

Dill and Dill (1995) describe the first nurse-led IBS model and its effectiveness in a single private practice in the USA in 1995. This study provides preliminary evidence to suggest the economic and clinical benefit of a nurse-led IMoC. Surprisingly, further assessment of this model did not occur for another 25 years. However, recent studies show benefits of integrated nurse-led models on symptoms, psychosocial well-being and quality of life (Buresi et al., 2014; Dill & Dill, 1995; Moore et al., 2014; Novak et al., 2014). In addition, nurse-led clinics were more cost-effective and may enable a larger volume of patients to be seen in specialist care. The use of a nurse to screen referrals and implement treatment trials in patients with no alarm features was effective, both independently of gastroenterology consultation (Moore et al., 2014) and in conjunction with specialist review (Buresi et al., 2014; Dill & Dill, 1995; Novak et al., 2014). The only ineffective nurse-led model was dependent upon an accurate primary care diagnosis (which was found to be lacking), giving further credence to the importance of including diagnosis in a model of care. Traditional gastroenterological care was assessed in only 1 study and was not effective in reducing symptoms, or improving quality of life. However, this study was not controlled, and the approach to diagnosis and management was not standardised.

Although these studies differed in the clinicians used and the role they played, several common features were apparent. All models included a standardised diagnostic pathway, provided patient education and reassurance, and focussed on enabling the patient to self-manage their condition. The nurse-led models also provided continuing review, support and co-ordination of care.

The overall quality of included studies is low, with most having design, sampling, or reporting limitations. All studies used convenience samples of referred patients, and most

study designs were observational or non-randomised control designs. In addition, all studies assessed either functional dyspepsia or irritable bowel syndrome, not a model of care for all FGIDs, and the long-term effect of these models was not assessed. Despite the low quality of evidence, these studies do provide preliminary evidence for the potential effectiveness of nurse-led, integrated models of care in FGID, and further larger scale, high quality trials are warranted.

The lack of research (and interest) in models of care for FGID to date, is most likely influenced by a poor understanding of the mechanism for pathogenesis in FGIDs, lack of diagnostic tests and uniformly effective management options, as well as differences between and changes within healthcare systems worldwide (Agréus, 2002; Levy et al., 2001a). However, with recent advances in the development of positive diagnostic criteria and effective global symptom management strategies, it is now possible to develop a model of care which can be implemented in virtually any developed country.

This review specifically targeted only those studies pertaining to an integrated approach to the diagnosis and management of FGIDs. The process of diagnosis is a critical component to the model of care. Many clinicians consider a functional diagnosis, but are reluctant to communicate this to the patient (Mearin & Lacy, 2012) or to document it (Harkness, Grant, O'Brien, Chew-Graham, & Thompson, 2013), and many patients are reluctant to accept a functional diagnosis (J. Collins et al., 2009). However, a timely, clear, accurate diagnosis is critical in FGIDs, as it provides reassurance, alleviates patients' concerns and helps move the patient from a diagnostic search to an effective management strategy [35, 42].

Recommendations

Despite the shortcomings in our understanding, we do have a useful biopsychosocial model (implicating psychological state, increased motor reactivity, visceral hypersensitivity, changes in mucosal immune/inflammatory function and altered enteric nervous system) (D. A. Drossman, 2006), diagnostic guidelines (NICE, 2016) and effective dietary/psychological treatment options (De Giorgio, Volta, & Gibson, 2016; Peters et al., 2015). Although guidelines recommend a biopsychosocial approach to the management of FGIDs, little direction is given on how (*Irritable Bowel Syndrome IBS*, 2003; Lacy et al., 2016; NICE, 2016; Quigley et al., 2016). The Rome IV criteria recommend a tiered approach to the management of FGIDs according to symptom severity (Lacy et al., 2016). Current recommendations from the National Institute for Health and Clinical Excellence (NICE) are that FGIDs are diagnosed in primary care based on characteristic symptoms without alarms, with the judicious use of investigations (Dalrymple & Bullock, 2008). Referral for psychological interventions are recommended if no symptom improvement after 12 months' treatment with lifestyle modification and symptom based pharmacotherapy. The development of a standard IMoC that incorporates both a diagnostic and evidence-based management pathway is the next step forward in improving patient care for FGIDs. Key components of such a model, include the provision of a timely, clear diagnosis, patient education, empowerment, care co-ordination, multi-disciplinary teams, and individual care plans (Carter, Chalouhi, McKenna, & Richardson, 2011).

Future Directions

This review highlights the paucity of research into the development and assessment of integrated models of care for FGIDs. However, the preliminary evidence indicates a role for nurse-led models of care in FGIDs. Future studies should be large, randomised controlled

trials, comparing standard gastroenterological care with integrated models, with both patient outcomes and cost evaluated. Detailed descriptions of the content of both the diagnostic and management arms of the model of care are also needed to evaluate whether components of IMoC are evidence-based, and effective. Furthermore, evidence of the standardisation of the IMoC within the trial is also necessary to ensure accuracy of the findings.

In conclusion, there is minimal research to date trialling models of care which incorporate a standardised approach to diagnosis as well as evidence-based management. Furthermore, no studies have assessed FGIDs in general, but restricted to either functional dyspepsia or irritable bowel syndrome. Existing research on full models of care is of low quality, with most pertaining to nurse models of care. However, these preliminary data suggest that models of care that incorporate protocol driven assessment and diagnosis, in conjunction with ongoing holistic care are economically viable, can be delivered by nurses, and may facilitate timely diagnosis and management, and improve patient outcomes.

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