

Exploring psychological factors and quality of life in individuals living with gastroparesis and the development of a brief online psychological support program.

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Submitted in fulfillment of the requirements for the degree of
Doctor of Philosophy (PhD)

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2018

Abstract

Gastroparesis is a neurogastroenterological disorder involving delayed gastric emptying in the absence of a mechanical obstruction of the stomach. The symptoms of gastroparesis typically include nausea, vomiting, early satiety, and postprandial fullness, with some individuals also reporting abdominal pain and fatigue (Cherian, Paladugu, Pathikonda, & Parkman, 2012; Cherian & Parkman, 2012; Dudekula, O'Connell, & Bielefeldt, 2011; Soykan, Sivri, Sarosiek, Kiernan, & McCallum, 1998; Tang & Friedenber, 2011). Individuals with gastroparesis may also experience psychological distress and poor quality of life (QoL), leading researchers to argue that psychologically-oriented support interventions are warranted (e.g., Abell et al., 2006; Bennell & Taylor, 2013; Bielefeldt, Raza, & Zickmund, 2009). However, to date, a systematic review of the literature addressing psychological factors and QoL in gastroparesis cohorts has not been conducted, and understanding of the psychological processes that may influence outcomes in gastroparesis is limited. Correspondingly, there is also a lack of theoretically derived psychological support programs designed to assist individuals living with gastroparesis in managing the physical and psychological impact of the condition. Guided by the Common Sense Model (CSM; Leventhal, Nerenz, & Steele, 1984), this PhD research sought to explore psychological factors and QoL in individuals living with gastroparesis, with the aim of developing an online psychological support program.

The PhD research project comprised of four studies: *(1) A systematic review of 16 studies assessing either prevalence of psychopathology, level of psychological distress and/or QoL, or psychological intervention in an adult gastroparesis cohort.* Common findings, limitations, and recommendations for future research are discussed. *(2) A qualitative exploration of the psychosocial impact of gastroparesis, with a focus on the strategies individuals use to cope with the illness.* Ten females with gastroparesis were interviewed (mean age: 40.2 years; mean duration of gastroparesis symptoms: 79.32 months) with three key themes being identified: frustration, identity, and coping and adaptation. *(3) A quantitative exploration of the psychosocial impact of gastroparesis and the potential psychological mediators*

of change guided by the CSM. One hundred and seventy-nine adults with gastroparesis (165 females; mean age: 41.82 years; mean duration of gastroparesis symptoms: 49.20 months) completed an online questionnaire assessing gastroparesis symptom severity, illness perceptions, coping styles, psychological distress, and QoL. Structural Equation Modeling (SEM) revealed the mediating roles of illness perceptions and maladaptive coping styles in psychosocial outcomes for individuals with gastroparesis. (4) *A pilot feasibility study of an online 6-week psychological intervention program targeted to address gastroparesis-related psychological distress.* Six female gastroparesis sufferers (mean age: 45.83 years; mean duration of gastroparesis symptoms: 42.84 months) completed pre- and post-intervention assessment questionnaires, with results providing valuable feedback about the program and indicating improvement in some psychological processes at post-intervention compared to baseline.

This PhD research significantly contributed to the scientific knowledge base on gastroparesis by addressing several key limitations within the literature. Specifically, the research generated improved understanding of the relationships between gastroparesis, psychological factors, and QoL through a systematic review of the literature. Using both qualitative and quantitative approaches, the research also identified psychological processes that can influence health outcomes in gastroparesis. Additionally, the research conducted the first evaluation of the CSM in a gastroparesis cohort, as well as developing and pilot testing an online psychological intervention for individuals with gastroparesis. Overall, the research demonstrates the significant psychosocial impact of gastroparesis, as well as the important role of psychological processes in health outcomes for individuals with gastroparesis, and provides preliminary evidence for the feasibility of an online psychological intervention program to help support individuals living with gastroparesis.

Acknowledgements

I have great appreciation for the countless individuals who offered their support and encouragement throughout my PhD candidature. The following deserve a special acknowledgement.

To all those who participated in my studies, thank you for sharing your experiences with me and for reminding me of the importance of this research.

To my primary supervisor, Dr Simon Knowles, your expertise, commitment to the project, and relentless enthusiasm for research have been invaluable. I can't thank you enough for all of the support and reassurance you have given me throughout this PhD.

To my secondary supervisor, Professor Geoff Hebbard, your guidance and wealth of experience were integral to this project. Thank you for your insight, and for the incredibly high level of care you show your patients.

Finally, to George and my family, thank you for tolerating me, distracting me, and never letting me take anything too seriously.

Declaration

I declare that this report contains no material which has been accepted for the award of any other degree or diploma, except where due reference is made in the text. To the best of my knowledge, this examinable outcome contains no material previously published or written by another person except where due reference is made in the text. Where the work is based on joint research or publications, the relative contributions of the respective workers or authors is disclosed in the text.

I further declare that the ethical principles and procedures specified in the Swinburne Human Research Ethics Committee document have been adhered to in the preparation of this dissertation.



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We hereby declare our contribution to the publication of the 'paper' entitled: Exploring symptom severity, illness perceptions, coping styles, and well-being in gastroparesis patients using the common sense model.

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List of Papers Included in the Thesis

- Woodhouse, S., Hebbard, G., & Knowles, S. R. (2017). Psychological controversies in gastroparesis: A systematic review. *World Journal of Gastroenterology*, 23(7), 1298–1309.
<http://doi.org/10.3748/wjg.v23.i7.1298>
- Woodhouse, S., Hebbard, G., & Knowles, S. R. (2017). Exploration of the psychosocial issues associated with gastroparesis: A qualitative investigation. *Journal of Clinical Nursing*, 26(21-22), 3553-3563.
<http://doi.org/10.1111/jocn.13725>
- Woodhouse, S., Hebbard, G. & Knowles, S.R. (2018). Exploring symptom severity, illness perceptions, coping styles, and well-being in gastroparesis patients using the common sense model. *Digestive Diseases and Sciences*, 63(4), 958-965. <https://doi.org/10.1007/s10620-018-4975-x>

Gastroparesis is a neurogastroenterological disorder involving delayed gastric emptying in the absence of a mechanical obstruction of the stomach (Tack, 2005). Typical gastroparesis symptoms include chronic nausea, vomiting, early satiety, postprandial fullness, and in some cases abdominal pain and fatigue (Cherian et al., 2012; Cherian & Parkman, 2012; Dudekula et al., 2011; Soykan et al., 1998; Tang & Friedenber, 2011). The disease burden of gastroparesis has been likened to that of inflammatory bowel disease (IBD) (Jung et al., 2009), with gastroparesis sufferers being hospitalised more than once per year for approximately eight days, on average (Dudekula et al., 2011). The prevalence of gastroparesis is currently unknown in Australia, however in 2006 the Australian government provided a conservative estimate that 120,000 Australians suffered from severe gastroparesis (Department of Health and Ageing, 2006).

Current treatment options for gastroparesis are limited and in many cases lack efficacy. Gastroparesis sufferers are often found to be nutritionally deficient (Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Calles, et al., 2011) and are frequently hospitalised for the placement of feeding tubes in order to maintain adequate hydration, nutrition, and medication delivery (Parkman, Hasler, & Fisher, 2004). Not surprisingly, gastroparesis has been associated with psychological distress and poor quality of life (QoL) (Bielefeldt et al., 2009; Harrell et al., 2008; Jaffe, Paladugu, Gaughan, & Parkman, 2011; Jung et al., 2009; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011; Soykan et al., 1998; Yu et al., 2017), and a repeated recommendation in the literature has been the exploration of psychological support or intervention for the cohort (Abell et al., 2006; Bennell & Taylor, 2013; Bielefeldt et al., 2009). However, the psychological processes that mediate the relationship between gastroparesis and psychosocial outcomes have not yet been identified, making it difficult to develop an intervention that is targeted to the needs of individuals living with gastroparesis.

The following research will build on current gastroparesis knowledge by exploring the psychosocial outcomes associated with gastroparesis, with a focus on the psychological mediators of change. The introductory chapter will define gastroparesis, review the known relationships between psychological distress and gastroparesis, investigate the impact of the condition on QoL, and examine the use of psychological treatments in gastroparesis. The chapter will also consider

potential psychological mediators of change and the Common Sense Model (CSM) (Leventhal et al., 1984) - a health psychology model which promises insight into the relationship between gastroparesis symptoms and illness outcomes. Due to the shortage of research investigating relationships between gastroparesis and psychosocial factors, the literature review will draw considerably on areas of gastrointestinal (GI) research where psychosocial correlates have been more widely explored. In particular, the review will evaluate findings relating to IBD, irritable bowel syndrome (IBS), and functional dyspepsia (FD) in order to assist in understanding the possible relationships between gastroparesis and psychosocial factors.

Following the introduction, three peer-reviewed published papers will be presented which document the research undertaken as part of this PhD program.

The papers include:

1. A systematic review of literature exploring the psychosocial factors associated with gastroparesis
2. A qualitative study investigating the psychosocial impact of gastroparesis and how individuals cope with the illness
3. A quantitative study guided by the CSM which explores the psychosocial impact of gastroparesis and the potential psychological mediators of change

In Chapter 5, a pilot feasibility study of an online psychological intervention program designed to target gastroparesis-related psychological distress is presented. The results of the pilot feasibility study were presented as a poster at the NeuroGASTRO 2017 conference (24-26th August, 2017).

Finally, in Chapter 6, a general overview and integration of the PhD research is provided. Limitations and implications of the research will be considered.

Chapter 1: Introduction

1.1 Overview

1.1.1 The GI tract

The digestive system consists of a hollow, muscular tube called the GI tract, and accessory organs such as the liver and pancreas. The GI tract begins at the mouth, and continues through to the pharynx, oesophagus, stomach, small intestine, and large intestine, ending at the anus (see Figure 1). The main digestive functions of the GI tract are to mechanically process food so that it can pass through the tract, chemically breakdown food, absorb nutrients, and excrete waste products (Martini, 2001). In addition to these duties, the tract also plays an important role in synthesising vitamins and maintaining immunity (Kau, Ahern, Griffin, Goodman, & Gordon, 2011).

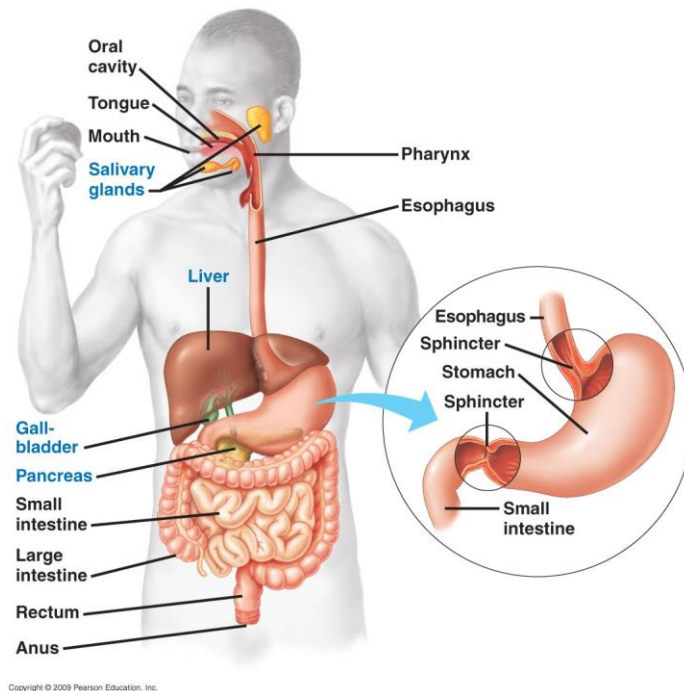


Figure 1. The digestive system, with accessory organs in blue text (StomachPics, 2014).

1.1.2 GI disorders and psychosocial outcomes

The health of the GI tract is integral to physical wellbeing, and also influences many psychosocial aspects of life. Individuals living with chronic GI disorders are likely to experience unpredictable and uncontrollable symptom episodes that disrupt their normal work, school, and social activities (Toner et al., 2006). In addition, individuals may encounter stigma and misunderstanding associated with having an illness that can be both embarrassing to talk about and invisible to others. Individuals may also lack hope for the future, as many of the most common GI disorders have no known cure, and treatments that focus on symptom reduction are often only minimally effective (Toner et al., 2006). An expanding base of evidence indicates that individuals with chronic GI disorders are more likely to experience decreased QoL, and a higher level of comorbid psychological symptoms compared to healthy individuals (Creed et al., 2006; Fullwood & Drossman, 1995; Shah, Rezaie, Riddle, & Pimentel, 2014)

While research into the relationship between GI disorders and psychological symptoms is growing, one area that deserves further attention is gastric motility disorders. In gastric motility disorders, the muscular contractions of the GI tract are compromised and, as a result, food is not propelled through the tract at the appropriate rate. This impaired muscular control can result in problems with gastric motility, accommodation, or emptying. Gastric motility disorders include gastroparesis, FD, and dumping syndrome (Tack, 2005). While each of these disorders would benefit from further investigation, this PhD research will focus on gastroparesis.

1.1.3 What is gastroparesis?

Gastroparesis has been referred to as “undoubtedly one of the most frustrating disorders in gastroenterology” (Falk, 2015, p. 1). Gastroparesis involves delayed gastric emptying in the absence of a mechanical obstruction of the stomach (Tack, 2005). Women are more likely to experience gastroparesis than men, with reports of between 67-88% of gastroparesis cohorts being female, with a mean age ranging between 40-45.5 years (Bielefeldt et al., 2009; Borges, Secaf, & Troncon, 2013; Cherian, Sachdeva, Fisher, & Parkman, 2010; Dudekula et al., 2011; Hasler et al., 2010; Karamanolis, Caenepeel, Arts, & Tack, 2007; Parkman, Yates,

Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011; Soykan et al., 1998). Symptoms generally include nausea, vomiting, early satiety, and postprandial fullness, but individuals may also complain of abdominal pain and fatigue (Cherian et al., 2012; Cherian & Parkman, 2012; Dudekula et al., 2011; Soykan et al., 1998; Tang & Friedenber, 2011). Since these symptoms are associated with a range of GI disorders, a test of gastric emptying must be performed to identify gastroparesis.

The main aetiologies of gastroparesis are idiopathic (35.6%), diabetic (28.8%), and post-surgical (13.0%) (Soykan et al., 1998). Other known causes include medication, virus-induced, neurological conditions (e.g., Parkinson's disease), connective tissue disorders, and intestinal pseudoobstruction (Jung et al., 2009; Yu et al., 2017). Symptoms tend to be similar across different aetiologies, however some differences have been found. For example, reports of vomiting have been more frequent in diabetic gastroparesis than idiopathic gastroparesis (Cherian & Parkman, 2012), while reports of abdominal pain are higher for those with an idiopathic aetiology (Cherian et al., 2010; Hasler et al., 2013). Unless otherwise specified, this thesis will use the term "gastroparesis" to refer to all aetiologies and considers them as a single disorder.

The symptoms of gastroparesis can be very debilitating for sufferers, impacting upon nearly every aspect of life. Individuals have reported that the nausea, discomfort, and pain associated with gastroparesis often interfere with their ability to work, socialise, and maintain normal eating patterns (Bennell & Taylor, 2013; Bielefeldt et al., 2009). It is not surprising then, that gastroparesis has also been associated with higher levels of psychological distress and decreased QoL (Bennell & Taylor, 2013; Cherian et al., 2012; Cherian & Parkman, 2012; Hasler et al., 2010; Hasler et al., 2013; Hasler et al., 2011; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Calles, et al., 2011; Pasricha et al., 2011; Soykan et al., 1998).

1.1.4 Prevalence and cost of gastroparesis

The prevalence of gastroparesis is difficult to ascertain for a number of reasons. Firstly, gastroparesis is not a condition that can be diagnosed by the administration of a questionnaire alone, which makes it challenging to attain

numbers across large groups (Moshiree, Bollipo, Horowitz, & Talley, 2012). The diagnostic testing that is required to determine gastroparesis (i.e., gastric emptying scintigraphy) is also not widely available (Rey et al., 2012), and over the years there has been a lack of consistency in the administration of the test and in the way that data has been reported (Abell et al., 2008). Finally, consideration should be given to the possibility that many individuals with gastroparesis may go unnoticed as a result of not receiving appropriate medical attention for the condition (Bielefeldt, 2012; Jung et al., 2009). For these reasons, it has been suggested that those who have been clinically diagnosed with gastroparesis may represent just the tip of the iceberg (Rey et al., 2012).

In Australia, the prevalence of gastroparesis is unknown, however in 2006 the Australian government provided an estimate that 120,000 Australians suffered from severe gastroparesis (Department of Health and Ageing, 2006). The only study to investigate the prevalence of gastroparesis was conducted in Minnesota (USA) using medical records from 1996 to 2006. Jung et al. (2009) found that after adjusting for age and gender (to 2000 US Caucasians), the incidence of definite gastroparesis per 100,000 person years was 9.8 in women, and 2.4 in men. In individuals over the age of 60 years, the incidence peaked at 10.5 per 100,000. In acknowledgement of the individuals who may never undergo the diagnostic testing required to determine definite gastroparesis, Rey et al. (2012) developed a model to estimate the likely prevalence of hidden gastroparesis in a US community. The results suggest that hidden gastroparesis may occur in 1.8% of community subjects.

It has been demonstrated that individuals with gastroparesis are hospitalised, on average, more than once per year and for an average of eight days per year (Dudekula et al., 2011), with a disease burden likened to that of IBD (Jung et al., 2009). To date, there is no Australian data on the cost of gastroparesis, however Wang and colleagues (2008) reported that in 1995 the costs of gastroparesis in the United States were 47.7 million dollars (primary diagnosis) and 863.3 million dollars (secondary diagnosis), while in 2004 costs were significantly higher at 208.3 million dollars (primary diagnosis) and 3.3 billion dollars (secondary diagnosis).

1.1.5 Current medical treatment approaches in gastroparesis

The choice of treatment for gastroparesis will generally depend on symptom severity. The less invasive treatment options include dietary therapy and medication to increase the rate of gastric emptying or reduce symptom severity, however procedures such as Botulinum toxin injections (Botox), gastric electrical stimulation (GES), and the use of enteral or parenteral feeding tubes may also be required (Camilleri, Parkman, Shafi, Abell, & Gerson, 2013). Additionally, researchers are beginning to recognise the importance of emotional support for individuals suffering from this condition. The main treatment options for gastroparesis are briefly discussed below, for a more comprehensive understanding of gastroparesis treatment options, please see articles by Hasler (2015), L. A. Lee, Chen, and Yin (2015), Parrish (2015), and Pasricha (2015) in the 2015 special issue of *Gastroenterology Clinics of North America*, which focuses on gastroparesis (Parkman & Pasricha, 2015).

Dietary therapy is often the first course of action for individuals with gastroparesis. Treatment focuses on limiting foods that slow down gastric emptying, while maintaining adequate intake of nutrients (Bielefeldt, 2012). Dietary recommendations generally involve eating smaller meals at more frequent intervals, and choosing options that are low in fat and fibre as these qualities can delay gastric emptying (Bielefeldt, 2012; Parkman et al., 2004). Individuals with more severe symptoms may be encouraged to replace solid foods with liquids, such as soups or smoothies. Supplements may also be required to ensure adequate nutrition (Bielefeldt, 2012; Parkman et al., 2004). While individuals with mild symptoms may benefit from dietary changes, for those with moderate to severe symptoms diet is generally used as an adjunct to other treatments (Abell et al., 2006).

Dietary management is especially important in the treatment of diabetic gastroparesis. It is known that blood sugar levels can have a significant impact on gastric emptying, and similarly, speed of gastric emptying can dramatically affect the absorption of sugars, nutrients, and medications into the blood stream (Ma, Rayner, Jones, & Horowitz, 2009). Chronic high blood glucose also has the potential to result in damage to the vagus nerve, which can affect contractions of the gastric muscles (National Institute of Diabetes and Digestive and Kidney Diseases, 2007).

Maintaining stable blood glucose then becomes essential, not only for managing diabetes, but also for gastroparesis.

When symptoms cannot be controlled solely through dietary changes, individuals may also need to trial different medications to find the best approach to managing symptoms. Since many painkillers can delay gastric emptying, these medications are usually reduced or stopped entirely and alternate pain management options explored (Tack, 2005). The primary medications utilised in gastroparesis are antiemetics (to reduce nausea and vomiting), and prokinetics (to encourage movement of the gastric muscles). Individuals may require a combination of the two drugs (Parkman et al., 2004). There is also some evidence that serotonin receptor antagonists may be helpful in treating the nausea and vomiting associated with the disorder (Abell et al., 2006; Bielefeldt, 2012). However, it is worth noting that the medications for gastroparesis can be costly, come with potentially serious side-effects, and have limited efficacy (Bielefeldt, 2012; Hejazi & McCallum, 2009).

For gastroparesis sufferers who do not experience relief through dietary changes and pharmacological agents, more invasive procedures may be required. These newer approaches are considered to be controversial and can be expensive (Bielefeldt, 2012). One available treatment involves a Botox injection into the pylorus to relax the sphincter and allow more food to pass through into the small intestine. However, critical reviews of the evidence for this treatment have concluded that it cannot yet be recommended as an effective treatment for gastroparesis (Bai et al., 2010; Camilleri et al., 2013). GES is another therapy that may be used for refractory gastroparesis, which involves electrical stimulation of the gastric muscles intended to accelerate gastric emptying (Abell et al., 2011). Again, reviews of the efficacy of GES report that, since symptom improvements have been variable, evidence for the use of this treatment in gastroparesis is lacking (Abell et al., 2006; Bielefeldt, 2012; Camilleri et al., 2013).

When gastroparesis sufferers do not respond well to dietary changes or pharmacological interventions, there are very few promising alternatives. In these cases, it can be difficult for individuals to maintain adequate nutrition, and as a result many suffer from nutrient and caloric-deficiencies. In an investigation of the nutritional status of individuals with gastroparesis, Parkman, Yates, Hasler,

Nguyen, Pasricha, Snape, Farrugia, Calles, et al. (2011) found that 64% had a caloric-deficient diet. In some cases, individuals may require hospitalization for the placement of gastrostomy or jejunostomy tubes in order to deliver adequate fluids, nutrition, and medications (Parkman et al., 2004).

To date, treatments for gastroparesis have primarily focused on accelerating gastric emptying, however research suggests that this may not resolve the symptoms. Contrary to expectations, it has been demonstrated that symptom severity does not always correlate well with speed of gastric emptying (Cherian et al., 2010; Hasler et al., 2010; Pasricha et al., 2011). For a review of the relationship between gastric emptying and symptom severity in gastroparesis, see Janssen et al. (2013).

In light of this, it has been suggested that rather than continuing to focus on gastric delay, it might be more appropriate to direct resources toward developing treatments that aid in the management of symptoms such as nausea and pain (Pasricha & Parkman, 2015). Similarly, a repeated recommendation has been the implementation of psychological support or intervention for individuals with gastroparesis (Abell et al., 2006; Bennell & Taylor, 2013; Bielefeldt et al., 2009). Little research has been conducted on the efficacy of psychological treatment for the cohort, however psychological support could help individuals manage the numerous burdens associated with gastroparesis (Abell et al., 2006; Bennell & Taylor, 2013) and, due to the complex interactions between the brain and the gut which will be discussed in Section 1.2: The brain-gut axis, may also be beneficial for gastric symptoms and function (Bielefeldt et al., 2009).

1.1.6 Summary

Gastroparesis is a disorder involving delayed gastric emptying in the absence of mechanical obstruction of the stomach. The main aetiologies are idiopathic, diabetic, and post-surgical. The gastroparesis cohort is predominantly female and symptoms typically include nausea, vomiting, early satiety, postprandial fullness, abdominal pain, and fatigue. Individuals with gastroparesis are also more likely to experience higher levels of psychological distress and decreased QoL.

There is limited understanding of the prevalence of gastroparesis, and in Australia only estimates are available. To date, most treatment approaches for gastroparesis have focused on speeding up gastric emptying in order to alleviate symptoms, however the treatments often lack efficacy. Recently it has been suggested that it may be more beneficial to focus on improving symptom management for the cohort, while a related suggestion has been the exploration of a psychological support program for individuals with gastroparesis.

1.2 *The brain-gut axis (BGA)*

An interaction between the mind and the gut has long been assumed by gastroenterologists, psychologists, and psychiatrists (Al Omran & Aziz, 2014; Mayer, 2011; Thompson, 2001). The study of this relationship has expanded considerably over recent years and multidisciplinary research indicates that the communication pathways between the brain and the gut are bidirectional, allowing both top-down and bottom-up modulation and signaling (Grenham, Clarke, Cryan, & Dinan, 2011; Mayer, 2011). These pathways are referred to as the brain-gut-axis (BGA) (Al Omran & Aziz, 2014; Borre, Moloney, Clarke, Dinan, & Cryan, 2014), and may offer an explanation for the frequent occurrence of psychological symptoms in GI conditions such as gastroparesis (see Section XX). This section will describe the communication pathways involved in the BGA, the causes and effects of axis dysregulation, and the potential implications of the BGA in relation to gastroparesis.

1.2.1 *Brain to gut communication*

The brain communicates with the gut via multiple parallel pathways (Al Omran & Aziz, 2014; Mayer, 2011), with the sympathetic and parasympathetic branches of the autonomic nervous system (ANS) playing key roles. The sympathetic nervous system is involved in suppressing secretions, motility, and immune cell modulation, while the parasympathetic nervous system accelerates these actions (Al Omran & Aziz, 2014). Other key components involved in brain to gut communication include the hypothalamic-pituitary-adrenal (HPA) axis which is the primary regulator of the stress response (Dinan & Cryan, 2017), the sympatho-adrenal axis which modulates lymphoid tissue (Mayer, 2011), and the

monoaminergic pathway which modulates spinal reflexes and dorsal horn excitability (Mayer, 2011). Additionally, the hypothalamus and amygdala assist in communication by integrating cortical information and generating outputs (Al Omran & Aziz, 2014; Mayer, 2011). Together, the pathways allow the central nervous system (CNS) to facilitate alterations in gut function according to environmental factors and psychological state (Al Omran & Aziz, 2014).

1.2.2 Gut to brain communication

Gut to brain communication is similarly complex. The GI tract contains a branch of the ANS called the enteric nervous system (ENS), which is sometimes referred to as the “second brain” (Al Omran & Aziz, 2014; Borre et al., 2014; Mayer, 2011). The ENS is comprised of over 200 million neurons (Al Omran & Aziz, 2014; Borre et al., 2014), and is able to regulate and synchronise gut functions and reflexes without input from the CNS (Mayer, Tillisch, & Bradesi, 2006; Prins, 2011). Although able to operate autonomously, the ENS uses endocrine, neuronal and immune signaling to relay information to the CNS so that gut function can be coordinated with overall homeostasis (Al Omran & Aziz, 2014; Mayer et al., 2006). For example, in the instance of psychological or environmental demands, the CNS can override the reflex functions of the ENS in order to maintain homeostasis (Mayer et al., 2006).

1.2.3 The role of gut microbiota

Another factor that appears to play an important role in the maintenance of homeostasis in the BGA is the gut microbiome (Borre et al., 2014). The human gut is home to 10^{13} - 10^{14} microorganisms, including more than one kilogram of bacteria (Dinan & Cryan, 2017). Recently, considerable research interest has been directed towards the role of the gut microbiota in the BGA (Moloney, Desbonnet, Clarke, Dinan, & Cryan, 2014). While the exact role of the microbiota is not yet clear, it is known that microbiota are necessary for normal gut and CNS development and function, and that altered microbial status affects the communication pathways of the BGA (Luczynski, McVey Neufeld, Clarke, Dinan, & Cryan, 2016).

1.2.4 *Dysregulation of the BGA*

Clearly, the BGA is integral for regulating and coordinating complex physiological processes (Grenham et al., 2011; Romijn, Corssmit, Havekes, & Pijl, 2008). Correspondingly, dysregulation of the BGA can result in a number of physical and psychological symptoms and disorders (Borre et al., 2014; Grenham et al., 2011; Mayer, 2011). For example, dysfunction in the BGA has been associated with alterations in cognition, memory formation, and sociability (Dinan & Cryan, 2017; Gareau, 2014; Moloney et al., 2014) and may contribute to the development of anxiety and depression (Dinan & Cryan, 2013; Gareau, 2014; Goehler, Lyte, & Gaykema, 2007; Marques et al., 2016).

Dysregulation of the BGA has also been associated with GI conditions such as IBD and IBS (Grenham et al., 2011; Marques et al., 2016; Mayer, 2011). Studies investigating the role of the BGA in upper GI disorders are scarce, however it has been suggested that changes in enteric neuron function and vagal nerve injury may underlie the hypomotility associated with gastroparesis (Bielefeldt, Tuteja, & Nusrat, 2016). Additionally, alteration of homeostatic reflexes in the BGA may cause chronic abdominal pain (Mayer & Tillisch, 2011), and dysregulation of neural and hormonal factors may explain the changes in appetite, satiety, and gastric function often noted in upper GI disorders (Sanger & Lee, 2008).

A key factor known to dysregulate the BGA is stress (Moloney et al., 2014). Stress dysregulates the HPA axis, and subsequently the BGA (Dinan & Cryan, 2017; Moloney et al., 2014). Stress has been shown to affect GI sensation, motility, immune function (Mayer et al., 2006), gut barrier functions, visceral perception (Moloney et al., 2016), and is also associated with changes in gut microbiota composition (Kelly, Clarke, Cryan, & Dinan, 2016; Marques et al., 2016; Moloney et al., 2014; Moloney et al., 2016). Fittingly, chronic stress is also a common factor in many GI disorders (Borre et al., 2014; Gareau, 2014). Thus, current research suggests that psychological distress may result from BGA dysregulation, while also contributing to the dysregulation. Therefore, the implementation of a psychological intervention may help to interrupt this potential vicious cycle while assisting individuals in managing both the psychological and GI symptoms associated with gastroparesis.

1.2.5 *Summary*

The BGA is a complex bidirectional communication network between the brain and the gut. The BGA regulates GI function, and plays an integral role in maintaining overall homeostasis. Dysregulation of the BGA has been implicated in some psychological functions and disorders, and has been associated with a number of GI conditions such as IBD and IBS. To date, little research has addressed the relationship between the BGA and upper GI disorders such as gastroparesis, however a number of possible associations have been suggested as focus points for future research.

Current research suggests that psychological distress may be both a result of BGA dysregulation and a cause of dysregulation. Due to this interplay between the brain and the gut, psychological intervention may be able to assist individuals in managing psychological distress, and in turn have a potentially beneficial impact on GI symptoms themselves.

1.3 *Psychological distress*

The BGA literature provides a physiological explanation for an association between gut dysfunction and psychological symptoms such as anxiety, depression, and stress. This understanding inherently raises questions around the prevalence, severity, and impact of psychological distress in individuals with a GI disorder like gastroparesis. Since anxiety, depression, and stress frequently coexist and even overlap, they are often assessed together to reflect a level of general psychological distress (Alfonsson, Wallin, & Maathz, 2017; Clarke & Currie, 2009). For example, one of the most commonly used tools to measure psychological distress is the Depression Anxiety Stress Scale (DASS), consisting of depression, anxiety, and stress subscales which can then be combined to provide a composite measure of psychological distress (Psychological Foundation of Australia, 2014). The DASS has demonstrated reliability and stronger psychometric properties than the Beck Depression and Anxiety Inventories (Lovibond & Lovibond, 1995). Consequently, this thesis (and associated papers) will refer to anxiety, depression, and stress separately, and also to overall psychological distress.

While it has been established that psychological distress may adversely impact GI function via the BGA, there is limited understanding of the psychological

distress experienced by individuals with gastroparesis. The following section will investigate research findings relating to psychological distress that may be relevant to the gastroparesis cohort, firstly by considering the association between psychological distress and chronic illness, followed by a review of the role of psychological distress in some of the most common GI conditions, namely IBD and functional gastrointestinal disorders (FGIDs), with an additional exploration relating to FD specifically. These discussions will lead to an evaluation of the evidence for the relationship between psychological distress and gastroparesis.

1.3.1 Chronic illness and psychological distress

Defined as diseases that endure over time and are rarely cured completely, chronic illnesses are associated with impairment across many aspects of life (National Center for Chronic Disease Prevention and Health Promotion, 2012). In addition to the physical symptoms and burden associated with chronic illness (e.g., pain, fatigue), individuals with chronic illness are also likely to experience a variety of psychosocial stressors. For example, increased health care costs, reduced ability to work, and changes in social relationships (Institute of Medicine, 2012). It is also common for individuals with chronic illness to experience psychological comorbidity, with depression being especially prevalent (National Center for Chronic Disease Prevention and Health Promotion, 2012). The Australian National Survey of Mental Health and Wellbeing conducted in 2007 (projected to represent 16,015,300 Australians aged between 16-85 years) indicated that 28.0% of Australians with a chronic physical condition experienced a comorbid mental disorder, compared to 17.6% of people who did not have a chronic physical condition (Slade et al., 2009).

In chronic illness cohorts such as those with heart disease, diabetes, and rheumatoid arthritis, psychological comorbidity can influence disease course and adherence to treatment programs. For example, individuals with chronic illness who also have comorbid psychological distress tend to be less compliant with medical treatments (DiMatteo, Lepper, & Croghan, 2000) and self-care activities (Lin et al., 2004). Comorbid psychological distress has also been associated with an increased number of symptoms (Katon, Lin, & Kroenke, 2007), more complications (Lin et al., 2010), greater healthcare costs (Simon et al., 2005), and impaired

outcomes including increased mortality (Egede, Nietert, & Zheng, 2005; Lin et al., 2009; van Melle et al., 2004). Given the high prevalence of psychological distress in chronic illness cohorts, and the potentially detrimental impact, these findings highlight the importance of promoting psychological support in the management of chronic illness.

1.3.2 IBD and psychological distress

Consistent with findings in general chronic illness cohorts, psychological comorbidity is also elevated in individuals with IBD. A recent systematic review ($k = 66$) by A. Mikocka-Walus, Knowles, Keefer, and Graff (2016) found that rates of anxiety and depression were higher in the IBD cohort (pooled mean rates - anxiety symptoms: 19.1%, depressive symptoms: 21.2%) compared to healthy controls (pooled mean rates - anxiety symptoms: 9.6%, depressive symptoms: 13.4%). However, rates of anxiety and depression tended to be lower in individuals with IBD (pooled mean rates - anxiety symptoms: 41.9%, depressive symptoms: 14.5%) compared to other chronic illnesses cohorts (pooled mean rates - anxiety symptoms: 48.2%, depressive symptoms: 28.4%). The systematic review also identified that rates of anxiety and depression were higher during active IBD states (pooled mean rates - anxiety symptoms: 66.4%, depressive symptoms: 34.7%) than inactive IBD (pooled mean rates - anxiety symptoms: 28.2%, depressive symptoms: 19.9%).

While an association between psychological distress and IBD has been clearly demonstrated in the literature, the nature of this relationship is not fully understood. At present there is insufficient evidence to determine whether psychological distress is a contributing factor to IBD onset (A. Mikocka-Walus, Knowles, et al., 2016). However, depression and anxiety have been associated with symptom flares (Bernstein et al., 2010; A. Mikocka-Walus, Pittet, Rossel, von Kanel, & Swiss, 2016), and a number of reviews have demonstrated a negative influence on IBD course in general (Graff, Walker, & Bernstein, 2009; Maunder & Levenstein, 2008; Rampton, 2009), as well as a detrimental impact on treatment outcomes and QoL (Graff et al., 2009).

1.3.3 FGIDs and psychological distress

The role of psychological distress has been explored more thoroughly in FGID cohorts than IBD cohorts and, consequently, there is greater understanding of the interactions between FGIDs and psychological distress. The Rome Foundation defines FGIDs as follows: “[FGIDs] are disorders of gut-brain interaction. It is a group of disorders classified by GI symptoms related to any combination of the following: motility disturbance, visceral hypersensitivity, altered mucosal and immune function, altered gut microbiota, and altered [CNS] processing” (p.1268, Drossman, 2016). According to the definitive text on FGIDs, the Rome IV, there are 33 adult and 20 pediatric FGIDs, including some of the most common illnesses in gastroenterology (e.g., IBS, FD) (Drossman, Chang, Kellow, Tack, & Whitehead, 2016). The Rome IV articulates that FGIDs are a product of interactions between biological, psychological, and social factors, making the study of psychological distress in FGIDs particularly important.

In the May 2016 special issue of *Gastroenterology* (Drossman & Hasler, 2016), a number of leading FGID experts reviewed what is known about FGIDs, including the associations with psychological distress. It was demonstrated that psychiatric comorbidity is elevated in FGIDs, with depression affecting approximately 30% of the cohort, and anxiety occurring in 30-50% (Van Oudenhove et al., 2016). Individuals with FGIDs have a higher rate of abuse history and stressful life events in general, with evidence that FGID onset is often associated with the experience of a threatening event (Van Oudenhove et al., 2016). Additionally, psychological distress may predispose an individual to develop an FGID following GI infection Drossman (2016). Consistent with findings in IBD cohorts, psychological distress can also exacerbate the GI symptoms of FGIDs and tends to be associated with poorer outcomes (Drossman, 2016).

A 12-year longitudinal study by Koloski et al. (2012) offers some of the strongest evidence for the brain-gut interactions involved in FGIDs. In the study, individuals reporting high levels of anxiety at baseline were more likely to develop an FGID 12 years later than those with lower anxiety (baseline controls n =626, 48.8% female, mean age: 45 years; baseline FGID cases n =376, 55.9% female, mean age: 45 years). Additionally, individuals with an FGID and low psychological distress at baseline tended to display higher levels of anxiety and depression at follow up. This study provided the first evidence that brain-gut interactions

operate bidirectionally in FGIDs. Overall, the researchers found that the brain-gut pathway was the more dominant pathway in their sample of individuals with IBS and FD, and recommended that early identification and treatment of psychological distress may help individuals avoid developing FGIDs later in life. Two large-scale studies by Koloski, Jones, and Talley (2016) and M. P. Jones et al. (2017) have recently provided further evidence for this recommendation, indicating that between 33-66% of individuals with FGID experience a mood disorder prior to receiving an FGID diagnosis. Additionally, M. P. Jones et al. (2017) identified that mood or anxiety disorder was diagnosed on average more than three years prior to FGID, offering considerable time for intervention and possible prevention.

1.3.4 FD and gastroparesis

Evidence relating to the role of psychological distress in FD deserves additional attention in this thesis. While gastroparesis sufferers primarily identify nausea and vomiting in conjunction with delayed gastric emptying, the predominant symptom in FD is typically considered to be abdominal pain (Bielefeldt, 2012; Parkman et al., 2010; Stanghellini & Tack, 2014). However, the distinction has been blurred by findings that many individuals with gastroparesis experience abdominal pain, while nausea and vomiting are present in 20-50% of those with FD (Lacy, 2012), and delayed gastric emptying is present in up to 40% of individuals with FD (Bielefeldt, 2012; Parkman et al., 2010). In some cases, the overlap in symptoms can leave the disorders indistinguishable (Bielefeldt, 2012; Parkman et al., 2010).

Consequently, experts in the field have questioned whether the definition of gastroparesis should be revised (Pasricha & Parkman, 2015). Suggestions have included refining the definition of gastroparesis to a higher degree of delayed gastric emptying, or diagnosing and treating by predominant symptoms (Stanghellini & Tack, 2014). Another alternative is that both FD and gastroparesis are diagnosed as FD, with a subclassification indicating the presence or absence of gastric delay (Parkman et al., 2010). Similarly, Lacy (2012) has proposed that the current classification system be restructured: “instead of categorising these two prevalent disorders as completely distinct disorders, we should view them as a broad, continuous spectrum” (p.6).

While a conclusion has not yet been reached about the classification of these disorders, the similarities between FD and gastroparesis suggest that it would be helpful to also consider literature on FD when exploring relationships between psychological factors and gastroparesis.

1.3.5 FD and psychological distress

Research indicates that the relationship between FD and psychological distress is similar to findings reported in IBD and general FGID, with between 33-100% of individuals diagnosed with FD meeting the criteria for a psychiatric diagnosis (Haug, Svebak, Wilhelmsen, Berstad, & Ursin, 1994; Malt, Berle, Olafsson, Lund, & Ursin, 2000; Sattar, Salih, & Jafri, 2010; Van Oudenhove et al., 2007). When compared to healthy controls, individuals with FD score higher on measures of anxiety and depression (Alexander & Tantry, 1993; De la Roca-Chiapas et al., 2010; Faramarzi, Kheirkhah, Shokri-shirvani, Mosavi, & Zarini, 2014; Faramarzi, Shokri-Shirvani, & Kheirkhah, 2012; Filipovic et al., 2013; Haag et al., 2008; Handa et al., 1999; Haug, Svebak, Hausken, et al., 1994; Haug, Svebak, Wilhelmsen, et al., 1994; Haug, Wilhelmsen, Berstad, & Ursin, 1995; S. Lee et al., 2000). Moreover, psychological distress appears to have a positive relationship with FD symptom severity (e.g., Chou et al., 2001; Fischler et al., 2003; Haug, Svebak, Hausken, et al., 1994; Strid et al., 2001)

Much like findings from general FGID cohorts, individuals with FD report higher levels of stress, more stressful life events, and more chronic stress in their lives than healthy controls (Chen, Luo, & Chang, 2010; De la Roca-Chiapas et al., 2010; Haug et al., 1995). While some studies have found that a history of abuse negatively influences somatic reports and affect in FD (Fischler et al., 2003; Geeraerts et al., 2009; M. P. Jones, Coppens, et al., 2013; Van Oudenhove, Vandenberghe, Vos, Fischler, et al., 2011), others have found that these relationships are mediated by psychological variables (e.g., neuroticism, coping, control) when included in a predictive model (e.g., M. P. Jones, Oudenhove, Koloski, Tack, & Talley, 2013; Koloski, Talley, & Boyce, 2005). Predictive models have also suggested that depression and somatization (“a tendency to experience and report multiple somatic symptoms that cannot be adequately explained by organic findings” p. 341, Van Oudenhove et al., 2008) may be the most important

determinants of symptom severity in FD (Kindt et al., 2011; Van Oudenhove et al., 2008). These findings highlight the important and influential role of psychological distress, not only in conditions of the lower GI tract, but also in disorders of the upper GI tract.

1.3.6 Gastroparesis and psychological distress

Compared to the GI conditions mentioned above, information regarding the role of psychological distress in gastroparesis is limited. The main psychopathologies that have been reported in the cohort include anxiety (Dudekula, Rahim, & Bielefeldt, 2014; Jung et al., 2009; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011; Yu et al., 2017), depression (Dudekula et al., 2014; Jung et al., 2009; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011; Soykan et al., 1998; Yu et al., 2017), and somatization (Soykan et al., 1998). However, due to the limited research on this topic, it is not yet clear how levels of psychopathology in individuals with gastroparesis compare to healthy controls or other chronic conditions.

Consistent with research on the FGIDs, the influence of abuse history has also been investigated in gastroparesis. After examining the medical files of individuals with gastroparesis ($N=146$; 82% female; mean age: 45.5 years), Soykan et al. (1998) identified that 62% of women with idiopathic gastroparesis reported a history of physical or sexual abuse. Individuals with a history of physical abuse tended to experience greater abdominal pain, somatization, GI symptoms, depression, and had more abdominal surgeries.

Perhaps the most common finding in the literature is that increased gastroparesis symptom severity tends to be associated with greater anxiety and depression (Bielefeldt et al., 2009; Hasler et al., 2010; Hasler et al., 2013; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011). However, longitudinal studies and predictive models have not yet been used to explore the relationship or identify potential causal processes.

Associations have also been made between psychopathology, demographic variables, and disorder characteristics in the gastroparesis cohort. For example, of 16 studies that assessed anxiety or depression in a gastroparesis cohort, one study

by Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al. (2011) ($N=243$; 88% female; mean age: 41.0 years) found that females with idiopathic gastroparesis experienced less clinically severe depression and were more likely to report comorbid anxiety disorder than males with idiopathic gastroparesis, while another study by Hasler et al. (2010) ($N=299$; 81.9% female; mean age: 43.0 years) found that males experienced higher state anxiety than females. It is possible that the high proportion of females to males in these samples may account for the discrepancy in findings, and therefore replication is required. The study by Hasler et al. (2010) also demonstrated that individuals with gastroparesis who had been hospitalised six or more times in the past year tended to report higher levels of depression, and if also taking antidepressants tended to score higher on trait anxiety.

In an exploration of individual gastroparesis symptoms, Hasler et al. (2010) found that nausea, vomiting, bloating, and postprandial fullness were all associated with greater depression scores, while bloating and postprandial fullness were also associated with greater state and trait anxiety scores. Finally, a study by Cherian et al. (2012) ($N=156$, 80.7% female; mean age: 41.1 years) demonstrated that higher levels of fatigue in individuals with gastroparesis was positively associated with depression, and negatively related to anxiety. However, it is important to bear in mind that the evidence for these associations is based on the findings of single studies, which are also cross-sectional and cannot show causal process, and is therefore tenuous.

Information gleaned from qualitative studies provides some additional insight into gastroparesis-related psychological distress. After in-depth interviews with gastroparesis sufferers ($N=9$; 8 female; 7 participants were aged between 31-40 years; all had been diagnosed for more than one year), Bennell and Taylor (2013) concluded that gastroparesis has a multifaceted effect on the sufferer's QoL. Influenced by less than desirable experiences with the medical profession, difficulty understanding gastroparesis, in addition to difficulty managing social situations which often revolve around food, individuals can end up feeling significant loss, isolation, and rejection, which then impacts upon sense of identity and security. The qualitative component of a study by Bielefeldt et al. (2009) ($N=55$; 80% females; mean age: 42.4 years; mean duration of gastroparesis

symptoms: 32.0 months) also found social functions to be a primary source of distress, followed by fatigue, and the frustration and emotional impact of the disease which often affected relationships with others. Some individuals also reported frustration around experiences with the medical profession and the influence that the condition had on professional activity.

1.3.7 Summary

Psychological distress is prevalent in chronic illness cohorts, having a significant impact on disease outcomes. In IBD and FGIDs, psychological comorbidities such as anxiety and depression are elevated compared to healthy controls. In these conditions, psychological distress tends to be associated with an exacerbation of GI symptoms and poorer treatment outcomes. Additionally, in FGIDs there is evidence that psychological distress may be associated with illness onset. Studies with FD cohorts indicate that psychological distress is also an important factor to consider in upper GI conditions, and is therefore relevant in gastroparesis.

The relationship between psychological distress and gastroparesis is not well understood. Currently, there is evidence of psychological comorbidity in the gastroparesis cohort, and also indication that increased gastroparesis symptom severity is associated with greater anxiety and depression, however other research on the topic requires replication. Qualitative studies offer valuable insight into the experience of living with gastroparesis, and the distress that is often associated with it. However, further research using longitudinal methodologies and predictive modeling (such as those used for other GI cohorts) is required to build greater understanding of the relationship between psychological distress and gastroparesis, and thus the potential impact of psychological intervention to improve QoL for individuals living with gastroparesis.

1.4 QoL

Helping individuals with gastroparesis manage psychological distress is important not only due the possible influence on gastric function via the BGA, but also due to the impact of psychological distress on QoL. QoL has been defined by the WHO (2017) as “an individual's perception of their position in life in the

context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns” (“WHOQOL: Measuring Quality of Life”, para. 2). Medical literature may also refer to Health-Related Quality of Life (HRQoL), meaning QoL domains specifically as they relate to the patient’s state of physical or mental health (Borgaonkar & Irvine, 2000).

Maintaining QoL and easing the burdens associated with chronic illness is an important aspect of treatment and care (Glise & Wiklund, 2002). As will be discussed below, QoL is commonly impaired in individuals with chronic illness. Since there is limited information pertaining specifically to QoL in the gastroparesis cohort, the following section will first review what is known about QoL in chronic illness, in IBD, IBS, and FD, before assessing the evidence in the gastroparesis cohort.

1.4.1 Chronic illness and QoL

In general, chronic illness cohorts demonstrate poorer QoL than the general population (Crouchley & Daly, 2007). The evidence for this association is vast, covering numerous illnesses, different levels of illness severity, and investigating various aspects of QoL. While it is beyond the scope of this thesis to review all of the available literature on this topic, a few examples will be outlined. One such example is a systematic review of 118 diabetes studies ($N=71,161$) which identified that when compared to population norms, QoL was lower in persons with type II diabetes (Norris et al., 2011). Similarly, poorer QoL has also been associated with rheumatoid arthritis through a meta-analysis of 31 studies ($N=22,335$) (Matcham et al., 2014). Further, large epidemiological studies of individuals with chronic obstructive pulmonary disease (COPD) have demonstrated that even in mild stages of the disease, QoL is impaired when compared to the general population (Carrasco Garrido et al., 2006; P. W. Jones et al., 2011). Poorer QoL in chronic illness has been associated with a number of factors, including increased symptoms and complications/comorbidities (Glasgow, Ruggiero, Eakin, Dryfoos, & Chobanian, 1997; Holmes et al., 2000; P. W. Jones et al., 2011; Mujais et al., 2009; Wexler et al., 2006), more hospital admissions (Carrasco Garrido et al., 2006; Monteagudo et al., 2013), and greater psychological distress

(Ali et al., 2010; Goldney, Phillips, Fisher, & Wilson, 2004; Holmes et al., 2000; Schram, Baan, & Pouwer, 2009; Wexler et al., 2006).

1.4.2 IBD and QoL

Like other chronic illnesses, IBD can pose significant psychosocial burden for individuals. Compared to healthy controls, individuals with IBD have demonstrated lower levels of QoL (Adler et al., 2008; Lix et al., 2008; Martin, Leone, Fries, & Naccarato, 1995; Nedelciuc, Pintilie, Dranga, Mihai, & Prelipcean, 2012; Pace et al., 2003; Schirbel, 2010; Turunen et al., 2009). Some key areas of concern for IBD sufferers include disease flares, the need for an ostomy bag or surgery, social restrictions, and sexual dysfunction (Borgaonkar & Irvine, 2000; Jelsness-Jorgensen, Moum, & Bernklev, 2011). Individuals with active disease tend to report lower QoL than those with quiescent IBD (Bryant, van Langenberg, Holtmann, & Andrews, 2011; Casellas et al., 2005; Graff et al., 2006; Hoivik et al., 2012; Lix et al., 2008), and similarly, increased IBD activity tends to be associated with poorer QoL (Adler et al., 2008; Almadani et al., 2014; Casellas et al., 2005; Nedelciuc et al., 2012).

IBD duration may also influence QoL, with a number of studies indicating that QoL improves over the duration of the disease (Benedini et al., 2012; Blondel-Kucharski et al., 2001; Burisch et al., 2014; Haapamaki, Turunen, Roine, Farkkila, & Arkkila, 2009). It has also been found that psychological distress plays an important role in determining QoL in this cohort, with increased levels of neuroticism, anxiety, and depression being associated with poorer QoL (Freitas et al., 2015; Ganguli et al., 2007; S. Liu et al., 2013; M. D. Rutter, Saunders, Wilkinson, Schofield, & Forbes, 2006). For a recent review of 131 studies pertaining to QoL in IBD, see the systematic review and meta-analyses by Knowles and colleagues (Parts I [2017] and II [2017]). Key findings of the review are aligned with much of what has been mentioned above, including evidence of lower QoL in the IBD cohort when compared to healthy individuals, poorer QoL during active states of disease, and an indication of improved QoL over time.

1.4.3 IBS and QoL

Similar QoL patterns have been identified in the IBS cohort. A systematic review by El-Serag, Olden, and Bjorkman (2002) ($k=17$) found that QoL was lower in individuals with IBS than in the general population and that IBS symptom severity had a corresponding impact on QoL. It has also been found that comorbidities, depression, and anxiety have a significant influence on QoL in the IBS cohort (Cho et al., 2011; Creed et al., 2001; Jamali et al., 2012; Michalsen, Vandvik, & Farup, 2015; Y. T. Wang et al., 2012). Additionally, a large cross-sectional study of 877 individuals with IBS demonstrated that the IBS cohort scored lower across several dimensions of QoL than individuals with gastroesophageal reflux disease (GERD), diabetes, or end-stage renal disease (Gralnek, Hays, Kilbourne, Naliboff, & Mayer, 2000). Some primary QoL concerns in the IBS cohort have been reported to include reduced sleep, decreased sexual function, increased psychological symptoms, and a change in activities, especially relating to employment, travel, and diet (Wells, Hahn, & Whorwell, 1997).

1.4.4 FD and QoL

Decreased QoL is also commonly identified in FD cohorts. Many studies have indicated that, when compared to healthy subjects and population norms, individuals with FD experience a general reduction in QoL (e.g., Aro et al., 2011; Filipovic et al., 2013; M. P. Jones & Maganti, 2004; Mones et al., 2002; Talley et al., 2006; Van Oudenhove, Vandenberghe, Vos, Holvoet, et al., 2011; Wahass, Khalil, Al Qurain, & Yasawy, 2006). When compared to individuals with chronic liver disease, individuals with FD were found to have a significantly lower Mental Composite Score on the SF-36 (Haag et al., 2008), and when compared to individuals with GERD were found to score lower on some psychological aspects of QoL such as knowledge/control and tension/mood (Wahass et al., 2006).

There is some evidence to suggest that symptom severity and gastric discomfort threshold may be associated with QoL (Haag et al., 2008; Mones et al., 2002; Talley et al., 2006; Van Oudenhove, Vandenberghe, Vos, Holvoet, et al., 2011). In particular, physical QoL appears to be associated with delayed gastric emptying time, somatization and somatic symptom reporting (M. P. Jones, Coppens, et al., 2013; Talley et al., 2006; Van Oudenhove, Vandenberghe, Vos, Fischler, et al., 2011; Van Oudenhove, Vandenberghe, Vos, Holvoet, et al., 2011).

However, correlations between dyspeptic symptoms and QoL have not been identified across the board (e.g., Strid et al., 2001). In terms of mental QoL, psychological factors including higher trait affectivity (M. P. Jones, Coppens, et al., 2013), abuse history and positive affect (Van Oudenhove, Vandenberghe, Vos, Fischler, et al., 2011) have all been associated with lower scores.

Two studies have examined QoL longitudinally in the FD cohort, with both studies highlighting the impact of psychological distress on QoL. Gutierrez et al. (2003) found that anxiety score and tobacco consumption were independently related to a reduction in QoL over a one-year follow up ($N=112$; 72.32% females; mean age: 45.0 years; mean duration of FD symptoms: 12 years). In a five year follow up study, Kindt et al. (2011) reported that weight loss, symptom severity and trait anxiety at baseline predicted QoL at five years. They also found that depression, chronic fatigue, and symptom severity at follow up were related to decreased QoL ($N=253$; 66.80% females; mean age: not provided; mean duration of FD symptoms: not provided).

1.4.5 *Gastroparesis and QoL*

Studies investigating QoL in the gastroparesis cohort have demonstrated some similar findings to those observed in other GI cohorts. For example, research has shown that individuals with gastroparesis also display lower QoL than population norms (Bielefeldt et al., 2009; Harrell et al., 2008; Jaffe et al., 2011), and that increased gastroparesis symptom severity tends to be associated with poorer QoL (Bielefeldt et al., 2009; Cherian et al., 2012; Cherian et al., 2010; Cutts et al., 2016; Friedenberg, Kowalczyk, & Parkman, 2013; Harrell et al., 2008; Hasler et al., 2013; Hasler et al., 2011; Jaffe et al., 2011). However, a recent study of a large community-based sample ($N=1423$; 92.8% female; median age: 44.0 years; mean duration of gastroparesis symptoms: 9.3 years) indicated that gastroparesis symptoms, combined with demographic variables, accounted for only 36% of the variation in physical QoL, and only 12% of the variation in mental QoL (Yu et al., 2017). This is aligned with an older study by Friedenberg et al. (2013) indicating that only 30% of variation in QoL could be explained by gastroparesis symptom severity ($N=255$; 83.3% females; mean age: 42.5 years; mean duration of gastroparesis symptoms: not provided).

There is currently little understanding of other factors that may influence QoL in gastroparesis. Specific symptoms and underlying mechanisms of the disorder do not appear to bear much influence on QoL. For example, Harrell et al. (2008) found that QoL was similarly decreased across individuals grouped by the predominant symptoms of either vomiting, dyspepsia, or regurgitation ($n = 100$; 87% females; mean age: 47.0 years; mean duration of gastroparesis symptoms: more than two months). Additionally, while one study found that there was little difference in QoL between individuals with a diabetic aetiology versus an idiopathic aetiology ($N = 59$; 88.14% female; mean age: 43.0 years; mean duration of gastroparesis symptoms: more than six months) (Jaffe et al., 2011), another study found significant difference in the dietary subscale where individuals with diabetic gastroparesis fared better ($N = 68$; 85.30% female; mean age: 40.0 years; mean duration of gastroparesis symptoms: 3.46 years) (Cherian et al., 2010). Unlike the GI disorders mentioned above, there has been no reported investigation into the relationship between psychological distress and QoL in a gastroparesis cohort to date.

1.4.6 Summary

QoL is a subjective measure of an individual's physical and psychosocial wellbeing. Maintaining QoL is particularly important for individuals with chronic illness, as they will often continue to experience symptoms and need to engage in symptom management strategies throughout their lifetime. However, chronic illness cohorts experience significantly impaired QoL when compared to the general population. Numerous studies have been conducted across IBD, IBS, and FD cohorts to examine the factors that may influence QoL in these common GI disorders. Consistent with findings in other chronic illnesses, some of the most influential factors have included symptom severity and psychological distress.

Research with gastroparesis cohorts similarly identifies impaired QoL compared to the general population, however there is little understanding of the factors that may influence or predict QoL in the cohort. While a number of studies support a link between gastroparesis symptom severity and QoL, this only appears to account for approximately one third of the variation in QoL. In a search for factors that can explain the remaining variance, studies have shown that

predominant symptoms and aetiology do not reliably explain QoL in this cohort. Thus, further research to identify factors that may promote or diminish QoL in the gastroparesis cohort is required. Research on other GI disorders indicates that an important area to focus on may be the relationship between psychological distress and QoL, as well as any influential psychological processes (e.g., illness perceptions, coping styles) that may play a role in determining psychosocial outcomes for the gastroparesis cohort.

1.5 Psychological treatments

While further understanding is required, research clearly suggests that psychological distress is a pertinent issue in gastroparesis. Psychological treatments may be able to help individuals with gastroparesis reduce distress by developing psychological processes and habits that can improve resilience in the face of chronic illness (Cal, Sa, Glustak, Santiago, & Walla, 2015; de Ridder, Geenen, Kuijer, & van Middendorp, 2008; White, 2001). There are also other advantages to psychological treatment that may be particularly relevant to individuals with gastroparesis. Psychological treatments are associated with few to no adverse side effects, and do not interact with the pharmacological agents that are commonly required in chronic illness cohorts (Palsson & Whitehead, 2013). A great number of studies have assessed the efficacy of psychological treatment in chronic illness, though the gastroparesis cohort has been largely overlooked. The following section will discuss evidence for the use of psychological treatments in chronic illness, with an emphasis on GI cohorts including IBD, IBS, FD, and finally gastroparesis. Firstly, though, it is important to identify what is encompassed by the term psychological treatment.

1.5.1 What are psychological treatments?

There are many different approaches to psychological treatment, with each intervention being dependent on a diverse range of factors. Essentially, a psychological treatment involves an interpersonal relationship between an individual and a therapist, in which the aim is to improve wellbeing by altering psychological processes (Eccleston, Hearn, & Williams, 2015; Galway et al., 2012). The type of treatment implemented will vary depending on factors such as the individual's concern (i.e., why is treatment being sought?), theoretical basis (e.g.,

psychodynamic, cognitive behavioural, interpersonal), the content that must be delivered (e.g., psychological, educational), the mode of delivery (e.g., individual or group, face-to-face or online), and the therapist's style (Galway et al., 2012; Michaelis et al., 2017; Pollok et al., 2016; Thomas, Thomas, Hillier, Galvin, & Baker, 2006). Treatment approaches may also be blended together, and/or combined with additional components such as relaxation techniques and social support (van der Heijden, Abrahams, & Sinclair, 2017). Additionally, the term therapist may be used to refer to a wide range of professionals with varying qualifications, such as psychologists, psychiatrists, social workers, counsellors, and nurses (Usmani et al., 2017). This diversity and flexibility of psychological treatment allows interventions to be tailored to the unique needs of the individual (Thomas et al., 2006), however it also poses considerable challenges in terms of assessing the value of psychological treatment, as will be discussed below.

1.5.2 Chronic illness and psychological treatments

The literature assessing psychological interventions in chronic illness cohorts is vast and extremely complex. Due to the diversity of treatment approaches described above, plus the multitude of possible chronic illness diagnoses, it is beyond the scope of this thesis to review all of the literature. In brief, Cochrane systematic reviews of psychological intervention trials across a range of chronic illnesses (e.g., multiple sclerosis, breast cancer, diabetes, epilepsy, COPD) demonstrate that some psychological treatments may be helpful under certain conditions (e.g., Chew, Vos, Metzendorf, Scholten, & Rutten, 2017; Galway et al., 2012; Michaelis et al., 2017; Mustafa, Carson-Stevens, Gillespie, & Edwards, 2013; S. H. Richards et al., 2017; Thomas et al., 2006; Usmani et al., 2017; van der Heijden et al., 2017). For example, group-based cognitive behavioural therapy (CBT) interventions may improve depression in individuals living with HIV if they were not depressed before starting therapy, however mindfulness based interventions do not seem to influence levels of psychological distress ($k=16$, $N=2520$) (van der Heijden et al., 2017). Diabetes related distress may improve following brief emotion-cognition focused interventions for individuals with type II diabetes, whereas cognition-focused interventions do not seem as beneficial ($k=30$, $N=9177$) (Chew et al., 2017). Additionally, psychological therapies may

increase metastatic breast cancer survival at 12 months, but not at longer-term follow up, and may assist with select aspects of psychological distress such as feelings of helplessness ($k=10$, $N=1378$) (Mustafa et al., 2013).

The results of these reviews illustrate some of the complexity involved in reviewing such a diverse topic. Studies can differ in cohort characteristics, as well as the treatment modality investigated, treatment duration, follow up intervals, and outcomes measures employed. Indeed, a number of reviewers have asserted that the heterogeneity of the literature makes it very challenging to draw meaningful conclusions about the efficacy of psychological interventions for individuals with chronic illness (e.g., Eccleston et al., 2015; Semple et al., 2013; Usmani et al., 2017; Webb, Kukuruzovic, Catto-Smith, & Sawyer, 2007; Yorke, Fleming, & Shuldham, 2006).

1.5.3 IBD and psychological treatments

The majority of research into psychological therapy for the treatment of GI disorders has focused on FGIDs, however IBD has also been considered. In 2011, a meta-analysis of 21 studies ($N=1745$) investigating this topic concluded that there was no evidence for the efficacy of psychological interventions in adults with IBD, which the authors stated was consistent with previous reviews (Timmer et al., 2011). After identifying methodological limitations in the meta-analysis, including the combination of different therapeutic approaches in analyses, Knowles, Monshat, and Castle (2013) performed another review in which intervention styles were assessed separately ($k=16$, $N= 839$). The review demonstrated that CBT and psychodynamic therapy were associated with reduced depression and anxiety but not IBD severity, whereas hypnosis appeared to benefit disease severity. In 2017 a systematic review and meta-analysis by Gracie et al. (2017) found further supportive evidence for the use of psychological treatment in IBD ($k=14$, $N=1196$). Namely, that psychological therapy, specifically CBT, may lead to short-term improvements in levels of depression and QoL in individuals with IBD.

1.5.4 IBS and psychological treatments

A number of systematic reviews and meta-analyses have investigated the efficacy of psychological treatment for individuals with IBS, with one of the most

recent assessing a total of 41 trials ($N=2290$) (Laird, Tanner-Smith, Russell, Hollon, & Walker, 2016). Predominantly, the reviews demonstrate that psychological treatments are effective at reducing IBS symptoms (Altayar, Sharma, Prokop, Sood, & Murad, 2015; Ford et al., 2014; Lackner, Mesmer, Morley, Dowzer, & Hamilton, 2004; Laird et al., 2016; Zijdenbos, de Wit, van der Heijden, Rubin, & Quartero, 2009), with additional indications of improvement in QoL (Altayar et al., 2015; Zijdenbos et al., 2009). In 2017, Laird, Tanner-Smith, Russell, Hollon, and Walker (2017) focused a systematic review and meta-analysis on the impact of psychological treatment on mental health and daily functioning in individuals with IBS ($k=31$, $N=1747$). The results indicated that psychological treatment was associated with improvements in mental health and daily functioning, with CBT, hypnosis, psychodynamic therapy, and relaxation having equal influence on mental health, while CBT had the greatest impact on daily functioning. The overwhelming efficacy of psychological treatment in the IBS cohort has led to the recommendation that individuals with IBS should have easier access to psychological therapies (Ford et al., 2014).

1.5.5 FD and psychological treatments

In 2004, Soo, Forman, Delaney, and Moayyedi (2004) published a systematic review of psychological therapies for FD ($k=4$, $N=404$). At this time, there were only four studies eligible for inclusion, all using different therapies, with results presented in such a way that precluded data synthesis. Based on this review, the authors concluded that there was insufficient evidence to support the use of psychological therapies for FD.

In the past 14 years, a number of studies have contributed to this research area which, combined with previous studies, provide varying results. CBT based therapy has been associated with reduction in the physical symptoms of FD (Dehghanizade, Zargar, Mehrabizadeh Honarmand, Kadkhodaie, & Eydi Baygi, 2015; Haug, Wilhelmsen, Svebak, Berstad, & Ursin, 1994; Orive et al., 2015), reduction in anxiety (Haag et al., 2007; Haug, Wilhelmsen, et al., 1994), reduction in complaints about family problems (Haug, Wilhelmsen, et al., 1994), and improved QoL (Orive et al., 2015). Hypnotherapy has also been associated with reduction in physical FD symptoms (Calvert, Houghton, Cooper, Morris, &

Whorwell, 2002; Chiarioni, Vantini, De Iorio, & Benini, 2006) and improved QoL (Calvert et al., 2002),

In addition, psychoanalytically oriented therapies have also been associated with improvement in FD symptoms (Faramarzi et al., 2013; Faramarzi et al., 2015; Hamilton et al., 2000) and improvement in psychiatric symptoms (Faramarzi et al., 2015). However, results are mixed regarding the efficacy of autonomic manipulation and relaxation techniques in FD (Bates, Sjöden, & Nyrén, 1988; Haag et al., 2007; Hjelland, Svebak, Berstad, Flatabo, & Hausken, 2007; Lunding et al., 2007; Schurman, Wu, Grayson, & Friesen, 2010), and there is some indication that the benefits of psychological treatment may be similar to those of supportive therapy (Cheng, Yang, Jun, & Hutton, 2007; Hamilton et al., 2000).

Two of the psychological interventions have targeted coping techniques in the FD cohort with evidence of long-term improvements in illness outcomes. The first of these studies, by Cheng et al. (2007), involved Flexible Coping Psychotherapy (FCP) which advocates the discriminative use of coping styles depending on the unique demands of the situation and symptom conditions. When compared to a series of supportive psychotherapy sessions of the same duration (six, one-hour, bi-weekly sessions over 12 weeks), both FCP and supportive therapy interventions were effective in reducing anxiety for individuals with FD, however FCP was also effective in reducing FD symptoms with improvements maintained at 12 month follow up (target group: $n=33$, 63.6% female, mean age: 39.06 years; control group: $n=31$, 71.0% female, mean age: 41.81 years).

Orive et al. (2015) also conducted a trial of an intervention aimed at teaching techniques for coping with FD. Individuals with FD who completed a 10-week program involving standard medical therapy in conjunction with eight group and two individual psychotherapy sessions demonstrated greater improvement in QoL and symptom severity compared to those who completed standard medical therapy alone (intervention group: $n=76$, 84.2% female, mean age: 44.28 years; control group: $n=82$, 80.5% female, mean age: 47.09 years). These improvements persisted at six-month follow up.

Overall, while the results are promising regarding the efficacy of psychological treatment for FD in the reduction of physical symptoms and some psychiatric symptoms, many findings are based on single studies and much further

research is required. However, the findings emphasise the potential for psychological treatment to support individuals in managing the challenges associated with chronic GI conditions.

1.5.6 Gastroparesis and psychological treatments

To date, only one study has investigated the use of psychological intervention for the gastroparesis cohort. Y. Liu, Song, Zhang, Zhou, and Ni (2014) allocated 120 individuals with post-surgical gastroparesis (41.67% female; mean age: 60.5 years; mean duration of gastroparesis symptoms: not provided) to either a mental intervention or control group. Both groups received conventional therapy consisting of three-cavity gastric tube, fasting, parenteral and enteral nutrition, routine nursing care, and health guidance. The mental intervention group received additional therapy including supportive mental consultations, symptomatic bedside mental interventions, and music with simultaneous abdominal acupuncture point massage over a period of 17 days. The authors found that depression scores were similar between the two groups at baseline, however at 3, 7, 10, and 17 days the intervention group demonstrated significantly lower depression levels. The intervention group also displayed improved gastric function, including shorter gastric drainage time, and fewer days spent in hospital. Unfortunately, as the intervention was comprised of multiple approaches, the true impact of the mental consultations cannot be determined.

Another study by Rashed et al. (2002) investigated the use of autonomic training in individuals with chronic gastric motility disorders. The study did not specify which disorders the participants suffered from, therefore making it impossible to know the benefit for individuals with gastroparesis specifically, however the results are still of interest. In the study, 26 participants (88.46% female; mean age: 33.6 years; mean duration of gastroparesis symptoms: not provided) with chronic nausea, vomiting, bloating, anorexia, and early satiety underwent eight sessions of autonomic training with directed imagery. The 30-minute training sessions were divided into relaxation, where participants were asked to think about events that helped them to relax, and stimulation phases where participants were instructed to think about aggravating events. During these phases, participants were instructed to increase or decrease certain

autonomic functions, using feedback from monitors that displayed participants' blood pressure, heart rate, skin temperature, blood flow, respiration, and GI wave recordings. While 58% of participants demonstrated improvement in GI symptoms through the training, individuals with the most severely delayed gastric emptying time did not respond well to the program.

1.5.7 Summary

The use of psychological treatments in chronic illness cohorts has been studied extensively, however the heterogeneity of data has made it difficult for reviewers to form conclusions regarding the efficacy of psychological interventions in general. Rather, it has been demonstrated that specific types of therapy may benefit different cohorts, depending on outcome measures, and the duration of treatment and follow-up. This has been illustrated in IBD, IBS, and FD cohorts, wherein different modalities of therapy (e.g., psychodynamic, hypnotherapy, CBT) have been associated with improvements across a range of physical and psychological outcomes (e.g., depression, anxiety, QoL, symptom severity).

Despite considerable literature investigating the use of psychological interventions in chronic illness cohorts, only one study has focused specifically on individuals with gastroparesis. While the study demonstrated that psychological intervention was associated with improved gastric function and depression levels at follow up, the intervention involved a combination of therapeutic approaches making it difficult to interpret the impact of the psychological components of the intervention. However, combined with evidence from other chronic illness cohort studies, this result highlights the need for further research into the potentially positive impact of psychological intervention for individuals with gastroparesis.

1.6 Possible mediators between symptom severity and psychosocial outcomes

There is considerable evidence supporting the development of a psychological intervention for the gastroparesis cohort. However, in order to develop the most appropriate psychological intervention for individuals with gastroparesis, it is important to first identify the psychological processes that must be targeted by the intervention.

An individual's response to chronic illness demands can be positive or negative, and is influenced by a range of individual qualities such as personality, motivation, and coping style (Dekker & de Groot, 2018). These qualities may explain how two individuals can experience the same illness and level of symptom severity yet report differing levels of distress and QoL (White, 2001). The following section discusses psychological processes that may help or hinder an individual in adjusting to gastroparesis, thus mediating (a mediator being defined as an internal process that occurs between stimulus and response, accounting for some or all of the relationship (Baron & Kenny, 1986)) the relationships between symptom severity and psychosocial outcomes. Two key potential mediators will be considered below: coping styles and illness perceptions.

1.6.1 Coping styles

One of the psychological factors that may mediate the relationship between gastroparesis symptom severity and psychosocial outcomes is the use of coping strategies. In general terms, coping refers to how an individual manages stress (Lazarus & Folkman, 1984). The coping strategies that an individual employs will depend firstly on his/her appraisal of the stressful event or threat (Carver, Scheier, & Weintraub, 1989), and secondly, on the resources that are available (e.g., social support, personality characteristics) (Goodhand & Rampton, 2008; Harding, Liu, Catalan, & Sherr, 2011). Understanding of the advantages and disadvantages associated with different coping strategies is developing over time as the conceptualization of coping styles and patterns evolves.

In a critical review of coping scales, Steed (1998) identified that coping was originally conceptualised as a disposition or trait that endures over the lifespan. However, in the 1980s, Lazarus and colleagues (Lazarus & Folkman, 1984) argued that there is both stability and change in coping styles, with variability across situations or episodes. Lazarus and Folkman (1984) identified two types of coping: problem-focused and emotion-focused. Problem-focused coping refers to problem-solving actions that are directed toward the cause of the stress (e.g., creating a plan or strategy), while emotion-focused coping aims to diminish the emotional distress associated with the event or situation (e.g., trying to make it seem more positive).

Finding that the two-category approach to coping may be overly simplistic, Carver et al. (1989) studied further possible distinctions in coping styles. Carver et al. argued that emotion-focused coping and problem-focused coping may each contain both positive and negative attributes and that these need to be measured separately in order to be properly understood. Accordingly, Carver et al. developed a new coping inventory (the COPE) that was proposed to assess three key dimensions of coping: problem-focused, emotion-focused, and maladaptive or disengaged. The coping dimensions were assessed by 13 distinct scales (see Table 1 for coping dimensions, scales, and examples of scale items), however after completion of initial research reports, the authors added two additional coping scales: humour (e.g., “I’ve been making jokes about it”) and alcohol/drug use (e.g., “I’ve been using alcohol or other drugs to help me get through it”). Importantly, the authors acknowledge that the relative benefit or dysfunction of coping responses may be dependent on the person using them, and the situation they are being used in. For example, distraction or ignoring an illness may become an adaptive response in cases where there are no treatment options available. Given this, Carver et al. (1989) recommend performing a factor analysis to determine the composition of coping factors for the cohort being evaluated.

Table 1

Examples of problem-focused, emotion-focused, and maladaptive coping styles, from the work of Carver et al. (1989)

Coping styles	Example item
<i>Problem-focused coping</i>	
- Active coping	I take additional action to try to get rid of the problem
- Planning	I try to come up with a strategy about what to do
- Suppression of competing activities	I put aside other activities in order to concentrate on this
- Restraint coping	I force myself to wait for the right time to do something
- Seeking of instrumental social support	I ask people who have had similar experiences what they did
<i>Emotion-focused coping</i>	
- Seeking of emotional social support	I talk to someone about how I feel
- Positive reinterpretation	I look for something good in what is happening
- Acceptance	I learn to live with it
- Denial	I refuse to believe that it has really happened
- Turning to religion	I seek God's help
<i>Maladaptive coping</i>	
- Focus on and venting of emotions	I get upset and let my emotions out
- Behavioural disengagement	I give up the attempt to get what I want
- Mental disengagement	I turn to work or other substitute activities to take my mind off things

1.6.1.1 *Chronic illness and coping*

Despite the literature presenting different approaches to the conceptualization and measurement of coping, there is considerable evidence for the importance of coping styles in cases of chronic illness. Studies examining the role of coping styles in chronic illness cohorts (e.g., chronic kidney disease [CKD], type I and II diabetes, multiple sclerosis, rheumatoid arthritis, Huntington's disease, end stage renal disease, chronic heart failure) have found associations between the use of certain coping styles and psychosocial outcomes (e.g., Di Benedetto et al., 2014; Dorrian, Dempster, & Adair, 2009; Evans & Norman, 2009; Gaston-Johansson, Haisfield-Wolfe, Reddick, Goldstein, & Lawal, 2013; Huang et al., 2015; Kaptein et al., 2006; Kiebles, Doerfler, & Keefer, 2010; Knowles, Swan, Salzberg, Castle, & Langham, 2014; Knowles, Tribbick, et al., 2014; Kraaij & Garnefski, 2015; Kristofferzon, Lindqvist, & Nilsson, 2011; Mikula et al., 2015; Roubinov, Turner, & Williams, 2015; Tan-Kristanto & Kiropoulos, 2015; Ziarko, Mojs, Piasecki, & Samborski, 2014). For example, coping styles considered to be more adaptive (e.g., acceptance, positive reframing, religious coping, active, emotion-focused, minimising) have been associated with lower levels of anxiety and depression (e.g., Huang et al., 2015; Knowles, Cook, & Tribbick, 2013; Kraaij & Garnefski, 2015; Roubinov et al., 2015; Tan-Kristanto & Kiropoulos, 2015). Conversely, coping strategies considered to be more maladaptive (e.g., denial, substance use, behavioural disengagement, self-blame, venting) have been associated with greater anxiety, depression and general psychological distress (Dorrian et al., 2009; Evans & Norman, 2009; Gaston-Johansson et al., 2013; Kaptein et al., 2006; Knowles, Swan, et al., 2014; Knowles, Tribbick, et al., 2014; Kraaij & Garnefski, 2015; Tan-Kristanto & Kiropoulos, 2015; Ziarko et al., 2014). Similarly maladaptive coping styles have also been associated with poorer QoL (e.g., behavioural disengagement, venting, self-distraction, self-blame, substance use, and avoidance) (Dorrian et al., 2009; Huang et al., 2015; Kiebles et al., 2010).

However, the relationship between coping style and psychosocial outcome is not always consistent across studies and cohorts. For example, while active forms of coping have been associated with lower levels of depression in individuals with type II Diabetes (Huang et al., 2015), they have also been associated with increased anxiety and depression in individuals with multiple

sclerosis (Roubinov et al., 2015). Similarly, in a study of individuals with CKD ($n=80$; 37.5% females; mean age: 62.66 years), Knowles, Swan, et al. (2014) found that both adaptive and maladaptive coping styles were associated with increased psychological distress. Heterogeneity in the use of coping scales throughout the literature may account for some inconsistencies in findings (McCombie, Mulder, & Geary, 2015; Surdea-Blaga, Baban, & Dumitrascu, 2012), however, as explained by Lazarus and Folkman (1984) and Carver et al. (1989), it must also be considered that coping styles may have a different impact in different situations, for different people. Thus, the adaptive qualities of certain coping styles may differ depending on the characteristics of the cohort being studied (e.g., diagnosis, time since diagnosis, disease severity, individual psychosocial factors).

Once again, research into the role of coping styles in the gastroparesis cohort is extremely limited. Therefore the following sections will focus on studies specific to the more highly researched GI cohorts that have been highlighted throughout this chapter, including IBD, IBS, and FD. Finally, the section will conclude by reviewing evidence pertaining specifically to the gastroparesis cohort.

1.6.1.2 IBD and coping

In terms of GI disease, coping has been most extensively explored within the IBD population. In 2013, McCombie, Mulder, and Geary (2013) conducted a comprehensive systematic review of literature investigating the coping styles of individuals with IBD ($k=39$). The reviewers found evidence that individuals with IBD tend to use more avoidant coping than healthy individuals and, among those with poorer psychological affect, also demonstrated greater emotion-focused coping. In fact, the most common finding in the review was that emotion-focused coping was associated with poorer psychological outcomes, while problem-focused coping was associated with better psychological outcomes, albeit inconsistently. A more recent systematic review ($k=25$) of psychological factors that may influence adjustment to IBD also concluded that emotion-focused coping was associated with increased psychological distress and reduced QoL (Jordan, Sin, Fear, & Chalder, 2016).

While these findings highlight the importance of coping styles for the IBD cohort, it should be noted that results have not been completely consistent. For

example, Larsson, Loof, Ronnblom, and Nordin (2008) did not find any association between coping and QoL ($n=742$, 51% female, mean age: 45 years, mean disease duration: 17 years), and Knowles, Wilson, Connell, and Kamm (2011) found that problem-focused coping was associated with lower levels of psychological distress in individuals with Crohn's disease (CD; $n=96$, 64.6% female, mean age: 38.0 years, mean disease duration: 11 years). As identified by McCombie et al. (2015), a possible reason for such inconsistencies is the use of a variety of different coping measures throughout the IBD literature, however there may also be individual differences in disease characteristics that can influence the use and effectiveness of different coping styles (McCombie et al., 2013).

The severity or activity of IBD is one of the characteristics that has been investigated in relation to coping style use in the cohort. For example, greater IBD severity has been associated with increased use of avoidant (Voth & Sirois, 2009) and problem-focused coping (Knowles et al., 2011). There is also evidence that coping styles may have a different impact on psychosocial outcomes depending on IBD status (i.e., relapse, remission). For example, Petrak et al. (2009) found that depressive coping had a negative impact on QoL only for individuals in an active state of disease, not for those in remission ($n= 1322$; 52.2% female; mean age: 39.6 years; mean disease duration: 11.3 years).

Coping styles may also play a mediating role in the relationship between other psychological processes and psychosocial outcomes in IBD cohorts. Voth and Sirois (2009) ($n=259$, 76.1% female, mean age: 36.6 years, mean disease duration: 9.3 years) found that attributions of self-blame were associated with increased avoidant coping and, in turn, poor psychological adjustment. Conversely, beliefs about responsibility for one's own health were associated with decreased avoidant coping and, in turn, improved psychological adjustment (Voth & Sirois, 2009). Similarly, Knowles et al. (2011) found that poor illness perceptions (illness perceptions will be discussed further in section 1.6.2 and refer to a cognitive representation of an illness (Leventhal et al., 1984)) were associated with increased emotion- and problem-focused coping in individuals with CD, with increased emotion-focused coping also being associated with greater anxiety and depression ($n=96$, 64.6% female, mean age: 38.0 years, mean disease duration: 11 years). The current findings suggest that coping styles may play an important

mediating role in psychosocial outcomes for individuals with IBD and a number of recommendations have been made for the use of psychological interventions that target coping strategies and related psychological processes (Knowles et al., 2011; McCombie et al., 2013, 2015; Sirois & Hirsch, 2017; Sweeney et al., 2018). Thus, the IBD literature provides considerable support for the exploration of coping styles in the gastroparesis cohort.

1.6.1.3 *IBS and coping*

The impact of coping style on psychosocial outcomes has also been explored in IBS populations, however the area remains understudied (Wilpart et al., 2017). IBS cohorts are reported to display lower coping ability and use less effective coping strategies than healthy individuals (Grodzinsky et al., 2015; M. P. Jones, Wessinger, & Crowell, 2006; Phillips, Wright, & Kent, 2013; Roohafza et al., 2016) and individuals with IBS-like symptoms who have not sought medical help (Hauser, Pletikotic, & Tkalcic, 2014). Additionally, lower physical and psychological coping resources have been associated with higher anxiety and depression symptoms in individuals with IBS (Wilpart et al., 2017). Further, increased maladaptive coping has been associated with greater psychological distress and decreased QoL (Knowles, Austin, et al., 2017), while avoidance and suppression have been associated with higher levels of depression in IBS cohorts (Sugawara et al., 2017). There is also evidence that maladaptive coping styles may have a greater impact on psychological distress and QoL in individuals with IBS than those with IBD (Crane & Martin, 2004; Seres et al., 2008). However, once again, a number of different questionnaires have been used in studies assessing coping styles in IBS cohorts, thereby making it difficult to form general conclusions (Surdea-Blaga et al., 2012).

Like IBD, the psychological characteristics and processes that may influence the use of coping styles in IBS cohorts have also been investigated. For example, Knowles, Austin, et al. (2017) demonstrated that illness perceptions directly influence maladaptive coping in individuals with IBS ($n=131$; 77.9% female; mean age: 37.85 years). Additionally, a review by Surdea-Blaga et al. (2012) concluded that an individual's personality traits may influence coping strategies as well. The authors report that neuroticism in particular is a predictor of illness perceptions

and influences coping strategies. While further research into factors that may interact with coping styles to influence psychosocial outcomes is required, the findings in IBS cohorts nonetheless highlight the positive potential for psychological interventions that focus on strengthening coping resources and strategies for individuals with a chronic GI condition (Knowles, Austin, et al., 2017; Sugawara et al., 2017; Wilpart et al., 2017).

1.6.1.4 *FD and coping*

Some findings within FD cohorts are comparable to those in IBS. For example, when compared to healthy individuals, individuals with FD have also displayed decreased adaptive and increased maladaptive coping styles (Faramarzi et al., 2012; Mazaheri, Afshar, Nikneshan, & Adibi, 2016), in addition to increased negative appraisal (De la Roca-Chiapas et al., 2010), reduced task-oriented coping (Tominaga et al., 2007), reduced problem-focused strategies and less reliance on social support (S. Lee et al., 2000). Unlike the IBS findings, however, individuals with FD symptoms who sought medical consultation have demonstrated more problem-focused coping and less emotion-focused coping than non-consulters (Cheng, 2000) ($n=129$; 62.8% female; mean age: 38.6 years). Additionally, when compared to a duodenal ulcer cohort, individuals with FD have displayed more negative appraisal, more problem-focused coping, and less emotion-focused coping (Cheng, Hui, & Lam, 2002) ($n=60$; 43.3% female; mean age: 52.03 years). Unfortunately, there is very limited understanding of how these coping patterns relate to psychosocial outcomes in the FD cohort.

Coping flexibility has been one of the focal points for research into the relationship between FD and coping. In particular, Cheng, Hui, and Lam (1999) ($n=90$, 46.7% female, age range: 35-62 years) found that individuals with FD tended to use direct-action, or problem-solving, strategies regardless of the stressor, while healthy individuals chose different strategies depending on the controllability of the stressor. Cheng et al. (1999) explain that problem-focused coping may be more useful for events over which the individual has some control, while emotion-focused coping may be more useful for uncontrollable events. Further, it is proposed that using problem-focused coping strategies in uncontrollable situations may actually provoke further anxiety and influence

illness outcomes in the cohort. Congruent with this suggestion, Cheng, Hui, and Lam (2004) found that individuals with FD who had higher levels of coping flexibility tended to report less perceived symptom severity than those with lower coping flexibility (n=396, 59.1% female, mean age: 43.29 years).

In conjunction with the promising results from psychological interventions mentioned in Section 1.5.5 which focused on improving coping skills in individuals with FD, these findings further highlight the potential benefit of coping-style targeted therapies in cohorts with upper GI disorders.

1.6.1.5 Gastroparesis and coping

To date, there have not been any studies investigating the relationship between coping styles used by individuals with gastroparesis and psychosocial outcomes, however qualitative studies provide some initial insight. A qualitative study by Bielefeldt et al. (2009) observed that some individuals with gastroparesis benefited from using relaxation techniques (n =55; 80.0% females; mean age: 42.4 years; mean duration of gastroparesis symptoms: 32 months). Another qualitative study by Bennell and Taylor (2013) reported that common adaptive strategies of individuals with gastroparesis included comparing oneself to others who appear less fortunate, planning for symptom flares, accepting the limitations of the illness, and finding ways to manage uncomfortable social situations - often through avoidance or trying to act like a 'normal' and healthy person (n =9; 88.9% female; 7 participants were aged between 31-40 years; mean duration of gastroparesis symptoms: more than one year).

1.6.1.6 Summary

Despite inconsistencies in the way that coping has been assessed throughout the literature, there is considerable evidence that coping styles have an influence on psychosocial outcomes in chronic illness, including GI conditions. Individuals with GI conditions tend to demonstrate greater use of coping styles that have been associated with increased psychological distress and poorer QoL. There is also evidence that factors such as disease severity, context, and illness perceptions may influence the outcomes associated with different coping styles. These findings encourage the exploration of coping styles as a potential mediator

in the relationship between symptom severity in gastroparesis and psychosocial outcomes.

The relationships between gastroparesis and coping styles have not yet been explored. Qualitative studies have provided some indication of the strategies individuals with gastroparesis use to manage the condition, however the impact of different coping styles on psychosocial outcomes is not understood. Further, the potential mediating role of coping styles has not been explored in the gastroparesis cohort. An exploration of the coping styles used by individuals with gastroparesis, and how they may be beneficial or detrimental, would provide much needed insight into the psychological processes associated with the condition. These findings would be of great assistance in the development of future psychologically-based interventions for the gastroparesis cohort.

1.6.2 Illness perceptions

Another psychological process that may influence how well an individual adjusts to living with gastroparesis is illness perceptions. Illness perceptions are cognitive representations that an individual creates in order to make sense of a health threat (i.e., their illness). Illness perceptions are based on the information that is available to the individual about their condition (e.g., from social communication or significant others) as well as their current experience of the illness (e.g., current symptoms) (Leventhal et al., 1984). The way that an individual perceives their illness has been shown to influence a number of health outcomes, including physical symptoms, psychological distress, and QoL (e.g., Nowicka-Sauer et al., 2015; Parry, Corbett, James, Barton, & Welfare, 2003; Vollmann, Scharloo, Langguth, Kalkouskaya, & Salewski, 2013). See Table 2 for a summary of the five key dimensions of illness perception.

Table 2

Key dimensions of illness perceptions

Illness perception	Description
Cause	Beliefs that an individual holds about the cause of their illness.
Consequence	Beliefs about the influence of an illness on QoL.
Identity	Beliefs about the label and symptoms associated with an illness.
Timeline	Beliefs about the course and duration of an illness.
Cure/controllability	Beliefs about the effectiveness of coping behaviours and treatments targeting an illness.

Note. See Broadbent, Petrie, Main, and Weinman (2006) for further details about these dimensions.

1.6.2.1 *Chronic illness and illness perceptions*

Illness perceptions have been investigated across a wide range of chronic health conditions. Results from these studies indicate that more positive illness perceptions (e.g., belief in the efficacy of treatment, feelings of control and manageability in relation to the illness, belief that the illness is chronic rather than acute) tend to be associated with better physical health and greater vitality (Gray & Rutter, 2007; Heijmans & de Ridder, 1998; Rozema, Vollink, & Lechner, 2009), improved QoL (Aalto et al., 2006; Gray & Rutter, 2007; Weldam, Lammers, Heijmans, & Schuurmans, 2014), and better psychological health (Greco et al., 2014; Heijmans & de Ridder, 1998; Kemp, Morley, & Anderson, 1999; Petrie, Weinman, Sharpe, & Buckley, 1996; Rozema et al., 2009; Vollmann et al., 2013).

Conversely, more negative illness perceptions (e.g., strong emotional response to the illness, belief that the illness has more severe consequences, less belief in the controllability of the illness) have been associated with poorer physical health status (Aalto et al., 2006; Borge, Moum, Puline Lein, Austegard, & Wahl, 2014; Carlisle, John, Fife-Schaw, & Lloyd, 2005; Heijmans, 1999; Heijmans & de Ridder, 1998; Kaptein et al., 2006; Pagels, Klang Soderquist, & Heiwe, 2015; Rozema et al., 2009; Scharloo et al., 1998; Vaughan, Morrison, & Miller, 2003),

impaired QoL (Borge et al., 2014), increased psychological distress (Carlisle et al., 2005; Cherrington, Moser, Lennie, & Kennedy, 2004; Heijmans, 1999; Heijmans & de Ridder, 1998; Kemp et al., 1999; Nowicka-Sauer et al., 2015; Philip, Lindner, & Lederman, 2009; Rees, Fry, Cull, & Sutton, 2004; Rozema et al., 2009; Vaughan et al., 2003), decreased social functioning (Heijmans, 1999; Heijmans & de Ridder, 1998; Scharloo et al., 1998), and lower self-esteem (Vaughan et al., 2003). Evidence also suggests that illness perceptions play a role in determining rehabilitation and treatment adherence (French, Cooper, & Weinman, 2006; Helder et al., 2002; Horne & Weinman, 2002; Lau-Walker, 2007; Llewellyn, Miners, Lee, Harrington, & Weinman, 2003; Petrie et al., 1996; Whitmarsh, Koutantki, & Sidell, 2003). These findings have led to the argument that challenging unhelpful illness perceptions may be an important aspect of treatment for chronic illness (e.g., Borge et al., 2014; S. S. Christensen, Frostholm, Ornbol, & Schroder, 2014; Petrie, Cameron, Ellis, Buick, & Weinman, 2002; Petrie, Jago, & Devcich, 2007).

1.6.2.2 IBD and illness perceptions

Investigations into the relationship between IBD and illness perceptions have led to similar findings. A collection of IBD studies by Knowles and colleagues has demonstrated that poorer illness perceptions are associated with reduced health status and greater IBD severity (Knowles, Cook, et al., 2013; Knowles et al., 2011), as well as increased anxiety and depression (Knowles, Cook, et al., 2013; Knowles, Gass, & Macrae, 2013; Knowles et al., 2011). Knowles, Gass, et al. (2013) also demonstrated that poorer illness perceptions had a negative influence on body image, self-consciousness, sexual problems, and sexual satisfaction in individuals with IBD.

There are also some findings regarding the influence of individual illness perceptions on IBD outcomes. Dorrian et al. (2009) identified that believing the condition to be more severe, and with more serious consequences, was associated with increased psychological distress, impaired QoL, and poorer functional independence. Additionally, a belief that the illness had a cyclical timeline was also associated with increased psychological distress and lower QoL. In contrast, Kiebles et al. (2010) found that emotional representation of illness had the most significant influence on IBD outcomes, and was associated with poorer adjustment,

psychological status, and QoL. Variation in the influence of individual illness perceptions suggests that a belief may be more adaptive for one person than another, depending on their unique situation. For example, recognising the cyclical nature of IBD symptoms may lead to frustration for some individuals, while for others the increased understanding may lead to greater acceptance and adaptation to the condition.

1.6.2.3 *IBS and illness perceptions*

Illness perceptions have also been associated with a number of health outcomes in IBS. Consistent with findings for other chronic illnesses and the IBD literature, more negative illness perceptions have been associated with poorer QoL, higher anxiety, depression, and psychological distress in IBS sufferers (Ben-Ezra, Hamama-Raz, Palgi, & Palgi, 2015; Chilcot & Moss-Morris, 2013; De Gucht, 2015; Knowles, Austin, et al., 2017; C. L. Rutter & Rutter, 2002). Illness perceptions have also been found to significantly predict IBS outcomes up to 12 months later (C. L. Rutter & Rutter, 2007).

Chilcot and Moss-Morris (2013) found that illness perceptions were improved through a course of CBT that was mostly self-directed ($n = 64$; 73% female; mean age CBT group: 40 years; mean age treatment as usual group: 39 years; mean duration of IBS symptoms: not provided). Compared to participants who were receiving treatment as usual, participants who underwent the intervention displayed greater perceived control over IBS, greater understanding of the illness, and reduced perception of the severity and consequences of the condition. These changes ultimately predicted improved work performance and social adjustment.

Further patterns have been identified between the dimensions of illness perception and illness outcomes. Higher anxiety and depression have been associated with beliefs that psychological factors were the cause of the illness, that the illness had serious consequences, and that the sufferer had little control over their IBS symptoms (C. L. Rutter & Rutter, 2002). Lower QoL has been linked to having a strong illness identity, belief that the illness had serious consequences, scoring higher on emotional representation, and feeling less control over symptoms (De Gucht, 2015; C. L. Rutter & Rutter, 2002). Finally, lower health

satisfaction has been associated with strong illness identity and consequences, and less feeling of control (C. L. Rutter & Rutter, 2002).

1.6.2.4 FD and illness perceptions

At present only one study has assessed the influence of illness perceptions in an FD cohort. The study by Parry et al. (2003) ($n = 217$; 57% female; mean age: 46.6 years) assessed individuals who were currently experiencing acute gastroenteritis and found that individuals who had a prior FGID were likely to experience more symptoms, and thought their illness would last longer and have more consequences than those without prior FGID. Additionally, individuals who went on to develop post-infectious FGID reported more symptoms, believed their gastroenteritis to be more serious, and thought the illness would last longer than those who did not develop a FGID. Although the authors state that FD sufferers were included in their FGID sample, they did not identify how many participants had FD. Additionally, the results of the FD cohort were not analysed separately from other participants. Therefore, the influence of illness perceptions on the outcomes of FD specifically is still uncertain.

1.6.2.5 Gastroparesis and illness perceptions

To date, there have not been any studies to investigate the influence of illness perceptions on gastroparesis outcomes. However, a recent study by Yu et al. (2017), noted that 47% of gastroparesis sufferers expected their health to deteriorate over time. Qualitative studies also indicate that individuals with gastroparesis have concerns about never being well again, about the challenges of trying to control their symptoms, and about the extensive impact that the condition has over their lives (Bennell & Taylor, 2013; Bielefeldt et al., 2009). Additionally, it has been found that feelings of hope may play a role in the psychological adjustment of individuals receiving a gastric pacemaker (Parenteau, Gallant, Sarosiek, & McCallum, 2006).

1.6.2.6 Summary

Research indicates that illness perceptions play a substantial role in the outcomes of chronic illnesses. Findings across chronic illness cohorts, including

IBD and IBS, indicate that positive illness perceptions are associated with better physical and psychological wellbeing, and greater QoL. Conversely, more negative illness perceptions have been associated with poorer physical and psychological health, and worse QoL. The influence of individual illness perceptions on various health outcomes has been studied, however further research is required before a consensus can be reached on the effects of specific dimensions of illness perceptions. Further investigation into the influence of illness perceptions in FD cohorts is also required.

To date, there has been no research into the effect of illness perceptions on health outcomes in gastroparesis cohorts. However, it is clear that individuals with gastroparesis have many concerns about living with the condition and what the future may hold. Common findings across other chronic illness cohorts suggest that identifying the role of illness perceptions in gastroparesis health outcomes may be an important step toward developing effective psychological support for individuals with this condition.

1.6.3 The Common Sense Model (CSM)

When investigating the impact of psychological processes on health outcomes, it is essential to work within an established and validated theoretical model. One such theoretical model that has demonstrated efficacy across a range of chronic illnesses, including GI disorders, is the CSM (for a review see Hagger & Orbell, 2003). Developed by Leventhal and colleagues (1984), the CSM (see Figure 2) proposes that when confronted with an illness, an individual creates a mental representation based on their experience of the illness and on information they receive about it (e.g., “I have no control over my gastroparesis”). This illness perception influences illness outcomes directly (e.g., anxiety, depression, QoL) but also affects the type of coping strategies that an individual employs to manage the illness. According to the model, whether an individual uses adaptive (e.g., looking for something good in what is happening) or maladaptive (e.g., criticising self) coping styles will also directly influence illness outcomes. Additionally, feedback loops allow the individual to appraise and evaluate at each stage of the model.

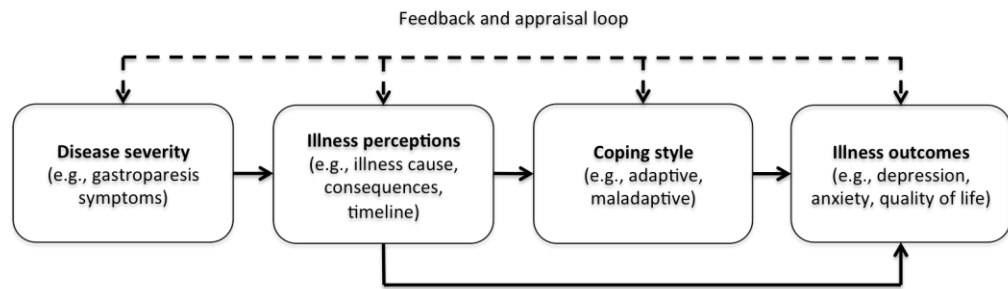


Figure 2. The Common Sense Model (Leventhal et al., 1984), adapted by Knowles et al. (2011).

1.6.4 Chronic illness and the CSM

In 2003, Hagger and Orbell systematically reviewed evidence for the CSM across 45 studies that were available at the time. A total of 23 different illness cohorts were involved in the meta-analysis, including chronic conditions such as diabetes mellitus (e.g., Eiser, Riazi, Eiser, Hammersley, & Tooke, 2007; Glasgow, Hampson, Strycker, & Ruggiero, 1997), rheumatoid arthritis (e.g., Hampson, Glasgow, & Zeiss, 1994; Scharloo et al., 1998), and chronic fatigue syndrome (e.g., Heijmans, 1998; Moss-Morris, Petrie, & Weinman, 1996). Based on their systematic review of the literature, the authors concluded that there was sufficient evidence of the theoretical relationships between illness perceptions and coping styles, as well as between illness perceptions and illness outcomes. However, the authors also noted insufficient evidence for the mediating hypothesis of the CSM since only a limited number of studies had examined the relationship between coping and illness outcomes or the potentially mediating role of coping in the model. Despite this inconsistency, Hagger and Orbell (2003) concluded that there was some support for the validity of the CSM and emphasised the need for further research addressing the influence of coping styles in the model. The authors also identified that assessing the CSM through the use of path analysis would be an important step for future research.

Due to continued utilisation of the CSM across multiple illness cohorts over the past decade, Hagger, Koch, Chatzisarantis, and Orbell (2017) recently revisited

the literature. In addition to a systematic review of the CSM literature, Hagger et al. (2017) also conducted an updated meta-analysis ($k=254$, $N=52,599$) and path analyses, with results indicating that the relationships between CSM components may be more complex than originally thought. In testing the sufficiency of the CSM, Hagger et al. (2017) found that while illness perceptions do have an indirect effect on outcomes via coping styles, illness perceptions also influence outcomes directly. However, the authors suggest that this finding might have been influenced by the use of generalised coping scales in many of the studies, which may not accurately reflect the coping styles relevant to different illness cohorts.

Hagger et al. (2017) also demonstrated that illness perception dimensions and coping styles could be associated with different outcomes depending on moderating contextual factors (e.g., illness characteristics, individual differences/personality, and emotional representations). For example, when perceived consequences motivated problem-focused coping it was associated with positive illness outcomes, however when perceived consequences motivated avoidance it was associated with negative illness outcomes. It is important to note, however, that problem-focused and emotion-focused coping could lead to either positive or negative illness outcomes. For example, the authors explain that problem-focused coping strategies may not be as effective for individuals who have an illness that is characterised as uncontrollable, and in this case adopting emotion-focused coping may actually be beneficial. Hagger et al. (2017) presented a speculative revision of the CSM reflecting the above findings.

The meta-analysis by Hagger et al. (2017) also identified a number of factors that have limited literature to date. Firstly, the majority of studies have relied on bivariate analyses, which do not account for the dynamic nature of the CSM, and it has therefore been encouraged that path analyses or SEMs are utilised in future. The importance of assessing multiple illnesses, illness perceptions, coping styles, and outcomes in order to better understand possible mediation pathways in different contexts was also emphasised. In particular, the authors discuss the importance of determining adaptive and maladaptive patterns that are unique to specific illness types in order to construct behavioural interventions that target the relevant illness perceptions and coping styles.

1.6.5 *IBD and the CSM*

The full CSM has been assessed three times in IBD cohorts. The first study to investigate the model in an IBD cohort reported that coping styles did not mediate the relationship between illness perceptions and psychological adjustment to IBD (Dorrian et al., 2009). Additionally, the study used hierarchical regression to assess the model rather than path analysis or SEM, and therefore patterns between model constructs may have been obscured. Additionally, coping styles were grouped together in one hierarchical step, leaving confusion over the relative contribution of problem-focused, emotion-focused, and maladaptive coping strategies to psychological adjustment.

Studies using SEM to assess the CSM in individuals with IBD have provided more consistent findings. For example, SEM studies by Knowles and colleagues have provided evidence that disease activity influences illness perception (Knowles, Cook, et al., 2013; Knowles et al., 2011), and that illness perceptions influence psychological outcomes (i.e., depression, anxiety) in IBD cohorts (Knowles, Cook, et al., 2013; Knowles et al., 2011). Additionally, Knowles, Cook, et al. (2013) demonstrated that maladaptive coping styles mediate the relationship between illness perceptions and anxiety and depression in individuals who had a stoma due to IBD. Further, in a study of individuals with CD, Knowles et al. (2011) reported that emotion-focused coping mediated the relationship between illness perceptions and depression and anxiety, while problem-focused coping mediated the relationship between illness perceptions and depression. The contrast in findings between Knowles and colleagues' SEM based studies and the study by Dorrian et al. (2009) highlights the importance of analysing the value of different coping styles separately and conducting SEM when assessing the complex pathways of the CSM.

1.6.6 *IBS and the CSM*

The mediation hypothesis of the CSM has also been assessed three times in IBS cohorts. The first study to examine the roles of illness perceptions and coping styles in an IBS cohort found evidence that illness perceptions were a predictor of QoL and psychological adjustment, and that coping style mediated this relationship in some cases (C. L. Rutter & Rutter, 2002). However, a follow-up longitudinal

study provided no evidence of mediation by coping styles (C. L. Rutter & Rutter, 2007). Unfortunately, C. L. Rutter and Rutter (2007) do not provide details regarding the regression-based path analysis that was conducted to assess mediation in the follow up study. This creates uncertainty around whether illness perceptions were modeled separately or as a group, and whether coping strategies were represented individually, categorised according to style, or grouped together. These factors may have influenced the potential mediating role of coping in the path analysis.

A recent study by Knowles, Austin, et al. (2017) sought to better understand these relationships by utilising SEM. Prior to conducting the SEM, illness perceptions and coping styles were subjected to factor analysis. This study found support for the CSM where IBS severity influenced illness perceptions, illness perceptions mediated the relationship between IBS severity and maladaptive coping, and the relationship between illness perceptions and illness outcomes (i.e., psychological distress, QoL) was mediated by maladaptive coping. These studies highlight the importance of clarity regarding the way in which CSM components are analysed, the usefulness of the CSM for understanding psychological processes involved in illness outcomes, and the potential value of SEM when assessing the CSM.

1.6.7 Gastroparesis, FD, and the CSM

To date, the CSM has not been applied to the study of FD or gastroparesis.

1.6.8 Summary

The CSM is a well-developed theoretical model describing the role of psychological processes in illness outcomes. There is strong empirical evidence for the model across multiple chronic illnesses, depicting a complex relationship in which illness perceptions and coping styles mediate the relationship between disease severity and illness outcomes. A recent meta-analysis of the available literature indicates that contextual factors such as illness characteristics may play a moderating role in the relationships between illness perceptions and coping styles, and also whether a particular coping strategy will be adaptive or maladaptive for the individual.

While the CSM has not yet been applied to gastroparesis or FD cohorts, there is promising evidence for its use in chronic illness cohorts, including GI conditions such as IBD and IBS. A key aspect of studies supporting the mediating hypothesis of the CSM in IBD and IBS cohorts is that the impact of different coping styles was assessed separately. In addition, the studies relied on SEM, which aligns well with the dynamic nature of the CSM and has been recommended as an optimal method of testing the model. These studies identify the CSM as a valuable theoretical model on which to base research aimed towards understanding the psychological processes and pathways specific to gastroparesis, which may later be targeted in a psychological intervention.

1.7 Limitations of the research to date

The most obvious limitation of research relating to gastroparesis is the scarcity of it. In general, gastroparesis is a poorly understood condition, with little epidemiological insight, discord around the definition of the disorder and the cause of symptoms (Pasricha & Parkman, 2015), and limited efficacy in many of the treatment options (Abell et al., 2006; Bielefeldt, 2012; Camilleri et al., 2013; Hejazi & McCallum, 2009). At present, the literature indicates an association between gastroparesis, increased psychological distress, and poor QoL (Bielefeldt et al., 2009; Cherian et al., 2012; Cherian et al., 2010; Cutts et al., 2016; Friedenberg et al., 2013; Harrell et al., 2008; Hasler et al., 2010; Hasler et al., 2013; Hasler et al., 2011; Jaffe et al., 2011; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011). However, little more is known about the relationship between gastroparesis and psychosocial outcomes. The inadequacy of information on this topic stands in stark contrast to the numerous studies that have been conducted across other chronic illness cohorts, including GI cohorts such as IBD, IBS and, in some instances, FD.

Although it has been repeatedly recommended that individuals with gastroparesis have access to psychological support and treatment options, there has been minimal investigation into the efficacy of such treatment for the cohort. Moreover, the studies that have been conducted are severely limited by lack of clarity or methodological limitations (e.g., Y. Liu et al., 2014; Rashed et al., 2002). In addition, there is a dearth of knowledge regarding the psychological processes or

mediators that assist an individual in adapting to life with gastroparesis, which therefore would be best targeted in a psychological intervention for the gastroparesis cohort. To date, the majority of understanding must be gleaned from qualitative studies, or extrapolated from studies utilising similar, but more thoroughly researched, GI cohorts.

In order to progress towards the development of a targeted psychological intervention for the gastroparesis cohort, a greater understanding of the related psychosocial factors and potential psychological mediators of change (e.g., illness perceptions, coping) is required. While qualitative studies and research across other cohorts can provide a basis from which to build understanding of what it is like to live with gastroparesis, and the psychological mechanisms that may advantage or disadvantage individuals with gastroparesis, quantitative studies can take this information further through predictive modeling using validated theoretical models of health. Gathering data relating to the potential psychological mediators of change in illness outcomes for individuals with gastroparesis is an essential step toward developing a targeted psychologically-based intervention program for the cohort.

1.7.1 Summary

Considerable research has been conducted to explore psychosocial outcomes, psychological mediators, and psychological interventions across GI conditions such as IBD, IBS, and FD. However, studies pertaining to these topics are scarce in gastroparesis. While the literature indicates an association between gastroparesis, increased psychological distress, and poor QoL, little is understood about the relationships. The use of psychological intervention for individuals with gastroparesis has been poorly researched, and psychological mechanisms that may help individuals adapt to the condition have only been briefly commented on in qualitative studies. Further research into the psychosocial impact of gastroparesis, and the potential psychological mediators of change, is required in order to work towards the development of a psychologically-based intervention for the cohort.

1.8 *Aims of the current research*

Guided by the CSM, this PhD research sought to explore psychological factors and QoL in individuals living with gastroparesis, with the aim of developing an online psychological support program. The project is comprised of four studies.

The first study is a peer-reviewed and published systematic review (Paper 1) that aimed to evaluate literature exploring the psychosocial factors associated with gastroparesis. Before conducting additional explorations into the psychological correlates of gastroparesis, it was deemed necessary to develop a comprehensive understanding of the available literature, including its implications and limitations. This was the first systematic review of literature relating specifically to gastroparesis and psychosocial factors.

The second study is a peer-reviewed and published qualitative exploration (Paper 2) that aimed to develop an understanding of the psychosocial impact of gastroparesis and how individuals cope with the illness. While previous qualitative studies have investigated the impact of gastroparesis, Paper 2 was unique in also focusing on the strategies used by individuals to manage gastroparesis. Gaining insight into the effectiveness of different coping strategies is an important step toward understanding the psychological mechanisms that play a role in the experience of gastroparesis.

The third study is a peer-reviewed and published quantitative exploration (Paper 3) of the psychosocial impact of gastroparesis and the potential psychological mediators of change, which is currently in press. Guided by the CSM, Paper 3 aimed to examine the relationships between gastroparesis symptom severity, illness perceptions, coping styles, QoL, and psychological distress in gastroparesis sufferers. This is the first study to apply the CSM to a gastroparesis cohort, and to evaluate psychological mediators in gastroparesis. In cultivating an understanding of the psychological mechanisms that influence psychological wellbeing in gastroparesis, the study provides guidance for the processes that should be targeted in a psychological intervention for gastroparesis the cohort.

The fourth study, presented as a poster at the NeuroGASTRO 2017 conference (24-26 August, 2017), is a pilot feasibility study of an online psychological intervention program designed to target the psychological distress associated with gastroparesis. This is the first evidence-based, online,

psychological intervention designed specifically for individuals with gastroparesis. This pilot study offers a starting point for the development of further psychological support programs for the gastroparesis cohort.

Ethics approval for the following studies was obtained from the Swinburne University Human Research Ethics Committee, reference number: 2013/261 (see Appendix 1).

Chapter 2: Systematic review

2.1 *Introduction to Paper 1*

As detailed in Chapter 1, although associations between psychosocial factors and gastroparesis have been identified, a comprehensive review of this information has not yet been performed. A review can help to improve understanding of a research topic by providing a summary and evaluation of the available evidence (O'Connor, Whitlock, & Spring, 2017). The purpose of the present paper was to perform a review of the literature addressing key psychological controversies in gastroparesis.

The literature review undertaken in Chapter 1 led to the formulation of clear research questions that were suited to a systematic review. A systematic review gathers all relevant data using a thorough, clearly documented, and reproducible methodology (Higgins & Green, 2011). The methodology is useful for summarising the position of available research, from which informed judgments and recommendations can be made (Higgins & Green, 2011). For these reasons, a systematic approach was determined as the most appropriate method for reviewing literature relating to the psychosocial factors associated with gastroparesis.

The paper, "Psychological controversies in gastroparesis: A systematic review", was co-authored with my supervisors Dr Simon R Knowles and Professor Geoff Hebbard, and was published in the World Journal of Gastroenterology in February 2017. This paper: (1) summarises the studies addressing psychological controversies in gastroparesis; (2) compiles findings; (3) highlights limitations and knowledge gaps in the available research; and (4) provides detailed recommendations for future research in the area. Systematic review protocol was guided by the PRISMA statement, which is endorsed by the Cochrane Collaboration (Moher, Liberati, Tetzlaff, Altman, & The PRISMA Group, 2009).

The following paper is a post-peer-review version of an article published in the World Journal of Gastroenterology. The final authenticated version is available online at: <http://dx.doi.org/10.3748/wjg.v23.i7.1298>. Further publication details are provided in Appendix 2.

2.2 Paper 1

Title: Psychological controversies in gastroparesis: a systematic review

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Author contributions: Woodhouse S, Hebbard G, and Knowles SR contributed to study concept and design; Woodhouse S performed the literature search; Woodhouse S and Knowles SR reviewed and analyzed the literature; Woodhouse S drafted the paper; Hebbard G and Knowles SR revised the paper.

Conflict-of-interest statement: The authors have no conflicting interests to declare.

Data sharing statement: No additional data are available.

Biostatistics statement: The statistical methods of this study were reviewed by Dr Fakir M Amirul Islam from the Department of Statistics, Data Science and Epidemiology, Swinburne University of Technology, Hawthorn, Victoria, 3122, Australia.

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Manuscript source: Invited manuscript

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2.2.1 Abstract

Aim: To systematically review literature addressing three key psychologically-oriented controversies associated with gastroparesis.

Methods: A comprehensive search of PubMed, CINAHL, and PsycINFO databases was performed to identify literature addressing the relationship between gastroparesis and psychological factors. Two researchers independently screened all references. Inclusion criteria were: an adult sample of gastroparesis patients, a quantitative methodology, and at least one of the following: (1) evaluation of the prevalence of psychopathology, (2) an outcome measure of anxiety, depression, or quality of life, (3) evidence of a psychological intervention. Case studies, review articles, and publications in languages other than English were excluded from the current review.

Results: Prevalence of psychopathology was evaluated by three studies (n=378), which found that combined anxiety/depression was present in 24% of the gastroparesis cohort, severe anxiety in 12.4%, depression in 21.8-23%, and somatization in 50%. Level of anxiety and depression was included as an outcome measure in six studies (n=1408), and while limited research made it difficult to determine the level of anxiety and depression in the cohort, a clear positive relationship with gastroparesis symptom severity was evident. Quality of life was included as an outcome measure in 11 studies (n=2076), with gastroparesis patients reporting lower quality of life than population norms, and a negative relationship between quality of life and symptom severity. One study assessed the use of a psychological intervention for gastroparesis patients (n=120) and found that depression and gastric function were improved in patients who received psychological intervention, however the study had considerable methodological limitations.

Conclusion: Gastroparesis is associated with significant psychological distress and poor quality of life. Recommendations for future studies and the development of psychological interventions are provided.

Keywords: Anxiety; depression; gastroparesis; quality of life; psychological distress

Core tip: Gastroparesis is associated with significant psychological distress and poor quality of life. Literature indicates that quality of life is lower in gastroparesis patients than population norms. Further, gastroparesis symptoms are adversely associated with increased anxiety and depression and impaired quality of life. Rates of psychopathology in gastroparesis cohorts range between 21.8 to 50%. Although a psychological intervention for gastroparesis has found improvements in depression and gastric function, it has not been replicated. Further research into potential mediating factors and the development of psychological interventions for individuals with gastroparesis is warranted.

Citation: Woodhouse S, Hebbard G, Knowles SR. Psychological controversies in gastroparesis: A systematic review.

2.2.2 Introduction

Gastroparesis is a gastrointestinal disorder involving delayed gastric emptying in the absence of a mechanical obstruction of the stomach (Tack, 2005). Patients living with gastroparesis typically experience chronic nausea, vomiting, early satiety, postprandial fullness, and in some cases abdominal pain and fatigue (Cherian et al., 2012; Cherian & Parkman, 2012; Dudekula et al., 2011; Soykan et al., 1998; Tang & Friedenberg, 2011). The mean age of diagnosis ranges between 40-45.5 years, with 67-88% of gastroparesis patients being female (Bielefeldt et al., 2009; Borges et al., 2013; Cherian et al., 2010; Dudekula et al., 2011; Hasler et al., 2010; Karamanolis et al., 2007; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011; Soykan et al., 1998).

In Australia, the prevalence of gastroparesis is unknown, however in 2006 the Australian government provided an estimate that 120,000 Australians suffered from severe gastroparesis (Department of Health and Ageing, 2006). The only study to investigate the prevalence of gastroparesis was conducted using medical records in Minnesota (United States) from 1996 to 2006. Jung et al. (2009) found that after adjusting for age and gender (to 2000 US Caucasians), the incidence of definite gastroparesis per 100,000 person years was 9.8 in women, and 2.4 in men. In patients over the age of 60 years, the incidence peaked at 10.5 per 100,000. It has been estimated that approximately one third of gastroparesis patients will be admitted to hospital for the condition (Dudekula et al., 2011), with a disease burden likened to that of Inflammatory Bowel Disease (Jung et al., 2009). In terms of financial burden, Wang and colleagues (Y. R. Wang et al., 2008) reported that in 1995 the costs of gastroparesis in the United States were 47.7 million dollars (primary diagnosis) and 863.3 million dollars (secondary diagnosis), while in 2004 costs were significantly higher at 208.3 million dollars (primary diagnosis) and 3.3 billion dollars (secondary diagnosis).

Individuals living with chronic gastrointestinal illness must make considerable physical, psychological, and social adjustments in order to manage their often debilitating symptoms (Creed et al., 2006; Moss-Morris, 2013). Not surprisingly, patients suffering from chronic gastrointestinal conditions frequently report psychological symptoms, such as anxiety, depression, and impaired quality of life (QoL) (e.g., Aro et al., 2011; Creed et al., 2006; Frank et al., 2002; Glise &

Wiklund, 2002; Gralnek et al., 2000; Haag et al., 2008; Haug et al., 1995; A. A. Mikocka-Walus et al., 2007; Pasricha et al., 2015; Van Oudenhove, Vandenberghe, Vos, Fischler, et al., 2011). With limited treatment options available for gastroparesis, the importance of psychological support or intervention has been repeatedly emphasised in the literature (Abell et al., 2006; Bielefeldt et al., 2009; Rashed et al., 2002). A systematic review of the gastroparesis literature exploring relationships between psychological distress, psychological processes, and gastroparesis has not yet been conducted.

The current systematic review will explore three key questions in relation to psychological features and processes associated with gastroparesis:

1) What is the prevalence of psychopathology in gastroparesis cohorts and how does it compare to other gastroenterological conditions?

2) What are the levels of anxiety, depression, and QoL in gastroparesis cohorts and do they differ with respect to gastroparesis symptom severity, aetiology, degree of gastric retention, and duration of symptoms/disease?

3) Do psychological interventions for gastroparesis patients reduce gastroparesis symptoms, anxiety, depression, and improve QoL?

2.2.3 Materials and methods

For this review, a comprehensive search of PubMed, CINAHL, and PsycINFO databases was performed. Search criteria used were: (gastroparesis OR 'gastric delay' OR 'gastric emptying' OR 'gastric motility' OR 'gastric timing') AND (anxiety OR 'affective state' OR cognition OR control OR coping OR depression OR distress OR emotion OR helplessness OR 'illness perception' OR 'life events' OR mastery OR mental OR mood OR neuropsychological OR panic OR personality OR psycholog* OR psychosocial OR 'quality of life' OR 'self-efficacy' OR stress). Research papers retrieved through the search were also reviewed for further relevant references.

Inclusion criteria were: an adult sample of gastroparesis patients, a quantitative methodology, and at least one of the following: (1) evaluation of the prevalence of psychopathology, (2) an outcome measure of anxiety, depression, or QoL, (3) evidence of a psychological intervention. Case studies, review articles, and publications in languages other than English were excluded from the current review.

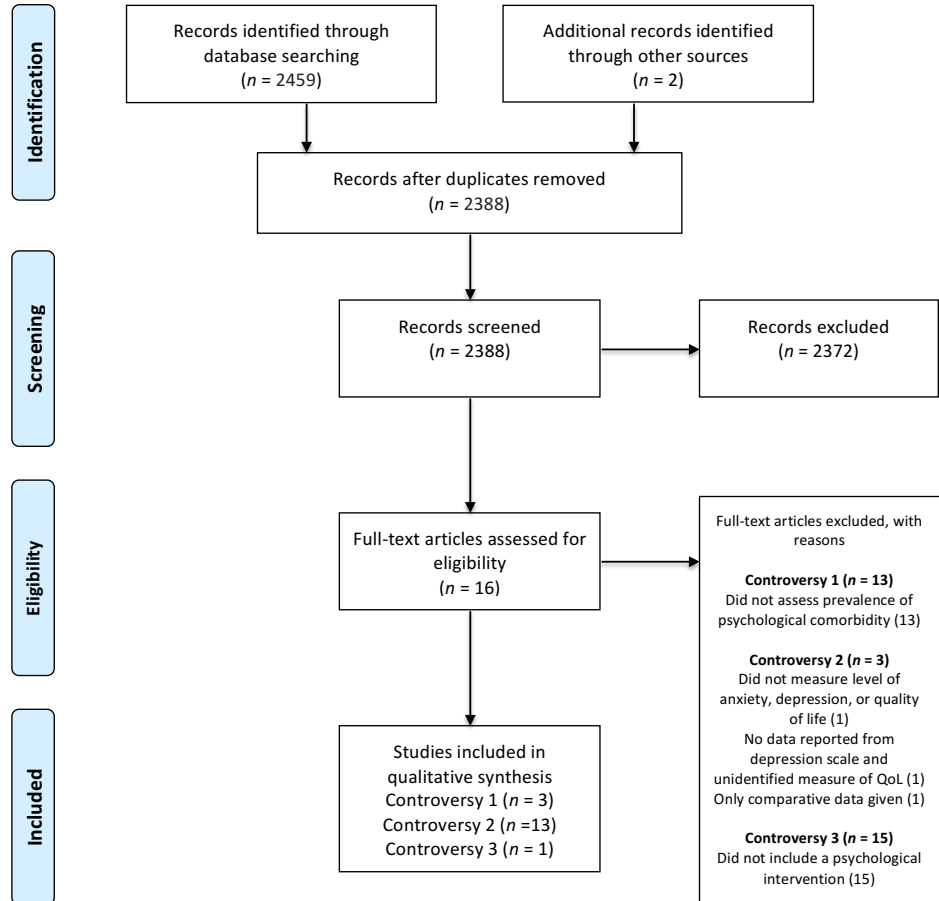
Two researchers (SRK and SW) independently screened all references retrieved through the search and categorised them according to the inclusion and exclusion criteria. The researchers also extracted data from the papers independently, including participant information, methodology, assessment tools, and study outcomes.

2.2.4 Results

After 73 duplicates were removed, a total of 2388 citations were identified through database searches and review of other relevant references. Of these, 2372 were excluded due to: 1) not meeting the inclusion criteria, or 2) lack of information (see Figure 3 for PRISMA diagram). This resulted in a total of 16 research reports which are summarized in Table 3.



PRISMA 2009 Flow Diagram



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097
For more information, visit www.prisma-statement.org.

Figure 3. PRISMA flow diagram, from Moher et al. (2009). For more information, visit www.prisma-statement.org.

Table 3

Summary of papers reviewed

Study	Study characteristics	Participant details	Psychological measures used	Relevant findings	Conclusions
Soykan et al. (1998)	Cohort study using six-years of hospital records. Demographic and clinical data evaluated at entry to the hospital and most recent follow-up.	N=146 (120 females, 26 males). Mean age: 45.0 years. Etiology: 42 DG, 52 IG, 19 post-surgical, 11 Parkinson's disease, 7 collagen vascular disorders, 6 intestinal pseudo-obstruction, 9 other.	CES-D, SCL-90	23% of IG patients were thought to be depressed, and 50% displayed significant elevations on gastrointestinal psychosomatic susceptibility.	Psychological status may be predictive of response to prokinetic therapy.
Harrell et al. (2008)	Cross-sectional study with an interview, patients classified into a clinical subgroup based on predominant symptoms.	N=100 (87 females, 13 males). Mean age: 48.0 years. Etiology: unspecified.	SF-12	QoL (subscales and mental/physical component summaries) was significantly diminished in all gastroparesis patients when compared to population norms, but did not differ between groups based on predominant gastroparesis symptoms. QoL negatively correlated with physical symptom scores.	Predominant-symptom classification may be useful in the management of gastroparesis.
Bielefeldt et al. (2009)	Cross-sectional study with a qualitative interview.	N=55 (44 females, 11 males). Mean age: 42.4 years. Etiology: 11 DG, 29 IG, 8 connective tissue disease, 4 post-surgery or trauma, 1 osteogenesis imperfect, 1 mitochondrial myopathy, 1 Marfan syndrome.	HADS, SF-12, open-ended interview questions	Patients had moderately elevated scores for anxiety and depression, 74% met screening criteria for anxiety or depression, 29% were above the threshold for clinically relevant affective spectrum disorders, and eighteen patients were receiving chronic anti-depressant medication. Patients demonstrated impaired QoL compared to population norm, with no differences between etiologies. Physical symptoms were inversely related to the physical component score on SF-12. Symptom severity was positively correlated with depression scores, but not anxiety, symptom duration or degree of gastric delay. <i>Qualitative data:</i> patients were asked to describe the impact of gastroparesis on their lives and three main topics were identified: 1) eating out/social functions, 2) fatigue, 3) strain on relationships. Nausea and vomiting were the most troublesome symptoms, and patients also reported a fear of unrelenting disease, as well as frustration/dissatisfaction with healthcare providers.	Gastroparesis treatment must focus on improving QoL. The results of this study provide support for the use of psychologically based interventions in gastroparesis.

Jung et al. (2009)	Cohort study using medical records.	Definite gastroparesis=83 (68 female, 15 males). Mean age at onset: 44.0 years. Etiology: 21 DG, 41 IG, connective tissue disease 9, hypothyroidism 1, malignancy 2, abdominal surgery 6, provocation drugs 19, end-stage renal disease 4.	None reported. Evidence obtained from medical records.	Of 83 patients with definite gastroparesis, 25 had evidence of comorbid psychiatric illness in their medical records. Twenty patients had 'anxiety/depression' and five had 'other'.	Gastroparesis is difficult to manage and represents a major disease burden.
Hasler et al. (2010)	Cross-sectional study. Data obtained from the Gastroparesis Registry.	N=299 (245 females, 54 males). Mean age: 43.0 years. Etiology: 100 DG, 199 IG.	BDI, STAI	Depression and anxiety scores increased with greater physician-rated, and patient-rated, symptom severity. Nausea and vomiting were greater in patients with more severe depressive symptoms. Bloating and postprandial fullness were greater in patients with more severe depressive symptoms, state and trait anxiety. Higher depression scores were associated with prokinetic or antiemetic drug use, and increased hospitalizations. Higher state anxiety was associated with anxiolytic use, while higher trait anxiety was associated with antidepressant use and increased hospitalizations. Depression and anxiety scores did not differ across etiology or degree of gastric retention. Higher symptom severity score was predictive of higher depression and state anxiety score. Use of anxiolytics was predictive of state anxiety, use of anti-depressants was predictive of greater trait anxiety score, and male gender was predictive of higher state anxiety.	The physical and psychological features of gastroparesis both need to be considered in the development of individualized patient treatment plans. Longitudinal studies must be conducted to evaluate the relationship between psychology and gastroparesis, and whether psychological treatment can affect the physical symptoms of gastroparesis.
Cherian et al. (2010)	Cross-sectional study.	N=68 (58 females, 10 males). Mean age: 42.6 years. Etiology: 18 DG, 50 IG. 52 Functional Dyspepsia patients also studied.	PAGI-QOL	DG patients scored significantly higher than IG patients on the following PAGI-QOL subscales: diet, daily activities, relationships. When pain severity was correlated with QOL subscales, there was a moderate correlation with avoiding physical activity, taking longer to perform daily activities, worry about having stomach problems in public, and depending on others to perform activities.	Abdominal pain is an important symptom of gastroparesis and is associated with decreased QoL.

Hasler et al. (2011)	Cross-sectional study. Data obtained from the Gastroparesis Registry.	N=243 (214 females, 29 males). Mean age: 41.0 years. Etiology: 116 DG, 219 IG.	PAGI-QOL, SF-36	Patients had moderately impaired QoL, with inverse correlation to bloating severity.	Bloating is a prevalent symptom in gastroparesis and is associated with impaired physical and mental QoL.
Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al. (2011)	Cross-sectional study. Data obtained from the Gastroparesis Registry.	N=243 (214 females, 29 males). Mean age: 41.0 years. Etiology: 243 IG.	BDI, STAI	36% of participants demonstrated severe state anxiety, 35% demonstrated severe trait anxiety, and 18% demonstrated severe depression. Overweight IG patients were more likely to have an anxiety disorder. Major depressive disorder was associated with greater symptom severity. Anxiety and depression scores tended to be higher in patients with more severely delayed gastric emptying.	Symptoms, gastric retention, current treatment, and psychosocial factors all play a role in the severity of IG.
Jaffe et al. (2011)	Cross-sectional study.	N=59 (52 females, 7 males). Mean age: 43.0 years. Etiology: 20 DG, 39 IG.	PAGI-QOL, SF-36	Nausea/vomiting subscale of PAGI-SYM correlated with lower scores on the PAGI-QOL. SF-36 scores were significantly decreased in gastroparesis patients compared to population norms.	Nausea is a predominant symptom of gastroparesis that is associated with impaired QoL.
Cherian et al. (2012) ¹	Cross-sectional study.	N=156 (126 females, 30 males). Mean age: 41.1 years. Etiology: 42 DG, 114 IG. 52 FD patients also studied.	HADS, PAGI-QOL	Increased fatigue was associated with decreased QoL, increased depression, and decreased anxiety. All but one patient met criteria for depression, and the same was found for anxiety.	Fatigue is a significant symptom in gastroparesis and is associated with decreased QoL. Psychiatric interventions may help in fatigue management.
Hasler et al. (2013)	Cross-sectional study. Data obtained from the Gastroparesis Registry.	N=393 (327 females, 66 males). Mean age: 42.9 years. Etiology: 137 DG, 256, IG.	BDI, STAI, PAGI-QOL, SF-36	Depression and anxiety were higher in those with greater symptom severity. Impaired PAGI- QOL and SF-36 physical component scores related to increased pain and/or discomfort severity.	The influence of predominant pain/discomfort on disease severity is at least as great as predominant nausea/vomiting.

Friedenberg et al. (2013)	Cross-sectional study.	N=255 (212 females, 43 males). Mean age: 42.0 years. Etiology: 180 IG, 64 DG, 4 post-surgical, 7 other.	PAGI-QOL	African American and Hispanic patients had lower scores on clothing and psychological PAGI-QOL subscales than Caucasian patients resulting in lower QoL overall. PAGI-SYM and PAGI-QOL had a negative correlation and 30% of the variation in QoL could be explained by symptom severity.	Future population-based studies into the influence of race on symptoms and QoL in gastroparesis are warranted.
Y. Liu et al. (2014)	Randomized controlled trial with follow-up at 3, 7, 10, and 17 days post intervention.	N=120 (70 females, 50 males). Mean age: 60.5 years. Etiology: 120 post-surgical.	CES-D	A group that underwent a mental intervention had faster recovery from post-surgical gastroparesis (e.g., extubation time, eating recovery) compared to a control group. Depression was comparable in groups at baseline, but mental intervention group had lower scores than control at 3, 7, 10, and 17 days post-intervention.	Mental intervention is important in post-surgical recovery, and primary nurses should be trained to care for patients physically and psychologically post-surgery.
Pasricha et al. (2015)	Cross-sectional study. Data obtained from the Gastroparesis Registry.	N=262 (215 females, 47 males). Mean age: 44.0 years. Etiology: 177 IG, 85 DG.	PAGI-QOL, BDI, STAI	Mild improvement in QoL from baseline to follow-up at 48 weeks (PAGI-QOL and SF-36 physical and mental component scores), with no significant difference in QoL improvement across etiologies. No significant changes in depression or anxiety levels over the 48-week follow-up period. Moderate to severe depression and the use of anxiolytics at baseline were negative predictors of symptomatic improvement at follow-up, while anti-depressant use was a positive predictor.	Less than a third of patients with gastroparesis experience symptomatic improvement over time and QoL remains impaired. Depression is an important predictor of symptomatic improvement.
Cutts et al. (2016)	Cross-sectional study.	N=235 (186 females, 49 males). Mean age: 47.0 years. Etiology: 125 IG, 68 DG, 28 post-surgical, 14 unspecified.	SF-36	Reports correlations between SF-36 subscales and gastroparesis symptoms. Negative correlations with Physical Function subscale: bloating severity, bloating frequency, epigastric pain severity. Negative correlations with Bodily Pain subscale: bloating severity, bloating frequency, epigastric pain severity, epigastric burn frequency. Negative correlations with Social Functioning subscale: epigastric pain frequency, vomiting severity. Negative correlations with Role Emotional subscale: bloating severity, bloating frequency. Negative correlation with mental health subscale: bloating severity. The only positive correlation was between the Role Emotional subscale and epigastric pain severity.	Generic and global QoL tools may not accurately reflect the experience of gastroparesis patients.

Lacy, Crowell, Mathis, Bauer, and Heinberg (2016)	Cross-sectional study.	N=250 (196 females, 54 males). Mean age: 46.8 years. Etiology: 126 IG, 37 DG, 34 post-viral, 17 post-surgical, 11 connective tissue disorder, 10 neurologic, 5 post-vaccination, 3 hollow visceral myopathy, 3 vascular, 4 miscellaneous.	SF-36	IG patients had higher physical functioning, mental health, and role-physical scores compared to DG patients. Patients with DG had lower physical component summary scores than patients with IG or other etiologies. Patients with IG had higher mental component summary scores than patients with DG or other etiologies.	It is important that gastroparesis interventions aim to lessen pain and improve QoL in patients.
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Note: DG = diabetic gastroparesis, IG = idiopathic gastroparesis, QoL = quality of life

Of these reports, three (18.75%) identified the prevalence of psychopathology in a gastroparesis cohort (Jung et al., 2009; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011; Soykan et al., 1998), 13 (81.25%) assessed levels of anxiety, depression, or QoL (Bielefeldt et al., 2009; Cherian et al., 2012; Cherian et al., 2010; Cutts et al., 2016; Friedenberg et al., 2013; Harrell et al., 2008; Hasler et al., 2010; Hasler et al., 2013; Hasler et al., 2011; Jaffe et al., 2011; Lacy et al., 2016; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011; Pasricha et al., 2015), and one (6.25%) involved a psychologically-based intervention for gastroparesis patients (Y. Liu et al., 2014). A summary of the studies' participant characteristics is presented in Table 4.

Table 4
Summary of participant characteristics

	N
Number of studies included in this review	16
Number of participants identified in the studies	2967
Disease etiology	
Unspecified	118
Idiopathic (IG)	1850
Diabetic (DG)	761
Post-surgical	198
Other (e.g., connective tissue disorder, Parkinson's disease)	151
Gender	
Female	2434
Male	533
Mean age	44.6

What is the prevalence of psychopathology in gastroparesis cohorts and how does it compare to other gastroenterological conditions?

Three studies reported on the prevalence of psychopathology in a gastroparesis cohort (n=378). Using the Center for Epidemiologic Studies Depression Scale (CES-D) and the hospital records of 52 idiopathic gastroparesis

(IG) patients, Soykan et al. (1998) note that 23% had a history of depression or antidepressant therapy, and 50% displayed clinically significant somatization using the SCL-90. The authors state that somatization was higher in the IG population than in the gastrointestinal population, however the difference was not significant.

In an exploration of the epidemiology of gastroparesis, Jung et al. (2009) identified that 25 out of 83 patients with definite gastroparesis (30%) had evidence of psychiatric comorbidity in their medical records. Twenty of these patients had evidence of anxiety or depression, and five had other psychiatric illness. This study did not compare the prevalence of psychopathology in gastroparesis to other gastroenterological cohorts.

In a larger sample of 243 IG patients, Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al. (2011) identify comorbid major depression in 21.8% of patients, and severe anxiety in 12.4% of patients through face-to-face interviews between patients and study physicians or coordinators. This study did not compare the prevalence of psychopathology in gastroparesis to other gastroenterological cohorts, however it was shown that females were more likely to report comorbid anxiety disorder than males, and patients with severe symptom severity or severe gastric retention were more likely to report major depression than those with milder symptoms. Participants in this study were mainly recruited from tertiary referral centers and therefore may not be representative of the general gastroparesis community.

What are the levels of anxiety, depression, and QoL in gastroparesis cohorts and do they differ with respect to gastroparesis symptom severity, etiology, degree of gastric retention, and duration of symptoms/disease?

Studies measuring anxiety and/or depression in gastroparesis cohorts

A total of six studies measured the level of anxiety and/or depression in gastroparesis cohorts (n=1408) (Bielefeldt et al., 2009; Cherian et al., 2012; Hasler et al., 2010; Hasler et al., 2013; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011; Pasricha et al., 2015). Of these studies, two used the Hospital Anxiety and Depression Scale (HADS) (Bielefeldt et al., 2009; Cherian et al., 2012). Bielefeldt et al. (2009) used a cut-off score of >8 and found that of the

55 participants, 74% met the criteria for either anxiety or depression, and 29% met the criteria for both conditions. No differences across etiology, gastric retention, or duration of symptoms/disease were reported, however symptom severity did correlate positively with depression score. Cherian et al. (2012) used a cutoff score of >10 and found that of 156 participants, 99% met the criteria for depression and anxiety. Differences across etiology, symptom severity, gastric retention, and duration of symptoms/disease were not reported in the study.

A further four studies measured depression using the Beck Depression Inventory (BDI) (Hasler et al., 2010; Hasler et al., 2013; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011; Pasricha et al., 2015). Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al. (2011) found that the average BDI score was 18.6 and 18% of the 243 IG participants fell into the range of 29-63 to indicate severe depression. Depression levels increased across mild to moderate symptom severity, however no difference was found in depression levels across degree of gastric retention. In a study of 299 gastroparesis patients by Hasler et al. (2010), BDI scores of ≥ 20 were present in 41.5% of participants. Higher BDI scores were associated with increased gastroparesis severity, nausea and vomiting, bloating, and postprandial fullness. The BDI scores were similar across diabetic gastroparesis (DG) and IG etiology, and degree of gastric retention. Self-reported gastroparesis severity and use of antiemetic/prokinetic medications were predictive of a BDI score ≥ 20 . Another study by Hasler et al. (2013) did not report overall BDI scores, but compared scores across pain severity, etiology, and symptom predominance. Hasler et al. (2013) found that in a study of 393 gastroparesis patients, increased BDI scores were associated with greater pain severity in both DG and IG patients. The most recent study by Pasricha et al. (2015) identified that 41.6% of 262 gastroparesis patients had BDI scores greater than 20, indicating moderate to severe depression. Unlike the aforementioned studies, this study also examined the impact of duration of disease on gastroparesis outcomes, finding no significant change in depression levels after 48 weeks of standard medical care for gastroparesis. However, depression level at baseline was a significant predictor of symptomatic improvement at 48 weeks.

Finally, four studies used the State-Trait Anxiety Inventory (STAI) to measure anxiety (Hasler et al., 2010; Hasler et al., 2013; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011; Pasricha et al., 2015). Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al. (2011) found that the average state anxiety score was 45.2 while trait anxiety was 43.9. Using an STAI score of ≥ 50 to denote severe anxiety, Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al. (2011) identified that 36% of 243 IG patients reported severe state anxiety, while 35% reported severe trait anxiety. State anxiety levels increased across mild to moderate symptom severity, however no difference was found in state or trait anxiety levels across degree of gastric retention. Hasler et al. (2010) noted that 50.2% of participants reported state anxiety ≥ 46 , and 51.5% reported trait anxiety ≥ 44 . Higher state and trait anxiety was associated with increased gastroparesis severity, bloating, and postprandial fullness. Increased self-reported gastroparesis severity and use of anxiolytic medications were predictive of higher state anxiety, while use of antidepressant medications was predictive of higher trait anxiety. State and trait anxiety were similar across DG and IG etiology, and degree of gastric retention. Hasler et al. (2013) found that increased STAI state and trait scores were associated with greater pain severity in both DG and IG patients. Finally, Pasricha et al. (2015) identified that 32.8% of participants reported state anxiety ≥ 50 at baseline, and 30.5% reported trait anxiety ≥ 50 with no significant change in state or trait anxiety levels after 48 weeks of standard medical care for gastroparesis. However, use of anxiolytics at baseline was a negative predictor of symptomatic improvement at follow-up.

Studies measuring QoL in gastroparesis cohorts

Eleven studies included an outcome measure of QoL (n=2076) (Bielefeldt et al., 2009; Cherian et al., 2012; Cherian et al., 2010; Cutts et al., 2016; Friedenberg et al., 2013; Harrell et al., 2008; Hasler et al., 2013; Hasler et al., 2011; Jaffe et al., 2011; Lacy et al., 2016; Pasricha et al., 2015).

The two earliest studies to measure QoL in gastroparesis used the SF-12. Harrell et al. (2008) found that in a sample of 100 gastroparesis patients, SF-12 subscale scores and component summary scores were significantly lower in

gastroparesis patients when compared to population norms, with a negative relationship to upper GI symptom severity. Similarly, in a study of 55 gastroparesis patients, Bielefeldt et al. (2009) found that both the physical and mental component scores of the SF-12 were lower than population norms, with no significant difference between DG and IG groups. Symptom severity was negatively correlated with the physical component score. The authors also identified that nausea and bloating severity, combined with the HADS score for depression, best predicted the physical health component score of the SF-12. The influence of gastric retention and duration of symptoms/disease on QoL was not assessed in either study.

Of the five studies that used the SF-36, Jaffe et al. (2011) found that both the mental and physical component scores were impaired in a sample of 59 gastroparesis patients compared to population norms. The study indicated that nausea and vomiting severity was inversely related to QoL, with no significant difference in QoL between DG and IG patients, or across degree of gastric retention. In a larger study of 335 patients, Hasler et al. (2011) noted that physical and mental component scores were negatively correlated to bloating severity, with higher mental component scores predicting greater bloating severity. Another study by Hasler et al. (2013) identified that physical and mental component scores were lower in both DG and IG patients with increased pain/discomfort scores. Additionally, when comparing between pain/discomfort predominant versus nausea/vomiting predominant symptoms, pain predominance was associated with greater impairment in the physical component score.

More recently, Pasricha et al. (2015) identified mild improvement in SF-36 scores (physical and mental components) after 48 weeks of standard medical care for gastroparesis. A 2016 study by Cutts et al. (2016) explored the relationships between symptom severity and the SF-36 subscales in a cohort of 235 gastroparesis patients, finding primarily negative correlations between symptom severity and Physical Functioning, Bodily Pain, Social Functioning, Role Emotional and Mental Health subscales (see Table 3 for details). The only positive correlation was between Role Emotional and epigastric pain severity. Finally, the most recent study using the SF-36 was conducted by Lacy et al. (2016) and identified that in 250 gastroparesis patients, those with IG had better physical functioning, mental

health, and role-physical than patients with DG. Similarly DG patients had lower physical component summary scores than patients with IG or gastroparesis from other causes, while DG patients and patients with gastroparesis from other causes also had lower mental component summary scores than those with IG.

Seven studies used the Patient Assessment of Upper Gastrointestinal Disorders Quality of Life (PAGI-QOL) to measure QoL. Using this assessment tool, Hasler et al. (2011) reported impaired QoL in individuals with gastroparesis. Cherian et al. (2010) assessed QoL across etiologies and found that, in their sample of 68 patients, IG patients scored significantly lower than DG patients on PAGI-QOL measures of diet, daily activities, and relationships. In addition, significant negative correlations have been identified between the PAGI-QOL and total upper GI symptom severity (Friedenberg et al., 2013), pain/discomfort severity (Cherian et al., 2010; Hasler et al., 2013), fatigue (Cherian et al., 2012), bloating severity (Hasler et al., 2011), and nausea/vomiting severity (Jaffe et al., 2011). Similar to their findings using the SF-36, Pasricha et al. (2015) identified mild improvement in PAGI-QOL scores after 48 weeks of standard medical care for gastroparesis. Despite these improvements in QoL over time, the authors note that QoL remained impaired in relation to the general population.

Do psychological interventions involving gastroparesis patients reduce gastroparesis symptoms, anxiety, depression, and improve QoL?

Only one study (Y. Liu et al., 2014) involved a psychological intervention for gastroparesis patients. Y. Liu et al. (2014) conducted a randomized controlled trial (RCT) with 120 post-surgical gastroparesis patients. Sixty patients were allocated to a control group that received conventional therapy (gastric tube, fasting, parenteral and enteral nutrition, routine nursing care, health guidance), while another 60 were allocated to a 'comprehensive mental intervention' group that received conventional therapy in addition to: supportive mental consultation, bedside symptomatic mental intervention, music and abdominal massage, and mental intervention for patients' families. While the groups had comparable CES-D scores at baseline, the mental intervention group scored significantly lower than the control group on days 3, 7, 10, and 17 after the intervention. The intervention group also had significantly improved gastric function following the intervention

compared to the control group. The study did not include measures of anxiety or QoL.

2.2.5 Discussion

Conclusions are presented according to the key questions of the systematic review. This is followed by a discussion of the strengths and limitations of the literature, and suggestions for future research in the area.

Prevalence of psychopathology in gastroparesis

This review found three studies that investigated the prevalence of psychopathology in gastroparesis patients. The reported prevalence of these psychopathologies were: combined anxiety/depression 24% (Jung et al., 2009), severe anxiety 12.4% (Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011), depression 21.8-23% (Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011; Soykan et al., 1998), somatization 50% (Soykan et al., 1998), other 5% (Jung et al., 2009). Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al. (2011) reported that females were more likely to report comorbid anxiety disorder, and patients with greater symptom severity and gastric delay were more likely to report major depression. Soykan et al. (1998) identified a non-significant difference in the prevalence of somatization in the gastroparesis cohort compared to other gastroenterological cohorts, while Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al. (2011) and Jung et al. (2009) did not make such comparisons.

It must be acknowledged that in addition to using the CES-D, Soykan et al. (1998) assessed whether patients had a medical history of either depression or anti-depressant use, which does not necessarily indicate prevalence of depression. Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al. (2011) only reported on severe anxiety, which is likely to underestimate the prevalence of anxiety in the cohort, and two studies (Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011; Soykan et al., 1998) only assessed psychopathology in IG patients so findings may not be representative of approximately two-thirds of gastroparesis patients. Finally, all

three studies lacked clarity around how patients obtained a psychiatric diagnosis, and two (Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011; Soykan et al., 1998) limited the psychopathologies that were included in the study. Based on these findings, it can be concluded that while there is psychopathology in gastroparesis patients, there has not been enough research conducted to provide a reliable prevalence rate. Further, no conclusion to date can be made with regard to whether rates of psychopathology are higher or lower in gastroparesis compared to cohorts that are healthy, chronically ill, or have other gastrointestinal conditions.

Level of anxiety and/or depression in gastroparesis

Overall, it is difficult to be definitive regarding the level of anxiety and depression in gastroparesis cohorts given the limited research conducted to date. Based on one study (Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011), 18% of gastroparesis patients have severe depression, 36% have severe state anxiety, and 35% have severe trait anxiety. Another study reported that 41.6% of patients had moderate to severe levels of depression at baseline, and identified that the percentage of patients scoring equal to or greater than 50 on the STAI at baseline was 32.8% for state anxiety, and 30.5% for trait anxiety (Pasricha et al., 2015). While other studies also measured and reported on anxiety and depression, they did not identify levels of severity. Three studies (Hasler et al., 2010; Hasler et al., 2013; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011) indicated that anxiety was positively associated with gastroparesis symptom severity, and one did not (Bielefeldt et al., 2009), while four (Bielefeldt et al., 2009; Hasler et al., 2010; Hasler et al., 2013; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011) indicated that depression increased with gastroparesis symptom severity. Two studies reported on the influence of gender on anxiety and depression levels, with one stating that females displayed less clinically severe depression (Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011), and the other indicating that male gender was associated with higher state anxiety (Hasler et al., 2010). One study demonstrated that depression and anxiety levels were similar across DG and IG etiologies (Hasler et al., 2010), and two showed

consistency across degree of gastric retention (Hasler et al., 2010; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011). Only one study (Pasricha et al., 2015) assessed the influence of duration of symptoms/disease, finding no significant improvement in anxiety or depression levels from baseline to follow-up at 48 weeks. However, depression level and use of anxiolytics at baseline were significant predictors of symptomatic improvement at 48 weeks.

The six studies that measured anxiety and/or depression in a gastroparesis cohort used a variety of assessment tools and cut-off scores, which makes it difficult to interpret the results as a whole. For example, the two studies employing the HADS each used a different cut-off score and did not give enough information to compare results across the studies. Similarly, of the four studies using the BDI and STAI only two reported the level of anxiety and depression in the sample, while the other two primarily used the scores for correlation analyses. Thus, although studies have been conducted on the severity of anxiety and depression in gastroparesis patients, the lack of consistency and scoring information limits the conclusions that can be made. With this being said, there is evidence to indicate that levels of psychopathology and gastroparesis symptom severity were positively correlated, and that this relationship tends to be consistent across the different forms of gastroparesis.

Level of QoL in gastroparesis

The eleven studies investigating QoL in gastroparesis demonstrated that QoL was lower in gastroparesis patients than population norms (Bielefeldt et al., 2009; Harrell et al., 2008; Jaffe et al., 2011), and that there was generally a negative relationship between QoL and gastroparesis symptom severity (Bielefeldt et al., 2009; Cherian et al., 2012; Cherian et al., 2010; Cutts et al., 2016; Friedenbergl et al., 2013; Harrell et al., 2008; Hasler et al., 2013; Hasler et al., 2011; Jaffe et al., 2011), although one study found a weak positive relationship between the Role Emotional subscale of the SF-36 and epigastric pain severity (Cutts et al., 2016). Two studies found no significant difference in QoL between DG and IG patients (Bielefeldt et al., 2009; Jaffe et al., 2011), however one found that IG scored lower than DG on measures of diet, daily activities, and relationships (Cherian et al., 2010), and conversely, another found IG scored higher than DG on both physical and mental

components of QoL (Lacy et al., 2016). Only one study assessed the relationship between degree of gastric retention and QoL, with no significant relationship demonstrated (Jaffe et al., 2011). One study assessed the impact of duration of symptoms/disease, finding a mild improvement in QoL after 48 weeks of standard medical care for gastroparesis (Pasricha et al., 2015).

Based on these results, it can be concluded that QoL is lower in the gastroparesis cohort than the general population, and greater gastroparesis symptom severity is associated with lower QoL. At this point, there is not enough evidence to make conclusions about the influence of etiology, gastric retention, or duration of symptoms/disease on QoL.

Psychological intervention in gastroparesis

Only one study has reported on a psychological intervention for gastroparesis patients. Y. Liu et al. (2014) found that depression scores and gastric function were significantly improved in patients who received a psychological intervention compared to those who received standard care, however the study had considerable methodological limitations. Firstly, the study was conducted only on post-surgical patients, making the results difficult to generalize to other etiologies. The study also utilized a number of different factors in the intervention condition (e.g., supportive mental consultation, abdominal massage, music) making it impossible to ascertain the impact of any one component of the intervention. Additionally, the study did not utilize long-term follow-up. While the results of this study are promising, there is currently limited evidence for the use of psychological intervention in gastroparesis, and measures of other important psychological factors such as anxiety and QoL have yet to be assessed in this context.

Summary of findings and limitations

Currently the literature indicates that QoL is lower in gastroparesis patients than population norms, and that as gastroparesis symptom severity increases, anxiety and depression also increase while QoL decreases. The studies are few in number, with variability in the assessments used and etiologies studied, making it difficult to form further conclusions. It also appears that five of the 15 studies

(Hasler et al., 2010; Hasler et al., 2013; Hasler et al., 2011; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011; Pasricha et al., 2015) have used overlapping samples as they were all recruited via the Gastroparesis Registry. Consequently, findings may not be reflected across different samples. The evidence for the use of psychological intervention in gastroparesis is minimal and is further weakened by significant methodological limitations in the single relevant study.

Inconsistency in the assessment of gastroparesis must also be considered when interpreting these findings. While the majority of studies used self-report in conjunction with a scintigraphic study where >60% retention at two hours, and/or >10% retention at four hours indicated gastroparesis, there was some variation in assessment (e.g., Bielefeldt et al., 2009; Cutts et al., 2016; Harrell et al., 2008; Soykan et al., 1998).

Future directions

In order to move forward in understanding this area, future research would benefit from undertaking the following recommendations. When assessing the prevalence of psychopathology in gastroparesis cohorts, studies should consider the broad range of psychopathologies, which should be diagnosed by an appropriately qualified individual. To gain greater insight into the relationship between psychological factors and gastroparesis, studies should use standardized assessment tools and cut off scores, and provide clear scoring information. Studies are also invited to look beyond basic correlation analyses, and explore possible mediating factors. Information regarding mediating factors would be especially useful in designing individualized psychological interventions for gastroparesis patients. To promote consistency and future comparison, recommendations for studies are summarized in Table 5, along with suggestions for the development of psychological interventions and future research questions.

Table 5

General recommendations and questions for future research

General recommendations:

- Identify prevalence of psychological conditions based upon standardized and validated assessment tools (e.g., SCID (First, Spitzer, Miriam, & Williams, 2002), MINI (Sheehan et al., 1998))
- Use standardized assessment of gastroparesis (e.g., gastric emptying scintigraphy, PAGA-SYM (Rentz et al., 2004))
- Use validated psychological scales to assess, anxiety, depression, stress (e.g., BDI (Beck, Steer, Ball, & Ranieri, 1996), BAI (Beck, Epstein, Brown, & Steer, 1988), STAI (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983), DASS (Lovibond & Lovibond, 1995)) and QoL measures relevant to individuals with upper gastrointestinal disorders (e.g., PAGA-QoL (de la Loge et al., 2004))
- Use and provide clear scoring information
- Report assessment results in a manner that allows comparison across studies (e.g., standardized cut-off scores)

Psychological interventions:

- Randomized control trial design
- Prior to intervention, power analyses conducted
- Clear details of intervention content made fully available to allow other researchers to review and undertake accurate replication
- Gastroparesis-focused interventions
- Include measures that assess a cost/benefit analysis, engagement of medical services
- Where possible, patients, assessors, and statistician blinded
- Independent evaluation of intervention session recordings to ensure protocol/treatment consistency
- Psychological interventions need to be clearly identified and undertaken by trained and appropriately qualified individuals (i.e., psychologists, psychiatrists)
- Identify clear inclusion and exclusion criteria
- Identifying if (and where possible control for) participants have/have not received or are currently receiving psychotherapy (including type, duration etc.), using psychotropic medication, are on specialized diets for their gastroparesis
- Utilize valid measures which can be accurately compared to other intervention studies
- Evaluate participant engagement in therapy (e.g., % attendance to sessions, completion of homework)
- Evaluate differences between completers versus non-completers
- Include long-term post-therapy efficacy review time points (i.e., 1 and 2 year post-intervention)

Future research questions:

- What is the prevalence of psychopathology in gastroparesis compared to other gastroenterological cohorts?
- What psychological processes act as moderating/mediating factors between gastroparesis symptom activity and outcome variables such as QoL, anxiety, and depression (e.g., personality, coping style, self-efficacy)?
- How may gender impact upon the presentation and course of gastroparesis and associated psychological distress?
- How may historical and current stressors and/or traumas impact upon the presentation and course of gastroparesis?
- To what extent does duration of symptoms/disease influence the relationship between gastroparesis and psychological distress?

Note: QoL = quality of life

Conclusion

In conclusion, increased levels of psychopathology are evident in patients suffering from gastroparesis, with associations between the severity of psychological factors and the severity of gastroparesis symptoms. Although only one study has utilized a psychologically-based intervention for gastroparesis patients to date, the intervention was associated with improvement in both gastroparesis symptoms and levels of depression. The results of this systematic review indicate the importance of further research into the relationship between psychological factors and gastroparesis, especially given that current medical treatments for gastroparesis are limited. In particular, further exploration of the prevalence of psychopathology in gastroparesis compared to other conditions is warranted, as well as an assessment of the factors that may mediate an individual's ability to adapt to, and manage, gastroparesis.

2.2.6 Comments

Background

Gastroparesis is a gastrointestinal disorder involving delayed gastric emptying in the absence of a mechanical obstruction of the stomach. Typical symptoms include: chronic nausea, vomiting, early satiety, postprandial fullness, and in some cases abdominal pain and fatigue. Patients suffering from chronic gastrointestinal conditions frequently report psychological symptoms, such as anxiety, depression, and impaired quality of life (QoL).

Research frontiers

With limited treatment options available for gastroparesis, the importance of psychological support or intervention for gastroparesis patients has been repeatedly emphasized in the literature. This is the first systematic review of the literature to explore the relationship between psychological factors and gastroparesis.

Innovation and breakthroughs

This systematic review reveals that QoL is lower in gastroparesis patients than population norms, and that as gastroparesis symptom severity increases,

anxiety and depression also increase while QoL decreases. Recommendations for the development of future research questions and psychological interventions are provided to encourage progress in this important research area.

Applications

The results of this systematic review indicate that further exploration of the prevalence of psychopathology in gastroparesis is warranted, as well as an assessment of the factors that may mediate an individual's ability to adapt to, and manage, gastroparesis. Better understanding of these factors will assist in the development of targeted psychological support programs for the gastroparesis cohort.

Terminology

Not applicable.

Chapter 3: Qualitative study

3.1 *Introduction to Paper 2*

As indicated in Paper 1, the literature currently demonstrates that QoL is lower in gastroparesis patients than population norms (Bielefeldt et al., 2009; Harrell et al., 2008; Jaffe et al., 2011). Additionally, increased gastroparesis symptom severity is associated with greater psychological distress (Bielefeldt et al., 2009; Hasler et al., 2010; Hasler et al., 2013; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011) and decreased QoL (Bielefeldt et al., 2009; Cherian et al., 2012; Cherian et al., 2010; Cutts et al., 2016; Friedenberg et al., 2013; Harrell et al., 2008; Hasler et al., 2013; Hasler et al., 2011; Jaffe et al., 2011). Although these findings provide foundational understanding about the psychosocial factors associated with gastroparesis, little can be inferred about the experience of living with gastroparesis and how individuals manage the condition. Moreover, while the findings substantiate previous suggestions that psychological support may be important for the gastroparesis cohort (Abell et al., 2006; Bennell & Taylor, 2013; Bielefeldt et al., 2009), there is currently little guidance on the factors that should be targeted in a psychological intervention.

One aspect that was highlighted in the review (Paper 1) as warranting further investigation included an exploration of the factors that may mediate an individual's ability to effectively adapt to living with gastroparesis. The following published paper sought to establish understanding of how individuals experience gastroparesis, how the condition impacts upon their lives, and how they cope with the condition.

Due to the limited information on this topic, a qualitative methodology was employed to give detailed insight into the experiences of gastroparesis patients. Unlike quantitative methodologies, the lack of rigidly defined variables in a qualitative approach allows for a more holistic understanding of the topic (Willig, 2001). While two qualitative studies have previously considered psychological factors and experiences in the gastroparesis cohort (Bennell & Taylor, 2013; Bielefeldt et al., 2009), neither explicitly addressed the issue of how individuals cope with the condition.

The paper, "Exploration of the psychosocial issues associated with gastroparesis: A qualitative investigation", was co-authored with my supervisors Dr Simon R Knowles and Professor Geoff Hebbard, and was published in the Journal of Clinical Nursing in January 2017. This paper reports on the findings from interviews with 10 individuals with gastroparesis. Three main themes are identified from the interviews and relationships between the themes are described, with an emphasis on the relevance to clinical nursing practice. The Participant Consent and Information Form for this study is included in Appendix 3.

The following paper is a post-peer-review version of an article published in the Journal of Clinical Nursing. The final authenticated version is available online at: <http://dx.doi.org/10.1111/jocn.13725>. Further publication details are provided in Appendix 4.

3.2 Paper 2

Descriptive title: Exploration of the psychosocial issues associated with gastroparesis: A qualitative investigation

Concise title: Psychosocial issues associated with gastroparesis

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Acknowledgements

Thank you to all those who took part in this study.

Contributions

Study design: SRK, GH, SW; Data collection and analysis: SRK, GH, SW; Manuscript preparation: SRK, SW.

Conflict of interest

The authors have no funding or competing interests to declare.

3.2.1 Abstract

Aims and objectives: To build on the understanding of how individuals experience gastroparesis, how gastroparesis impacts on their lives, and how they adapt to living with gastroparesis.

Background: Gastroparesis is a neurogastroenterological disorder associated with increased psychological distress and reduced quality of life. Research shows that gastroparesis poses a significant burden across many facets of life, however less is known about how individuals cope and adapt to living with the condition.

Design: The study employed an interpretive phenomenological approach with semi-structured interviews and thematic analysis.

Methods: Ten gastroparesis patients were interviewed over the telephone (n=8), Skype (n=1), or face-to-face (n=1). All interviews were audio-recorded and transcribed.

Results: Key themes identified: 1) Frustration, 2) Identity, and 3) Coping and adaptation. Gastroparesis patients experience significant frustration around their diagnostic journey, being misunderstood, and the burden of living with the illness. Patients differed in how they identified with the illness, and this appeared to be associated with adaptation and whether they remained socially engaged.

Conclusions: Gastroparesis is associated with significant frustration and burden, however some patients adapt to living with the condition more effectively than others. Identity appears to play an important role in this relationship. Support aimed at fostering a health-focused and resilient identity may assist gastroparesis patients in adaptation.

Relevance to clinical practice: The findings of this study can help nurses and other health professionals better understand the experience of living with gastroparesis and the factors that help patients best adapt to living with the

condition. Nurses can help promote resilience in patients by discussing the importance of being health-focused rather than illness-focused. Nurses can also support patients by helping them problem solve issues that may arise around social eating and remaining socially engaged.

Keywords: gastroparesis, quality of life, anxiety, depression, identity, coping, adaptation, distress, frustration, burden.

What does this paper contribute to the wider global clinical community?

- 1) Gastroparesis patients experience significant frustration around their diagnostic journey, feeling misunderstood, and the general burdens associated with the condition.
- 2) Patients who identify as being resilient tend to adapt more effectively to living with gastroparesis.
- 3) Remaining socially engaged is an important aspect of adapting effectively to life with gastroparesis.

3.2.2 *Introduction*

Gastroparesis is a neurogastroenterological disorder involving delayed gastric emptying in the absence of a mechanical obstruction of the stomach (Tack, 2005). Typical gastroparesis symptoms include chronic nausea, vomiting, early satiety, postprandial fullness, bloating, and abdominal pain (Camilleri et al., 2013). The incidence of definite gastroparesis per 100,000 person years is 9.8 in women and 2.4 in men (Jung et al., 2009), with approximately one third of patients being admitted to hospital for the condition (Dudekula et al., 2011), and a disease burden likened to that of Inflammatory Bowel Disease (Jung et al., 2009). The treatment options currently available for this chronic and debilitating condition are limited and in many cases lack efficacy (Abell et al., 2006; Bielefeldt, 2012; Camilleri et al., 2013).

3.2.2.1 *Background*

Research involving gastroparesis cohorts has identified that psychological distress is common, with greater symptom severity linked to increased psychological distress (Bielefeldt et al., 2009; Hasler et al., 2010; Hasler et al., 2013; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011). Similarly, individuals with gastroparesis have demonstrated decreased quality of life (QoL) compared to population norms (Bielefeldt et al., 2009; Harrell et al., 2008; Hasler et al., 2011; Jaffe et al., 2011), where greater gastroparesis symptom severity is associated with poorer QoL (Bielefeldt et al., 2009; Cherian et al., 2012; Cherian et al., 2010; Cutts et al., 2016; Friedenberget al., 2013; Harrell et al., 2008; Hasler et al., 2013; Hasler et al., 2011; Jaffe et al., 2011).

At present, two qualitative studies have been conducted to provide further insight into how an individual experiences gastroparesis. After in-depth interviews with nine gastroparesis patients, Bennell and Taylor (2013) concluded that gastroparesis can affect every aspect of the patient's life. Patients reported undesirable experiences with medical professionals who often didn't understand gastroparesis and its impact on the individual. Patients also described feeling accused of fabricating their illness, significant difficulty in managing social settings, as well as changes to sense of identity and security. Consistent with Bennell and Taylor (2013), based upon 55 interviews with gastroparesis patients, Bielefeldt et

al. (2009) also found that primary concerns related to attending social events and eating out, as well as frustration with healthcare providers. Other issues raised included fatigue, strain placed on relationships by the illness, and the influence that the condition had on professional activity.

The literature demonstrates that gastroparesis poses a significant burden across many facets of life, however less is known about how individuals cope and adapt to living with the chronic condition. Beyond standard treatment approaches to symptom management (e.g., dietary therapy, medication), Bielefeldt et al. (2009) observed that a small number of patients were aided by using relaxation techniques, however no details about the techniques were offered. Bennell and Taylor (2013) delved further into the topic and found that common coping strategies included comparing the condition to that of people perceived to be less fortunate (e.g., “I haven’t got cancer”), and preparing for the likelihood of nausea by planning food intake and carrying vomit bags. Importantly, the authors identified that a key step toward coping with gastroparesis was for patients to accept the limitations of the illness. Bennell and Taylor (2013) also noted that participants managed social situations in varying ways. Some individuals completely withdrew in order to avoid the stigma and difficulties associated with gastroparesis, while others played down the impact of gastroparesis and engaged in ‘normal’ activities in order to prove to themselves and others that they were well.

Clearly, the impact of gastroparesis reaches far beyond the physical symptoms. In order to develop more holistic management of gastroparesis and improve QoL in this cohort, further insight into patient experience is needed. The current study sought to build on the understanding of how individuals experience gastroparesis, how gastroparesis impacts on their lives, and how they adapt to living with gastroparesis.

3.2.3 *Methods*

The study employed an interpretive phenomenological approach (IPA) with semi-structured interviews and thematic analysis. The phenomenological perspective is ideal for examining the lived-experience of individuals, allowing rich description of personal accounts (Giorgi, 1997). At the same time the IPA recognises that the researcher plays an active role in interpreting the interviewee's experience, acknowledging that the researcher's perspective, and the interaction between the researcher and the interviewee, will influence the research outcomes (Willig, 2001).

3.2.3.1 *Sample*

Ten adults with gastroparesis participated in this study (mean age: 40.2 years). Inclusion criteria were: 1) aged 18 years or older, 2) diagnosed with gastroparesis and currently under the care of a gastroenterologist, and 3) English as a first language or able to read English. Exclusion criterion: 1) currently experiencing severe mental illness.

3.2.3.2 *Data collection*

Ethics approval was attained through the local University Human Research Ethics Committee (protocol number: 2013/261).

Participants were recruited either through online advertising, or through personal invitation from private gastroenterologists. All participants were presented with a detailed information form about the study and gave signed consent to be interviewed and audio-recorded. Each participant gave one interview which was conducted either over the telephone (n=8), Skype (n=1), or face-to-face (n=1) depending on the participant's preference.

The interviews were conducted by one research team member, were semi-structured, and were partially directed by the information that the participant wanted to share. Example interview questions and prompts are listed in Table 6, and were developed in consultation with all members of the research team who provided expert advice based on their experience working with the cohort. Questions were generally open-ended and addressed the experience of living with gastroparesis, and how to cope with the illness.

Participants were recruited until data saturation was met. The average interview duration was 48 minutes (range: 20-80 minutes). After transcribing was complete, all audio-recordings were deleted and transcripts were stored on a password-protected computer. Transcripts were de-identified and each participant given a pseudonym.

Table 6

Examples of interview questions and prompts used

Please tell me about your experience of gastroparesis.

How does gastroparesis impact on your relationships?

How does gastroparesis impact on your personal and social life?

How does gastroparesis impact on your mental health?

What strategies help you to manage your gastroparesis symptoms?

Please describe any positive aspects to your experience with gastroparesis.

What advice would you give others managing gastroparesis?

3.2.3.3 Data analysis

Thematic analysis was conducted based on the steps recommended by Braun and Clarke (2006):

Step 1: Interviews were transcribed verbatim, with names changed to protect anonymity. A copy of the transcript was emailed to the interviewee for review, after which they could inform the researcher (by phone or email) of any changes they would like to make to the record. A number of participants were able to clarify words and sentences that were not comprehensible on the recording, and two participants requested that certain information be deleted from the transcript. Once these changes were made, the transcripts were read a number of times, with initial reflections noted in a separate document.

Step 2: Transcripts were re-read with meaningful or interesting features marked in the document and coded. Data relevant to each code was collected in a separate document.

Step 3: Codes and transcripts were evaluated to establish broader level themes. A separate document was created for each theme, with all relevant data collected in this file.

Step 4: The effectiveness of the selected themes was assessed by re-reading transcripts and coded data to ensure that key information was reflected in the themes and that important features had not been overlooked. A visual map of the themes was created to examine possible relationships between themes, including the hierarchical structure.

Step 5: Themes were reviewed and refined to ensure that each was essential to describe the experience of the participants. Themes were labeled and defined by appropriate exemplars.

3.2.3.4 Results

All 10 participants were female, with the average duration of gastroparesis being 6.61 years (range: 0.5-21 years), and the majority of participants experiencing idiopathic gastroparesis (n=8) (see Table 7 for demographic information). Eight participants were married, five were unemployed, and seven were receiving tube feedings to meet their nutrition requirements.

Table 7
Demographic information for sample

Demographic information	Sample (n = 10)
Sex	
Female	10
Age	
21-30	4
31-40	2
41-50	2
61-70	2
Marital status	
Single	1
In a relationship	1
Married	8
Employment status	
Full time work	1
Part time work	1
Part time study	1
Unemployed	5
Retired	2
Aetiology	
Idiopathic	8
Post-surgical	1
Post-viral	1
Nutrition	
Modified oral diet	3
Tube feeding	7
Treatment	
Botox	2
Gastric electrical stimulation	1
Medication	7
Non-medically approved marijuana	1
Allied health	
Clinical nutrition	2
Counselling/psychological therapy	3
Exercise physiology	1
Naturopathy	1
Osteopathy	1
Rheumatology	1

Three themes were identified through analysis of the qualitative data: frustration, identity, and coping and adaptation. See Table 8 for overview of themes.

Table 8

Main themes and subthemes

Theme one: Frustration

- Diagnostic journey and being misunderstood by others

- Burden of gastroparesis

Theme two: Identity

Theme three: Coping and adaptation

Theme one: Frustration

Frustration was the main theme that was evident throughout the interviews, pervading many of the experiences associated with having gastroparesis. The frustration stemmed from negative experiences with the medical profession and in social settings, as well as the physical and social limitations imposed on them by gastroparesis.

Frustration with the diagnostic journey and being misunderstood by others

All participants reported frustration regarding the lack of awareness around gastroparesis. *"It's a horrible disease and I feel really sorry for people that are diagnosed because there's no awareness. And it's not just the awareness amongst patients, it's an awareness from doctors knowing how to treat it, and what to do, and what options are available"* (p3). Participants repeatedly spoke about the challenges of getting an initial diagnosis. *"The biggest thing that everybody finds the most frustrating is that you have to run around to a lot of different people before you eventually get the diagnosis and the help and that just delays the help and you get even sicker and sicker"* (p10). There was a feeling of being blamed and misunderstood. *"I'd seen lots of different specialists and lots of doctors sort of told me 'oh, it's in your head', 'there's nothing wrong with you' that sort of thing"* (p6). In addition to finding little awareness of the illness, participants strongly felt that doctors did not listen to them. One participant described her desperation:

“You get so frustrated and down that no one’s listening to you and that no one will do anything to help. It’s very very overwhelming. I got very very upset. I was pretty much sitting in doctors’ offices saying ‘I’m not coping and I’m begging for help’, and they were just telling me to go away” (p10).

Another common experience for participants was that their illness was mistaken for an eating disorder. *“For many years I was told that it must be an eating disorder because it had no medical name...that for some reason I must be in my head psychologically making myself feel sick and that I had to just push through it...” (p3).* At times, the lack of understanding led some to question their own experience of the illness. *“Not knowing whether you’re imagining it because they couldn’t find anything that was wrong” (p5).*

Participants also reported feeling judged and misunderstood in social situations. *“Some people say to you ‘just get over it, you’ll be fine, get over it’. And you think, you just don’t know what I’ve been through” (p8).* Some reported discomfort going out in public due to their feeding tubes. *“You’re sitting there just going about your own business and people just stand around and stare. Or they’ll be sitting at a table near where I’m sitting with friends and they’ll just sit there and stare at you” (p4).* There were also reports of being challenged by others to eat certain foods. *“There’s been times where she’s said ‘come on, what if you just ate that party pie, what would happen?’” (p5).*

As a result of the limited understanding relating to gastroparesis, participants also expressed frustration over not knowing what their future would look like. *“Just not knowing if you’re going to get any better. If you’re going to be like this forever, or if it’s going to get worse. Yeah, not knowing if you’re ever going to be able to eat normally again. That’s pretty hard” (p6).* This contributed to difficulty in social situations: *“I guess it’s frustrating and aggravating for me, because they don’t have any answers to give me, and then when my family and friends ask, I don’t have any answers to give them” (p7).*

Frustration with the burden of gastroparesis

Participants commented on the stress caused by the limitations associated with gastroparesis. At times, participants felt as if their lives had been reduced to an intrapersonal battle with their stomach: *“Well, usually in the morning I’m woke*

up with nausea. And then the rest of the day is a mixture of trying to figure out how to eat so I won't throw up and not eating so I won't throw up" (p9). In many ways the illness had prevented them from being the person they wanted to be:

"I mentally want to be able to go and work or study or, you know, be able to go out and see people and do all these different things but even though I'm so much better than I was, my body still can't cope with all of that at the moment. And I think that's, you know, the most frustrating thing." (p10)

Participants also raised many concerns about the interpersonal burden of gastroparesis. In particular, they expressed anguish about burdening friends and family. *"I really feel like I've held everyone back..." (p5). A participant spoke of the guilt she felt about not being able to help around the house. "When one can't do it the other one is pulling more of the weight and it's just hard to, to swallow that, for want of a better word. That you're doing that to someone you love" (p9). The concern also contributed to feelings of isolation:*

"I don't ever want to be one of those friends or one of those family members that's constantly whining and complaining... and I guess that can leave you very alone, because there are times where it can be hard and you need someone to talk to" (p7)

The illness also led to isolation for other reasons. Some participants spoke about losing friends due to gastroparesis. *"I lost quite a few friends when I was in hospital. Just because they taper off, because they think that hospitals are going to give you the magic pill and you're all better, but it doesn't always occur like that" (p4). Another commented that being chronically unwell has "basically taken away your whole social life" (p5). There was also an emphasis on the way that social situations tend to revolve around food and drinking and the problems this raises when an individual cannot eat or drink in the 'normal' way. "Everything you tend to do with your friends is like we'll meet for dinner, we'll meet for lunch, like all that has stopped. You know, you can't do that so, I guess like your whole dynamic, your everything changes. Like, it's the weirdest thing, it's not just an illness, and I guess people don't understand that" (p7).*

The relationship between gastroparesis and social engagement was also highlighted in theme three – coping and adaptation. However, as will be outlined, this relationship appeared to be moderated by the role of identity.

Theme two: Identity

Participants varied in how they felt about living with the effects and demands of gastroparesis. Some participants demonstrated remarkable resilience and a determination to maintain the identity of being a 'healthy' person. *"I will not let this make an invalid out of me"* (p2). Similarly: *"I'm fine, I'm healthy, that's the main thing"* (p8). Participants viewed themselves as being able to recover from medical and social setbacks. *"But most of the time I'll bounce back. I'm pretty good at bouncing back from those kind of things"* (p4). Participants also considered themselves to be persevering when confronted by difficulties:

"I'm not one to just give up and say I'm not going to do the shopping, I'm not going to do this, I'm not going to do that...because I don't want to be that person that just can't do anything. That's when I just think I'll get really depressed." (p5)

Participants who identified as being resilient were also likely to report that having gastroparesis had positively affected their sense of self in some way. *"I think it has made me stronger"* (p6), and *"I've been able to learn just how strong and resilient I can be, you know, given something massive, you know, you learn about yourself as well"* (p10).

However, it was clear that at times the burden of gastroparesis was too much to bear. For some, there was a feeling that the illness had completely taken control of their lives. *"Honestly, I feel like my gut rules my world, and I try not to let it rule my world, but it does"* (p3). For these participants there was a focus on the limitations associated with gastroparesis (Theme 1), and on what gastroparesis had taken away from them: *"it stops me from eating, it stops me from drinking, stops me from having the social life that..."* (p5); *"It makes you homebound"* (p9). In some cases, participants felt they could no longer be themselves and that gastroparesis had consumed their identity:

"I'm not the person I am, I can't be, I'm emaciated, and I'm malnourished, and I don't think right. All of those things are because I can't eat food and drink and without those things I'm not a normal person because I'm not a healthy person. For me, I'm constantly living in a state of grief over who I know I am, and what I show the world, and my symptoms and what I have to feel every day is unbearable. That's the worst for me." (p3)

In most cases, patients identified times in their journey where they had given up, and times where they had approached gastroparesis with positivity and resilience. Here one participant explains her experience of both responses and the interplay between them:

"I think anybody with any chronic illness goes through the point where 'ok, I'm gonna fight this, I can do this' and then you just keep getting beat down and beat down and beat down and you're like 'I can't do this', and you give up. And then something kicks in and it's like 'no, I'm not going to give up'. When you start fighting back, it makes you realise how strong you can be as a person" (p7).

As will be discussed in Theme 3, the way an individual identified themselves in relation to gastroparesis appeared to be associated with how they coped and adapted to living with the condition.

Theme three: Coping and adaptation

Participants acknowledged the importance of finding coping strategies to help manage symptoms and get through difficult times. One participant commented: *"You have to find something, and I think if I could tell anyone, it's like you have to find what works for you to get you through it because if you don't you could drive yourself crazy"* (p7). For many participants, keeping busy and finding distractions from symptom flares was an important coping strategy. *"Distractions are often the best. Anything from playing board games with a friend, or boyfriend. Just any kind of distraction... Talking"* (p4); *"I might just put on my favourite movie and just relax and watch that and try not to think about missing out on my favourite foods and stuff. I might just go shopping and try to cheer myself up a bit"* (p6).

Cultivating a positive attitude appeared to be an intrinsic element in coping with the illness. One participant expressed: *"a positive attitude towards anything will help you feel better"* (p7). When asked about advice she would give to someone managing gastroparesis, another participant stated: *"Well, just be positive. Very positive. Think about what you're going to eat and yeah, just be positive"* (p8). Acknowledging that gastroparesis can present in varying degrees of severity, another participant commented: *"there's always a way of living to your best, within it"* (p3). Another participant shared the importance of keeping a positive attitude to her:

"I know if I stayed in bed all day and didn't get up, I'd bury myself in a hole I think. I'd just spiral down. So, just got to look at the positives... You've got to look at the other things in life that are good and not just all bad to help you get through each day I think." (p1)

The results demonstrated that individuals who were able to maintain a more positive attitude and a health-focused identity tended to be more proactive in adapting to their current health situation. In particular, this was demonstrated by making an effort to remain active and engaged in their social life. In most cases, this involved thinking of ways to socialise that did not involve food:

"I sort of like just go to the movies now. Try and find something that doesn't involve food. Going bowling or..." (p6)

"I learnt to find other things, like yoga and Pilates was something that I found that I could do in small moderation." (p4)

"I've definitely been trying to think of things that don't involve food that I can catch up with friends. So, one of my friends, we will go for a walk together, and I've got another bunch of friends that come over and there's like a TV show that we're all a bit obsessed with and so every once in a while we'll kind of all sit down and watch that together. Had to get a bit creative, but we've gotten there." (p10)

"I go for a walk every day. I walk about 3 kilometres every day Monday to Friday with my friend and I've done that for about 3-4 years now." (p8)

Participants reported arranging their activities around feeding routines and symptoms in order to stay engaged:

"So night times, evening time things, we can't generally do, and we don't generally do. We go to the theatre and we go to a matinee, we go to the cinema - we go during the day. We still do all of those sorts of things, but we have to fine-tune it a bit, if you know what I mean. So that it fits in with my feeding regime." (p2)

"I try and get out of the house and go for a walk, or I started running which has been really fun. Yeah, I need to make sure I don't run too much though because otherwise I end up in hospital. But, yeah, I try. Even if I'm not, like if I'm feeling terrible I won't go out running, but even if I'm, like, if I'm feeling sort of slightly not great I'll try and push myself to go out because I often do feel better afterwards. Especially, like, yeah if I'm slightly nauseous or I've got a stomach ache that kind of moving around I find helps calm it, so..." (p10)

Patients also took the time to explain their situation so that friends and family would feel comfortable eating around them, and continue inviting them to gatherings:

"They feel guilty, almost. That they eat things and they feel guilty sitting and eating a meal if I'm there and not eating and things. And I think a lot of my friends still have that guilt but then some of them know, 'cause like, I've spoken to them and said 'it doesn't bother me, it's ok, you're allowed to eat', so yeah, it's been a bit of a learning curve with that." (p10)

"My circle of friends have been very supportive. What I've had to say to them, the sort of thing that would happen, people would say 'oh, it's awful that you can't eat and we don't like sitting here eating all this stuff while you can't eat'. In the finish, I said to them all 'that's your problem, don't put that one on me, it's your problem. I'm quite happy to sit here and drink my latte while you eat whatever you want to eat.' " (p2)

Participants with a more positive identity regarding gastroparesis were also more likely to use the internet to create beneficial connections with other gastroparesis patients. Online communities gave patients an outlet to express their frustrations with gastroparesis and compare experiences:

"I just made my own Instagram the other day about it to get my feelings out a bit, when you have a bad day. I found a few, most of them overseas, a few other ones that suffer from it. Sort of seeing what their journey...sort of similar to your journey. And you see some of them are really bad, and I'm a bit grateful I'm not that bad." (p1)

In addition, the online gastroparesis communities provided an opportunity to support others:

"I sort of made friends with people who have gastroparesis, and I think it's good for them to be able to talk to someone about it." (p6)

"Being able to have a reciprocal friendship with someone who understands what you're going through has been a massive massive help for me, for myself. And then I've also been able to support other people and that kind of gives you a bit of purpose back in life and helps you feel like you're doing something to help someone else, and so, you don't kind of dwell on your own situation as much. " (p10)

In contrast, individuals who had a more illness-focused identity tended to be less active: *"Yeah, it's been really hard for me to maintain anything. I do everything from home, from my armchair, and that's what I do."* (p3). Often unable to perform basic home duties or attend medical appointments: *"I can barely go to the doctor. That kind of thing. I haven't been to the grocery store in months."* (p9), and *"I've cancelled so many appointments with my gastroenterologist, not because I can't be bothered to go, but because I'm too sick to even go"* (p3).

These participants reported that the symptoms of gastroparesis made it difficult, and sometimes impossible, to maintain social connections:

"My husband wanted to ask the neighbours down the road for a swim, and I just said 'you do what you want but I'm staying inside'. I just feel that awful I can't even come outside and talk to them." (p5)

"I've lost count of the times that I've picked up the phone to my mum or dad who've called and I've just said "I can't talk to you at the moment" and put the phone down. I don't even want to talk to someone when I feel that sick. Taking my kids out is impossible." (p3)

One participant reported that attending social functions was often not worth the effort:

"Quite often (my husband) and my girls go out together to family functions or lunches or whatever, and I stay home because it's either too hard or I'm not well or sometimes it's not worth the effort if I've got to go there and watch them all eat and I can't eat anyway then it's more detrimental." (p5)

While, another reported that having gastroparesis had completely eliminated her social life: *"I have none. Literally."* (p9)

Despite having a more illness-focused identity, two participants did continue to socialise when they could. However, for these participants, the social events were often followed by feelings of distress. For example, one of the participants felt that she was wearing a social mask around her friends, which she thought contributed to her feeling isolated and misunderstood:

"I put a front on for all my friends, really. Because, you know, everyone will say 'oh she's still the same, always the joke of the party', like I always have a smart-ass comment for everybody. I always have an answer for everyone and have everyone

laughing but then that's how everyone would see me and I don't think that has changed." (p7)

For the other participant, social occasions seemed to remind her of the person she was before she had gastroparesis, and how the illness had changed her:

"So Sunday night after the people left I actually just burst out crying because I hate being antisocial, I used to be the life of the party, I used to be the one that drunk too much and offended my mother-in-law and everything. But now, I just can't, and I'm just so worn out all the time." (p5).

See Figure 4 for an illustration of the relationship between identity and adaptation.

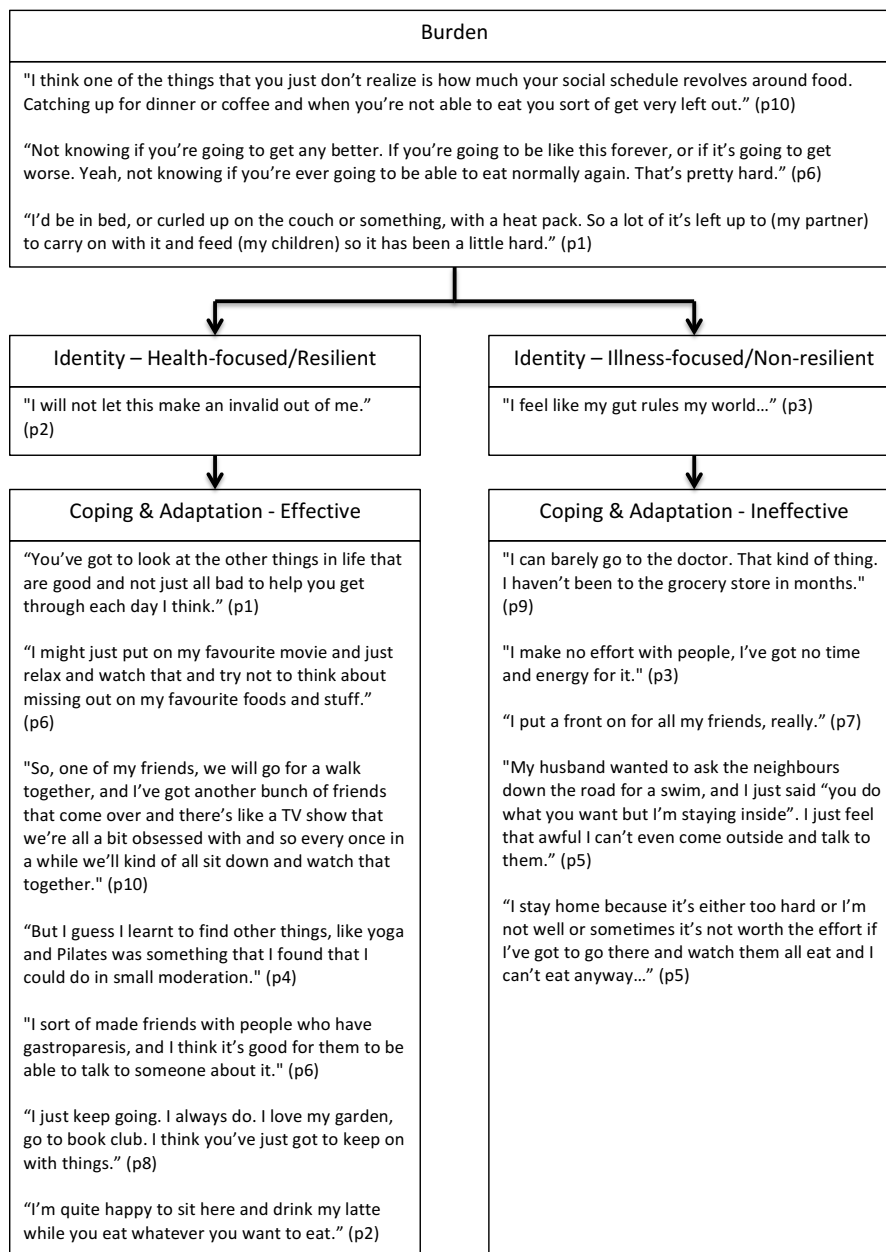


Figure 4. The relationship between illness burden, identity, and coping and adaptation in gastroparesis patients.

3.2.4 Discussion

The results of the present study provide insight into the experience of living with gastroparesis. While the physical symptoms of gastroparesis were clearly a significant issue, patients tended to place a greater emphasis on their frustration with the journey of reaching a gastroparesis diagnosis, being misunderstood and judged by healthcare professionals, friends and family, as well as the general burden of living with the condition. Identity was another clear theme in the present study, specifically relating to whether the individual identified as being resilient (health-focused) or less resilient (illness-focused). How an individual identified herself in relation to the illness appeared to be associated with how well she adapted to living with the condition, and particularly whether she remained engaged in social activities.

Consistent with previous qualitative studies (i.e., Bennell & Taylor, 2013; Bielefeldt et al., 2009), the results of the present study found that the impact of gastroparesis was not limited to physical wellbeing, but was instead pervasive throughout the individual's life. Some predominant concerns for gastroparesis patients that were reiterated by the present study included frustration regarding medical experiences, and feelings of being burdened by the condition, including loss of wellbeing, loss of relationships, and difficulty attending social occasions. Consistent with Bennell and Taylor (2013), the present study also found that gastroparesis had an impact on an individual's identity, significantly influencing how some individuals perceived themselves. Additionally, several participants reported that the intrapersonal and interpersonal burdens associated with gastroparesis led to psychological distress, which is generally consistent with previous research identifying an association between psychological factors and gastroparesis (e.g., Bielefeldt et al., 2009; Harrell et al., 2008; Hasler et al., 2010; Hasler et al., 2013; Hasler et al., 2011; Jaffe et al., 2011; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011).

With regard to coping and adaptive strategies used by gastroparesis patients, there was some disparity between previous findings and the current study. Although approaches such as the use of relaxation techniques (Bielefeldt et al., 2009), comparing self to others, and diligent planning around symptoms (Bennell & Taylor, 2013) were brought up throughout the interviews, they were

not the main strategies reported by the present sample. Rather, patients identified the importance of utilising distraction techniques, working to maintain a positive attitude, and making an effort to remain engaged in social activities as integral to coping with, and adapting to, gastroparesis. This finding suggests that the benefit of particular coping techniques may be individual specific.

The findings of this study demonstrate that the impact of gastroparesis is far-reaching, with patients reporting a significant impact across all areas of life. As there appears to be limited understanding of gastroparesis in the medical community, it is likely that patients are not being informed about the widespread impact that gastroparesis can have and may not be prepared for the tremendous influence on QoL. The impact of gastroparesis on social connections was particularly evident throughout the interviews, with participants highlighting the strong links between socialising, eating, and drinking. Being unable to eat and drink was associated with social isolation and distress, however some participants were able to adapt to the demands of gastroparesis more effectively than others. Participants who identified as being more resilient and health-focused tended to find ways to restructure their social life in order to accommodate gastroparesis symptoms. For example, going for a walk with friends rather than meeting for lunch/dinner, connecting with other gastroparesis patients online, or meeting friends at a café and being comfortable with not ordering food. Remaining socially engaged appeared to be an important factor in adapting to life with gastroparesis.

Before discussing the implications of these findings, it is important to note the methodological limitations of the present research. Firstly, as with all interview-based studies, it is possible that participants may not have been comfortable divulging personal information to the interviewer. The interviewer had no previous contact with participants other than to arrange interviews, and had no prior experience with the gastroparesis cohort. While these factors may have created a barrier between interviewer and participant, efforts were made to establish rapport and participants did not appear to be holding back. It may have been influential that the interviewer was female, had a background in psychology and mental health, and was not a health professional. As recognised by the IPA, the unique experiences of the interviewer, who was also the primary data analyst, would have had an inherent influence on data collection and data interpretation in

the present study. Therefore, future studies by other researchers may identify alternative themes.

In addition, this study utilised an all female sample, and while gastroparesis is more prevalent in females than males, key concerns relating to gastroparesis may differ between the sexes. Finally, while the qualitative nature of the present study provided a depth of understanding that could not be attained through other methodologies, there are limitations associated with it. For example, and as mentioned by Bennell and Taylor (2013), the impact of symptom severity on the key interview themes of frustration, identity, and coping and adaptation is not yet understood. Similarly, the relationships between these factors and levels of psychological distress or QoL cannot be directly assessed through a qualitative methodology.

The results of this study have clear implications for future gastroparesis research and for the healthcare needs of individuals with gastroparesis. It is evident that gastroparesis patients require treatment and support that stretches beyond physical symptom intervention and dietary advice. As highlighted by Bennell and Taylor (2013), gastroparesis patients must be provided with more holistic support. Based on the findings of the present study, a psychological support program aimed at fostering a health-focused and resilient identity may assist gastroparesis patients in adaptation. While current research provides some insight into the mechanisms that could be targeted in a psychological intervention, further research is required to build on this understanding, and to assess the effectiveness of such a program at maintaining, or improving, psychological wellbeing and QoL.

3.2.4.1 Conclusion

In summary, the present study has shown that gastroparesis patients experience significant frustration around their diagnostic journey, being misunderstood, and the burden of living with the illness. However, some patients adapt to living with the condition more effectively than others. Identity appears to play an important role in this relationship, with participants who identify as being health-focused and resilient tending to adapt more effectively and remaining more socially engaged. In order to provide the best possible support for gastroparesis

patients, it is important that a more holistic approach to treatment is embraced. The results of the present study suggest that fostering a health-focused and resilient identity in gastroparesis patients may be an important component of a targeted psychological support program for this cohort.

3.2.5 Relevance to clinical practice

The findings of this study can help nurses and other health professionals better understand the experience of living with gastroparesis and the factors that help patients best adapt to living with the condition. Nurses play an essential role in gastroparesis care and are in a position to offer support and understanding throughout the difficult diagnostic journey that patients experience. Nurses can also help promote resilience in patients by discussing the importance of being health-focused rather than illness-focused. In addition, nurses can also support patients by helping them problem solve issues that may arise around social eating and remaining socially engaged. Finally, nurses can also help to identify patients requiring further psychological support, and direct them to the appropriate services.

Chapter 4: Quantitative study

4.1 *Introduction to Paper 3*

As discussed in Paper 2, some individuals adapt to living with gastroparesis more effectively than others. Previous research demonstrates that living with gastroparesis can have a dramatic impact on an individual's life, with an influence not only on health and healthcare related concerns (Bennell & Taylor, 2013; Bielefeldt et al., 2009), but also personal relationships (Bielefeldt et al., 2009), social life (Bennell & Taylor, 2013; Bielefeldt et al., 2009), sense of identity and security (Bennell & Taylor, 2013), and professional activity (Bielefeldt et al., 2009). Paper 2 built on this understanding by identifying factors that differentiated individuals who were living well with gastroparesis from those who were not. The main differentiating factors were: (1) the way the individual identified herself in relation to the illness; and (2) the coping strategies used to manage the burdens associated with the condition.

To extend upon the findings of Paper 2, the next paper in the series sought to develop a better understanding of the relationships between gastroparesis, illness perceptions, coping styles, and psychosocial outcomes using the CSM. As explained in Section 1.7, the CSM (Leventhal et al., 1984) is a model of health psychology that has been effectively utilised across many chronic illness cohorts (Hagger & Orbell, 2003), and may provide insight into the psychological mechanisms associated with gastroparesis. Structural Equation Modeling (SEM) was used to investigate the validity of the CSM for the gastroparesis cohort. SEM allows evaluation of how well a theoretical model fits the data, and can assess the simultaneous interactions between variables that are predicted by the CSM (Craig, 2008).

The paper, "Exploring symptom severity, illness perceptions, coping styles and wellbeing in gastroparesis patients using the Common Sense Model", was co-authored with my supervisors Dr Simon R Knowles and Professor Geoff Hebbard, and was published in *Digestive Diseases and Sciences* in February 2018. This paper reports on the role of psychological mechanisms in health outcomes for gastroparesis patients, and the validity of the CSM for the gastroparesis cohort.

The Participant Consent and Information Form for this study is included in Appendix 5, and the full questionnaire is included in Appendix 6.

The following paper is a post-peer-review version of an article published in Digestive Diseases and Sciences. The final authenticated version is available online at: <http://dx.doi.org/10.1007/s10620-018-4975-x>. Further publication details are provided in Appendix 7.

4.2 Paper 3

Title: Exploring symptom severity, illness perceptions, coping styles and wellbeing in gastroparesis patients using the Common Sense Model

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Acknowledgements: This research is supported by an Australian Government Research Training Program Scholarship.

Conflict of interest statement: The authors declare that they have no conflict of interest to disclose.

4.2.1 Abstract

Aims: This study aimed to examine the relationships between gastroparesis symptom severity, illness perceptions, coping styles, quality of life (QoL), and psychological distress in patients with gastroparesis, guided by the Common Sense Model.

Methods: One hundred and seventy nine adults with gastroparesis (165 females, 14 males; mean age 41.82 years) completed an online questionnaire. The Gastroparesis Cardinal Symptom Index was used to measure gastroparesis symptom severity, QoL was explored using the PAGO-QOL, illness perceptions were measured using the Brief Illness Perception Questionnaire, the Carver Brief COPE scale assessed coping styles, and psychological distress was investigated using the DASS21.

Results: Structural equation modeling resulted in a final model with excellent fit. Gastroparesis symptom severity directly influenced illness perceptions ($\beta = .52$, $p < .001$) and QoL ($\beta = .30$, $p < .001$). Illness perceptions directly influenced maladaptive coping ($\beta = -.64$, $p < .001$), psychological distress ($\beta = -.32$, $p < .001$), and QoL ($\beta = .30$, $p = .01$). Maladaptive coping directly influenced psychological distress ($\beta = .62$, $p < .001$), which in turn had a direct influence on QoL ($\beta = -.38$, $p < .001$).

Conclusions: The final model showed that the influence of gastroparesis symptom severity on psychological distress was fully mediated by illness perceptions, while the influence on QoL was partially mediated by illness perceptions. The study provides guidance for the development of psychological interventions targeted towards improving mediating psychological factors.

Keywords: gastroparesis, quality of life, anxiety, depression, illness perception, coping

4.2.2 Introduction

Gastroparesis is a neurogastroenterological disorder associated with chronic nausea, vomiting, early satiety, bloating, postprandial fullness, and abdominal pain (Camilleri et al., 2013). The authors recently conducted a systematic review of literature examining the relationship between gastroparesis and psychosocial factors and identified that patients with gastroparesis reported significant psychological distress and poor quality of life (QoL) (Woodhouse, Hebbard, & Knowles, 2017b). One of the recommendations of the review was that future studies investigate the psychological processes that may moderate or mediate the relationship between gastroparesis symptoms and psychosocial outcomes.

There is limited understanding of the psychological factors associated with gastroparesis, however some patterns have emerged from the literature. Anxiety, depression, and somatization have been identified within the cohort (Jung et al., 2009; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011; Soykan et al., 1998; Yu et al., 2017), and it has been demonstrated that gastroparesis patients are more likely to experience lower QoL than the general population (Bielefeldt et al., 2009; Harrell et al., 2008; Jaffe et al., 2011; Yu et al., 2017). Additionally, increased gastroparesis symptom severity has been associated with greater anxiety (Hasler et al., 2010; Hasler et al., 2013; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011), depression (Bielefeldt et al., 2009; Hasler et al., 2010; Hasler et al., 2013; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011), and poorer QoL (Bielefeldt et al., 2009; Cherian et al., 2012; Cherian et al., 2010; Cutts et al., 2016; Friedenberg et al., 2013; Harrell et al., 2008; Hasler et al., 2013; Hasler et al., 2011; Jaffe et al., 2011).

In the most recent of these studies, Yu et al. (Yu et al., 2017) made a significant contribution to the literature with a large community-based study of 1423 adult gastroparesis patients. Analysis of a predictive model indicated that gastroparesis symptoms, combined with demographic variables, accounted for only 36% of the variation in physical QoL, and only 12% of the variation in mental QoL. This finding raises questions regarding other factors that may play a role in

determining QoL in the cohort. To date, the influence of psychological processes on QoL outcomes in gastroparesis has not been explored.

When considering psychological processes involved in illness outcomes such as QoL, it is helpful to consult validated models of health psychology. The Common Sense Model (CSM) has demonstrated efficacy across a range of illnesses (for a review see Hagger & Orbell, 2003), including gastrointestinal conditions such as Irritable Bowel Syndrome (IBS) (De Gucht, 2015; Knowles, Austin, et al., 2017; C. L. Rutter & Rutter, 2002) and Inflammatory Bowel Disease (IBD) (Knowles, Cook, et al., 2013; Knowles, Gass, et al., 2013; Knowles et al., 2011). Developed by Leventhal and colleagues Leventhal et al. (1984), the CSM (see Figure 5) proposes that when confronted with an illness, an individual creates a mental representation based on their experience of the illness and on information they receive about it, including factors such as cause, consequences, timeline, and controllability (e.g., “I have no control over my gastroparesis”). Illness perceptions influence illness outcomes directly (e.g., anxiety, depression, QoL) but also affect the type of coping strategies that an individual employs to manage the illness. According to the model, whether an individual uses adaptive (e.g., looking for something good in what is happening) or maladaptive (e.g., criticizing self) coping styles will also directly influence illness outcomes. Additionally, feedback loops allow the individual to appraise and evaluate at each stage of the model.

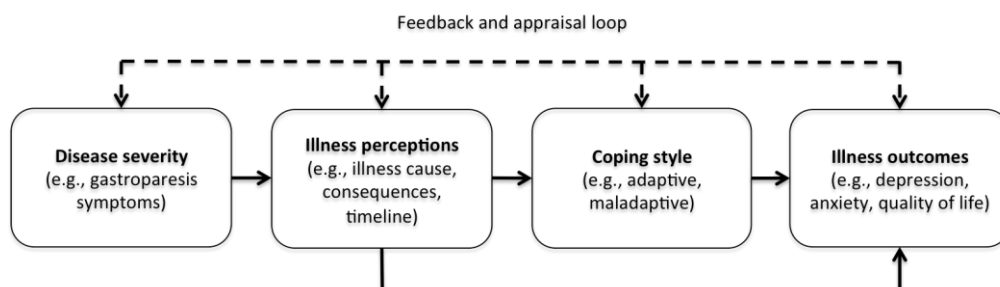


Figure 5. The Common Sense Model (Leventhal et al., 1984) adapted by Knowles et al. (2011).

Little is known about illness perceptions and coping styles of individuals living with gastroparesis. In terms of illness perceptions, the aforementioned study by Yu et al. (Yu et al., 2017) noted that 47% of patients expected their health to get worse over time and, similarly, in qualitative studies patients have reported concerns about whether they will ever be well again (Bennell & Taylor, 2013; Bielefeldt et al., 2009; Woodhouse, Hebbard, & Knowles, 2017a). Patients have also reported significant concerns around controlling their symptoms, and the feeling that gastroparesis has an extensive impact over their lives (Bennell & Taylor, 2013; Bielefeldt et al., 2009; Woodhouse et al., 2017a).

Qualitative studies also offer insight into the coping strategies used by gastroparesis patients. Some strategies have included relaxation techniques (Bielefeldt et al., 2009), comparing oneself to others who are less fortunate (Bennell & Taylor, 2013; Woodhouse et al., 2017a), preparing for symptom flares by carrying vomit bags (Bennell & Taylor, 2013), scheduling around peak symptom times (Woodhouse et al., 2017a), learning to accept the limitations of the illness (Bennell & Taylor, 2013), maintaining a positive attitude (Woodhouse et al., 2017a), using distraction techniques (Woodhouse et al., 2017a), and changing behaviour to manage the stress associated with social situations and social eating (e.g., withdrawing) (Bennell & Taylor, 2013; Woodhouse et al., 2017a). To date, a quantitative exploration of illness perceptions and coping styles in gastroparesis patients has not been conducted.

The aim of the present study was to examine the relationships between gastroparesis symptom severity, illness perceptions, coping styles, QoL, and psychological distress in patients with gastroparesis, guided by the CSM. It was hypothesised that greater gastroparesis symptoms would be associated with poorer illness perceptions, greater engagement in maladaptive coping as well as increased psychological distress and poorer QoL. It was also expected that illness perceptions and coping styles would mediate the relationships between gastroparesis symptoms, psychological distress, and quality of life.

4.2.3 Methods

4.2.3.1 Participants

Two hundred and eighty-eight participants responded to an online questionnaire. Twelve responses were deleted due to duplication across survey platforms, and 97 responses were deleted due to missing over 5% of data within a scale. The results of independent samples t-tests and one way ANOVAs demonstrated that completers and non-completers did not differ significantly in demographic characteristics.

Of the remaining 179 participants (165 females, 14 males; mean age 41.82 years), the majority were either single (39.1%) or married (37.4%), and lived in either Australia (26.8%) or the United States of America (55.9%). Participants self-reported as having been diagnosed with gastroparesis and reported experiencing gastroparesis symptoms for an average of 49.15 months ($SD=58.83$). A summary of participant characteristics is shown in Table 9.

Table 9

Demographic and disorder characteristics of the gastroparesis cohort (N=179)

Age (SD), years	41.82 (12.2)
Gender (%)	
- Female	165 (92.2)
- Male	14 (7.8)
Marital status (%)	
- Single	70 (39.1)
- Married	67 (37.4)
- Defacto	7 (3.9)
- Separated	5 (2.8)
- Divorced	26 (14.5)
- Widowed	4 (2.2)
Location (%)	
- United States of America	100 (55.9)
- Australia	48 (26.8)
- United Kingdom	16 (8.9)
- Canada	8 (4.5)
- New Zealand	2 (1.1)
- Other	5 (2.8)
Highest level of education (%)	
- Primary school	2 (1.1)
- Secondary school	11 (6.1)
- Certificate	12 (6.7)
- Diploma	42 (23.5)
- Undergraduate	53 (29.6)
- Postgraduate	44 (24.6)
- Other	15 (8.4)
Self-reported gastroparesis etiology	
- Diabetes Type I	8
- Diabetes Type II	10
- Idiopathic	101
- Post-infection	25
- Post-surgical	24
- Other (e.g., Connective Tissue Disease, neurological, medication, comorbidity)	159

4.2.3.2 *Measures****Gastroparesis Cardinal Symptom Index (GCSI)*** (Revicki et al., 2003)

The GCSI subscale of the Patient Assessment of Upper Gastrointestinal Disorders - Symptom Severity Index (PAGI-SYM) (Rentz et al., 2004) was used to assess the severity of gastroparesis symptoms. The GCSI is a 9-item scale that assesses gastroparesis symptom severity (subscales: nausea/vomiting, post-prandial fullness/early satiety, and bloating) over the past 2 weeks on a 6-point scale where 0 = “none or absent” and 5 = “very severe”. Subscale scores were

calculated by taking the mean of the items making up each subscale. The total GCSI score was calculated by taking the mean of the subscale scores, with higher scores indicating greater symptom severity (range 0-5). The GCSI demonstrated good internal consistency (.77).

Patient Assessment of Upper Gastrointestinal Disorders – Quality of Life (PAGI-QOL) (de la Loge et al., 2004)

The PAGI-QOL measured QoL in respondents. The PAGI-QOL is a 30-item scale that assesses QoL across five dimensions: daily activities, clothing, diet and food habits, relationship, and psychological wellbeing and distress. Items are prefaced with “During the past week, because of your gastrointestinal problems, how often...” and are measured on a 6-point Likert type scale where 0 = “none of the time” and 5 = “all of the time”. After reversing item scores, subscale scores were calculated by taking the mean of the items in each subscale. The total PAGI-QOL score was calculated by taking the mean of the subscale scores, with higher scores indicating higher QoL (range 0-5). The PAGI-QOL demonstrated excellent internal consistency (.95).

Brief Illness Perceptions Questionnaire (BIPQ) (Broadbent et al., 2006)

The BIPQ was used to measure cognitive and emotional representations of the illness. The BIPQ includes eight items measured on an 11-point Likert type scale (range 0-10), and one open-ended causal item. In the present study, only the eight items with numeric responses were utilised. The eight items assessed the following dimensions: consequences, timeline, personal control, treatment control, identity, concern, understanding, and emotional response. Items 3, 4, and 7 were reverse scored. Items were summed and averaged to create a total BIPQ score (range 0-10), where higher scores reflected a more threatening perception of the illness. The BIPQ had adequate internal consistency (.69).

Brief COPE (Carver, 1997)

The Brief COPE was used to assess different coping reactions in response to illness. The Brief COPE consists of 28 items measured on a 4-point scale where 0 = “I haven’t been doing this at all” and 3 = “I’ve been doing this a lot”. Consistent with

Carver (Carver, 1997), a PCA with an Oblimin rotation was performed using all scale items. An eight component pattern was indicated, however the first two components accounted for the most variance and had strong component weights. The first component was identified as maladaptive coping and consisted of 10 items (Cronbach's alpha: 0.77): "I've been saying to myself 'this isn't real'", "I've been using alcohol or other drugs to make myself feel better", "I've been giving up trying to deal with it", "I've been refusing to believe that it has happened", "I've been saying things to let my unpleasant feelings escape", "I've been using alcohol or other drugs to help me get through it", "I've been criticizing myself", "I've been giving up the attempt to cope", "I've been expressing my negative feelings", and "I've been blaming myself for things that happened".

The second component was identified as adaptive coping and consisted of 18 items (Cronbach's alpha: 0.87): "I've been turning to work or other activities to take my mind off things", "I've been concentrating my effort on doing something about the situation I'm in", "I've been getting emotional support from others", "I've been taking action to try to make the situation better", "I've been getting help and advice from other people", "I've been trying to see it in a different light, to make it seem more positive", "I've been trying to come up with a strategy about what to do", "I've been getting comfort and understanding from someone", "I've been looking for something good in what is happening", "I've been making jokes about it", "I've been doing something to think about it less, such as going to movies, watching TV, reading, daydreaming, sleeping, or shopping", "I've been accepting the reality of the fact that it has happened", "I've been trying to find comfort in my religion or spiritual beliefs", "I've been trying to get advice or help from other people about what to do", "I've been learning to live with it", "I've been thinking hard about what steps to take", "I've been praying or meditating", and "I've been making fun of the situation". Coping scores were calculated by averaging subscale item scores, with higher scores indicating a greater use of the coping style (range 0-3).

DASS-21 (Lovibond & Lovibond, 1995)

The DASS-21 was used to measure psychological distress. The DASS-21 consists of 21 items assessing depression, anxiety, and stress, on a scale where 0 =

“did not apply to me at all”, 1 = “applied to me to some degree, of some of the time”, 2= “applied to me to a considerable degree, or a good part of time”, and 3 = “applied to me very much, or most of the time”. Items were summed and multiplied by two to attain an overall measure of psychological distress, with higher scores reflecting higher levels of psychological distress (range 0-126). The DASS-21 demonstrated excellent internal consistency (.95).

4.2.3.3 *Procedure*

Data was collected via an online questionnaire that was advertised through gastroparesis-related websites, forums, and social media. Participants were not offered any compensation for taking part in the study. After following a link and providing consent, participants were able to access the questionnaire at a time and place convenient to them between August 2015 and December 2016. The questionnaire took approximately 45-60 minutes to complete. Inclusion criteria were: aged 18 years or older, diagnosed with gastroparesis, English as a first language or able to read English, and not currently experiencing severe mental illness.

The questionnaire could be accessed via two online platforms and to ensure that participants had not completed the questionnaire on both platforms, responses were assessed for duplicate patterns in demographic variables (e.g., age, height, postcode, marital status, number of dependents, years living with gastroparesis symptoms). If a duplicate was identified, the response with the greatest number of items answered was retained or, if both responses provided equal data, the first dated response was retained. This study was approved by the university ethics committee.

4.2.3.4 *Statistical analysis*

Data analysis was performed using SPSS v24 and AMOS v24. All data were subjected to exploratory and visual analysis to assess assumptions for statistical analysis. The following transformations for skewness were performed: GCSI – moderate negative skewness, PAGI-QOL – substantial positive skewness, BIPQ – moderate negative skewness, and maladaptive coping – substantial positive skewness. Correlational analyses were conducted to determine the relationships

between all study variables. A multi-factor confirmatory analysis (MF-CFA) was also conducted to assess discriminant validity between variables. A Structural Equation Model (SEM) was specified using AMOS and an iterative process was used to derive the final model. The process involved adding pathways and removing variables, while inspecting changes in standardized residuals, modification indices, and goodness of fit. Goodness of fit was assessed according to recommendations made by Kline (2016): CFI > .95, RMSEA <.10, SRMR <.10. However, RMSEA may not perform as well for models with low degrees of freedom (Kenny, Kaniskan, & McCoach, 2015).

4.2.4 Results

As shown in Table 10, on average participants reported moderate to high levels of gastroparesis symptom severity, threatening illness perceptions, moderate use of adaptive coping styles, low use of maladaptive coping styles, poor QoL, and moderate psychological distress. Gastroparesis symptom severity was found to have a significant positive relationship with illness perceptions, maladaptive coping and psychological distress, and a significant negative relationship with QoL. Illness perceptions had a significant positive correlation with maladaptive coping and psychological distress, and a significant negative correlation with QoL. Maladaptive coping had a significant positive relationship with psychological distress, and a significant negative relationship with QoL. Psychological distress had a significant negative correlation with QoL. Finally, adaptive coping was not significantly related to any other variable in the study.

Table 10

Pearson's correlations (and significance values) and descriptive values of non-transformed CSM variables (N=179)

	Gastroparesis symptom severity	Illness perceptions	Maladaptive coping	Adaptive coping	Psychological distress	Mean (SD)
Gastroparesis symptom severity	-	-	-	-	-	3.49 (.83)
Illness perceptions	.36*	-	-	-	-	7.13 (1.24)
Maladaptive coping	.29*	.45*	-	-	-	.82 (.54)
Adaptive coping	.12	-.15	-.08	-	-	1.49 (.57)
Psychological distress	.40*	.56*	.75*	-.08	-	52.00 (31.57)
Quality of life	-.54*	-.61*	-.55*	-.02	-.67*	1.78 (1.03)

Note. *p<.01.

A MANOVA was conducted to examine the relationships between demographic variables and outcome measures with results indicating that gender and self-reported etiology had a significant effect on psychological distress and QoL. Specifically, females were likely to report lower QoL than males, and individuals who believed the cause of their gastroparesis was post-surgical tended to report lower QoL than individuals who did not report post-surgical gastroparesis. While a report of diabetic (Type II) gastroparesis significantly influenced the combination of distress and QoL in the MANOVA, the influence was not noted in subsequent univariate analyses. Due to this, demographic factors were not included in the SEM.

An MF-CFA and the Fornell and Larcker (Fornell & Larcker, 1981) test were performed to assess discriminant validity of variables included in the final model. For every pair of latent variables, the average variance extracted exceeded the square of the correlation, indicating that each pair were different enough to be considered separate variables.

An SEM was developed to examine the relationships between study variables. In order to reduce measurement error, single indicator latent variables were specified with subscale internal consistency and variance. Consistent with the CSM, the focus was on understanding the impact of gastroparesis symptom severity on psychosocial outcomes through psychological mediators (i.e., illness perceptions, coping styles). Thus, pathways were added, and variables included or excluded, according to the strongest modification indices that were also consistent with the CSM research. When there were no further logical changes to be made based on the modification indices, additional pathways were added based on the CSM. Standardized residuals, modification indices, and improvement in fit were examined to assess the benefit of changes to the model.

The final model (see Figure 6) met the criteria for an excellent fit ($\chi^2 (3) = 6.43, p = .09, \chi^2/N = 2.14, CFI > 0.99, RMSEA = 0.08, SRMR < 0.03, GFI > 0.98$). The model accounted for 27 percent of the variance in illness perceptions, 41 percent of the variance in maladaptive coping, 75 percent of the variance in psychological distress, and 67 percent of the variance in QoL. Consistent with the CSM and study hypotheses, gastroparesis symptom severity had a significant direct influence on illness perceptions ($\beta = .52, p < .001$). Illness perceptions had a significant direct

effect on maladaptive coping ($\beta=-.64, p<.001$), psychological distress ($\beta=-.32, p<.001$) and QoL ($\beta=.30, p=.01$), and maladaptive coping had a significant direct effect on psychological distress ($\beta=.62, p<.001$). Illness perceptions fully mediated the relationship between gastroparesis symptom severity and maladaptive coping, gastroparesis symptom severity and distress, and partially mediated the relationship between gastroparesis symptom severity and QoL. Maladaptive coping partially mediated the relationship between illness perceptions and psychological distress.

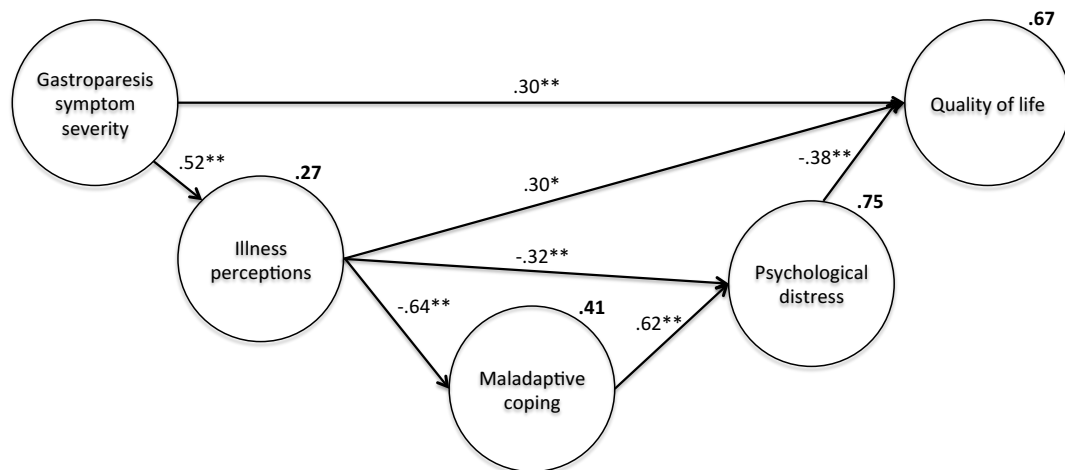


Figure 6. Final model (note: only latent variables presented with error terms removed; $***<.001$, $**=.01$; values in bold indicate the amount of variance that the model accounts for in the associated variable; values located in the centre of a pathway reflect the correlation between the variables at each end of the pathway).

Contrary to expectations, psychological distress and gastroparesis symptom severity each had a significant direct effect on QoL ($\beta=-.38, p<.001$; $\beta=.30, p<.001$, respectively). In addition, psychological distress was found to mediate the relationship between maladaptive coping and QoL. Finally, a pathway was not identified between maladaptive coping and QoL, and adaptive coping did not contribute significantly to the model and was subsequently removed.

4.2.5 Discussion

As hypothesised, the present study found that gastroparesis symptom severity was associated with poorer illness perceptions, greater engagement in maladaptive coping, increased psychological distress, and poorer QoL. Partial support was found for the second hypothesis that illness perceptions and coping styles would mediate the relationships between gastroparesis symptom severity, psychological distress, and QoL. While illness perceptions fully mediated the relationship between gastroparesis symptom severity and psychological distress, they only partially mediated the relationship with QoL. Maladaptive coping partially mediated the relationship between illness perceptions and psychological distress.

The findings lend support to previous research exploring the use of the CSM in gastrointestinal cohorts, and suggest that psychological processes may play a similar role across gastroparesis, IBS, and IBD cohorts. For example, study results are consistent with previous findings that symptom severity directly influences illness perceptions (Knowles, Austin, et al., 2017; Knowles, Cook, et al., 2013; Knowles et al., 2011), and that illness perceptions influence the use of maladaptive coping styles (Knowles, Austin, et al., 2017; Knowles, Cook, et al., 2013; Knowles et al., 2011; C. L. Rutter & Rutter, 2002). Further, results are also aligned with evidence in IBS and IBD cohorts that increased maladaptive coping leads to greater psychological distress (Knowles, Austin, et al., 2017; Knowles, Cook, et al., 2013; Knowles et al., 2011; C. L. Rutter & Rutter, 2002) and ultimately, for IBS patients, poorer QoL (Knowles, Austin, et al., 2017; C. L. Rutter & Rutter, 2002). Additionally, in finding that maladaptive coping styles influenced psychological outcomes more than adaptive coping styles, the results of the current study align with recent work

by Knowles and colleagues (Knowles, Austin, et al., 2017) focusing on the IBS cohort.

However, the model developed in the present study did not completely adhere to the CSM. Notably, the impact of symptom severity on QoL was only partially mediated by illness perceptions and maladaptive coping. This suggests that gastroparesis symptoms may have a unique influence on QoL. Although, it should also be acknowledged that these scales do have some overlap (i.e., both assess physical symptoms or the impact associated with them). Additionally, maladaptive coping had only an indirect effect on QoL via psychological distress, and did not mediate the relationship between illness perceptions and QoL. These results add to the complex and mixed findings in relation to the mediating role of coping in the CSM (Carlisle et al., 2005; Gray & Rutter, 2007; Kaptein et al., 2006; Rozema et al., 2009).

The present study also highlights the complexity of the CSM in finding that illness perceptions had an unexpected influence on coping and psychosocial wellbeing. Unlike previous studies with IBS and IBD cohorts (Knowles, Austin, et al., 2017; Knowles, Cook, et al., 2013; Knowles et al., 2011), the present study found that poorer illness perceptions led to decreased use of maladaptive coping strategies, reduced psychological distress, and improved QoL. It is possible that this disparity is due to differences in the calculations of scale scores across the studies, however the result aligns with the findings of a recent systematic review by Hagger et al. (2017), which identified that illness perceptions may motivate different coping styles and lead to different outcomes for different individuals. Hagger et al. (2017) suggest that illness characteristics and individual differences such as personality may play moderating roles in the CSM.

In addition to contributing to the CSM literature, the present study has also built on the knowledge base regarding illness perceptions and coping styles in the gastroparesis cohort. While previous studies had primarily used qualitative approaches to gain insight into how patients think about and manage gastroparesis (Bennell & Taylor, 2013; Bielefeldt et al., 2009; Woodhouse et al., 2017a), the present study was able to quantify responses from a larger sample, utilizing gold standard self-report questionnaires.

It is important to note the methodological limitations of the present study. Firstly, the study employed a predominantly female sample, and while gastroparesis is more common in females than males, there may be a difference in psychological processes and correlates between the sexes. The study utilised self-report measures for all variables and these measures can be influenced by factors such as biases and mental state at the time of completion. While the questionnaires account for these potential influences by providing anonymity and asking participants to consider their feelings over a period of time, these factors must still be considered. Additionally, the study relied on self-reported gastroparesis diagnosis and cannot ensure that the participant had actually received a formal gastroparesis diagnosis, or whether it was accurate.

Further, since the questionnaire was available online and advertised solely through websites, it is possible that a self-selection bias may have occurred. There are also other potential influencers such as gender, etiology of gastroparesis, years living with gastroparesis, personality and self-efficacy that were not evaluated in the present study. Future research could explore the impact of these, and other, patient characteristics further. It is also acknowledged that the results are reflective of the sample that was being investigated and must be repeated for generalisability to the wider gastroparesis community.

Additionally, this study was correlational and cannot determine causation. By exploring the mediating roles of illness perceptions and coping styles in the relationship between symptom severity and QoL over time, future studies could gain insight into the psychological processes that may precipitate, perpetuate, or protect against, the impact of gastroparesis symptoms on QoL. Another potential avenue for future research is to explore how psychological interventions may be able to improve QoL. It is also acknowledged that the brain-gut axis identifies bidirectional pathways between gastrointestinal symptoms and psychological processes or outcomes (Ishiguchi, Itoh, & Ichinose, 2003). Similarly, the CSM recognizes bidirectional feedback loops between the components of the model (Leventhal et al., 1984). However, the design of the present study did not allow for evaluation of the bidirectional pathways between variables, and future studies could explore these potential relationships through longitudinal and/or intervention-based studies.

These findings offer guidance for the clinical management of gastroparesis patients. It is clear that QoL is determined by far more than symptom severity and, consequently, support must be more holistic. In particular, it is indicated that by recognising relevant illness perceptions and maladaptive coping styles in patients, health professionals may be able to identify those more likely to experience reduced QoL. Psychological treatments targeting illness perceptions and maladaptive coping may be beneficial for gastroparesis patients and it is likely that mental health assessment and treatment could greatly benefit medical programs that treat patients with gastroparesis.

In conclusion, this is the first study to evaluate the CSM in a gastroparesis cohort. Using SEM, the present study demonstrates the relationships between gastroparesis symptom severity, illness perceptions, coping styles, psychological distress, and QoL. Results provide considerable support for the CSM and related research in gastroenterological cohorts, however some unpredicted relationships highlight the complexity involved in modeling psychological processes. The findings suggest that gastroparesis patients may benefit from psychological interventions targeting illness perceptions and maladaptive coping.

Chapter 5: Pilot feasibility study

5.1 *Introduction to the pilot feasibility study*

Despite evidence that gastroparesis can have a considerable psychosocial impact, in addition to recommendations that individuals with gastroparesis may benefit from psychological support (e.g., Bennell & Taylor, 2013; Bielefeldt et al., 2009), there has been little investigation into the efficacy of psychological intervention for the cohort to date. As discussed in Paper 1, only one trial of psychological intervention for individuals with gastroparesis has been documented (i.e., Y. Liu et al., 2014). While the trial revealed an improvement in depression scores following intervention, the impact of this finding was diminished due to significant methodological limitations.

The present study sought to expand on the findings of Papers 2 and 3, by conducting a pilot feasibility study of an online open intervention program targeting the psychological mechanisms found to influence psychosocial outcomes in gastroparesis patients. The main aim of the study was to attain feedback about the intervention program, including suggestions for how it could be improved or better tailored to the gastroparesis cohort. It was hypothesised that individuals who completed the program would report reduced upper GI symptom severity, psychological distress, and maladaptive coping, in addition to improved illness perceptions, adaptive coping, and QoL at post-intervention assessment compared to baseline.

This pilot feasibility study was presented at the NeuroGASTRO 2017 conference held by the European Society of Neurogastroenterology and Motility from the 24-26th August, 2017. The poster was co-authored by my supervisors Dr Simon R Knowles and Professor Geoff Hebbard and summarised the information below.

5.2 *Materials and method*

5.2.1 *Participants*

Of 97 participants who completed the pre-intervention assessment ($M=40.47$ years, $SD=12.23$), six also completed the 6-week post-intervention

assessment ($M=45.83$ years, $SD=12.61$; completion rate: 6.19%). With regard to demographic variables, completers and non-completers only differed significantly in location. For example, participants living in Canada had a 100% completion rate, while participants living in the United Kingdom had a 0% completion rate. It is also worthy of note that all completers were female. A summary of participant characteristics for post-intervention assessment completers and non-completers is shown in Table 11.

Table 11

Demographic information for post-intervention assessment completers and non-completers

	Non-completers (n= 91)	Completers (n=6)
Age (mean, SD)	40.47 (12.23)	45.83 (12.61)
Gender		
- Female	81 (89.01%)	6 (100%)
- Male	10 (10.99%)	0 (0.0%)
Marital status		
- Single	38 (41.76%)	2 (33.33%)
- Married	31 (34.07%)	3 (50.00%)
- De facto	6 (6.59%)	0 (0.0%)
- Separated	1 (1.10%)	1 (16.67%)
- Divorced	13 (14.29%)	0 (0.0%)
- Widowed	2 (2.20%)	0 (0.0%)
Highest level of education		
- Primary school	1 (1.10%)	0 (0.0%)
- Secondary school	4 (4.40%)	0 (0.0%)
- Certificate	6 (6.59%)	0 (0.0%)
- Diploma	17 (18.68%)	2 (33.33%)
- Undergraduate degree	32 (35.16%)	0 (0.0%)
- Post-graduate degree	24 (26.37%)	3 (50.00%)
- Unspecified	7 (7.69%)	1 (16.67%)
Employment status		
- Full-time	23 (25.27%)	1 (16.67%)
- Part-time	11 (12.09%)	0 (0.0%)
- Casual	5 (5.49%)	1 (16.67%)
- Self-employed	6 (6.59%)	1 (16.67%)
- Home duties	8 (8.79%)	0 (0.0%)
- Student	12 (13.19%)	0 (0.0%)
- Retired	3 (3.30%)	1 (16.67%)
- Pensioner	3 (3.30%)	1 (16.67%)
- Unemployed	11 (12.09%)	0 (0.0%)
- Unspecified	9 (9.89%)	1 (16.67%)
Location		
- Australia	29 (31.875)	2 (33.33%)
- Canada	0 (0.0%)	2 (33.33%)
- United States of America	49 (53.85%)	2 (33.33%)
- United Kingdom	9 (9.89%)	0 (0.0%)
- Other	4 (4.40%)	0 (0.0%)
Self-reported gastroparesis aetiology		
- Idiopathic	52	3
- Diabetes Type I	1	0
- Diabetes Type II	5	1
- Post-infection	15	1
- Post-surgical	10	1
- Other (e.g., Connective Tissue)	76	6
Disease, neurological, medication, comorbidity)		

5.2.2 *Materials*

5.2.2.1 *Assessments*

The pre-intervention assessment consisted of a series of demographic questions followed by validated scales assessing upper GI symptom severity and psychological factors. Due to the small sample size of this feasibility study, internal consistencies of the scales were not calculated and the full-scale scores were utilised in all analyses.

Symptom severity was assessed using the PAGA-SYM (Rentz et al., 2004). Due to the bidirectional nature of the BGA (as explained in Chapter 1.2), it is possible that a psychological intervention may be beneficial for a range of GI symptoms, not just those typically associated with gastroparesis as measured by the GCSI. For this reason, the pilot feasibility study assessed all six subscales of the PAGA-SYM (i.e., nausea/vomiting, post-prandial fullness/early satiety, bloating, upper abdominal pain, lower abdominal pain, and heartburn/regurgitation). The PAGA-SYM is a 20-item scale that assesses symptom severity relating to upper GI disorders over the past two weeks on a 6-point scale where 0="none or absent" and 5="very severe". Subscale scores were calculated by taking the mean of the subscale items, and the total PAGA-SYM score was calculated by taking the mean of the subscale scores. Higher scores indicate greater symptom severity (range 0-5).

Please see Paper 3 for detailed descriptions of the psychological assessments that were utilised in the pre-intervention questionnaire to assess illness perceptions (BIPQ; Broadbent et al., 2006), coping styles (Brief COPE; Carver, 1997), psychological distress (DASS-21; Lovibond & Lovibond, 1995), and QoL (PAGA-QoL; de la Loge et al., 2004).

The post-intervention assessment used the same scales as the pre-intervention assessment to measure upper GI symptom severity and psychological factors. The post-intervention assessment also asked participants to rate the helpfulness of each intervention module (1 = "not helpful at all" - 10 = "very helpful"). Additional feedback was attained from an adapted version of the Credibility/Expectancy Questionnaire (CEQ) (Deville & Borkovec, 2000). The CEQ assesses cognitive and affective components of belief regarding treatment expectancy and rationale credibility. Items were adapted to be more applicable to

the gastroparesis cohort, to reflect the physical and psychological aspects of the condition, and to be relevant at post-intervention rather than during intervention. The six items were assessed on a 10-point scale (e.g., “how logical does this type of treatment seem to you for helping you reduce your gastroparesis?” where 1 = “not at all logical” and 10 = “very logical”).

Feedback regarding acceptance of the intervention program was assessed using an adapted version of the Treatment Evaluation Inventory – Short Form (TEI-SF) (Kelley, Heffer, Gresham, & Elliott, 1989). The TEI-SF consists of nine items designed to measure parents’ acceptance of behavioural interventions for children. For the purposes of the present study, four items pertaining specifically to children were removed (e.g., “I believe that it would be acceptable to use this treatment without children’s consent”), leaving five items in the scale (e.g., “I liked the procedures used in this treatment”). Items were assessed on a 5-point scale where 1 = “strongly disagree” and 5 = “strongly agree”.

Finally, participants were given the opportunity to offer suggestions on how the program could be improved, and any other feedback or comments they wanted to provide, in a free-text format. A copy of the pre- and post-intervention assessments are included in Appendix 8 and Appendix 9, respectively.

5.2.2.2 *Intervention*

The present study’s intervention program (gastroparesisclinic.org) was largely based on the work of Boyce, Gilchrist, Talley, and Rose (2000). Boyce et al. (2000) developed a cognitive behaviour program for individuals with IBS that was associated with improvement in bowel symptom severity and reduction in trait anxiety and depression. Gastroparesisclinic.org was also informed by programs developed by Knowles and colleagues (i.e., IBScclinic.org.au, IBDclinic.org.au) which were adapted from the original intervention manual by Boyce et al. (2000). Gastroparesisclinic.org omitted the problem-solving module of Boyce et al.’s original manual, and included two additional modules from the work of Knowles and colleagues that related to the management of distress through distraction, cognitive diffusion, mindfulness, and guided imagery (Module 3) and pain management (Module 5). The content of each module was also modified to focus specifically on concerns and examples relevant to the gastroparesis cohort.

The program was designed to provide step-by-step therapeutic treatment, combining education about the association between gastroparesis and psychological distress with targeted behavioural and psychological strategies to help reduce distress. The intervention was accessed online via gastroparesisclinic.org and consisted of six modules (see Table 12 for a summary of program modules) to be completed over 6 weeks, with each module requiring a time commitment of approximately 1.5 hours per week.

Table 12

Summary of the gastroparesisclinic.org intervention modules

Module	Title	Content
1	Gastroparesis, personality and moving towards a positive future	<ul style="list-style-type: none"> • Information on gastroparesis and the digestive system • Link between personality and gastroparesis • Relationship between physical and psychological health, and how distress can exacerbate gastroparesis symptoms • Importance of managing unhelpful thoughts in order to manage gastroparesis • Homework: goal setting, time management, symptom monitoring
2	Reducing gastroparesis related physical and psychological distress through breathing	<ul style="list-style-type: none"> • The importance of slow breathing • The fight-flight response • Impact of hyperventilation on the digestive system • Homework: slow monitored breathing techniques, activity diary
3	Managing distress through distraction, cognitive diffusion, mindfulness, and guided imagery	<ul style="list-style-type: none"> • Distraction and cognitive diffusion techniques • Using mindfulness to reduce stress, anxiety, and gastroparesis symptoms • Mindfulness and guided imagery exercises • Homework: thoughts and feelings diary, relaxation exercises
4	Thinking straight and cognitive-challenging	<ul style="list-style-type: none"> • The influence of thoughts on feelings, anxiety, and gastroparesis • Different types of automatic thoughts • How to challenge unhelpful thoughts • Homework: thought challenging diary, relaxation exercises
5	Pain management associated with gastroparesis	<ul style="list-style-type: none"> • Physiological and psychological processes behind pain • Factors that influence the experience of pain • Overcoming common traps for individuals experiencing chronic pain • Pain management strategies • Unhelpful thoughts related to pain • Homework: thought challenging diary, pain diary, relaxation exercises
6	Challenging gastroparesis through exposure work, and keeping your progress going	<ul style="list-style-type: none"> • Guidance on how to test unhelpful thoughts through exposure • Action plans, setting goals, implementing a program to manage anxiety-provoking activities • Imaginal exposure • How to cope with setbacks • Summary of modules 1-6

5.2.3 Procedure

Adults with gastroparesis were invited through either private gastroenterologist referral or advertisements in online gastroparesis groups to participate in an online intervention program for gastroparesis-related psychological distress. After reading and accepting an online Participant Consent and Information Form (see Appendix 10), participants were able to create a login at gastroparesisclinic.org and complete a pre-intervention assessment (approximately taking 45 minutes to complete). After completing the pre-intervention assessment, participants were automatically emailed a summary of their results, and in the event of severe or very severe anxiety or depression, were advised to discuss this with their doctor.

After completing the pre-intervention assessment, participants were able to access the intervention program and were asked to complete one module of the intervention per week over six weeks. Participants were sent a reminder email if they had not logged in to their gastroparesisclinic.org account after a period of seven days. Six weeks after completing the pre-intervention assessment, participants were emailed an invitation to complete a post-intervention assessment that took approximately 30 minutes.

Individuals took part in this open trial for free, and could access the program online through the gastroparesisclinic.org website at a time and place convenient to them between February 2016 and May 2017. Inclusion criteria for the study were: aged 18 years or older, diagnosed with gastroparesis, and English as a first language or able to read English. Exclusion criteria were: currently experiencing severe mental illness or seeking support from a mental health expert.

5.3 Results

During data screening, it was identified that four of the six post-intervention assessment completers were seeking help from a mental health expert. Although it had been intended that participants seeking support from a mental health expert would be excluded according to the aforementioned exclusion criteria, due to the small number of completers, and in order to best utilise the available data, it was decided that each of the six completers would be investigated as individual case studies.

Prior to conducting the case studies, Wilcoxon Signed-Rank tests were performed to examine any differences between completers and non-completers across the CSM variables. The results indicated that completers and non-completers did not differ significantly on reports of upper GI symptom severity, illness perceptions, maladaptive coping, adaptive coping, anxiety, depression, stress, or QoL.

5.3.1 Case study 1: Jane

Jane was a 60-year-old female who self-reported experiencing gastroparesis symptoms for 5.42 years, with a post-viral aetiology. She attended sessions with a psychologist fortnightly throughout the intervention period and reported discussing the modules with her psychologist and working together to implement changes.

As shown in Table 13, Jane demonstrated post-intervention improvement in upper GI symptom severity (relative change: -26.80%), with primary reductions in the upper abdominal pain subscale (relative change: -60.00%) and the nausea/vomiting subscale (relative change: -40.00%). Despite a worsening in the timeline subscale of the BIPQ (relative change: 30.00%), there was an overall improvement in illness perceptions (relative change: -7.50%), with key subscale improvements including perceptions of personal control (relative change: -20.00%), identity (relative change: -20.00%), and emotional representation (-20.00%). The use of both maladaptive and adaptive coping styles had reduced at post-intervention assessment (relative change: -6.67% and -9.33%, respectively). Psychological distress also reduced following intervention (relative change: -41.27%), with the stress subscale offering the most notable improvement (relative change: -57.14%). Finally, QoL also demonstrated an overall improvement (relative change: 21.00%), with the most prominent changes in the daily activities (relative change: 32.00%) and psychological wellbeing and distress (relative change: 27.40%) subscales.

Jane rated Modules 4 and 6 as the most helpful modules in the intervention (helpfulness score: 10/10), followed by Module 3 (helpfulness score: 9/10), Modules 2 and 5 (helpfulness score: 8/10), and finally Module 1 as the least helpful module (helpfulness score: 5/10) (see Table 14). Jane also gave extremely positive

responses to all feedback items, indicating that she had an overall positive reaction to the treatment and believed that it was likely to be both an effective and successful approach to reducing and managing the distress associated with gastroparesis. Open-ended feedback included the following: *“So many of the things were “ah hah!” moments for me. I took notes and will continue to use the information I was taught to help me the rest of my life. Thank you so much!”*. In terms of improvements that could be made to the program, Jane noted that her psychologist was unable to log in to the program and did not receive a response after using the “contact us” email address.

Table 13

Jane's self-reported upper GI symptom severity, illness perceptions, coping styles, psychological distress, and QoL scores before and after psychological intervention

	Theoretical range	Pre-intervention score	Post-intervention score	Percentage of relative change	Direction of effect
Upper GI symptom severity	0-5	4.20	2.86	-26.80%	IMPROVED
- Nausea/vomiting	0-5	3.33	1.33	-40.00%	IMPROVED
- Post-prandial fullness/early satiety	0-5	5.00	4.25	-15.00%	IMPROVED
- Bloating	0-5	5.00	5.00	0.00%	NO CHANGE
- Upper abdominal pain	0-5	5.00	2.00	-60.00%	IMPROVED
- Lower abdominal pain	0-5	5.00	4.00	-20.00%	IMPROVED
- Heartburn/regurgitation	0-5	1.86	.57	-25.80%	IMPROVED
Illness perceptions	0-10	6.75	6.00	-7.50%	IMPROVED
- Consequences	0-10	10	10	0.00%	NO CHANGE
- Timeline	0-10	7	10	30.00%	WORSENER
- Personal control (r)	0-10	5	3	-20.00%	IMPROVED
- Treatment control (r)	0-10	3	2	-10.00%	IMPROVED
- Identity	0-10	10	8	-20.00%	IMPROVED
- Concern	0-10	9	8	-10.00%	IMPROVED
- Coherence (r)	0-10	1	0	-10.00%	IMPROVED
- Emotional representation	0-10	9	7	-20.00%	IMPROVED
Coping styles	-	-	-	-	-
- Maladaptive coping	0-3	.50	.30	-6.67%	IMPROVED
- Adaptive coping	0-3	2.22	1.94	-9.33%	WORSENER
Psychological distress	0-126	56	4	-41.27%	IMPROVED
- Depression	0-42	12	0	-28.57%	IMPROVED
- Anxiety	0-42	18	2	-38.10%	IMPROVED
- Stress	0-42	26	2	-57.14%	IMPROVED
QoL	0-5	1.37	2.42	21.00%	IMPROVED
- Daily activities	0-5	1.20	2.80	32.00%	IMPROVED
- Clothing	0-5	1.50	2.00	10.00%	IMPROVED
- Diet and food habits	0-5	0.00	1.14	22.80%	IMPROVED
- Relationship	0-5	2.00	2.67	13.40%	IMPROVED
- Psychological wellbeing and distress	0-5	2.13	3.50	27.40%	IMPROVED

Notes. (r) indicates that items have been reverse scored.

Table 14

Jane: Feedback on the gastroparesisclinic.org intervention program

Helpfulness of intervention ¹			Credibility/expectations of intervention ²			Acceptance of intervention ³		
Module	Rating scale	Score	Item	Rating scale	Score	Item	Rating scale	Score
Module 1	1 = "not at all helpful" - 10 = "very helpful"	5	How <i>logical</i> does this type of treatment seem to you for helping you reduce your gastroparesis?	1 = "not at all logical" - 10 = "very logical"	10	I find this treatment to be an acceptable way of dealing with my gastroparesis symptoms.	1 = "strongly disagree" - 5 = "strongly agree"	5
Module 2	1 = "not at all helpful" - 10 = "very helpful"	8	How <i>confident</i> are you that this therapy helped reduce your gastroparesis?	1 = "not at all confident" - 10 = "very confident"	10	I liked the procedures used in this treatment.	1 = "strongly disagree" - 5 = "strongly agree"	5
Module 3	1 = "not at all helpful" - 10 = "very helpful"	9	How <i>confident</i> would you be in recommending this intervention program to a friend who was suffering from the symptoms of gastroparesis?	1 = "not at all confident" - 10 = "very confident"	10	I believe this treatment is likely to be effective.	1 = "strongly disagree" - 5 = "strongly agree"	5
Module 4	1 = "not at all helpful" - 10 = "very helpful"	10	If you were suffering from extremely high levels of gastroparesis symptoms, would you be <i>willing to undergo</i> such treatment?	1 = "not at all willing" - 10 = "very willing"	10	I believe this treatment is likely to result in permanent improvement.	1 = "strongly disagree" - 5 = "strongly agree"	5
Module 5	1 = "not at all helpful" - 10 = "very helpful"	8	How <i>successful</i> do you feel this therapy would be in decreasing other problems involving depression and anxiety?	1 = "not at all successful" - 10 = "very successful"	10	Overall, I have a positive reaction to this treatment.	1 = "strongly disagree" - 5 = "strongly agree"	5
Module 6	1 = "not at all helpful" - 10 = "very helpful"	10	How <i>successful</i> do you feel this therapy would be in decreasing other gastro-intestinal related symptoms?	1 = "not at all successful" - 10 = "very successful"	10			

Notes. ¹Helpfulness of intervention modules scale; ²CEQ scale (adapted) (Devilley & Borkovec, 2000); ³TEI-SF scale (adapted) (Kelley et al., 1989).

5.3.1.1 *Jane: Summary*

Overall, Jane demonstrated improvements across upper GI symptom severity, illness perceptions, maladaptive coping, psychological distress and QoL at post-intervention assessment compared to pre-intervention assessment. Contrary to expectations, Jane's reported use of adaptive coping styles decreased after using the intervention program. Perhaps due to the reduction in symptom severity she did not find herself needing to turn to coping styles as frequently as at pre-intervention. Jane also reported a more chronic view of her gastroparesis at post-intervention and while this is technically a more negative illness perception, in the case of gastroparesis it may also be considered more realistic.

Jane's reports of improved wellbeing align with her very positive response to the intervention program in general. From her helpfulness ratings of the intervention modules it is indicated that she gained the most value from modules that provided guidance and activities to help challenge unhelpful thoughts, and less from the module providing information on gastroparesis and related psychological factors. Since Jane completed the intervention with the assistance of her psychologist, this may have influenced her experience of the program and could have helped her to gain increased benefit from the content. If further cases support this idea, a recommendation could be made that the program be completed with the assistance of a mental health expert. Further, Jane's open feedback highlights the need to ensure intervention email accounts are in working order and monitored regularly.

5.3.2 *Case Study 2: Nicole*

Nicole was a 38-year-old female who self-reported experiencing the symptoms of gastroparesis for five years due to diabetes (type II). Nicole was attaining mental health support from both a psychiatrist and a psychologist.

As shown in Table 15, Nicole reported reduced upper GI symptom severity at post-intervention (relative change: -18.40%). While there was an increase in post-prandial fullness/early satiety (relative change: 20.00%) the most prominent changes were reductions in bloating (relative change: -40.00%) and upper abdominal pain (relative change: -40.00%). Despite a worsening in the personal control subscale of the BIPQ, overall there was improved perception of illness at

post-intervention (relative change: -3.70%), with key changes in the coherence (relative change: -30.00%) and treatment control (relative change: -10.00%) subscales. Reports of both adaptive and maladaptive coping increased at post-intervention (relative change: 5.33% and 10.00%, respectively). Psychological distress had reduced at post-intervention assessment (relative change: -7.94%), with the largest change in the depression subscale (relative change: -19.05%) and a small increase in anxiety at post-intervention (relative change: 4.76%). Nicole reported a reduction in QoL at post-intervention assessment (relative change: -6.00%), with significant changes in two subscales: clothing (relative change: 90.00%) and relationship (relative change: -100.00%).

Nicole rated the helpfulness of all modules as five out of ten (see Table 16). While Nicole reported being very willing to undergo the gastroparesisclinic.org intervention if she were experiencing high levels of symptom severity (rating: 10/10), she did not report a positive reaction to program overall. In particular, she did not have confidence that the program could help reduce gastroparesis (rating: 1/10) or other gastrointestinal symptoms (rating: 1/10). She also did not seem to like the program in general, or believe that it was an appropriate, or potentially successful, way of targeting the symptoms often associated with gastroparesis. Nicole's open-ended feedback reflected this: *"This approach feels very much like someone telling you it is all in your head. My stomach empties slowly due to nerve damage. Deep breathing and relaxation/meditation does not make my stomach empty any more quickly. The nausea I feel is due to food sitting in my stomach too long. I don't believe this can be reduced by this program. I am malnourished due to lack of nutrients. Perhaps this program can help people with milder forms of gastroparesis"*.

Table 15

Nicole's self-reported upper GI symptom severity, illness perceptions, coping styles, psychological distress, and QoL scores before and after psychological intervention

	Theoretical range	Pre-intervention score	Post-intervention score	Percentage of relative change	Direction of effect
Upper GI symptom severity	0-5	3.78	2.86	-18.40%	IMPROVED
- Nausea/vomiting	0-5	3.33	3.00	-6.60%	IMPROVED
- Post-prandial fullness/early satiety	0-5	4.00	5.00	20.00%	WORSENERD
- Bloating	0-5	5.00	3.00	-40.00%	IMPROVED
- Upper abdominal pain	0-5	4.00	2.00	-40.00%	IMPROVED
- Lower abdominal pain	0-5	3.50	2.00	-30.00%	IMPROVED
- Heartburn/regurgitation	0-5	2.86	2.14	-14.40%	IMPROVED
Illness perceptions	0-10	8.75	8.38	-3.70%	IMPROVED
- Consequences	0-10	10	10	0.00%	NO CHANGE
- Timeline	0-10	10	10	0.00%	NO CHANGE
- Personal control (r)	0-10	9	10	10.00%	WORSENERD
- Treatment control (r)	0-10	8	7	-10.00%	IMPROVED
- Identity	0-10	10	10	0.00%	NO CHANGE
- Concern	0-10	10	10	0.00%	NO CHANGE
- Coherence (r)	0-10	3	0	-30.00%	IMPROVED
- Emotional representation	0-10	10	10	0.00%	NO CHANGE
Coping styles	-	-	-	-	-
- Maladaptive coping	0-3	0.90	1.20	10.00%	WORSENERD
- Adaptive coping	0-3	1.06	1.22	5.33%	IMPROVED
Psychological distress	0-126	78	68	-7.94%	IMPROVED
- Depression	0-42	38	30	-19.05%	IMPROVED
- Anxiety	0-42	16	18	4.76%	WORSENERD
- Stress	0-42	24	20	-9.52%	IMPROVED
QoL	0-5	1.57	1.27	-6.00%	WORSENERD
- Daily activities	0-5	1.00	0.40	-12.00%	WORSENERD
- Clothing	0-5	0.00	4.50	90.00%	IMPROVED
- Diet and food habits	0-5	0.71	1.43	14.40%	IMPROVED
- Relationship	0-5	5.00	0.00	-100.00%	WORSENERD
- Psychological wellbeing and distress	0-5	1.13	0.00	-22.60%	WORSENERD

Note: (r) indicates that items have been reverse scored.

Table 16

Nicole: Feedback on the gastroparesisclinic.org intervention program

Helpfulness of intervention ¹			Credibility/expectations of intervention ²			Acceptance of intervention ³		
Module	Rating scale	Score	Item	Rating scale	Score	Item	Rating scale	Score
Module 1	1 = "not at all helpful" - 10 = "very helpful"	5	How <i>logical</i> does this type of treatment seem to you for helping you reduce your gastroparesis?	1 = "not at all logical" - 10 = "very logical"	5	I find this treatment to be an acceptable way of dealing with my gastroparesis symptoms.	1 = "strongly disagree" - 5 = "strongly agree"	2
Module 2	1 = "not at all helpful" - 10 = "very helpful"	5	How <i>confident</i> are you that this therapy helped reduce your gastroparesis?	1 = "not at all confident" - 10 = "very confident"	1	I liked the procedures used in this treatment.	1 = "strongly disagree" - 5 = "strongly agree"	2
Module 3	1 = "not at all helpful" - 10 = "very helpful"	5	How <i>confident</i> would you be in recommending this intervention program to a friend who was suffering from the symptoms of gastroparesis?	1 = "not at all confident" - 10 = "very confident"	5	I believe this treatment is likely to be effective.	1 = "strongly disagree" - 5 = "strongly agree"	2
Module 4	1 = "not at all helpful" - 10 = "very helpful"	5	If you were suffering from extremely high levels of gastroparesis symptoms, would you be <i>willing to undergo</i> such treatment?	1 = "not at all willing" - 10 = "very willing"	10	I believe this treatment is likely to result in permanent improvement.	1 = "strongly disagree" - 5 = "strongly agree"	2
Module 5	1 = "not at all helpful" - 10 = "very helpful"	5	How <i>successful</i> do you feel this therapy would be in decreasing other problems involving depression and anxiety?	1 = "not at all successful" - 10 = "very successful"	5	Overall, I have a positive reaction to this treatment.	1 = "strongly disagree" - 5 = "strongly agree"	2
Module 6	1 = "not at all helpful" - 10 = "very helpful"	5	How <i>successful</i> do you feel this therapy would be in decreasing other gastro-intestinal related symptoms?	1 = "not at all successful" - 10 = "very successful"	1			

Notes. ¹Helpfulness of intervention modules scale; ²CEQ scale (adapted) (Devilley & Borkovec, 2000); ³TEI-SF scale (adapted) (Kelley et al., 1989).

5.3.2.1 *Nicole: Summary*

Based on pre- and post-intervention assessment, Nicole reported improvement in upper GI symptom severity, illness perceptions, and psychological distress, with greater reliance on adaptive coping styles. There was also greater use of maladaptive coping styles at post-intervention, with a possible explanation for this being that the program may have increased Nicole's awareness of maladaptive coping styles leading to increased identification. Despite reporting improvements across the majority of outcome measures, Nicole demonstrated a small decrease in QoL, which appears to have been largely due to a 100% reduction in the reported quality of her relationships. It is also noteworthy that Nicole was attaining additional support from both a psychiatrist and a psychologist during the intervention period and it is impossible to determine the impact that receiving concurrent psychological support from three separate sources had on Nicole.

While Nicole reported a number of improvements post-intervention, her feedback communicated significant concerns about the treatment program. Specifically, Nicole did not believe that the treatment could be helpful for managing gastroparesis-related symptoms and, most troublingly, believed the program implied that gastroparesis was all in the individual's mind. Although the intervention website states that the aim of the program is to provide psychological support for gastroparesis-related distress and the psychological patterns known to impact gastroparesis symptoms, Nicole's feedback suggests that the description of the gastroparesisclinic.org intervention should be revised. In particular, the description must better highlight the understanding that gastroparesis symptoms have physiological foundations *not* psychological, and that gastroparesis symptoms can exacerbate psychological distress. It must be further emphasised that the program does not aim to cure the symptoms of gastroparesis, but rather to develop psychological skills to help manage the distress associated with the condition.

5.3.3 Case study 3: Sarah

Sarah was a 31-year-old female who self-reported experiencing gastroparesis symptoms for six months, with an idiopathic aetiology. Sarah also reported attaining mental health support from a psychologist.

Sarah's pre- and post-intervention assessment scores are displayed in Table 17. Sarah reported increased upper GI symptom severity post-intervention (relative change: 4.60%), with key contributing changes in the nausea/vomiting (relative change: 20.00%) and post-prandial fullness/early satiety (relative change: 10.00%) subscales. The illness was perceived as less threatening at post-intervention assessment (relative change: -8.80%), with reductions in the concern (relative change: -30.00%), coherence (relative change: -20.00%), and emotional representation (relative change: -20.00%) subscales. It is also worth noting that the perception of illness consequences increased by 20.00%. While reported use of maladaptive coping styles remained the same as at pre-assessment, the use of adaptive coping increased (relative change: 9.33%). Increases in the depression (relative change: 33.33%) and stress (relative change: 9.52%) subscale scores resulted in an overall increase in Sarah's reported psychological distress. QoL had improved at post-intervention (relative change: 28.20%), with higher scores across all subscales and greatest changes in clothing (relative change: 50.00%) and psychological wellbeing and distress (relative change: 35.00%).

As shown in Table 18, Sarah rated all modules as very helpful (rating: 10/10), except for Module 5 (rating 5/10). Despite reporting limited confidence that the program had helped reduce her gastroparesis (rating: 5/10), Sarah reported a positive response to the program, liking the procedures and believing them to be logical and potentially successful for reducing gastrointestinal symptoms. Open-ended feedback included the following: *"Many strategies have notably helped - particularly breathing in 4s, and different thinking patterns, and goal-setting. Thank you for this opportunity to give me strategies to manage my illness. I'm still worried about the future but feel a lot better about ways to manage my health"*. Sarah also provided a suggestion for the improvement of the program: *"Shorter modules with more time commitment - the length of the modules and the variety of homework each week was difficult to juggle with my multiple other jobs. I*

would have liked time to focus on particular exercises rather than have multiple concepts covered per week.”

Table 17

Sarah's self-reported upper GI symptom severity, illness perceptions, coping styles, psychological distress, and QoL scores before and after psychological intervention

	Theoretical range	Pre-intervention score	Post-intervention score	Percentage of relative change	Direction of effect
Upper GI symptom severity	0-5	2.89	3.12	4.60%	WORSENER
- Nausea/vomiting	0-5	1.33	2.33	20.00%	WORSENER
- Post-prandial fullness/early satiety	0-5	3.00	3.50	10.00%	WORSENER
- Bloating	0-5	5.00	5.00	0.00%	NO CHANGE
- Upper abdominal pain	0-5	2.00	2.00	0.00%	NO CHANGE
- Lower abdominal pain	0-5	4.00	4.00	0.00%	NO CHANGE
- Heartburn/regurgitation	0-5	2.00	1.86	-2.80%	IMPROVED
Illness perceptions	0-10	8.13	7.25	-8.80%	IMPROVED
- Consequences	0-10	8	10	20.00%	WORSENER
- Timeline	0-10	10	10	0.00%	NO CHANGE
- Personal control (r)	0-10	8	7	-10.00%	IMPROVED
- Treatment control (r)	0-10	5	5	0.00%	NO CHANGE
- Identity	0-10	9	8	-10.00%	IMPROVED
- Concern	0-10	10	7	-30.00%	IMPROVED
- Coherence (r)	0-10	5	3	-20.00%	IMPROVED
- Emotional representation	0-10	10	8	-20.00%	IMPROVED
Coping styles	-	-	-	-	-
- Maladaptive coping	0-3	0.50	0.50	0.00%	NO CHANGE
- Adaptive coping	0-3	0.83	1.11	9.33%	IMPROVED
Psychological distress	0-126	22	38	12.70%	WORSENER
- Depression	0-42	0	14	33.33%	WORSENER
- Anxiety	0-42	4	2	-4.76%	IMPROVED
- Stress	0-42	18	22	9.52%	WORSENER
QoL	0-5	1.50	2.91	28.20%	IMPROVED
- Daily activities	0-5	2.60	3.30	14.00%	IMPROVED
- Clothing	0-5	0.00	2.50	50.00%	IMPROVED
- Diet and food habits	0-5	0.00	1.43	28.60%	IMPROVED
- Relationship	0-5	3.67	4.33	13.20%	IMPROVED
- Psychological wellbeing and distress	0-5	1.25	3.00	35.00%	IMPROVED

Note: (r) indicates that items have been reverse scored.

Table 18

Sarah: Feedback on the gastroparesisclinic.org intervention program

Helpfulness of intervention ¹			Credibility/expectations of intervention ²			Acceptance of intervention ³		
Module	Rating scale	Score	Item	Rating scale	Score	Item	Rating scale	Score
Module 1	1 = "not at all helpful" - 10 = "very helpful"	10	How <i>logical</i> does this type of treatment seem to you for helping you reduce your gastroparesis?	1 = "not at all logical" - 10 = "very logical"	10	I find this treatment to be an acceptable way of dealing with my gastroparesis symptoms.	1 = "strongly disagree" - 5 = "strongly agree"	5
Module 2	1 = "not at all helpful" - 10 = "very helpful"	10	How <i>confident</i> are you that this therapy helped reduce your gastroparesis?	1 = "not at all confident" - 10 = "very confident"	5	I liked the procedures used in this treatment.	1 = "strongly disagree" - 5 = "strongly agree"	5
Module 3	1 = "not at all helpful" - 10 = "very helpful"	10	How <i>confident</i> would you be in recommending this intervention program to a friend who was suffering from the symptoms of gastroparesis?	1 = "not at all confident" - 10 = "very confident"	10	I believe this treatment is likely to be effective.	1 = "strongly disagree" - 5 = "strongly agree"	5
Module 4	1 = "not at all helpful" - 10 = "very helpful"	10	If you were suffering from extremely high levels of gastroparesis symptoms, would you be <i>willing to undergo</i> such treatment?	1 = "not at all willing" - 10 = "very willing"	10	I believe this treatment is likely to result in permanent improvement.	1 = "strongly disagree" - 5 = "strongly agree"	4
Module 5	1 = "not at all helpful" - 10 = "very helpful"	5	How <i>successful</i> do you feel this therapy would be in decreasing other problems involving depression and anxiety?	1 = "not at all successful" - 10 = "very successful"	7	Overall, I have a positive reaction to this treatment.	1 = "strongly disagree" - 5 = "strongly agree"	5
Module 6	1 = "not at all helpful" - 10 = "very helpful"	10	How <i>successful</i> do you feel this therapy would be in decreasing other gastro-intestinal related symptoms?	1 = "not at all successful" - 10 = "very successful"	9			

Notes. ¹Helpfulness of intervention modules scale; ²CEQ scale (adapted) (Deville & Borkovec, 2000); ³TEI-SF scale (adapted) (Kelley et al., 1989).

5.3.3.1 Sarah: Summary

Sarah demonstrated improved illness perceptions, increased use of adaptive coping, and better QoL at post-intervention assessment. However, she also reported increased symptom severity and greater psychological distress, with a substantial increase in the depression score. What is of interest here is that although psychological distress had increased at post-intervention, QoL had improved. This finding might suggest that illness perceptions and adaptive coping play a more protective role in relation to QoL than psychological distress. It is also interesting to note that despite the increased distress as measured by the DASS-21, the QoL subscale measuring psychological wellbeing and distress had actually improved. Perhaps illness perceptions and adaptive coping have a different mediating effect on different aspects of psychological distress.

Although Sarah provided primarily positive feedback for the program, she was not confident that the program had helped reduce her gastroparesis symptoms, and this aligns with her ratings of increased symptom severity at post-intervention. Sarah also noted that the pain management module (Module 5) was not very helpful. Sarah reported experiencing low levels of upper abdominal pain, and fairly high levels of lower abdominal pain, suggesting that the module was appropriate for her symptoms, but that the content was not useful for some reason. If this proves to be a common finding, qualitative data on how the content could be better targeted to the gastroparesis cohort would be helpful. Further, although Sarah reported seeing a psychologist, the degree of input and support that Sarah received from the psychologist during completion of the intervention cannot be ascertained from the available data and perhaps this could be addressed in future versions of the assessments. Finally, Sarah offered practical suggestions about the structure of the program, and how to make participation more manageable (e.g., shorter and more focused modules).

5.3.4 Case study 4: Leigh

Leigh was a 37-year-old female who self-reported experiencing gastroparesis symptoms for seven months, with an idiopathic aetiology. Leigh did not report attaining support from a mental health professional.

As shown in Table 19, Leigh demonstrated reduced upper GI symptom severity at post-intervention assessment (relative change: -7.80%), with key contributors being reduction in nausea/vomiting (relative change: -26.60%) and upper abdominal pain (relative change: -20.00%). Leigh also reported improved illness perceptions (relative change: -10.00%), with the coherence (relative change: -40.00%), concern (relative change: -20.00%), and timeline (relative change: -20.00%) subscales showing the most notable improvements. However, despite the overall improvement in illness perceptions, personal control and treatment control subscales worsened (relative change for each subscale: 10.00%). Reported use of maladaptive coping styles (relative change: 13.33%) increased considerably more than the use of adaptive (relative change: 1.67%) coping styles. Psychological distress decreased at post-intervention (relative change: -15.87%), with primary changes in the anxiety (relative change: -19.05%) and stress (relative change: -19.05%) subscales. Finally, QoL also decreased over the intervention period (relative change: -11.60%), with the most evident decline in the clothing subscale (relative change: -40.00%).

Leigh rated Modules 2, 3, 4, and 6 as moderately helpful (rating: 7/10), and Modules 1 and 5 as less helpful (rating: 5/10, 4/10, respectively) (see Table 20). Leigh gave varied feedback regarding the use of the program, indicating that while she would be very willing to use the program if her gastroparesis symptoms were severe, she was not confident that the program had helped reduce her gastroparesis symptoms, and she thought the program would be slightly more appropriate for addressing mental health problems than gastrointestinal symptoms. In general, she had a fairly neutral response to the program, indicating limited belief in its effectiveness, but still finding it to be an acceptable, though not particularly logical, treatment approach. Leigh's open-ended feedback indicates that she would like a greater level of support than the gastroparesisclinic.org intervention was able to provide: *"My gastroparesis symptoms don't include pain or vomiting, just nausea, feeling very full, and being unable to eat because of that. The techniques in this program were helpful and I will continue to use them but due to my long history of severe depression, I feel like I need more than 6 weeks plus regular guidance from a therapist in order for this treatment to work for me. That said, I would still recommend this course to others"*.

Table 19

Leigh's self-reported upper GI symptom severity, illness perceptions, coping styles, psychological distress, and QoL scores before and after psychological intervention

	Theoretical range	Pre-intervention score	Post-intervention score	Percentage of relative change	Direction of effect
Upper GI symptom severity	0-5	1.71	1.32	-7.80%	IMPROVED
- Nausea/vomiting	0-5	2.33	1.00	-26.60%	IMPROVED
- Post-prandial fullness/early satiety	0-5	3.50	3.75	5.00%	WORSENER
- Bloating	0-5	1.00	1.00	0.00%	NO CHANGE
- Upper abdominal pain	0-5	2.00	1.00	-20.00%	IMPROVED
- Lower abdominal pain	0-5	1.00	1.00	0.00%	NO CHANGE
- Heartburn/regurgitation	0-5	0.43	0.14	-5.80%	IMPROVED
Illness perceptions	0-10	7.63	6.63	-10.00%	IMPROVED
- Consequences	0-10	7	6	-10.00%	IMPROVED
- Timeline	0-10	10	8	-20.00%	IMPROVED
- Personal control (r)	0-10	6	7	10.00%	WORSENER
- Treatment control (r)	0-10	5	6	10.00%	WORSENER
- Identity	0-10	6	5	-10.00%	IMPROVED
- Concern	0-10	10	8	-20.00%	IMPROVED
- Coherence (r)	0-10	7	3	-40.00%	IMPROVED
- Emotional representation	0-10	10	10	0.00%	NO CHANGE
Coping styles	-	-	-	-	-
- Maladaptive coping	0-3	0.90	1.30	13.33%	WORSENER
- Adaptive coping	0-3	1.06	1.11	1.67%	IMPROVED
Psychological distress	0-126	72	52	-15.87%	IMPROVED
- Depression	0-42	36	32	-9.52%	IMPROVED
- Anxiety	0-42	14	6	-19.05%	IMPROVED
- Stress	0-42	22	14	-19.05%	IMPROVED
QoL	0-5	2.22	1.64	-11.60%	WORSENER
- Daily activities	0-5	2.20	2.20	0.00%	NO CHANGE
- Clothing	0-5	5.00	3.00	-40.00%	WORSENER
- Diet and food habits	0-5	0.57	0.00	-11.40%	WORSENER
- Relationship	0-5	3.33	3.00	-6.60%	WORSENER
- Psychological wellbeing and distress	0-5	0.00	0.00	0.00%	NO CHANGE

Note: (r) indicates that items have been reverse scored.

Table 20

Leigh: Feedback on the gastroparesisclinic.org intervention program

Helpfulness of intervention ¹			Credibility/expectations of intervention ²			Acceptance of intervention ³		
Module	Rating scale	Score	Item	Rating scale	Score	Item	Rating scale	Score
Module 1	1 = "not at all helpful" - 10 = "very helpful"	5	How <i>logical</i> does this type of treatment seem to you for helping you reduce your gastroparesis?	1 = "not at all logical" - 10 = "very logical"	6	I find this treatment to be an acceptable way of dealing with my gastroparesis symptoms.	1 = "strongly disagree" - 5 = "strongly agree"	5
Module 2	1 = "not at all helpful" - 10 = "very helpful"	7	How <i>confident</i> are you that this therapy helped reduce your gastroparesis?	1 = "not at all confident" - 10 = "very confident"	4	I liked the procedures used in this treatment.	1 = "strongly disagree" - 5 = "strongly agree"	4
Module 3	1 = "not at all helpful" - 10 = "very helpful"	7	How <i>confident</i> would you be in recommending this intervention program to a friend who was suffering from the symptoms of gastroparesis?	1 = "not at all confident" - 10 = "very confident"	7	I believe this treatment is likely to be effective.	1 = "strongly disagree" - 5 = "strongly agree"	3
Module 4	1 = "not at all helpful" - 10 = "very helpful"	7	If you were suffering from extremely high levels of gastroparesis symptoms, would you be <i>willing to undergo</i> such treatment?	1 = "not at all willing" - 10 = "very willing"	10	I believe this treatment is likely to result in permanent improvement.	1 = "strongly disagree" - 5 = "strongly agree"	3
Module 5	1 = "not at all helpful" - 10 = "very helpful"	4	How <i>successful</i> do you feel this therapy would be in decreasing other problems involving depression and anxiety?	1 = "not at all successful" - 10 = "very successful"	9	Overall, I have a positive reaction to this treatment.	1 = "strongly disagree" - 5 = "strongly agree"	3
Module 6	1 = "not at all helpful" - 10 = "very helpful"	7	How <i>successful</i> do you feel this therapy would be in decreasing other gastro-intestinal related symptoms?	1 = "not at all successful" - 10 = "very successful"	8			

Notes. ¹Helpfulness of intervention modules scale; ²CEQ scale (adapted) (Deville & Borkovec, 2000); ³TEI-SF scale (adapted) (Kelley et al., 1989).

5.3.4.1 *Leigh: Summary*

Overall, Leigh demonstrated improvements across upper GI symptom severity, illness perceptions, adaptive coping, and psychological distress after completion of the gastroparesisclinic.org intervention program. Leigh also reported increased use of maladaptive coping styles at post-intervention, which, as mentioned previously, may be due to increased awareness of coping styles following completion of the intervention. Despite improvements across nearly all measures, Leigh also reported reduced QoL with particular concerns about being able to dress comfortably and in a way that she wanted to. Interestingly, there were no post-intervention increases in bloating or abdominal pain to coincide with the concern about clothing.

Although Leigh reported improvements across the majority of measures, her feedback was quite neutral, perhaps reflecting the reduction in QoL that she identified, and also her belief that the program could not offer enough support for her particular situation. Leigh's feedback implies that the program may be more successful if completed alongside regular sessions with a mental health expert, particularly if there is a history of mental health concerns. Leigh primarily valued modules that offered guidance on managing and challenging unhelpful thoughts, and did not benefit as much from the module that focused on information provision (Module 1). Leigh also identified that the module on pain management (Module 5) was not useful to her, which aligns with her limited experience of pain as a symptom of gastroparesis. These findings offer suggestions for the improvement of the intervention by placing greater emphasis on cognitive challenging in the future, and perhaps presenting the pain management module as optional.

5.3.5 *Case study 5: Denise*

Denise was a 61-year-old female who self-reported experiencing the symptoms of gastroparesis for 23 months. Denise identified that her gastroparesis had an idiopathic aetiology, and did not report attaining support from a mental health professional at any time during the intervention period.

Based on pre- and post-intervention assessment scores (see Table 21), Denise reported a small increase in upper GI symptom severity (relative change:

4.00%) at post intervention, with notable elevations in bloating (relative change: 20.00%) and upper abdominal pain (relative change: 20.00%). Denise's perception of her gastroparesis was slightly more negative at post-intervention (relative change: 5.00%), with a substantial increase in concerns about personal control (relative change: 60.00%) countered by a more positive view of treatment control (relative change: -20.00%). The reported use of maladaptive and adaptive coping strategies had both increased at post-intervention assessment (relative change: 10.00%, 14.67%, respectively). Increases in the stress (relative change: 14.29%) and anxiety (relative change: 4.67%) DASS-21 subscales were associated with an increase in overall psychological distress at post-intervention (relative change: 6.35%). A reduction in QoL was also demonstrated (relative change: -12.60%), which was primarily influenced by reductions in the diet and food habits subscale (relative change: -31.40%) and the relationship (relative change: -26.60%) subscale.

As shown in Table 22, Denise rated all modules as moderately helpful (rating for all modules: 7/10) and had a fairly neutral response to the intervention program in general. Denise answered most of the feedback items at the most neutral point of the rating scale, other than indicating that she would be very willing to undergo the gastroparesisclinic.org treatment program if her symptoms became severe (rating: 10/10). She also noted that the program did not seem to be a very logical type of treatment for reducing gastroparesis (rating: 3/10), and that she was not very confident that the program had helped reduce her symptoms (rating: 3/10). Denise did not provide any free-text feedback responses.

Table 21

Denise's self-reported upper GI symptom severity, illness perceptions, coping styles, psychological distress, and QoL scores before and after psychological intervention

	Theoretical range	Pre-intervention score	Post-intervention score	Percentage of relative change	Direction of effect
Upper GI symptom severity	0-5	1.93	2.13	4.00%	WORSENER
- Nausea/vomiting	0-5	2.67	3.33	13.20%	WORSENER
- Post-prandial fullness/early satiety	0-5	3.75	3.00	-15.00%	IMPROVED
- Bloating	0-5	2.00	3.00	20.00%	WORSENER
- Upper abdominal pain	0-5	1.00	2.00	20.00%	WORSENER
- Lower abdominal pain	0-5	2.00	1.00	-20.00%	IMPROVED
- Heartburn/regurgitation	0-5	0.14	0.43	5.80%	WORSENER
Illness perceptions	0-10	5.63	6.13	5.00%	WORSENER
- Consequences	0-10	10	9	-10.00%	IMPROVED
- Timeline	0-10	6	5	-10.00%	IMPROVED
- Personal control (r)	0-10	4	10	60.00%	WORSENER
- Treatment control (r)	0-10	3	1	-20.00%	IMPROVED
- Identity	0-10	8	7	-10.00%	IMPROVED
- Concern	0-10	10	10	0.00%	NO CHANGE
- Coherence (r)	0-10	2	4	20.00%	WORSENER
- Emotional representation	0-10	2	3	10.00%	WORSENER
Coping styles	-	-	-	-	-
- Maladaptive coping	0-3	0.00	0.30	10.00%	WORSENER
- Adaptive coping	0-3	0.56	1.00	14.67%	IMPROVED
Psychological distress	0-126	2	10	6.35%	WORSENER
- Depression	0-42	2	2	0.00%	NO CHANGE
- Anxiety	0-42	0	2	4.76%	WORSENER
- Stress	0-42	0	6	14.29%	WORSENER
QoL	0-5	4.03	3.40	-12.60%	WORSENER
- Daily activities	0-5	4.40	4.00	-8.00%	WORSENER
- Clothing	0-5	5.00	5.00	0.00%	NO CHANGE
- Diet and food habits	0-5	2.14	0.57	-31.40%	WORSENER
- Relationship	0-5	4.00	2.67	-26.60%	WORSENER
- Psychological wellbeing and distress	0-5	4.63	4.75	2.40%	IMPROVED

Note: (r) indicates that items have been reverse scored.

Table 22

Denise: Feedback on the gastroparesisclinic.org intervention program

Helpfulness of intervention ¹			Credibility/expectations of intervention ²			Acceptance of intervention ³		
Module	Rating scale	Score	Item	Rating scale	Score	Item	Rating scale	Score
Module 1	1 = "not at all helpful" - 10 = "very helpful"	7	How <i>logical</i> does this type of treatment seem to you for helping you reduce your gastroparesis?	1 = "not at all logical" - 10 = "very logical"	3	I find this treatment to be an acceptable way of dealing with my gastroparesis symptoms.	1 = "strongly disagree" - 5 = "strongly agree"	3
Module 2	1 = "not at all helpful" - 10 = "very helpful"	7	How <i>confident</i> are you that this therapy helped reduce your gastroparesis?	1 = "not at all confident" - 10 = "very confident"	3	I liked the procedures used in this treatment.	1 = "strongly disagree" - 5 = "strongly agree"	3
Module 3	1 = "not at all helpful" - 10 = "very helpful"	7	How <i>confident</i> would you be in recommending this intervention program to a friend who was suffering from the symptoms of gastroparesis?	1 = "not at all confident" - 10 = "very confident"	5	I believe this treatment is likely to be effective.	1 = "strongly disagree" - 5 = "strongly agree"	3
Module 4	1 = "not at all helpful" - 10 = "very helpful"	7	If you were suffering from extremely high levels of gastroparesis symptoms, would you be <i>willing to undergo</i> such treatment?	1 = "not at all willing" - 10 = "very willing"	10	I believe this treatment is likely to result in permanent improvement.	1 = "strongly disagree" - 5 = "strongly agree"	3
Module 5	1 = "not at all helpful" - 10 = "very helpful"	7	How <i>successful</i> do you feel this therapy would be in decreasing other problems involving depression and anxiety?	1 = "not at all successful" - 10 = "very successful"	5	Overall, I have a positive reaction to this treatment.	1 = "strongly disagree" - 5 = "strongly agree"	3
Module 6	1 = "not at all helpful" - 10 = "very helpful"	7	How <i>successful</i> do you feel this therapy would be in decreasing other gastro-intestinal related symptoms?	1 = "not at all successful" - 10 = "very successful"	5			

Notes. ¹Helpfulness of intervention modules scale; ²CEQ scale (adapted) (Devilly & Borkovec, 2000); ³TEI-SF scale (adapted) (Kelley et al., 1989).

5.3.5.1 *Denise: Summary*

Overall, Denise's pre- and post-intervention assessment responses indicated that only her use of adaptive coping styles had improved at post-intervention, while scores across all other variables had become worse. It is interesting to note, however, that despite a number of scores getting worse, many of them were still quite low. For example, Denise's pre- and post-intervention upper GI symptom severity scores were mild. Similarly, her post-intervention level of psychological distress was within the normal range, and although her use of maladaptive coping had increased at post-intervention, it was still an extremely low level of maladaptive coping. It is difficult to determine why Denise experienced a worsening across these variables, however it is possible that the intervention caused Denise to focus more on her illness and the limitations that are associated with it.

Feedback from Denise provides little insight into the reason for her increased symptoms and distress. Although indicating that the modules were helpful to her, Denise's feedback was quite neutral. It was clear that Denise was willing to take part in the program, but had little confidence in using the treatment to reduce gastroparesis symptoms. Perhaps since her symptoms were quite mild at pre-intervention, she did not gain as much benefit from the program. It is difficult to interpret Denise's responses to the treatment program, and it would be helpful to speak to her about her experience to gain a better understanding. In future, it may be helpful to run a trial of the intervention followed by qualitative interviews with participants to gain more detailed feedback.

5.3.6 *Case study 6: Michelle*

Michelle was 48-years-old and self-reported as having experienced gastroparesis symptoms for eight years, with a post-surgical aetiology. She reported currently attaining support from a psychologist and a psychiatrist.

As shown in Table 23, Michelle reported a worsening of upper GI symptom severity following completion of the intervention program (relative change: 12.20%), with key contributors being an increase in lower abdominal pain (relative change: 50.00%) and post-prandial fullness/early satiety (relative change: 30.00%). Illness perceptions had improved at post-intervention (relative

change: -2.50%), with a significant reduction in the treatment control (relative change: -70.00%) and emotional representation (relative change: -40.00%) subscales, and a substantial increase in the personal control subscale (relative change: 80.00%). Following intervention, maladaptive coping reduced (relative change: -23.33%) and adaptive coping remained constant. Psychological distress increased slightly at post-intervention (relative change: 4.76%), due largely to a greater report of stress level (relative change: 14.29%). Finally, the post-intervention assessment described improved QoL, with the most prominent changes in the clothing subscale (relative change: 40.00%), and the diet and food habits subscale (relative change: 34.20%).

Michelle rated all modules as being very helpful (rating for all modules: 10/10) and appeared to have a positive response to the intervention program in general (see Table 24). Michelle believed in the potential success of the program for reducing both gastrointestinal and mental health symptoms, despite reporting that the program was not particularly logical, that she was not confident that it had helped reduce her own gastroparesis symptoms, and she may not be very willing to undergo the treatment if experiencing high levels of gastroparesis symptoms. Michelle did not provide free-text feedback.

Table 23

Michelle's self-reported upper GI symptom severity, illness perceptions, coping styles, psychological distress, and QoL scores before and after psychological intervention

	Theoretical range	Pre-intervention score	Post-intervention score	Percentage of relative change	Direction of effect
Upper GI symptom severity	0-5	3.33	3.94	12.20%	WORSENERD
- Nausea/vomiting	0-5	2.67	1.33	-26.80%	IMPROVED
- Post-prandial fullness/early satiety	0-5	3.50	5.00	30.00%	WORSENERD
- Bloating	0-5	5.00	5.00	0.00%	NO CHANGE
- Upper abdominal pain	0-5	4.00	5.00	20.00%	WORSENERD
- Lower abdominal pain	0-5	2.50	5.00	50.00%	WORSENERD
- Heartburn/regurgitation	0-5	2.29	2.29	0.00%	NO CHANGE
Illness perceptions	0-10	7.63	7.38	-2.50%	IMPROVED
- Consequences	0-10	10	10	0.00%	NO CHANGE
- Timeline	0-10	10	10	0.00%	NO CHANGE
- Personal control (r)	0-10	1	9	80.00%	WORSENERD
- Treatment control (r)	0-10	7	0	-70.00%	IMPROVED
- Identity	0-10	10	10	0.00%	NO CHANGE
- Concern	0-10	10	10	0.00%	NO CHANGE
- Coherence (r)	0-10	4	4	0.00%	NO CHANGE
- Emotional representation	0-10	10	6	-40.00%	IMPROVED
Coping styles	-	-	-	-	-
- Maladaptive coping	0-3	1.60	0.90	-23.33%	IMPROVED
- Adaptive coping	0-3	1.67	1.67	0.00%	NO CHANGE
Psychological distress	0-126	70	76	4.76%	WORSENERD
- Depression	0-42	30	32	4.76%	WORSENERD
- Anxiety	0-42	22	20	-4.76%	IMPROVED
- Stress	0-42	18	24	14.29%	WORSENERD
QoL	0-5	0.48	1.13	13.00%	IMPROVED
- Daily activities	0-5	0.50	0.20	-6.00%	WORSENERD
- Clothing	0-5	0.00	2.00	40.00%	IMPROVED
- Diet and food habits	0-5	0.00	1.71	34.20%	IMPROVED
- Relationship	0-5	0.00	0.00	0.00%	NO CHANGE
- Psychological wellbeing and distress	0-5	1.88	1.75	-2.60%	WORSENERD

Note: (r) indicates that items have been reverse scored.

Table 24

Michelle: Feedback on the gastroparesisclinic.org intervention program

Helpfulness of intervention ¹			Credibility/expectations of intervention ²			Acceptance of intervention ³		
Module	Rating scale	Score	Item	Rating scale	Score	Item	Rating scale	Score
Module 1	1 = "not at all helpful" - 10 = "very helpful"	10	How <i>logical</i> does this type of treatment seem to you for helping you reduce your gastroparesis?	1 = "not at all logical" - 10 = "very logical"	5	I find this treatment to be an acceptable way of dealing with my gastroparesis symptoms.	1 = "strongly disagree" - 5 = "strongly agree"	5
Module 2	1 = "not at all helpful" - 10 = "very helpful"	10	How <i>confident</i> are you that this therapy helped reduce your gastroparesis?	1 = "not at all confident" - 10 = "very confident"	5	I liked the procedures used in this treatment.	1 = "strongly disagree" - 5 = "strongly agree"	5
Module 3	1 = "not at all helpful" - 10 = "very helpful"	10	How <i>confident</i> would you be in recommending this intervention program to a friend who was suffering from the symptoms of gastroparesis?	1 = "not at all confident" - 10 = "very confident"	10	I believe this treatment is likely to be effective.	1 = "strongly disagree" - 5 = "strongly agree"	5
Module 4	1 = "not at all helpful" - 10 = "very helpful"	10	If you were suffering from extremely high levels of gastroparesis symptoms, would you be <i>willing to undergo</i> such treatment?	1 = "not at all willing" - 10 = "very willing"	5	I believe this treatment is likely to result in permanent improvement.	1 = "strongly disagree" - 5 = "strongly agree"	5
Module 5	1 = "not at all helpful" - 10 = "very helpful"	10	How <i>successful</i> do you feel this therapy would be in decreasing other problems involving depression and anxiety?	1 = "not at all successful" - 10 = "very successful"	10	Overall, I have a positive reaction to this treatment.	1 = "strongly disagree" - 5 = "strongly agree"	5
Module 6	1 = "not at all helpful" - 10 = "very helpful"	10	How <i>successful</i> do you feel this therapy would be in decreasing other gastro-intestinal related symptoms?	1 = "not at all successful" - 10 = "very successful"	10			

Notes. ¹Helpfulness of intervention modules scale; ²CEQ scale (adapted) (Deville & Borkovec, 2000); ³TEI-SF scale (adapted) (Kelley et al., 1989).

5.3.6.1 *Michelle: Summary*

Based on pre- and post-intervention assessments, Michelle demonstrated improvements in illness perceptions, maladaptive coping, and QoL at post-intervention. Interestingly, Michelle reported greater QoL despite identifying increased symptom severity, suggesting that the improvement in psychological processes (i.e., illness perceptions, maladaptive coping) may have played a protective role. Michelle also reported increased distress at post-intervention, which was particularly noticeable on the stress subscale. While the cause of this cannot be determined, the increased stress may have had a negative influence on gastroparesis symptom severity or vice versa. Finally, attention should be given to the largest relative changes at post-intervention: personal control and treatment control. After completion of the intervention, Michelle had a much stronger belief that treatments could help her gastroparesis, and significantly reduced belief in her own control over her illness. Perhaps this is also related to her experience of elevated symptom severity.

In accordance with the improvement reported across a number of variables, Michelle provided very positive feedback for the program. Although she was not confident that the program had helped her gastroparesis symptoms, this was consistent with her increased report of gastroparesis symptom severity. It was also interesting that Michelle may not be willing to participate in the program if she was experiencing high levels of gastroparesis symptom severity, and this might indicate that she believes the program would be most effective for milder symptoms. Finally, like the majority of cases presented above, Michelle did not think the treatment was a very logical approach to reducing gastroparesis symptoms. It may be worth exploring whether further information on the link between the brain and gut could help participants understand the logic behind the treatment approach, and whether this could benefit treatment outcomes.

5.4 Discussion

The present study was the first to explore the feasibility of an online intervention program designed to target gastroparesis-related psychological distress. While the key aim of the study was to attain feedback about the program and suggestions for how it could be improved, findings also provided support for the prediction that individuals who completed the intervention program would report improved illness perceptions and adaptive coping at post-intervention compared to baseline. Contrary to expectations, half of the completers also reported increased use of maladaptive coping, and an equal number of participants reported increases and decreases in psychological distress, QoL, and upper GI symptom severity including gastroparesis symptoms specifically as well as related symptoms such as pain and heartburn/regurgitation.

As the findings of the present study are based on a small number of case studies, they offer only a starting point and should be interpreted with caution. For three of the six cases there was no improvement in upper GI symptom severity following completion of the intervention, and for the same number there was no improvement in psychological distress, or QoL. However, the majority of cases did report perceiving their gastroparesis as less threatening (five out of six cases), as well as reporting increased usage of adaptive coping styles (four out of six cases) after completing the intervention. Three of the six cases also reported increased use of maladaptive coping styles. Unfortunately, due to the limited data attained, it is difficult to determine the implications of these results or to meaningfully compare the findings to those of previous studies. Rather, the key insights afforded by the present study relate to the feedback and comments provided by completers of the intervention.

In terms of the feedback received, participants tended to prefer the modules that focused on providing psychoeducation and activities about challenging unhelpful thoughts, and managing difficult situations (i.e., Modules 4 and 6). It was evident that Module 5 was the least helpful module in the intervention. Module 5 focused on pain management, and while some participants appeared to find this less useful because pain was not a common symptom of their gastroparesis, others did not elaborate on their reasons. Module 1 also did not rate as highly as others,

perhaps because it was introductory and primarily focused on information provision rather than advising on techniques to manage distress.

The majority of participants described a positive response to the program, although they were not certain that it could result in permanent improvement in gastroparesis symptoms or that it had reduced their own symptoms. Two participants offered less enthusiastic feedback for the program, and while one of these participants offered little insight into her responses, the other stressed that the psychological focus of the intervention underestimated the physiological foundations and experience of gastroparesis. Free-text responses offered some of the most useful feedback, providing insight into participants' experiences, giving suggestions for the way that the structure of the program could be improved, offering comments on the techniques that were useful, and indicating that working with a mental health expert during completion of the program may be beneficial for some individuals.

Finally, since individuals who were seeking support from a mental health expert were included in the sample, some consideration should be given to potential differences between participants who were and were not receiving additional mental health support. Individuals who were not receiving additional support reported lower symptom severity and higher QoL at pre-intervention than those who were seeking mental health support. There did not appear to be a pattern in relative post-intervention changes between those who were seeking support and those who were not, however participants who were not receiving mental health support appeared to have a less positive reaction to the program and provided more neutral feedback overall. This may be because their challenges relating to symptom severity and QoL were not as severe as other participants and therefore the program was not as useful to them, or perhaps completing the program with the support of a mental health expert made the program more enjoyable and increased participant confidence in the program.

5.4.1 Limitations of the present study

The present feasibility study had a number of limitations, with the dropout rate for the program being a key concern. High dropout rates have been identified as one of the primary methodological challenges involved in online interventions

(Eysenbach, 2005), with greater attrition in unguided and open-access interventions than in guided programs and RCTs (H. Christensen, Griffiths, Korten, Brittliffe, & Groves, 2004; D. Richards & Richardson, 2012). A recent meta-analysis of ten self-guided web-based intervention RCTs for depression indicated that only 17% of participants completed all modules (Karyotaki et al., 2015). Similarly, another review of internet-based treatment programs with minimal therapist contact indicated an average dropout rate of 31% (range: 2-83%) (Melville, Casey, & Kavanagh, 2010). However, the dropout rate of the present feasibility study was considerably higher (i.e., 93.81%), and it is not clear why this occurred. One contributing factor may have been that participants only received emails prompting them to continue with the program, whereas phone calls or meetings may have been more effective reminders. Additionally, checking in with participants in this manner would have enabled them to provide ongoing feedback throughout the program.

The present study collected very little information on the experiences and progress of participants after registering for the intervention. Due to the intervention program being conducted as an open trial, it was not possible to identify how much of the program participants completed before dropping out, or whether they completed the entire intervention but just opted out of the post-intervention assessment. Similarly, the trial did not assess compliance, so even among participants who did complete the intervention it cannot be determined whether they read all of the intervention modules and completed the homework tasks.

Finally, due to the very small number of intervention completers in the present study, participants who were seeking support from a mental health expert were included in the sample. This is clearly a significant confounding factor in the study as the influence of external therapeutic relationships on the effectiveness of the intervention, and attitude towards the intervention, cannot be determined. Future revisions and evaluations of the gastroparesisclinic.org program should address these methodological limitations.

5.4.2 *Directions for future research*

Further trials of this intervention program are required. Prior to conducting these trials, program content should first be revised to address the feedback from participants in the present feasibility study. The priority should be to check website content and make necessary edits to ensure that the physiological basis of gastroparesis and its symptoms are clearly acknowledged. It is crucial for readers to understand that while gastroparesis can exacerbate psychological distress, it is not caused by psychological distress.

However, given the bidirectional understanding of the brain-gut axis, a properly powered psychological intervention may influence gastroparesis symptom severity. Additionally, a psychological intervention may have beneficial effects for other symptoms that individuals with gastroparesis may report. Thus, while a primary outcome measure for gastroparesis is the GCSI subscale of the PEGI-SYM, future research benefit from including the other PEGI-SYM subscales as the present feasibility study has suggested some improvements may be evident across related symptoms.

Further changes relate to the topics addressed in intervention modules, and the type of feedback that should be attained from participants. Firstly, modules could be amended to be shorter and more focused, and the module on pain could be removed from the program and replaced by greater detail on topics that participants found more helpful (e.g., cognitive challenging). In this case, the information on pain management may be made available as an optional module or a handout for those who wish to read it. A number of participants used this intervention while also seeing a mental health expert, and for some this appeared to be a positive combination. If including participants who are seeing a mental health expert in future studies, it may be useful to have a question about what kind of support was provided so that more can be learnt about the beneficial aspects of this addition to the intervention. Finally, the program should be developed in a way that enables systematic feedback about engagement and compliance. A function that may be helpful is the integration of feedback requests as a prerequisite for progressing to the next module in the intervention.

After addressing the above recommendations, it is suggested that the next trial of gastroparesisclinic.org should incorporate a qualitative component. For example, a moderate number of participants (e.g., an n of 23 would be needed to obtain statistical power at the .80 level) could receive weekly contact from researchers to discuss their progress in the intervention, including any issues encountered or problems with compliance. Further, a qualitative interview could be conducted at the end of the intervention to attain additional feedback and recommendations, and discuss the general experience of using the program. After alterations are made to the program based on this qualitative evaluation, the next step would be to conduct a RCT to assess the efficacy of the intervention.

5.4.3 Conclusion

The present study contributed to the literature on gastroparesis by developing and implementing a psychological intervention program to address the psychological distress and poor QoL that is often associated with gastroparesis. In particular, the pilot intervention program sought to target psychological processes that have previously been shown to influence health outcomes in the gastroparesis cohort (Paper 3). Due to the limited number of participants who completed the intervention program, little meaning could be inferred from the results pertaining to the impact of the intervention on psychosocial outcomes. Rather, the present study contributed to the literature by gathering valuable comments and feedback from participants regarding the online program, which will help to refine future iterations of the intervention. While the present study has provided an important starting point for the use of online psychological interventions to support individuals with gastroparesis, further research that addresses the limitations of the study and the feedback from participants is required.

Chapter 6: Discussion

The main aim of this PhD research project was to better understand the relationships between gastroparesis, psychological factors, and QoL. The final goal of the research project was to develop and pilot test an online psychological intervention program for individuals with gastroparesis. This was achieved by conducting a systematic review of the relevant literature and a qualitative study that focused on investigating the impact of gastroparesis and how individuals manage the illness. Additionally, using SEM, the CSM was applied to investigate possible psychological mediators of change in the relationship between gastroparesis and psychosocial outcomes. Finally, a pilot study was conducted to assess the feasibility of an online psychological intervention program for individuals with gastroparesis. Chapter 6 will now present the findings of the studies conducted, as well as the limitations and implications of the research.

6.1 *Paper 1: Systematic review*

The first study in this series sought to summarise and evaluate what was already known about the association between gastroparesis and psychosocial outcomes. The systematic review (Paper 1) aimed to explore the prevalence of psychopathology within the gastroparesis cohort, as well as the levels of anxiety, depression, and QoL, and how they relate to characteristics of the disorder such as aetiology, duration of symptoms, and degree of gastric retention. Additionally, the review sought to investigate the application and efficacy of psychological interventions for individuals with gastroparesis.

The main findings of the systematic review were that increased gastroparesis symptom severity was associated with greater psychological distress and poorer QoL, and that QoL was lower in the gastroparesis cohort than in the general population. These findings are aligned with what has been demonstrated across many chronic illness cohorts, including those with gastrointestinal conditions (e.g., Aro et al., 2011; Chou et al., 2001; Filipovic et al., 2013; Fischler et al., 2003; Frank et al., 2002; Gralnek et al., 2000; Haug, Svebak, Hausken, et al., 1994; M. P. Jones & Maganti, 2004; Jonsson, Theorell, & Gotthard, 1995; Koloski et al., 2012; Mones et al., 2002; Pace et al., 2003; Pizzi et al., 2006; Strid et al., 2001;

Talley et al., 2006; Van Oudenhove, Vandenberghe, Vos, Holvoet, et al., 2011; Wahass et al., 2006). The findings offer further evidence of the psychosocial distress associated with chronic gastrointestinal symptoms, and point toward the need for gastroparesis sufferers to have access to appropriate psychological support.

The systematic review concluded that there was either too little research or the available research was too methodologically inconsistent to resolve other research questions that had been raised. For example, the review was unable to determine the prevalence of psychopathology in gastroparesis, to assess the severity of anxiety and depression in the gastroparesis cohort, or to compare levels of psychological distress and QoL in the gastroparesis cohort across disorder characteristics or to other chronic illness cohorts. Additionally, there was not enough evidence to determine the efficacy of psychological intervention for individuals with gastroparesis. The review emphasised the need for further research in this area, and a thorough list of suggestions for future research was provided.

6.2 *Paper 2: Qualitative study*

After establishing that psychological distress and poor QoL were evident in the gastroparesis cohort, focus was then directed towards developing a deeper understanding of how individuals experience living with gastroparesis. Specifically, the qualitative study (Paper 2) aimed to improve understanding of how gastroparesis impacts upon the lives of sufferers and the strategies used to manage it. Findings of the study indicated that the negative impact of gastroparesis stretched far beyond the experience of physical symptoms, with participants emphasising the frustration around trying to obtain a diagnosis, the feeling of being misunderstood by others, and the loss of wellbeing and social life. This finding was consistent with previous qualitative research highlighting the variety of challenges that individuals with gastroparesis experience, particularly around medical situations, relationships, and social events (Bennell & Taylor, 2013; Bielefeldt et al., 2009).

Paper 2 also highlighted the important role of identity for individuals with gastroparesis. A previous study by Bennell and Taylor (2013) had also found an

association between gastroparesis and identity, whereby the way in which individuals related to the illness influenced how they described themselves, activities that they would participate in, and also how they related to others. Similarly, our study demonstrated that how the individual identified herself in relation to the illness played a role in how she adapted to living with gastroparesis, and particularly whether or not she remained socially engaged.

Participants reported utilising a number of different strategies to help manage the burdens associated with gastroparesis. Some of the coping strategies reported in our study (e.g., relaxation techniques, planning events around symptoms) overlapped with those mentioned in previous studies (Bennell & Taylor, 2013; Bielefeldt et al., 2009). However, participants also emphasised strategies that had not been mentioned previously, including the significance of maintaining a positive attitude and remaining socially engaged. While it was clear that some individuals adapted to gastroparesis more effectively than others, the importance of different strategies to different people suggested that the benefit of particular coping styles might be specific to the individual.

6.3 *Paper 3: Quantitative study*

Having gained preliminary insight into psychological processes that may influence adaptation to gastroparesis, the third study (Paper 3) in this project sought to further explore the role of potential psychological mediators in the relationship between gastroparesis symptoms and psychosocial outcomes using the CSM. The results of the third study supported the hypothesis that gastroparesis symptom severity would be associated with more negative illness perceptions, increased maladaptive coping, greater psychological distress, and poorer QoL. These relationships align with previous evidence that increased gastroparesis symptom severity is associated with greater psychological distress (Bielefeldt et al., 2009; Hasler et al., 2010; Hasler et al., 2013; Parkman, Yates, Hasler, Nguyen, Pasricha, Snape, Farrugia, Koch, Abell, et al., 2011) and lower QoL (Bielefeldt et al., 2009; Cherian et al., 2012; Cherian et al., 2010; Cutts et al., 2016; Friedenberg et al., 2013; Harrell et al., 2008; Hasler et al., 2013; Hasler et al., 2011; Jaffe et al., 2011), as detailed in the systematic review (Paper 1). While illness perceptions and coping styles had not been previously explored in the gastroparesis cohort, finding

that greater symptom severity was associated with poorer illness perceptions and increased maladaptive coping aligns with findings in other gastrointestinal cohorts (e.g., Knowles, Austin, et al., 2017; Knowles, Cook, et al., 2013; Knowles et al., 2011).

Based on the CSM, it was also hypothesised that illness perceptions and coping styles would mediate the relationships between gastroparesis symptom severity, psychological distress, and QoL. This hypothesis was partly supported, with findings that illness perceptions fully mediated the relationship between symptom severity and psychological distress, and partially mediated the relationship with QoL. Additionally, maladaptive coping partially mediated the relationship between illness perceptions and psychological distress. In many ways the results are aligned with similar CSM research using IBS and IBD cohorts. For example, by demonstrating that symptom severity directly influences illness perceptions (Knowles, Austin, et al., 2017; Knowles, Cook, et al., 2013; Knowles, Gass, et al., 2013), that illness perceptions influence the use of maladaptive coping styles (Knowles, Austin, et al., 2017; Knowles, Cook, et al., 2013; Knowles, Gass, et al., 2013; C. L. Rutter & Rutter, 2002), and also by demonstrating that the use of maladaptive coping styles influences psychological wellbeing (Knowles, Austin, et al., 2017; Knowles, Cook, et al., 2013; Knowles, Gass, et al., 2013; C. L. Rutter & Rutter, 2002).

As explained in Paper 3, these findings emphasise that psychological processes play an important role in the experience of gastroparesis. Further, the final model developed as part of this study suggests that there may be additional and unaccounted for factors that influence psychosocial outcomes in the gastroparesis cohort. While it is a limitation of the study that only two mechanisms were investigated, the findings highlight that this is an area requiring further research. Finally, in finding that the influence of coping styles deviated somewhat from expectations, the results have contributed to literature documenting mixed findings relating to the role of coping styles in the CSM.

6.4 Pilot feasibility study

After identifying psychological mechanisms that may influence psychological distress and QoL in individuals with gastroparesis, the PhD research

project culminated in a pilot feasibility study of an online psychological intervention. Guided by the findings of the previous studies (Papers 1-3), in addition to evidence for CBT-based interventions in gastrointestinal conditions such as IBS (e.g., Boyce et al., 2000), an intervention was designed to help individuals with gastroparesis develop more positive illness perceptions and more effective coping strategies, with the anticipation that this may ultimately improve psychosocial wellbeing. The structure and content of the intervention were based on the work of Boyce et al. (2000) and adaptations of Boyce et al.'s program by Knowles and colleagues for IBSclinic.org.au and IBDclinic.org.au. The intervention provided evidence-based psychological treatment, online and free-of-charge to individuals with gastroparesis, over a period of six weeks.

The pilot feasibility study involved case studies of six post-intervention assessment completers, providing a combination of expected and unexpected results. As hypothesised, individuals who completed the intervention program reported improved illness perceptions and adaptive coping at post-intervention compared to baseline. However, contrary to expectations, half of the intervention completers also reported increased use of maladaptive coping, and an equal number of participants reported increases and decreases in upper GI symptom severity, psychological distress, and QoL.

Due to the limited number of intervention completers, little could be inferred from the data concerning the influence of the program on psychosocial outcomes for individuals with gastroparesis. Rather, the focus of the study was redirected towards gathering feedback from participants about the online psychological intervention program. The majority of participants reported a positive response to the program and found the intervention modules helpful, although it was clear that some modules were more helpful than others (e.g., Modules 4 and 6 were more helpful than Module 5). Participants offered detailed comments on the experience of using the program, possible structural changes to the intervention, and using additional support from a mental health expert. Notably, two participants did not report a positive response of the intervention, with one emphasising that the psychological focus undermined the physical reality of gastroparesis.

Despite the methodological limitations of this study (e.g., small sample, inclusion of participants who were seeking mental health support, open-trial with high dropout rate, no evidence relating to compliance), the feedback obtained from this feasibility study offers valuable guidance for the refinement of the program. Future iterations of the program should address the limitations and feedback identified through this feasibility study, in preparation for future evaluations and RCTs of the intervention program.

6.5 *Limitations of the PhD research*

While this PhD research project has contributed substantially to the literature on relationships between gastroparesis, psychological factors, and psychosocial outcomes, the limitations of the research must be considered. The limitations pertaining to each individual study have been noted in the relevant papers, thus only the limitations of the research project in general will be discussed here.

Firstly, all of the studies used a predominantly female sample and therefore the findings may not be as applicable to males with gastroparesis. Further, since recruitment was largely accomplished through online community pages, and studies 3 and 4 were conducted completely online, a self-selection bias may have occurred. Additionally, individual characteristics such as aetiology of gastroparesis, duration of symptoms, personality, locus of control, and self-efficacy may also impact upon results and were not evaluated in the research project.

The use of self-report measures throughout all studies in the project also poses a limitation. For example, it cannot be ensured that participants had received a formal gastroparesis diagnosis. Additionally, while psychological assessments endeavor to account for influences such as mental state at time of completion, such potential influences cannot be discounted. These limitations emphasise that the findings are reflective of the samples involved in the studies and replication is required to determine generalizability.

6.6 *Implications of the research*

While further research is needed to support and build on the findings of this PhD research, the current results have important implications for the treatment of

individuals with gastroparesis. It is evident that the challenges associated with living with gastroparesis extend far beyond the experience of physical symptoms. Thus, treatment must also extend beyond symptom management and dietary support. In particular, gastroparesis sufferers may benefit from psychological support that targets the psychological distress and poor QoL commonly associated with gastroparesis.

The research also indicates that psychological support that aims to develop resilience by targeting negative illness perceptions and maladaptive coping styles may be particularly beneficial for the gastroparesis cohort. Further, health care practitioners trained to recognise illness perceptions and coping styles may be able to identify individuals at risk for poor psychosocial outcomes and ensure that they are provided with appropriate support options. Such psychological support could be a valuable addition to standard medical care for individuals with gastroparesis.

6.7 *Conclusion*

This PhD research has significantly contributed to scientific understanding of the associations between gastroparesis, psychological distress, and QoL by addressing several key limitations of the literature. Firstly, the project has generated a comprehensive understanding of what is known about the interplay between gastroparesis and psychosocial factors. A systematic review (Paper 1) demonstrated that increased gastroparesis symptom severity is associated with greater psychological distress and poorer QoL, and that QoL is lower in gastroparesis cohorts than in the general population. The systematic review also highlighted the substantial limitations of the available research, and provided guidance for the development of future studies.

Secondly, the project has built on previous knowledge by exploring the experiences of individuals with gastroparesis, with a particular focus on the coping strategies employed by the cohort. Thematic analysis of interviews with gastroparesis sufferers supported the findings of previous studies identifying that the burdens associated with gastroparesis extend beyond the physical experience of the disorder. Study 2 (Paper 2) contributed to the knowledge base by identifying that some individuals adapt to gastroparesis more effectively than others, and by

documenting associations between particular coping strategies and level of adaptation to gastroparesis. The study also noted the important role of identity in gastroparesis sufferers and how it relates to coping styles and adaptation.

Thirdly, this PhD research included the first study to investigate the role of psychological mediators in psychosocial outcomes for the gastroparesis cohort. Using the CSM, Study 3 (Paper 3) demonstrated that illness perceptions and maladaptive coping play a mediating role in the relationship between gastroparesis symptom severity and psychosocial outcomes. In doing so, the study contributed to the literature on the CSM, and also identified psychological mechanisms that may be beneficial to target in psychological interventions for the gastroparesis cohort.

Finally, this PhD project conducted the first pilot feasibility study of a theoretically-derived psychological treatment program designed to target gastroparesis-related psychological distress. While further exploration is required, the majority of participants reported a positive response to the program and offered valuable feedback that can be used to improve the program and prepare for future trials of the intervention.

Overall, this research has highlighted the breadth of psychosocial challenges gastroparesis sufferers may experience. The research has also demonstrated the influence of psychological processes on psychosocial outcomes within the cohort, thus recognising the potential benefit of psychological treatment for the gastroparesis cohort. Finally, the PhD research has provided preliminary evidence for the feasibility of a free, online, psychological intervention program to help support individuals living with gastroparesis.

References

- Aalto, A.-M., Aro, A. R., Weinman, J., Heijmans, M., Manderbacka, K., & Elovainio, M. (2006). Sociodemographic, disease status, and illness perceptions predictors of global self-ratings of health and quality of life among those with coronary heart disease - one year follow-up study. *Quality of Life Research, 15*, 1307-1322. doi:10.1007/sl
- Abell, T., Bernstein, R. K., Cutts, T., Farrugia, G., Forster, J., Hasler, W. L., . . . Vinik, A. I. (2006). Treatment of gastroparesis: a multidisciplinary clinical review. *Neurogastroenterology and Motility, 18*(4), 263-283. doi:10.1111/j.1365-2982.2006.00760.x
- Abell, T., Camilleri, M., Donohoe, K., Hasler, W. L., Lin, H. C., Maurer, A. H., . . . the Society of Nuclear, M. (2008). Consensus recommendations for gastric emptying scintigraphy: a joint report of the American Neurogastroenterology and Motility Society and the Society of Nuclear Medicine. *American Journal of Gastroenterology, 103*(3), 753-763. doi:10.1111/j.1572-0241.2007.01636.x
- Abell, T., Johnson, W. D., Kedar, A., Runnels, J. M., Thompson, J., Weeks, E. S., . . . Griswold, M. E. (2011). A double-masked, randomized, placebo-controlled trial of temporary endoscopic mucosal gastric electrical stimulation for gastroparesis. *Gastrointestinal Endoscopy, 74*(3), 496-503 e493. doi:10.1016/j.gie.2011.05.022
- Adler, J., Raju, S., Berveridge, A. S., Wang, S., Zhu, J., & Zimmerman, E. M. (2008). College adjustment in University of Michigan students with Crohn's and Colitis. *Inflammatory Bowel Diseases, 14*(9), 1281-1286.
- Al Omran, Y., & Aziz, Q. (2014). The brain-gut axis in health and disease. *Advances in Experimental Medicine and Biology, 817*, 135-153. doi:10.1007/978-1-4939-0897-4_6
- Alexander, P. J., & Tantry, B. V. (1993). Role of anxiety and personality in non-ulcer dyspepsia: a comparative study with duodenal ulcer. *Indian Journal of Gastroenterology, 12*(3), 86-88.
- Alfonsson, S., Wallin, E., & Maathz, P. (2017). Factor structure and validity of the Depression, Anxiety and Stress Scale-21 in Swedish translation. *Journal of*

Psychiatric and Mental Health Nursing, 24(2-3), 154-162.

doi:10.1111/jpm.12363

- Ali, S., Stone, M., Skinner, T. C., Robertson, N., Davies, M., & Khunti, K. (2010). The association between depression and health-related quality of life in people with type 2 diabetes: a systematic literature review. *Diabetes/Metabolism Research and Reviews*, 26(2), 75-89. doi:10.1002/dmrr.1065
- Almadani, S. B., Adler, J., Browning, J., Green, E. H., Helvie, K., Rizk, R. S., & Zimmermann, E. M. (2014). Effects of inflammatory bowel disease on students' adjustment to college. *Clinical Gastroenterology and Hepatology*, 12(12), 2055-2062 e2051. doi:10.1016/j.cgh.2014.03.032
- Altayar, O., Sharma, V., Prokop, L. J., Sood, A., & Murad, M. H. (2015). Psychological therapies in patients with irritable bowel syndrome: a systematic review and meta-analysis of randomized controlled trials. *Gastroenterol Res Pract*, 2015, 549308. doi:10.1155/2015/549308
- Aro, P., Talley, N. J., Agreus, L., Johansson, S. E., Bolling-Sternevald, E., Storskrubb, T., & Ronkainen, J. (2011). Functional dyspepsia impairs quality of life in the adult population. *Alimentary Pharmacology and Therapeutics*, 33(11), 1215-1224. doi:10.1111/j.1365-2036.2011.04640.x
- Bai, Y., Xu, M. J., Yang, X., Xu, C., Gao, J., Zou, D. W., & Li, Z. S. (2010). A systematic review on intrapyloric botulinum toxin injection for gastroparesis. *Digestion*, 81(1), 27-34. doi:10.1159/000235917
- Baron, R. M., & Kenny, D. A. (1986). The moderator-mediator variable distinction in social psychology research: conceptual, strategic, and statistical considerations. *Journal of Personality and Social Psychology*, 51(6), 1173-1182.
- Bates, S., Sjöden, P.-O., & Nyrén, O. (1988). Behavioral Treatment of Non-Ulcer Dyspepsia. *Scandinavian Journal of Behaviour Therapy*, 17(2), 155-165. doi:10.1080/16506078809456271
- Beck, A. T., Epstein, N., Brown, G., & Steer, R. A. (1988). An inventory for measuring clinical anxiety: psychometric properties. *Journal of Consulting and Clinical Psychology*, 56(6), 893-897. doi:10.1037/0022-006X.56.6.893
- Beck, A. T., Steer, R. A., Ball, R., & Ranieri, W. (1996). Comparison of Beck Depression Inventories -IA and -II in psychiatric outpatients. *Journal of*

- Personality Assessment*, 67(3), 588-597.
doi:10.1207/s15327752jpa6703_13
- Ben-Ezra, M., Hamama-Raz, Y., Palgi, S., & Palgi, Y. (2015). Cognitive appraisal and psychological distress among patients with Irritable Bowel Syndrome. *Israel Journal of Psychiatry and Related Sciences*, 52(1), 54-60.
- Benedini, V., Caporaso, N., Corazza, G. R., Rossi, Z., Fornaciari, G., Cottone, M., . . . Colombo, G. L. (2012). Burden of Crohn's disease: economics and quality of life aspects in Italy. *Clinicoecon Outcomes Res*, 4, 209-218.
doi:10.2147/CEOR.S31114
- Bennell, J., & Taylor, C. (2013). A loss of social eating: the experience of individuals living with gastroparesis. *Journal of Clinical Nursing*, 22(19-20), 2812-2821.
doi:10.1111/jocn.12196
- Bernstein, C. N., Singh, S., Graff, L. A., Walker, J. R., Miller, N., & Cheang, M. (2010). A prospective population-based study of triggers of symptomatic flares in IBD. *American Journal of Gastroenterology*, 105(9), 1994-2002.
doi:10.1038/ajg.2010.140
- Bielefeldt, K. (2012). Gastroparesis: Concepts, Controversies, and Challenges. *Scientifica (Cairo)*, 2012, 424802. doi:10.6064/2012/424802
- Bielefeldt, K., Raza, N., & Zickmund, S. L. (2009). Different faces of gastroparesis. *World Journal of Gastroenterology*, 15(48), 6052 - 6060.
doi:10.3748/wjg.15.6052
- Bielefeldt, K., Tuteja, A., & Nusrat, S. (2016). Disorders of gastrointestinal hypomotility. *F1000Res*, 5. doi:10.12688/f1000research.8658.1
- Blondel-Kucharski, F., Chircop, C., Marquis, P., Cortot, A., Baron, F., Gendre, J., . . . Groupe d'Etudes Therapeutique des Affections Inflammatoires Digestives (GETAID). (2001). Health-related quality of life in Crohn's disease: A prospective longitudinal study in 231 patients. *The American Journal of Gastroenterology*, 96(10), 2915-2920.
- Borgaonkar, M. R., & Irvine, E. J. (2000). Quality of life measurement in gastrointestinal and liver disorders. *Gut*, 47, 444-454.
- Borge, C. R., Moum, T., Puline Lein, M., Austegard, E. L., & Wahl, A. K. (2014). Illness perception in people with chronic obstructive pulmonary disease.

Scandinavian Journal of Psychology, 55(5), 456-463.

doi:10.1111/sjop.12150

Borges, C. M. R., Secaf, M., & Troncon, L. E. (2013). Clinical features and severity of gastric emptying delay in Brazilian patients with gastroparesis. *Arquivos de Gastroenterologia*, 50(4), 270-276. doi:10.1590/S0004-28032013000400006

Borre, Y. E., Moloney, R. D., Clarke, G., Dinan, T. G., & Cryan, J. F. (2014). The impact of microbiota on brain and behavior: mechanisms & therapeutic potential. *Advances in Experimental Medicine and Biology*, 817, 373-403. doi:10.1007/978-1-4939-0897-4_17

Boyce, P. M., Gilchrist, J., Talley, N. J., & Rose, D. (2000). Cognitive-behaviour therapy as a treatment for irritable bowel syndrome: a pilot study. *Australian and New Zealand Journal of Psychiatry*, 34, 300-309.

Broadbent, E., Petrie, K. J., Main, J., & Weinman, J. (2006). The brief illness perception questionnaire. *Journal of Psychosomatic Research*, 60(6), 631-637. doi:10.1016/j.jpsychores.2005.10.020

Bryant, R. V., van Langenberg, D. R., Holtmann, G. J., & Andrews, J. M. (2011). Functional gastrointestinal disorders in inflammatory bowel disease: impact on quality of life and psychological status. *Journal of Gastroenterology and Hepatology*, 26(5), 916-923. doi:10.1111/j.1440-1746.2011.06624.x

Burisch, J., Weimers, P., Pedersen, N., Cukovic-Cavka, S., Vucelic, B., Kaimakliotis, I., . . . EpiCom, g. (2014). Health-related quality of life improves during one year of medical and surgical treatment in a European population-based inception cohort of patients with inflammatory bowel disease--an ECCO-EpiCom study. *J Crohns Colitis*, 8(9), 1030-1042. doi:10.1016/j.crohns.2014.01.028

Cal, S. F., Sa, L. R. d., Glustak, M. E., Santiago, M. B., & Walla, P. (2015). Resilience in chronic diseases: A systematic review. *Cogent Psychology*, 2(1). doi:10.1080/23311908.2015.1024928

Calvert, E. L., Houghton, L. A., Cooper, P., Morris, J., & Whorwell, P. J. (2002). Long-term improvement in functional dyspepsia using hypnotherapy. *Gastroenterology*, 123(6), 1778-1785. doi:10.1053/gast.2002.37071

- Camilleri, M., Parkman, H. P., Shafi, M. A., Abell, T. L., & Gerson, L. (2013). Clinical guideline: management of gastroparesis. *American Journal of Gastroenterology*, *108*(1), 18-37. doi:10.1038/ajg.2012.373
- Carlisle, A. C., John, A. M., Fife-Schaw, C., & Lloyd, M. (2005). The self-regulatory model in women with rheumatoid arthritis: relationships between illness representations, coping strategies, and illness outcome. *British Journal of Health Psychology*, *10*(Pt 4), 571-587. doi:10.1348/135910705X52309
- Carrasco Garrido, P., de Miguel Diez, J., Rejas Gutierrez, J., Centeno, A. M., Gobartt Vazquez, E., Gil de Miguel, A., . . . Jimenez Garcia, R. (2006). Negative impact of chronic obstructive pulmonary disease on the health-related quality of life of patients. Results of the EPIDEPOC study. *Health Qual Life Outcomes*, *4*, 31. doi:10.1186/1477-7525-4-31
- Carver, C. S. (1997). You want to measure coping but your protocol's too long: Consider the brief COPE. *International Journal of Behavioral Medicine*, *4*, 92-100.
- Carver, C. S., Scheier, M. F., & Weintraub, J. K. (1989). Assessing coping strategies: A theoretically based approach. *Journal of Personality and Social Psychology*, *56*(2), 267-283.
- Casellas, F., Arenas, J. I., Baudet, J. S., Fabregas, S., Garcia, N., Gelabert, J., . . . Malagelada, J. R. (2005). Impairment of health-related quality of life in patients with inflammatory bowel disease: A Spanish multicenter study. *Inflammatory Bowel Diseases*, *11*(5), 488-496.
- Chen, T.-S., Luo, J.-C., & Chang, F.-Y. (2010). Psychosocial-spiritual factors in patients with functional dyspepsia: a comparative study with normal individuals having the same endoscopic features. *European Journal of Gastroenterology and Hepatology*, *22*(1), 75-80.
- Cheng, C. (2000). Seeking medical consultation: Perceptual and behavioral characteristics distinguishing consulters and nonconsulters with functional dyspepsia. *Psychosomatic Medicine*, *62*, 844-852.
- Cheng, C., Hui, W. M., & Lam, S. (2002). Coping With First-Time Endoscopy for a Select Sample of Chinese Patients With Functional Dyspepsia and Duodenal Ulcer: An Observational Study. *Psychosomatic Medicine*, *64*(6), 867-873. doi:10.1097/01.psy.0000024233.11538.1d

- Cheng, C., Hui, W. M., & Lam, S. (2004). Psychosocial Factors and Perceived Severity of Functional Dyspeptic Symptoms: A Psychosocial Interactionist Model. *Psychosomatic Medicine*, 66(1), 85-91.
doi:10.1097/01.psy.0000106885.40753.c1
- Cheng, C., Hui, W. M., & Lam, S. K. (1999). Coping style of individuals with functional dyspepsia. *Psychosomatic Medicine*, 61(6), 789-795.
- Cheng, C., Yang, F. C., Jun, S., & Hutton, J. M. (2007). Flexible coping psychotherapy for functional dyspeptic patients: a randomized, controlled trial. *Psychosomatic Medicine*, 69(1), 81-88.
doi:10.1097/01.psy.0000249734.99065.6f
- Cherian, D., Paladugu, S., Pathikonda, M., & Parkman, H. P. (2012). Fatigue: a prevalent symptom in gastroparesis. *Digestive Diseases and Sciences*, 57(8), 2088-2095. doi:10.1007/s10620-012-2241-1
- Cherian, D., & Parkman, H. P. (2012). Nausea and vomiting in diabetic and idiopathic gastroparesis. *Neurogastroenterology and Motility*, 24(3), 217-222, e103. doi:10.1111/j.1365-2982.2011.01828.x
- Cherian, D., Sachdeva, P., Fisher, R. S., & Parkman, H. P. (2010). Abdominal pain is a frequent symptom of gastroparesis. *Clinical Gastroenterology and Hepatology*, 8(8), 676-681. doi:10.1016/j.cgh.2010.04.027
- Cherrington, C. C., Moser, D. K., Lennie, T. A., & Kennedy, C. W. (2004). Illness representation after acute myocardial infarction: impact on in-hospital recovery. *American Journal of Critical Care*, 13(2), 136-145.
- Chew, B. H., Vos, R. C., Metzendorf, M. I., Scholten, R. J., & Rutten, G. E. (2017). Psychological interventions for diabetes-related distress in adults with type 2 diabetes mellitus. *Cochrane Database Syst Rev*, 9, CD011469.
doi:10.1002/14651858.CD011469.pub2
- Chiarioni, G., Vantini, I., De Iorio, F., & Benini, L. (2006). Prokinetic effect of gut-oriented hypnosis on gastric emptying. *Alimentary Pharmacology and Therapeutics*, 23(8), 1241-1249. doi:10.1111/j.1365-2036.2006.02881.x
- Chilcot, J., & Moss-Morris, R. (2013). Changes in illness-related cognitions rather than distress mediate improvements in irritable bowel syndrome (IBS) symptoms and disability following a brief cognitive behavioural therapy

- intervention. *Behaviour Research and Therapy*, 51(10), 690-695.
doi:10.1016/j.brat.2013.07.007
- Cho, H. S., Park, J. M., Lim, C. H., Cho, Y. K., Lee, I. S., Kim, S. W., . . . Chung, Y. K. (2011). Anxiety, depression and quality of life in patients with irritable bowel syndrome. *Gut Liver*, 5(1), 29-36. doi:10.5009/gnl.2011.5.1.29
- Chou, L. T., Wu, C. Y., Chen, H. P., Chang, C. S., Wong, P. G., Ko, C. W., & Chen, G. H. (2001). The correlation of depression and gastric dysrhythmia in functional dyspepsia. *Journal of Clinical Gastroenterology*, 33(2), 127-131.
- Christensen, H., Griffiths, K. M., Korten, A. E., Brittliffe, K., & Groves, C. (2004). A comparison of changes in anxiety and depression symptoms of spontaneous users and trial participants of a cognitive behavior therapy website. *Journal of Medical Internet Research*, 6(4), e46. doi:10.2196/jmir.6.4.e46
- Christensen, S. S., Frostholm, L., Ornbol, E., & Schroder, A. (2014). Changes in illness perceptions mediated the effect of cognitive behavioural therapy in severe functional somatic syndromes. *Journal of Psychosomatic Research*. doi:10.1016/j.jpsychores.2014.12.005
- Clarke, D. M., & Currie, K. C. (2009). Depression, anxiety and their relationship with chronic diseases: A review of the epidemiology, risk and treatment evidence. *Medical Journal of Australia*, 190(7), S54-S60.
- Craig, B. A. (2008). Structural Equation Modeling. Retrieved from [http://www.stat.purdue.edu/~bacraig/SCS/Structural Equation Modeling.doc](http://www.stat.purdue.edu/~bacraig/SCS/Structural%20Equation%20Modeling.doc), <http://www.stat.purdue.edu/~bacraig/SCS/>
- Crane, C., & Martin, M. (2004). Social learning, affective state and passive coping in irritable bowel syndrome and inflammatory bowel disease. *General Hospital Psychiatry*, 26(1), 50-58. doi:10.1016/j.genhosppsych.2003.07.005
- Creed, F., Levy, R. L., Bradley, L. A., Francisconi, C., Drossman, D. A., Naliboff, B. D., & Olden, K. W. (2006). Psychosocial aspects of Functional Gastrointestinal Disorders. In D. A. Drossman, E. Corazziari, M. Delvaux, R. Spiller, N. J. Talley, W. G. Thompson, & W. E. Whitehead (Eds.), *Rome III: The Functional Gastrointestinal Disorders* (3 ed., pp. 295-368). Lawrence, KS: Allen Press, Inc.
- Creed, F., Ratcliffe, J., Fernandez, L., Tomenson, B., Palmer, S., Rigby, C., . . . Thompson, D. (2001). Health-related quality of life and health care costs in

severe, refractory irritable bowel syndrome. *Annals of Internal Medicine*, 134, 860-868.

Crouchley, K., & Daly, A. (2007). *Chronic disease and quality of life in Western Australia*. Western Australia: Department of Health.

Cutts, T., Holmes, S., Kedar, A., Beatty, K., M, K. M., & Abell, T. (2016). Twenty-five years of advocacy for patients with gastroparesis: support group therapy and patient reported outcome tool development. *BMC Gastroenterology*, 16(107). doi:10.1186/s12876-016-0523-3

De Gucht, V. (2015). Illness perceptions mediate the relationship between bowel symptom severity and health-related quality of life in IBS patients. *Quality of Life Research*. doi:10.1007/s11136-015-0932-8

de la Loge, C., Trudeau, E., Marquis, P., Kahrilas, P., Stanghellini, V., Talley, N. J., . . . Dubois, D. (2004). Cross-cultural development and validation of a patient self-administered questionnaire to assess quality of life in upper gastrointestinal disorders: The Pagi-QOL. *Quality of Life Research*, 13, 1751-1762. doi:10.1007/s11136-004-8751-3

De la Roca-Chiapas, J. M., Solis-Ortiz, S., Fajardo-Araujo, M., Sosa, M., Cordova-Fraga, T., & Rosa-Zarate, A. (2010). Stress profile, coping style, anxiety, depression, and gastric emptying as predictors of functional dyspepsia: a case-control study. *Journal of Psychosomatic Research*, 68(1), 73-81. doi:10.1016/j.jpsychores.2009.05.013

de Ridder, D., Geenen, R., Kuijjer, R., & van Middelndorp, H. (2008). Psychological adjustment to chronic disease. *The Lancet*, 372(9634), 246-255. doi:10.1016/s0140-6736(08)61078-8

Dehghanizade, Z., Zargar, Y., Mehrabizadeh Honarmand, M., Kadkhodaie, A., & Eydi Baygi, M. (2015). The effectiveness of cognitive behavior stress management on functional dyspepsia symptoms. *J Adv Med Educ Prof*, 3(2), 45-49.

Dekker, J., & de Groot, V. (2018). Psychological adjustment to chronic disease and rehabilitation - an exploration. *Disability and Rehabilitation*, 40(1), 116-120. doi:10.1080/09638288.2016.1247469

- Department of Health and Ageing. (2006). Enterra Therapy Gastric Electrical Stimulation (GES) System for the treatment of the symptoms of medically refractory gastroparesis.
- Deville, G. J., & Borkovec, T. D. (2000). Psychometric properties of the credibility/expectancy questionnaire. *Journal of Behavior Therapy and Experimental Psychiatry, 31*, 73-86.
- Di Benedetto, M., Lindner, H., Aucote, H., Churcher, J., McKenzie, S., Croning, N., & Jenkins, E. (2014). Co-morbid depression and chronic illness related to coping and physical and mental health status. *Psychology, Health & Medicine, 19*(3), 253-262. doi:10.1080/13548506.2013.803135
- DiMatteo, M. R., Lepper, H. S., & Croghan, T. W. (2000). Depression is a risk factor for noncompliance with medical treatment. *Archives of Internal Medicine, 160*, 2101-2107.
- Dinan, T. G., & Cryan, J. F. (2013). Melancholic microbes: a link between gut microbiota and depression? *Neurogastroenterology and Motility, 25*(9), 713-719. doi:10.1111/nmo.12198
- Dinan, T. G., & Cryan, J. F. (2017). The Microbiome-Gut-Brain Axis in Health and Disease. *Gastroenterology Clinics of North America, 46*(1), 77-89. doi:10.1016/j.gtc.2016.09.007
- Dorrian, A., Dempster, M., & Adair, P. (2009). Adjustment to inflammatory bowel disease: the relative influence of illness perceptions and coping. *Inflammatory Bowel Diseases, 15*(1), 47-55. doi:10.1002/ibd.20583
- Drossman, D. A. (2016). Functional Gastrointestinal Disorders: History, Pathophysiology, Clinical Features and Rome IV. *Gastroenterology*. doi:10.1053/j.gastro.2016.02.032
- Drossman, D. A., Chang, L. C., Kellow, W. J., Tack, J., & Whitehead, W. E. e. (2016). *Rome IV functional gastrointestinal disorders: disorders of gut-brain interaction*. Raleigh, NC: The Rome Foundation.
- Drossman, D. A., & Hasler, W. (2016). Rome IV - Functional GI Disorders: Disorders of Gut-Brain Interaction. *Gastroenterology, 150*.
- Dudekula, A., O'Connell, M., & Bielefeldt, K. (2011). Hospitalizations and testing in gastroparesis. *Journal of Gastroenterology and Hepatology, 26*(8), 1275-1282. doi:10.1111/j.1440-1746.2011.06735.x

- Dudekula, A., Rahim, S., & Bielefeldt, K. (2014). Time trends in gastroparesis treatment. *Digestive Diseases and Sciences*, *59*(11), 2656-2665.
doi:10.1007/s10620-014-3369-y
- Eccleston, C., Hearn, L., & Williams, A. C. (2015). Psychological therapies for the management of chronic neuropathic pain in adults. *Cochrane Database Syst Rev*(10), CD011259. doi:10.1002/14651858.CD011259.pub2
- Egede, L. E., Nietert, P. J., & Zheng, D. (2005). Depression and all-cause and coronary heart disease mortality among adults with and without diabetes. *Diabetes Care*, *28*, 1339-1345.
- Eiser, J. R., Riazi, A., Eiser, C., Hammersley, S., & Tooke, J. E. (2007). Predictors of psychological well-being in types 1 and 2 diabetes. *Psychology & Health*, *16*(1), 99-110. doi:10.1080/08870440108405492
- El-Serag, H. B., Olden, K. W., & Bjorkman, D. (2002). Health-related quality of life among persons with irritable bowel syndrome: A systematic review. *Alimentary Pharmacology and Therapeutics*, *16*, 1171-1185.
- Evans, D., & Norman, P. (2009). Illness representations, coping and psychological adjustment to Parkinson's disease. *Psychology & Health*, *24*(10), 1181-1196. doi:10.1080/08870440802398188
- Eysenbach, G. (2005). The law of attrition. *Journal of Medical Internet Research*, *7*(1), e11. doi:10.2196/jmir.7.1.e11
- Falk, G. W. (2015). Gastroparesis. *Gastroenterology Clinics of North America*, *44*(1), xiii. doi:10.1016/j.gtc.2014.12.002
- Faramarzi, M., Azadfallah, P., Book, H. E., Tabatabaei, K. R., Taheri, H., & Shokri-shirvani, J. (2013). A randomized controlled trial of brief psychoanalytic psychotherapy in patients with functional dyspepsia. *Asian Journal of Psychiatry*, *6*(3), 228-234. doi:10.1016/j.ajp.2012.12.012
- Faramarzi, M., Azadfallah, P., Book, H. E., Tabatabaei, K. R., Taherim, H., & Kashifard, M. (2015). The effect of psychotherapy in improving physical and psychiatric symptoms in patients with functional dyspepsia. *Iran J Psychiatry*, *10*(1), 43-49.
- Faramarzi, M., Kheirkhah, F., Shokri-shirvani, J., Mosavi, S., & Zarini, S. (2014). Psychological factors in patients with peptic ulcer and functional dyspepsia. *Caspian J Intern Med*, *5*(2), 71-76.

- Faramarzi, M., Shokri-Shirvani, J., & Kheirkhah, F. (2012). The role of psychiatric symptoms, alexithymia, and maladaptive defenses in patients with functional dyspepsia. *Indian Journal of Medical Sciences, 66*(1-2), 40-48. doi:10.4103/0019-5359.110865
- Filipovic, B. F., Randjelovic, T., Ille, T., Markovic, O., Milovanovic, B., Kovacevic, N., & Filipovic, B. R. (2013). Anxiety, personality traits and quality of life in functional dyspepsia-suffering patients. *European Journal of Internal Medicine, 24*(1), 83-86. doi:10.1016/j.ejim.2012.06.017
- First, M. B., Spitzer, R. L., Miriam, G., & Williams, J. B. W. (2002). *Structured Clinical Interview for DSM-IV-TR Axis I Disorders, Research Version, Non-patient Edition*. New York: Biometrics Research, New York State Psychiatric Institute.
- Fischler, B., Tack, J., De Gucht, V., Shkedy, Z. I., Persoons, P., Broekaert, D., . . . Janssens, J. (2003). Heterogeneity of symptom pattern, psychosocial factors, and pathophysiological mechanisms in severe functional dyspepsia. *Gastroenterology, 124*(4), 903-910. doi:10.1053/gast.2003.50155
- Ford, A. C., Quigley, E. M., Lacy, B. E., Lembo, A. J., Saito, Y. A., Schiller, L. R., . . . Moayyedi, P. (2014). Effect of Antidepressants and Psychological Therapies, Including Hypnotherapy, in Irritable Bowel Syndrome: Systematic Review and Meta-Analysis. *American Journal of Gastroenterology, 109*(9), 1350-1365. doi:10.1038/ajg.2014.148
- Fornell, C., & Larcker, D. F. (1981). Evaluating structural equation models with unobservable variables and measurement error. *Journal of marketing research, 18*(1), 39-50.
- Frank, L., Kleinman, L., Rentz, A., Ciesla, G., Kim, J. J., & Zacker, C. (2002). Health-Related Quality of Life Associated with Irritable Bowel Syndrome: Comparison with Other Chronic Diseases. *Clinical Therapeutics, 24*(4), 675-689. doi:10.1016/S0149-2918(02)85143-8
- Freitas, T. H., Andreoulakis, E., Alves, G. S., Miranda, H. L., Braga, L. L., Hyphantis, T., & Carvalho, A. F. (2015). Associations of sense of coherence with psychological distress and quality of life in inflammatory bowel disease. *World Journal of Gastroenterology, 21*(21), 6713-6727. doi:10.3748/wjg.v21.i21.6713

- French, D. P., Cooper, A., & Weinman, J. (2006). Illness perceptions predict attendance at cardiac rehabilitation following acute myocardial infarction: a systematic review with meta-analysis. *Journal of Psychosomatic Research, 61*(6), 757-767. doi:10.1016/j.jpsychores.2006.07.029
- Friedenberg, F. K., Kowalczyk, M., & Parkman, H. P. (2013). The influence of race on symptom severity and quality of life in gastroparesis. *Journal of Clinical Gastroenterology, 47*(9), 757-761. doi:10.1097/MCG.0b013e3182819aae
- Fullwood, A., & Drossman, D. A. (1995). The relationship of psychiatric illness with gastrointestinal disease. *Annual Review of Medicine, 46*, 483-496.
- Galway, K., Black, A., Cantwell, M., Cardwell, C. R., Mills, M., & Donnelly, M. (2012). Psychosocial interventions to improve quality of life and emotional wellbeing for recently diagnosed cancer patients. *Cochrane Database Syst Rev, 11*, CD007064. doi:10.1002/14651858.CD007064.pub2
- Ganguli, S. C., Kamath, M. V., Redmond, K., Chen, Y., Irvine, E. J., Collins, S. M., & Tougas, G. (2007). A comparison of autonomic function in patients with inflammatory bowel disease and in healthy controls. *Neurogastroenterology and Motility, 19*(12), 961-967. doi:10.1111/j.1365-2982.2007.00987.x
- Gareau, M. G. (2014). Microbiota-gut-brain axis and cognitive function. *Advances in Experimental Medicine and Biology, 817*, 357-371. doi:10.1007/978-1-4939-0897-4_16
- Gaston-Johansson, F., Haisfield-Wolfe, M. E., Reddick, B., Goldstein, N., & Lawal, T. A. (2013). The relationships among coping strategies, religious coping, and spirituality in African American women with breast cancer receiving chemotherapy. *Oncology Nursing Forum, 40*(2), 120-131.
- Geeraerts, B., Van Oudenhove, L., Fischler, B., Vandenberghe, J., Caenepeel, P., Janssens, J., & Tack, J. (2009). Influence of abuse history on gastric sensorimotor function in functional dyspepsia. *Neurogastroenterology and Motility, 21*(1), 33-41. doi:10.1111/j.1365-2982.2008.01178.x
- Giorgi, A. (1997). The theory, practice, and evaluation of the phenomenological method as a qualitative research. *Journal of Phenomenological Psychology, 28*(2), 235-261.

- Glasgow, R. E., Hampson, S. E., Strycker, L. A., & Ruggiero, L. (1997). Personal-model beliefs and social-environmental barriers related to diabetes self-management. *Diabetes Care*, *20*(4), 556-561.
- Glasgow, R. E., Ruggiero, K. J., Eakin, E. G., Dryfoos, J., & Chobanian, L. (1997). Quality of life and associated characteristics in a large national sample of adults with diabetes. *Diabetes Care*, *20*(4), 562-567.
- Glise, H., & Wiklund, I. (2002). Health-related quality of life and gastrointestinal disease. *Journal of Gastroenterology and Hepatology*, *17*(Suppl.), S72-S84. doi:10.1046/j.1440-1746.17.s1.6.x
- Goehler, I. E., Lyte, M., & Gaykema, R. P. A. (2007). Infection-induced viscerosensory signals from the gut enhance anxiety: implications for psychoneuroimmunology. *Brain, Behavior, and Immunity*, *21*(6), 721-726.
- Goldney, R. D., Phillips, P. J., Fisher, L. J., & Wilson, D. H. (2004). Diabetes, depression, and quality of life. *Diabetes Care*, *27*, 1066-1070.
- Goodhand, J., & Rampton, D. (2008). Psychological stress and coping in IBD. *Gut*, *57*(10), 1345-1347.
- Gracie, D. J., Irvine, A. J., Sood, R., Mikocka-Walus, A., Hamlin, P. J., & Ford, A. C. (2017). Effect of psychological therapy on disease activity, psychological comorbidity, and quality of life in inflammatory bowel disease: A systematic review and meta-analysis. *Lancet Gastroenterol Hepatol*, *2*(3), 189-199.
- Graff, L. A., Walker, J. R., & Bernstein, C. N. (2009). Depression and anxiety in inflammatory bowel disease: a review of comorbidity and management. *Inflammatory Bowel Diseases*, *15*(7), 1105-1118. doi:10.1002/ibd.20873
- Graff, L. A., Walker, J. R., Lix, L., Clara, I., Rawsthorne, P., Rogala, L., . . . Bernstein, C. N. (2006). The relationship of inflammatory bowel disease type and activity to psychological functioning and quality of life. *Clinical Gastroenterology and Hepatology*, *4*(12), 1491-1501. doi:10.1016/j.cgh.2006.09.027
- Gralnek, I. M., Hays, R. D., Kilbourne, A., Naliboff, B., & Mayer, E. A. (2000). The impact of irritable bowel syndrome on health-related quality of life. *Gastroenterology*, *119*(3), 654-660. doi:10.1053/gast.2000.16484
- Gray, S. E., & Rutter, D. R. (2007). Illness representations in young people with Chronic Fatigue Syndrome. *Psychology & Health*, *22*(2), 159-174. doi:10.1080/14768320600774595

- Greco, A., Steca, P., Pozzi, R., Monzani, D., D'Addario, M., Villani, A., . . . Parati, G. (2014). Predicting depression from illness severity in cardiovascular disease patients: self-efficacy beliefs, illness perception, and perceived social support as mediators. *International Journal of Behavioral Medicine*, *21*(2), 221-229. doi:10.1007/s12529-013-9290-5
- Grenham, S., Clarke, G., Cryan, J. F., & Dinan, T. G. (2011). Brain-gut-microbe communication in health and disease. *Frontiers in Physiology*, *2*, 94. doi:10.3389/fphys.2011.00094
- Grodzinsky, E., Walter, S., Viktorsson, L., Carlsson, A. K., Jones, M. P., & Faresjo, A. (2015). More negative self-esteem and inferior coping strategies among patients diagnosed with IBS compared with patients without IBS - a case-control study in primary care. *BMC Family Practice*, *16*(1), 6. doi:10.1186/s12875-015-0225-x
- Gutierrez, A., Rodrigo, L., Riestra, S., Fernandez, E., Cadahia, V., Tojo, R., . . . Olcoz, J. L. (2003). Quality of life in patients with functional dyspepsia: a prospective 1-year follow-up study in Spanish patients. *European Journal of Gastroenterology and Hepatology*, *15*(11), 1175-1181. doi:10.1097/01.meg.0000085483.12407.05
- Haag, S., Senf, W., Hauser, W., Tagay, S., Grandt, D., Heuft, G., . . . Holtmann, G. (2008). Impairment of health-related quality of life in functional dyspepsia and chronic liver disease: the influence of depression and anxiety. *Alimentary Pharmacology and Therapeutics*, *27*(7), 561-571. doi:10.1111/j.1365-2036.2008.03619.x
- Haag, S., Senf, W., Tagay, S., Langkafel, M., Braun-Lang, U., Pietsch, A., . . . Holtmann, G. (2007). Is there a benefit from intensified medical and psychological interventions in patients with functional dyspepsia not responding to conventional therapy? *Alimentary Pharmacology and Therapeutics*, *25*(8), 973-986. doi:10.1111/j.1365-2036.2007.03277.x
- Haapamaki, J., Turunen, U., Roine, R. P., Farkkila, M. A., & Arkkila, P. E. (2009). Impact of demographic factors, medication and symptoms on disease-specific quality of life in inflammatory bowel disease. *Quality of Life Research*, *18*(8), 961-969. doi:10.1007/s11136-009-9514-y

- Hagger, M. S., Koch, S., Chatzisarantis, N. L. D., & Orbell, S. (2017). The common sense model of self-regulation: Meta-analysis and test of a process model. *Psychological Bulletin, 143*(11), 1117-1154. doi:10.1037/bul0000118
10.1037/bul0000118.supp
- Hagger, M. S., & Orbell, S. (2003). A Meta-Analytic Review Of The Common-Sense Model Of Illness Representations. *Psychology and Health, 18*(2), 141-184.
- Hamilton, J., Guthrie, E., Creed, F., Thompson, D., Tomenson, B., Bennett, R., . . . Liston, R. (2000). A randomized controlled trial of psychotherapy in patients with chronic functional dyspepsia. *Gastroenterology, 119*(3), 661-669. doi:10.1053/gast.2000.16493
- Hampson, S. E., Glasgow, R. E., & Zeiss, A. M. (1994). Personal models of osteoarthritis and their relation to self-management activities and quality of life. *Journal of Behavioral Medicine, 17*(2), 143-158.
- Handa, M., Mine, K., Yamamoto, H., Tsutsui, S., Hayashi, H., Kinukawa, N., & Kubo, C. (1999). Esophageal motility and psychiatric factors in functional dyspepsia patients with or without pain. *Digestive Diseases and Sciences, 44*(10), 2094-2098.
- Harding, R., Liu, L., Catalan, J., & Sherr, L. (2011). What is the evidence for effectiveness of interventions to enhance coping among people living with HIV disease? A systematic review. *Psychology, Health & Medicine, 16*(5), 564-587. doi:10.1080/13548506.2011.580352
- Harrell, S. P., Studts, J. L., Dryden, G. W., Eversmann, J., Cai, L., & Wo, J. M. (2008). Novel classification scheme for gastroparesis based on predominant-symptom presentation. *Journal of Clinical Gastroenterology, 42*(5), 455-459. doi:10.1097/MCG.0b013e31815ed084
- Hasler, W. L. (2015). Symptomatic management for gastroparesis. *Gastroenterology Clinics of North America, 44*(1), 113-126. doi:10.1016/j.gtc.2014.11.009
- Hasler, W. L., Parkman, H. P., Wilson, L. A., Pasricha, P. J., Koch, K. L., Abell, T. L., . . . Consortium, N. G. C. R. (2010). Psychological dysfunction is associated with symptom severity but not disease etiology or degree of gastric retention in patients with gastroparesis. *American Journal of Gastroenterology, 105*(11), 2357-2367. doi:10.1038/ajg.2010.253

- Hasler, W. L., Wilson, L. A., Parkman, H. P., Koch, K. L., Abell, T. L., Nguyen, L., . . . Hamilton, F. (2013). Factors related to abdominal pain in gastroparesis: contrast to patients with predominant nausea and vomiting. *Neurogastroenterology and Motility*, *25*(5), 427-438, e300-421. doi:10.1111/nmo.12091
- Hasler, W. L., Wilson, L. A., Parkman, H. P., Nguyen, L., Abell, T. L., Koch, K. L., . . . Consortium, N. G. C. R. (2011). Bloating in gastroparesis: severity, impact, and associated factors. *American Journal of Gastroenterology*, *106*(8), 1492-1502. doi:10.1038/ajg.2011.81
- Haug, T. T., Svebak, S., Hausken, T., Wilhelmsen, I., Berstad, A., & Ursin, H. (1994). Low vagal activity as mediating mechanism for the relationship between personality factors and gastric symptoms in functional dyspepsia. *Psychosomatic Medicine*, *56*(3), 181-186.
- Haug, T. T., Svebak, S., Wilhelmsen, I., Berstad, A., & Ursin, H. (1994). Psychological factors and somatic symptoms in functional dyspepsia. A comparison with duodenal ulcer and healthy controls. *Journal of Psychosomatic Research*, *38*(4), 281-291.
- Haug, T. T., Wilhelmsen, I., Berstad, A., & Ursin, H. (1995). Life events and stress in patients with functional dyspepsia compared with patients with duodenal ulcer and healthy controls. *Scandinavian Journal of Gastroenterology*, *30*(6), 524-530. doi:10.3109/00365529509089784
- Haug, T. T., Wilhelmsen, I., Svebak, S., Berstad, A., & Ursin, H. (1994). Psychotherapy in Functional Dyspepsia. *Journal of Psychosomatic Research*, *38*(7), 735-744.
- Hauser, G., Pletikosic, S., & Tkalcic, M. (2014). Cognitive behavioral approach to understanding irritable bowel syndrome. *World Journal of Gastroenterology*, *20*(22), 6744-6758. doi:10.3748/wjg.v20.i22.6744
- Heijmans, M. (1998). Coping and adaptive outcome in chronic fatigue syndrome: Importance of illness cognitions. *Journal of Psychosomatic Research*, *45*(1), 39-51.
- Heijmans, M. (1999). The role of patients' illness representations in coping and functioning with Addison's disease. *British Journal of Health Psychology*, *4*, 137-149.

- Heijmans, M., & de Ridder, D. (1998). Assessing illness representations of chronic illness: explorations of their disease-specific nature. *Journal of Behavioral Medicine, 21*(5), 485-503.
- Hejazi, R. A., & McCallum, R. W. (2009). Treatment of refractory gastroparesis: gastric and jejunal tubes, botox, gastric electrical stimulation, and surgery. *Gastrointestinal Endoscopy Clinics of North America, 19*(1), 73-82, vi. doi:10.1016/j.giec.2008.12.010
- Helder, D. I., Kaptein, A. A., Van Kempen, G. M. J., Weinman, J., Van Houwelingen, H. J. C., & Roos, R. A. C. (2002). Living with Huntington's disease: illness perceptions, coping mechanisms, and patients' well-being. *British Journal of Health Psychology, 7*, 449-462.
- Higgins, J. P. T., & Green, S. (2011). *Cochrane Handbook for Systematic Reviews of interventions Version 5.1.0 [updated March 2011]* Retrieved from <http://handbook.cochrane.org>
- Hjelland, I. E., Svebak, S., Berstad, A., Flatabo, G., & Hausken, T. (2007). Breathing exercises with vagal biofeedback may benefit patients with functional dyspepsia. *Scandinavian Journal of Gastroenterology, 42*(9), 1054-1062. doi:10.1080/00365520701259208
- Hoivik, M. L., Bernklev, T., Solberg, I. C., Cvancarova, M., Lygren, I., Jahnsen, J., . . . Group, I. S. (2012). Patients with Crohn's disease experience reduced general health and vitality in the chronic stage: ten-year results from the IBSEN study. *J Crohns Colitis, 6*(4), 441-453. doi:10.1016/j.crohns.2011.10.001
- Holmes, J., McGill, S., Kind, P., Bottomley, J., Gillam, S., & Murphy, M. (2000). Health-related quality of life in type 2 diabetes (TARDIS-2). *Value in Health, 3 Suppl 1*, 47-51. doi:10.1046/j.1524-4733.2000.36028.x
- Horne, R., & Weinman, J. (2002). Self-regulation and Self-management in Asthma: Exploring The Role of Illness Perceptions and Treatment Beliefs in Explaining Non-adherence to Preventer Medication. *Psychology & Health, 17*(1), 17-32. doi:10.1080/08870440290001502
- Huang, C. Y., Lai, H. L., Lu, Y. C., Chen, W. K., Chi, S. C., Lu, C. Y., & Chen, C. I. (2015). Risk Factors and Coping Style Affect Health Outcomes in Adults With Type 2 Diabetes. *Biological Research for Nursing. doi:10.1177/1099800415569845*

- Institute of Medicine. (2012). *Living well with chronic illness: A call for public health action*. Washington, DC: The National Academies Press.
- Ishiguchi, T., Itoh, H., & Ichinose, M. (2003). Gastrointestinal motility and the brain-gut axis. *Digestive Endoscopy*, *15*, 81-86.
- Jaffe, J. K., Paladugu, S., Gaughan, J. P., & Parkman, H. P. (2011). Characteristics of nausea and its effects on quality of life in diabetic and idiopathic gastroparesis. *Journal of Clinical Gastroenterology*, *45*(4), 317-321. doi:10.1097/MCG.0b013e3181eeb5e9
- Jamali, R., Jamali, A., Poorrahnama, M., Omid, A., Jamali, B., Moslemi, N., . . . Daryani, N. E. (2012). Evaluation of health related quality of life in irritable bowel syndrome patients. *Health and Quality of Life Outcomes*, *10*(12).
- Janssen, P., Harris, M. S., Jones, M., Masaoka, T., Farre, R., Tornblom, H., . . . Tack, J. (2013). The relation between symptom improvement and gastric emptying in the treatment of diabetic and idiopathic gastroparesis. *American Journal of Gastroenterology*, *108*(9), 1382-1391. doi:10.1038/ajg.2013.118
- Jelsness-Jorgensen, L. P., Moum, B., & Bernklev, T. (2011). Worries and Concerns among Inflammatory Bowel Disease Patients Followed Prospectively over One Year. *Gastroenterol Res Pract*, *2011*, 492034. doi:10.1155/2011/492034
- Jones, M. P., Coppens, E., Vos, R., Holvoet, L., Luyten, P., Tack, J., & Van Oudenhove, L. (2013). A multidimensional model of psychobiological interactions in functional dyspepsia: a structural equation modelling approach. *Gut*, *62*(11), 1573-1580. doi:10.1136/gutjnl-2012-302634
- Jones, M. P., & Maganti, K. (2004). Symptoms, gastric function, and psychosocial factors in functional dyspepsia. *Journal of Clinical Gastroenterology*, *38*(10), 866-872.
- Jones, M. P., Oudenhove, L. V., Koloski, N., Tack, J., & Talley, N. J. (2013). Early life factors initiate a 'vicious circle' of affective and gastrointestinal symptoms: A longitudinal study. *United European Gastroenterol J*, *1*(5), 394-402. doi:10.1177/2050640613498383
- Jones, M. P., Tack, J., Van Oudenhove, L., Walker, M. M., Holtmann, G., Koloski, N. A., & Talley, N. J. (2017). Mood and Anxiety Disorders Precede Development of Functional Gastrointestinal Disorders in Patients but Not in the Population.

Clinical Gastroenterology and Hepatology, 15(7), 1014-1020 e1014.
doi:10.1016/j.cgh.2016.12.032

- Jones, M. P., Wessinger, S., & Crowell, M. D. (2006). Coping strategies and interpersonal support in patients with Irritable Bowel Syndrome and Inflammatory Bowel Disease. *Clinical Gastroenterology and Hepatology*, 4, 474-481.
- Jones, P. W., Brusselle, G., Dal Negro, R. W., Ferrer, M., Kardos, P., Levy, M. L., . . . Banik, N. (2011). Health-related quality of life in patients by COPD severity within primary care in Europe. *Respiratory Medicine*, 105(1), 57-66.
doi:10.1016/j.rmed.2010.09.004
- Jonsson, B. H., Theorell, T., & Gotthard, R. (1995). Symptoms and personality in patients with chronic functional dyspepsia. *Journal of Psychosomatic Research*, 39(1), 93-102.
- Jordan, C., Sin, J., Fear, N. T., & Chalder, T. (2016). A systematic review of the psychological correlates of adjustment outcomes in adults with inflammatory bowel disease. *Clinical Psychology Review*, 47, 28-40.
doi:10.1016/j.cpr.2016.06.001
- Jung, H. K., Choung, R. S., Locke, G. R., 3rd, Schleck, C. D., Zinsmeister, A. R., Szarka, L. A., . . . Talley, N. J. (2009). The incidence, prevalence, and outcomes of patients with gastroparesis in Olmsted County, Minnesota, from 1996 to 2006. *Gastroenterology*, 136(4), 1225-1233.
doi:10.1053/j.gastro.2008.12.047
- Kaptein, A. A., Helder, D. I., Scharloo, M., Van Kempen, G. M. J., Weinman, J., Van Houwelingen, H. J. C., & Roos, R. A. C. (2006). Illness perceptions and coping explain well-being in patients with Huntington's disease. *Psychology & Health*, 21(4), 431-446. doi:10.1080/14768320500456947
- Karamanolis, G., Caenepeel, P., Arts, J., & Tack, J. (2007). Determinants of symptom pattern in idiopathic severely delayed gastric emptying: gastric emptying rate or proximal stomach dysfunction? *Gut*, 56(1), 29-36.
doi:10.1136/gut.2005.089508
- Karyotaki, E., Kleiboer, A., Smit, F., Turner, D. T., Pastor, A. M., Andersson, G., . . . Cuijpers, P. (2015). Predictors of treatment dropout in self-guided web-based interventions for depression: an 'individual patient data' meta-

- analysis. *Psychological Medicine*, 45(13), 2717-2726.
doi:10.1017/S0033291715000665
- Katon, W., Lin, E. H., & Kroenke, K. (2007). The association of depression and anxiety with medical symptom burden in patients with chronic medical illness. *General Hospital Psychiatry*, 29(2), 147-155.
doi:10.1016/j.genhosppsy.2006.11.005
- Kau, A. L., Ahern, P. P., Griffin, N. W., Goodman, A. L., & Gordon, J. I. (2011). Human nutrition, the gut microbiome and the immune system. *Nature*, 474(7351), 327-336. doi:10.1038/nature10213
- Kelley, M. L., Heffer, R. W., Gresham, F. M., & Elliott, S. N. (1989). Development of a modified treatment evaluation inventory. *Journal of Psychopathology and Behavioral Assessment*, 11(3), 235-247.
- Kelly, J. R., Clarke, G., Cryan, J. F., & Dinan, T. G. (2016). Brain-gut-microbiota axis: challenges for translation in psychiatry. *Annals of Epidemiology*, 26(5), 366-372. doi:10.1016/j.annepidem.2016.02.008
- Kemp, S., Morley, S., & Anderson, E. (1999). Coping with epilepsy: do illness representations play a role? *Br J Clin Psych*, 38, 43-58.
- Kenny, D. A., Kaniskan, B., & McCoach, D. B. (2015). The performance of RMSEA in models with small degrees of freedom. *Sociological Methods and Research*, 44(3), 486-507.
- Kiebles, J. L., Doerfler, B., & Keefer, L. (2010). Preliminary evidence supporting a framework of psychological adjustment to inflammatory bowel disease. *Inflammatory Bowel Diseases*, 16(10), 1685-1695. doi:10.1002/ibd.21215
- Kindt, S., Van Oudenhove, L., Mispelon, L., Caenepeel, P., Arts, J., & Tack, J. (2011). Longitudinal and cross-sectional factors associated with long-term clinical course in functional dyspepsia: a 5-year follow-up study. *American Journal of Gastroenterology*, 106(2), 340-348. doi:10.1038/ajg.2010.406
- Kline, R. B. (2016). *Principles and practice of structural equation modelling* (4th ed. ed.). New York: The Guilford Press.
- Knowles, S. R., Austin, D. W., Sivanesan, S., Tye-Din, J., Leung, C., Wilson, J., . . . Hebbard, G. (2017). Relations between symptom severity, illness perceptions, visceral sensitivity, coping strategies and well-being in irritable bowel syndrome guided by the common sense model of illness.

Psychology, Health & Medicine, 22(5), 524-534.

doi:10.1080/13548506.2016.1168932

Knowles, S. R., Cook, S. I., & Tribbick, D. (2013). Relationship between health status, illness perceptions, coping strategies and psychological morbidity: A preliminary study with IBD stoma patients. *J Crohns Colitis*, 7(10), e471-478. doi:10.1016/j.crohns.2013.02.022

Knowles, S. R., Gass, C., & Macrae, F. (2013). Illness perceptions in IBD influence psychological status, sexual health and satisfaction, body image and relational functioning: A preliminary exploration using Structural Equation Modeling. *J Crohns Colitis*, 7(9), e344-350.

doi:10.1016/j.crohns.2013.01.018

Knowles, S. R., Graff, L., Wilding, H., Hewitt, C., Keefer, L., & Mikocka-Walus, A. (2017). Quality of life in inflammatory bowel disease: A systematic review and meta-analyses - Part 1. *Inflammatory Bowel Diseases*, *In press*.

Knowles, S. R., Keefer, L., Wilding, H., Hewitt, C., Graff, L., & Mikocka-Walus, A. (2017). Quality of life in inflammatory bowel disease: A systematic review and meta-analyses - Part II. *Inflammatory Bowel Diseases*, *In press*.

Knowles, S. R., Monshat, K., & Castle, D. J. (2013). The efficacy and methodological challenges of psychotherapy for adults with Inflammatory Bowel Disease: A review. *Inflammatory Bowel Diseases*, 19(12), 2704-2715.

Knowles, S. R., Swan, L., Salzberg, M., Castle, D., & Langham, R. (2014). Exploring the relationships between health status, illness perceptions, coping strategies and psychological morbidity in a chronic kidney disease cohort. *The American Journal of the Medical Sciences*, 348(4), 271-276.

Knowles, S. R., Tribbick, D., Connell, W. R., Castle, D., Salzberg, M., & Kamm, M. A. (2014). Exploration of health status, illness perceptions, coping strategies, and psychological morbidity in stoma patients. *Journal of Wound, Ostomy and Continence Nursing*, 41(6), 573-580.

doi:10.1097/WON.0000000000000073

Knowles, S. R., Wilson, J. L., Connell, W. R., & Kamm, M. A. (2011). Preliminary examination of the relations between disease activity, illness perceptions, coping strategies, and psychological morbidity in Crohn's disease guided by

- the common sense model of illness. *Inflammatory Bowel Diseases*, 17(12), 2551-2557. doi:10.1002/ibd.21650
- Koloski, N. A., Jones, M., Kalantar, J., Weltman, M., Zaguirre, J., & Talley, N. J. (2012). The brain--gut pathway in functional gastrointestinal disorders is bidirectional: a 12-year prospective population-based study. *Gut*, 61(9), 1284-1290. doi:10.1136/gutjnl-2011-300474
- Koloski, N. A., Jones, M., & Talley, N. J. (2016). Evidence that independent gut-to-brain and brain-to-gut pathways operate in the irritable bowel syndrome and functional dyspepsia: a 1-year population-based prospective study. *Alimentary Pharmacology and Therapeutics*, 44(6), 592-600. doi:10.1111/apt.13738
- Koloski, N. A., Talley, N. J., & Boyce, P. M. (2005). A history of abuse in community subjects with irritable bowel syndrome and functional dyspepsia: the role of other psychosocial variables. *Digestion*, 72(2-3), 86-96. doi:10.1159/000087722
- Kraaij, V., & Garnefski, N. (2015). Cognitive, behavioral and goal adjustment coping and depressive symptoms in young people with diabetes: a search for intervention targets for coping skills training. *Journal of Clinical Psychology in Medical Settings*, 22(1), 45-53. doi:10.1007/s10880-015-9417-8
- Kristofferzon, M. L., Lindqvist, R., & Nilsson, A. (2011). Relationships between coping, coping resources and quality of life in patients with chronic illness: a pilot study. *Scandinavian Journal of Caring Sciences*, 25(3), 476-483. doi:10.1111/j.1471-6712.2010.00851.x
- Lackner, J. M., Mesmer, C., Morley, S., Dowzer, C., & Hamilton, S. (2004). Psychological treatments for irritable bowel syndrome: a systematic review and meta-analysis. *Journal of Consulting and Clinical Psychology*, 72(6), 1100-1113. doi:10.1037/0022-006X.72.6.1100
- Lacy, B. E. (2012). Functional dyspepsia and gastroparesis: one disease or two? *American Journal of Gastroenterology*, 107(11), 1615-1620.
- Lacy, B. E., Crowell, M. D., Mathis, C., Bauer, D., & Heinberg, L. J. (2016). Gastroparesis: Quality of life and health care utilization. *Journal of Clinical Gastroenterology*, 1. doi:10.1097/mcg.0000000000000728

- Laird, K. T., Tanner-Smith, E. E., Russell, A. C., Hollon, S. D., & Walker, L. S. (2016). Short-term and Long-term Efficacy of Psychological Therapies for Irritable Bowel Syndrome: A Systematic Review and Meta-analysis. *Clinical Gastroenterology and Hepatology*, 14(7), 937-947 e934.
doi:10.1016/j.cgh.2015.11.020
- Laird, K. T., Tanner-Smith, E. E., Russell, A. C., Hollon, S. D., & Walker, L. S. (2017). Comparative efficacy of psychological therapies for improving mental health and daily functioning in irritable bowel syndrome: A systematic review and meta-analysis. *Clinical Psychology Review*, 51, 142-152.
doi:10.1016/j.cpr.2016.11.001
- Larsson, K., Loof, L., Ronnblom, A., & Nordin, K. (2008). Quality of life for patients with exacerbation in inflammatory bowel disease and how they cope with disease activity. *Journal of Psychosomatic Research*, 64(2), 139-148.
doi:10.1016/j.jpsychores.2007.10.007
- Lau-Walker, M. (2007). Importance of illness beliefs and self-efficacy for patients with coronary heart disease. *Journal of Advanced Nursing*, 60(2), 187-198.
doi:10.1111/j.1365-2648.2007.04398.x
- Lazarus, R. S., & Folkman, S. (1984). *Stress, appraisal and coping*. New York: Springer.
- Lee, L. A., Chen, J., & Yin, J. (2015). Complementary and alternative medicine for gastroparesis. *Gastroenterology Clinics of North America*, 44(1), 137-150.
doi:10.1016/j.gtc.2014.11.011
- Lee, S., Park, M., Choi, S. W., Nah, Y., Abbey, S. E., & Rodin, G. (2000). Stress, coping, and depression in non-ulcer dyspepsia patients. *Journal of Psychosomatic Research*, 49(1), 93-99.
- Leventhal, H., Nerenz, D. R., & Steele, D. J. (1984). *Illness representation and coping with health threats* (Vol. 4). New Jersey: Earlbaum.
- Lin, E. H., Heckbert, S. R., Rutter, C. M., Katon, W. J., Ciechanowski, P., Ludman, E. J., . . . Von Korff, M. (2009). Depression and increased mortality in diabetes: unexpected causes of death. *Annals of Family Medicine*, 7(5), 414-421.
doi:10.1370/afm.998

- Lin, E. H., Katon, W., Von Korff, M., Rutter, C. L., Simon, G. E., Oliver, M., . . . Young, B. (2004). Relationship of depression and diabetes self-care, medication adherence, and preventive care. *Diabetes Care*, *27*, 2154-2160.
- Lin, E. H., Rutter, C. M., Katon, W., Heckbert, S. R., Ciechanowski, P., Oliver, M. M., . . . Von Korff, M. (2010). Depression and advanced complications of diabetes: a prospective cohort study. *Diabetes Care*, *33*(2), 264-269. doi:10.2337/dc09-1068
- Liu, S., Ren, J., Hong, Z., Li, X., Yao, M., Yan, D., . . . Li, J. (2013). An evil backstage manipulator: psychological factors correlated with health-related quality of life in Chinese patients with Crohn's disease. *ScientificWorldJournal*, *2013*, 464698. doi:10.1155/2013/464698
- Liu, Y., Song, X., Zhang, Y., Zhou, L., & Ni, R. (2014). The effects of comprehensive mental intervention on the recovery time of patients with postsurgical gastroparesis syndrome. *Journal of Clinical Nursing*. doi:10.1111/jocn.12554
- Lix, L. M., Graff, L. A., Walker, J. R., Clara, I., Rawsthorne, P., Rogala, L., . . . Bernstein, C. N. (2008). Longitudinal study of quality of life and psychological functioning for active, fluctuating, and inactive disease patterns in inflammatory bowel disease. *Inflammatory Bowel Diseases*, *14*(11), 1575-1584. doi:10.1002/ibd.20511
- Llewellyn, C. D., Miners, A. H., Lee, C. A., Harrington, C., & Weinman, J. (2003). The Illness Perceptions and Treatment Beliefs of Individuals with Severe Haemophilia and their Role in Adherence to Home Treatment. *Psychology & Health*, *18*(2), 185-200. doi:10.1080/0887044031000098198
- Lovibond, P. F., & Lovibond, S. H. (1995). The structure of negative emotional states: comparison of the Depression Anxiety Stress Scales (DASS) with the Beck Depression and Anxiety Inventories. *Behaviour Research and Therapy*, *33*(3), 335-343. doi:10.1016/0005-7967(94)00075-U
- Luczynski, P., McVey Neufeld, K. A., Clarke, G., Dinan, T. G., & Cryan, J. F. (2016). Germ-Free Animals: A Key Tool in Unraveling How the Microbiota Affects the Brain and Behavior. In N. Hyland & C. Stanton (Eds.), *The Gut-Brain Axis: Dietary, Probiotic, and Prebiotic Interventions on the Microbiota* (pp. 109-140). London: Academic Press.

- Lunding, J. A., Gilja, O. H., Hausken, T., Bayati, A., Mattsson, H., & Berstad, A. (2007). Distension-induced gastric accommodation in functional dyspepsia: effect of autonomic manipulation. *Neurogastroenterology and Motility*, *19*(5), 365-375. doi:10.1111/j.1365-2982.2006.00896.x
- Ma, J., Rayner, C. K., Jones, K. L., & Horowitz, M. (2009). Diabetic Gastroparesis: Diagnosis and management. *Drugs*, *69*(8), 17.
- Malt, E. A., Berle, J. E., Olafsson, S., Lund, A., & Ursin, H. (2000). Fibromyalgia is associated with panic disorder and functional dyspepsia with mood disorders, A study of women with random sample population controls. *Journal of Psychosomatic Research*, *49*(5), 285-289.
- Marques, T. M., Holster, S., Wall, R., König, J., Brummer, R. J., & de Vos, W. M. (2016). Correlating the Gut Microbiome to Health and Disease. In N. Hyland & C. Stanton (Eds.), *The Gut-Brain Axis: Dietary, Probiotic, and Prebiotic Interventions on the Microbiota* (pp. 261-291). London: Academic Press.
- Martin, A., Leone, L., Fries, W., & Naccarato, R. (1995). Quality of life in inflammatory bowel disease. *Italian Journal of Gastroenterology*, *27*, 450-454.
- Martini, F. H. (2001). *Fundamentals of anatomy and physiology* (5th ed ed.). New Jersey: Prentice Hall.
- Matcham, F., Scott, I. C., Rayner, L., Hotopf, M., Kingsley, G. H., Norton, S., . . . Steer, S. (2014). The impact of rheumatoid arthritis on quality-of-life assessed using the SF-36: a systematic review and meta-analysis. *Seminars in Arthritis and Rheumatism*, *44*(2), 123-130. doi:10.1016/j.semarthrit.2014.05.001
- Maunder, R. G., & Levenstein, S. (2008). The role of stress in the development and clinical course of inflammatory bowel disease: Epidemiological evidence. *Current Molecular Medicine*, *8*, 247-252.
- Mayer, E. A. (2011). Gut feelings: the emerging biology of gut-brain communication. *Nature Reviews: Neuroscience*, *12*(8), 453-466. doi:10.1038/nrn3071
- Mayer, E. A., & Tillisch, K. (2011). The brain-gut axis in abdominal pain syndromes. *Annual Review of Medicine*, *62*, 381-396. doi:10.1146/annurev-med-012309-103958

- Mayer, E. A., Tillisch, K., & Bradesi, S. (2006). Review article: modulation of the brain-gut axis as a therapeutic approach in gastrointestinal disease. *Alimentary Pharmacology and Therapeutics*, *24*(6), 919-933. doi:10.1111/j.1365-2036.2006.03078.x
- Mazaheri, M., Afshar, H., Nikneshan, S., & Adibi, P. (2016). Cognitive emotion regulation strategies in patients with functional dyspepsia and healthy controls - A comparative study. *Adv Biomed Res*, *5*, 196. doi:10.4103/2277-9175.190937
- McCombie, A. M., Mulder, R. T., & Geary, R. B. (2013). How IBD patients cope with IBD: a systematic review. *J Crohns Colitis*, *7*(2), 89-106. doi:10.1016/j.crohns.2012.05.021
- McCombie, A. M., Mulder, R. T., & Geary, R. B. (2015). Coping Strategies and Psychological Outcomes of Patients with Inflammatory Bowel Disease in the First 6 Months After Diagnosis. *Inflammatory Bowel Diseases*, *21*(10), 2272-2280. doi:10.1097/MIB.0000000000000476
- Melville, K. M., Casey, L. M., & Kavanagh, D. J. (2010). Dropout from Internet-based treatment for psychological disorders. *British Journal of Clinical Psychology*, *49*(Pt 4), 455-471. doi:10.1348/014466509X472138
- Michaelis, R., Tang, V., Wagner, J. L., Modi, A. C., LaFrance, W. C., Jr., Goldstein, L. H., . . . Reuber, M. (2017). Psychological treatments for people with epilepsy. *Cochrane Database Syst Rev*, *10*, CD012081. doi:10.1002/14651858.CD012081.pub2
- Michalsen, V. L., Vandvik, P. O., & Farup, P. G. (2015). Predictors of health-related quality of life in patients with irritable bowel syndrome. A cross-sectional study in Norway. *Health Qual Life Outcomes*, *13*, 113. doi:10.1186/s12955-015-0311-8
- Mikocka-Walus, A., Knowles, S. R., Keefer, L., & Graff, L. (2016). Controversies Revisited: A Systematic Review of the Comorbidity of Depression and Anxiety with Inflammatory Bowel Diseases. *Inflammatory Bowel Diseases*, *22*(3), 752-762. doi:10.1097/MIB.0000000000000620
- Mikocka-Walus, A., Pittet, V., Rossel, J. B., von Kanel, R., & Swiss, I. B. D. C. S. G. (2016). Symptoms of Depression and Anxiety Are Independently Associated With Clinical Recurrence of Inflammatory Bowel Disease. *Clinical*

- Gastroenterology and Hepatology*, 14(6), 829-835 e821.
doi:10.1016/j.cgh.2015.12.045
- Mikocka-Walus, A. A., Turnbull, D. A., Moulding, N. T., Wilson, I. G., Andrews, J. M., & Holtmann, G. J. (2007). Controversies surrounding the comorbidity of depression and anxiety in inflammatory bowel disease patients: a literature review. *Inflammatory Bowel Diseases*, 13(2), 225-234.
doi:10.1002/ibd.20062
- Mikula, P., Nagyova, I., Krokavcova, M., Vitkova, M., Rosenberger, J., Szilasiova, J., . . . van Dijk, J. P. (2015). The mediating effect of coping on the association between fatigue and quality of life in patients with multiple sclerosis. *Psychology, Health & Medicine*, 1-9. doi:10.1080/13548506.2015.1032310
- Moher, D., Liberati, A., Tetzlaff, J., Altman, D. G., & The PRISMA Group. (2009). Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement. *PLoS Medicine*, 6(7), 1-6. doi:10.1371/journal.pmed.1000097
- Moloney, R. D., Desbonnet, L., Clarke, G., Dinan, T. G., & Cryan, J. F. (2014). The microbiome: stress, health and disease. *Mammalian Genome*, 25(1-2), 49-74.
doi:10.1007/s00335-013-9488-5
- Moloney, R. D., Johnson, A. C., O'Mahony, S. M., Dinan, T. G., Greenwood-Van Meerveld, B., & Cryan, J. F. (2016). Stress and the Microbiota-Gut-Brain Axis in Visceral Pain: Relevance to Irritable Bowel Syndrome. *CNS Neuroscience & Therapeutics*, 22(2), 102-117. doi:10.1111/cns.12490
- Mones, J., Adan, A., Segu, J. L., Lopez, J. S., Artes, M., & Guerrero, T. (2002). Quality of life in functional dyspepsia. *Digestive Diseases and Sciences*, 47(1), 20-26.
- Monteagudo, M., Rodriguez-Blanco, T., Llagostera, M., Valero, C., Bayona, X., Ferrer, M., & Miravittles, M. (2013). Factors associated with changes in quality of life of COPD patients: a prospective study in primary care. *Respiratory Medicine*, 107(10), 1589-1597. doi:10.1016/j.rmed.2013.05.009
- Moshiree, B., Bollipo, S., Horowitz, M., & Talley, N. J. (2012). Epidemiology of Gastroparesis *Gastroparesis: Pathophysiology, Presentation and Treatment* (pp. 11-23).

- Moss-Morris, R. (2013). Adjusting to chronic illness: time for a unified theory. *British Journal of Health Psychology, 18*(4), 681-686.
doi:10.1111/bjhp.12072
- Moss-Morris, R., Petrie, K., & Weinman, J. (1996). Functioning in chronic fatigue syndrome: Do illness perceptions play a regulatory role? *British Journal of Health Psychology, 1*, 15-25.
- Mujais, S. K., Story, K., Brouillette, J., Takano, T., Soroka, S., Franek, C., . . . Finkelstein, F. O. (2009). Health-related quality of life in CKD Patients: correlates and evolution over time. *Clinical Journal of the American Society of Nephrology, 4*(8), 1293-1301. doi:10.2215/CJN.05541008
- Mustafa, M., Carson-Stevens, A., Gillespie, D., & Edwards, A. G. (2013). Psychological interventions for women with metastatic breast cancer. *Cochrane Database Syst Rev*(6), CD004253. doi:10.1002/14651858.CD004253.pub4
- National Center for Chronic Disease Prevention and Health Promotion. (2012). Mental health and chronic diseases. Retrieved from <http://www.cdc.gov/nationalhealthyworksites/docs/issue-brief-no-2-mental-health-and-chronic-disease.pdf>
- National Institute of Diabetes and Digestive and Kidney Diseases. (2007). Gastroparesis. 6.
- Nedelciuc, O., Pintilie, I., Dranga, M., Mihai, C., & Prelipcean, C. C. (2012). Quality of life in patients with ulcerative colitis. *Rev Med Chir Soc Med Nat, 116*(3), 756-760.
- Norris, S. L., McNally, T. K., Zhang, X., Burda, B., Chan, B., Chowdhury, F. M., . . . Patrick, D. (2011). Published norms underestimate the health-related quality of life among persons with type 2 diabetes. *Journal of Clinical Epidemiology, 64*(4), 358-365. doi:10.1016/j.jclinepi.2010.04.016
- Nowicka-Sauer, K., Banaszkiwicz, D., Staskiewicz, I., Kopczynski, P., Hajduk, A., Czuszyńska, Z., . . . Siebert, J. (2015). Illness perception in Polish patients with chronic diseases: Psychometric properties of the Brief Illness Perception Questionnaire. *Journal of Health Psychology*.
doi:10.1177/1359105314565826
- O'Connor, E., Whitlock, E., & Spring, B. (2017). Introduction to systematic reviews. Retrieved from http://ebbp.org/course_outlines/systematic_review/

- Orive, M., Barrio, I., Orive, V. M., Matellanes, B., Padierna, J. A., Cabriada, J., . . . Quintana, J. M. (2015). A randomized controlled trial of a 10week group psychotherapeutic treatment added to standard medical treatment in patients with functional dyspepsia. *Journal of Psychosomatic Research*. doi:10.1016/j.jpsychores.2015.03.003
- Pace, F., Molteni, P., Bollani, S., Sarzi - Puttini, P., Stockbrügger, R., Porro, G. B., & Drossman, D. A. (2003). Inflammatory bowel disease versus irritable bowel syndrome: a hospital - based, case - control study of disease impact on quality of life. *Scandinavian Journal of Gastroenterology*, 38(10), 1031-1038. doi:10.1080/00365520310004524
- Pagels, A. A., Klang Soderquist, B., & Heiwe, S. (2015). Differences in illness representations in patients with chronic kidney disease. *Journal of Renal Care*, 1-10.
- Palsson, O. S., & Whitehead, W. E. (2013). Psychological treatments in functional gastrointestinal disorders: a primer for the gastroenterologist. *Clinical Gastroenterology and Hepatology*, 11(3), 208-216; quiz e222-203. doi:10.1016/j.cgh.2012.10.031
- Parenteau, S. C., Gallant, S., Sarosiek, I., & McCallum, R. W. (2006). The role of hope in the psychological adjustment of gastropareutic patients receiving the gastric pacemaker: A longitudinal study. *Journal of Clinical Psychology in Medical Settings*, 13(1), 46-53. doi:10.1007/s10880-005-9005-4
- Parkman, H. P., Camilleri, M., Farrugia, G., McCallum, R. W., Bharucha, A. E., Mayer, E. A., . . . Hamilton, F. (2010). Gastroparesis and functional dyspepsia: excerpts from the AGA/ANMS meeting. *Neurogastroenterology and Motility*, 22(2), 113-133. doi:10.1111/j.1365-2982.2009.01434.x
- Parkman, H. P., Hasler, W. L., & Fisher, R. S. (2004). American Gastroenterological Association medical position statement: Diagnosis and treatment of gastroparesis. *Gastroenterology*, 127(5), 1589-1591. doi:10.1053/j.gastro.2004.09.054
- Parkman, H. P., & Pasricha, P. J. (2015). Gastroparesis [special issue]. *Gastroenterology Clinics of North America*, 44(1).
- Parkman, H. P., Yates, K., Hasler, W. L., Nguyen, L., Pasricha, P. J., Snape, W. J., . . . National Institute of Diabetes Digestive Kidney Diseases Gastroparesis

- Clinical Research Consortium. (2011). Clinical features of idiopathic gastroparesis vary with sex, body mass, symptom onset, delay in gastric emptying, and gastroparesis severity. *Gastroenterology*, *140*(1), 101-115. doi:10.1053/j.gastro.2010.10.015
- Parkman, H. P., Yates, K., Hasler, W. L., Nguyen, L., Pasricha, P. J., Snape, W. J., . . . Consortium, N. I. o. D. a. D. a. K. D. G. C. R. (2011). Similarities and differences between diabetic and idiopathic gastroparesis. *Clinical Gastroenterology and Hepatology*, *9*(12), 1056-1064; quiz e1133-1054. doi:10.1016/j.cgh.2011.08.013
- Parkman, H. P., Yates, K. P., Hasler, W. L., Nguyen, L., Pasricha, P. J., Snape, W. J., . . . Consortium, N. G. C. R. (2011). Dietary intake and nutritional deficiencies in patients with diabetic or idiopathic gastroparesis. *Gastroenterology*, *141*(2), 486-498, 498 e481-487. doi:10.1053/j.gastro.2011.04.045
- Parrish, C. R. (2015). Nutritional considerations in the patient with gastroparesis. *Gastroenterology Clinics of North America*, *44*(1), 83-95. doi:10.1016/j.gtc.2014.11.007
- Parry, S. D., Corbett, S., James, P., Barton, R., & Welfare, M. R. (2003). Illness perceptions in people with acute bacterial gastroenteritis. *Journal of Health Psychology*, *8*(6).
- Pasricha, P. J. (2015). Future directions in the treatment of gastroparesis. *Gastroenterology Clinics of North America*, *44*(1), 185-189. doi:10.1016/j.gtc.2014.11.014
- Pasricha, P. J., Colvin, R., Yates, K., Hasler, W. L., Abell, T. L., Unalp-Arida, A., . . . Hamilton, F. (2011). Characteristics of patients with chronic unexplained nausea and vomiting and normal gastric emptying. *Clinical Gastroenterology and Hepatology*, *9*(7), 567-576 e561-564. doi:10.1016/j.cgh.2011.03.003
- Pasricha, P. J., & Parkman, H. P. (2015). Gastroparesis: definitions and diagnosis. *Gastroenterology Clinics of North America*, *44*(1), 1-7. doi:10.1016/j.gtc.2014.11.001
- Pasricha, P. J., Yates, K. P., Nguyen, L., Clarke, J., Abell, T. L., Farrugia, G., . . . Parkman, H. P. (2015). Outcomes and Factors Associated With Reduced Symptoms in Patients With Gastroparesis. *Gastroenterology*, *149*(7), 1762-1774 e1764. doi:10.1053/j.gastro.2015.08.008

- Petrak, F., Hardt, J., Clement, T., Borner, N., Egle, T., & Hoffman, S. O. (2009). Impaired Health-Related Quality of Life in Inflammatory Bowel Diseases: Psychosocial Impact and Coping Styles in a National German Sample. *Scandinavian Journal of Gastroenterology*, *36*(4), 375-382. doi:10.1080/00365520118423
- Petrie, K., Cameron, L. D., Ellis, C. J., Buick, D., & Weinman, J. (2002). Changing illness perceptions after myocardial infarction: an early intervention randomized controlled trial. *Psychosomatic Medicine*, *64*, 580-586.
- Petrie, K., Jago, L. A., & Devcich, D. A. (2007). The role of illness perceptions in patients with medical conditions. *Current Opinion in Psychiatry*, *20*, 163-167.
- Petrie, K., Weinman, J., Sharpe, N., & Buckley, J. (1996). Role of patients' view of their illness in predicting return to work and functioning after myocardial infarction: longitudinal study. *BMJ*, *312*, 1191-1194.
- Philip, E. J., Lindner, H., & Lederman, L. (2009). Relationship of illness perceptions with depression among individuals diagnosed with lupus. *Depression and Anxiety*, *26*(6), 575-582. doi:10.1002/da.20451
- Phillips, K., Wright, B. J., & Kent, S. (2013). Psychosocial predictors of irritable bowel syndrome diagnosis and symptom severity. *Journal of Psychosomatic Research*, *75*(5), 467-474. doi:10.1016/j.jpsychores.2013.08.002
- Pizzi, L. T., Weston, C. M., Goldfarb, N. I., Moretti, D., Cobb, N., Howell, J. B., . . . Cohen, S. (2006). Impact of chronic conditions on quality of life in patients with Inflammatory Bowel Disease. *Inflammatory Bowel Diseases*, *12*(1), 47-52.
- Pollok, J., van Agteren, J. E. M., Carson, K. V., Esterman, A. J., Smith, B. J., Licinio, J., & Pollok, J. (2016). Psychological therapies for the treatment of depression in chronic obstructive pulmonary disease. doi:10.1002/14651858.cd012347
- Prins, A. (2011). The brain-gut interaction: the conversation and the implications. *S Afr J Clin Nutr*, *24*(3), S8-S14.
- Psychological Foundation of Australia. (2014, Nov 10). Depression Anxiety Stress Scales (DASS). Retrieved from <http://www2.psy.unsw.edu.au/dass/>
- Rampton, D. (2009). Does stress influence inflammatory bowel disease? The clinical data. *Digestive Diseases*, *27 Suppl 1*, 76-79. doi:10.1159/000268124

- Rashed, H., Cutts, T., Abell, T. L., Cowings, P., Toscano, W., El-Gammal, A., & Adl, D. (2002). Predictors of response to a behavioural treatment in patients with chronic gastric motility disorders. *Digestive Diseases and Sciences*, *47*(5), 1020-1026.
- Rees, G., Fry, A., Cull, A., & Sutton, S. (2004). Illness perceptions and distress in women at increased risk of breast cancer. *Psychology & Health*, *19*(6), 749-765. doi:10.1080/08870440412331279764
- Rentz, A. M., Kahrilas, P., Stanghellini, V., Tack, J., Talley, N. J., de la Loge, C., . . . Revicki, D. A. (2004). Development and psychometric evaluation of the patient assessment of upper gastrointestinal symptom severity index (PAGI-SYM) in patients with upper gastrointestinal disorders. *Quality of Life Research*, *13*, 14. doi:10.1007/s11136-004-9567-x
- Revicki, D. A., Rentz, A. M., Dubois, D., Kahrilas, P., Stanghellini, V., Talley, N. J., & Tack, J. (2003). Development and validation of a patient-assessed gastroparesis symptom severity measure: the Gastroparesis Cardinal Symptom Index. *Alimentary Pharmacology and Therapeutics*, *18*(1), 141-150. doi:10.1046/j.0269-2813.2003.01612.x
- Rey, E., Choung, R. S., Schleck, C. D., Zinsmeister, A. R., Talley, N. J., & Locke, G. R., 3rd. (2012). Prevalence of hidden gastroparesis in the community: the gastroparesis "iceberg". *Journal of Neurogastroenterology and Motility*, *18*(1), 34-42. doi:10.5056/jnm.2012.18.1.34
- Richards, D., & Richardson, T. (2012). Computer-based psychological treatments for depression: a systematic review and meta-analysis. *Clinical Psychology Review*, *32*(4), 329-342. doi:10.1016/j.cpr.2012.02.004
- Richards, S. H., Anderson, L., Jenkinson, C. E., Whalley, B., Rees, K., Davies, P., . . . Taylor, R. S. (2017). Psychological interventions for coronary heart disease. *Cochrane Database Syst Rev*, *4*, CD002902. doi:10.1002/14651858.CD002902.pub4
- Romijn, J. A., Corssmit, E. P., Havekes, L. M., & Pijl, H. (2008). Gut-brain axis. *Current Opinion in Clinical Nutrition and Metabolic Care*, *11*, 518-521.
- Roohafza, H., Keshteli, A. H., Daghighzadeh, H., Afshar, H., Erfani, Z., & Adibi, P. (2016). Life stressors, coping strategies, and social supports in patients

with irritable bowel syndrome. *Adv Biomed Res*, 5, 158. doi:10.4103/2277-9175.190935

- Roubinov, D. S., Turner, A. P., & Williams, R. M. (2015). Coping Among Individuals With Multiple Sclerosis: Evaluating a Goodness-of-Fit Model. *Rehabilitation Psychology*. doi:10.1037/rep0000032
- Rozema, H., Vollink, T., & Lechner, L. (2009). The role of illness representations in coping and health of patients treated for breast cancer. *Psycho-Oncology*, 18(8), 849-857. doi:10.1002/pon.1488
- Rutter, C. L., & Rutter, D. R. (2002). Illness representation, coping and outcome in irritable bowel syndrome (IBS). *British Journal of Health Psychology*, 7, 377-391.
- Rutter, C. L., & Rutter, D. R. (2007). Longitudinal analysis of the illness representation model in patients with irritable bowel syndrome (IBS). *Journal of Health Psychology*, 12(1), 141-148. doi:10.1177/1359105307071748
- Rutter, M. D., Saunders, B. P., Wilkinson, K. H., Schofield, G., & Forbes, A. (2006). Intangible costs and benefits of ulcerative colitis surveillance: A patient survey. *Diseases of the Colon and Rectum*, 49(8), 1177-1183.
- Sanger, G. J., & Lee, K. (2008). Hormones of the gut-brain axis as targets for the treatment of upper gastrointestinal disorders. *Nat Rev Drug Discov*, 7(3), 241-254. doi:10.1038/nrd2444
- Sattar, A., Salih, M., & Jafri, W. (2010). Burden of common mental disorders in patients with functional dyspepsia. *Journal of the Pakistan Medical Association*, 60(12), 995-997.
- Scharloo, M., Kaptein, A. A., Weinman, J., Hazes, J. M., Willems, L. N. A., Bergman, W., & Rooijmans, H. G. M. (1998). Illness perceptions, coping and functioning in patients with rheumatoid arthritis, chronic obstructive pulmonary disease and psoriasis. *Journal of Psychosomatic Research*, 44(5), 573-585.
- Schirbel, A. (2010). Impact of pain on health-related quality of life in patients with inflammatory bowel disease. *World Journal of Gastroenterology*, 16(25), 3168. doi:10.3748/wjg.v16.i25.3168
- Schram, M. T., Baan, C. A., & Pouwer, F. (2009). Depression and quality of life in patients with diabetes: A systematic review from the European Depression

- in Diabetes (EDID) Research Consortium. *Current Diabetes Reviews*, 5, 112-119.
- Schurman, J. V., Wu, Y. P., Grayson, P., & Friesen, C. A. (2010). A pilot study to assess the efficacy of biofeedback-assisted relaxation training as an adjunct treatment for pediatric functional dyspepsia associated with duodenal eosinophilia. *Journal of Pediatric Psychology*, 35(8), 837-847.
doi:10.1093/jpepsy/jsq010
- Semple, C., Parahoo, K., Norman, A., McCaughan, E., Humphris, G., & Mills, M. (2013). Psychosocial interventions for patients with head and neck cancer. *Cochrane Database Syst Rev*(7), CD009441.
doi:10.1002/14651858.CD009441.pub2
- Seres, G., Kovacs, Z., Kovacs, A., Kerekgyarto, O., Sardi, K., Demeter, P., . . . Tury, F. (2008). Different associations of health related quality of life with pain, psychological distress and coping strategies in patients with irritable bowel syndrome and inflammatory bowel disorder. *Journal of Clinical Psychology in Medical Settings*, 15(4), 287-295. doi:10.1007/s10880-008-9132-9
- Shah, E., Rezaie, A., Riddle, M., & Pimentel, M. (2014). Psychological disorders in gastrointestinal disease: epiphenomenon, cause or consequence? *Annals of Gastroenterology*, 27, 224-230.
- Sheehan, D. V., Lecrubier, Y., Sheehan, K. H., Amorim, P., Janavs, J., Weiller, E., . . . Dunbar, G. C. (1998). The Mini-International Neuropsychiatric Interview (M.I.N.I.): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. *Journal of Clinical Psychiatry*, 59, 22-33.
- Simon, G. E., Katon, W. J., Lin, E. H., Ludman, E., VonKorff, M., Ciechanowski, P., & Young, B. A. (2005). Diabetes complications and depression as predictors of health service costs. *General Hospital Psychiatry*, 27(5), 344-351.
doi:10.1016/j.genhosppsy.2005.04.008
- Sirois, F. M., & Hirsch, J. K. (2017). A longitudinal study of the profiles of psychological thriving, resilience, and loss in people with inflammatory bowel disease. *British Journal of Health Psychology*, 22(4), 920-939.
doi:10.1111/bjhp.12262

- Slade, T., Johnston, A., Teesson, M., Whiteford, H., Burgess, P., Pirkis, J., & Saw, S. (2009). *The mental health of Australians 2: report on the 2007 National Survey of Mental Health and Wellbeing*. Retrieved from Canberra:
- Soo, S., Forman, D., Delaney, B. C., & Moayyedi, P. (2004). A systematic review of psychological therapies for nonulcer dyspepsia. *American Journal of Gastroenterology*, 99(9), 1817-1822. doi:10.1111/j.1572-0241.2004.30086.x
- Soykan, I., Sivri, B., Sarosiek, I., Kiernan, B., & McCallum, R. (1998). Demography, clinical characteristics, psychological and abuse profiles, treatment, and long-term follow-up of patients with gastroparesis. *Digestive Diseases and Sciences*, 43(11), 2398-2404.
- Spielberger, C. D., Gorsuch, R. L., Lushene, R., Vagg, P. R., & Jacobs, G. A. (1983). *Manual for the State-Trait Anxiety Inventory*. Palo Alto, CA: Consulting Psychologists Press.
- Stanghellini, V., & Tack, J. (2014). Gastroparesis: separate entity or just a part of dyspepsia? *Gut*. doi:10.1136/gutjnl-2013-306084
- Steed, L. G. (1998). A critique of coping scales. *Australian Psychologist*, 33(3), 193-202.
- StomachPics. (2014). Digestive system diagrams. Retrieved from <http://stomachpicture.com/digestive-system-diagrams/>
- Strid, H., Norstrom, M., Sjoberg, J., Simren, M., Svedlund, J., Abrahamsson, H., & Bjornsson, E. (2001). Impact of sex and psychological factors on the water loading test in functional dyspepsia. *Scandinavian Journal of Gastroenterology*, 36(7), 725-730.
- Sugawara, N., Sato, K., Takahashi, I., Satake, R., Fukuda, S., Nakaji, S., & Yasui-Furukori, N. (2017). Depressive Symptoms and Coping Behaviors among Individuals with Irritable Bowel Syndrome in Japan. *Internal Medicine*, 56(5), 493-498. doi:10.2169/internalmedicine.56.7695
- Surdea-Blaga, T., Baban, A., & Dumitrascu, D. L. (2012). Psychosocial determinants of irritable bowel syndrome. *World Journal of Gastroenterology*, 18(7), 616-626. doi:10.3748/wjg.v18.i7.616
- Sweeney, L., Moss-Morris, R., Czuber-Dochan, W., Meade, L., Chumbley, G., & Norton, C. (2018). Systematic review: psychosocial factors associated with

- pain in inflammatory bowel disease. *Alimentary Pharmacology and Therapeutics*. doi:10.1111/apt.14493
- Tack, J. (2005). Gastric motility disorders. In W. M. Weinstein, C. J. Hawkey, & J. Bosch (Eds.), *Clinical Gastroenterology and Hepatology* (pp. 261-266). St Louis, MO: Elsevier.
- Talley, N. J., Locke, G. R., 3rd, Lahr, B. D., Zinsmeister, A. R., Tougas, G., Ligozio, G., . . . Tack, J. (2006). Functional dyspepsia, delayed gastric emptying, and impaired quality of life. *Gut*, *55*(7), 933-939. doi:10.1136/gut.2005.078634
- Tan-Kristanto, S., & Kiropoulos, L. A. (2015). Resilience, self-efficacy, coping styles and depressive and anxiety symptoms in those newly diagnosed with multiple sclerosis. *Psychology, Health & Medicine*, 1-11. doi:10.1080/13548506.2014.999810
- Tang, D. M., & Friedenberg, F. K. (2011). Gastroparesis: approach, diagnostic evaluation, and management. *Disease-a-Month*, *57*(2), 74-101. doi:10.1016/j.disamonth.2010.12.007
- Thomas, P. W., Thomas, S., Hillier, C., Galvin, K., & Baker, R. (2006). Psychological interventions for multiple sclerosis. *Cochrane Database Syst Rev*(1), CD004431. doi:10.1002/14651858.CD004431.pub2
- Thompson, D. G. (2001). Descartes and the gut: "I'm pink therefore I am". *Gut*, *49*(2), 165-166. doi:10.1136/gut.49.2.165
- Timmer, A., Preiss, J. C., Motschall, E., Rucker, G., Jantschek, G., & Moser, G. (2011). Psychological interventions for treatment of inflammatory bowel disease (Review). *The Cochrane Collaboration*(2).
- Tominaga, K., Higuchi, K., Iketani, T., Ochi, M., Kadouchi, K., Tanigawa, T., . . . Arakawa, T. (2007). Comparison of gastrointestinal symptoms and psychological factors of functional dyspepsia to peptic ulcer or panic disorder patients. *Inflammopharmacology*, *15*(2), 84-89. doi:10.1007/s10787-006-0011-4
- Toner, B. B., Chang, L., Fukudo, S., Guthrie, E., Locke, G. R., Norton, N., & Sperber, A. D. (2006). Gender, age, society, culture, and the patient's perspective. In D. A. Drossman, E. Corazzari, M. Delvaux, R. C. Spiller, N. J. Talley, W. G. Thompson, & W. E. Whitehead (Eds.), *Rome III: The functional gastrointestinal disorders* (3 ed.). Virginia: Degnon Associates, Inc.

- Turunen, P., Ashorn, M., Auvinen, A., Iltanen, S., Huhtala, H., & Kolho, K. L. (2009). Long-term health outcomes in pediatric inflammatory bowel disease: a population-based study. *Inflammatory Bowel Diseases*, *15*(1), 56-62. doi:10.1002/ibd.20558
- Usmani, Z. A., Carson, K. V., Heslop, K., Esterman, A. J., De Soyza, A., & Smith, B. J. (2017). Psychological therapies for the treatment of anxiety disorders in chronic obstructive pulmonary disease. *Cochrane Database Syst Rev*, *3*, CD010673. doi:10.1002/14651858.CD010673.pub2
- van der Heijden, I., Abrahams, N., & Sinclair, D. (2017). Psychosocial group interventions to improve psychological well-being in adults living with HIV. *Cochrane Database Syst Rev*, *3*, CD010806. doi:10.1002/14651858.CD010806.pub2
- van Melle, J. P., de Jonge, P., Spijkerman, T. A., Tijssen, J. G., Ormel, J., van Veldhuisen, D. J., . . . van den Berg, M. P. (2004). Prognostic association of depression following myocardial infarction with mortality and cardiovascular events: a meta-analysis. *Psychosomatic Medicine*, *66*(6), 814-822. doi:10.1097/01.psy.0000146294.82810.9c
- Van Oudenhove, L., Crowell, M. D., Drossman, D. A., Halpert, A. D., Keefer, L., Lackner, J. M., . . . Levy, R. L. (2016). Biopsychosocial Aspects of Functional Gastrointestinal Disorders. *Gastroenterology*. doi:10.1053/j.gastro.2016.02.027
- Van Oudenhove, L., Vandenberghe, J., Geeraerts, B., Vos, R., Persoons, P., Demyttenaere, K., . . . Tack, J. (2007). Relationship between anxiety and gastric sensorimotor function in functional dyspepsia. *Psychosomatic Medicine*, *69*(5), 455-463. doi:10.1097/PSY.0b013e3180600a4a
- Van Oudenhove, L., Vandenberghe, J., Geeraerts, B., Vos, R., Persoons, P., Fischler, B., . . . Tack, J. (2008). Determinants of symptoms in functional dyspepsia: gastric sensorimotor function, psychosocial factors or somatisation? *Gut*, *57*(12), 1666-1673. doi:10.1136/gut.2008.158162
- Van Oudenhove, L., Vandenberghe, J., Vos, R., Fischler, B., Demyttenaere, K., & Tack, J. (2011). Abuse history, depression, and somatization are associated with gastric sensitivity and gastric emptying in functional dyspepsia.

- Psychosomatic Medicine*, 73(8), 648-655.
doi:10.1097/PSY.0b013e31822f32bf
- Van Oudenhove, L., Vandenberghe, J., Vos, R., Holvoet, L., Demyttenaere, K., & Tack, J. (2011). Risk factors for impaired health-related quality of life in functional dyspepsia. *Alimentary Pharmacology and Therapeutics*, 33(2), 261-274. doi:10.1111/j.1365-2036.2010.04510.x
- Vaughan, R., Morrison, L., & Miller, E. (2003). The illness representations of multiple sclerosis and their relations to outcome. *British Journal of Health Psychology*, 8, 287-301.
- Vollmann, M., Scharloo, M., Langguth, B., Kalkouskaya, N., & Salewski, C. (2013). Illness representations as mediators of the relationship between dispositional optimism and depression in patients with chronic tinnitus: a cross-sectional study. *Psychology & Health*, 29(1), 81-93.
doi:10.1080/08870446.2013.828294
- Voth, J., & Sirois, F. M. (2009). The role of self-blame and responsibility in adjustment to inflammatory bowel disease. *Rehabilitation Psychology*, 54(1), 99-108. doi:10.1037/a0014739
- Wahass, S., Khalil, M. S., Al Qurain, A. A., & Yasawy, M. I. (2006). The impact of functional dyspepsia on health-related quality of life in Saudi patients. *The Saudi Journal of Gastroenterology*, 12(3), 123-129.
- Wang, Y. R., Fisher, R. S., & Parkman, H. P. (2008). Gastroparesis-related hospitalizations in the United States: trends, characteristics, and outcomes, 1995-2004. *American Journal of Gastroenterology*, 103(2), 313-322.
doi:10.1111/j.1572-0241.2007.01658.x
- Wang, Y. T., Lim, H. Y., Tai, D., Krishnmoorthy, T. L., Tan, T., Barbier, S., & Thumboo, J. (2012). The impact of irritable bowel syndrome on health-related quality of life: A Singapore perspective. *BMC Gastroenterology*, 12(104).
- Webb, A. N., Kukuruzovic, R. H., Catto-Smith, A. G., & Sawyer, S. M. (2007). Hypnotherapy for treatment of irritable bowel syndrome. *Cochrane Database Syst Rev*(4), CD005110. doi:10.1002/14651858.CD005110.pub2
- Weldam, S. W. M., Lammers, J.-W. J., Heijmans, M. J. W. M., & Schuurmans, M. J. (2014). Perceived quality of life in chronic obstructive pulmonary disease

- patients: a cross-sectional study in primary care on the role of illness perceptions. *BMC Family Practice*, 15(140).
- Wells, N. E. J., Hahn, B. A., & Whorwell, P. J. (1997). Clinical economics review: Irritable bowel syndrome. *Alimentary Pharmacology and Therapeutics*, 11, 1019-1030.
- Wexler, D. J., Grant, R. W., Wittenberg, E., Bosch, J. L., Cagliero, E., Delahanty, L., . . . Meigs, J. B. (2006). Correlates of health-related quality of life in type 2 diabetes. *Diabetologia*, 49(7), 1489-1497. doi:10.1007/s00125-006-0249-9
- White, C. (2001). Cognitive behavioral principles in managing chronic disease. *Western Journal of Medicine*, 175, 338-342.
- Whitmarsh, A., Koutantki, M., & Sidell, K. (2003). Illness perceptions, mood and coping in predicting attendance at cardiac rehabilitation. *British Journal of Health Psychology*, 8, 209-221.
- Willig, C. (2001). *Introducing qualitative research in psychology: Adventures in theory and method*. Berkshire: Open University Press, McGraw-Hill Education.
- Wilpart, K., Tornblom, H., Svedlund, J., Tack, J. F., Simren, M., & Van Oudenhove, L. (2017). Coping Skills Are Associated With Gastrointestinal Symptom Severity and Somatization in Patients With Irritable Bowel Syndrome. *Clinical Gastroenterology and Hepatology*, 15(10), 1565-1571 e1563. doi:10.1016/j.cgh.2017.02.032
- Woodhouse, S., Hebbard, G., & Knowles, S. R. (2017a). Exploration of the psychosocial issues associated with gastroparesis: a qualitative investigation. *Journal of Clinical Nursing*. doi:10.1111/jocn.13725
- Woodhouse, S., Hebbard, G., & Knowles, S. R. (2017b). Psychological controversies in gastroparesis: A systematic review. *World Journal of Gastroenterology*, 23(7), 1298-1309. doi:10.3748/wjg.v23.i7.1298
- World Health Organization. (2017). WHOQOL: Measuring quality of life. Retrieved from <http://www.who.int/healthinfo/survey/whoqol-qualityoflife/en/>
- Yorke, J., Fleming, S. L., & Shuldham, C. M. (2006). Psychological interventions for adults with asthma. *Cochrane Database Syst Rev*(1), CD002982. doi:10.1002/14651858.CD002982.pub3

- Yu, D., Ramsey, F. V., Norton, W. F., Norton, N., Schneck, S., Gaetano, T., & Parkman, H. P. (2017). The Burdens, Concerns, and Quality of Life of Patients with Gastroparesis. *Digestive Diseases and Sciences*, 62(4), 879-893.
doi:10.1007/s10620-017-4456-7
- Ziarko, M., Mojs, E., Piasecki, B., & Samborski, W. (2014). The Mediating Role of Dysfunctional Coping in the Relationship between Beliefs about the Disease and the Level of Depression in Patients with Rheumatoid Arthritis. *ScientificWorldJournal*, 2014, 585063. doi:10.1155/2014/585063
- Zijdenbos, I. L., de Wit, N. J., van der Heijden, G. J., Rubin, G., & Quartero, A. O. (2009). Psychological treatments for the management of irritable bowel syndrome. *Cochrane Database Syst Rev*(1), CD006442.
doi:10.1002/14651858.CD006442.pub2

Appendix 1: Ethics clearance

From: Keith Wilkins
Sent: Tuesday, 18 February 2014 12:00 PM
To: Simon Knowles
Cc: RES Ethics
Subject: SUHREC Project 2013/261 Ethics Clearance

To: Dr Simon Knowles, FLSS

Dear Simon

SUHREC Project 2013/261 Gastroparesisclinic.org: an online evaluation and validation

Dr S Knowles, FLSS; Ms Sally Woodhouse et al

Approved Duration: 18/02/2014 To 18/02/2018 [Adjusted]

I refer to the ethical review of the above project revised protocol by Swinburne's Human Research Ethics Committee (SUHREC) on 13 December 2013. Your responses to the review, as emailed on 8 January 2014 with attachments, were put to the Committee delegate for consideration and feedback sent to you on 29 January and 3 February 2014. Your further responses, as emailed on 3 February 2014 with attachments, accord with the feedback.

I am pleased to advise that ethics clearance has been given for the above project to proceed in line with standard on-going ethics clearance conditions outlined below.

- All human research activity undertaken under Swinburne auspices must conform to Swinburne and external regulatory standards, including the *National Statement on Ethical Conduct in Human Research* and with respect to secure data use, retention and disposal.
- The named Swinburne Chief Investigator/Supervisor remains responsible for any personnel appointed to or associated with the project being made aware of ethics clearance conditions, including research and consent procedures or instruments approved. Any change in chief investigator/supervisor requires timely notification and SUHREC endorsement.
- The above project has been approved as submitted for ethical review by or on behalf of SUHREC. Amendments to approved procedures or instruments ordinarily require prior ethical appraisal/ clearance. SUHREC must be notified immediately or as soon as possible thereafter of (a) any serious or unexpected adverse effects on participants and any redress measures; (b) proposed changes in protocols; and (c) unforeseen events which might affect continued ethical acceptability of the project.
- At a minimum, an annual report on the progress of the project is required as well as at the conclusion (or abandonment) of the project. Information on project monitoring, self-audits and progress reports can be found at: <http://www.research.swinburne.edu.au/ethics/human/monitoringReportingChanges/>
- A duly authorised external or internal audit of the project may be undertaken at any time.

Please contact the Research Ethics Office if you have any queries about on-going ethics clearance, citing the SUHREC project number. Please retain a copy of this email as part of project record-keeping.

Best wishes for the project.

Yours sincerely

Keith

Keith Wilkins
Secretary, SUHREC & Research Ethics Officer
Swinburne Research (H68)
Swinburne University of Technology
P O Box 218
HAWTHORN VIC 3122
Tel +61 3 9214 5218
Fax +61 3 9214 526

From: resethics@swin.edu.au [mailto:resetethics@swin.edu.au]
Sent: Monday, 12 February 2018 1:24 PM
To: Simon Knowles <sknowles@swin.edu.au>
Cc: RES Ethics <resetethics@swin.edu.au>
Subject: Acknowledgement of Report for SUHREC Project - 2013/261

Dear Simon,

Re: Progress Report for the project 2013/261

'Gastroparesisclinic.org: an online evaluation and validation Study 1 (Qualitative); Study 2 (Quantitative); Study 3 (Pilot Study Evaluation)' (Report Date: 12-02-2018)

The Progress report for the above project has been processed and satisfies the reporting requirements set under the terms of ethics clearance.

Thank you for your attention to this matter.

Regards
Research Ethics Team

Swinburne Research (H68)
Swinburne University of Technology
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Appendix 2: Publication information for Paper 1

Publisher: World Journal of Gastroenterology

About the World Journal of Gastroenterology: The World Journal of Gastroenterology is a peer-reviewed academic journal publishing original articles and reviews pertaining to gastroenterology, hepatology, gastrointestinal surgery and endoscopy.

Citations:

Liu, D. S., Tog, C., Lim, H. K., Stiven, P., Thompson, S. K., Watson, D. I., Aly, A. (2017) Delayed Gastric Emptying Following Laparoscopic Repair of Very Large Hiatus Hernias Impairs Quality of Life. *World Journal of Surgery*. doi: [10.1007/s00268-017-4362-3](https://doi.org/10.1007/s00268-017-4362-3)

Teigland, T., Iversen, M. M., Sangnes, D. A., Dimcevski, G., Søfteland, E. (2018). A longitudinal study on patients with diabetes and symptoms of gastroparesis – associations with impaired quality of life and increased depressive and anxiety symptoms. *Journal of Diabetes and its Complications*, 32(1), 89. doi: [10.1016/j.jdiacomp.2017.10.010](https://doi.org/10.1016/j.jdiacomp.2017.10.010)

Woodhouse, S., Hebbard, G., Knowles, S. R. (2018). Exploring Symptom Severity, Illness Perceptions, Coping Styles, and Well-Being in Gastroparesis Patients Using the Common Sense Model. *Digestive Diseases and Sciences*, 63(4), 958. doi: [10.1007/s10620-018-4975-x](https://doi.org/10.1007/s10620-018-4975-x)

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Peer-review comments:



ESPS PEER-REVIEW REPORT

Name of journal: World Journal of Gastroenterology
ESPS manuscript NO: 31658
Title: Psychological controversies in gastroparesis: A systematic review
Reviewer's code: 03563654
Reviewer's country: Turkey
Science editor: Yuan Qi
Date sent for review: 2016-12-02 20:08
Date reviewed: 2016-12-16 16:30

CLASSIFICATION	LANGUAGE EVALUATION	SCIENTIFIC MISCONDUCT	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input type="checkbox"/> Grade A: Priority publishing	Google Search:	<input type="checkbox"/> Accept
<input type="checkbox"/> Grade B: Very good	<input type="checkbox"/> Grade B: Minor language polishing	<input type="checkbox"/> The same title	<input type="checkbox"/> High priority for publication
<input type="checkbox"/> Grade C: Good	<input type="checkbox"/> Grade C: A great deal of language polishing	<input type="checkbox"/> Duplicate publication	<input type="checkbox"/> Rejection
<input type="checkbox"/> Grade D: Fair	<input type="checkbox"/> Grade D: Rejected	<input type="checkbox"/> Plagiarism	<input type="checkbox"/> Minor revision
<input type="checkbox"/> Grade E: Poor		<input type="checkbox"/> No	<input type="checkbox"/> Major revision
		BPG Search:	
		<input type="checkbox"/> The same title	
		<input type="checkbox"/> Duplicate publication	
		<input type="checkbox"/> Plagiarism	
		<input type="checkbox"/> No	

COMMENTS TO AUTHORS

This is an actual study about gastroparesis. All over manuscript is very well written. "Gastroparesis may be also seen in very rare diseases such as dieulafoy lesion or even at gists"(Minerva Chir. 2014 Jun;69(3):147-53.) and (Case Rep Gastroenterol. 2008 Sep;2(3):469-73. doi: 10.1159/000175414) I suggest both of these uptodate studies for the references.

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ESPS PEER-REVIEW REPORT

Name of journal: World Journal of Gastroenterology
ESPS manuscript NO: 31658
Title: Psychological controversies in gastroparesis: A systematic review
Reviewer's code: 03645427
Reviewer's country: South Korea
Science editor: Yuan Qi
Date sent for review: 2016-12-02 20:08
Date reviewed: 2016-12-19 15:02

CLASSIFICATION	LANGUAGE EVALUATION	SCIENTIFIC MISCONDUCT	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input checked="" type="checkbox"/> Grade A: Priority publishing	Google Search:	<input type="checkbox"/> Accept
<input checked="" type="checkbox"/> Grade B: Very good	<input type="checkbox"/> Grade B: Minor language polishing	<input type="checkbox"/> The same title	<input type="checkbox"/> High priority for publication
<input type="checkbox"/> Grade C: Good	<input type="checkbox"/> Grade C: A great deal of language polishing	<input type="checkbox"/> Duplicate publication	<input type="checkbox"/> Rejection
<input type="checkbox"/> Grade D: Fair	<input type="checkbox"/> Grade D: Rejected	<input type="checkbox"/> Plagiarism	<input type="checkbox"/> Minor revision
<input type="checkbox"/> Grade E: Poor		<input checked="" type="checkbox"/> No	<input type="checkbox"/> Major revision
		BPG Search:	
		<input type="checkbox"/> The same title	
		<input type="checkbox"/> Duplicate publication	
		<input type="checkbox"/> Plagiarism	
		<input checked="" type="checkbox"/> No	

COMMENTS TO AUTHORS

This study is a systemic review that evaluated the clinical correlation between major psychologic disease and gastroparesis. Your study is very reasonably described and even informative to the clinician in practice. Although the definition of gastroparesis is not well established, your results are inspiring and helpful to clarify the correlation between th psychologic disease and other functional GI disease.



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ESPS PEER-REVIEW REPORT

Name of journal: World Journal of Gastroenterology
ESPS manuscript NO: 31658
Title: Psychological controversies in gastroparesis: A systematic review
Reviewer's code: 03487098
Reviewer's country: Japan
Science editor: Yuan Qi
Date sent for review: 2016-12-02 20:08
Date reviewed: 2016-12-20 14:01

CLASSIFICATION	LANGUAGE EVALUATION	SCIENTIFIC MISCONDUCT	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input type="checkbox"/> Grade A: Priority publishing	Google Search:	<input type="checkbox"/> Accept
<input type="checkbox"/> Grade B: Very good	<input type="checkbox"/> Grade B: Minor language polishing	<input type="checkbox"/> The same title	<input type="checkbox"/> High priority for publication
<input type="checkbox"/> Grade C: Good	<input type="checkbox"/> Grade C: A great deal of language polishing	<input type="checkbox"/> Duplicate publication	<input type="checkbox"/> Rejection
<input type="checkbox"/> Grade D: Fair	<input type="checkbox"/> Grade D: Rejected	<input type="checkbox"/> Plagiarism	<input type="checkbox"/> Minor revision
<input type="checkbox"/> Grade E: Poor		<input type="checkbox"/> No	<input type="checkbox"/> Major revision
		BPG Search:	
		<input type="checkbox"/> The same title	
		<input type="checkbox"/> Duplicate publication	
		<input type="checkbox"/> Plagiarism	
		<input type="checkbox"/> No	

COMMENTS TO AUTHORS

General comment This paper conducted for systematic review of psychological aspects of gastroparesis. Authors concluded that “gastroparesis is associated with significant psychological distress and poor quality of life. Recommendations for future studies and the development of psychological interventions are provided”. As authors described, this paper has some flaw, but it is relatively well written, organized, and within the scope of the World Journal of Gastroenterology. Major revision This manuscript needs no major revision. Minor revision Although authors described “one (0.06%) involved a psychologically-based intervention for gastroparesis patients [36]” in page 8, “one (6.25%)” is correct?

**PARTICIPANT INFORMATION SHEET
TELEPHONE INTERVIEW**

Swinburne University of Technology, Royal Melbourne Hospital
& St Vincent's Hospital (Melbourne)



FULL PROJECT TITLE:

Exploration of the psychosocial issues associated with gastroparesis: A qualitative investigation

NAME/S OF INVESTIGATORS

Dr Simon Knowles (Swinburne University), Associate Professor Geoff Hebbard (Royal Melbourne Hospital), Professor David Castle (St Vincent's Hospital Melbourne) and Ms Sally Woodhouse (Swinburne University).

1. Introduction

You are invited to take part in this research project. This is because you currently experience gastroparesis. We are aware that having gastroparesis can have a significant impact on your health, both physiologically and well as psychologically. It is well recognised that individuals undergoing treatment for a medical condition also report anxiety, stress, and even depression.

We are looking to gain a better understanding as to the psychosocial impact of having gastroparesis.

This Participant Information and Consent Form tells you about the research project. It explains the procedures involved. Knowing what is involved will help you decide if you want to take part in the research. This consent form is six pages long.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or healthcare worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether you take part or not.

If you decide you want to take part in the research project, you will be asked to participate in a telephone interview (further details are provided under 'What does participation in this research project involve').

The return of the consent form will be signalling that you are telling us that you:

- understand what you have read;
- consent to take part in the research project; and,
- consent to participate in the research processes that are described.

2. What is the purpose of this research project?

The purpose of this study is to explore the how you experience your gastroparesis symptoms and how it impacts on your life, including relationships, educational and social activities. Consequently, understanding your symptoms and how you cope with time is important. Under the supervision of the primary investigator, data from this study will also be used by Ms Sally Woodhouse as part of her PhD research. We aim to recruit a total of 10 participants.

3. What does participation in this research project involve?

If you wish to join the study, please contact the chief investigator, Dr Simon Knowles (ph +61 3 9214 8206, sknowles@swin.edu.au). If you are willing, we would like to interview you (conducted by Ms Sally Woodhouse, PhD candidate) over the telephone for approximately 45-60 minutes. The telephone interview is completely voluntary and all information will be transcribed and all identifiable information removed. You will be offered a transcript of the interview to review and provide comments on, which should take no longer than an hour of your time.

This research involves the collaboration between the Royal Melbourne Hospital, St Vincent's Hospital, and Swinburne University.

4. Participant Inclusion/exclusion criteria

Inclusion criteria:

- (1) Aged 18 year or older
- (2) Having been diagnosed with Gastroparesis and currently under the care of a gastroenterologist
- (3) English as a first language or able to read English

Exclusion criteria:

- (1) Not currently experiencing severe mental illness
- (2) Not currently seeking support from a mental health expert (i.e., psychologist or psychiatrist)

5. What are the possible risks?

It is recommended that you discuss your participation in this research with your gastroenterologist or health professional. If you become upset or distressed as a result of your participation in the research, the researcher is able to arrange a referral for counselling and/or other appropriate support. Any counselling or support will be provided by individuals who are not members of the research team.

6. Do I have to take part in this research project?

Participation in this research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at a later stage. If you do decide to leave this project, the researchers would like to keep the personal and health information about you that has been collected. This is to help them make sure that the results of the research can be measured properly. If you do not want them to do this, you must tell them before you withdraw from the study.

7. How will I be informed of the results of this research project?

The research group conducting the study plan to write a report, which will be made available to anyone who is interested. The report will be available via www.Gastroparesisclinic.org. The results will also be written for publication in a scientific medical journal.

8. What will happen to information about me?

Any information obtained in connection with this project and that can identify you will remain confidential. It will only be disclosed with your permission, except as required by law. No information used in future presentations or written publications like articles or books will identify any participant. This is done through coding all participants using numbers and keeping all documents involved with individuals in a locked cabinet, accessible only to people involved in the project. All information will be kept at Swinburne University of Technology, in a locked filing cabinet (or secured computer) for a period of 7 years after last access/use and subsequently shredded (or deleted).

9. Can I access research information kept about me?

In accordance with relevant Australian and /or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information, with which you disagree, be corrected. Please contact one of the researchers named at the end of this document if you would like to access your information.

10. Is this research project approved?

The ethical aspects of this research project have been approved by the Swinburne University Human Research Ethics Committee (SUHREC).

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007 – updated May 2013)* produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

11. Who can I contact?

If you want further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the Principal Researcher, Dr Simon Knowles, on +61 3 9214 8206 or sknowles@swin.edu.au.

12. Complaints

If you have any complaints about any aspect of the study or the way in which it is being conducted you may contact the Research Ethics Officer, Swinburne Research (H68), Swinburne University of Technology, PO BOX 218, HAWTHORN VIC 3122. Tel +61 3 9214 5218 or +61 3 9214 5218 or resethics@swin.edu.au

Consent Form: Exploration of the psychosocial issues associated with gastroparesis: A qualitative investigation

NAME/S OF INVESTIGATORS

Dr Simon Knowles (Swinburne University), Associate Professor Geoff Hebbard (Royal Melbourne Hospital), Professor David Castle (St Vincent's Hospital Melbourne), and Ms Sally Woodhouse (Swinburne University).

The purpose of this study is to explore the how you experience your gastroparesis symptoms, how it impacts on your life, including relationships, educational and social activities. Consequently, understanding your symptoms and how you cope with them is important. Under the supervision of the primary investigator, data from this study will also be used by Ms Sally Woodhouse as part of her PhD research.

Some of the question will be:

- How long have you experienced gastroparesis?
- What do you believe is the cause of your gastroparesis?
- Please tell me about how you experience gastroparesis?
- How does gastroparesis impact on your relationships?
- How does gastroparesis impact on your personal and social life?
- How does gastroparesis impact on your mental health?
- What strategies help you manage your gastroparesis symptoms?
- What advice would you give others in managing gastroparesis?

The interview will be conducted by a student researcher, Ms Sally Woodhouse and will form part of their PhD thesis. The interview will be recorded and transcribed, and you will be asked to comment on the transcription, which may require up to another hour of your time. Care will be taken to ensure confidentiality and to ensure that the recording can't be accessed by anyone other than the investigators. The recording will be destroyed after the transcription.

1. I consent to participate in the project named above. I have read the project consent information statement to which this consent form relates and any questions I have asked have been answered to my satisfaction.

2. ***In relation to this project, please circle your response to the following:***

- I agree to be interviewed by the researcher **Yes No**
- I agree to allow the interview to be recorded by electronic device and transcribed **Yes No**
- I agree to make myself available for further information if required **Yes No**

3. I acknowledge that:

- (a) my participation is voluntary and that I am free to withdraw from the project at any time without explanation;
- (b) the Swinburne project is for the purpose of research and not for profit;
- (c) any identifiable information about me which is gathered in the course of and as the result of my participating in this project will be (i) collected and retained for the purpose of this project and (ii) accessed and analysed by the researcher(s) for the purpose of conducting this project;
- (d) my anonymity is preserved and I will not be identified in publications or otherwise without my express written consent.

4. My preferred contact is via phone _____ or Skype _____
_____. I'm free for an interview on the _____ at _____
_____ AM / PM

By signing this document I agree to participate in this project.

Name of Participant:
Signature & Date:

Please email (sknowles@swin.edu.au) or mail (Dr Simon Knowles, Swinburne University PO BOX 218 Hawthorn Victoria, 3122) this consent form to Dr Simon Knowles

Appendix 4: Publication information for Paper 2

Publisher: Journal of Clinical Nursing

About the Journal of Clinical Nursing: The Journal of Clinical Nursing is an international, peer-reviewed journal that is focused on gathering and presenting information relevant to all aspects of nursing practice including clinical need, cultural comparisons, and the consequences of different nursing interventions and services.

Citations:

Woodhouse, S., Hebbard, G., Knowles, S. R. (2018). Exploring Symptom Severity, Illness Perceptions, Coping Styles, and Well-Being in Gastroparesis Patients Using the Common Sense Model. *Digestive Diseases and Sciences*, 63(4), 958. doi: [10.1007/s10620-018-4975-x](https://doi.org/10.1007/s10620-018-4975-x)

Copyright statement: I warrant that I have obtained, where necessary, permission from the copyright owners to use any third party copyright material reproduced in the thesis (such as artwork, images, unpublished documents), or to use any of my own published work (such as journal articles) in which the copyright is held by another party (such as publisher, co-author).

Peer-review comments:

Reviewer: 1

Comments to the Author

This is a nicely written paper that takes the reader on an interesting journey with these study participants. I will just raise two issues in terms of clarity and cohesiveness:

1. Page 10, paragraph 2, and Table 2: it is unclear what the difference is between idiopathic gastroparesis and gastroparesis with no stated or known cause.

2. In line with what is stated on page 7 about IPA and acknowledgement of the researcher's perspective it would be important to address this perspective in the Discussion.

Reviewer: 2

Comments to the Author

Thank you for the opportunity to review this paper. It is clearly an under-researched topic and I feel that you have added to what little is already known.

**PARTICIPANT INFORMATION SHEET
ONLINE QUESTIONNAIRE**

Swinburne University of Technology, Royal Melbourne Hospital
& St Vincent's Hospital (Melbourne)



FULL PROJECT TITLE:

Exploration of the psychosocial issues associated with gastroparesis: A quantitative investigation.

NAME/S OF INVESTIGATORS

Dr Simon Knowles (Swinburne University), Associate Professor Geoff Hebbard (Royal Melbourne Hospital), Professor David Castle (St Vincent's Hospital Melbourne) and Ms Sally Woodhouse (Swinburne University).

1. Introduction

You are invited to take part in this research project. This is because you currently experience gastroparesis. We are aware that having gastroparesis can have a significant impact on your health, both physiologically and well as psychologically. It is well recognised that individuals undergoing treatment for a medical condition also report anxiety, stress, and even depression.

We are looking to gain a better understanding as to the psychosocial impact of having gastroparesis. This Participant Information and Consent Form tells you about the research project. It explains the procedures involved. Knowing what is involved will help you decide if you want to take part in the research. This consent form is four pages long.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or healthcare worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether you take part or not.

If you decide you want to take part in the research project, you will be asked to complete an online questionnaire (further details are provided under 'What does participation in this research project involve').

Clicking continue and completing the questionnaire will be signalling that you are telling us that you:

- understand what you have read;
- consent to take part in the research project; and,
- consent to participate in the research processes that are described.

2. What is the purpose of this research project?

The purpose of this study is to explore how you experience your gastroparesis and how it impacts on your life. Questions will explore gastroparesis symptoms (e.g., How often do you experience nausea, pain?), illness perceptions (e.g., How much control do you feel you have over your illness?), coping (e.g., I've been turning to work or other activities to take my mind off things), psychological distress (e.g., I found it difficult to work up the initiative to do things), personality (e.g., I am extraverted, enthusiastic), and quality of life (e.g., have you restricted eating at restaurants or at someone's home?).

Under the supervision of the primary investigator, data from this study will also be used by Ms Sally Woodhouse as part of her PhD research. We aim to recruit a total of 200 participants. This research involves the collaboration between the Royal Melbourne Hospital, St Vincent's Hospital, and Swinburne University.

3. What does participation in this research project involve?

If you wish to join the study, please click continue and complete the questionnaire. The questionnaire will take between 45-60 minutes to complete.

4. Participant Inclusion/exclusion criteria

Inclusion criteria:

- (4) Aged 18 years or older
- (5) Having been diagnosed with Gastroparesis
- (6) English as a first language or able to read English

Exclusion criteria:

- (3) Not currently experiencing severe mental illness
- (4) Not currently seeking support from a mental health expert (i.e., psychologist or psychiatrist)

5. What are the possible risks?

It is recommended that you discuss your participation in this research with your gastroenterologist or health professional. If you become upset or distressed as a result of your participation in the research, the researcher is able to arrange a referral for counselling and/or other appropriate support. Any counselling or support will be provided by individuals who are not members of the research team.

6. Do I have to take part in this research project?

Participation in this research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you

are free to withdraw from the project at a later stage. If you do decide to leave this project, the researchers would like to keep the personal and health information about you that has been collected. This is to help them make sure that the results of the research can be measured properly. If you do not want them to do this, you must tell them before you withdraw from the study.

If you are completing this questionnaire from outside of Australia, please be alert to any local restrictions in your home country on participating in foreign research activity.

7. How will I be informed of the results of this research project?

The research group conducting the study plan to write a report, which will be made available to anyone who is interested. The report will be available via www.gastroparesisclinic.org. The results will also be written for publication in a scientific medical journal.

8. What will happen to information about me?

Any information obtained in connection with this project and that can identify you will remain confidential. It will only be disclosed with your permission, except as required by law. No information used in future presentations or written publications like articles or books will identify any participant. This is done through coding all participants using numbers and keeping all documents involved with individuals in a locked cabinet, accessible only to people involved in the project. All information will be kept at Swinburne University of Technology, in a locked filing cabinet (or secured computer) for a period of 7 years and subsequently shredded (or deleted).

9. Can I access research information kept about me?

In accordance with relevant Australian and /or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information, with which you disagree, be corrected. Please contact one of the researchers named at the end of this document if you would like to access your information.

10. Is this research project approved?

The ethical aspects of this research project have been approved by the Swinburne University Human Research Ethics Committee (SUHREC).

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007 – updated May 2013)* produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

11. Who can I contact?

If you want further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the Principal Researcher, Dr Simon Knowles, on +61 3 9214 8206 or sknowles@swin.edu.au.

12. Complaints

If you have any complaints about any aspect of the study or the way in which it is being conducted you may contact the Research Ethics Officer, Swinburne Research (H68), Swinburne University of Technology, PO BOX 218, HAWTHORN VIC 3122. Tel +61 3 9214 5218 or +61 3 9214 5218 or resethics@swin.edu.au

Consent

I have read this document and I understand the purposes, procedures and risks of this research project as described within it.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described.

I understand that I can print off or contact the principle researcher to attain a copy of the information and consent form.

If you have read and agree to participate, please click on the CONTINUE button.

Appendix 6: Questionnaire (Paper 3)

Section 1. Demographic details

1. What year were you born? _____
2. Gender? Male Female
3. Marital Status:
 Single Married DeFacto
 Widowed Divorced Separated
4. Number of dependants: _____
5. Who do you live with?
 Alone Partner Parent/s Friend/s
6. In what country were you born? _____
7. In what country do you live? _____
8. What is the postcode/zipcode where you live? _____
9. What is your highest level of education completed?
 Primary school Undergraduate degree
 Secondary school Postgraduate degree
 Certificate Other (please specify) _____
 Diploma
10. What type of accommodation do you live in?
 Private rental Own house Public housing
 Boarding house Supported accommodation Homeless
 Board with friends/family Other (please specify) _____
11. What is your combined yearly household (before tax) income?
 <\$17,000 \$17,001-\$40,000 \$40,001-\$70,000
 \$70,001-\$100,000 \$100,001+
12. Average weekly household income: _____
13. What is your employment situation?
 Full-time employed Part-time employed Casually employed
 Self-employed Unemployed Retired
 Pensioner Home duties Student

- Other (please specify) _____
14. What ethnic background do you identify with? _____
15. How tall are you in centimetres? _____ (note: 1 foot is 30.5 centimetres; 1 inch is 2.54 centimetres)
16. How much do you currently weigh in kilograms? _____ (note: 1 kilogram = 2.2 pounds)
17. What type of setting do you live in?
- Metropolitan Regional Rural Remote
18. How many days off from work, study or activities at home have you had in the **last month** due to sickness? _____
19. Do you feel that you have an adequate level of social support? Yes No
20. In regards to making changes to reduce your gastroparesis – are you:
- Not interested or no need at this point in time
- Neither here nor there
- Prepared to take action
- Already in the process of making changes
- Relapsed (previously well controlled) and looking for additional assistance
21. Please rate your overall level of self-confidence when it comes to managing your own mental health:
- Very poor
- Poor
- Neither poor or good
- Good
- Very good
22. On average, how many cigarettes do you smoke per day? _____
23. On average, how many standard alcoholic drinks do you consume per day? _____
24. Considering a 7-day period, how many times on average do you do the following kinds of exercise for more than 15 minutes during your free time?
- Strenuous exercise (heart beats rapidly): _____ times per week
- Moderate exercise (not exhausting): _____ times per week
- Mild exercise (minimal effort): _____ times per week

Section 2. Mental health

Do you CURRENTLY experience *Depression*? (i.e., Severe depressed mood for most of the day, every day for at least 14 days; other symptoms include: feeling worthless, guilty, diminished weight, diminished pleasure in activities, loss of energy, concentration problems)

- YES – **DIAGNOSED by a medical doctor, psychiatrist or psychologist**
- YES – **NOT DIAGNOSED by a medical doctor, psychiatrist or psychologist**
- NO

Have you experienced *Depression* in the past? If YES, please identify when and how long you experienced it.

Do you CURRENTLY experience *persistent depressive disorder/Dysthymia*? (i.e., low-to-moderate depressed mood for most of the day, every day for the last 2 years; other symptoms include: feeling hopeless, low self-esteem, loss of energy)

- YES – **DIAGNOSED by a medical doctor, psychiatrist or psychologist**
- YES – **NOT DIAGNOSED by a medical doctor, psychiatrist or psychologist**
- NO

Have you experienced *Dysthymia* in the past? If YES, please identify when and how long you experienced it.

Do you CURRENTLY experience *Bi-polar Disorder*? (i.e., Symptoms of depression in addition to periods of persistent elevated mood lasting for 1 week which also include inflated self-esteem, racing thoughts, distractibility, excessive involvement in pleasurable activities)

- YES – **DIAGNOSED by a medical doctor, psychiatrist or psychologist**
- YES – **NOT DIAGNOSED by a medical doctor, psychiatrist or psychologist**
- NO

Have you experienced *Bi-polar Disorder* in the past? If YES, please identify when and how long you experienced it.

Do you CURRENTLY experience *Panic Disorder*? (i.e., Recurrent periods of sudden anxiety [often referred to as panic attacks], that can include symptoms of sweating, increased hearts rate, breathing, trembling, chest pain, dizziness, fear of dying/losing control)

- YES – **DIAGNOSED by a medical doctor, psychiatrist or psychologist**
- YES – **NOT DIAGNOSED by a medical doctor, psychiatrist or psychologist**
- NO

Have you experienced *Panic Disorder* in the past? If YES, please identify when and how long you experienced it.

Do you CURRENTLY experience *Panic Disorder with Agoraphobia*? (i.e., Panic Disorder with the additional concern of being in places where escape might be difficult)

- YES – **DIAGNOSED by a medical doctor, psychiatrist or psychologist**
- YES – **NOT DIAGNOSED by a medical doctor, psychiatrist or psychologist**
- NO

Have you experienced *Panic Disorder with Agoraphobia* in the past? If YES, please identify when and how long you experienced it.

Do you CURRENTLY experience *Generalised Anxiety Disorder*? (i.e., Anxiety and worry about multiple aspects of life and occurring most days for at least 6 months, experiences difficulty controlling worry, fatigue, restlessness, difficulty concentrating, muscle tension and irritability)

- YES – **DIAGNOSED by a medical doctor, psychiatrist or psychologist**
- YES – **NOT DIAGNOSED by a medical doctor, psychiatrist or psychologist**
- NO

Have you experienced *Generalised Anxiety Disorder* in the past? If YES, please identify when and how long you experienced it.

Do you CURRENTLY experience *Post-traumatic Stress Disorder*? (i.e., Experienced or witnessed a significantly traumatic event which causes an individual to re-experience recollections of the event, avoiding situations which remind individual of the traumatic event, experiences difficulty sleeping and concentration and having periods of anger) fatigue, restlessness, difficulty concentrating, muscle tension and irritability)

- YES – **DIAGNOSED by a medical doctor, psychiatrist or psychologist**
- YES – **NOT DIAGNOSED by a medical doctor, psychiatrist or psychologist**
- NO

Have you experienced *Post-traumatic Stress Disorder* in the past? If YES, please identify when and how long you experienced it.

Do you CURRENTLY experience *Social Anxiety Disorder*? (i.e., Persistent fear of a social or performance situation leading to avoidance, fear is excessive)

- YES – **DIAGNOSED by a medical doctor, psychiatrist or psychologist**
- YES – **NOT DIAGNOSED by a medical doctor, psychiatrist or psychologist**
- NO

Have you experienced *Social Anxiety Disorder* in the past? If YES, please identify when and

how long you experienced it.

Do you CURRENTLY experience *Obsessive-Compulsive Disorder*? (i.e., Recurrent and persistent thoughts/images that are unwanted, causing anxiety that may result in repetitive behaviours (e.g., hand washing, checking, counting))

- YES – **DIAGNOSED by a medical doctor, psychiatrist or psychologist**
- YES – **NOT DIAGNOSED by a medical doctor, psychiatrist or psychologist**
- NO

Have you experienced ***Obsessive-Compulsive Disorder*** in the past? If YES, please identify when and how long you experienced it.

Do you CURRENTLY experience *Anorexia Nervosa*? (i.e., Intense fear of gaining weight despite being underweight, refusal to maintain normal body weight, distorted perception of body weight)

- YES – **DIAGNOSED by a medical doctor, psychiatrist or psychologist**
- YES – **NOT DIAGNOSED by a medical doctor, psychiatrist or psychologist**
- NO

Have you experienced ***Anorexia Nervosa*** in the past? If YES, please identify when and how long you experienced it.

Do you CURRENTLY experience *Bulimia Nervosa*? (i.e., Over-concerned with weight, a sense of lack of control over eating, recurrent episodes of binge eating coupled with purging behaviour such as vomiting and taking laxatives)

- YES – **DIAGNOSED by a medical doctor, psychiatrist or psychologist**
- YES – **NOT DIAGNOSED by a medical doctor, psychiatrist or psychologist**
- NO

Have you experienced ***Bulimia Nervosa*** in the past? If YES, please identify when and how long you experienced it.

Do you experience any other mental health condition, if YES, please identify below (include if it was diagnosed by a medical doctor, psychiatrist or psychologist AND what treatment you may be currently having):

Is there anything you would like to mention about any current OR past mental health concerns in relation to your Gastroparesis?

Did you experience any mental health problems BEFORE experiencing Gastroparesis?

- YES
- NO

Did you begin to experience mental health problems AFTER developing Gastroparesis?

- YES
- NO

Are you currently seeking help for a mental health issue?

- YES
- NO

If YES:

Which of the following practitioners are you currently seeing for this health issue? (select more than one if relevant):

- Psychiatrist
- Psychologist
- General practitioner
- Nurse
- Counsellor
- Social worker
- Other _____

When did you start seeing someone for this current mental health issue? _____ months ago

How often do you meet with your primary mental health expert?

- Weekly
- Fortnightly
- Once a month
- Other _____

Section 3. Other health conditions and medications

Apart from Gastroparesis, what (if any) other physical conditions have you been diagnosed with that currently impact upon your health?

What medications (and dosage) are you currently taking?

What (if any) over the counter health supplements (and dosage) are you currently taking (e.g., probiotics, vitamins)?

What (if any) naturopathic/homeopathic medications (and dosage) are you currently taking?

Section 4. Gastroparesis diagnosis and support

Have you been formally diagnosed with having Gastroparesis

- No
- Yes, by a medical doctor
- Yes, by a gastroenterologist
- Yes, by other _____

How many months have you experienced Gastroparesis symptoms for: _____ months

Apart from your medical doctor, who are you currently seeking help from to address your Gastroparesis symptoms? (select more than one if relevant)

- Gastroenterologist
- Nurse
- Counsellor
- Social worker
- Dietitian
- Naturopath
- Homeopath
- Osteopath
- Chiropractor
- Physiotherapist
- Other _____

What is your reason for attending these practitioners

- Dissatisfied with medical care/diagnosis
- Extra treatment
- Advice from friend/relative

Other _____

Do you feel that the non-medical health practitioner has been helpful in managing your symptoms?

If you have been diagnosed with Gastroparesis, what reason was given to you for the cause of your symptoms:

What do you believe is the cause of your Gastroparesis: (select more than one if relevant)

- Idiopathic – The term used when no known cause for the condition can be identified.
- Post infection – Symptoms coming on after gastroenteritis or another infection.
- Diabetic – Symptoms caused by complications associated with diabetes I
- Diabetic – Symptoms caused by complications associated with diabetes II
- Post-surgical – Symptoms following surgery to the stomach or esophagus (gullet)
- Neurological conditions – Symptoms caused by disorders that affect the neural control of the stomach (e.g., Parkinson’s disease, multiple sclerosis, amyloidosis, and paraneoplastic disease).
- Connective tissue disorders - Symptoms caused by complications associated with connective tissue disorders (e.g., systemic sclerosis, and scleroderma).
- Medication - Symptoms caused by complications associated with medications.
- Comorbidity - Symptoms caused by conditions that are also associated with a delay in gastric emptying (e.g., hypothyroidism, gastroesophageal reflux disease, anorexia nervosa and bulimia).
- Food intolerance – _____
- Unhealthy diet (e.g., skipping meals, low fluid and fibre intake, high fatty diet)
- Genetic factors
- Psychological factors

Is there a history of gastroparesis in your family?

- Yes
- No

Have you made any changes to your diet because of your gastroparesis?

- No
- Yes, minimal changes only
- Yes, significant changes

If YES:

Who has guided this change?

- I have made changes based on my symptoms
- Advice from friends/relatives
- The internet
- Dietitian
- Doctor
- Other (please specify): _____

Which of the following diets are you following? You may select as many as apply.

- Small, frequent meals
- Low fat/fibre

- Texture modified (e.g. puree/liquid diet)
- High fibre
- Low FODMAP
- Low food chemical
- Elimination
- Other (please specify): _____

Do you feel that these changes have improved your gastroparesis symptoms?

- No
- Yes, a little
- Yes, a lot

Have you lost weight as a result of your gastroparesis?

- Yes. Please specify how much over the 6 months _____ (note: 1 kilogram – 2.2 pounds)
- No

Section 5. Patient Assessment of Upper Gastrointestinal Symptom Severity (PAGI-SYM; Rentz et al., 2004)

The PAGI-SYM is a copyrighted instrument that cannot be reproduced in this thesis. For a copy of the PAGI-SYM, please consult:

Rentz, A. M., Kahrilas, P., Stanghellini, V., Tack, J., Talley, N. J., de la Loge, C., . . . Revicki, D. A. (2004). Development and psychometric evaluation of the patient assessment of upper gastrointestinal symptom severity index (PAGI-SYM) in patients with upper gastrointestinal disorders. *Quality of Life Research, 13*, 14. doi:10.1007/s11136-004-9567-x

Section 6. Patient Assessment of Upper Gastrointestinal Disorders: Quality of Life (PAGI-QOL; de la Loge et al., 2004)

The PAGI-QOL is a copyrighted instrument that cannot be reproduced in this thesis. For a copy of the PAGI-QOL, please consult:

de la Loge, C., Trudeau, E., Marquis, P., Kahrilas, P., Stanghellini, V., Talley, N. J., . . . Dubois, D. (2004). Cross-cultural development and validation of a patient self-administered questionnaire to assess quality of life in upper gastrointestinal disorders: The PAGI-QOL. *Quality of Life Research, 13*, 1751-1762. doi:10.1007/s11136-004-8751-3

Section 7. Brief illness perception questionnaire (BIPQ; Broadbent et al., 2006)

The BIPQ is a copyrighted instrument that cannot be reproduced in this thesis. For a copy of the BIPQ, please consult:

Broadbent, E., Petrie, K. J., Main, J., & Weinman, J. (2006). The brief illness perception questionnaire. *Journal of Psychosomatic Research*, *60*(6), 631-637. doi:10.1016/j.jpsychores.2005.10.020

Section 8. Brief COPE questionnaire (Carver, 1997)

We are interested in how people respond when they confront difficult or stressful events in their lives. There are lots of ways to try to deal with stress. This questionnaire asks you to indicate what you generally do and feel, when you experience stressful events. Obviously, different events bring out somewhat different responses, but think about what you usually do when you are under a lot of stress. Please try to respond to each item separately in your mind from each other item. Choose your answers thoughtfully, and make your answers as true FOR YOU as you can. Select the box that best corresponds to your answer

	I haven't been doing this at all	I've been doing this a little bit	I've been doing this a medium amount	I've been doing this a lot
I've been turning to work or other activities to take my mind off things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been concentrating my efforts on doing something about the situation I'm in.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been saying to myself "this isn't real".	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been using alcohol or other drugs to make myself feel better.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been getting emotional support from others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been giving up trying to deal with it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been taking action to try to make the situation better.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been refusing to believe that it has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been saying things to let my unpleasant feelings escape.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been getting help and advice from other people.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been using alcohol or other drugs to help me get through it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been trying to see it in a different light, to make it seem more positive.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been criticizing myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been trying to come up with a strategy about what to do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been getting comfort and understanding from someone.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been giving up the attempt to cope.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been looking for something good in what is happening.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been making jokes about it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been doing something to think about it less, such as going to movies, watching TV,	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

reading, daydreaming, sleeping, or shopping.				
I've been accepting the reality of the fact that it has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been expressing my negative feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been trying to find comfort in my religion or spiritual beliefs.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been trying to get advice or help from other people about what to do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been learning to live with it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been thinking hard about what steps to take.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been praying or meditating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been making fun of the situation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been blaming myself for things that happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section 9. Psychological distress (DASS-21; Lovibond & Lovibond, 1995)

DASS₂₁		<i>Name:</i>	<i>Date:</i>
<p>Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you <i>over the past week</i>. There are no right or wrong answers. Do not spend too much time on any statement.</p> <p><i>The rating scale is as follows:</i></p> <p>0 Did not apply to me at all 1 Applied to me to some degree, or some of the time 2 Applied to me to a considerable degree, or a good part of time 3 Applied to me very much, or most of the time</p>			
1	I found it hard to wind down	0	1 2 3
2	I was aware of dryness of my mouth	0	1 2 3
3	I couldn't seem to experience any positive feeling at all	0	1 2 3
4	I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1 2 3
5	I found it difficult to work up the initiative to do things	0	1 2 3
6	I tended to over-react to situations	0	1 2 3
7	I experienced trembling (eg, in the hands)	0	1 2 3
8	I felt that I was using a lot of nervous energy	0	1 2 3
9	I was worried about situations in which I might panic and make a fool of myself	0	1 2 3
10	I felt that I had nothing to look forward to	0	1 2 3
11	I found myself getting agitated	0	1 2 3
12	I found it difficult to relax	0	1 2 3
13	I felt down-hearted and blue	0	1 2 3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1 2 3
15	I felt I was close to panic	0	1 2 3
16	I was unable to become enthusiastic about anything	0	1 2 3
17	I felt I wasn't worth much as a person	0	1 2 3
18	I felt that I was rather touchy	0	1 2 3
19	I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat)	0	1 2 3
20	I felt scared without any good reason	0	1 2 3
21	I felt that life was meaningless	0	1 2 3

Thank you for completing this questionnaire.

Appendix 7: Publication information for Paper 3

Publisher: Digestive Diseases and Sciences

About Digestive Diseases and Sciences: Digestive Diseases and Sciences is a peer-reviewed journal publishing papers on gastroenterology, hepatology, and related fields, with a focus on pathophysiological, technological, and clinical developments and advancements in care.

Copyright statement: I warrant that I have obtained, where necessary, permission from the copyright owners to use any third party copyright material reproduced in the thesis (such as artwork, images, unpublished documents), or to use any of my own published work (such as journal articles) in which the copyright is held by another party (such as publisher, co-author).

Peer-review comments:

Feedback on version 1 of the manuscript (received 19 July 2017)

Reviewer #1:

This manuscript describes the interactions of gastroparesis symptoms with quality of life and psychological traits. I find this very interesting. Clinically, many patients with gastroparesis have psychological traits that physicians often wonder how these impact on the gastroparesis symptoms.

The following points are made to help improve the manuscript:

1. Abstract needs to be improved to deliver the major points
 - 1a. Suggest moving "Guided by the Common Sense Model" to the end of the sentence, so that the overall aim stands out more coherently.
 - 1b. Suggest removing the fit numerical values. Most readers will not understand these terms.
 - 1c. Describe the final model.
2. Introduction, first paragraph. Suggest acknowledging that the systemic review was written by the authors.
3. Introduction aims. The aims statement needs to be rewritten. The CSM and SEM are a means to the end. The rewritten aims statement in the abstract should be used as the primary aim.
4. How was it determined that the patients actually had gastroparesis? Were the tests and/or test results asked for?

5. Apparently, there are two survey platforms. It is not clear what these are. Why was there not just one large questionnaire.

6. The authors take the overall PAGI-SYM score as the gastroparesis symptom severity. The PAGI-SYM has symptoms of gastroparesis, dyspepsia, and reflux disease. A better approach would have been using the GCSI score which can be obtained in the PAGI-SYM. The GCSI score was developed to measure symptom severity of gastroparesis.

7. Methods, page ? (there are no page numbers). There is testing of each of the questionnaires that sees what questions best provide the overall response in the questionnaire. It is not clear if the overall score was used as validated for the questionnaires, or a shortened version used.

8. How was it determined that the number of patients was the appropriate number to study with this type of analysis.

9. Results. The results should start out with a paragraph and a table that describes the results of the questionnaires. What was the symptom severity of the patients, what was the QOL score, etc.

10. The results frequently describe "gastroparesis severity". This should be more appropriately termed "gastroparesis symptom severity".

11. What happens to the model values if there are extremes of different patient characteristics. This is somewhat like a sensitivity analysis.

12. Suggest in the model adding a pathway where the psychological symptoms could impact on the gastroparesis symptoms. Clinically, this is often suspected.

13. Figure 2. There are numbers by the factors (circles) and in the paths between the factors. These need to be described what these are.

Reviewer #2: Thank you for the opportunity to review the manuscript entitled, "Exploring symptom severity, illness perceptions, coping styles, and wellbeing in gastroparesis patients using the Common Sense Model." The authors' introduction provides an excellent and well-written rationale for the importance of this work in understanding course of illness in patients with gastroparesis. The questionnaires and use of SEM read as very natural extensions of the body of research discussed. However, the authors' data preparation/analysis is of concern. For each of the questionnaires they used in the study, they chose only items that were cohesive in their participant sample, despite the fact that these scales have been published and validated in their full forms. Further, the internal consistency in some of these adjusted scales is questionable (e.g., .68) with others just barely meeting the minimum for acceptability (see Tavakol & Dennick, 2013, International Journal of

Medical Education). Some of the authors' scale transformations are also questionably necessary; in the DASS-21, they selected 10 final items & then multiplied the item sum by 2 - why is this transformation necessary?

Other more minor points are as follows:

1. Were participants paid? Please include.

2. Inclusion/exclusion criteria:

a. Authors should comment on the 97 participants excluded due to incomplete data. What was the cut-off for missing data for exclusion? X number of items per

questionnaire, x number of uninterpretable questionnaires, etc.?

b. Authors should also include data on whether these 97 participants were significantly different from the retained sample on any of the key study variables.

c. When responses were deleted due to duplication, how did the authors choose which response to delete?

d. Please comment on the rationale behind excluding participants who were receiving any mental health services, and the impact this exclusion has on generalizability.

e. Please comment on the self-report of gastroparesis diagnosis as a potential limitation.

3. SEM models:

a. Authors should explicitly name the CSM and modification indices based model as Model 1 and Model 2, as they later reference the models by those labels

b. What was the value used for suggested modification indices?

4. Authors may want to suggest to readers that mental health assessment and/or treatment would likely be of great benefit to medical programs treating patients with gastroparesis.

Discussion is also very well written and ties the study findings nicely to the literature.

Feedback on version 2 of the manuscript (received 5 December 2017)

Reviewer #1:

1. The authors need to use the GCSI as the base of the symptoms, not the PAGI-SYM. In the current format, half of the symptoms are reflux related symptoms, not gastroparesis related symptoms.

2. The authors use validated questionnaires, but then refine them by dropping questions that did not apply to their patient sample. This is inappropriate. The whole validated scoring system should be used.

3. Need to comment on if the GI Symptoms lead to psychological issues and/or the psychological issues lead to GI Symptoms. Which one is driving the other?

Appendix 8: Pre-intervention questionnaire

Pre-assessment information

Please note:

This online self-help psychological treatment service is NOT appropriate for individuals who experience serious mental illness.

If you have been seeing things that other people did not see; or hearing voices or someone talking when no one else was around; or felt that something very odd was going on, that people were testing you or trying to hurt you so you felt that you had to be on your guard most or all of the time; or if you currently feel so unwell that you have thought about hurting yourself: you should talk to your local health professional, and if urgent, see a medical doctor.

For other information on crisis mental health services, please go to:

<https://www.mentalhealthonline.org.au/pages/useful-resources/crisis-services>

To start the gastroparesisclinic.org assessment:

I identify that I DO NOT have a serious mental illness AND have sought advice from relevant medical professionals BEFORE starting this program:

YES – Start the questionnaire

NO – Go back to home page

Gastroparesisclinic.org online assessment:

A validation trial of the Gastroparesisclinic.org an online assessment and psychological treatment program.

Introduction:

The following questions are designed to find out the impact of Gastroparesis on your psychological well-being. You will be asked questions about symptoms you have been having as a result of your Gastroparesis and how you have been feeling overall.

Each component of the questionnaire is slightly different. You will be asked to select an answer for each question. Please ensure that you've answered every question.

If you are having trouble understanding a question, STOP for a moment and think about what the question means to you. Please note there are no right or wrong answers, and you should simply give the answer that is most appropriate for you.

The questionnaires will take approximately 45 minutes to complete.

After completing this online assessment you will be given the option to start the 6 week online intervention. After the completion of the online assessment, you will be invited to complete a post-assessment, and then further post-assessments at 12 and 24 months.

Thank you for your time.

Section 1. Demographic details

1. Where did you hear about gastroparesisclinic.org? (select more than one if relevant)
 - Online search
 - Friend/family member
 - General practitioner
 - Gastroenterologist
 - Other (please specify) _____
2. If you are participating as part of a research trial please identify your research code or treating gastroenterologist: _____
3. What year were you born? _____
4. Gender? Male Female
5. Marital Status:
 - Single
 - Married
 - DeFacto
 - Widowed
 - Divorced
 - Separated
6. Number of dependants: _____
7. Who do you live with?
 - Alone
 - Partner
 - Parent/s
 - Friend/s
8. In what country were you born? _____
9. In what country do you live? _____
10. What is the postcode/zipcode where you live? _____
11. What is your highest level of education completed?
 - Primary school
 - Undergraduate degree
 - Secondary school
 - Postgraduate degree
 - Certificate
 - Other (please specify) _____
 - Diploma
12. What type of accommodation do you live in?
 - Private rental
 - Own house
 - Public housing
 - Boarding house
 - Supported accommodation
 - Homeless
 - Board with friends/family
 - Other (please specify) _____
13. What is your combined yearly household (before tax) income?
 - <\$17,000
 - \$17,001-\$40,000
 - \$40,001-\$70,000
 - \$70,001-\$100,000
 - \$100,001+
14. Average weekly household income: _____

15. What is your employment situation?

- Full-time employed Part-time employed Casually employed
 Self-employed Unemployed Retired
 Pensioner Home duties Student
 Other (please specify) _____

16. What ethnic background do you identify with? _____

17. How tall are you in centimetres? _____ (note: 1 foot is 30.5 centimetres; 1 inch is 2.54 centimetres)

18. How much do you currently weigh in kilograms? _____ (note: 1 kilogram = 2.2 pounds)

19. What type of setting do you live in?

- Metropolitan Regional Rural Remote

20. How many days off from work, study or activities at home have you had in the **last month** due to sickness? _____

21. Do you feel that you have an adequate level of social support? Yes
No

22. In regards to making changes to reduce your gastroparesis – are you:

- Not interested or no need at this point in time
 Neither here nor there
 Prepared and ready to take action
 Already in the process of making changes
 Relapsed (previously well controlled) and looking for additional assistance

23. Please rate your overall level of self-confidence when it comes to managing your own mental health:

- Very poor
 Poor
 Neither poor or good
 Good
 Very good

24. On average, how many cigarettes do you smoke per day? _____

25. On average, how many standard alcoholic drinks do you consume per day? _____

26. Considering a 7-day period, how many times on average do you do the following kinds of exercise for more than 15 minutes during your free time?

Strenuous exercise (heart beats rapidly): _____ times per week

Moderate exercise (not exhausting): _____ times per week

Mild exercise (minimal effort): _____ times per week

The purpose of using the gastroparesisclinicl.org intervention program is:

To help reduce my psychological distress and gastroparesis symptoms

To help others – my clients/patients

Other: _____

Section 2. Mental health

Please refer to Section 2. Mental Health in Appendix 6, page 234.

Section 3. Other health conditions and medications

Please refer to Section 3. Other health conditions and medications in Appendix 6, page 238.

Section 4. Gastroparesis diagnosis and support

Please refer to Section 4. Gastroparesis diagnosis and support in Appendix 6, page 238.

Section 5. Patient Assessment of Upper Gastrointestinal Symptom Severity (PAGI-SYM; Rentz et al., 2004)

The PAGI-SYM is a copyrighted instrument that cannot be reproduced in this thesis. For a copy of the PAGI-SYM, please consult:

Rentz, A. M., Kahrilas, P., Stanghellini, V., Tack, J., Talley, N. J., de la Loge, C., . . . Revicki, D. A. (2004). Development and psychometric evaluation of the patient assessment of upper gastrointestinal symptom severity index (PAGI-SYM) in

patients with upper gastrointestinal disorders. *Quality of Life Research*, 13, 14.
doi:10.1007/s11136-004-9567-x

Section 6. Patient Assessment of Upper Gastrointestinal Disorders: Quality of Life (PAGI-QOL; de la Loge et al., 2004)

The PAGI-QoL is a copyrighted instrument that cannot be reproduced in this thesis. For a copy of the PAGI-QoL, please consult:

de la Loge, C., Trudeau, E., Marquis, P., Kahrilas, P., Stanghellini, V., Talley, N. J., . . . Dubois, D. (2004). Cross-cultural development and validation of a patient self-administered questionnaire to assess quality of life in upper gastrointestinal disorders: The PAGI-QOL. *Quality of Life Research*, 13, 1751-1762.
doi:10.1007/s11136-004-8751-3

Section 7. Brief illness perception questionnaire (BIPQ; Broadbent et al., 2006)

The BIPQ is a copyrighted instrument that cannot be reproduced in this thesis. For a copy of the BIPQ, please consult:

Broadbent, E., Petrie, K. J., Main, J., & Weinman, J. (2006). The brief illness perception questionnaire. *Journal of Psychosomatic Research*, 60(6), 631-637.
doi:10.1016/j.jpsychores.2005.10.020

Section 8. Brief COPE questionnaire (Carver, 1997)

Please refer to Section 8. Brief COPE questionnaire (**Carver, 1997**) in Appendix 6, page 242.

Section 9. Psychological distress (DASS-21; Lovibond & Lovibond, 1995)

Please refer to Section. 9 Psychological distress in Appendix 6, page 244.

Thank you for completing this assessment, you will now be directed to the online intervention program.

Appendix 9: Post-intervention questionnaire

A validation trial of the GASTROPARESISClinic.org.au an online assessment and psychological support program.

Introduction:

As you have completed just the online gastroparesisclinic.org intervention program we would like you to spend 45 minutes undertaking a psychological assessment of your symptoms and providing us feedback about the intervention.

The following questions are designed to find out the impact of gastroparesis on your psychological well-being. You will be asked questions about symptoms you have been having as a result of your gastroparesis and how you have been feeling overall.

Each component of the questionnaire is slightly different. You will be asked to select an answer for each question. Please ensure that you've answered every question.

If you are having trouble understanding a question, STOP for a moment and think about what the question means to you. Please note there are no right or wrong answers, and you should simply give the answer that seems most appropriate.

The questionnaires will take approximately 30 minutes to complete.

Thank you for your time.

Section 1. Module review

Over the last 6 weeks which modules did you complete:

- ALL 6 modules; (or select below which module/s you completed)
- Module 1: Gastroparesis, personality, unhelpful thinking and moving towards a positive future
- Module 2: Reducing gastroparesis related physical and psychological distress through breathing
- Module 3: Managing physical and psychological gastroparesis related distress through distraction, cognitive diffusion, mindfulness and guided imagery
- Module 4: Challenging unhelpful thoughts associated with gastroparesis physical and psychological distress

Module 5: Pain management associated with Gastroparesis

Module 6: Challenging gastroparesis through exposure work, and keeping your progress going

How would you rate module 1:

1 2 3 4 5 6 7 8 9 10
Not helpful Somewhat Very
at all helpful helpful

How would you rate module 2:

1 2 3 4 5 6 7 8 9 10
Not helpful Somewhat Very
at all helpful helpful

How would you rate module 3:

1 2 3 4 5 6 7 8 9 10
Not helpful Somewhat Very
at all helpful helpful

How would you rate module 4:

1 2 3 4 5 6 7 8 9 10
Not helpful Somewhat Very
at all helpful helpful

How would you rate module 5:

1 2 3 4 5 6 7 8 9 10
Not helpful Somewhat Very
at all helpful helpful

How would you rate module 6:

1 2 3 4 5 6 7 8 9 10
Not helpful Somewhat Very
at all helpful helpful

Since participating in the online intervention at GASTROPARESISCLINIC.ORG.AU 6 weeks ago, have you engaged in any further psychological or medical interventions relating to your gastroparesis? Please let us know what they were, and if they were helpful.

Section 2. Mental health

Please refer to Section 2. Mental Health in Appendix 6, page 234.

Section 3. Patient Assessment of Upper Gastrointestinal Symptom Severity (PAGI-SYM; Rentz et al., 2004)

The PAGI-SYM is a copyrighted instrument that cannot be reproduced in this thesis. For a copy of the PAGI-SYM, please consult:

Rentz, A. M., Kahrilas, P., Stanghellini, V., Tack, J., Talley, N. J., de la Loge, C., . . . Revicki, D. A. (2004). Development and psychometric evaluation of the patient assessment of upper gastrointestinal symptom severity index (PAGI-SYM) in patients with upper gastrointestinal disorders. *Quality of Life Research, 13*, 14. doi:10.1007/s11136-004-9567-x

Section 4. Patient Assessment of Upper Gastrointestinal Disorders: Quality of Life (PAGI-QOL; de la Loge et al., 2004)

The PAGI-QoL is a copyrighted instrument that cannot be reproduced in this thesis. For a copy of the PAGI-QoL, please consult:

de la Loge, C., Trudeau, E., Marquis, P., Kahrilas, P., Stanghellini, V., Talley, N. J., . . . Dubois, D. (2004). Cross-cultural development and validation of a patient self-administered questionnaire to assess quality of life in upper gastrointestinal disorders: The PAGI-QOL. *Quality of Life Research, 13*, 1751-1762. doi:10.1007/s11136-004-8751-3

Section 5. Brief illness perception questionnaire (BIPQ; Broadbent et al., 2006)

The BIPQ is a copyrighted instrument that cannot be reproduced in this thesis. For a copy of the BIPQ, please consult:

Broadbent, E., Petrie, K. J., Main, J., & Weinman, J. (2006). The brief illness perception questionnaire. *Journal of Psychosomatic Research, 60*(6), 631-637. doi:10.1016/j.jpsychores.2005.10.020

Section 6. Brief COPE questionnaire (Carver, 1997)

Please refer to Section 8. Brief COPE questionnaire (Carver, 1997) in Appendix 6, page 242.

Section 7. Psychological distress (DASS-21; Lovibond & Lovibond, 1995)

Please refer to Section. 9 Psychological distress in Appendix 6, page 244.

Section 11. Feedback about the intervention

Please indicate below your views on the therapy you received for gastroparesis on gastroparesisclinic.org. (Note: questions adapted from the CEQ by Devilly & Borkovec, 2000)

1. How *logical* does this type of treatment seem to you for helping people reduce your gastroparesis?

1	2	3	4	5	6	7	8	9	10
Not at all logical				Somewhat logical				Very logical	

2. How *confident* are you that this therapy helped reduced your gastroparesis?

1	2	3	4	5	6	7	8	9	10
Not at all confident				Somewhat confident				Very confident	

3. How *confident* would you be in recommending this intervention program to a friend who was suffering from the symptoms of gastroparesis?

1	2	3	4	5	6	7	8	9	10
Not at all confident				Somewhat confident				Very confident	

4. If you were suffering from extremely high levels of gastroparesis symptoms, would you be *willing to undergo* such treatment?

1	2	3	4	5	6	7	8	9	10
Not at all willing				Somewhat willing				Very willing	

5. How *successful* do you feel this therapy would be in decreasing other problems involving depression and anxiety?

1	2	3	4	5	6	7	8	9	10
Not at all successful				Somewhat successful				Very successful	

6. How *successful* do you feel this therapy would be in decreasing other gastro-intestinal related symptoms?

1	2	3	4	5	6	7	8	9	10
Not at all				Somewhat				Very	

successful

successful

successful

Please complete the items listed below by circling the number next to each question that best indicates how you feel about the treatment received at gastroparesisclinic.org. (Note: questions adapted from the TEI-SF by Kelley et al., 1989)

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	I find this treatment to be an acceptable way of dealing with my gastroparesis symptoms.	1	2	3	4	5
2	I liked the procedures used in this treatment.	1	2	3	4	5
3	I believe this treatment is likely to be effective.	1	2	3	4	5
4	I believe this treatment is likely to result in permanent improvement.	1	2	3	4	5
5	Overall, I have a positive reaction to this treatment.	1	2	3	4	5
6	I find this treatment to be an acceptable way of dealing with my gastroparesis symptoms.	1	2	3	4	5

1. How could we improve this online intervention?

2. Any other feedback/comments?

THANK YOU for completing the post-intervention assessment.

I hope that you have found the last six modules helpful and that you will continue to be successful at challenging your gastroparesis symptoms and psychological distress.

Dr Simon Knowles and the gastroparesisclinic.org research team.

Appendix 10: Participant Consent and Information Form (pilot study)

PARTICIPANT INFORMATION SHEET ONLINE RESEARCH PARTICIPATION

Swinburne University of Technology,
Royal Melbourne Hospital & St Vincent's Hospital (Melbourne)



FULL PROJECT TITLE:

Evaluation of the efficacy of www.gastroparesisclinic.org a 6-week online psychological support program for gastroparesis.

NAME/S OF INVESTIGATORS

Dr Simon Knowles (Swinburne University), Professor David Castle (St. Vincent's Hospital Melbourne), A/Prof Geoff Hebbard (Royal Melbourne Hospital) and Ms Sally Woodhouse (Swinburne University).

1. Introduction

You are invited to take part in this research project. This is because you are currently seeking treatment for gastroparesis and associated psychological distress. Due to the psychological distress often associated with gastroparesis, our research group has developed an online psychological treatment program for gastroparesis.

Funded by Associate Professor Geoff Hebbard, this online support program (www.gastroparesisclinic.org) is now available and we ask if you would volunteer to participate in undertaking the program and provide feedback from a consumer's perspective.

This Participant Information and Consent Form tells you about the research project. It explains the procedures involved. Knowing what is involved will help you decide if you want to take part in the research. This consent form is five pages long.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or healthcare worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether you take part or not.

If you decide you want to take part in the research project, you will be asked to complete several online questionnaires, an online 6-module treatment program and participate in a telephone interview (further details are provided under 'What does participation in this research project involve').

The return of the consent form will be signalling that you are telling us that you:

- understand what you have read;
- consent to take part in the research project; and,
- consent to participate in the research processes that are described.

2. What is the purpose of this research project?

The purpose of this study is to validate and attain consumer feedback regarding an online psychological support program for individuals with gastroparesis. We are aware that having gastroparesis can have a significant impact on your health, both physiologically and well as psychologically. It is well recognised that individuals undergoing treatment for a medical condition also report anxiety, stress, and even depression. Consequently, our research team has developed an online assessment and psychological treatment service for gastroparesis. We aim to recruit a total of 60 participants.

Your participation in this study will help us to gather important information about the ways in which the online service is used, what changes can be made to improve its relevance and effectiveness for treating common psychological problems identified by individuals with gastroparesis. Under the supervision of the primary investigator, data from this study will also be used by Ms Sally Woodhouse as part of her PhD research.

3. What does participation in this research project involve?

If you wish to join the study, please contact your Gastroenterologist or contact the chief investigator, Dr Simon Knowles (ph +61 3 9214 8206, sknowles@swin.edu.au) who can assess your suitability for this research program (i.e., have gastroparesis and low to mild levels of psychological distress).

Upon creating a login at www.gastroparesisclinic.org and identifying your acceptance of participating in this research you will then be asked to complete:

- (1) an online psychological and well-being assessment (approximately 45 minutes). Assessment involves answering questions relating to your demographic details (age, marital status), physiological symptoms (e.g., pain, nausea) and psychological symptoms (e.g., feeling tense, worried, sad).
- (2) an online 6 module psychological support program (approximately 1.5 hours per module per week) focused around your psychological distress and gastroparesis symptoms. Each module is designed to provide a step-by-step therapeutic program which aims to help you develop strategies to reduce your symptoms. Modules will include a combination of education about the psychological distress as well as targeted behavioural and psychological strategies (e.g., identifying and challenging thoughts that contribute to your distress, relaxation and breathing retraining), to help you overcome your psychological distress.
- (3) after the 6th module (at the end of week 6) you will be asked to complete the online post-intervention assessment (approximately 30 minutes). You may also be contacted and asked if you would participate in a brief interview via telephone (approximately 30 minutes) regarding your thoughts about the online treatment program and how it could be improved. You will also be contacted 1 and 2 years after completing the intervention to complete the online post-assessment program again.

Further details about the telephone interview:

At the completion of the intervention program (week 6), you will be invited (via email) to take part in a 30 minute telephone interview (conducted by Ms Sally Woodhouse, PhD candidate). The aim of the telephone interview will be to attain qualitative information about your perceptions of the intervention and how it can be improved. The telephone interview is completely voluntary. All information will be transcribed and identifiable

information removed. You will be offered a transcript of the interview to review and provide comments on, which should take no longer than an hour of your time.

This research involves the collaboration between the Royal Melbourne Hospital, St Vincent's Hospital, and Swinburne University.

4. Participant Inclusion/exclusion criteria

Inclusion criteria:

- (7) Aged 18 year or older
- (8) Having been diagnosed with Gastroparesis and currently under the care of a gastroenterologist
- (9) English as a first language or able to read English

Exclusion criteria:

- (5) Not currently experiencing severe mental illness
- (6) Not currently seeking support from a mental health expert (i.e., psychologist or psychiatrist)

5. What are the possible risks?

It is recommended that you discuss your participation in this research with your gastroenterologist or health professional. If you become upset or distressed as a result of your participation in the research, the researcher is able to arrange a referral for counselling and/or other appropriate support. Any counselling or support will be provided by individuals who are not members of the research team.

6. Do I have to take part in this research project?

Participation in this research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at a later stage. If you do decide to leave this project, the researchers would like to keep the personal and health information about you that has been collected. This is to help them make sure that the results of the research can be measured properly. If you do not want them to do this, you must tell them before you withdraw from the study.

If you are completing this questionnaire from outside of Australia, please be alert to any local restrictions in your home country on participating in foreign research activity.

7. How will I be informed of the results of this research project?

The research group conducting the study plan to write a report, which will be made available to anyone who is interested. The report will be available via www.Gastroparesisclinic.org. The results will also be written for publication in a scientific medical journal. Under the supervision of the primary investigator, data from this study will also be used by Ms Sally Woodhouse as part of her PhD research.

8. What will happen to information about me?

Any information obtained in connection with this project and that can identify you will remain confidential. It will only be disclosed with your permission, except as required

by law. No information used in future presentations or written publications like articles or books will identify any participant. This is done through coding all participants using numbers and keeping all documents involved with individuals in a locked cabinet, accessible only to people involved in the project. All information will be kept at Swinburne University of Technology, in a locked filing cabinet (or secured computer) for a period of 7 years after last access/use and subsequently shredded (or deleted).

9. Can I access research information kept about me?

In accordance with relevant Australian and /or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information, with which you disagree, be corrected. Please contact one of the researchers named at the end of this document if you would like to access your information.

10. Is this research project approved?

The ethical aspects of this research project have been approved by the Swinburne University Human Research Ethics Committee (SUHREC).

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007 – updated May 2013)* produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

11. Who can I contact?

If you want further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the Principal Researcher, Dr Simon Knowles, on +61 3 9214 8206 or sknowles@swin.edu.au.

12. Complaints

If you have any complaints about any aspect of the study or the way in which it is being conducted you may contact the Research Ethics Officer, Swinburne Research (H68), Swinburne University of Technology, PO BOX 218, HAWTHORN VIC 3122. Tel +61 3 9214 5218 or +61 3 9214 5218 or resethics@swin.edu.au

Consent

I have read this document and I understand the purposes, procedures and risks of this research project as described within it.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described.

I understand that I can print off or contact the principle researcher to attain a copy of the information and consent form.

If you have read and agree to participant, please click on the AGREE button.