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INVESTIGATING THE ROLE OF PSYCHOLOGICAL
FLEXIBILITY AND THE USE OF AN ACCEPTANCE AND
COMMITMENT THERAPY BASED INTERVENTION IN
IRRITABLE BOWEL SYNDROME

(VOLUME I)

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(Licenciature in Clinical Psychology)

A Thesis submitted for the degree of Doctor of Philosophy

The University of Edinburgh

2011

In memoriam Manuel Bravo Ferreira (1948-2003)

DECLARATION

I hereby declare that I am the sole author of this thesis and that the work described within, except where specifically acknowledged, is my own and that it has not been submitted in any previous application for a degree in this or another University. The information obtained from sources other than this study is acknowledged in the text or included in the references.

Nuno Bravo Ferreira

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Investigating the role of Psychological Flexibility and the use of an Acceptance and Commitment Therapy based intervention in Irritable Bowel Syndrome

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ABSTRACT

Irritable Bowel Syndrome (IBS) is a common chronic illness thought to be originated and maintained by a combination of physiological, psychological and social factors. IBS is known to be associated with a high psychosocial impact on patients' lives. Acceptance and Commitment Therapy (ACT) is an emerging model of conceptualization and treatment that states that most suffering in chronic illness can be explained by a lack of psychological flexibility or acceptance to experience aversive bodily sensations, thoughts or emotions. ACT treatments target the increase of psychological flexibility as a key change for improvement in outcomes. Recent studies suggest that ACT could not only be an effective alternative treatment for IBS, as it might provide a valuable model of understanding of the relations between the different factors related to this condition and its outcomes. The first aim of the present research was to investigate the role of psychological flexibility in IBS, in particular, how acceptance relates to psychological, emotional and physical factors in this condition. The second aim was to investigate the effectiveness of an ACT based intervention in increasing psychological flexibility in IBS and thereby improving IBS Outcomes.

These aims were addressed by conducting two related studies. In Study 1, a sample of 121 IBS patients attending a specialized gastroenterology clinic completed a series of self-report measures of psychological flexibility (acceptance), psychological factors known to be associated with IBS and IBS outcomes. Results indicated that

higher levels of acceptance were generally associated with and predicted better levels of IBS biopsychosocial factors. Results also showed that acceptance mediated most of the relationships between IBS predictors and Outcomes. Also, psychometric analyses of a novel measure of IBS Acceptance (i.e. IBS Acceptance and Action Questionnaire) created for this study demonstrated that it had good reliability and validity. In Study 2, fifty six IBS patients enrolled in an intervention involving a one day ACT workshop and an ACT based self-help workbook. Thirty six participants provided follow-up data up to 6 months after the workshop. Results indicated that there were significant increases in acceptance and significant improvement in IBS outcomes between pre-treatment and follow-up. Further to that, analyses indicated that changes in IBS Outcomes occurred through changes in acceptance as hypothesized by the ACT model.

These studies suggest that psychological flexibility processes are important in the understanding of IBS and that improvement in this condition may result from a more psychologically flexible stance to it. Although preliminary, these studies provide a basis for the further development and application of the ACT model of conceptualization and treatment in IBS.

CHAPTER 1

INTRODUCTION

CHAPTER 1- INTRODUCTION

1.1 INTRODUCTION

Irritable Bowel Syndrome (IBS) is the most common functional gastrointestinal disorder with an estimated prevalence in adults of 3-25% worldwide (Grundmann & Yoon, 2010; Spiller et al., 2007). A positive diagnosis can be established using symptom based criteria that include abdominal pain or discomfort combined with disordered bowel function such as diarrhoea and/or constipation (Rome III criteria; Longstreth et al., 2006). IBS is associated with high economic and personal costs (Simren et al. 2004). Regarding the latter, although not life threatening, IBS is a chronic condition that may significantly impair a person's quality of life with many individuals reporting IBS as the cause for the avoidance of many day to day activities, e.g. eating specific foods, work, travel, sex, socializing, exercising or leisure activities (Corney & Stanton, 1990; Lea & Whorwell, 2001). Also, at least half of the patients are commonly diagnosed with psychiatric disorders such as depression, generalized anxiety or panic disorder (Spiller et al., 2007).

So far, the biopsychosocial model has been the most consensual in providing an understanding of this condition (Drossman et al., 1999). Recently, several studies have highlighted the role of psychosocial factors in the aetiology and maintenance of IBS symptoms and in the impact this condition has on quality of life (Levy et al., 2006). To support this model, several randomized controlled trials have also shown that psychological interventions (e.g. Cognitive Behavioural Therapy and Hypnosis) can be particularly effective in improving IBS outcomes such as symptoms, psychological distress or quality of life (Spiller et al., 2007). However inconsistent findings regarding mechanisms of action or of the long term effectiveness of these psychological approaches have highlighted the need for further and more careful study.

In a recent paper Naliboff, Frese, & Rapgay (2008) proposed that Acceptance and Commitment Therapy (ACT) should be tried as an alternative form of treatment for

IBS. However ACT is more than an approach that can be applied at the level of technique, it is also a model of psychopathology supported on strong philosophical (Functional Contextualism) and theoretical (Relational Frame Theory) roots (Hayes et al., 2006).

This model of psychopathology essentially proposes that at the core of most problems is psychological inflexibility. One of the key processes of psychological inflexibility is an unwillingness or lack of acceptance to experience aversive bodily sensations, thoughts or emotions also referred to as experiential avoidance. Experiential avoidance is thought to be associated with suffering, as attempts from patients to control/eliminate/change internal experiences that are not under their behavioural control can lead the patient away from more valued behaviours. Also it is proposed that experiential avoidance will actually increase the experience of aversive content as its functional importance will be heightened (Hayes et al., 2006). Several studies support the association of psychological inflexibility with poorer psychological, physical and quality of life outcomes (Hayes et al., 2006; Ruiz, 2010). In particular, studies in the area of health and chronic pain suggest that psychological inflexibility is a key process at work and a significant predictor of poorer psychological, emotional, functional and quality of life outcomes (e.g. McCracken, Vowles, & Zhao-O'Brien, 2010; Vowles et al., 2008; Wicksell et al., 2008).

As a model of treatment, ACT has as a main goal the increase of psychological flexibility as opposed to an agenda of elimination of aversive experiences. It is hypothesized that the positive skills (e.g. acceptance, cognitive defusion) trained in ACT help the individual to be able to contact their difficult private experiences more fully while behaving in a way that is in service of their values, therefore improving outcomes such as quality of life independently of improvements in factors such as symptom severity (Hayes et al., 2006). Several studies support the effectiveness of ACT at improving outcomes for a number of chronic illness conditions such as diabetes (Gregg et al., 2007), epilepsy (Lundgren, Dahl, & Hayes, 2008), tinnitus (Hesser et al., 2009) and chronic pain (e.g. Veehof et al., 2011; Vowles & McCracken, 2010; Wicksell, Olsson, & Hayes, 2010). The mediational components

of some of these studies also support the hypothesis that improvements in outcomes were achieved via increases in psychological flexibility. Of interest is the fact that all these conditions have features similar to IBS like chronic nature, association with adverse physical, psychological and emotional experiences and a tendency to avoid certain behaviours.

The findings of both ACT and IBS literature and the suggestion provided by Naliboff and colleagues (2008) regarding the possible utility of ACT in IBS, provided the basis for the studies to be presented in this thesis. The first general aim was to investigate the role of psychological (In)Flexibility in IBS, in particular the role of acceptance/experiential avoidance in the relations between physical, psychological and emotional factors in IBS. The second general aim was to investigate the effectiveness of an ACT based intervention in increasing psychological flexibility in IBS and thereby improving IBS Outcomes.

For this purpose this thesis has been divided into 8 chapters. This first chapter has the main objective of giving the reader some brief background and context to the work to be presented before engaging with this thesis.

The second and third chapters aim to comprehensively review the fields of IBS and ACT with particular attention being paid to the areas that bear most relevance to this thesis.

The fourth chapter presents a rationale for the work undertaken, drawing on the reviews of both fields. It also launches the specific aims and hypotheses that oriented this thesis.

Chapter five sets out the methodological approach taken to address the aims set out in the previous chapter with a detailed account of the designs, protocols, assessment instruments, materials and statistical analysis used in the two studies presented in this thesis.

In chapters six and seven the results of the two studies are presented. Chapter six refers to the cross-sectional study aimed at investigating the role of psychological (In)Flexibility in IBS while chapter 7 deals with the longitudinal study investigating the effectiveness of an ACT intervention for IBS.

Finally, chapter eight addresses the discussion of the results as well as the limitations of the studies and possible implications for both theory and practice.

It is hoped that this thesis and the results presented in it, constitute a significant contribution regarding the usefulness of ACT as an approach to both the understanding and the treatment of IBS.

CHAPTER TWO
IRRITABLE BOWEL SYNDROME

CHAPTER TWO – IRRITABLE BOWEL SYNDROME

2.1. INTRODUCTION

Irritable Bowel Syndrome (IBS) is a common, complex, chronic, relapsing gastrointestinal problem (Spiller et al., 2007). Although research on this disorder has increased significantly in the last decade, many questions still remain (Thompson, 2006).

A thorough discussion of the full body of research surrounding IBS would be an unfeasible task. So, this chapter aims to present a summary of what are considered some of the most relevant issues in IBS research with particular emphasis being taken with the most pertinent areas for the present research. This review will start by addressing questions of definition (and how this has historically evolved), epidemiology, diagnosis and classification of IBS. A biopsychosocial account of IBS will be reviewed with particular attention paid to psychosocial factors and their influence on the patients' quality of life. Finally, an account of current approaches to the care of IBS patients will be reviewed with particular emphasis being taken on the psychological management of this condition.

2.2. DEFINITION OF IBS

Described as the most frequent cause of work absenteeism after the common cold, IBS is one of the most common non-infectious diagnoses seen by gastroenterologists and accounting for about 1 in 20 of all general practice consultations (Thompson, 2002; Thompson et al., 2000). IBS has been defined by Longstreth et al., (2006) as:

“... a functional bowel disorder in which abdominal pain or discomfort is associated with defecation or a change in bowel habit and with features of disordered defecation.”

Like in other functional bowel disorders, neither structural abnormalities nor biochemical causes like inflammation or infection seem to account for the origin of

the symptoms, with an alteration of the bowel's physiological function being the best explanation for the abnormal bowel behaviour (Bradesi et al., 2003; Drossman, 2006). A functional diagnosis often poses a challenge to a classically trained physician due to the lack of a clear pathophysiology. This often results in the diagnosis being made through exclusion of organic disease rather than by the symptom characteristics being presented (Dapoigny, 2009). This exclusion approach is commonly associated with negative and potentially harmful connotations for both physicians (who don't feel at ease to make a diagnosis without a clear pathological cause), and patients (who might feel this type of diagnosis to be inaccurate or demeaning) (Drossman, 2006).

Nowadays, a model taking into account the numerous physiological symptoms (e.g. altered motility, gut hypersensitivity) but also psychosocial factors and interactions between brain and gut seems to be shifting the understanding of IBS from a disease-based model to a biopsychosocial one (Drossman, 2006).

An increase in research and media attention about IBS has also seen the World Health Organization (WHO) recognizing this condition by including it in the 10th revision of the International Classification of Diseases (ICD-10) manual (WHO, 2007).

2.3. HISTORY OF IBS

References to gut or intestine dysfunction date back as far as ancient Greece or early European Literature (Thompson, 2006). However it was not until the beginning of the 19th century that the first English language descriptions of what would later be known as Irritable Bowel Syndrome (IBS) appeared. Powell (1818), while describing painful afflictions of the intestinal canal, drew attention to three key symptoms of IBS: abdominal pain, “derangement of digestion” and “flatulence”. Twelve years later Howship (1830) described the “spasmodic stricture of the colon” reflecting the (now discredited) beliefs at that time that gut spasms contribute to functional gut disorders. These beliefs endured for many years with the term “spastic colon” or

“spastic colitis” being used to describe IBS symptoms and aetiologies (Thompson, 1989). The mid 19th century also saw Cumming (1849) exclaim “the bowels are at one time constipated and at another lax in the same person...how the disease has two such different symptoms I do not purpose to explain”. This perplexity about the presentation of IBS is something that continues even 150 years later (Thompson, 2006). The late 19th and early 20th centuries saw several attempts to describe functional bowel disorders in descriptors such as the above mentioned “spastic colitis”, “hyperacidity” or “autointoxication of the colon” (Hale-White, 1895; Thompson, 1989). Beliefs that functional bowel disorders were related to retained colon contents that needed to be purged or that they were “psychogenic” or “neurogenic” contributed to a pejorative view of these conditions all through the 1920’s and 30’s (Hutchison, 1927; Thompson, 2006).

The concept of an “irritable bowel” appeared for the first time in the Rocky Mountain Medical Journal in 1950 to describe patients who developed symptoms of diarrhoea, abdominal pain, constipation, but where no well-recognized infective cause could be found (Brown, 1950). Although pioneering, this paper was widely ignored and it wasn’t until Chaudhary & Truelove's (1962) review on “irritable colon syndrome” that a new era of research and publications about functional bowel disorders really started.

The first attempt to classify and describe functional bowel disorders came in the form of the book “The Irritable Gut” (Thompson, 1979). In the previous year a study of Bristol outpatients with abdominal pain and disordered bowel habit found that 6 specific symptoms (out of 15) were more common in IBS patients than in patients with organic gut disease (Manning, Thompson, Heaton, & Morris, 1978). This later gave origin to the first symptom criteria for IBS, known as the Manning Criteria.

Ever since these early works, the field of research in IBS has seen an exponential increase in publications about aetiology, features, diagnostic criteria, epidemiology and treatment (Thompson, 2006). However there is still no consensus on many of these subjects, which contributes to IBS being a confusing clinical syndrome.

2.4. MODERN APPROACHES TO DIAGNOSIS AND CLASSIFICATION OF IBS

The process by which the diagnosis of IBS is achieved is still a matter of contention despite all the recent research interest in this subject. Although several biological markers have been investigated (for a recent review refer to Barbara & Stanghellini, 2009), there is still no objective diagnostic test or physical finding that confirms the presence of IBS.

There are currently two opposing views on how to make a diagnosis of IBS: IBS as a “diagnosis of exclusion” or IBS as a condition on its own with identifiable symptom characteristics. Supporters of the first view defend an approach that includes more or less extensive diagnostic testing and the use of invasive investigative procedures with the intent of excluding possible organic disease. Several criticisms have been made to this approach as it is very expensive and may increase patients’ anxiety. The supporters of the second view defend instead that by using symptom-based criteria for IBS it is possible to establish a positive diagnosis (Jellema et al., 2009).

Several studies have confirmed the reliability and validity of symptom based diagnosis of IBS. Hamm et al. (1999) found no significant benefit of the use of screening tests for colonic pathology, thyroid function, lactose malabsorption, faecal ova and parasite detection in 1452 patients with IBS previously identified by symptom based criteria (Rome). In another study, with 95 IBS patients meeting Rome criteria, it was found that the positive predictive value in distinguishing between IBS and organic disease was 98% with the diagnosis being maintained in 100% of patients after 2 years (Vanner et al., 1999).

On the other hand several reviews have put into question the accuracy of symptom based diagnosis to reliably exclude organic disease (Jellema et al., 2009; Longsreth, 2005) fostering the divide in this field.

Although firmly established in research and in specialist clinics, the use of symptom based criteria is very limited in primary care practice. This was evidenced by Lea et al's., (2004) study in which only 4% of contacted GP's made regular use of symptom-based criteria to diagnose IBS.

Currently the recommendations of the British Gastroenterology Society adopt a somewhat consensual approach. The physician is encouraged to make a positive diagnosis based on symptom criteria, and also to assess possible psychological factors that might contribute to the patient's presentation. Part of the initial screening should also involve a check for alarm symptoms that might suggest organic disease (bowel cancer, inflammatory bowel disease), and minimum investigations (full blood count, coeliac disease testing). Only when patients present with alarm features (e.g. rectal bleeding, sudden weight loss) is the physician to refer to secondary care for further investigations (Spiller et al., 2007).

2.4.1. Symptom criteria

Several symptom based criteria have been developed and validated for IBS through the years. The first one to emerge was the Manning criteria (Manning et al., 1978) followed by the Rome I (Thompson et al., 1992), Rome II (Thompson et al., 1999) and Rome III (Drossman, 2006).

The Rome III criteria were used for the purposes of this study and its features can be seen in Table 2.1 along with its predecessor Rome II. Other symptoms like heartburn, excessive flatulence, fibromyalgia, headache, backache and genito-urinary symptoms are commonly associated with IBS but have been found to be of no diagnostic use (Longstreth et al., 2006; Spiller et al., 2007). Another symptom reported by the vast majority of IBS patients is bloating (Changet al., 2001). This symptom was included in previous diagnostic criteria (Manning et al., 1978) but it has been since dropped as a diagnostic marker.

Table 2.1: Symptom-based Criteria for IBS (adapted from Longstreth et al., 2006), (Thompson et al., 1999)

Rome II Diagnostic criteria*	Rome III Diagnostic Criteria** for IBS
Twelve consecutive weeks of abdominal discomfort or pain that has 2 of the following features:	Recurrent abdominal pain or discomfort***at least 3 days per month in the last 3 months associated with 2 or more of the following:
1. Relieved with defecation	1. Improvement with defecation
2. Onset associated with a change in frequency of stool	2. Onset associated with a change in frequency of stool
3. Onset associated with a change in stool form	3. Onset associated with a change in form (appearance) of stool
*Criteria fulfilled in the preceding 12 months	**Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis. ***Discomfort means an uncomfortable sensation not described as pain.

The Rome III criteria have some important changes when compared to its predecessor, the main one being the more inclusive prevalence of symptoms (3days per month) criteria. Other advantages reported are clearer distinctions between IBS and Functional Diarrhoea with presence of pain being a key criteria for this distinction. It also includes a simple classification related to stool pattern that allows the easy identification of IBS sub-type (Table 2.2). In comparison with its predecessor the Rome III criteria has been found to be easier to use (Longstreth et al., 2006) and more sensitive and inclusive (Baber et al, 2008). There is still some dispute regarding the changes to sub-typing with some studies finding low agreement (Ersryd et al., 2007) and others high agreement (Dorn et al., 2009) between Rome II and Rome III.

Table 2.2: Sub-typing IBS by Predominant Stool Pattern (adapted from Longstreth et al., 2006)

-
1. IBS with constipation (IBS-C)—hard or lumpy stools $\geq 25\%$ and loose (mushy) or watery stools $< 25\%$ of bowel movements.
 2. IBS with diarrhoea (IBS-D)—loose (mushy) or watery stools $\geq 25\%$ and hard or lumpy stool $< 25\%$ of bowel movements
 3. Mixed IBS (IBS-M)—hard or lumpy stools $\geq 25\%$ and loose (mushy) or watery stools $\geq 25\%$ of bowel movements
 4. Unsubtyped IBS—insufficient abnormality of stool consistency to meet criteria for IBS-C, D, or M
-

Some alarm features that should be considered along with symptom-based criteria like Rome III include onset of symptoms after 50 years of age, short history of symptoms, weight loss, nocturnal symptoms, patient being male, family history of colon cancer, anaemia, rectal bleeding and recent antibiotic use. The presence of any of these features should be further investigated by the consultant physician (Spiller et al., 2007).

2.5. EPIDEMIOLOGY

2.5.1. Prevalence

IBS is the most common functional bowel disorder affecting between 3-25% of people at any one time (Chang, 2004; Grundmann & Yoon, 2010). This wide range of prevalence is mainly due to the different criteria used to assess the presence of IBS in the populations studied. The use of the Manning criteria seems to increase prevalence and variability in prevalence across samples while numbers seem to be lower and less variable when using Rome criteria (Spiller et al., 2007).

Differences in cultural settings might also explain the variance in prevalence. Using Rome II criteria, recent studies have found a certain worldwide consistency, with

prevalence in Singapore (8.6%) and Japan (9.8%) being comparable to Australia (6.9%) and Europe (9.6%) (Gwee et al., 2009). There are although exceptions like New Zealand reporting as low as 3.3% (Barbezat et al., 2002) or Turkey reporting up to 19.1% (Karaman et al., 2003) of prevalence.

Another factor affecting prevalence rates seems to be related to consultation behaviour. It is estimated that between 33-90% of IBS sufferers do not consult or are not identified by their physician (Spiller et al., 2007).

The prevalence in the general population of different sub-classifications of IBS seems to be quite consistent in studies conducted in western countries with prevalence of IBS-D (diarrhea predominant) found to be between 5-5.5%, IBS-C (constipation predominant) between 5.2-5.4% and IBS-M (mixed, alternating between diarrhea and constipation) 5.2% (Talley, Zinmeister, & Melton, 1995; Thompson et al., 2002). However, studies in Asian populations suggest a higher prevalence of IBS-C over IBS-D (Gwee et al., 2004; Lau et al., 2002).

IBS seems to affect all ages, although there is a peak of reports between the ages of 20 and 30 (Spiller et al., 2007). A study in the USA found that prevalence of IBS was higher in patients aged 30-64 years (17%) when compared to patients aged 65-93 years (10.9%) (Camilleri et al., 2002).

2.5.2. Gender differences

Most studies report a higher prevalence of IBS in female patients with the majority of female-to-male ratios varying between 2:1 and 3:1 in primary care settings (Chang et al., 2006) and between 4 and 5:1 in tertiary care settings (Frissora & Koch, 2005). Factors like hormonal differences, cultural pressures, response bias towards potentially harmful events and different brain serotonin synthesis have all been suggested to play a part in this disparity (Camilleri et al., 2002). However some studies in the USA, Pakistan and Hong-Kong found no significant differences in prevalence between male and female patients (Chang et al., 2006; Gwee et al., 2009).

Studies in Asian populations seem to suggest quite different results with a higher prevalence being found in the male population in India (Ghoshal, Abraham, & Bhatt, 2008) and Korea (Han et al., 2006), however, it is more likely in these countries for males to have access to health services than females and therefore to be identified as IBS patients.

2.5.3. Incidence

It is still unclear what the precise incidence of new cases of IBS is, since few studies have assessed this parameter. In a recent study Locke et al. (2004) calculated that, based on a 10 year period of medical records, every year there are 2 new cases of IBS per 1000 people after adjusting for age and gender. The incidence in the community is still unknown since data suggests that only a small percentage of patients present to physicians (Camilleri et al., 2002).

2.6. AETIOLOGY OF IBS

To this day, the aetiology of IBS is still unknown but the understanding of it has evolved a great deal in the past few decades. One of the main contributors to this was a shift in paradigm from a biological reductionist model heavily embedded with the Decartian concepts of separation of mind and body, to a more holistic paradigm of a biopsychosocial model of disease (Drossman & Dumitrascu, 2006). Thanks to this more broad view of illness, many mechanisms have been put forward as being involved in the expression of IBS such as: early life factors (genetic or environmental), abnormal gut motility, visceral hypersensitivity, brain-gut interactions or psychological morbidity (Drossman et al., 1999; Spiller et al., 2007).

2.6.1. A biopsychosocial model of IBS

At the end of the last millennium a new model of IBS started being proposed, heavily influenced by the biopsychosocial model of Engel (1980) and recent discoveries in the fields of psychosomatics and psychoneuroimmunology. Mayer (1999) proposed a model in which an interaction between cognitive, behavioural, emotional and physiological components would explain the development and maintenance of IBS

symptoms. In the same year Drossman et al. (1999) also proposed a biopsychosocial interpretation of IBS which is now recognized as one of the most complete and best fitting models for this illness. An adapted diagram of this model can be seen below in Figure 2.1.

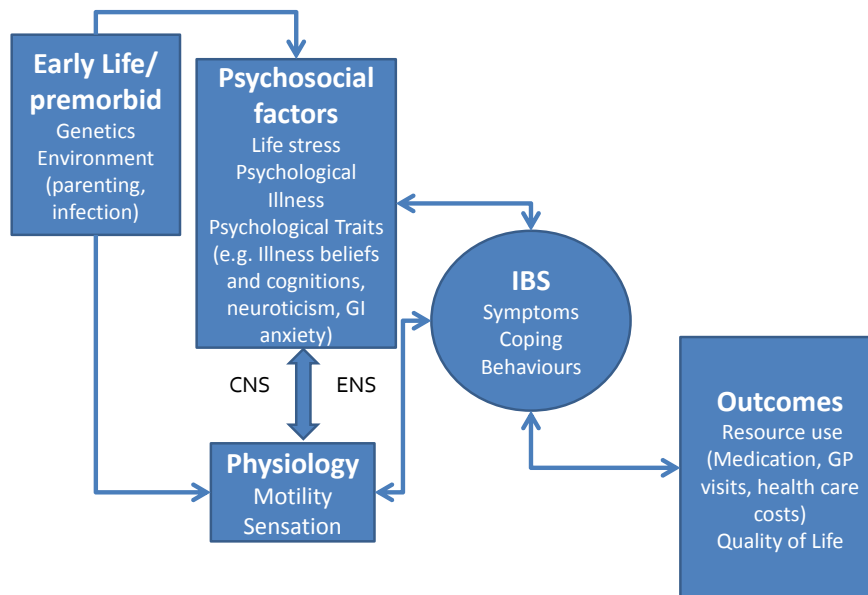


Figure 2.1: Biopsychosocial conceptualization of IBS (Drossman et al., 1999)

In this model we can see how changes in early life/premorbid genetic and environmental factors (e.g. parenting, infection) might play a role in the development of both psychosocial (susceptibility to stress, psychological illness, psychological traits) and physiological (abnormal motility, visceral hypersensitivity) factors leading to the expression of IBS symptoms and coping behaviours. Also, interplay between psychosocial and physiological factors via the interactions between Central Nervous System (CNS) and the Enteric Nervous System (ENS) are highlighted as an influence in IBS expression (Drossman et al., 1999). These biopsychosocial interactions are therefore thought to have an impact on patients' quality of life and the use they make of health care. As an example of this model at work, one could consider the case of two individuals that go through a bout of bacterial gastroenteritis. The first one who has good coping skills and no other psychosocial

difficulties may not develop IBS (or be aware of it) or may not perceive the need to consult a physician even if IBS develops. The second individual who has more maladaptive coping and a history of psychosocial difficulties might have an increased chance of developing IBS and perceive a greater need to consult or have a worse outcome (Drossman & Dumitrascu, 2006).

In the rest of this section a brief review on early life/premorbidity factors, physiological factors and brain-gut interactions will be undertaken. A more in depth review of psychosocial factors, coping behaviour and outcomes will then follow.

2.6.2. Early life/Premorbidity factors

The role of distal early life (genetic, parenting, trauma) or proximal (infection) premorbidity factors in the development of IBS is still controversial, especially early life factors. However, it is a fertile area of study due to its possibilities of suggesting potential risk factors associated with the onset of IBS.

2.6.2.1. Genetics and parental influences

Findings in both familial aggregation and twin studies suggest that there might be a genetic component in IBS (Camilleri, 2009). It has been found that IBS seems to aggregate within families, with direct relatives of patients being twice as likely to have IBS when compared to relatives of their spouses (Kalantar et al., 2003; Saito et al., 2010). Twin studies have also shown that there is a higher concordance of IBS diagnoses between monozygotic twins than dizygotic twins (Bengtson et al., 2006; Levy et al., 2001). These studies prompted several investigations into the possible association between candidate genes (e.g. serotonin transporter 5-HTT, α adrenergic receptor, interleukin IL-10, tumour necrosis factor α) and IBS (Spiller et al., 2007). Although several associations between candidate genes and IBS have been reported, these studies have usually been underpowered and have not been able to disentangle the contributions of genes from the contributions of other environmental factors like parenting (Camilleri, 2009; Levy et al., 2001; Spiller et al., 2007).

As mentioned before, twin studies suggest a genetic involvement in IBS, but these same studies also support a strong environmental contribution from parental influences. Levy et al. (2001) found in their study a stronger concordance between parent and child rather than between twins in dizygotic twins. This seems to indicate that the interaction between the parent-child dyad is more important than genetic influences. Several studies have highlighted that the reinforcement and modelling of illness behaviour in children by their parents is likely to contribute to the development of IBS (for a review see Spiller et al., 2007). For example, individuals suffering from IBS are more likely to recall being given reinforcements (treats, food) in childhood while being ill (Whitehead et al., 1982). Children of IBS patients are also more likely to consult with or without gastrointestinal symptoms and to have a higher number of school absences than children of non-IBS parents (Levy et al., 2004; Levy et al., 2000).

It is therefore, thought that although genetic factors might have a minor contribution to the development of IBS, early factors related to parenting styles and behaviour modelling seem to have a greater influence, especially during childhood.

2.6.2.2. Traumatic events

Traumatic events during infancy and/or childhood are also thought to be associated with later development of IBS (Chitkara et al., 2008). Bengtson et al., (2006) demonstrated that restricted foetal growth and low birth weight, due to nutritional problems, have a significant influence in the development of IBS. Annand et al. (2004) also found that noxious stimulation caused by gastric suction at birth may promote long-term visceral hypersensitivity and is associated with the development of functional gastrointestinal disorders. These studies suggest therefore that prenatal and perinatal traumatic events might influence the expression of IBS later in life.

Reports of physical and sexual abuse during childhood have also been implicated in the development of IBS. In a large population based study Talley et al. (1994) reported a significant association between IBS and childhood abuse (sexual,

emotional, verbal and physical) with individuals abused in childhood being more likely to consult for IBS symptoms. In another study comparing IBS patients with patients with an organic illness (Inflammatory Bowel Disease), it was found that IBS patients significantly recalled more episodes of abuse and tended to have a greater levels of anxiety, somatisation and depression (Salmon et al., 2003).

2.6.2.3. Infection

Between 5% and 32% of IBS patients have the onset of their symptoms within 6 months after an acute episode of gastroenteritis (Spiller et al., 2007; Thabane & Marshall, 2009). The mechanisms underlying this form of Post-Infectious IBS (PI-IBS) are still poorly understood, but it is believed that the experience of gastroenteritis might contribute to continuous sub-clinical inflammation due to changes in intestinal permeability (Thabane & Marshall, 2009). Changes in gut permeability have been observed in PI-IBS patients in several studies (see Spiller & Garsed, 2009 for a review) and are thought to be responsible for the disturbances observed in enteric sensation and motility.

The toxicity of the infecting bacteria and the severity of the initial illness are considered to be risk factors to the development of PI-IBS, with greater toxicity and longer period of illness being associated with a higher likelihood of developing PI-IBS (Spiller & Garsed, 2009). The development of PI-IBS does not appear to be specific to any particular bacteria since it has been reported in patients who had cases of *Shigella*, *Campylobacter*, *Salmonella* and *Escherichia Coli* infection (Thabane & Marshall, 2009). Factors like depression, anxiety, somatisation and negative perceptions of illness have also been considered as risk factors for the development of PI-IBS (Thabane & Marshall, 2009). Spence & Moss-Morris (2007) found in a recent prospective study, that participants who developed PI-IBS had higher levels of perceived stress, anxiety, somatisation and negative illness beliefs at the time of infection than participants who did not develop PI-IBS.

2.6.3. Physiological Factors

Throughout the years several physiological factors have been implicated in the pathophysiology of IBS contributing to the main symptoms of abdominal pain/discomfort, abnormal bowel function and other symptoms like bloating. Evidence has supported primarily the involvement of disturbances in gastrointestinal motility and in gastrointestinal sensation (visceral hypersensitivity) as contributors to the symptoms of IBS. The role of gastrointestinal secretions and gas handling is still controversial (Gunnarsson & Simrén, 2009).

2.6.3.1. Disturbance of gastrointestinal motility

Gastrointestinal motility is responsible for key processes in digestion like the propulsion of food contents from one area of the gut to another, mixing of the contents with digestive secretions, exposing them to absorptive surfaces and finally disposing any remaining residues. Both internal and external stimuli induce specific motor reflexes all across the digestive system (oesophagus, stomach, small bowel, colon) which are controlled both peripherally (Enteric Nervous System) and centrally (Central Nervous System) (Kellow et al., 2006). It has been shown that IBS patients tend to present with motility problems in the upper GI (oesophagus and stomach), small bowel and colon (Gunnarsson & Simrén, 2009).

Evidence on upper GI (oesophagus and stomach) dysmotility is divergent and seems to be present only in IBS patients with predominant constipation or that have co-morbid upper GI dysfunctions (e.g. dyspepsia) (Gunnarsson & Simrén, 2009; Spiller et al., 2007). However, it has been shown that a significant proportion of IBS patients present with delayed gastric emptying, in particular of solid foods (Caballero-Plasencia et al., 1999; van Der Voort et al., 2003) and that this might be affected by emotional states such as anger (Welgan et al., 2000).

Small bowel dysmotility has been shown to exist in IBS patients and seems to be associated with alterations in the periodicity of the migrating motor complex (MMC) (Gunnarsson & Simrén, 2009). The MMC are waves of activity that sweep through

the intestines at a regular cycle and that help facilitate the transportation of indigestible substances (e.g. fibres). It has been found that diarrhoea predominant IBS patients have a shorter MMC periodicity (Kellow et al., 1990) while constipation predominant patients have a longer periodicity (Kellow et al., 1992). Transit studies have also shown that diarrhoea predominant IBS patients have an accelerated transit while constipation predominant patients have a delayed transit. These findings seem to indicate an association between small bowel dysmotility and alteration in bowel function, yet there are also several studies that have failed to find such a clear correlation (Gunnarsson & Simrén, 2009).

It has long been thought that disturbances in colorectal motility play a key role in IBS due to the characteristic changes in bowel habit and it has recently been suggested that these disturbances are the most prevalent pathophysiological alteration in IBS patients (Camilleri et al., 2008). Exaggerated colonic motility response has been observed and associated with meal ingestion, cholecystokinin and corticotrophin release, and rectal balloon distension (Gunnarsson & Simrén, 2009). Psychological and emotional factors like stress and anger have also been associated with an increased colonic response (Welgan et al., 1985; Welgan et al., 2000). It has been shown that patients with predominant diarrhoea have an increased number of high amplitude propagating contractions (HAPCs)¹ and accelerated colonic motility, while constipation predominant patients have fewer HAPCs and delayed transit (Spiller et al., 2007).

In summary, disturbed motility has been found in all sites of the digestive tract in IBS patients. Small-Bowel and Colonic disturbance of motility seem to be associated with the abnormalities of bowel function observed in IBS. It must also be noted that most of the disturbances in gastrointestinal motility described in this section also occur in healthy subjects, although to a lesser extent, and are not associated with any

¹ High amplitude propagating contractions (HAPC) are specialized propagating pressure waves with high amplitude (> 105 mmHg) and prolonged duration (> 14 s) observed on manometric recordings. HAPC are often associated with colonic mass movements and are thought to be a precursor of bowel evacuation; they occur mostly after arousal from sleep and after ingestion of meals (Ancha et al., 2010).

symptoms. This suggests that IBS patients might have: a particular hypersensitivity to these events; they might have different appraisals regarding these events; or they might relate to these events differently from healthy subjects.

2.6.3.2. Visceral Hypersensitivity

It has been shown that approximately 50% to 70% of IBS patients have enhanced pain sensitivity to experimental gut stimulation (Kellow et al., 2006). This phenomenon known as visceral hypersensitivity is thought to play an important role in the development of pain and discomfort in IBS patients (Spiller et al., 2007). It is still not fully understood how visceral hypersensitivity develops in IBS patients.

Some studies show that infection might play a part in some cases by causing peripheral sensitization of the gut, i.e. infection is thought to affect the excitability and sensitivity of the sensory receptors of the gut therefore increasing pain/discomfort sensations (Naliboff et al., 1997; Spiller et al., 2007). Some other studies suggest that visceral hypersensitivity occurs as a result of modulation of the pain processing in the spine (Spiller et al., 2007). Also, because the cortex exerts final control of visceral perception it has been defended that visceral hypersensitivity might be a consequence of altered central processing of gut nervous stimulus (Gunnarsson & Simrén, 2009; Naliboff et al., 1997; Spiller et al., 2007). This latter hypothesis has been supported by recent positron emission tomography (PET) and functional magnetic resonance imaging (fMRI) studies that have shown that visceral sensations are represented both in the primary and the secondary somatosensory cortex as well as in the limbic and paralimbic structures of the brain. Some of these studies show that IBS patients, when subjected to experimental rectal pain, have an enhanced activation of regions involved in central pain processing when compared to healthy controls (Bonaz et al., 2002; Mertz et al., 2000). Also a study has shown that emotional distress might be associated with alterations in brain activity that cause visceral pain (Drossman, et al., 2003 a).

Colorectal sensitivity has been demonstrated to be present in IBS in several studies (e.g. Bradette et al., 1994; Posserud et al., 2007; Whitehead et al., 1990) with Mertz et al. (1995) proposing that this could be used as a biological marker for IBS. This has however been questioned, since visceral hypersensitivity is not present in all IBS patients (Whitehead & Palsson, 1998). Several recent studies have shown an association between colorectal sensitivity and the severity of pain reported by patients which strengthens the role of visceral hypersensitivity in the expression of the pain/discomfort symptoms observed in IBS (Kanazawa et al., 2008; Posserud et al., 2007; Van Der Veek et al., 2007). There have been however, studies that found no such association or only a weak one (Lee et al., 2006; Sabate et al., 2008). No significant relationship between colorectal sensitivity and bowel habit has been established (Gunnarsson & Simrén, 2009).

Enhanced sensitivity has also been found in other parts of the digestive tract like the oesophagus, stomach and small bowel in IBS patients, although this seems to be limited to patients who display multiple symptomatic sites (Gunnarsson & Simrén, 2009).

In summary, visceral hypersensitivity in the colon seems to be a key factor in the development of the pain/discomfort symptoms observed in IBS and it seems to be modulated by both external and internal factors.

2.6.4. Brain-gut interactions

The Enteric Nervous System (ENS) is a subdivision of the peripheral nervous system that controls the gastrointestinal system (Burns & Thapar, 2006). It communicates with the Central Nervous System (CNS) via the parasympathetic (e.g. vagus nerve) and sympathetic (e.g. prevertebral or paravertebral ganglia) nervous systems and shares many neurotransmitters with the CNS like Cholecystokinin (CCK) or Substance P (Gershon, 1999). It has been hypothesized by various authors (Drossman 1998) that this close connection between ENS and CNS might be related to the close relationship between the events observed in both gut and psyche.

The brain-gut axis model proposed by Drossman (1998) proposes that key symptoms in IBS (altered motility, visceral hypersensitivity) are the result of the deregulation in the activity of one or more of the bidirectional communication pathways between ENS and CNS. This communication is influenced by inputs from the neuroendocrine and neuroimmunological systems that are themselves modulated by psychosocial factors. Many neurotransmitters (e.g. serotonin, CCK, cytokines) have been implicated in this brain-gut deregulation model (Ringel et al, 2001).

One of the clearest examples of this brain-gut connection comes from the evidence collected by studies on the effect of stress in IBS. As previously mentioned, stress seems to have an impact both on motility and sensitivity of the colon (Drossman et al., 2003 b; Welgan et al., 1985). It is thought that many of the IBS manifestations are part of a response to internal and external stressors through the integration of the hypothalamo-pituitary-adrenal (HPA) axis and the sympathetic nervous system. Life stressors, psychiatric illness, anxiety-provoking situations as well as psychological traits like somatisation, anxiety and low mood have all been linked with an exaggerated HPA response which is thought to be in turn associated with the immune activation of the gut mucosa in IBS patients (Spiller et al., 2007).

Due to the importance of psychosocial factors in the regulation of gut sensitivity and motility and their corresponding neurophysiologic correlates, (CNS and ENS), a closer look at these factors will follow.

2.6.5. Psychosocial factors

The role of psychosocial factors in the pathogenesis and expression of IBS is an issue that has attracted increased scientific interest in the last 2 decades, with the number of journal articles and reviews published increasing almost twofold in this time period. The presence and impact of stressful life events, psychological morbidity and certain psychological characteristics in IBS patients will be critically evaluated.

2.6.5.1. Stressful life events

Stressful life events have long been considered one of the key elements in the onset and/or exacerbation of IBS since its earliest descriptions (e.g. Chaudhary & Truelove, 1962), with a majority of patients acknowledging the role of stress in their condition (Blanchard et al., 2008).

Early anecdotal observations established a link between psychological distress and IBS. Chaudhary & Truelove (1962) using an unstructured psychiatric interview and no control group reported a relationship between psychological distress and functional GI complaints in over 80% of the patients studied. It was concluded that IBS was in general preceded by a stressful life episode. Hislop (1971) also concluded that IBS patients were more likely than controls to report a stressful life episode prior to the onset of their first symptoms than matched controls. However, in this study, assessments were again made by unstructured interviews. A more rigorous methodology for the measuring of stress was therefore needed.

According to Blanchard et al. (2008), three main methodologies have been used to study the role of stress or stressful events in IBS in the past three decades.

The first approach looks at the frequency and intensity of major life events or changes in the last 6 to 12 months in IBS patients when compared to organic GI disease or healthy controls. Craig & Brown (1984) and Mendeloff et al. (1970) found that IBS patients reported significantly more stressful major life events (e.g. death in the family, divorce, recent unemployment) prior to illness onset when compared to groups of organic GI patients (e.g. ulcerative colitis). However in a similar study Ford et al. (1987) found no significant differences in experience of life stressors between IBS and organic GI patients. In fact they noted that only stressful situations that provoked a concomitant state of anxiety were associated with IBS. Schwarz et al. (1993) also reported no significant differences in stressful life events scores between IBS and Inflammatory Bowel Disease (IBD) patients. More recently Bennett et al. (1998) showed that IBS and Functional Dyspepsia patients had

significantly more chronic life stressors than patients with other Functional GI disorders and that this might predict severity and extent of gastrointestinal, emotional, and extraintestinal symptoms over time.

Several studies have shown that when compared to healthy controls, IBS patients have a higher frequency of major life events (Blanchard et al., 1986; Mendeloff et al., 1970; Whitehead et al., 1992). This was however not corroborated by the studies of Schwarz et al. (1993) and of Levy et al. (1997) in which no such differences were found. Faresjo et al. (2007) also did not find a significant difference in daily stress exposure perception in the last 6 months between IBS patients and normal controls in a population based study. Bennett (1999) proposes that most of these differences in findings are due to different methodological approaches, with more consistent findings being reported in studies using a structured interview (Life Events and Difficulties Schedule; Brown & Harris, 1978) and less consistent findings in studies that used self-report life stress inventories. This is interesting because it suggests that sometimes IBS patients do not spontaneously recognize they own stressful life events.

The second approach according to Blanchard et al. (2008) looks at the frequency and intensity of minor stress and hassles in the last month. Some studies carried out in this area used IBS patients only samples with no normal or other illness comparison groups. Data from the studies of Suls, Wan, & Blanchard (1994), Dancey et al. (1995) and Payne & Blanchard (1995) suggests though, that daily hassles are not significantly related to IBS symptoms. Elsenbruch, Lovallo, & Orr (2001) studied the impact on symptomatic, psychological and physiological parameters of a stressful mental task associated with food ingestion in both IBS patients and normal controls. They found that IBS patients only differed from normal controls in their affective response to the task, with no differences being found for symptomatic or physiological parameters. In a more recent study Blanchard et al. (2008) found that IBS patients significantly reported more daily hassles than healthy controls, although the average intensity rating of these events was significantly lower for IBS patients. This meant that on the overall score of daily hassles there were no significant

differences between the groups. Finally, Fujii & Nomura (2008) found that daily hassles significantly predicted the change from IBS non-consulter to IBS consulter over a period of 3 years, although these changes seem to be influenced by the type of coping used to respond to daily hassles (e.g. avoidant).

The third approach consists of prospective studies in which the experience of symptoms and minor stressors are reported on a daily or weekly basis in order to assess the value of stressors in the previous weeks/days in predicting GI symptoms in the following weeks/days. Five prospective studies report a strong association between stress measured on week/day and GI symptoms measured on the same week/day (Blanchard et al., 2008; Dancey, Taghavi, & Fox, 1998; Levy et al., 1997; Suls, Wan, & Blanchard, 1994; Whitehead et al., 1992). Using time series analysis Levy et al., (1997) found that previous stress significantly correlated with later GI symptoms in 38% of the IBS patients in their study. Dancey, Taghavi, & Fox (1998) also found that daily hassles in the previous 4 days had a small but additional effect on current symptom severity. However no effects of previous stress on current symptoms were found in the other 3 studies. In fact both Blanchard et al. (2008) and Suls, Wan, & Blanchard (1994) criticise the use of small samples and lack of correction for autocorrelation in other studies. Overall, prospective studies seem to infer that life event stresses and hassles have at most a minor effect on GI symptoms.

In summary, it seems that the role of stress is recognized by most patients and physicians as taking a part in the development or exacerbation of IBS. However the data is still quite controversial, with some studies supporting or disconfirming these claims.

2.6.5.2. Psychological morbidity

Historically, the absence of a structural or organic explanation for IBS and anecdotal observations of patients' behaviour has always been seen as support to the possible presence of psychological morbidity. Early research described the aetiology of IBS to be linked with hypochondriasis or psychogenic traits (e.g. Hislop, 1971) with

some authors going as far as considering IBS to be part of a diagnosable psychiatric illness (Liss, Alpers, & Woodruff, 1973). But it was not until the last three decades that an increasing amount of studies, using a more comprehensive evaluation of both IBS and psychological/psychiatric illness, have looked at the overlap between these two types of disorders.

In most studies it was found that between 54% and 94% of IBS patients meet criteria for at least one (Axis I) psychiatric disorder (Whitehead, Palsson, & Jones, 2002). Also between 40% and 80% of IBS patients report their psychiatric conditions to have been present before the onset of their GI symptoms (Mayer, Craske, & Naliboff, 2001). Psychological morbidities like depression, general anxiety disorder, panic disorder, posttraumatic stress, schizophrenia, somatisation disorder and obsessive compulsive disorder have all been associated with IBS, with patients with these conditions being more likely to have a concurrent IBS diagnosis than healthy subjects (Garakani et al., 2003; Pae et al., 2007). When compared to normal controls or to patients with similar symptoms, but with a clearly identifiable organic cause, it has been found that IBS patients have an increased prevalence (20% and 25% respectively) of psychiatric diagnoses (Levy et al., 2006). It has been suggested that increased psychological illness in IBS patients might be a consequence of a history of abuse, especially in more severe cases (Talley et al., 1994). However Creed et al., (2005) while comparing IBS patients with no history of abuse with patients with history of rape or forced touching, found only the somatisation index of the SCL-90 to be higher on the patients with history of abuse, while no differences were found regarding the anxiety and depression indexes. It had also been previously suggested that increased prevalence of psychological morbidity in IBS was a characteristic of treatment seeking patients (in particular those in secondary and tertiary care), yet recent population based studies have suggested that even non-consulting IBS patients are more likely to have a concurrent psychiatric diagnosis when compared with people who don't have IBS (Locke et al., 2004; Sykes et al., 2003; Whitehead, Palsson, & Jones, 2002).

Although panic disorder has a high prevalence in treatment seeking IBS patients (15%-41%), there might be an overestimation of this association because symptoms of diarrhoea and abdominal pain characteristic of panic attacks might be mistaken for the chronic symptoms of IBS and vice-versa. On the other hand somatisation disorder is thought to be underestimated in IBS because the diagnostic procedure in itself usually underestimates the presence of this disorder in the general population (Whitehead, Palsson, & Jones, 2002).

The most common psychopathologies associated with treatment seeking IBS patients are depression and general anxiety disorders with up to 38.5% and 37% of IBS patients meeting criteria for these disorders respectively (Mayer, Craske, & Naliboff, 2001). Recently, Guthrie et al. (2003) found in their study sample (n=107) using structured interviews that 44% of presenting IBS patients had a psychiatric diagnosis with general anxiety disorders being the most common (30%) followed by depression (26%). They also found that IBS patients rated psychological distress twice as high when comparing their scores on the Symptom Check List (SCL-90-R) with those of healthy controls. Although depression and anxiety seemed to be related to a higher reporting of GI symptoms (Creed, 1999; Hillila et al., 2008; Mayer, Craske, & Naliboff, 2001) they do not seem to be predictors of symptom severity as a recent study by Spiegel et al. (2008) shows. In this study depression and anxiety did not predict IBS severity, however illness-related fears and cognitions were found to be significant predictors. Also it has been show that depression alone does not predict symptom severity (Drossman, 1999) and that the relation between depression and symptom severity is mediated by the patients beliefs (Lackner, Quigley, & Blanchard, 2004). Labus et al. (2007) also propose that the capacity for general anxiety disorder to predict symptom severity is mediated by the patient's specific anxious beliefs about IBS. Regarding the capacity for GI symptoms to predict Psychological disorders, Mikocka-Walus et al. (2008), have shown that a greater load of FGIDs (therefore a greater load of GI symptoms) was not associated with more depression or anxiety disorders. Therefore, although there is a clear co-occurrence of depression and anxiety diagnosis with IBS it seems that they do not linearly affect each other in terms of symptom severity.

It has been suggested by Creed (1999) that anxiety and depression might have different roles and prevalence according to the sub-type of population in IBS. In Mayer, Craske, & Naliboff's (2001) review of previous studies regarding psychological morbidities and IBS, the authors note that recently referred IBS patients have a tendency to have more anxiety than depression, while more chronic refractory patients seem to have more depression than anxiety. A possible explanation for this might be that initial uncertainty about the symptoms might prompt anxiety in the recently referred patient while the chronic patient might become more depressed as a consequence of its continuous exposure to the symptomatic stressors or a potential restriction of goal directed behaviours as a response to avoid anxiety provoking situations and symptoms. Another difference in the roles of depression and anxiety in IBS seems to also be related to the different subtypes of IBS. It has been recently reported in two studies (Eriksson, 2008; Muscatello et al., 2010) that patients with constipation predominant IBS have significantly higher levels of depression and anxiety when compared to patients with diarrhoea predominant IBS. In another study, Medeiros et al. (2008) found that depressive symptoms were associated with visceral sensitivity in alternating IBS patients, but not in diarrhoea/constipation predominant patients, suggesting a different role of depression in symptom severity.

In summary, the overlap between IBS and psychopathology is evident and suggests that especially depression and anxiety might play a role in the onset and maintenance of IBS. Also, it seems that according to subtype and length of diagnostic either depression or anxiety will be more prevalent. However, the relation between psychological disorders and IBS symptoms does not seem to be linear and is likely to be affected by other psychosocial variables (e.g. beliefs).

2.6.5.3. Psychological characteristics

Further than the role of stressful events and psychological co-morbidities several other psychological characteristics and traits have been described in IBS patients.

2.6.5.3.1. *Illness beliefs/cognitions*

There is consistent evidence that IBS patients have very particular beliefs/cognitions about their illness and that many times these are erroneous and probably generated from a lack of information or some form of cognitive bias. Initial studies on this matter showed that worry about the symptoms, perception of anxiety and attribution style (Illness caused by stress vs. caused by biological causes) were significant factors in the prognosis of IBS (Bleijenberg & Fennis, 1989; Fowlie, Eastwood, & Ford, 1992). Gomborone et al. (1995) found for instance that when compared to groups of healthy controls, GI disease and depressed patients, IBS patients reported significantly more concerns about their body, more hypocondriacal beliefs and more disease phobia. In the same study it was reported that these cognitions were experienced as difficult to ignore by the patients and that they were associated with another belief that their doctors had not correctly diagnosed their condition.

One of the best insights into IBS specific cognitions came from the Toner et al. (1998) study, in which the authors developed a cognitive scale for functional bowel disorders (72 out of the 75 participants had IBS). The final 25 item scale was based on 95 initial items drawn from patients' Automatic Thought Records and presented the most frequent and representative thoughts/beliefs patients had about their condition. Some overarching categories of thoughts included worry thoughts (e.g. about having symptoms in public situations or not being able to find/get to a toilet in time), thoughts about the impact of the condition on their lives (e.g. symptoms are too hard to handle or they keep me from functioning normally), emotional reactions to the experience of the symptoms (e.g. frustration, depression, embarrassment or guilt), timeline of the illness (e.g. beliefs that the illness is ever present and will not go away), lack of control and perfectionism. These cognitive domains were shown to be associated with dysfunctional attitudes related to cognitive vulnerability and depression and to a higher level of self perceived IBS interference in life activities.

A recent study by Lacy et al. (2007) in which 261 IBS patients responded about their knowledge and attitudes about IBS also highlights some of the beliefs held by these

patients. Two thirds of the patients inquired believed that IBS would develop into an even worst problem (e.g. 15.3% cancer) or increase the risk of developing into a more serious situation (21.5% increased risk cancer, 29.9% increased risk IBD). Again around two thirds or more of the patients believed that dietary factors (75.1%), anxiety (80.5%), depression (63.2%) and changes in their daily routine (60.5%) were responsible for their symptoms development while around half considered genetics (52.1%) and food allergies/intolerances (47.9%) to be important. Although the majority (72.4%) of patients believed that a gastroenterologist or a GP would be the best providers of treatment, some also believed that their gastroenterologist (40%) or their GP (33%) had not taken their complaints seriously. Also most patients found that investigations were essential for the diagnosis of IBS, especially a colonoscopy (40.6%). In terms of beliefs regarding the effectiveness of treatment, patients endorsed diet changes and prescription or over the counter medication as the most effective treatments. Surprisingly, given the beliefs that anxiety and depression are possible causes of IBS, only less than a third believed that any type of psychological intervention (counselling or support group) would be effective.

Several qualitative studies addressing IBS patients' experience have also emphasized the importance of how the patient thinks about her own condition. IBS patients in Schneider & Fletcher (2008) study describe anxious thoughts (about the availability of a toilet, the degree to which the symptoms will escalate and whether the symptoms will occur in a public situation) before, during and after the onset of an attack. The authors note that the patients identify anxious thoughts as being part of the cascade of impact of an attack, but that only depending on the context would they believe anxiety to be the cause of an attack. Helplessness thoughts regarding the lack of control over the condition and its perennial status also permeate these patients' minds. Cognitions about the embarrassment or possible embarrassment provoked by some of the symptoms or by having to disclose their illness to another person are also common in IBS patients. It is also common for these patients to experience guilt regarding how much they think they are an imposition on others. It is noted as well in this study, although not explicitly addressed, that IBS patients have frequent thoughts about what other people think of them. A more recent and larger qualitative study by

Drossman et al. (2009) also found that patients report having unwanted thoughts (both in the presence or absence of symptoms) about anticipatory concerns, loss of control or fear of loss of control, about the physical and emotional impact the illness has on their lives and that others (significant, non-significant, doctors) do not understand their situation.

All these studies on general beliefs/cognitions in IBS have found these to be associated with symptom severity, illness behaviours and quality of life, reiterating the importance of these processes in the overall presentation of IBS.

It is also important to mention some studies that have focused on more particular cognitive processes in IBS like attribution style, risk perception and stigma perception. In an international study comprising eight countries Gerson et al. (2006) reported that patients who attribute their symptoms primarily to physical factors are more likely to suffer from more intense symptoms, while patients who attribute their symptoms to psychological factors are more likely to suffer less. The authors note that psychologically minded patients are maybe more likely to minimize their physical symptoms because they believe them to be a representation of their psychological distress. However, Bray et al. (2006) found psychological attribution styles to be more strongly associated with pain severity than physical attribution styles, suggesting that this might be related to increased psychological co-morbidity. In the same study, the authors also found no differences in attribution style between IBS and non-IBS patients attending a GI clinic, dismissing the idea defended by previous authors (e.g. Whitehead, Palsson, & Jones, 2002) that IBS patients are more committed to a somatic explanation for their symptoms. Riedl et al., (2009) recently found that IBS patients who present more somatic attributions have more impaired physical quality of life and higher physical complaints while those who make more intrapsychic attributions have a more impaired mental quality of life and better physical symptoms outcomes. This recent study seems therefore to present a more conciliatory view regarding the different contextual influences that attribution style might have on IBS outcomes. Regarding risk perception Crane & Martin (2004 a) reported that, when compared to other chronic illness patients (asthma, eczema) and

healthy controls, IBS patients are more likely to believe they will be at risk to develop a health related condition. However, they do not perceive increased risk for non-health related situations (mugging, traffic accident) any differently from any of the other groups. Concerning stigma perception, and although this is deemed to be a very important issue in IBS, no differences were found between IBS and IBD patients, and IBS patients were found to report less stigma perception than Chronic Fatigue Syndrome patients (Looper & Kirmayer, 2004). The authors attribute these findings to a belief that IBS is somehow seen as a more legitimate diagnosis amongst the medical community. This conclusion seems to be at odds with the debate that still remains in the medical sector regarding IBS and also the experiences of patients who in large majority still feel misunderstood and unsupported (Looper & Kirmayer, 2004).

One model that seems to constitute a good framework for all the different types of cognitions/beliefs in IBS is the Self-Regulation Model (Leventhal, Meyer, & Nerenz, 1980). Central to this model is the concept of illness representation (i.e. the cognitions that patients have about their illness). Illness representations are thought to give meaning to symptoms and are closely related to the coping efforts put in place by the patient, thereby influencing outcomes. Leventhal and colleagues propose that five essential representation dimensions are formed by the patients:

- Identity: patients beliefs about the nature of its condition and how it links with the symptoms
- Timeline: patients beliefs about the likely duration of the problem (acute, chronic or cyclical)
- Cause: patients beliefs about the possible cause of their illness (psychological, environmental, biological)
- Consequence: patients beliefs about the emotional, physical and social impact of the illness on their functioning
- Cure/Control: patients beliefs about how much their condition is curable or controllable

An initial cross-sectional study from Rutter & Rutter (2002) showed that reporting higher consequences and attributing cause to psychological factors were associated with greater levels of anxiety and depression. Lower quality of life was associated with greater reporting of consequences, and lower sense of cure/control. A more recent prospective study by the same authors (Rutter & Rutter, 2007), has shown that these representations are stable, with no significant differences found between them when measured at 3 time points during 12 months. The authors suggest that illness representations are developed in the early stages of illness and that unless challenged they will remain stable over time and possibly become even stronger. In both studies by Rutter & Rutter, the link between illness representations and outcomes were shown to be mediated by acceptance and avoidant coping strategies. In another prospective investigation, stronger negative illness representations were also found to be good predictors of development of IBS following gastroenteritis infection in a community sample (Spence & Moss-Morris, 2007).

In summary, IBS patients have very specific cognitions and beliefs about their condition and the contextual factors surrounding it. These seem to be related to symptom reporting, psychological co-morbidity and to coping behaviour. Whether these cognitions/beliefs are part of some personality trait of IBS patients, the result of biased learning or a consequence of the illness presentation in itself is still debatable. The biopsychosocial approach and the research reviewed here would suggest that these beliefs and cognitions play an important part both before and after illness onset.

2.6.5.3.2. Neuroticism, Anxiety Sensitivity and Gastrointestinal Specific Anxiety

Several early studies proposed that IBS might be linked to neurotic or anxious personality traits rather than psychological illness. For example Kingham & Dawson (1985) describe these patients as being generally nervous, sensitive and high strung while Hill & Blendis (1967) noticed that they tend to have rigid or perfectionist attitudes. This is further supported by the fact that many patients exhibit some of these anxiety related characteristics without meeting DSM-IV diagnostic criteria for an anxiety disorder (Hazlett-Stevens, et al., 2003).

One of the first and most studied personality traits in IBS was neuroticism or trait anxiety. This has been defined as a general predisposition to experience a broad spectrum of negative emotions and to respond fearfully to a wide range of stressors (Matthews & Deary, 1998). Neuroticism/trait anxiety has been found to be elevated in IBS and to be higher than in healthy controls (Gick & Thompson, 1997; Talley, Boyce, & Jones, 1998). When compared to patient groups (e.g. IBD), the findings are mixed with some studies suggesting that IBS patients have higher neuroticism/trait anxiety (Esler & Goulston, 1973; Smith et al., 1990) and others suggesting no differences at all (Bleijenberg & Fennis, 1989; Schwarz et al., 1993). The role of neuroticism/trait anxiety has not however, been firmly established as a good predictor of IBS related outcomes. Talley, Boyce, & Jones (1997) found no influence of neuroticism scores on patients seeking health care in a community sample. Gick & Thompson (1997) also observed that trait anxiety scores were no different between students with IBS consulting for their problem and students with IBS not consulting. Both Hazlett-Stevens (2003) and Labus et al. (2007) also found that neuroticism was not a significant predictor of IBS status or symptom severity.

Another possible personality trait suggested to play a key role in IBS is anxiety sensitivity. This has been defined as an inherent predisposition characterized by a person's tendency to fear anxiety-related symptoms (e.g. increased heart rate, sweating, muscle tension, headaches) due to the belief that these sensations will bring about some form of harmful physical, social or psychological consequences (Taylor & Cox, 1998). This concept is clearly distinct from trait anxiety as it refers to a tendency to respond fearfully to the interoceptive sensations of anxiety rather than the predisposition to respond anxiously to a wide range of stressors. In agreement with this notion, Norton et al. (1999) found anxiety sensitivity to be predictive of the presence of functional gastrointestinal disorders in a university student sample.

With the emergence of the biopsychosocial model of IBS (Drossman et al., 1999) it was suggested that anxiety sensitivity could in fact be specific to gastrointestinal symptoms (Mayer et al., 2001). The concept of GI specific anxiety (GSA) can be defined as the collection of cognitive, affective and behavioural responses that arise

from the fear of GI symptoms, sensations or the context in which these occur (Labus et al., 2007). Dimensions of GSA would include increased vigilance to, excessive worry and fear of GI symptoms, sensations or contexts in which these might arise (e.g. situations involving food and eating, situations in which the location of toilet facilities is unknown or difficult to access), a heightened perception of GI sensations, and avoidance of GI anxiety related contexts (Labus et al., 2004; Labus et al., 2007). It was initially hypothesized by Mayer et al. (2001) that GSA would be an important endogenous stressor that perpetuated IBS symptoms through alterations in autonomic and neuroendocrine responses even in the absence of external stressors. The association of GSA with distressing beliefs about poor symptom control and high impact on daily function were also suggested to have an influence in the perception of decreased quality of life in IBS patients (Gralnek et al., 2000). Several studies have confirmed the preponderant role of GSA in IBS. Hazlett-Stevens et al., (2003) found GSA to be the only significant predictor of IBS status in a large student population (n=1021) when compared to measures of neuroticism and trait anxiety. In two separate studies Labus et al. (2004 & 2007) showed that GSA not only predicted IBS status, but it also was a significant predictor for symptom severity and quality of life. The same studies also showed that GSA was a mediator of the relationship between neuroticism and anxiety symptoms and IBS symptom severity. The latter study also showed that a measure of GSA (Visceral Sensitivity Index) discriminated between IBS and non IBS controls. More recently Jerndal et al. (2010) also found GSA to be one of the strongest predictors of symptom severity, and to be associated with quality of life in IBS patients.

In summary, particular personality traits like neuroticism and trait anxiety have not been consistently shown to predict outcomes in IBS. However the development of specific constructs such as GSA have been shown to specifically predict or influence a range of outcomes in the IBS population.

2.6.6. Coping Behaviours

It has long been noted that IBS patients have distinct behavioural responses to their illness. In early works several authors highlight, excessive consultation for GI and non GI symptoms (Kingham & Dawson, 1985; Whitehead et al., 1982), an abnormal lifestyle (Johnsen, Jacobsen, & Førde, 1986) or a tendency to avoid certain situations or foods (Bleijenberg & Fennis, 1989). According to the biopsychosocial model (Drossman et al., 1999), these types of behaviours could be seen as part of the coping strategies IBS patients employ to try to deal with their illness. Coping behaviours are defined as the behavioural efforts taken by the individual to bring a state of harmony between specific external or internal demands (Folkman & Lazarus, 1988). In IBS, these behaviours can therefore be seen as the actions a person takes in response to their symptoms, to external stressors and to the internal interpretation they make of these experiences, with the aim of maintaining some form of psychosomatic homeostasis. As Whitehead et al. (1992) point out; it seems that the difference between IBS and healthy individuals is not in the amount of distress caused by symptoms or life events, but in how they react to it.

With over 140 studies carried out, excessive consultation behaviour has received a great deal of attention due to its impact in the use of human (physicians time) and economic (tests and investigations) resources. Several studies have looked at the possible factors that influence this type of behaviour and seem to confirm a biopsychosocial influence. In a comprehensive review of the literature Koloski, Talley, & Boyce (2001) suggest that although symptom severity (in particular abdominal pain/discomfort) is a significant predictor of health care seeking behaviour, it only partly explains this behaviour. The authors highlight that when compared with IBS patients who do not seek health care, IBS consulters tend to have increased life event stress, more psychological morbidity, abuse history and abnormal illness beliefs. More recently Perveen et al. (2009) have proposed that a high number of dyspeptic symptoms predicted consultation over a period of 12 months. They did not, however control for any psychosocial variables. Dyspeptic symptoms had also been proposed to be a significant predictive factor in a 10 year

prospective study by Ford et al. (2008), however baseline quality of life was also found to contribute to the prediction of consultation behaviour. Ringström et al. (2007) found no differences in symptom severity between consulters and non-consulters in a cross sectional study, however consulters were shown to have poorer Quality of life, more severe psychological symptoms, higher GSA and poorer coping than non-consulters. Some of the reasons non-consulters in this study gave for their behaviour was that they perceived their symptoms as being mild and controlled, and that they preferred to seek help with alternative care or friends/family. Several authors also highlight the specific cognitive factor of concern about the possible serious nature of the patients concern as a significant predictor of health seeking behaviour (Kettel, Jones, & Lydeard, 1992; Dulmen et al., 1996 b; van der Horst et al., 1998). No study has indicated any net benefit to IBS patients from continuous consultation behaviour, and many point this as one of the biggest burdens on health associated costs (e.g. Pen et al., 2004).

Coping strategies in general have also received some attention regarding their association with IBS or their ability to moderate or predict outcomes in IBS. In a study looking at jejunal motor activity Evans et al. (1996) found that a more infrequent use of mature coping strategies and the use of anger suppression significantly predicted motor dysfunction. Several studies have also looked at the role of catastrophizing in IBS with this strategy being linked to previous abuse (Drossman, 1997), pain severity (Lackner, Quigley, & Blanchard, 2004), and being a significant predictor of quality of life (Seres et al., 2008). Both Fujii & Nomura (2008) and Pellissier et al. (2010) have found that IBS patients tend to use a more task oriented or problem solving type of coping.

However, the coping strategy that seems to appear more consistently found is avoidance. Several types of avoidant behaviour have been identified, mainly through qualitative studies. In the studies of Drossman et al. (2009), Kennedy, Robinson, & Rogers (2003), Rønnevig, Vandvik, & Bergbom (2009) and Schneider & Fletcher (2008) the following avoidance behaviours were reported by patients attending focus groups, or responding to individualized semi-structured interviews. Most of them

displayed avoidance behaviours surrounding food. Some avoided foods that they considered to be triggers for their symptoms (e.g. high fat foods, dairies); some avoided eating food outside the house (e.g. at a restaurant); some avoided eating altogether before a particular event (e.g. before a meeting); and a few reduced their intake to an absolute minimum. Many avoided social situations (e.g. going out to a friend's house); work related situations (e.g. meetings); leisure situations (e.g. going to a gym); any type of food related situations (e.g. parties) or situations in which a toilet would not be available (e.g. travelling). Some people avoided intimate contact (e.g. sexual intercourse) or any type of personal relation that would lead to the disclosure of their situation (e.g. close friendships). Almost all patients exhibited excessive planning prior to some situations in order to avoid feelings of anticipatory anxiety or fear of loss of control. Some of this planning behaviour would include inquiring about the locations of bathrooms ahead of time, carrying extra medication or an extra change of clothes, or planning routes that passed through "safe places" where they would be able to access a toilet. Although most patients identified these behaviours as necessary to the management of their condition, they also identified them as being the most problematic in their lives and to have severe costs on their quality of life. This was probably due to the fact that IBS patients have a tendency to maintain these avoidance behaviours even in the absence of active symptoms, as described by Corney & Stanton (1990). The maintenance of avoidance behaviours might therefore seem to be adaptive to these patients on the short-term as they deal with the immediate nature of the difficult experiences of symptoms, thoughts and emotions; however they become quite maladaptive in the long-term since the symptoms are of a benign nature and the discontinuation of normal activities will bring little to no benefit. In fact avoidance behaviours might actually worsen symptoms through physical deconditioning. Crane & Martin's (2004b) study suggests that an avoidant type of coping behaviour might be a characteristic learned from parental reinforcement in IBS patients and is a distinctive feature when comparing with IBD patients. In 2 studies, (Rutter & Rutter, 2002; Rutter & Rutter, 2007), avoidant coping was shown to mediate the links between illness representations and quality of life, while having a direct effect on anxiety and depression. Recently, a study has also shown that a lesser use of avoidant coping at the beginning of

psychotherapy (Cognitive Behavioural Therapy) is a good predictor of better work and social adjustment 12 months later (Reme et al., 2010).

In summary, IBS patients could be characterized by an excessive use of consultation and maladaptive coping behaviours, in particular avoidance. These behaviours seem to be a response to the symptoms of the illness and to contextual factors; however the use of these behaviours does not seem to be associated with any benefits for the patient and might actually impact on its outcomes.

2.6.7. Outcomes

Both economic costs and quality of Life stand out in IBS literature as being, beyond symptoms, the two most important outcomes to take into consideration in an individual's (and society's) approach to this illness.

2.6.7.1. Economic costs

By affecting primarily people during their productive working age, IBS imposes a substantial burden in terms of economic costs (Olden, 2002). The total economic cost of IBS can be divided into two main categories: direct and indirect costs. Direct costs relate for example to resource consumption for inpatient and outpatient care, diagnostic and therapeutic procedures, laboratory tests and rehabilitation. Indirect costs are more related to the consequence an illness has on work absenteeism, earning capability, long-term disability or changes to employment type (Maxion-Bergemann et al., 2006).

In the US direct costs attributable to IBS have been estimated to be as high a \$10 billion per year, with indirect costs in loss of productivity estimated to be as high as \$20 billion, although these figures are said to be underestimated since they are based on patients who sought medical attention (Cash, Sullivan, & Barghout, 2005). In a recent review of the direct and indirect costs of IBS in the UK, Maxion-Bergemann et al., (2006) place direct costs per year of IBS patients to the NHS to range from \$84.5 million to \$358 million. According to the same authors, the individual direct

cost of an IBS patient would be between \$348 and \$2013. They have also reported the indirect individual costs to range from \$355 to \$3344.

Another type of cost not usually reported refers to out-of-pocket expenses for IBS therapy (e.g. over the counter drugs, alternative therapies). In a rare study concerning these types of costs, Wilson et al., (2002) report that over a period of 3 months, 79% of their sample spent money on over the counter drugs, and 40% spent money in alternative therapies, averaging \$US258.

IBS patients are estimated to take between 8.5 to 21.6 days off work per year (Maxion-Bergemann et al., 2006), and are likely to take an excess of 0.2 more days off work during a 3 month period when compared to non-IBS controls (other GP attenders) (Akehurst et al., 2002). Dean et al. (2005) have also shown that IBS is associated with a 21% reduction in overall work productivity, with IBS patients working an equivalent to less than 4 days in a 5 day workweek. So even when present at work, IBS patients tended to be less productive when compared to controls.

Economic costs, direct or indirect are difficult to ascertain and several factors contribute to the range of values found in the different studies. Maxion-Bergemann et al., (2006) note that age, consultation behaviour, co-morbidity or symptom severity, methods of data collection or the way IBS diagnosis is established all contribute to great variation in the estimation of costs in this illness. Independently of these limitations, most studies agree with the principle that the IBS burden in terms of economic costs is considerable and that measures need to be taken to address this.

2.6.7.2. Quality of Life

Although IBS is not a life threatening condition, its clinical course has a tendency to be chronic and to impact on several domains of a patient's life (Jones et al., 2000). It has been recognized that in IBS, Quality of Life (QoL) is an important outcome (e.g. Amouretti et al., 2006) since measuring symptoms alone may present an incomplete

measure of patient's overall well being, impact of illness on daily functioning and how they respond to therapeutic interventions (El-Serag, Olden, & Bjorkman, 2002). The World Health Organization (WHO) as defined health as being more than just the "absence of disease or infirmity" (WHO, 1952) and QoL as being "the 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 and concerns" (WHO, 1998). Health Related Quality of Life (HRQoL) seeks therefore to encompass both emotional and social dimensions of the patient's illness as well as physical function.

Three types of measurements have been used to assess HRQoL in IBS; global assessments, generic instruments and illness specific instruments. Global assessments are quite general and consist normally of a single question (e.g. "How do you rate your quality of life?") answered on a multiple choice format (e.g. good, fair, poor) or on a visual analogue scale. These types of assessments are considered poor due to the complexity of the disease and have been replaced by generic or disease specific measures since the 1990's. Generic instruments are usually composed of multiple general questions that are not specific to any disease and allow for a comparison along a broad spectrum of diseases (El-Serag, Olden, & Bjorkman, 2002). One of the most used generic measurements in IBS is the Medical Outcomes Study Short Form 36 (SF-36) that assesses the following domains in HRQoL: physical functioning, role function, bodily pain, general health, vitality, social functioning, emotional and mental health (Ware, 1996). However some authors have recently argued that shorter measures like the EuroQol 5 items (EQ-5D) (Bushnell, Martin, & Bracco, 2006) or the Centre for Disease Control HRQOL-4 items (CDC-HRQOL4) (Lackner et al., 2006) perform just as well in assessing general HRQoL when compared to larger generic or disease specific measures. Finally, disease-specific instruments are developed to detect changes in HRQoL taking into account specific manifestations of a certain disorder and are primarily used in treatment studies or studies comparing subgroups of a disorder (Lea & Whorwell, 2001). Examples of these disease specific measures are the IBS-QOL (Patrick, Drossman, & Frederick, 1998) or the IBS36 (Groll et al., 2002).

Several studies have looked at the differences in HRQoL between IBS patients and healthy controls, with most of them showing that HRQoL is significantly reduced in IBS patients (El-Serag, Olden, & Bjorkman, 2002). Whitehead et al.'s (1996) population based study was one of the first high quality studies to show that IBS patients had worse HRQoL (as measured by the SF-36) than IBS non-patients (people with IBS identified by a symptom questionnaire who are not currently seeking medical care) and healthy controls. Several other studies have shown as well that IBS patients score lower on both physical and mental composites of HRQoL than healthy controls or when compared to the normative score of the general population (e.g. Halder et al., 2004; Portincasa et al., 2003). Some studies reported no differences between IBS patients and healthy controls (Hahn et al., 1997 a; O'Keefe et al., 1995), however these studies had severe limitations (e.g. small sample sizes). It is therefore generally accepted that IBS has a significant negative effect on quality of life when compared to a healthy state (Spiller et al., 2007).

When compared to other disease groups IBS patients also tend to exhibit a lower HRQoL in some cases. Frank et al. (2002) and Gralnek et al. (2000) found that IBS patients' scores on most SF-36 domains were lower than in patients with gastro-oesophageal reflux disease (GERD), type 2 diabetes, end stage renal disease (ESRD), asthma and chronic migraine. However the same authors report that HRQoL in IBS patients was similar to those with dyspepsia, or better than those with depression, panic disorder and rheumatoid arthritis. It should be noted that all these comparisons were made between IBS patients recruited for these studies and previously published scores for the other populations. When compared with IBD (e.g. Chron's disease, ulcerative colitis) IBS patients seem to score similarly in HRQoL measures with better outcomes in the physical components as demonstrated, for example, by the studies of Pace et al. (2003) and more recently Tkalčić, Hauser, & Stimac (2009). Drossman et al. (2007) also did not find any differences in HRQoL between IBS and other functional bowel disorders (e.g. chronic functional constipation).

When compared amongst themselves, IBS patients also exhibit some differences according to their characteristics. Several studies report a predominance of poorer

HRQoL in female patients (e.g. Amouretti et al., 2006; Faresjo et al., 2006; Simren et al., 2001). There also seems to be a difference between patients seen in primary care and those seen in secondary/tertiary care with the latter having a more severe impact on their HRQoL (Simren et al., 2001). Cultural differences have also been reported in HRQoL for IBS patients with Hahn, Yan, & Strassels, (1999) reporting more impact on quality of life in UK patients than US patients. A similar cultural difference was reported by Faresjo et al. (2006), between Swedish and Cretan samples, with the Swedish patients having better HRQoL. Also of interest are comparisons of HRQoL between the different bowel predominant patterns in IBS patients. In El-Serag, Olden, & Bjorkman's, (2002) review, the authors highlight 3 studies, in Sweden (Simren et al., 2001), UK (Creed et al., 2001) and US (Schmulson et al., 1999) where no differences were found in HRQoL between IBS patients with a constipation predominant bowel (IBS-C) habit and patients with a diarrhoea predominant bowel habit (IBS-D). More recently Tillisch et al. (2005) and Drossman et al. (2007) have also found no differences between IBS subtypes while also comparing for alternating bowel habit. Therefore, predominant bowel habit does not seem to affect the degree of impact of the disease on HRQoL.

As HRQoL has taken its place as one of the main outcomes to be studied in IBS, many studies have looked into what are the factors that are associated or predict a better HRQoL in IBS. Spiegel et al. (2004) found HRQoL, as measured by the SF-36, to be better predicted by factors not associated with symptoms (e.g. number of medical visits, fatigue, anxiousness or difficult cognitions “there is something seriously wrong with my body”) than by the gastrointestinal symptoms of IBS. The authors note as well that factors like age, length of illness or gender did not contribute to the prediction of any of the HRQoL composites (physical or mental). A more recent study by Lee et al. (2008) looked at predictors for both generic HRQoL and disease specific HRQoL. The authors found that the severity of psychological distress, symptom severity, abdominal pain and employment were the best predictors of generic physical HRQoL. For the generic mental HRQoL composite, psychological distress and neuroticism were considered to be the best predictors. Regarding the overall disease specific HRQoL, psychological distress was again the

best predictor, followed by symptom duration, severity of symptoms and neuroticism. Finally (Jerndal et al., 2010) found that GSA, general anxiety, depression, age and socioeconomic status independently predicted mental HRQoL, while the physical composite was better predicted by symptom severity and comorbidity with other functional GI diagnoses. These studies present some contradictory evidence to the contributions of certain factors like length of illness or age, however it seems that both psychological factors and symptom severity seem to play an important role in the perception of QoL by IBS patients and should be taken into account by physicians in their approach to the treatment of IBS (Spiller et al., 2007).

Finally, Simren et al. (2004) remind us that nowadays it is almost compulsory to include a measure of QoL as a main outcome in any treatment study while Lea & Whorwell (2001) advocate the use of both generic and disease specific measures for these types of studies. Some details of the efficacy of treatments to change HRQoL scores in IBS will be reviewed in the IBS management sections.

2.7. CURRENT APPROACHES TO THE MANAGEMENT OF IBS

Although the previously reviewed studies have established the contribution of biological, psychological and social factors to the presentation of the different forms of IBS, the precise pathophysiology of this complex illness is still unknown. This has meant that the current goal of treatments in IBS focus primarily on symptom management and attempts to improve quality of life (Grundmann & Yoon, 2010). Therefore, after a positive diagnosis has been made, several treatment avenues are at the disposal of physicians with lifestyle and dietary management, pharmacological treatments, and psychological interventions as the most used and recommended (Grundmann & Yoon, 2010; Spiller et al., 2007).

The following figure (Figure 2.2) presents an adapted flow chart of care resulting from a consensus between the recommendations of the British Society of Gastroenterology (Spiller et al., 2007), the National Institute for Health and Clinical

Excellence (NHS/NICE, 2008) and the American College of Gastroenterology (Brandt et al., 2009). These approaches are not mutually exclusive and can at some points be used in conjunction with one another.

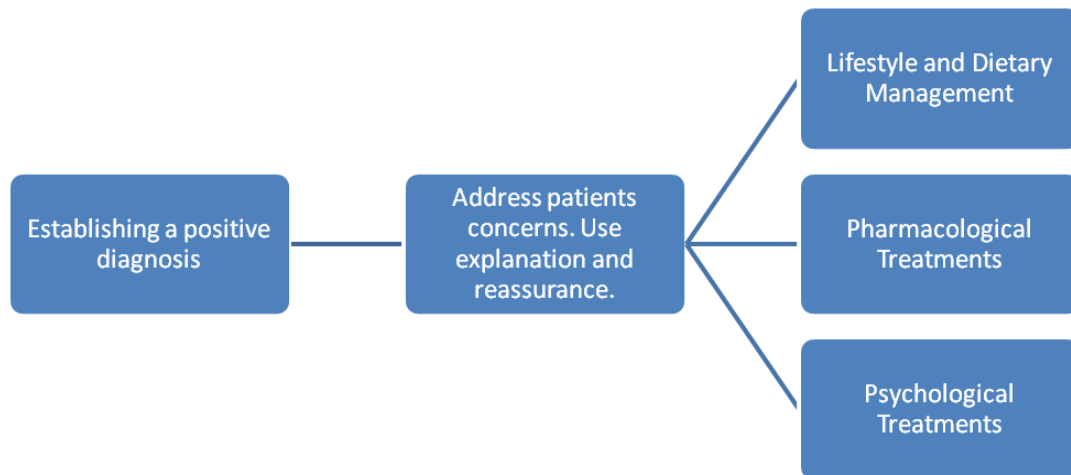


Figure 2.2: Flowchart of care in IBS

2.7.1. Explanation/Addressing patients concerns

The patients' perception of their own disease is an important factor that should be addressed by the physician after the diagnosis of IBS is made. Lack of knowledge or an unclear diagnosis is sometimes associated with poorer outcome or with difficulties in the implementation of treatment (Lacy et al., 2007). It is therefore important for a physician to clearly explain the diagnostic process, and to address the patients' own explanatory model so that future treatment or investigative procedures match the patients' disease perceptions and expectations (Casiday et al., 2009).

It is also important to address patients' concerns regarding IBS, with particular emphasis to whether it poses a risk for the development of a life threatening illness (e.g. cancer). Schmulson et al. (2006) have found that a single session of reassurance, in which the diagnosis of IBS was thoroughly explained and fear of cancer

misconceptions were directly addressed, was effective at improving patients' perception of daily impairment. However, many patients and clinicians feel uneasy with the possibility of an alternative diagnosis to have been ignored or overlooked, prompting the use of supplementary diagnosis procedures like colonoscopy to address these concerns. This is in fact so common, that a population based survey found that up to 50% of IBS patients receive a colonoscopy during the course of their diagnostic evaluation (Yawn et al., 2001). Although common, these types of diagnostic procedures have been found by Spiegel et al. (2005) to have no impact on improving patients' sense of reassurance or their perceived HRQoL.

Education about the diagnostic procedure and a positive physician-patient relationship characterized by a more in depth addressing of patients concerns in consultation (rather than by extensive investigative procedures use) are therefore considered to be the cornerstone for a good outcome (Hammerle & Surawicz, 2008).

2.7.2. Lifestyle and Dietary Management

Before considering pharmacological treatment, physicians are encouraged to propose an initial management plan based on relatively simple lifestyle and/or dietary changes (Grundmann & Yoon, 2010; NHS/NICE, 2008).

One of the key lifestyle changes to be firstly considered is to encourage the patient to engage in regular exercise, especially those patients who seem to have reduced their activity levels (NHS/NICE, 2008). Although this seems like a logical approach, little is known about the efficacy of this type of recommendation. Simrén (2002) reports in his review, that physical activity can have both beneficial and harmful effects on the gastrointestinal tract by inducing changes in gastrointestinal blood flow, motility and neuroendocrinology. In a recent study, Daley et al. (2008) found that physical exercise was mainly beneficial for constipation related symptoms and for the improvement of general HRQoL.

Another lifestyle recommendation concerns the encouragement for the patients to

identify and make the most of their leisure time while trying to reduce their overall stress levels (NHS/NICE, 2008). However, little research has been conducted on this subject, with most studies incorporating a general lifestyle advice for reduction of stress that is either not consistently defined or that is presented to the patient without a plan of how to put it in practice. Kennedy, Robinson, & Rogers (2003) highlight in their study the perspective of some patients who feel that they are given little to no constructive help by their physicians on how to manage their stress.

Lifestyle changes are also commonly linked with dietary management, with IBS patients being recommended to take time to have regular meals and to avoid missing a meal or leaving too much time between meals. Some foods or products are also generally recommended to be avoided, like caffeinated or alcoholic drinks and high fat foods like chocolate or rich meats (NHS/NICE, 2008). No studies have looked at the specific effect of these recommendations for IBS; they are usually considered as part of a group of strategies that are geared towards general health improvement, and therefore considered to be of low risk of harm to the patient, with potential net benefit.

Dietary management options follow essentially two main approaches: alterations of fibre intake and trigger food product exclusion.

A change in daily fibre intake is one of the most common recommendations for IBS patients, although the evidence to support this recommendation is scarce and mixed (Spiller et al., 2007). It is proposed that fibre helps the stool to hold more water, enhances gel formation to provide lubrication, improves bulking and the binding of agents such as bile (Friedman, 1991). First line recommendations are for patients to increase their intake of fibre via dietary changes, by consuming more insoluble (e.g. cereal bran) or soluble fibres (e.g. fruit) and if this is not achievable then supplements such as psyllium (Isphagula husk), sterculia or methyl cellulose can be prescribed (Spiller et al., 2007). A survey study by Francis & Whorwell (1994) showed that in around 55% of cases, bran consumption actually aggravates IBS symptoms with only 10 % of responders reporting any type of improvement. A more recent study has

shown that bran or soluble fibre consumption was beneficial for 27% of primary care and only 10% of secondary care patients while it exacerbated the symptoms in 22% of primary care and 55% secondary care patients (Miller et al., 2006). In a review of 17 clinical trials of fibre use in the treatment of IBS Bijkerk et al. (2004) concluded that fibre had a marginal benefit and that insoluble fibre in particular was more likely to make symptoms worse. It is therefore recommended that there is a trial period of fibre supplementation or fibre exclusion, with a later re-evaluation to assess the benefits of this type of intervention (Spiller et al., 2007).

Trigger food product exclusion follows the logic that patients should avoid food products or food groups (e.g. dairy foods) that they consider to be triggers to their symptoms. The identification of such trigger foods is usually done via the use of a food diary (Fernández-Bañares, 2006) although the only way to robustly identify a food intolerance is by doing a double blind food challenge, and this is an expensive and time consuming process (Spiller et al., 2007). There is also an added confounding factor that some patients experience symptoms as a response to the consumption of any type of food (Hadley & Gaarder, 2005). A systematic review of 7 studies has found the response rates to dietary exclusion approach were too variable and therefore this approach is not recommended for routine use (Niec, Frankum, & Talley, 1998). However, dietary exclusion is still one of the hallmark management approaches used by physicians and has improved somewhat since the previously mentioned review. The measurement of IgC antibodies as shown promise by successfully guiding physicians in their recommendations on which foods to be eliminated (e.g. Zar, Benson, & Kumar, 2005). The quality of evidence for dietary exclusion as a whole is still considered to be low (Spiller et al., 2007) and in some cases it might promote an exacerbation of food avoidance behaviours to the point of some IBS patients displaying behaviour comparable to that of persons diagnosed with eating disorders (Sullivan et al., 1997).

In summary, although lifestyle and dietary management have limited efficacy in IBS in general, their safety and general health net benefits seem to justify their inclusion as a first line of management.

2.7.3. Pharmacological Treatments

Pharmacological therapy is a second line of treatment which is recommended (depending on the severity of symptoms) to be used in conjunction with lifestyle and dietary changes (NHS/NICE, 2008). Several pharmacological agents have been tried with mixed results, however the high rate of placebo-response is commonly found as a confounder for many studies evaluating the efficacy of these agents (Spiller et al., 2007).

2.7.3.1. Antispasmodic agents

Antispasmodic agents function is to attenuate pain and bloating caused by heightened smooth muscle contractions in the gut by blocking the effects of acetylcholine (Poynard, Regimbeau, & Benhamou, 2001). Agents like mebeverine and hyoscine have been show to have some efficacy, to be well tolerated and are recommended to be used with IBS patients (in particular diarrhoea predominant patients) (NHS/NICE, 2008; Spiller et al., 2007).

2.7.3.2. Fibre and Laxatives

Fibre and laxatives are commonly used when constipation is present and are thought to increase faecal mass and accelerate transit (Spiller et al., 2007). Fibre supplements such as isphagula husk, sterculia and methyl cellulose have been shown to benefit constipation symptoms, although not pain symptoms in IBS (Bijkerk et al., 2004) and are generally recommended (NHS/NICE, 2008). Some other forms of laxatives like lactulose (stimulant laxative) are associated with tachyphylaxis² and dependency and its use is discouraged (NHS/NICE, 2008; Spiller et al., 2007).

2.7.3.3. Antidiarrhoeal agents

For patients with diarrhoea predominant IBS, guidelines favour the prescription of loperamide and diphenoxylate as antidiarrhoeal agents (NHS/NICE, 2008; Spiller et al., 2007). The substances are opioid analogues that enhance absorption of water and

² tachyphylaxis -rapidly decreasing response to a drug or physiologically active agent after administration of a few doses

ions, increase resting anal sphincter tone, and slow transit time in the gut by acting on the longitudinal muscle of the intestine. This action reduces the frequency of defecation and helps the stool to be more consistent and less watery (Camilleri et al., 2006; Spiller et al., 2007). Loperamide is very effective in reducing diarrhoea in IBS patients, although it does not have an impact on pain/discomfort symptoms (Sellin, 2007). Over the 2 substances, loperamide is preferred as it has fewer side effects (Spiller et al., 2007).

2.7.3.4. Antidepressants

Antidepressants such as tricyclic (e.g. amitriptyline, paroxetine) or serotonin reuptake inhibitors (SSRIs) are usually considered as a second line of treatment in IBS when pain is the predominant symptom or when patients have not responded to the antidiarrhoeal/antispasmodic/laxative treatments (Morgan et al., 2005; NHS/NICE, 2008). Tricyclic antidepressants (TCAs) benefit seems to be associated with features of pain and it works better for patients with diarrhoea predominant IBS. The common occurrence of several side effects (constipation, dry mouth, drowsiness and fatigue) and recent studies that show no benefit in an intent-to-treat analysis (Drossman, et al., 2003 b) make the use of TCAs less attractive. As alternatives, SSRIs seem to be much better tolerated and have been shown to improve HRQoL in treatment resistant IBS patients (Tack et al., 2006). However, the benefit of SSRIs seems to be general and specific symptoms have not shown to improve significantly (e.g. Kuiken, Tytgat, & Boeckxstaens, 2003), suggesting that the general improvement comes from the antidepressant addressing co-morbid depression or anxiety.

2.7.3.5. Serotonin receptor agonists/antagonists

Recent attention has been paid to the use of 5HT₃ receptor antagonists (Alosetron) and 5HT₄ receptor agonists (Tegaserod) in IBS. Alosetron slows down gastrointestinal transit and reduces visceral sensation and has been shown to be effective in the relief of abdominal pain and discomfort, and with improvements in bowel frequency, consistency and feelings of urgency in diarrhoea predominant IBS

patients (Ford et al., 2009; Spiller et al., 2007). However there are still a lack of extended use studies and several dangerous side effects caused a previous temporary withdrawal of this drug from the US market (Spiller et al., 2007). Tegaserod enhances gastrointestinal propulsion and has been shown to be quite effective in improving bowel frequency, HRQoL, work absenteeism and activity impairment (Ford et al., 2009). However this drug has been restricted in some countries due to concerns with safety, and there is a general consensus that more studies are needed (Spiller et al., 2007).

2.7.3.6. Probiotics

Probiotics are defined as “live organisms that when ingested in an adequate amount, exert a health benefit to the host” (Quigley, 2008). The use of probiotics is still controversial, mainly due to a lack of quality studies. Two recent meta-analyses (Mcfarland & Dublin, 2008; Nikfar et al., 2008) concluded that probiotics could be useful in IBS, however the authors note that the studies present great variability in the type, dose or formulation of the probiotic agents used; different outcomes were measured and the IBS population characteristics were too diverse as well. A recent large, randomized, placebo controlled study (Drouault-Holowacz, Bieuvelet, & Burckel, 2008), found probiotics to not be better than placebo at relieving IBS symptoms.

2.7.3.7. Other agents

Many other agents have also been tried, such as herbal preparations, immunodepressive agents or peppermint oil just to name a few. Immunodepressive agents have not shown great promise and herbal preparations seem to improve symptoms, although the active ingredient is not known and the studies performed have not included a placebo control (Spiller et al., 2007). Peppermint Oil has been shown to have relaxing effects on gastrointestinal smooth muscle by blocking the Ca^{2+} ion channels in the gut and has been the most reliably studied of these alternative agents (Merat et al., 2010). Recent studies have shown that peppermint oil capsules are better than placebo at improving IBS symptoms and HRQoL, with no

adverse effects (Cappello et al., 2007; Merat et al., 2010). Currently Peppermint Oil is still not part of the treatment guidelines for IBS in the UK (Ford et al., 2008) and its effectiveness is still described as only probable (Heizer, Southern, & McGovern, 2009).

2.7.4. Psychological Management

Several studies and reviews have highlighted the limited efficacy of conventional medical treatment (i.e. pharmacological) in providing adequate relief for IBS patients, therefore alternative approaches to care have been considered and investigated (Zijdenbos et al., 2009). Also, the emergence of a myriad of studies that link IBS with psychological co-morbidities (e.g. anxiety, depression) or psychological characteristics (e.g. illness beliefs, GSA) has prompted the research of psychological treatments as an alternative or complement to standard care in IBS (Spiller et al., 2007).

Most forms of psychological therapies studied have been shown to be helpful in reducing symptoms, improving psychological components of anxiety and depression and to improve HRQoL (Ford et al., 2009; Spiller et al., 2007; Zijdenbos et al., 2009). The success of psychological therapies for IBS global outcomes has seen it being implemented as a standard adjunctive treatment in the UK. According to current NICE/NHS (2008) guidelines, physicians should consider referral for psychological treatment in patients who do not respond to pharmacotherapy for a period of 12 months and develop a continuing symptom profile (described as refractory IBS).

The most studied and used forms of psychological treatment for IBS have been relaxation training, brief psychodynamic psychotherapy, cognitive behavioural therapy (CBT), hypnotherapy and several forms of self-help. These forms of treatment have been used both in individual and group settings and are thought to be acceptable to patients, especially those who identify psychological factors as triggers for their IBS (Naliboff, Frese, & Rapgay, 2008). Recent reviews and meta-analyses

recognize that psychological therapies seem to be superior to usual care and comparable to antidepressants in efficacy, however a lack of high quality studies with adequate outcomes, power, methodology or follow-ups has limited the strength of recommendation for the use of these approaches (Ford et al., 2009; Zijdenbos et al., 2009).

2.7.4.1. Relaxation training

The rationale behind relaxation training as an intervention for IBS lies in the assumption that stress is inherently related to the IBS symptoms and that by inducing relaxation, stress and emotional tension will reduce, as well as IBS symptoms.

In an early study with 16 patients Blanchard et al. (1993) found that 50% of the patients receiving 8 instruction sessions on progressive muscle relaxation plus additional home training with an audiotape (n=8), had less symptom severity at the end of treatment (8 weeks) than patients who were only monitoring their symptoms.

In a later study, Keefer & Blanchard (2001) tested a relaxation response meditation programme (6 x 30 minute's sessions) with 16 patients. Half of the patients were randomly assigned to the programme and the other half was assigned to a waiting list control after which they received the same treatment. The meditation group was shown to have had significant improvements in IBS symptoms at the end of treatment and at 3 month follow-up when compared to the control group. A one year follow-up on this study revealed that the symptoms reduction had been sustained on the long-term (Keefer & Blanchard, 2002). Although quite promising, these studies have been criticized for the low number of participants and the recruitment methods.

More recent studies have found contrasting evidence for the use of relaxation training. In a large randomized control trial Boyce et al. (2003) found no significant differences in outcome improvement (symptoms, anxiety, depression and functioning) between patients receiving relaxation training, CBT and standard care at post-treatment and at 1 year follow-up. On the other hand, van Der Veek, Van Rood,

& Masclee (2007) found that 4 sessions of relaxation training in a group format significantly improved symptom severity, HRQoL and reduced medical consumption in 52 patients when compared to 46 patients receiving standard care alone.

Finally, a new form of relaxation training, called functional relaxation (FC) has also shown promise in IBS with Lahmann et al (2010) reporting that impairment and severity were significantly reduced at 3 month follow-up in a group of 39 patients receiving a 5 week FC course when compared to 39 patients receiving enhanced medical care (treatment as usual plus two counselling interviews). This last study has the flaw of not having used any validated outcome measure.

2.7.4.2. Brief psychodynamic psychotherapy

In brief psychodynamic psychotherapy for IBS the therapist tries to help the patient to explore the links between his/her symptoms and emotional or interpersonal conflicts. The expectation is that by gaining insight on these connections, the patient will change his/her behaviours in a healthy direction so that the symptoms are ameliorated (Guthrie, 1991).

In an early study Svedlund et al. (1983) randomized 101 patients into either medical treatment alone or medical treatment plus 10 one-hour sessions of individual psychodynamic therapy over a period of 3 months. At 3 months follow-up the therapy group had shown significant improvement in somatic complaints when compared with the medical treatment alone group. At 15 month follow-up the psychotherapy group continued to improve while the medical treatment group showed some deterioration. However medical treatment was as effective in improving mental wellbeing as psychotherapy.

Guthrie et al. (1991) found that adding psychodynamic therapy to medication resulted in greater improvement of pain and diarrhoea when compared to medication alone (this group received equivalent contact time with the therapist in which symptoms were reviewed and discussed). The authors also reported an association

between the reduction in symptoms and a reduction in psychological distress.

However, in a recent large trial with 257 patients, Creed et al. (2003) found no differences in symptom improvement between a medication (antidepressant), medication plus 8 sessions of psychodynamic therapy and standard medical care at 3 months follow-up. Both medication and medication plus therapy were associated with greater improvements in physical HRQoL, however there were no significant differences between these groups and standard care for improvements in mental HRQoL. The only outcome in which psychotherapy distinguished itself was that it was associated with a lower consultation rate in the year following the intervention.

Brief psychodynamic therapy, although apparently beneficial for IBS poses many problems. Its length (3-4 hour initial consultation followed by 10-12 one hour sessions) and delivery style (individual) pose great costs in terms of human resources and might be less cost effective than other approaches. Also, this type of approach is heavily dependent on the characteristics of the therapist and the strength of the therapeutic alliance making it harder to generalize. Finally, most of the studies seem to suggest that curiously this psychologically oriented approach is no more effective than standard medical care (Svedlund et al., 1983) or medication (Creed et al., 2003) at improving mental wellbeing.

2.7.4.3. Cognitive Behavioural Therapy

In Cognitive behaviour therapy (CBT) for IBS it is assumed that the symptoms the patient experiences are part of a response to stressful life events or daily hassles, and that particular distorted cognitions (or misinterpretations) lead to maladaptive behaviour, which in turn further aggravates the symptoms and / or how they are responded to (Spiller et al., 2007). Typical CBT treatment packages include an educational component based on the biopsychosocial model, followed by the patient's exploration of the connections between, emotions, thoughts, physical sensations and behaviours, through the use of diaries. Patterns of distorted thoughts that are related to or influence the patient's behaviours and symptoms are then

identified with the help of the therapist and modified by logical analysis or empirical hypothesis testing (cognitive part of the therapy). The patient is then trained in using relaxation techniques and encouraged to re-engage with previously avoided activities or food (behavioural part of the therapy). The patient is asked to try to modify their usual response while monitoring their feelings, symptoms and physical sensations (Hutton, 2005; Kearney & Brown-Chang, 2008).

Several studies have investigated the applicability and efficacy of different CBT packages in different contexts (individual, group, combined with medical treatment or drugs, cognitive alone, primary vs. secondary care patients) with mixed results. In fact most reviews find that CBT in general might be beneficial for the improvement of IBS symptoms and associated psychological distress, however these conclusions are admittedly based on studies with some methodological flaws (Toner, 2005; Zijdenbos et al., 2009).

Drossman et al. (2003) published one of the largest randomized control trials regarding the use of individual CBT sessions when compared to educational attention control. The intention to treat analysis showed that CBT was significantly more effective than the education control with the exception of a subgroup of patients who had co-morbid depression. However, although satisfaction with treatment and global well-being had both improved at the end of treatment, abdominal pain and IBS specific QoL were not significantly different compared to the beginning of the treatment.

In two studies using the same individual treatment package Boyce et al. (2000) and Boyce et al. (2003) found mixed results. In the first study CBT appeared to reduce Psychological distress and disability associated with IBS but not the frequency of symptoms. In the second study, bowel symptoms, psychological distress, disability and HRQoL all improved with the same CBT package; however these improvements were no better than the ones obtained by patients undergoing relaxation training or routine medical care.

Also Blanchard and colleagues, in one of the longest series of studies of the application of CBT to IBS, found very mixed results. An initial study suggested that individual CBT was effective for the treatment of IBS (Neff & Blanchard, 1987); however this study had very low participant numbers. In a later study comparing the same CBT package with two attention-placebo condition (pseudo-meditation) and electroencephalogram biofeedback no differences were found in terms of improvement of symptoms or psychological distress, even at 6 month follow-up (Blanchard et al., 1992).

This research group was one of the first to investigate the possibility of using CBT in a group treatment package. In their first study they found CBT delivered in a small group format to produce improvements in symptoms of abdominal pain and diarrhoea in 9 out of 14 patients (64.3%) when compared with a 12 week baseline (Blanchard & Schwarz, 1987).

Dulmen, Fennis, & Bleijenberg (1996 a) reported better outcomes (less abdominal complaints, more successful coping behaviours, less avoidance) in patients attending 8 two hour group therapy sessions over a period of 3 months than in patients in a waiting list control. The improvements were found to be sustained up to an average of 2.25 years follow-up, making a case for cost-effectiveness of group interventions. In a later randomized controlled study by Tkachuk et al. (2003), significant improvements at 3 month follow-up in GI symptoms, psychological distress and HRQoL were reported in patients attending 10 sessions of group CBT, when compared to a group monitoring their symptoms at home with weekly telephonic support.

Some studies have looked at the possible added benefit of combining CBT packages with standard medical care or medication. Heymann-Mönnikes et al. (2000) randomly allocated secondary care patients to either 10 weeks of CBT with medical consultations every 2 weeks or medical consultations alone. The results showed that patients in the CBT plus medical care group significantly improved in symptoms and overall well-being when compared to the medical care alone group. The authors

suggested that the addition of CBT to medical care might be of great benefit to IBS patients.

In a more recent study in primary care Kennedy et al. (2006) compared a group taking medication (mebeverine) only with a group taking the same drug and attending 6 sessions of individual CBT for IBS. The results showed that the addition of CBT to medication produced an enhanced benefit on symptom severity, quality of life, psychological distress, disability and coping behaviour at 3 months follow-up when compared to medication alone. These effects seemed to wane at 6 months with the exception of quality of life, disability and coping behaviours, suggesting that CBT might be effective at changing the patient's approach to her illness and their perception of impairment without necessarily improving their symptoms. This study also suggests that the behavioural part of the CBT treatment might be a more important ingredient than the cognitive part, since cognitions about IBS appeared to remain the same even after 6 months.

In fact some studies have looked at the separation of the components of CBT applied to IBS with the cognitive side being the most explored. A series of 3 small scale studies found cognitive therapy (CT) alone to be more effective at reducing symptoms, anxiety and depression than symptoms monitoring controls (Greene & Blanchard, 1994; Vollmer & Blanchard, 1998) or a support group (Payne & Blanchard, 1995). These results have been criticized due to the small sample sizes and the self-selection bias in the recruitment of patients to these studies (Toner, 2005). To respond to this Blanchard et al. (2007) recently conducted a large scale study comparing 120 patients attending group CT sessions, with 46 patients attending a psychoeducational group and 40 patients monitoring their symptoms for a period of 10 weeks. Although both treatment conditions were better at reducing symptoms than symptom monitoring at 3 month follow-up, CT was no better than the psychoeducational group.

The uncertainty of what are the key ingredients at work during a CBT intervention are further emphasized by the recent study of Lackner et al. (2007) that used a

structural equation model to try to ascertain the “how and why CBT works” for IBS. The authors were able to establish that CBT seems to positively affect the symptoms of IBS; however changes in variables associated with the psychological distress (the main aim of the cognitive arm of CBT) were not found to moderate these improvements. Also specific IBS QoL was found to be only moderated by symptom improvement and not psychological distress. Therefore, it seems that changes in cognition are not related with the gains obtained from using CBT as a treatment. It is not possible however to affirm that it was the behavioural arm of the intervention that caused the improvements since this study did not use any formal measure of behavioural change.

In summary, CBT appears to be more effective than standard care or wait list controls and could enhance the effectiveness of drug treatment; however more high quality studies are needed to confirm this, as well as longer follow-ups are needed to confirm the sustainability of treatment gains. Also, it is still not known what the active ingredient of treatment in CBT is: the cognitive part, the behavioural part, or both?

2.7.4.4. Hypnotherapy

Hypnotherapy has shown promising results in the treatment of IBS and is now one of the most used treatments, especially in refractory cases (Spiller et al., 2007). The full mechanisms by which hypnotherapy works are not yet known and theoretical models are based mostly on speculation. The proposed mechanism of action of hypnosis is that during the hypnotic trance the individual will have his/her conscious critical mind put on hold, making the person more susceptible to accept the suggestions provided by the therapist at an unconscious level. This is supposed to allow the individual to unconsciously control physiological processes that are usually not under conscious control. Rainville et al. (1997) further propose that hypnosis works by affecting the brain’s response to pain through the reduction of the activation of the anterior cingulate cortex. On the other hand some studies have pointed to cognitive changes occurring after hypnotherapy rather than physiological changes (Gonsalkorale, Toner, & Whorwell, 2004; Palsson et al., 2002).

The first study of the application of hypnotherapy to IBS was conducted by Whorwell, Prior, & Faragher (1984) and it showed that when compared to supportive therapy with placebo drug, it produced greater improvement over a period of 3 months. Several studies followed that found similar benefits of hypnotherapy for IBS symptoms, psychological distress and HRQoL, although most were plagued by low sample sizes or lack of control group (e.g. Galovski & Blanchard, 1998; Smith, 2006).

Gonsalkorale et al. (2003) found the improvement of symptoms after a course of hypnotherapy to still be present after as much as 5 years later. However reductions in quality of life and increased psychological distress were also found and the study had no control group.

In a recent randomized controlled study, Roberts et al. (2006) compared primary care IBS patients undergoing 5 sessions of hypnotherapy with primary care IBS patients undergoing normal medical care. Results showed that both groups improved over a period of 12 month follow-up and that hypnotherapy only produced a greater symptom improvement in the first 3 months with no differences found between groups for QoL. However patients in the hypnotherapy condition showed a lower resource use over the 12 month follow-up.

A recent review by Webb et al. (2007) states that hypnotherapy is safe and well tolerated by patients, although a lack of good quality studies prevent any conclusion about the effectiveness of this form of psychological therapy for the treatment of IBS. Spiller et al. (2007) in their guidelines for treatment of IBS state that evidence regarding hypnotherapy seems to favour mostly its application to refractory patients, although it is very labour intensive and operator dependent.

In summary, hypnotherapy appears to be an effective treatment for refractory patients, although more evidence is needed, especially to understand the mechanisms of action of this form of therapy.

2.7.4.5. Self-Help

With high human resource and economic costs involved in the care of IBS patients, more emphasis is being put on the possibility of patients self-managing their condition with minimal health care provider contact. Self-Help (or self-management) interventions provide a cost-effective way to provide patients with the knowledge and skills necessary to effectively manage their condition (Dorn, 2010). These types of intervention usually provide the patient with information about their condition and with a group of cognitive and behavioural techniques that will help with the transition to more adjustable self-care behaviours. These interventions can be delivered by a health care provider in person (normally in a group format) or at distance (via telephone, internet) and are usually supported by a media based format (e.g. book, CDs), although the presentation of the media format might be the only intervention (Richards, Lovell, & McEvoy, 2003). Self-Help interventions have been found to be effective for several chronic conditions (e.g. asthma, diabetes, arthritis) at improving symptom management, QoL or functional status (Barlow et al., 2002) and have been investigated for IBS in the past 20 years (Dorn, 2010).

A good example in the UK is the self-help management program offered by the IBS Network charity (<http://www.theibsnetwork.org>). This program developed by Professor Nick Read, contains a plethora of information and guidance regarding the diagnosis, aetiology and management of IBS. It is tailored to be used at the patients own pace and is easily accessible either via internet or through a group of factsheets that are mailed to the patient. Although very well received by the IBS network users, to date there isn't any data regarding its effectiveness. A high quality study is therefore in need regarding this program.

Purely educational interventions have been tried in several formats. Saito et al. (2004) used a lecture format with supportive written materials, slides and in-class exercises with 298 referred IBS patients. At 6 month follow-up, 29%, of the 211 patients that had data for both baseline and follow-up, no longer met Rome criteria for IBS. However no control condition was provided and no changes were reported

in pain severity, generic QOL, psychological distress, satisfaction with care, or health care utilization. In a recent study (Ringström et al., 2009) used 6 two hour educational sessions with 5 different health care providers (nurse, gastroenterologist, dietician, physiotherapist and psychologist) giving advice in their area of expertise for the management of IBS. At the end of the course, and 3 months later, the participants reported improvement in symptoms, better HRQoL and increased knowledge about IBS, however this study involved a very low total number of participants (n=12). Robinson et al. (2006) compared a group of patients receiving an educational guidebook on IBS (n=141) with a group of patients receiving the same guidebook and attending support group meetings (n=139) and a control group receiving neither intervention (n=140). At 1 year follow-up patients using the guidebook (both groups) reported less perceived severity of symptoms and less health care use when compared to the control group. The addition of the support group sessions did not produce significant changes. However no changes in symptoms were found and no measure of QoL was used, therefore the two main outcomes of an intervention for IBS were not achieved or investigated.

Educational interventions seem therefore to be somewhat effective delivered in several formats, however these interventions do not usually follow a treatment model and there is a lack of quality studies comparing it to an active treatment.

Other studies have investigated the delivery of psychological therapies via self-help formats like hypnotherapy or CBT.

Self-administered hypnotherapy was first studied by Forbes, MacAuley, & Chiotakakou-Faliakou (2000) in a randomized controlled trial comparing a group of patients attending 6 hypnotherapy sessions and a group of patients using an audiotape format of hypnotherapy during 12 weeks. Both formats of delivery of hypnotherapy led to significant improvements in symptoms, although no changes were reported in other outcomes (e.g. anxiety). More recently Palsson, Turner, & Whitehead (2006) compared a home based hypnotherapy program delivered by CD with a control group receiving standard medical care and found that at 3 month

follow-up, the hypnotherapy group reported improvements in symptom severity and IBS QoL, although not on anxiety, depression, or general psychological distress. Both these studies, although promising, have a severe limitation in their sample sizes and high dropout rates.

Sanders, Blanchard, & Sykes (2007) have compared the delivery of CBT via a self-help book (n=7) with a wait list control group (n=9). At 3 month follow-up participants using the self-help book reported significantly less GI symptoms when compare to the waiting list, although no significant improvements were observed in any of the groups for QoL or psychological distress. Like most studies on self-help for IBS this study also suffered from limited sample size, making it difficult to ascertain the usefulness of this approach. However, in a recent high quality study by Ljótsson et al. (2010) 85 patients were randomly assigned to an internet delivered form of CBT (based on exposure and mindfulness) or to a placebo control condition (internet group forum). At 3 month follow-up participants in the treatment condition had their symptoms improved (by 42%) while participants in the control condition had seen their symptoms worsen (by 12%). When compared to the control condition the treatment condition participants also significantly improved on secondary outcomes of IBS QoL, GSA, depression and disability.

In summary, self-help interventions seem promising and might be an alternative cost-effective approach to the management of IBS, although only one good quality study has been reported, so more are needed.

2.8. SUMMARY

IBS is therefore a complex and highly prevalent functional gastrointestinal disorder with as much as 25% of the world population suffering from its key symptoms of abdominal pain and change in stool frequency and form. At this moment IBS is clearly defined and can be positively diagnosed without the use of many invasive investigations. Although the clear aetiology of IBS and its maintenance are still unknown it is thought that a model that combines the effect of early life events or

infection, altered physiology and interplay between psychological factors and gut motility and sensitivity is the best explanation so far.

Psychological factors have taken a central role in the study of IBS in the last few decades and have been shown to be strongly related to secondary outcomes of resource use and quality of life, as well as the primary outcomes of symptom frequency and severity. It is therefore of interest to continue the exploration of psychological factors that influence the behaviour of IBS patients, and subsequently their quality of life.

Several approaches have been tried to manage IBS with mixed success. Several pharmacological approaches have shown some success, however they are symptom specific, not always well tolerated, have the danger of side effects and don't always target secondary outcomes. Psychological therapies have shown to be a less dangerous alternative or compliment to pharmacological approaches, and to be as effective. Psychological approaches also seem to target more effectively the secondary outcomes of change in consultation behaviour and of QoL with CBT, and in particular the behavioural component of this form of therapy showing the best evidence. Another advantage of psychological therapies is how they can effectively be delivered in groups or by self-help materials, making it a very cost-effective approach; however more studies are needed to further strengthen the case for the use of these approaches.

This thesis hopes, therefore to make a contribution to both the study of psychological factors as well as to the study of psychological therapies in IBS.

CHAPTER 3
ACCEPTANCE AND COMMITMENT
THERAPY

CHAPTER 3 – ACCEPTANCE AND COMMITMENT THERAPY

3.1. INTRODUCTION

Acceptance and Commitment Therapy (pronounced as one word, “ACT”; Hayes, Strosahl, & Wilson, 1999) is a new behavioural therapeutic approach that uses processes of acceptance, mindfulness, commitment and behaviour change to increase psychological flexibility, defined as “the ability to contact the present moment more fully as a conscious human being, and to either change or persist when doing so serves valued ends” (Hayes et al, 2004, p.5).

This chapter’s main aim is to give an overview of the model of psychopathology and treatment underlying ACT and the empirical data that supports it. First a brief description of ACT’s philosophical and theoretical underpinnings is presented. Subsequently an account of how psychopathology can be understood from an ACT perspective will be described paying particular attention to the key features of psychological inflexibility. This will be followed by a description of the key therapeutic processes involved in an ACT intervention and how they promote psychological flexibility. Empirical evidence that supports the ACT model of psychopathology and intervention will be briefly reviewed paying attention to correlational, mediational, component and outcome studies, and to issues of measurement. Particular attention will be paid to the contributions of the ACT model of psychopathology and intervention in health contexts. Finally a brief review of the main criticisms of ACT will also be addressed.

3.2. THE BASIS OF ACT

3.2.1. Third wave

ACT is part of the “third wave” (Hayes et al., 2004) of behavioural therapies which include Dialectical Behaviour Therapy (DBT; Robins, Schmidt III, & Linehan, 2004), Mindfulness Based Cognitive Therapy (MBCT; Segal, Williams, & Teasdale, 2001), Behavioural Activation (BA; Kanter, Busch, & Rusch, 2009) as well as Functional Analytic Psychotherapy (FAP; Kohlenberg et al., 2002), Cognitive Behavioural

Analysis System of Psychotherapy (CBASP; McCullough, 2000) and Integrative Behavioural Couples Therapy (IBCT; Hayes et al., 2004). Third generation cognitive behavioural therapy is considered to have developed from first wave basic behavioural therapy and second wave Cognitive Behavioural Therapy (CBT). Third wave therapies draw from the basic tenets of behavioural therapy (operant and classical conditioning) however it recognizes the limitations of this model in giving an account of human cognitive processes (Hayes, Strosahl, & Wilson, 1999; Hayes et al., 2004). Third wave therapies also recognize the great step forward provided by CBT in addressing human cognition as part of a behavioural treatment model; however they are critical of CBT's core conception of direct cognitive change as a requirement for clinical improvement and of its departure from basic applied science (Hayes et al., 2006).

In order to avoid the pitfalls of its predecessors ACT has placed its approach to human behaviour and cognition at a more basic level. Therefore, the development of ACT as a philosophy, theory and technique, occurred in parallel with all these components dynamically informing each other (Zettle, 2005), allowing for the approach to keep its roots in basic applied science.

3.2.2. Philosophical and theoretical roots of ACT

On a philosophical level, ACT aligns itself with the pragmatic philosophy of Functional Contextualism (Biglan & Hayes, 1996; Hayes, 1993; Hayes, Hayes, & Reese, 1988). In general, contextualism views events as ongoing actions of the whole organism in a clear historical and situational context. Unlike mechanistic approaches these actions are understood as whole events that can only be broken up for pragmatic purposes and not ontologically. This means that in contextualism, phenomena are analysed as acts-in-context and that the separation of an event from its context or the breaking of an action into parts would only be done to achieve a practical purpose (Hayes et al., 2006; Hayes, Strosahl, & Wilson, 1999; Ruiz, 2010). Functional Contextualism differs from other forms of contextualism (e.g. constructivism, narrative psychology) in its goals. As described by Hayes (1993) the

goal of Functional Contextualism is to predict and influence psychological events with precision, scope, and depth rather than describing or seeking a personal appreciation of the whole. Both analytical criteria and goals are intrinsically related to the truth criterion of Functional Contextualism, dubbed “successful working”, whereby an analysis is said to be true or valid insofar as it leads to effective action, or achievement of some goal (Hayes, Strosahl, & Wilson, 1999).

ACT reflects its philosophical roots in many ways by emphasizing workability as a truth criterion. Therefore psychological events (e.g. thoughts, memories, emotions) are not seen as being correct or incorrect but seen as being useful or not in the pursuit of a more valued life by the client (Ruiz, 2010). Also, the contextualistic analysis of behaviour in ACT poses that psychological events only influence behaviour according to the context in which they occur. So, for ACT, private events like thoughts or feelings are not be seen as causes of overt behaviour (like it is proposed by mechanistic based therapies such as Cognitive Therapy), rather it’s the context in which these private events are experienced that influences behaviour. Therefore ACT focuses on the change of the context in which psychological events affect overt behaviour rather than on attempts to change the content or form of psychological events as it is seen in more mechanistic based forms of therapy (e.g. Cognitive therapy) (Hayes et al., 2006; Hayes, Strosahl, & Wilson, 1999). Finally ACT also reflects its philosophical roots in its therapeutic goals, as it seeks to predict and influence the client’s behaviour in context in order to improve outcomes. ACT uses therefore the processes of influence and change as the key metric for success (Hayes, Strosahl, & Wilson, 1999).

On a theoretical level ACT is based on a Functional Contextual program of basic research on human language and cognition called Relational Frame Theory (RFT; Hayes, Barnes-Holmes, & Roche, 2001). The development of RFT picked up basic behaviour research at the point where the first wave of behaviourism had left it. Early behaviourists such as Skinner had pointed out the necessity of understanding behaviour as a whole, while at the same time being able to predict and influence it. This was achieved for animal behaviour and much of human behaviour; however the

stimulus-response associationism and behaviour analytic approaches of the time had failed to provide an adequate account of human language and cognition (Bach & Moran, 2008). RFT not only provides a behavioural account of human language and cognition for ACT but it also keeps this interventional model grounded in a comprehensive basic science program (Hayes, Follette, & Lineham, 2004).

According to RFT the foundation of human language and higher cognition lies in the inherent ability humans have to learn how to derive and combine stimulus relationships and to bring them under arbitrary contextual control (Hayes, Follette, & Lineham, 2004; Ruiz, 2010). RFT postulates that human behaviour is influenced by the relationships that we derive between stimuli. Whereas animals are able to respond to relations between stimuli, based only on the formal properties of the stimuli (e.g. same colour, larger, smaller), human beings are able to derive relations (and therefore respond to them) based on arbitrary features of the stimuli (Bach & Moran, 2008). This derivation of relations based on arbitrary stimulus properties is called relational framing and it shows three key characteristics: mutual entailment, combinatorial entailment and transformation of functions (Hayes, Barnes-Holmes, & Roche, 2001; Ruiz, 2010).

So for example a small child will know that a 2 pence coin is physically bigger than a 20 pence coin and than a 5 pence coin (Figure 3.1), however an older child will know that the 2 pence is smaller than the 5 pence, and this is smaller than the 20 pence by social convention (monetary value). We can see this last complex psychological relation is arbitrary (20 pence is only bigger than 2 pence by social attribution not by its non-arbitrary property of size), mutual or bidirectional (if 20 pence is bigger than a 2 pence, then a 2 pence is smaller than a 20 pence), combinatorial (if a 2 pence is smaller than 5 pence then it will also be smaller than 20 pence) and it alters the functions of related events (e.g. if 5 pence has been shown to buy more candy than 2 pence on a previous occasion then 20 pence will be preferred now even if it has never been used to buy sweets before).



Figure 3.1: Relational Frame (coin example)

Some important features of human cognition can therefore be derived from the basic tenets of RFT: 1. the notion that human cognition is a type of behaviour that can be trained; 2. That cognition produces changes on the effect of other behavioural processes (e.g. if a person learns to fear X and separately learns that X is smaller than Y than a greater fear response will be elicited in the presence of Y, even though only X was directly paired with the initial fear reaction); 3. Arbitrary contextual cues regulate the cognitive relations and functions (e.g. in the coin situation 20 pence would buy more candy in a shop, however if the child was buying candy from a machine that only took 2 pence coins than the 20 pence coin would be of no use in that context) (Hayes et al., 2006).

These key features can extend to implications (three of which will be highlighted) on the field of psychopathology and psychotherapy, upon which ACT draws extensively. The first is that psychopathology and verbal problem solving share the same cognitive processes, as they are both a product of learned behaviour, therefore elimination of these processes is not a viable option. The second is that attempts to control or suppress the content of these cognitive psychopathologic networks will actually lead to an extension (verbal relations work by addition, not subtraction) or strengthening of the network itself (the more the network is accessed the more it is trained). Finally, because the impact of cognitive networks is controlled by

contextual cues it is possible to reduce the impact of psychopathological networks by changing the contextual cues influencing behaviour and not the content (Hayes et al., 2006; Ruiz, 2010).

In summary, RFT assumptions imply that due to the nature of language and cognition, it is more sensible to focus on changing the functions of private events (e.g. Thoughts, memories) rather than focusing on changing their content. These assumptions will be the core of the ACT intervention; however RFT also provides ACT a model of psychopathology and health, making it therefore something more than just a specific intervention technology. It is on this model of psychopathology that the next section will focus.

3.3. PSYCHOPATHOLOGY IN ACT

According to ACT, psychopathology can result from (or be exacerbated by) either an absence of relational abilities (i.e. learning disability) or by psychological inflexibility (Hayes et al., 2006). From an ACT/RFT point of view the problem is that the otherwise useful properties of literality of language and cognition, lead to an increase in pain (psychological or physical) and to an overextension of a control approach to deal with this pain. This result in attempts to avoid, escape or control our feelings which in turn leads to a further entanglement with our thoughts. A relational network of evaluations, predictions and judgements is constantly activated while present moment contact is lost. Important goals are put on hold or relegated to the background, and action towards those goals becomes conditioned by the removal of pain. In short, overextension of the properties of human language and cognition lead to a rigid or inflexible approach to life (Luoma, Hayes, & Walser, 2007). Psychological inflexibility can be defined as “the inability to modulate behaviour in response to how helpful it is, that is, changing behaviour when it is helpful to do so and persisting when persistence is needed to achieve desired ends (Hayes et al., 2004, p. 25). The ACT model of psychopathology posits that there are six core processes that contribute to psychological inflexibility: cognitive fusion, experiential avoidance, attachment to a conceptualized self, dominance of the conceptualized past

or future, lack of values clarity and inaction towards valued directions (Bach & Moran, 2008; Hayes et al., 2006; Luoma, Hayes, & Walser, 2007). This model of psychopathology is illustrated in Figure 3.2 in the form of a hexagon with each corner corresponding to one of the processes thought to contribute to psychological inflexibility and therefore suffering. One of the key features of this model of psychopathology is that it deviates from the traditional mechanistic linear presentation of A leading to B that leads to C and so forth. The ACT model of psychopathology sees these processes occurring simultaneously and interacting with each other, therefore contributing to a narrowing of the patient's behavioural repertoire (Bach & Moran, 2008). Another key feature of this model is that it describes general processes rather than specific psychopathological processes associated with a particular disorder. This makes the model amenable to be used as an account of any kind of disorder in which psychological inflexibility is thought to contribute to its inception or maintenance (this includes both psychological and physical forms of suffering) (Luoma, Hayes, & Walser, 2007).

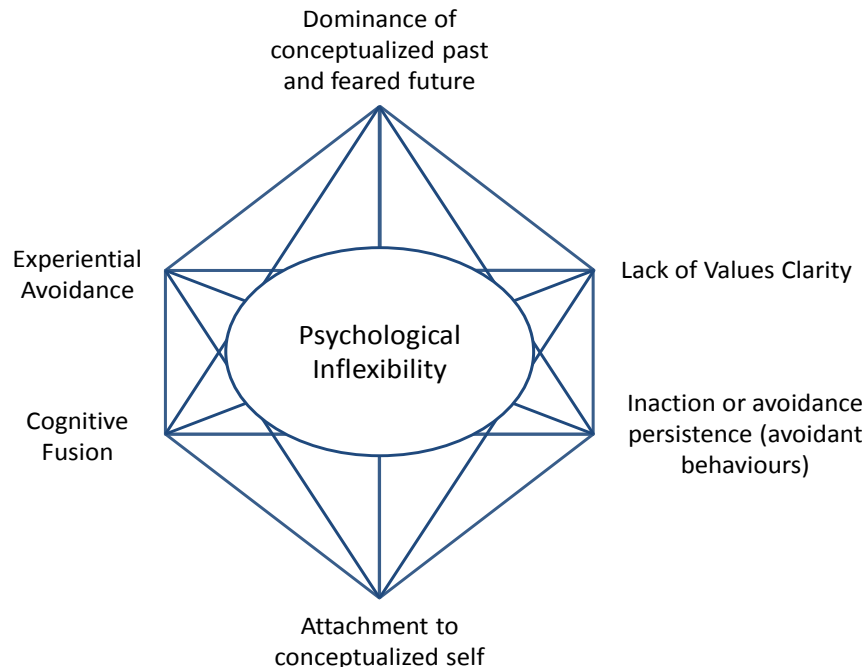


Figure 3.2: ACT model of Psychological Inflexibility

The key features of the core processes of ACT's psychopathology model will be presented.

3.3.1 Cognitive Fusion

Cognitive fusion can be defined as the instance in which behaviour is dominated by verbally related antecedents and consequences (e.g. thoughts, feelings, judgements), rather than by directly contacted non-arbitrary contingencies (Bach & Moran, 2008). Putting it more simply, cognitive fusion is said to occur when people's behaviour is guided by the literal content of their thoughts rather than by their direct experience with the world. It is as if people get so caught up in their thoughts that they lose the ability to make the distinction between what they are thinking and the ongoing process of thinking (Fletcher & Hayes, 2005; Luoma, Hayes, & Walser, 2007). As a result of cognitive fusion, people's behaviour might become inconsistent with their values and goals even in the presence of environmental opportunities to follow these valued directions (Hayes et al., 2006).

In ACT, the content or form of the cognition is thought not to be the main problem or the originator of psychopathology; instead ACT pays particular attention to the contextual situations that lead particular cognitive contents to regulate human action in unhelpful ways (Hayes et al., 2006). The social/verbal community is thought as being the main provider of these contexts that have such deleterious effects by overextending some of language/cognition's useful properties.

Contexts of literality are trained as part of language acquisition. People are taught early on to equate certain symbols with the reality they represent. As a child one is taught to equate a real lemon with the spoken word "lemon", with pictures depicting a lemon and with the written word "L-e-m-o-n". Therefore the literal properties of lemon (its yellow colour, sourness or smell) can be experienced in one's mind upon the presentation of any of the symbols that represent it (spoken/written word, picture). In this context, literality has no particular deleterious effect on behaviour; however an extension of this language property can be quite problematic. In

cognitive fusion, people equate thoughts with reality; for example, if someone fuses with the private experience of having the thought “I am panicking” they will be relating with the consequences of being literally in panic (e.g. rapid heart-beat, sweaty palms, feelings of panic), rather than simply experiencing this thought as part of a private verbal comment on an ongoing physical sensation with unpleasant but not harmful consequences. Cognitive fusion may then lead to a narrowing of behaviour, because actions will be mainly centred in avoiding situations in which one would “become panicky” (Hayes, Strosahl, & Wilson, 1999).

Another type of context trained very early as well is the context of reason-giving. Reason-giving is initially trained with children in order to expand their reasoning abilities and to help them keep their actions within the boundaries of what can be verbally justified in the social community (Luoma, Hayes, & Walser, 2007). People are taught therefore that they are expected to justify their actions and that, emotions and thoughts are valid causes for behaviour. The extension of reason giving combined with literality supports the idea that reasons are literal causes and that they explain and condition certain forms of behaviour (e.g. “I can’t do X because I’m too nervous”, “You don’t have to do X if it upsets you”) (Hayes et al., 2006; Luoma, Hayes, & Walser, 2007). The implication of reasons being viewed as literal causes is that one way to achieve behavioural control is to first remove or change private events (e.g. thoughts, emotions, sensations).

The bases are then set for the formation of a context of experiential control in which the primary goal is the manipulation of emotional and cognitive states (Hayes et al., 2006). In other words, the pursuit of valued life goals will be dependent on the success with which one can eliminate, change, control or avoid unwanted private events. Some ACT authors suggest that in Western culture, this approach to behavioural change is regarded as the norm (e.g. Hayes & Smith, 2005); however this seems to create more problems than solve them, as will be presented next.

3.3.2 Experiential Avoidance

Experiential avoidance is defined by Hayes et al. (1996) as “the attempt to alter the form, frequency, or situational sensitivity of private events even when doing so causes behavioural harm”. In other words, it is attempting to eradicate or limit the contact one has with unwanted thoughts, feelings, sensations or any other type of private events (e.g. memories). According to the ACT model, experiential avoidance emerges from our innate linguistic and cognitive abilities to evaluate, predict and avoid. These abilities lead humans to sort private events into positive and negative categories. Private events will then be sought or avoided based on their categorization rather than on their functional contextual properties (Luoma, Hayes, & Walser, 2007). The contexts of literality and reason-giving present in cognitive fusion contribute to experiential avoidance since: If thoughts are literal representations of reality and emotions, thoughts and feeling states are causes for behaviour, then reducing the contact with the experience of these negative private events would seem a logical and natural step towards behavioural control.

The expression of experiential avoidance is presented in two main forms: suppression and situational avoidance (Hayes et al., 2004). Suppression is the deliberate attempt to actively control or eliminate the experience of an unwanted thought, feeling, memory or physical sensation (Beavers et al., 1999; Hayes et al., 1996). For example, a person with an obsessive-compulsive disorder might engage in counting procedures as a way to neutralize an intrusive distressing thought, or a depressed person might try to force herself to “think happy thoughts” as a way to keep negative thoughts at bay. Situational avoidance is related to attempts to alter or control the antecedent contextual features that might trigger the appearance of unwanted private experiences (Hayes et al., 1996). For example, a person who is afraid of flying might avoid getting in an aeroplane in order not to experience the anxiety associated with this fear, or a depressed person might avoid work in order not to experience thoughts that they are no good at what they do. However experiential avoidance is not limited to these two forms, it can also include daydreaming, distraction, use of substances like drugs or alcohol, gambling and excessive eating

(Hayes & Smith, 2005). In fact, any form of behaviour, overt or private, that has the aim of altering the form or frequency of a private experience can be considered a form of experiential avoidance (Chawla & Ostafin, 2007). Experiential avoidance has been found to contribute to poorer outcomes, and paradoxically to an exacerbation of the experiences trying to be avoided in the first place (Chawla & Ostafin, 2007; Ruiz, 2010).

This last paradoxical effect of experiential avoidance occurs due to the natural properties of language. For example, if X is a negative private experience that is trying to be avoided, then the predictive properties of language and cognition will facilitate the creation of rules like “I must not think of X”. The verbal relations of equivalency and literality will make the creation of the rule “don’t think X” to actually elicit X, therefore amplifying the functional importance of X. A person who behaves according to the rules generated within an experiential avoidant frame will narrow the range of available behaviours (since many of these have the capacity to evoke unwanted private experiences) to the point that the possibility to experience positive contingencies will also become narrowed, and therefore the outcomes will be poorer (Hayes et al., 2006; Hayes, Strosahl, & Wilson, 1999). In other words, rule-governed behaviour is likely to result in less desired outcomes.

Finally one has to consider the influence of society and culture as a form of support for experiential avoidance. In western societies the idea of health is mainly associated with a concept of “absence of disease” which also generalizes to a concept of “absence of painful experiences (physical or psychological)”. There is enormous pressure and a general societal focus on “feeling good” as the normal state of health. In other words, physical, psychological and emotional pains are negative private events that should be avoided if one desires to be considered healthy (Hayes, Strosahl, & Wilson, 1999; Luoma, Hayes, & Walser, 2007). Societal pressures go even further in terms of suggesting that not only we should “feel good” but that we are entitled to “feel good”. For that effect an endless number of control solutions are put at our disposal like, alcohol, drugs, medications or entertainment (as a form of distraction). The repeated use of these escape mechanisms provided by the culture

perpetuates this “feel good” myth (Luoma, Hayes, & Walser, 2007). From an ACT point of view this health model is sometimes at the core of pathology itself. ACT sees the struggles that human beings engage to get rid of negative private experiences, not the content of these experiences as the real problem as it tends to keep people away from valued life directions (Hayes, Strosahl, & Wilson, 1999; Hayes et al., 2004; Luoma, Hayes, & Walser, 2007).

3.3.3. Attachment to the Conceptualized Self

In ACT, another process considered to contribute to psychological inflexibility is an excessive attachment to the conceptualized self or to the sense of self as content. The conceptualized self is made up from a collection of verbal content that seeks to define and describe ourselves as human beings in relation to how we interpret, construct, view or understand the world (Bach & Moran, 2008; Hayes, Strosahl, & Wilson, 1999). In other words the conceptualized self involves a group of self referential statements that people use to tell their life story. Conceptualized self statements can be found in descriptions of relatively stable characteristics (e.g. “I am Male”, “I have blue eyes”), descriptions of one’s activities (e.g. “I am a student”, “I am an accountant”) or on evaluative statements (e.g. “I am Susan’s best friend”, “I am terrible at cooking”). The way we see ourselves is so pervasive that in many instances we fuse the description of an ongoing experience with our sense of self. For example instead of noticing that “I feel hungry” one might actually say “I am hungry”. Again RFT explains this fusion of ongoing experience with sense of self as part of the multiple exemplar training human beings are subjected to everyday from an early age. Self referential statements are an intricate part of the building of a social being, since it allows the individual to situate itself in the verbal community and be able to reply to questions such as “What is your name?”, “What do you do?” “Where do you live?” (Bach & Moran, 2008).

A sense of conceptualized self is therefore a useful feature derived from our language and cognition abilities; however the problem occurs when by attempting to hold on to a particular self description the individual engages in ineffective behaviour (Bach

& Moran, 2008). Therefore, some stories we create about ourselves and how strongly we attach ourselves to them may result in inflexible behaviour patterns (Luoma, Hayes, & Walser, 2007). For example a person who is attached to the self-conceptualization of being an “agoraphobic” might be particularly fused with the thought “Because I am an agoraphobic, if I go to work I will get very anxious”. Supported by this view of herself this person might give up work altogether, in order to avoid distressing experiences (experiential avoidance) while at the same time being able to give a perfectly logical explanation for her behaviour “because I’m an agoraphobic”.

Also, when a person identifies herself or is particularly attached to a specific self conceptualization, the idea of an alternative conceptualization can become extremely threatening. In other words, if “I am my conceptualized self” then to conceptualize myself in a different way “I have to cease being me”. This realization is resisted, therefore mechanisms are put in action to defend this conceptualized self at all costs, “even if it is loathsome” (Hayes, Strosahl, & Wilson, 1999, p.182). So, following the previous example, if this person seeks help because she feels socially isolated, she might resist the idea of going back to work as a form of socialization “because she is an agoraphobic”. Therefore the self conceptualization of being “agoraphobic”, although undesirable, might actually be defended as the immediate gains of anxiety reduction might outweigh the long term gains of not being socially isolated anymore.

3.3.4. Dominance of conceptualized past or future

One of the key features of psychological inflexibility is that it seems to be related to a lack of awareness of the present moment. It is often the case that fusion with the conceptualized past or future gains more regulatory power over behaviour, further contributing to psychological inflexibility (Hayes et al., 2006). This often takes the form of rumination, in which the person fuses with the verbally constructed past or future instead of paying attention to what is happening in the here and now (Zettle, 2007). For example, repeatedly thinking about past failures or shortcomings (e.g. “If I had studied more I would have gone to college and have a better life”) becomes

more pervasive than contacting the contingencies available in the present, and therefore more opportunities to behave effectively may be missed. On the other hand people who become attached to thoughts of a possible negative future /negative future consequence (e.g. “Things will always be unbearable”/“If I leave the house I will feel bad”) are more likely to engage in behaviours that will foster avoidance of these hypothetically perceived futures, taking over from alternative effective behaviours. Therefore it can be said that a dominance of a conceptualized past or future not only diminishes the contact with the present moment, as it also takes over from effective action (Luoma, Hayes, & Walser, 2007).

3.3.5. Lack of Values Clarity

In ACT, values are “chosen qualities of purposive action that can never be obtained as an object but can be instantiated moment by moment” (Hayes et al., 2006). In other words, values are chosen life directions that are exhibited by an ongoing pattern of behaviours (Luoma, Hayes, & Walser, 2007). Values act like guidelines to meaningful or purposeful behaviours that will contribute to a greater sense of vitality.

A lack of clarity or contact with values will contribute to psychological inflexibility by allowing rule-governed behaviour to take over forms of behaviour that could be more value consistent (Bach & Moran, 2008). Several factors contribute to this lack of clarity or contact with values. One of the factors is that people avoid thinking about what is most important for them, because this brings up unwanted negative private events. For example, a person with severe agoraphobia might avoid thinking of making new friends because this would involve thinking of leaving the house to socialize and experiencing anxiety or panic feelings.

Another factor that contributes to a lack of clarity of values is a dominance of compliance or an excessive reliance on social acceptance. It is often the case that individuals avoid choosing values that are important to them from the fear of not being accepted by their peers, and therefore conform to more socially accepted values. For example, a person might stay in an abusive or loveless marriage due to the fear of a divorce not being socially accepted (Bach & Moran, 2008). The

dominance of pliance is so pervasive that sometimes people might be acting according to their values without actually being in contact with them. For example a mother might actually value taking care of her children and be taking steps towards that value and still be doing it because it is what is expected of her (i.e. in “autopilot”) and not because she is actively contacting and choosing this valued life direction.

Also the dominance of avoidant tracking plays a part in people’s movements away from their values. It is in some instances more immediately reinforcing to attend to immediate goals of avoiding painful experiences rather than pursuing a chosen life path (Bach & Moran, 2008; Luoma, Hayes, & Walser, 2007). So for example, for a socially anxious person the behaviour of staying quiet at a work meeting might take precedence over the behaviour of speaking. This happens because the avoidance behaviour is more likely to lead to a short term reduction in anxiety, which is more immediately reinforcing than the more difficult behaviour of speaking up which could lead to a greater exposure of the person’s capabilities and a possible desired advancement in her career.

Fusion with beliefs that living according to a particular value will never be achieved can also lead people away from their own values as any attempt to do so will be immediately discarded (Dahl, Wilson, & Nilsson, 2004). For example a mother that has had difficulties taking care of her children while she was struggling with depression in the past might believe that getting closer to her children again will be an impossible task and give up on it all together. Several psychologically inflexible processes can be seen at work in this example. For instance there is an excessive fusion to a conceptualized past of failure to take care of her children and to a future in which proximity will be impossible and to a conceptualized self of being depressive and incapable of proximity; and this lack of present moment contact leads to a diversion in behaviour away from the originally desired life direction.

Therefore lack of values clarity contributes to psychological inflexibility because people become more invested in living according to their conceptualized self, past or

future, doing what they should or ought to do or to avoid psychological or emotional pain. Valued directed behaviour takes a backseat to more immediate goals of living pain-free, according to society rules or according to how one sees herself. Patterns of behaviour become narrowly focused on these immediate goals and people become less sensitive to the opportunities available for effective valued action in the present context (Hayes et al., 2006).

3.3.6 Inaction, impulsivity or avoidant persistence

In many ways, this process of psychological inflexibility is the most visible one and is usually identified as the symptomatic part that leads people to seek help (Bach & Moran, 2008). Inaction, impulsivity or avoidant persistence are the behavioural manifestations of experiential avoidance supported by a mix of fusion, dominance of conceptualized self, past or future and lack of values clarity (Luoma, Hayes, & Walser, 2007). We can say that it is what the patient is doing too much, too little or doing in an inappropriate context in the service of experiential avoidance. For example, it could be the repetitive washing of hands that a person with obsessive-compulsive disorder does in order to avoid having thoughts or anxiety about contamination. As another example, it could be the inactivity of a depressed patient who is fused with the idea that he or she will never be able to do anything of worth, so by remaining inactive these thoughts and the adjoining emotional distress are avoided.

From a functional point of view these type of behaviours instead of serving a workability agenda, they serve and reinforce an inflexible approach to living. By engaging in these behaviours, there will be less room for effective behaviour that will lead to valued living, experiential avoidance will be reinforced in the short-term as a viable solution, contact with the present moment will be lost and the conceptualized self will be reinforced. In ACT, the aim of any intervention is to change this process of unworkable behaviour into a pattern of flexible behaviour that allows the person to respond to each situational context in accordance with their valued life directions (Bach & Moran, 2008).

In summary, the ACT model of psychopathology focuses on psychological inflexibility, the result of the interaction of cognitive fusion, experiential avoidance, attachment to a conceptualized self, lack of present moment awareness, lack of clarity of values and inaction towards one's own values. In other words, being caught up in the content of our private experiences or trying to avoid them will result in a loss of contact with the present moment and a less effective regulation of our behaviour in order to act in line with a valued life direction.

3.4. THE ACT APPROACH

3.4.1. Preparing the ground (Creative Hopelessness)

Creative hopelessness is the process by which the model of psychopathology just presented is drawn out for the patient and can be considered the first step towards a move from psychological inflexibility to psychological flexibility. In this process, the therapist focuses the attention on the questions 1. What does the client want? 2. What has the client tried? and 3. How has that worked? The rationale for this line of initial questioning is to confront the client with the change agenda she has been working with so far, one that is based on: Identifying a problem (unwanted experiences), and eliminate or change the problem so that life can improve (Hayes, Strosahl, & Wilson, 1999). By using several examples of the clients own history it is possible to map out contexts in which the experiential avoidant approach (elimination, change, control of unwanted experiences) is not working in terms of delivering the desired better life outcomes. This will confront the client with the paradox that the logical, socially acceptable and culturally reinforced solution to one's problems might actually be the very source of those problems. This leads the client to be faced with the hopeless position in which she has tried everything that is logical and this has not worked. This is why ACT uses "hopelessness" as part of the name of this process. The client is faced with the question of not knowing what to do next. This is in fact a very creative position as well (hence the creative hopelessness) as it opens the field to entirely new strategies that can be developed without being overwhelmed by

previous rule systems (Hayes, Strosahl, & Wilson, 1999). The establishment of creative hopelessness serves therefore the double purpose of undermining the psychological inflexibility processes while at the same time preparing the client for the alternative processes of psychological flexibility which will be described next.

3.4.2. Psychological Flexibility

As a psychotherapeutic approach ACT is different from most conventional forms of therapy as the goal is not to eliminate psychopathology, but rather to increase psychological flexibility. In ACT, just as there are six core processes that promote psychological inflexibility, there are six core processes that promote psychological flexibility. These six core ACT processes are all interrelated and can be identified as: acceptance, cognitive defusion, being present, self as context, values and committed action (Hayes et al., 2006) as shown in Figure 3.3. The processes that lead to psychological flexibility are thought to be diametrically opposed, and to exist in a continuum with the processes that lead to psychological inflexibility. Therefore if acceptance is diametrically opposed to experiential avoidance, then high levels of acceptance will equate to low levels of experiential avoidance. Another characteristic of the processes in ACT is that they are considered positive skills that help the individual to be able to contact her difficult private experiences more fully while behaving in a way that is in service of her values, rather than a set of skills that will allow the individual to avoid these difficult experiences (Hayes et al., 2006; Luoma, Hayes, & Walser, 2007). These processes will be described in detail below.

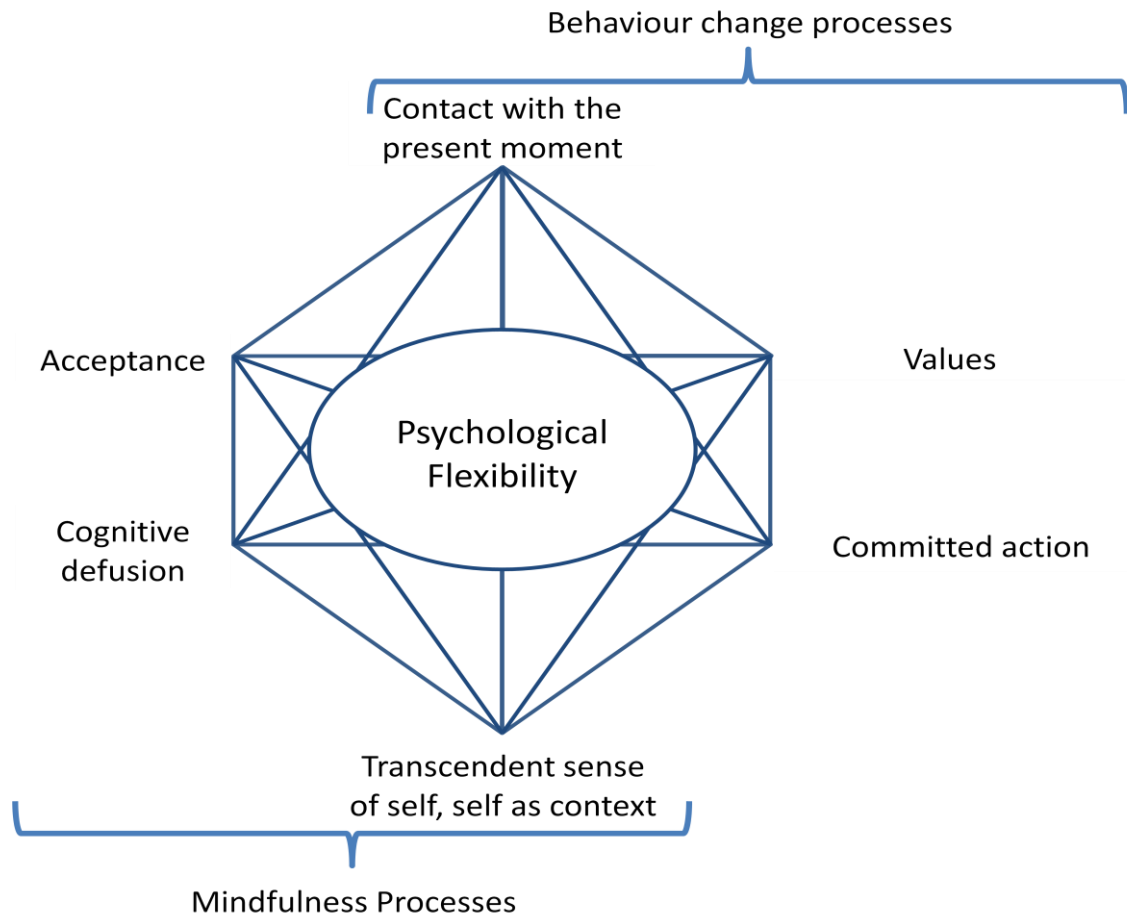


Figure 3.3: ACT Model of Psychological Flexibility

3.4.2.1. Acceptance

As mentioned in section 3.4.2 acceptance is considered to be the opposite process of experiential avoidance, and it involves “the active and aware embrace of private events that are occasioned by our history, without unnecessary attempts to change their frequency or form” (Luoma, Hayes, & Walser, 2007). In other words acceptance can be seen as a behavioural process of experiencing fully and without defence our difficult private experiences (body sensations, thoughts, emotions) without trying to reduce them or alter their form, in a context in which doing so will be a more workable solution (Hayes et al., 2006; Hayes et al., 2004). Therefore, acceptance fosters valued-based action by promoting a more flexible interaction with previously avoided experience.

For example, acceptance could involve a socially anxious parent fully experiencing her feelings of anxiety and panic, and not leaving a children's school party in order for her children to have a good time. Another example might be a person with chronic pain experiencing it while also doing something valued like going to work.

An important distinction made in ACT is that acceptance is a dynamic process that intends to create a more vital life as opposed to resignation (i.e. giving-up) or tolerance, which are both passive and fatalistic, and that eventually lead to different forms of avoidance (Hayes, 2005; Hayes et al., 2004). For example an anxious person can accept or resign herself never to leave the house again as a way to avoid the feelings of anxiety, yet this form of acceptance (resignation) is only in the service of avoidance and not the person's values. Tolerance also comes with "strings attached" since it involves accepting something up to an arbitrarily defined point and then avoiding it. For example a person who will tolerate pain only while they feel comfortable with it and who then resorts to medication that impairs their actions (e.g. some pain medications can cause drowsiness) to escape it (Dahl & Lundgren, 2006). Therefore acceptance is not an end in itself since it is about promoting valued living.

Another important distinction made by ACT regarding acceptance is that this is a choice that has to be willingly taken. What this means is that acceptance is not a matter of wanting or desiring negative private events to occur, but instead it is the choice of having them be present when this allows the individual to engage in more valued behaviour. That is why many times acceptance is also referred to as "willingness" (Hayes & Smith, 2005).

In ACT acceptance is trained through a series of exercises that encourage contact with previously avoided experiences when this is in service of one's values. Although most of these exercises are similar in form to the classical exposure exercises from the behavioural therapy tradition, they are significantly different in terms of purpose, as they aim to increase willingness and response flexibility rather than reduce the frequency or form of the private experiences, such as reducing the intensity of arousal experienced (Luoma, Hayes, & Walser, 2007).

3.4.2.2. Defusion

Defusion is a new word created by the authors of ACT to refer to the process of undoing cognitive fusion and it refers to the creation of “non-literal contexts in which language can be seen as active, ongoing, relational process that is historical in nature and present in the current moment” (Luoma, Hayes, & Walser, 2007). What this means is that in a defused context a word can be viewed as what it is (e.g. a group of written characters, a spoken sound) and not as what it means. From an RFT point of view this can therefore be applied to private experiences, since most of them (e.g. thoughts, emotions, and memories) are likely to be represented in a verbal form. Therefore, defusion intends to disrupt the verbal processes (e.g. literalness, reasoning) that give rise to problematic behavioural regulation (experiential avoidance), by changing not the content or form of the private experience (thought or emotion) but rather by changing the way one interacts with or relates to these experiences (Hayes et al., 2006; Hayes et al., 2004; Luoma, Hayes, & Walser, 2007).

From a technical point of view, defusion sets ACT apart from other therapeutic approaches within the Cognitive Behavioural tradition as the goal is no longer to alter the form or frequency of negative thoughts or feelings but to help people to see them for what they are (products of language and cognition) rather than seeing them as binding realities (Blackledge, 2007). For example, defusion might help a person not to treat a thought as what it refers to (e.g. “I am a bad person”) but rather as what it is experienced to be (“I am a person having the thought that I am bad”). This example also highlights the use of defusion in undermining the conceptualized self, since most problematic descriptions about the self appear in this “I am...” format (Hayes et al., 2004).

Several techniques have been developed to promote defusion in a wide variety of clinical situations. For example, a difficult thought can be observed dispassionately (e.g. it can be watched as if it’s written on a leaf floating down a stream), it can be repeated out loud several times until only the sound properties remain or it can be treated as an external event with a concrete shape, size and colour (Luoma, Hayes, &

Walser, 2007). Another defusion technique involves constant labelling of thoughts or emotions (e.g. “I am having the feeling of...” or “I am having the thought...”) in order to promote a cognitive distancing between the thinker and what is being thought (Hayes, Strosahl, & Wilson, 1999). As a whole, these techniques attempt to decrease the attachment person has to a particular thought and how she relates to it rather than attempting to reduce its frequency or alter its form. This usually leads to a lesser influence of these thoughts in action choice. This release from the constraint of thoughts and emotions as behavioural causes enables the person to become more flexible and freer to choose her actions according to her values rather than thoughts.

3.4.2.3. Self as context

ACT uses contact with the self as context as another process to foster psychological flexibility. From an ACT perspective, deictic relational frames (e.g. I versus You, Now versus Then) establish a sense of self as a perspective or locus. The self is seen as a context or arena for life’s experiences rather than the experience in itself (as it occurs when one fuses with the conceptualized self) (Luoma, Hayes, & Walser, 2007). For example, when a person is asked about her history of experiences, although the content of experiences can change significantly from one to another, the perspective from which these experiences are described to occur are always from an “I” perspective. So the self is a continuous and secure “I” that is capable of experiencing events of all forms (e.g. thoughts, sensations, emotions, memories) and valence (positive, negative, neutral), but that is also distinct from those events. In other words self as context is like a vehicle through which experiences occur (Hayes et al., 2004).

ACT posits that lack of contact with this sense of self leads to struggle with private experiences and therefore to psychological inflexibility because there is no distinction between thought and thinker or feeling and feeler. Therefore if one is aware that the experiences are part of one’s history and not the definition of oneself a necessity for struggle will be of no need (Hayes, Strosahl, & Wilson, 1999). For example, a person that sees the thought of “I am bad” as part of a myriad of thoughts

that can be experienced and not a definition of oneself, will be less inclined to try to change the form or frequency of this thought, and therefore engage in less experiential avoidance behaviours.

The goal of contacting the self as a context is therefore to help develop a sense of self as an observer or experiencer of the present events independently of the type of experience being had. ACT uses experiential exercises (e.g. observer exercise; Hayes, Strosahl, & Wilson, 1999, p.193) metaphors (e.g. chessboard metaphor; Hayes, Strosahl, & Wilson, 1999, p.190) and mindfulness as techniques to promote this sense of self as a context. Observing experiences has the effect of making unwanted experiences look less threatening and enables defusion from content to occur more easily, as thoughts and feelings are experienced as a process rather than a conceptualized reality.

3.4.2.4. Contact with the present moment

ACT also promotes ongoing non-judgemental contact with the psychological and environmental events as they occur in the present moment as a way to increase psychological flexibility (Hayes et al., 2006; Luoma, Hayes, & Walser, 2007). Having an increased sense of present moment awareness will allow a person to contact the world more directly and therefore become aware of more possibilities and learning opportunities afforded by the current situation (Luoma, Hayes, & Walser, 2007). This in turn will allow for behaviour to be more flexible, increasing the chances of acting according to one's values (Hayes et al., 2006). In other words, contact with the present moment reduces the control that fusion with the conceptualized past or future exerts over behaviour, allowing the exploration of more valued directions to become the primary motor for behaviour.

Contact with the present moment is fomented by an exploration of a sense of “self as process”, that is “the defused, non-judgemental ongoing description of thoughts, feelings and other private events” (Luoma, Hayes, & Walser, 2007). Firstly a person has to be able to observe and notice what is present at that moment in the realm of

private experiences (e.g. thoughts, memories, and sensations) and in the surrounding environment (e.g. sounds or smells). This can be enabled by mindfulness exercises. The second step involves making a more workable use of language by describing and labelling (as opposed to judging or evaluating) what is happening in that moment (e.g. “now I am thinking...”) which can be achieved by defusion exercises. By focusing on the “here and now”, rather than the “then and there” the individual will be more able to act according to what the situation affords rather than according to what her judgements or predictions about the situation tell him.

3.4.2.5. Values

Clarifying values and valued directions is one of the most important processes in ACT, as it asks clients to look at what gives meaning to their life or what they want their life to stand for, in order to guide constructive action (Luoma, Hayes, & Walser, 2007). Values are “chosen qualities of purposive action that can never be obtained as an object but can be instantiated moment by moment” (Hayes et al., 2006). As Luoma, Hayes, & Walser (2007) note, the action qualities of values can be seen in their linguistic presentation, as they are a combination of gerunds and adverbs, not nouns (e.g. to act *lovingly*; to relate *caringly*).

ACT uses a series of exploratory exercises that help clients identify chosen life directions in various domains like for example, relationships, family or career (Hayes et al., 2006). Some of these exercises include listing what the client would like to hear other people say about what their life stands for, completing a values assessment or a journal about what is most important for them in their life (Hayes, Strosahl, & Wilson, 1999). One of the most important features of values clarification is the distinction between values driven by personal choice and those driven by the verbal processes of experiential avoidance, social compliance and cognitive fusion. In fact the latter ones would not even be considered values from an ACT point of view. For example, valuing putting other people’s needs first in order not to feel guilty is a form of avoidance; valuing working hard at school because my parents want me to would be a form of social compliance; or valuing doing charity work because you are

fused with the thought “A good person would value doing charity work” (Luoma, Hayes, & Walser, 2007). Once the client has been able to define their valued life directions in different domains then concrete goals and specific behaviours that will lead her along that valued path can be defined. The use of the previously defined processes of acceptance, defusion or being present will facilitate effective action towards a desired life direction (Hayes, Strosahl, & Wilson, 1999).

As Wilson & Murrell (2004) note, values work’s importance lies in its potential to fundamentally alter the client’s relationship with unwanted experiences by changing the context in which these occur. For example, when acceptance of an unwanted experience is placed in the context of taking a step towards an important life domain, acceptance becomes more acceptable. Therefore, in ACT, acceptance, defusion and being present are not ends in themselves; rather they promote the pursuit of a more vital and values consistent life (Hayes et al., 2006).

3.4.2.6. Committed action

Finally, ACT encourages “the development of larger and larger patterns of effective action linked to chosen values” (Hayes et al., 2006). In other words, the client is encouraged to gradually increase the size and breadth of value consistent actions. Committed action aims therefore to help the client develop behaviour patterns that work for her not against her. For example, a socially anxious person may commit to go to a party, even though this will provoke anxiety, in order to live the value of being closer to her friends instead of staying home to avoid anxiety.

Since ACT is part of the behavioural tradition the application of classic behaviour change methods can be easily fitted to any ACT intervention, including exposure, skills acquisition, shaping methods or goal setting (Hayes et al., 2006). The same authors note that “Unlike values, which are constantly instantiated but never achieved as an object, concrete goals that are values consistent can be achieved and ACT protocols almost always involve therapy work and homework linked to short, medium, and long-term behaviour change goals.”(Hayes et al., 2006; p.9) However

moving in a valued direction always stimulates psychological content in one way or another, and when this content is negative or undesired it can function as a barrier to action. These barriers can be addressed through other ACT processes like acceptance, defusion or being present (Hayes et al., 2006; Hayes, Strosahl, & Wilson, 1999). Following the previous example, this person might experience an increase in anxiety while in the party and experience the thought “This anxiety is unbearable”. Defusing from this thought by noticing it as it occurs “I am having the thought that this anxiety is unbearable” and accepting the occurrence of such thought will help this person to stay with her committed action.

All the ACT processes described have only one goal, increasing psychological flexibility: “the process of contacting the present moment fully as a conscious human being and persisting or changing behaviour in the service of chosen values” (Hayes et al., 2006). These processes are both overlapping and interrelated, as each one in some form supports aspects of any of the others. These six processes can be divided into two overarching groups, the mindfulness processes and the behaviour change processes (as shown in Figure 3.3). Mindfulness processes include acceptance, defusion, contact with present moment and self as context. These processes have been considered to be a workable behavioural definition of mindfulness (Fletcher & Hayes, 2005) and target mainly areas in which change is not possible or necessary (e.g. thoughts, emotions). Behaviour change processes on the other hand target areas in which change is possible or needed (e.g. overt behaviour) and include committed action, values, self as context and contact with the present moment. Contact with the present moment and self as context are present in both process groups because all psychological activity of conscious human beings involves the now as known (Hayes et al., 2006).

Hayes et al., (2006, p.10) give a very simple definition of ACT based on theory and processes:

“...we can define ACT as a psychological intervention based on modern behavioural psychology, including RFT, that applies mindfulness and

acceptance processes, and commitment and behaviour change processes, to the creation of psychological flexibility.”

3.5. SUPPORT FOR THE ACT MODEL OF PSYCHOLOGICAL (IN)FLEXIBILITY

Support for the ACT model of psychological (in)flexibility has come from several type of studies. Correlational and mediational studies have looked at the relation between psychological (in)flexibility or some of its core processes and psychological outcomes (e.g. mental health or quality of life scores). Experimental studies have looked at the key ACT processes to see if each is psychologically active and working according to the theoretical model proposed. And finally outcome studies have also looked at how ACT interventions, aimed at increasing psychological flexibility have impacted on outcomes in several areas.

One of the first challenges in ACT was therefore to create a measure that could tap into the complicated constructs of inflexibility/flexibility. The measurement of psychological (in)flexibility will therefore be addressed before reviewing the evidence for this model of psychopathology.

3.5.1. Measuring Psychological (In)Flexibility

Most studies looking at psychological (in)flexibility have used some form of the Acceptance and Action Questionnaire (AAQ; Hayes et al., 2004). The AAQ was originally developed as a measure experiential avoidance. This was because when ACT was originally developed the overarching term for its underlying model of psychopathology was experiential avoidance. The authors pointed out two main reasons for the development of the measure. The first reason was that experiential avoidance had been highlighted as a promising functional category of disordered behaviour, pervasive in many forms of psychopathology (for a review see Hayes et al., 1996), and there was no research instrument to measure this construct. The second reason was more conceptual and it referred to the ACT model itself. It was hypothesized that if the psychopathology model based of psychological inflexibility

was correct, than it would be possible to develop a measure that taps into its several components (e.g. cognitive fusion, avoidance of private events). Psychological (in)flexibility is therefore not meant to be treated as an underlying trait but rather as a functional response category that integrates into a theoretically coherent perspective the relations between several specific behavioural phenomena. This measure would then correlate with a broad range of measures of psychopathology, quality of life and behavioural health while adding “something above and beyond more specific dimensions that are part of experiential avoidance, such as thought suppression” (Hayes et al., 2004). Therefore the development of the AAQ was related to the assessment of a model of mental health that emphasizes psychological (in)flexibility rather than a tool to identify specific mental disorders.

Two versions of the AAQ were evaluated at that time. A 16 item version was shown to load on two factors: one of acceptance and another of values based action. Both of these factors were also shown to load onto a second-order factor labelled psychological flexibility (Bond & Bunce, 2003). A second 9 item version of this measure loads only on this general factor of psychological flexibility (Hayes et al., 2004). The AAQ has shown to correlate significantly with several constructs related with experiential avoidance (positively correlated with thought suppression and avoidance in Hayes et al., 2004; negatively correlated with mindfulness in Baer, Smith, & Allen, 2004) while at the same time remaining an independent factor. So, both versions of the AAQ have adequate criterion-related, predictive and convergent validities (Bond & Bunce, 2003; Hayes et al., 2004). For a more detailed description of the AAQ-9 please refer to section 5.5.4.4 However the authors alert to the limitations of this measurement, as the contextual nature of psychological (in)flexibility and its multiple features does not fully fit psychometric assumptions because the core elements of this concept are considered to be situated actions rather than stable underlying features that don't vary much from time to time (Hayes et al., 2004). The difficulty of measuring such a construct through self-reports is further enhanced by the very language entanglement issues that it addresses. Therefore the AAQ is seen as a starting point to the study of psychological (in)flexibility.

More recently (Bond et al., in press) developed the AAQ-II that has better psychometric properties and factorial structure. The AAQ-II is a 10 item measures that correlates highly ($r=.82$) with the original AAQ and both exploratory and confirmatory factor analyses confirm its one-dimensional assessment of the construct of psychological flexibility.

Measures of psychological (in)flexibility have also been adapted to several specific domains in order to measure change processes in specific populations. The most prolific area of development of specific psychological (in)flexibility measures has been the health psychology area. Specific measures of psychological (in)flexibility in health conditions include for example the Acceptance and Action Diabetes Questionnaire (AADQ; Gregg et al., 2007), the Acceptance and Action Questionnaire for Weight-Related Difficulties (AAQ-W, Lillis & Hayes, 2008), or the Tinnitus Acceptance Questionnaire (TAQ, (Westin, Hayes, & Andersson, 2008). The area of Chronic Pain alone has seen several measures being created to assess psychological (in)flexibility or different facets of it. The most developed one is the Chronic Pain Acceptance Questionnaire (CPAQ). Initially developed by Geiser (1992) as a 34-item measure of acceptance of pain, this questionnaire was then revised into 20-item version (CPAQ-R; McCracken, Vowles, & Ecclesston, 2004) and has more recently been refined into an 8-item version (Fish et al., 2010). More specific measures have also been created to assess other processes. The Psychological Inflexibility in Pain Scale (PIPS) assesses avoidance and cognitive fusion (Wicksell et al., 2008) while the Chronic Pain Values Inventory (CPVI, McCracken & Yang, 2006) assesses valued living in chronic pain. Recently, McCracken, Vowles, & Zhao-O'Brien (2010) developed a more general measure, the Brief Pain Response Inventory (BPRI) that attempts to tap into psychological flexibility as a whole, tapping into acceptance, committed action, values and defusion (some items address more than one concept at a time).

Although general measures of psychological (in)flexibility have been and are still used to study specific health conditions, these seem to be more strongly related to other more general concepts rather than illness specific concepts. For example, in a

sample of Chronic Pain sufferers, McCracken & Zhao-O'Brien (2009) found that a general measure of acceptance was more strongly correlated with general measures of mindfulness and depression while a specific measures of pain acceptance was more strongly correlated with more specific measures of pain related anxiety and avoidance. These results would seem to support the utility of specific measures of acceptance to more powerfully detect effects on specific outcomes, however in the same study the authors also found general acceptance to account for significant amounts of variance beyond the effects of pain acceptance in specific outcomes. Therefore the debate on the sensitivity of general and specific measures to specific outcomes remains open.

As a final note the term (in)flexibility has been used throughout this section due to the different ways that the AAQ and its alternative versions have been scored or keyed. Some authors prefer to use a positive or a negative keying depending on what they would like to emphasize: experiential avoidance/psychological inflexibility processes (so that lower scores are good) or acceptance/psychological flexibility processes (in which higher scores are better) (Hayes et al., 2006). Psychological (In)flexibility tries therefore to incorporate both views.

3.5.2. Correlational and mediational studies

A detailed review of all the correlational and mediational studies that support the ACT model would be too lengthy and out of the scope of this research. Therefore focus will be given on two recent reviews by Hayes et al. (2006) and Ruiz (2010) which provides a good summary of the existing evidence for the ACT model from correlational and mediational data. Some specific studies mentioned in these reviews will be highlighted in order to clarify some aspects of the model's support. A more specific review of the use of ACT in health contexts will be presented in section 3.6.

In Hayes et al. (2006) review, the authors showed that in thirty two studies involving 6628 participants, higher levels of psychological flexibility as measured by the AAQ were associated with better quality of life and outcomes (weighed effect size of the

correlations $r=.42$). The outcomes included ranged from psychopathology measures (e.g. depression, anxiety, post-traumatic stress, agoraphobia) to stress, pain, job performance or negative affectivity. These findings attest to the functional nature of the construct of psychological flexibility as it correlates in the expected direction across a large number of different outcomes. Ruiz (2010) highlights the relation of experiential avoidance with measures of depressive and anxiety symptoms. In a total of 20 studies with a total of 3323 participants experiential avoidance has been positively associated with depressive symptoms (weighed effect size of the correlations $r=.55$). Experiential avoidance has also been found to be significantly associated with anxiety symptoms in 14 studies with a total of 3043 participants (weighed effect size of the correlations $r=.52$). Both reviews emphasize how psychological inflexibility is significantly related to some of the most common psychopathological outcomes; however the cross-sectional nature of the studies do not allow us to say that psychological inflexibility causes psychopathology. Process studies are needed in ACT for such claims to be made.

A step forward was provided by a series of three longitudinal studies (Bond & Bunce, 2000; Bond & Bunce, 2003; Donaldson-Feilder & Bond, 2004) that showed that higher levels of psychological flexibility (as measured by the AAQ) predicted a lower probability of developing a psychiatric disorder (as measured by the General Health Questionnaire; Goldberg, 1978) at 1 year follow-up, after controlling for negative affectivity, locus of control and amount of perceived control. The General Health Questionnaire had no predictive validity on AAQ scores. These studies were essential in showing that psychological flexibility impacts on mental health and not the reverse. In two studies Bond & Bunce (2003) and Bond & Flaxman (2006) have also shown that psychological flexibility was associated with the prediction of improved behavioural effectiveness in the form of job performance (learning new software, lower number of computer errors). This is in line with one of the core philosophical targets of this functional contextual approach: prediction of behaviour. These studies are promising in providing evidence regarding the causal impact of psychological (in)flexibility on the development of psychopathology, however the populations used were limited to a work environment context which limits the

generalization of these findings. More studies are needed, especially of a prospective nature, that could look at at-risk populations and to the influence of psychological (in)flexibility in the development of their specific problems (e.g. depression, anxiety).

Mediational studies have also supported the model of psychological (in)flexibility as these show that the way human beings relate to their historical personal experiences has an impact on how they ultimately behave or feel (outcomes). For example Reddy, Pickett, & Orcutt (2005) found experiential avoidance to mediate the relation between childhood psychological abuse and current mental distress in college students. As another example, Norberg et al. (2007) showed that experiential avoidance was a full or partial mediator between dysfunctional beliefs about appearance, shameful cognitions and fear of negative evaluation and hair pulling severity in a sample of individuals with trichotillomania. Tull & Gratz (2008) have also found experiential avoidance to mediate the relation between anxiety sensitivity and the experience of depressive symptoms. In these studies the behavioural reaction of experiential avoidance of several forms of distress (in the examples given: painful memories, difficult cognitions or negative feelings) is shown to have an impact on the development of outcomes in several forms of psychopathology which is in line with the proposed theoretical model. Although these studies expose the role of psychological (in)flexibility as a behavioural category that is capable of influencing outcomes, they do not provide any evidence that targeting this cluster of behaviours is effective in producing better outcomes. Evidence towards the role of the impact that changes in psychological (in)flexibility has on outcomes will be reviewed in section 3.5.4.

In summary, a great number of correlational, longitudinal and mediational studies so far support the ACT model of psychological (in)flexibility. These studies have highlighted not only the relation between psychological (in)flexibility and several forms of psychopathology, they have also provided initial evidence that the way one relates (more or less flexibly) with his distress will predict how one will behave or how well one will adjust.

3.5.3. Experimental studies

Experimental studies are an essential component of the development of ACT theory as they provide information regarding the validity and theoretical workability of each of the key processes or components (acceptance, defusion, values, self as context, contact with present moment and commitment) on their own. To date most experimental studies have focused mainly on acceptance/experiential avoidance and defusion; however new studies are starting to look at self as context and values. One added value of these studies is that they are mainly conducted in controlled laboratory settings and use primarily non-clinical populations, allowing for precise manipulation of independent variables and control of extraneous sources of variance, such as other features of psychopathology (e.g. fatigue, concentration, medication side effects). Some of the most significant studies will be reviewed here, however for a full review please see Hayes et al. (2006) and Ruiz (2010).

Some studies have looked at the predictive power of experiential avoidance in the performance of experimental tasks. For example some of these studies have shown that participants who scored higher in Experiential Avoidance had lower pain tolerance (Zettle et al., 2005) and higher recovery time (Feldner et al., 2006) in a cold pressor task (keeping the hand in cold water). High experiential avoiders were also shown to have more discomfort and worse performance in a challenging sorting task while experiencing sensations similar to drunkenness (Zettle et al., 2007). Karekla, Forsyth, & Kelly (2004) found that individuals low in acceptance endorsed more panic symptoms, fear and uncontrollability than individuals high in acceptance when exposed to a CO² enriched air environment (this task simulates the physiological characteristics of a panic attack). Individuals high in experiential avoidance have also been shown to increase latency time in a matching task that involved the posterior presentation of unpleasant images (Cochrane et al., 2007).

Other studies focused primarily on the effect of acceptance coping instructions versus other types of coping instructions (e.g. suppression) in the performance of experimental tasks that involved aversive stimulation (e.g cold pressor task, exposure

to aversive images). These studies have had mixed results in terms of support for the model. For example Marcks & Woods (2007) showed that individuals assigned to an acceptance based instruction group had less intrusive thoughts, lower levels of anxiety and negative evaluations while imagining a loved one having a traffic accident (experimental task) than individuals assigned to a suppression based group. On the other hand, Dunn et al. (2009) found suppression to be more effective than acceptance in dealing with distressing material. These studies although important, have some limitations: the first is that according to ACT acceptance is something that needs to be experienced therefore experimental protocols that instruct acceptance may be missing in that experiential facet; the second limitation is that these studies did not include any valued context, bypassing therefore the assumption that acceptance is a contextual action done in the service of values. Therefore these studies might not be the best way to explore the key processes of psychological (in)flexibility.

An alternative research strategy being used is the comparison of the effect of brief protocols on experimental tasks. These protocols are usually a condensation of the main components of the therapies being tested or integrate key exercises that are part of these therapeutic packages. For example studies by Hayes et al. (1999) and Masedo & Esteve (2007) have shown that participants who received a brief acceptance based protocol were able to keep their hands in cold water for longer in a cold pressor task than participants who received a control or suppression based protocol. Branstetter-Rost, Cushing, & Douleh, (2009) have also shown that adding a values component to the acceptance protocol increases pain tolerance in this type of task. This type of acceptance and values based protocol has also shown to increase tolerance to pain and to reduce believability in pain experience in participants undergoing an electric shock task, when compared to participants who received a cognitive control based protocol (Gutierrez et al., 2004). Forman et al. (2007) have shown that an acceptance based protocol is more effective at helping people cope with food cravings rather than a protocol based on distraction and cognitive restructuring. Finally, a series of studies have shown that a deliteralization exercise that promotes defusion was more effective than diaphragmatic breathing and

distraction in dealing with self-referential negative thoughts (Masuda et al., 2009; Masuda et al., 2010; Masuda et al., 2004).

In summary, the existing evidence from experimental psychology and component studies seems to support the correlational studies, since the level of psychological flexibility seems to influence the individual's performance in experimental tasks. The evidence also supports that protocols involving processes of acceptance, defusion and values are not only efficacious at improving performance in experimental challenges, they are also more effective than control strategies based protocols.

3.5.4. Outcome studies

Research on the efficacy of ACT as a therapeutic model is still in its early stages; however several studies have provided support to this approach with a wide variety of problems. ACT has been shown to be effective in improving outcomes in a variety of psychological problems (depression, obsessive-compulsive disorder, general anxiety disorder, trichotillomania, skin picking, psychosis, borderline personality disorder, addictive behaviour), in improving sport or work performance and at reducing stigma (Ruiz, 2010). Several studies have also shown the efficacy of ACT in health contexts and these will be reviewed in section 3.6.2.

Most of the evidence for ACT's efficacy comes from 3 meta-analytic reviews conducted in the last 4 years. Hayes et al., (2006) provided the first meta-analysis of the ACT data available up to the Spring of 2005. In 21 Randomized Control Trials (RCT) the authors examined the strength of ACT outcomes when compared with control conditions, wait-lists or treatment as usual (TAU). Between conditions effect sizes (Cohen's d^3) at post treatment and follow-up (between 8 to 52 weeks) were $d = .66$. Twelve studies analysed provided comparisons between ACT and structural interventions designed to impact the problem (e.g. group CBT for social phobia), with ACT showing advantage at post treatment $d = .48$ and at follow-up $d = .63$. When compared to wait list, treatment as usual and placebo conditions the effect

³ The effect size is considered medium if $50 < d < 80$ or large if $d > 80$.

sizes were $d = .99$ at post treatment and $d = .71$ at follow-up in ACT's favour. Finally the authors also compared ACT with Cognitive Therapy (CT) or Cognitive Behavioural Therapy (CBT) with between conditions effect sizes being $d = .73$ at post treatment and $d = .83$ at follow-up in favour of ACT on outcome. The authors also highlight that in these comparisons ACT produces greater change than CT or CBT on primary processes of change. Although Hayes and colleagues acknowledge some methodological shortcomings in some of the RCT's reviewed, they conclude that the preliminary evidence suggests that ACT is effective for a range of problems with different severities. They also emphasise that the medium to large effect sizes, in particular at follow-up, show pragmatically the usefulness of ACT on the long-term.

In a later meta-analysis of third wave therapies, Ost (2008) reviewed 13 RCT's involving ACT. The effect sizes found were very similar to the ones of Hayes et al. (2006), with $d=.68$ for all conditions. When comparing with a no treatment control the effect size was $d=.96$, when compared with TAU it was $d=.79$ and when compared to active treatments it was $d=.53$. Although obtaining similar results, Ost also performed a quantitative analysis of the quality of ACT studies, which lead him to conclude that ACT could not yet be considered an empirically supported treatment. This author's criticisms will be further explored in section 3.8.

Finally, a more recent meta-analytic review of 18 RCT's involving ACT was conducted by Powers, Zum Vorde Sive Vording, & Emmelkamp (2009). Effect sizes were computed using Hedges's g . Overall, the authors found a clear advantage of ACT when compared to control conditions (waiting list, placebo, TAU) with a medium effect size ($g=.42$) with the average ACT treated participant showing more improvement than 66% of the control conditions. When analysed separately, ACT was superior to waiting list or placebo conditions ($g=.68$), better than TAU ($g=.42$). However, when compared to established treatments, ACT was not significantly better ($g=.18$; $p=.13$). This finding in itself is not a weakness, as it shows that ACT is at least as effective as some well established treatments (e.g. CBT). The authors also noted that in fourteen of the studies analyzed ACT was significantly better than

control conditions (waiting list, placebo, TAU) with effect sizes ranging $g=.39-.76$, however in four studies dealing with distress problems like anxiety or depression, ACT was not superior to any of the control conditions ($g=.03$; $p=.84$). These authors conclude therefore that although ACT is more effective than control conditions, it is not better than any established treatment. This study has recently been reanalyzed by Levin & Hayes (2009) who based on the same database, but correcting for some methodological errors of the original analysis, concluded that ACT was more effective than established treatments ($g=.27$; $p=.03$).

It is possible, based on these studies to conclude that overall, ACT seems to be an effective form of therapy, which has consistently proved to be better than waiting-list, placebo or TAU conditions. Contention still exists regarding whether ACT is more effective than established treatments; however so far meta-analyses have show ACT to be at least of equivalent benefit.

3.6. ACT IN HEALTH CONTEXTS

ACT's functional approach, both in conceptualization and in intervention has given this model a flexibility that allows it to be adapted and applied to several fields of psychology (e.g. clinical or organizational). The field of health psychology in particular has been one that ACT has paid particular attention to.

Health conditions are usually associated with a varying degree of limitations in physical, emotional, social and occupational functioning. From a functional contextual perspective, some of these limitations are often related to an attempt from the patient to eliminate or control unwanted physical, emotional or cognitive aspects of her illness. In other words, some limitations might stem from an inflexible stance from the patient to her experience of illness. ACT would posit that patients who are more willing to contact their difficult illness experiences in the context of engaging in valued activities will experience less limitations than those who engage in inflexible coping strategies. ACT would also posit that interventions designed to

target a greater acceptance of illness experiences would improve some outcomes, in particular those related to the patient's behavioural control.

Several studies have looked at the role of psychological (in)flexibility in several health conditions and the effect of ACT consistent interventions in health related contexts. A brief review of these studies will be undertaken with particular attention being paid to the field of chronic pain since chronic abdominal pain or discomfort is one of the key features of IBS.

3.6.1. The role of Psychological (in)flexibility in health outcomes

Correlation, prospective and mediation studies have been used to investigate the role of psychological (in)flexibility or any of its specific components (e.g. acceptance, values) in different outcomes in several health conditions.

In a study with patients suffering from Chronic Fatigue, Van Damme et al. (2006) found higher acceptance of illness to be associated with better outcomes like patient functioning, anxiety, depression and fatigue scores. Acceptance also proved to be a good predictor of emotional stability and psychological distress beyond the effect of demographic variables or fatigue severity. Lillis & Hayes (2008) found that higher acceptance of weight related difficulties was associated with better quality of life, lower psychological distress and the use of healthier behaviours in a sample of patients enrolled in a weight maintenance program. In a recent study Ciarrochi, Fisher, & Lane (2010) looked at the role of values in cancer related distress in a sample of 107 cancer patients. In this study greater success at living values was associated with better well-being and less distress. These studies were however limited by their cross-sectional design which prevented conclusions to be drawn about the causality of the relationships found.

Kortte et al. (2009) used a prospective design to look at the role of General Acceptance (as measured by the AAQ-9) in the outcomes of a sample of patients in rehabilitation for conditions as diverse as spinal cord dysfunction, amputations or hip

replacement. In this study, cross-sectional data indicated that lower acceptance was associated with greater levels of depression and negative affect while higher levels of acceptance were associated with more positive affect, greater spiritual well-being and greater hope. Longitudinal data further supported the association of Acceptance with better outcomes as higher levels of Acceptance at baseline predicted greater life satisfaction and lower level of disability at 3 months follow-up. However the use of a multitude of conditions experienced by the participants is a limitation to this study as reactions to illness might be influenced by the specific characteristics of the illness itself.

In a longitudinal study Westin, Hayes, & Andersson (2008) obtained preliminary data for the mediational role of Acceptance in tinnitus. At 7 month follow-up, Acceptance of tinnitus was show to fully mediate the relationship between tinnitus distress at baseline and depression and quality of life at follow-up; to partly mediate the relationship between tinnitus distress at baseline and follow-up. However a small sample size (N=47) means that generalizations must be done cautiously.

It is important however to highlight that despite the limitations of each of these studies they have all provided preliminary evidence to the importance of psychological (in)flexibility processes across a wide range of health conditions with relevant and significant associations between these processes and several outcomes being consistently found.

Within the research of ACT into health conditions, the field of chronic pain has been one of the most prolific with more than 20 studies dedicated to the investigation of the role of psychological (in)flexibility processes in chronic pain outcomes. Cross-sectional studies have consistently shown that (in)flexibility processes are related to better outcomes.

In an early study McCracken (1998) found that acceptance of pain was associated with lower levels of pain intensity, pain related anxiety and avoidance, depression, physical and psychosocial disability, and with more up-time and better work status.

Acceptance of pain also predicted better outcomes over the effect of pain intensity. A later study (McCracken, Vowles, & Eccleston, 2004) with a more refined scale of acceptance of pain (CPAQ-R), confirmed these results. Acceptance of pain has also been associated with better outcomes in adolescent populations (McCracken, Gauntlett-Gilbert, & Eccleston, 2010). Wicksell, Olsson, & Melin (2009) have also shown that pain acceptance is a significant predictor of pain intensity, disability, life satisfaction and depression over the effects of kinesiophobia. Mason, Mathias, & Skevington (2008) found that acceptance of chronic pain was a significant predictor of both general and pain specific quality of life. Vowles et al. (2008) have also shown significant differences in outcomes across different groups of chronic pain sufferers discriminated by their level of acceptance (high, medium, low). McCracken & Eccleston (2006) showed that pain acceptance was not only more strongly associated with several indices of distress and disability than traditional coping strategies (e.g. relaxation, pacing); pain acceptance was also a better predictor of outcomes, even taking into account the effects of traditional coping strategies.

Looking at other processes of psychological flexibility McCracken & Yang (2006) showed that values were also useful in the prediction of disability, depression and anxiety in chronic pain and that they incremented the amount of variance explained in these variables over pain acceptance. McCracken, Gauntlett-Gilbert, & Vowles (2007) found that mindfulness was also significantly associated with patient functioning and that it significantly added to the explained variance of outcomes (e.g. disability, depression and anxiety) over the effects of pain intensity and pain acceptance.

Some studies have looked at psychological flexibility as a whole, using a mixture of composite measures, that address several processes or by using several process measures at the same time. McCracken & Vowles (2007) found the psychological flexibility factor of a composite measure (BPCI-2) to be a significant predictor of better outcomes in eight measures of functioning over the traditional pain management strategies factor of the same scale. A more refined version of this scale measuring only psychological flexibility (BPRI, see section 3.5.1) has been shown

recently by McCracken, Vowles, & Zhao-O'Brien (2010) to be a good predictor of emotional, physical and psychosocial functioning. In a study by Wicksell et al. (2008) a different measure of pain related psychological inflexibility was also found to predict better outcomes like well-being, quality of life and interference of pain in life activities. In this last study the authors found the process of experiential avoidance to be a better predictor than cognitive fusion; however they note that the cognitive fusion factors in their scale might not be well developed. A recent study (McCracken & Velleman, 2010) has looked at several processes of psychological flexibility (general and specific pain acceptance, mindfulness and value based action) in a primary care sample with chronic pain. Data from this study suggested that psychological flexibility processes were generally better predictors of functioning over pain intensity.

Some other cross-sectional studies have found some results that challenge the importance of psychological (in)flexibility processes in chronic pain. For example, Viane et al. (2003) found acceptance of pain to be a good predictor of mental quality of life over the effects of pain severity and catastrophizing, however acceptance did not significantly account for physical functioning. Similarly Nicholas & Asghari (2006) found pain acceptance to be predictive of depression but not of physical disability when taking into account cognitive variables like, fear of movement or catastrophizing. Finally, Esteve, Ramírez-Maestre, & López-Marínez (2007) using structural equation modelling found pain acceptance to determine functional status and functional impairment, while coping and cognitive measures were primarily related to components of emotional distress. However it is important to say that although these studies challenge the importance of pain acceptance in some outcomes, they have also found utility in this construct in explaining other outcomes.

The evidence provided by cross-sectional studies has shown to be consistent with the assumption that higher psychological flexibility allows people to better adapt and adjust to particular health challenges, leading therefore to better outcomes. As all cross-sectional data, the conclusion drawn from these studies are limited, as no causality can be established. However, further support has been lent to the

importance of psychological (in)flexibility processes by prospective and mediational studies.

An initial study by McCracken & Eccleston (2005) prospectively investigated the relationships between acceptance of pain at an initial assessment and patient functioning almost 4 months later in chronic pain patients. The authors found that patients who reported higher acceptance at the first assessment also reported better functioning at Time 2. Also, acceptance at Time 1 was consistently found to be a good predictor of patient functioning at Time 2 beyond the effects of pain intensity at Time 2. In another study McCracken, Vowles, & Gauntlett-Gilbert (2007) found that acceptance based coping strategies were associated with better functioning about 4 months later, while control oriented strategies were found to be associated with greater difficulties. Finally a prospective analysis of both pain acceptance and value-based action by McCracken & Vowles (2008), showed that the combined effect of these two processes at Time 1 significantly accounted for variance in several facets of patient functioning about 18.5 weeks later. Acceptance of pain was a significant predictor of pain related anxiety, depression and psychosocial disability while value-based action significantly predicted depression, depression related interference with functioning, physical disability, psychosocial disability and work status. The results from these prospective studies are limited as all studies used highly selective samples of patients seeking help in tertiary settings, reducing therefore the scope of applicability of the findings. Also the use of a correlation based methodology of study again does not account for causality and only establishes a relation between levels of acceptance at one point and outcomes at a later point. However, these results provide longitudinal support to the findings of the cross-sectional studies by minimizing the possible inflating influences of current mood or level of pain of patients at time of response.

Two recent studies have also provided initial support for the mediational role of acceptance in chronic pain. In Vowles, McCracken, & Eccleston (2008) pain acceptance was shown to mediate the effects of catastrophizing on depression, anxiety, avoidance and, physical and psychosocial functioning. That is the effect of

catastrophizing on outcomes seems to be buffered by higher acceptance in some individuals, which leads to better outcomes. Fish et al. (2010) also found pain acceptance to partially mediate the relationship between pain severity and depression, anxiety and pain interference. Although both studies are limited by their cross sectional nature which does not account for the possible variation of both predictor and mediator variables across time, they provide the initial steps for the development of future longitudinal studies. Proof of causality continue to be the main issue in these studies, although the theoretical models tested, that pose acceptance as a mediator in chronic pain are quietly gaining some evidence with the addition of more intervention studies that look at the process measures (these will be reviewed in the next section).

In general, the literature of ACT concerning health conditions and chronic pain in particular seems to be in line with a contextual view of the role of psychological (in)flexibility in health. Psychological (in)flexibility or some of its processes have been consistently show to be related to health outcomes, to predict them and to influence the relation amongst them and other variables of interest.

3.6.2 ACT efficacy for health problems

Following the encouraging data regarding the role of psychological (in)flexibility processes in health conditions, researchers turned to the study of how changes in these processes could lead to better outcomes. Several studies have looked at ACT based interventions in different health conditions. We review some of the most important ones with again particular attention being paid to the field of chronic pain.

Gregg et al. (2007) explored the effects of an ACT intervention versus education alone on diabetes self-care and glycemic control (physiological measurement of HbA1c levels) in type II diabetes patients (N=81). At 3 months follow-up, patients who had participated in a 1 day ACT workshop and used an ACT based workbook for diabetes reported better diabetes self-care behaviours and had better glycemic control than patients who had education alone. Mediation analyses showed that

changes in glycemic control were mediated by changes in diabetes acceptance and self-care behaviours.

Three studies have looked at applications of ACT to weight related problems. Preliminary evidence of the effectiveness of an acceptance based intervention (12 week group program) for weight loss was provided by Forman et al. (2009). In this study participant's reported to have lost 9.6% of their body weight at 6 month follow-up and acceptance measures changed in the expected directions. However this was a single group trial and no mediation analyses were conducted. Tapper et al. (2009) also shown that participants of a four session (2 hours each) mindfulness program in addition to a weight loss program were more physically active at 6 month follow-up than those doing the weight loss program alone. Further analyses showed that those who reported following the principles of the mindfulness program also had a significant weight loss when compared to those who didn't. However, mediational analyses did not find any significant mediation effect from psychological (in)flexibility measures on the outcomes. Finally, Lillis et al. (2009), showed that a 1 day ACT workshop followed by work with a general ACT self-help workbook was effective at improving obesity-related stigma, quality of life, psychological distress and Body Mass Index at 3 month follow-up when compared to a waiting list. This study also showed that general and obesity related acceptance mediated changes in outcomes.

Two RCT's have shown the effectiveness of ACT for epilepsy. Lundgren et al. (2006) found that patients attending a 9 hour ACT intervention (2 individual sessions + 2 group sessions) had a significant decrease in frequency and duration of seizures and improved quality of life at 6 and 12 month follow-up when compared to patients receiving 9 hours of support therapy. In a later analyses of this study, Lundgren, Dahl, & Hayes (2008) found that changes in acceptance and valued activity mediated the changes in seizures, well being and in one of the quality of life measures used. The effectiveness of ACT for epilepsy has also been compared with yoga by Lundgren et al. (2008). Both conditions were found to be effective at reducing

seizures and improving quality of life, however ACT had a greater effect on seizure frequency when compared to yoga.

The application of ACT to smoking cessation has also been investigated by two RCT's. Gifford et al. (2004) showed that a 7 week smoking focused ACT treatment (1 individual and one group session per week) was as effective as Nicotine Replacement Therapy in quitting rates at 1 year follow-up. Mediation analyses showed that improvement in acceptance skills mediated outcomes. In another recent study Hernández-López et al. (2009) compared two programs of 7 group sessions, one ACT based and the other CBT based. Participants in the ACT condition had higher abstinence rates at 1 year follow-up compared to the CBT participants. More recently, promising results have also been reported for an ACT based telephonic intervention for smoking cessation with quit rates at 1 year follow-up reported for 29% of the participants (Bricker et al., 2010). This study also showed that changes in acceptance were associated with changes in outcomes, however, this was a very small study (N=14) with no control condition.

Recently, Hesser et al. (2009) reported on the effects of an acceptance based treatment on tinnitus distress. In this study, changes in acceptance at session 2 were shown to predict symptom reduction at 6 month follow-up. Although these results are already very encouraging, the most interesting aspect of this study was that the changes in acceptance were shown to occur prior to changes in tinnitus distress therefore providing preliminary evidence of a chain of causality. This was however again a very small study (N=19) with no control condition.

As previously noted, chronic pain has been the field within health psychology with the greatest number of ACT studies. The first study to tackle chronic pain was a small study with people at risk of long term disability by Dahl, Wilson & Nilsson (2004). In this study an ACT intervention proved to be more effective at reducing the number of sick leave days and medical treatment usage at 6 month follow-up when compared with treatment as usual. Limitations to this study include the small sample (N=19) and the lack of use of a psychological (in)flexibility measure which meant

that it was impossible to know if the intervention had worked by the hypothesized processes of increasing psychological flexibility. However the authors note an improvement in the use of valued behaviours, in the ACT condition, which is a key target of any ACT intervention.

Three large studies have looked at the effectiveness of a 3-4 weeks residential/hospital-based acceptance based multidisciplinary treatment package for chronic pain. This treatment was described by the authors as an exposure and experiential based program that is focused on “...increasing (a) engagement in daily activities regardless of pain and (b) willingness to have pain present without responding to it.” (McCracken, Vowles, & Eccleston, 2005). In the first study McCracken, Vowles, & Eccleston (2005) showed that participants (N=108) with a long history of chronic pain had significantly reduced their use of healthcare services and improved in emotional, social and physical functioning at the end of the treatment period. Also it was shown that these improvements had been sustained at 3 month follow-up. Finally improvement in outcomes was positively associated with increases in acceptance, therefore suggesting that the hypothesized process of treatment was supported. In the second study by Vowles, McCracken & Eccleston (2007), similar results were found with psychosocial and physical outcomes significantly improving at post-treatment and being maintained at 3 month follow-up. This study not only confirmed the results of the previous study with a larger sample (N=252), it also investigated the contributions of changes in pain intensity, acceptance and catastrophizing to changes in the outcomes. The authors found that changes in acceptance and catastrophizing were more strongly related with changes in outcomes than changes in pain intensity. These results are consistent with the hypothesized mechanism of change, as acceptance was directly targeted and as the authors note, catastrophizing frequency was probably reduced due to a new contextual frame for the occurrence of these type of thoughts. In a third recent study Vowles & McCracken (2010) showed that changes in psychological flexibility after the treatment program were better predictors of changes in outcomes (e.g. pain related anxiety, physical and psychosocial disability) than traditional pain management techniques. Therefore, not only does the treatment program seem to be

effectively changing psychological flexibility, as this is having a significant impact on outcomes. Two major limitations are present in these studies; the first is the lack of a control group, however the authors in the first study do note that every patient had a waiting phase period of about 4 months prior to being entered in the treatment with no significant changes in outcomes being noted between the first assessment and pre-treatment phases; the second limitation is the form of treatment used which due to its complexity and high use of resources (multidisciplinary team, residential or hospital based care) might not be effectively generalized to many treatment contexts. However, these studies offer initial support for the proposal that not only an ACT based intervention is effective in chronic pain; it also seems to work through the proposed processes.

Recently several small studies have tried to deal with the first limitation noted above. Wicksell et al. (2008) conducted a small (N=21) randomized control trial comparing TAU (e.g. medication, acupuncture, osteopathy) with TAU plus an ACT based intervention for chronic pain in whiplash associated disorders. Patients in the ACT condition had better outcomes (pain disability, life satisfaction, kinesiophobia, and depression) and significantly lower psychological inflexibility at post-treatment than patients in the TAU condition. Also, patients in the ACT condition were shown to have sustained their outcome improvements at 7 month follow-up. A recent further analysis of this study (Wicksell, Olsson & Hayes, 2010) also showed that changes in psychological flexibility significantly mediated the changes in pain disability and life satisfaction between pre and post treatment. This mediational study also showed that improvement in outcomes was not mediated by the effects of changes in pain intensity, anxiety, depression, kinesiophobia or self-efficacy, therefore supporting even further the importance of psychological inflexibility as an effective process of change. Vowles, Wetherell & Sorrell (2009) have also shown in a small (N=11) nonrandomized trial that an ACT condition was generally equivalent in improving outcomes to a CBT condition for chronic pain in veterans. However, the ACT condition produced greater improvement in measures of depression and pain related anxiety when compared with the CBT condition. Regarding younger populations, recent evidence has been given by Wicksell et al's. (2009) study that found ACT to

contribute to improvement in outcomes in longstanding paediatric pain patients (N=32), and to perform significantly better than a multidisciplinary treatment (including medication, physical training and individual psychiatric and psychological consultation) at increasing perceived functional ability and reducing fear of injury, pain intensity and pain related discomfort. Although the sample sizes and the specific populations recruited for the studies limit the possibility of further generalizations, both studies provide preliminary evidence that ACT seems to perform better or at par with established forms of treatment in patients suffering from chronic pain.

Finally, a recent study by Johnston et al. (2010) has shown the utility of an ACT based self-help intervention for chronic pain patients. In this study patients in the ACT condition showed improved quality of life and reduced anxiety when compared to a waiting list sample. After all the participants were pooled together ACT showed to positively impact on all outcomes measured and to produce increases in acceptance. This study was limited by its small sample (N=11) and by the lack of follow-up measurement, however it provides evidence that a self-help form of delivery for ACT seems to be effective.

The findings of acceptance-based interventions for the treatment of chronic pain have recently been the subject of a review and meta-analysis (Veehof et al, 2011). In this study, acceptance-based interventions were found not to be superior to CBT, however they were considered to be viable alternatives in improving both physical and mental health.

In summary, so far a growing number of studies have highlighted the usefulness of ACT in improving outcomes in several health conditions. Although more studies are needed, ACT has shown to be an effective form of treatment in health conditions by either promoting healthier behaviours (e.g. diabetes, smoking cessation or weight maintenance) or by changing the relation patients have with their difficult illness experiences (e.g. chronic pain or tinnitus) so that significant improvements are experienced in quality of life. A further strong point of ACT studies in health has

been the attention to the process of change, with most studies providing evidence that the impact of ACT is being made by the processes hypothesized by the theoretical model, that is, by increasing psychological flexibility.

3.7. DELIVERING ACT

A further note should be made regarding the form in which ACT can be delivered as a form of treatment. Although ACT was originally described as an individual form of therapy (Hayes, Strosahl & Wilson, 1999) practitioners quickly realized that the very flexible nature of the model meant it could be easily adapted into several forms of delivery. Supporting this notion is the different forms in which ACT has been used in effectiveness studies, of which we will give some brief examples from the studies reviewed in the previous section (3.6). ACT has been successfully used in: multi-session group formats (e.g. Forman et al., 2009), as part of multidisciplinary treatments (e.g. McCracken, Vowles & C Eccleston, 2005), as a one day short group intervention (e.g. Gregg et al., 2007), a combination of group format with individual sessions (e.g. Lundgren et al., 2006), a combination of group format with a workbook (e.g. Lillis et al., 2009), by telephone (e.g. Bricker et al., 2010) or delivered by workbook with telephonic support (e.g. Johnston et al., 2010).

ACT has effectively proven itself to be a versatile model which can be adapted to the resources of different practitioners. From a research point of view this versatility also allows ACT to be more easily compared with established models, since its delivery can be transformed into many forms that can be equivalent (in contact time or form) to other forms of treatment.

3.8. CRITICISMS OF ACT

Since the publication of the first book describing the full model of ACT (Hayes, Strosahl, & Wilson, 1999), several criticisms and misconceptions have appeared with some being reported in the literature.

Corrigan (2001) criticized ACT for placing itself ahead of the data and for being presented as a therapeutic approach with no sufficient empirical support that made overblown claims. However, as Hayes (2002) points out these claims were made based on a higher ratio of non-empirical publications about ACT over empirical publications at that point in time, rather than on an analysis of the existing empirical data. At this point in time, this criticism is even less justified, since over 250 empirical studies have been published supporting the ACT model with a steady number of studies being added every year (ACBS, 2010).

Corrigan's initial criticism links with the more recent one's that have focused on the differential effect and methodologies of ACT when compared with other conditions. In his comparison between ACT and CBT studies, Ost (2008) not only highlights that ACT does not seem to be more effective than CBT, but it also scores lower in methodological rigor with flaws in: reliability of the diagnosis, reliability and validity of outcome measures, checks for treatment adherence, control of concomitant treatments, representativeness of the sample, assignment to treatments, number of therapists, and therapist training/experience. These shortcomings have been openly recognized by ACT authors (Gaudiano, 2009; Hayes et al., 2006; Ruiz, 2010) who also recognize that ACT is still a growing scientific program that needs more studies to investigate its assumptions and claims. However Gaudiano (2009) notes that the CBT studies used by Ost to match the ACT studies were not adequate (38% were in different disorders); more difficult populations were used in the ACT studies; also ACT studies were not supported by grants as large as the ones available for CBT studies, therefore making it more difficult to satisfy some of the methodological issues (e.g. number of therapists per condition). Ost (2008) also points out that according to the task force criteria for Empirically Supported Therapies (Chambless et al., 1998) "ACT was not empirically supported", however he bases this opinion in only three of the five criteria stipulated, and does so by himself although he recognizes the necessity for this judgement to be obtained by a task force rather than by a single individual. Despite this individual criticism, at this point in time ACT is recognized by the Clinical Psychology Division (Division 12) of the American Psychology Association (APA) as an empirically supported

treatment for both depression and chronic pain (APA, 2010) with a moderate level of recommendation for efficacy in these conditions.

Other criticisms of ACT are directed at how original this form of therapy really is, with some authors implying that it is not much different from CBT (Arch & Craske, 2008; Hofmann & Asmundson, 2008), or that it draws extensively from old practices like Morita Therapy (Hofmann, 2008). ACT sees itself as part of the of the CBT tradition, therefore many of the practices that according to the model are seen to be useful or workable are clearly drawn from CBT, as much as they are drawn from early behavioural therapy or from mindfulness practices. Therefore the similarities pointed by the previously mentioned authors are natural. However, ACT has consistently proposed a new approach to the development of its scientific program. As Hayes (2008) notes, many steps were and are continuously being taken in the development of ACT. An integrated and parallel development of both philosophical assumptions (functional contextualism) the creation of a basic account of behaviour that continuously informs treatment and vice-versa (RFT) has kept ACT grounded in its basic applied science roots. The model of psychopathology and intervention was then developed linking these theoretical principles and successfully demonstrated by process change and component studies. Finally, ACT has paid particular attention to moderation and mediation, emphasizing in many studies that the changes in outcomes are primarily achieved by changes in the processes theorized by the ACT model of psychopathology and intervention. Many of these steps are still lacking in firmly established forms of therapy like CBT which has been criticized by lacking a link with basic science or lacking mediation and moderation studies to support its claims. This last point is important, as ACT shows that it works through its hypothesized processes, while CBT dismantling studies have shown that most behavioural change occurs before cognitive techniques have been put in place (Hofmann & G. J. G. Asmundson, 2008). These steps are probably the most distinguishing feature of ACT when compared to other forms of therapy, as the development of the program was done through an inductive technique building route.

3.9 SUMMARY

In summary, ACT is a new behavioural therapy that is firmly rooted in a specific set of philosophical assumptions and that is supported by a theoretical model of human language and cognition. ACT's understanding of human suffering is based on a model of psychological inflexibility that is brought upon by the extension or overuse of naturally occurring language and cognition capabilities. The core intervention processes of ACT are targeted at dismantling this psychological inflexibility by promoting a more accepting and mindful stance in the service of valued goals in order to promote more effective behaviour. A large number of correlation, experimental and outcome studies have provided strong support for the fundamental tenets of this model, although more work is needed in the future to continue to develop ACT's program of science. It is worth noticing that ACT's functional approach, both in conceptualization and in intervention has meant that its model of psychopathology is applicable to several problems and that its intervention model is equally effective in addressing a wide number of different problems. In particular, the application of ACT's model of pathology and intervention has been quite successful in the area of health related problems. Finally, it is important to notice that, although more studies are needed, ACT has so far consistently shown to work through the hypothesized mechanism of change proposed, that is, that improvement in outcomes is related with increases in psychological flexibility.

The next chapter will give a rationale as to why ACT's model of pathology and intervention might be useful in the context of IBS.

CHAPTER 4
RATIONALE, AIMS AND HYPOTHESIS

CHAPTER 4 – RATIONALE, AIMS AND HYPOTHESIS

4.1. INTRODUCTION

The main aim of this chapter is to draw on the literature reviews presented in the previous two chapters to provide a rationale for the research aims and hypotheses of this thesis. Firstly an overview of how some of the features of IBS can be interpreted as part of a context of psychological (in)flexibility is presented. This will provide the basis for the presentation of an ACT formulation of IBS. Next, an overview of how Psychological (in)flexibility might relate to some of IBS's outcomes and how it can be integrated in the biopsychosocial model of IBS will also be made. Based on this ACT model of IBS an argument will also be made for the possible use of ACT interventions in the improvement of IBS outcomes. Finally, the research aims and hypothesis that direct this thesis will be presented.

4.2. PSYCHOLOGICAL (IN)FLEXIBILITY IN IBS

As reviewed in chapter 2, the biopsychosocial model of IBS (Drossman et al., 1999) (Figure 2.1) states that IBS patient's suffering surpasses the mere experience of symptoms, with distressing cognitions and emotional states accompanying exacerbations of this condition and being present even in the absence of symptoms (Drossman et al., 2009). Taking a functional contextual approach to look at some of the characteristics of IBS patients, it is apparent that much of the suffering associated with this illness can be explained in a context of psychological inflexibility. In fact, from an ACT point of view, the content or nature of these distressing experiences is not the main cause of suffering, but rather, it's the way IBS patients relate to these experiences and try to deal with them that exacerbates their suffering.

The types of behaviours that IBS patients report using to deal with their illness experience (Drossman et al., 2009; Kennedy, Robinson, & Rogers, 2003; Rønnevig, Vandvik, & Bergbom, 2009; Schneider & Fletcher, 2008) seem to be in their majority directed at avoiding negatively evaluated aspects of their experience (e.g. pain, discomfort, feelings of lack of control, embarrassment, health anxiety). That is,

most behaviours used by IBS patients can be seen as expressions of experiential avoidance, as they are trying to, in some way “alter the form, frequency or situational sensitivity of private events” (Hayes et al., 1996).

For example a patient who reports “Because of my IBS I avoid going to social gatherings with my friends. If I had an accident while out with my friends I would be so embarrassed. The possibility of embarrassing myself in front of my friends is unbearable”. Experiential avoidance is quite clear in this situation as this person is trying to eliminate or control her possible contact with the feeling of embarrassment by using the avoidant behaviour of not attending the social gatherings. From this example other aspects of psychological inflexibility at work can be derived as well. We can see that the avoidance behaviour is being guided by this person fusing with the literal content of her thoughts. In this example, her behaviour is highly regulated by the presence of thoughts relating to an imagined future of possible embarrassment. She need not in fact ever had experienced this embarrassing event directly for thoughts about it to excessively regulate her actions. Another form of cognitive fusion that could be evidenced from this example is that the behaviour might be explained by a fusion with a reason giving statement like “I can’t go because being embarrassed would be unbearable”, so in this case the excessive fusion with content of the thought that “embarrassment = something that cannot be tolerated” has led this to become a reason for the avoidant behaviour. We can also see that there is a great identification with the conceptualized self of being “an IBS patient” that drives both the behaviour and the reasoning behind the behaviour. That is, the story of this patient’s negative feelings of embarrassment and reasoning for avoidance stem from the key identification “Because of my IBS...” A lack of contact with the present moment is also at hand, since the contact with a potential future situation that has been evaluated as negative exerts more influence in the choice of an avoidant behaviour rather than the contact with the present situation in which she also has the choice of moving towards a more valued action of being with her friends. Finally, we can see a departure from valued living as avoidant tracking takes over, that is, in this instance it was more important for this patient to attend to the immediate goal of reducing her anxiety about a possible embarrassment rather than

pursuing a valued path of being with her friends. This form of avoidant behaviour and the reasoning behind it is one of the most commonly reported by IBS patients with most patients reporting avoidance of several social situations due to the possibility of embarrassment occurring. In fact, the literature is replete with similar examples of behaviours that can be interpreted under the same frame of psychological inflexibility. That is several behaviours that, although in different form, serve the same function of avoiding distressing experiences. Reported examples include: Avoidance of certain food types because they might cause discomfort, avoidance of leisure activities because there might not be a toilet available, avoidance of work because this might cause anxiety and trigger an IBS bout, avoidance of close contact with other people because they might not understand your situation, etc... (Drossman et al., 2009; Kennedy, Robinson, & Rogers, 2003; Rønnevig, Vandvik, & Bergbom, 2009; Schneider & Fletcher, 2008). Similarly there are also many reports in literature about the thoughts that drive these behaviours, that is, the type of contents with which IBS patients seem to more commonly fuse (Gomborone et al., 1995; Lacy et al., 2007; Toner et al., 1998). These seem to revolve essentially around anxious thoughts about the symptoms or their consequences and several studies have established this GI specific anxiety as a key characteristic of IBS patients (Hazlett-Stevens, et al., 2003; Labus et al., 2004; Labus et al., 2007). Reported examples include thoughts like: “I will not make it to the toilet”, “I will never get rid of my IBS”, “My IBS is unbearable”, “I need to get rid of my IBS to continue with my life”, “If I get anxious I will have a bout of IBS” etc... In Schneider & Fletcher's (2008) study the impact of cognitions is clearly stated as patients report that having anxious thoughts about the symptoms/consequences or thinking about the possibility of embarrassment is an intricate part of the cascade of impact of IBS.

Another less obvious example of psychological inflexibility in IBS comes from another common form of behaviour exhibited by these patients: excessive consultation. Excessive consultation has been linked with abnormal illness beliefs like the belief that IBS will develop into something more serious like cancer or inflammatory bowel disease (Kettel, Jones, & Lydeard, 1992; Dulmen et al., 1996 b;

der Horst et al., 1998). Again we can see psychological inflexibility at work here. The fusion of the patient with the content of the thought “What if my IBS is actually a cancer” will provoke anxiety in the patient because she is contacting the literal consequences of the thought (e.g. Having to undergo chemotherapy/radiotherapy, death) rather than the present moment in which she has not been diagnosed with cancer. This anxiety associated with the thought is likely to originate the rule that “In order to lower my anxiety I have to get the doctor to do tests to confirm that I don’t have cancer” and precipitate the health seeking behaviour. The behaviour can then be interpreted as experiential avoidance as it functions to control or eliminate the emotional state of anxiety. In some cases, valued activities might be put on hold while the patient seeks to have her fears disconfirmed (e.g. the patient might limit her activities until the results are back). Even when patients have a confirmation of their diagnosis supported by examinations and tests, some continue to seek help. This excessive repetition of the health seeking behaviour is usually associated with another common dysfunctional belief displayed by IBS patients: “The doctor must have missed something”. Again, fusion with the literal content of this thought drives the patient to re-engage in the health seeking behaviour. In these cases a greater identification with self conceptualizations of being “a sick person” or “someone who will never get better” may be at work, since most of the thought content with which the patient is fusing is likely to stem from these forms of self-conceptualization. Also there seems to be a dominance of an idealized past in which “everything was fine, I was healthy” and a feared future of “this will turn into something bad if they don’t find out what it is”.

A final example of inflexibility present in IBS comes from the excessive use of planning behaviour by these patients (Drossman et al., 2009). Many of these behaviours (e.g.inquiring about the locations of bathrooms ahead of time, carrying extra medication/extra change of clothes, planning “safe routes”), although seemingly adaptive can be viewed as expressions of psychological inflexibility. The use of these behaviours is usually supported by a fusion with the belief that “as long as I plan ahead I’ll be fine”, and this fusion is reinforced every time the behaviour is repeated. Although the behaviours themselves can actually be adaptive as previously

said, from an ACT point of view the motivation for these behaviours is what distinguishes them as being part of a flexible or inflexible repertoire. When these behaviours are mainly directed at trying to control the uncontrollable aspects of IBS like the occurrence of symptoms or occurrence of distress about the symptoms they are part of an inflexible repertoire. On the other hand if they are motivated as part of a larger context of making it possible for the person to carry a valued activity we can then say they are part of a more flexible repertoire.

From these examples and the literature reviewed on the psychosocial aspects of IBS patients it is apparent that many features indicate that psychological inflexibility might be a key factor at play in IBS. A general functional analysis of IBS that highlights the psychological inflexibility features of this condition could therefore be defined as follows:

A proportion of IBS patients can be functionally characterized by the use behaviours that seek to control, eliminate or alter the physical, emotional and cognitive experiences associated with IBS both in the presence or absence of symptoms. These behaviours seem to be motivated by an excessive fusion with a self conceptualization of being an IBS patient; fusion with unhelpful illness specific beliefs or cognitions; and by a dominance of feared future consequences or comparison with an idealized past. IBS patients also tend to choose to engage in these avoidant behaviours that provide short-term relief from their experiences over engaging in behaviours that are values-consistent and that might lead to better life satisfaction on the long-term.

4.3. POSSIBLE EFFECTS OF PSYCHOLOGICAL INFLEXIBILITY IN IBS

Revisiting the biopsychosocial model of IBS (Drossman et al., 1999) (Figure 2.1), it is shown that coping behaviours, along with symptoms, occupy the central part of the model. According to this model, coping behaviours are not only influenced by but they also influence psychosocial, physiological and outcome factors in IBS, therefore being one of the central parts of a loop mechanism of ongoing mutual influence between several IBS factors.

In the previous section it was proposed that some of these coping behaviours could be an expression of experiential avoidance, or more generally of psychological inflexibility. From an ACT point of view one of the most deleterious effects of psychological inflexibility is that it reduces the behavioural repertoire available to a subject by constricting it to a limited scope of behaviours that are directed mainly at avoiding the negatively evaluated experiences. Another effect of psychological inflexibility is that it reinforces the use of these avoidant behaviours over the use of more valued or workable behaviours (Hayes, Strosahl, & Wilson, 1999). Studies in IBS literature seem to confirm this, showing for example that IBS patients continue to use avoidant behaviours even in the absence of any symptoms (Corney & Stanton, 1990). Therefore, the overarching influence of psychological inflexibility in behavioural choice is thought to lead people away from a valued agenda and this is seen in ACT as the main form of suffering or of poorer outcomes. It is not therefore a leap in logic to hypothesize that a psychological inflexibility will contribute to a narrowing of effective behaviour and therefore have a negative impact on an outcome like quality of life.

At the same time, the ACT model of pathology also states that paradoxically, the more people try to avoid, change, control or eliminate their experiences (be it physical, psychological or emotional) the more they actually come into contact with them, resulting in less desired outcomes (Hayes et al., 2006; Hayes, Strosahl, & Wilson, 1999). So it is also possible to hypothesize that the psychological inflexible approach of an IBS patient to her thoughts, emotional states or symptoms will also have a negative impact by amplifying the functional importance of these experiences. Psychological inflexibility could therefore be an important predictor of both IBS outcomes and IBS experiences.

Several studies seem to support these assumptions. As noted in chapter 2, changes in behaviour due to the experiences related to IBS (physiological, cognitive or emotional) are identified by most patients as being one of the most difficult parts of the illness as they have a great impact on quality of life, emotional states and symptoms (Drossman et al., 2009; Kennedy, Robinson, & Rogers, 2003; Rønnevig,

Vandvik, & Bergbom, 2009; Schneider & Fletcher, 2008). GI Specific Anxiety, for example, which has a contextual avoidance related dimension, has been shown to be a strong predictor of symptom severity and quality of life (Jerndal et al., 2010; Labus et al., 2004; Labus et al., 2007). Several studies from the ACT literature, reviewed in sections 3.5 and 3.6 of the previous chapter, also support the association of psychological (in)flexibility with psychological, physical and quality of life outcomes (Hayes et al., 2006; Ruiz, 2010). In particular, studies in the area of health and chronic pain suggest that psychological (in)flexibility is a key process at work in that condition and a significant predictor of psychological, emotional, functional and quality of life outcomes (e.g. McCracken, Vowles, & Zhao-O'Brien, 2010; Vowles et al., 2008; Wicksell et al., 2008). This is particularly important since chronic pain or discomfort is one of the main symptomatic characteristics of IBS.

4.3.1. The mediating role of Psychological (In)Flexibility in IBS

It is ACT's understanding that psychological (in)flexibility is a reaction to life experiences that influences behavioural choice and subsequently levels of suffering (depending if the subject decides to chose value consistent actions or experiential avoidance consistent actions) (Hayes, Strosahl, & Wilson, 1999). Therefore we can say that the influence of physiologic, cognitive and emotional experiences on outcomes like behaviours and quality of life are mediated by how flexibly one reacts to these experiences.

In the review of ACT studies (sections 3.5 and 3.6) it was shown that psychological (in)flexibility or some of its components (e.g. acceptance/ experiential avoidance) seem to mediate the relations between physiologic, cognitive, emotional factors and outcomes (distress, disability, quality of life) in several conditions. Particular support is given to the assumption that psychological (in)flexibility might be a mediator between predictors and outcomes of IBS by studies in the areas of Chronic pain (Vowles, McCracken, & Eccleston, 2008) and Tinnitus (Westin, Hayes, & Andersson, 2008). In both these studies acceptance of the specific conditions was shown to be a significant mediator between psychological predictors and outcomes.

This is encouraging to our proposition since these conditions possess some similar features to IBS as they are both chronic in nature and they are characterized by a group of specific bodily sensations, cognitions and emotions that cause distress to the patients.

However the biggest support for the possible mediating role of psychological (in)flexibility comes from the IBS literature, specifically from the studies by Rutter & Rutter (2002; 2007) on the self regulation model. These authors showed that coping strategies like acceptance, suppression, restraint coping and behavioural disengagement had a mediating role between illness representations and outcomes of impact of quality of life and depression. In these studies, acceptance of the perceived consequences of IBS was shown to have a positive influence on quality of life. However, acceptance in this case was measured with the subscale of the COPE inventory (Carver, Scheier, & Weintraub, 1989) which uses a definition of this concept closer to resignation (i.e. giving-up) or tolerance, which are both passive and fatalistic forms of coping rather than the more dynamic definition provided by the ACT model of “the active and aware embrace of private events that are occasioned by our history, without unnecessary attempts to change their frequency or form” (Luoma, Hayes, & Walser, 2007). It was also shown that behavioural disengagement as a response to perceived consequences and to feelings of weak control, was associated with greater levels of depression. This seems to be in line with the psychological (in)flexibility model in which inaction and the giving up of certain activities will lead to a less valued life with consequent higher level of suffering. Finally, restraint coping was show to positively influence the relation between perceived consequences and depression. This finding seems to contradict the ACT model of IBS in which one would expect that restraining activities could be part of an experiential avoidance pattern, however, this coping strategy can also be viewed as part of an active attempt of “dealing effectively with the stressor” (Carver, Scheier, & Weintraub, 1989). However the way restraint coping is evaluated in the COPE inventory, is somewhat ambiguous regarding the contextual motivators for the use of that coping strategy (e.g. I put off doing anything until the situation permits), not taking into account the possible future benefit of this avoidant action. From an

ACT point of view the putting-off of some behaviours might actually be of value if it's associated with a later valued action. For example, a mother with severe abdominal pain might put-off the cleaning of the house during the afternoon and have a rest so that she can attend her child's school play that evening. Therefore these results should be interpreted with some care as they might have been influenced by the responder's interpretation of the motivational context.

In Figure 4.1 a graphical representation of the possible role of Psychological (In)Flexibility in IBS is presented. In this representation the mutual influence of IBS experiences and avoidant behaviour in Psychological (In)Flexibility itself is highlighted. Also represented is the proposition that Psychological (In)Flexibility will have a key mediating role in the relations between IBS experiences and how IBS patients behave. Finally, it is also shown how influence on behaviour and subsequent influence on quality of life, feedback on the experience of IBS. This model, in many ways guided our exploration of Psychological (In)Flexibility in IBS.

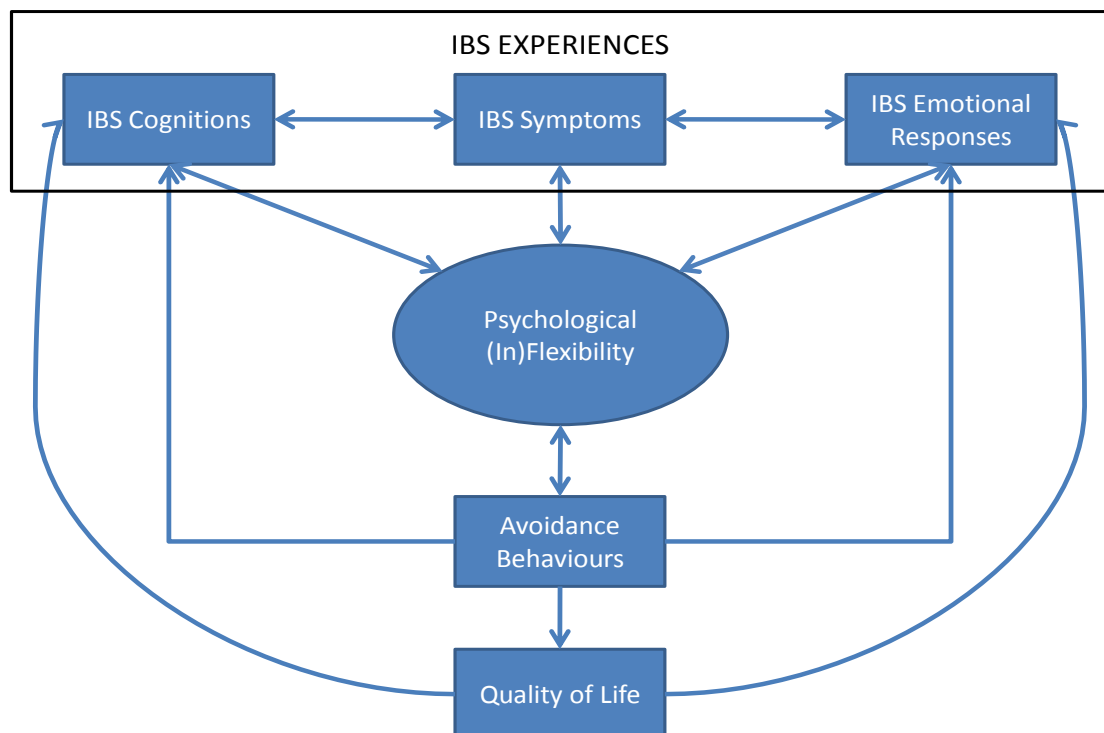


Figure 4.1: Role of Psychological (In)Flexibility in IBS

4.4. ACT INTERVENTIONS AND IBS

In a review of mind/body interventions for IBS, Naliboff, Frese, & Rapgay (2008) were the first to suggest that ACT interventions might be of use in the context of IBS, and there are several reasons to think that.

As previously noted, the ACT model of intervention is based on a functional analysis of the patient's behaviour, in which it is thought that attempts to eliminate, control or change unwanted private sensations (physical symptoms, emotions, thoughts) lead to a narrow behavioural repertoire that diverts the individual from more valued actions, therefore causing more suffering (Hayes, Strosahl, & Wilson, 1999). It is also thought that, paradoxically, the more a patient tries to suppress, avoid or control her private experiences, the more likely it is that this will lead to more of the sensations, emotions and thoughts the person was trying to avoid in the first place (Chawla & Ostafin, 2007; Ruiz, 2010).

In its approach to these problems, ACT tries to develop in clients a more accepting stance regarding their unpleasant internal events in the service of moving in a more valued and meaningful life direction. Therefore in cases in which the client's struggle to control, eliminate or change has led her to a less effective behaviour, ACT encourages the client to observe non-judgementally and accept these experiences as part of their human experience that need not be changed. This movement will free up the client to better focus on chosen values and goals in life and to be more aware of alternative behavioural possibilities that are more value coherent. A commitment to behaviours that are value consistent is then encouraged, despite the presence or not of aversive private events.

In the context of IBS, this would mean that patients would be guided to developing willingness to come in contact with their unpleasant experiences of physical symptoms and with the feelings of embarrassment, anticipatory anxiety and distressing thoughts commonly associated with their condition. The former agenda of trying to eliminate symptoms or prevent the occurrence of distressful cognitive or emotional states could then be abandoned in favour of an agenda focused on creating

a more meaningful life, with or without IBS. One would expect this sort of intervention would lead to a change in the function of symptoms cognitions and emotions experienced by IBS patients, so that these become a part of the living experience that can be integrated in the context of living a valued life, rather than being regarded as experiences that have to disappear or be controlled in order for effective action to be engaged. Therefore an ACT intervention could result in a better quality of life of the IBS patient due to the reduction of experiential avoidance (or the increase of acceptance) and the associated increase in valued behaviours (or decrease in avoidance behaviours) independently of the presence of difficult IBS experiences. As a side effect that is commonly noticed in ACT interventions (Hayes et al., 2006), one could even expect that due to the reduced focus on the aversive experiences; patients might even experience a reduction in these experiences. From an ACT point of view this often, but not always, happens because the naturally occurring pattern of negative reinforcing “Aversive Experience → Control Behaviour → Immediate Relief” cycle would be disturbed, lowering the functional importance of the original experience, therefore removing some of the aversive features of the experience.

Further than theoretical reasons to employ ACT in the treatment of IBS, empirical evidence seems to support this proposition. Several studies reviewed in chapter 2 suggest that elimination/control approaches might not be the most effective for IBS. For instance, pharmacological approaches targeting the elimination of symptoms or psychopharmacological approaches targeting the control of underlying traits of depression or anxiety seem to be of limited efficacy (Zijdenbos et al., 2009). In fact, from an ACT point of view one could say that these approaches might actually have a deleterious influence in some patients, as they reinforce the notion that health can only be equated to the absence of difficult experiences associated with IBS. If a patient identifies with this, it is more likely that valued behaviours will be put on hold until the medication removes the unwanted experiences. Another form of support comes from studies regarding the efficacy of CBT for IBS. Although generally effective, several studies (some of them looking at the components of therapy) have suggested that the main improvements delivered by CBT in IBS result from behavioural change rather than cognitive change (e.g. Kennedy et al., 2006;

Lackner et al., 2007). Therefore the aim of changing aversive cognitions might not be warranted in IBS and it might even not be advisable for some patients. This is because, as ACT would propose, further engagement with difficult cognitions (through Cognitive therapy steps like thought disputation) might actually overemphasize the function of these cognitions over behavioural control and therefore not only increase their frequency but also increase their influence over effective behaviour.

We can also find support for ACT interventions for IBS from the ACT literature. Preliminary evidence can be found in a pilot study by Greco et al. (under review) in which it was shown that 12-14 ACT sessions were effective at improving quality of life, depression, anxiety and somatic complaints at 1 month follow-up in adolescents suffering from functional abdominal pain. Methodological flaws limit the conclusions that can be drawn due to the study being underpowered, having no control group, only having 60% of patients with IBS and no process measures were collected. However it can be seen as some form of preliminary evidence that suggests that ACT might be an effective approach for IBS.

Furthermore additional evidence for the potential efficacy of ACT interventions for IBS comes from the plethora of studies of ACT interventions for other chronic health conditions. As reviewed in section 3.6.2 ACT seems to be effective at improving outcomes for a number of chronic illness conditions like diabetes (Gregg et al., 2007), epilepsy (Lundgren, Dahl, & Hayes, 2008), tinnitus (Hesser et al., 2009) and chronic pain (e.g. Veehof et al., 2011; Vowles & McCracken, 2010; Wicksell, Olsson, & Hayes, 2010) In these conditions, ACT was not only shown to be effective but also that it works through the proposed processes of increasing acceptance and valued behaviour. The biggest support from these studies comes not only from the effectiveness of the interventions, but also from the fact that all conditions had features similar to IBS like chronic nature and association with adverse physical experiences. In some conditions like tinnitus and some forms of chronic pain, the unknown nature of the aversive experiences was also a feature commonly shared with IBS.

4.5. AIMS AND HYPOTHESIS

4.5.1. Study 1

The general aim of this first study was to investigate the possible role of Psychological (In)Flexibility in IBS.

One of the first challenges posed by this aim was how to measure Psychological (In)Flexibility in IBS. Early on, it was decided that we would target the concept of Acceptance as our key metric for Psychological (In)Flexibility. For the purposes of measuring acceptance a general measure of acceptance, the AAQ-9 developed by Hayes et al. (2004) was used; however the same authors advocate the construction/adaptation of specific versions of measures of acceptance according to the to the condition being studied. This is thought to be advisable because specific measures might be more sensitive to specific outcomes being studied. Therefore the first aim was to develop a specific measure of IBS acceptance and investigate its psychometric qualities.

Since this is the first time acceptance is being studied in IBS the second aim of this study was to explore if acceptance (general or IBS specific) differed according to demographic variables, in particular gender, education, marital status, vocational status, ethnicity, nationality, IBS type, age and length of illness. Regarding the first two aims, no hypothesis were generated as these first steps were purely exploratory.

The third aim of this study was to investigate how Acceptance (General or IBS specific) is associated to IBS outcomes and to psychological factors known to be related to IBS. Based on both the IBS and ACT literature reviews, the following hypothesis was generated:

Hypothesis 1 & 2- Higher levels of Acceptance (general or IBS specific) will be associated and predict (beyond the effects of demographic variables):

- a) IBS outcomes (Symptom Severity, Ease of Illness Related Behaviours, Impact on Quality of Life both and General Quality of Life)
- b) Psychological variables related to IBS (General Depression, General Anxiety, General Stress, Specific Visceral Anxiety and frequency of Illness Related cognitions)

As a fifth aim for this study it was thought to be interesting to study how strongly general and IBS specific measures of Acceptance relate to other variables being measured. It was intended therefore to investigate if general acceptance differs from IBS specific acceptance in the strength of its association with general or IBS specific variables. It was expected that:

Hypothesis 3 - General Acceptance will have a stronger association with general factors (General Depression, Anxiety, Stress, General Quality of Life) when compared with IBS specific Acceptance. Conversely IBS specific Acceptance will have a stronger association with IBS specific Factors (Symptom Severity, Illness Related Cognitions and Behaviours, Specific Quality of Life) when compared with General Acceptance.

As GI specific anxiety has been shown to be a strong predictor of IBS outcomes (Jerndal et al., 2010), the sixth aim was to compare the contributions of Acceptance (general or IBS specific) with those of GI specific anxiety in the amount of explained variance in IBS outcomes beyond the effects of demographic variables. As this aim was purely exploratory no hypothesis were made regarding which concept contributes more strongly in the prediction of IBS Outcomes; however it was expected that acceptance would at least contribute with a significant amount of variance over the effects of GI specific anxiety and background variables.

The seventh aim was to investigate the role of Acceptance as a possible mediator of the relationships between established IBS predictors and IBS Outcomes. From the previously proposed model of the role of acceptance in IBS (Figure 4.1) and from the revision of IBS literature we hypothesized that:

Hypothesis 4 – Acceptance (general or IBS specific) will be a significant mediator between Symptom Severity and:

- a) General Quality of Life
- b) IBS Impact on Quality of Life
- c) IBS Related Behaviours

Hypothesis 5 - Acceptance (general or IBS specific) will be a significant mediator between GI Anxiety and:

- a) Symptom Severity
- b) General Quality of Life
- c) IBS Impact on Quality of Life
- d) IBS Related Behaviours

As a final aim, it was also intended to investigate the concept of acceptance as defined from an ACT perspective in the context of the Illness Representations Model. This was thought to be of interest since previous research on this model had highlighted some concepts akin to Acceptance as key mediators between Illness representations and IBS outcomes. It was sought therefore to explore the relations between acceptance and the dimensions of this model. It was also intended to investigate the possible mediating role of acceptance (general or IBS specific) between Illness representations and the outcomes of General Quality of Life, IBS Impact on Quality of Life, IBS behaviours and Symptom Severity. No specific hypothesis was generated as this step was purely exploratory.

4.5.2. Study 2

The general aim of Study 2 was to test an experimental ACT-based treatment designed to target psychological flexibility in IBS and thereby improving IBS Outcomes. A brief comment needs to be made regarding the nature of the study performed regarding this aim. This study can be said to be a preliminary treatment development and feasibility study or a stage I study in the Stage Model of Behaviour Therapies Research (Rounsaville, Carroll, & Onken, 2001). Stage I studies are primarily directed at pilot/feasibility testing, manual writing, and training program development for new and experimental treatments, therefore not being as stringent in design as Stage II (RCT studies) and Stage III (generalization and implementation studies). This study attempted therefore to merely test feasibility of the application of ACT treatments in IBS and the construction of a treatment manual.

Therefore the first aim of study 2 was to investigate if levels of acceptance (general and specific) and IBS outcomes change after a brief intervention based on acceptance and commitment therapy. Based on previous ACT studies it was expected that:

Hypothesis 1 - Participant's Acceptance (general and specific) and General Quality of Life will increase after participating in a brief Acceptance and Commitment Therapy intervention for IBS (at 2 and 6 months post intervention).

Hypothesis 2 - Participant's IBS Impact on Quality of Life, Symptoms Severity and Illness Related Behaviours will decrease after participating in a brief Acceptance and Commitment Therapy intervention for IBS (2 and 6 months post intervention)

The second aim of this study was to investigate if the changes in outcomes at 6 months follow-up were mediated by the changes in Acceptance (general and IBS specific) as predicted by the ACT model. Therefore it was expected that:

Hypothesis 3 - Differences in IBS outcomes scores between pre-intervention (Time 2) and 6 months follow-up (Time 4) will be mediated by changes in Acceptance.

As a secondary aim and due to the longitudinal nature of this study, the test-retest reliability of the IBS Acceptance measure developed for this research was also investigated.

CHAPTER FIVE
METHODOLOGY

CHAPTER FIVE – METHODOLOGY

5.1. INTRODUCTION

In this chapter the methodological approach taken to address the aims set out in the previous chapter will be described. The subject selection, recruitment and the ethical implications of this research will be discussed. A detailed account of the designs, protocols, assessment instruments, materials and statistical analysis used in the two studies developed to address the aims of the research will be delineated.

5.2. PARTICIPANTS

5.2.1. Identification

Possible participants were identified by a Gastroenterology consultant who runs a specialized motility clinic. The identification of IBS patients was done both by clinician interview and by using Rome III criteria (Longstreth et al., 2006), as suggested by the British Society of Gastroenterology (Spiller et al., 2007). All potential participants were identified before being offered the chance to meet with the researcher.

5.2.2. Inclusion criteria

For the purpose of this research, inclusion and exclusion criteria were set prior to recruitment. The inclusion criteria for participants were:

- 1) To have a positive IBS diagnosis made by a Gastroenterology consultant based on ROME III criteria
- 2) To be eighteen years of age or above
- 3) To be an fluent English speaker in order to understand the information in the participant information sheet and the consent form

Participants would not be approached if:

- 1) They were pregnant or breastfeeding
- 2) They reported any alarm symptoms suggestive of significant inflammatory or neoplastic gastrointestinal disorder (such as unexplained weight loss or unexplained rectal bleeding)
- 3) They had a known cognitive impairment that would prevent the understanding of the information in the participant information sheet or the consent form

Only after meeting all these criteria were possible participants then approached by the researcher. As final inclusion/exclusion criteria, only participants who signed the consent form were included in the research.

5.3. RECRUITMENT

Recruitment for study 1 was conducted between April 2009 and February 2010. Recruitment for study 2 occurred simultaneously with recruitment for study 1 between April and December 2009.

5.3.1. Setting

The recruitment phase for both studies took part in a Gastroenterology outpatients' clinic of a hospital located in Edinburgh, Scotland. This hospital is one of the main university teaching hospitals in Scotland and is part of the Scottish NHS Services. This particular clinic was selected due to its specialization in motility problems, making it a service that receives one of the highest numbers of referrals for IBS in the region. Patients are commonly referred from primary care or other GI clinics.

5.3.2. Approach

After eligibility for the research was confirmed in consultation by the Gastroenterology consultant, potential participants were then invited to a separate room at the clinic where they would meet with the researcher. In this meeting the

researcher would give a brief oral description of the research studies and answer any immediate questions. The potential participant would then be given a package that contained a detailed information sheet (see Appendix 1), the consent form(s) (see Appendix 2), the questionnaire survey of study 1 and a prepaid return envelope. Subjects were then asked to read through the information sheet at home before making a decision. Potential participants were also made aware of the contacts of an independent study adviser and of the researcher's contacts in case they required further information or if any of the information in the information sheet was not clear to them. In the case of wishing to participate these subjects were instructed to post back the envelope with the questionnaires and the consent forms signed inside.

5.4. ETHICAL CONSIDERATIONS

Many of the possible ethical issues that could arise from this type of research were considered and addressed prior to the beginning of recruitment.

Issues of informed consent were addressed by producing a clear Participant information sheet (see Appendix 1) and by ensuring that all subjects approached had at least a period of 24 hours to consult with others before making a decision whether to participate. Issues of confidentiality were addressed by attributing a coding number to each participant's data and by keeping all data in secured locations (both physical and digital). All participants were made aware of these confidentiality procedures.

Regarding study 2, particular attention was paid to make clear to participants what the nature of the intervention being studied was. This was done via the information sheet provided (see Appendix 1). Also, participants were made aware that they were free to discontinue their participation in this part of the research without their standard of care being affected in any way. During the intervention workshops were jointly delivered by the researcher and by a Chartered Clinical Psychologist with expertise in ACT (Dr. David Gillanders).

The British Psychological Society Code of Ethics and Conduct (BPS, 2009) were followed at all times to ensure patient safety. For example, if a participant communicated any danger to himself or others, the researcher would inform the designated carer (consultant, GP or designated other).

5.4.1. Ethical approval

Ethical approval for this study was obtained from the Ethics Committee of the Department of Clinical and Health Psychology of the University of Edinburgh and from the Lothian Local Research Ethics Committee (REC number (08/S1103/67) prior to the beginning of data collection.

5.5. STUDY 1

The first study of this research was designed to investigate the possible role of Acceptance in IBS patients.

5.5.1. Design

A cross sectional design was chosen for this study. A cross-sectional study can be defined as a form of observational study that provides a “snapshot” of the characteristics of a population and that at the same time aims to find relationships between these characteristics at that point in time (Trochim, 2006). This survey design was thought to be appropriate as it is a quick method of measuring factors that can be easily self-reported by the respondent.

5.5.2. Procedure

Recruitment for this study has been previously described in section 5.3. All participants included in this study returned by mail the survey given to them at the clinic and a signed consent form for Study 1. In this study, participants were asked to answer to as many questions possible in a survey that included several outcome measures related to IBS, to general and specific psychological factors and to general and specific Acceptance (see section 5.5.2.1). The survey itself consisted of 13 self-

report questionnaires selected by the author for the purposes of assessing the variables of interest for the current project (Table 5.1). A more detailed description of the measures can be found in the assessment instruments section 5.5.4.

Table 5.1: Variables and the measures used in Study 1 in the order as they appear in the survey

Variable	Measure
Gender, date of birth, education, marital and vocational status, ethnic and national origin, length of illness	Demographic Questionnaire
Symptom Severity	IBSSSS
Diagnosis and Type of IBS	Rome III - IBS module
General Acceptance	AAQ-9
IBS Acceptance	IBSAAQ
Depression, Anxiety and Stress	DASS
GI Specific Anxiety	VSI
IBS Related Cognitions	CSFBD
IBS Related Behaviours	BSIBS
IBS Impact on Quality of Life	IBS36
Illness Perceptions	B-IPQ
General Quality of Life	EUROHIS-QOL

5.5.2.1. IBSAAQ Development

In order to measure acceptance in IBS a specific measure needed to be constructed. The Irritable Bowel Acceptance and Action Questionnaire (IBSAAQ) was developed by adapting items of the Chronic Pain Acceptance Questionnaire-Revised (CPAQ-R) (McCracken, Vowles, & Ecclesston, 2004) to reflect IBS related avoidance of activity and acceptance of IBS symptoms.. The CPAQ-R is a 20 item scale that assesses the Acceptance of chronic pain and was considered a good starting point for the IBSAAQ, because it is related to one of the cardinal symptoms of IBS, chronic pain. In order to adapt the CPAQ-R to the IBS population, license was obtained from

the original authors. Each of the items of the CPAQ-R was reworded to make it IBS relevant. The word “pain” in the original scale was replaced by the words “Bowel Discomfort” or “IBS” according to the contextual and grammatical correctness. For example:

Item 1 Original: “I am getting on with the business of living no matter what my level of *pain* is.”

Item 1 Reworded: “*I am getting on with the business of living no matter what my level of **bowel discomfort** is.*”

Item 5 Original: “It's not necessary for me to control my *pain* in order to handle my life well.”

Item 5 Reworded: “*It's not necessary for me to control my **IBS** in order to handle my life well.*”

The full version of this measure is presented in Appendix 7.

5.5.3. Sampling

An a-priori sample size calculation was made based on the maximum number of predictors possibly being used in a multiple regression analysis in this study. An on-line sample size calculator was used (Sopper, 2004) setting the power at 0.8 to detect a medium effect size of 0.15, with p set at $<.05$ and with a maximum number of 9 predictors. The calculator suggested a minimum sample of 113 subjects. This served as a guide for recruiting, although the aim was to recruit as many subjects as possible.

As shown in Figure 5.1, 122 out of 201 patients invited agreed to participate in this study. One of these patients had to be removed during the course of the study due to a change in their diagnosis. The final sample comprised 121 participants representing a 60.2% response rate to the study. Further descriptions of this sample are provided in the Results chapter.

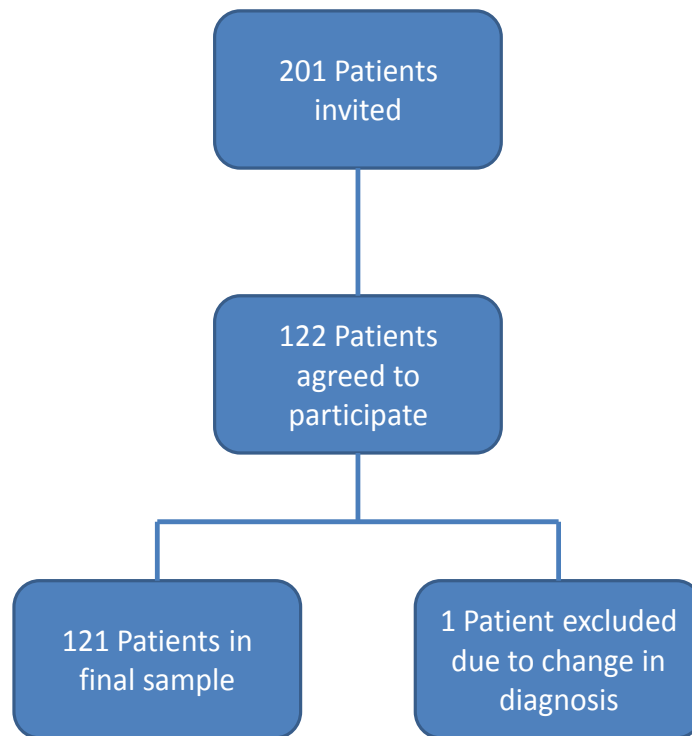


Figure 5.1: Recruitment diagram for study 1

5.5.4. Assessment Instruments

All assessment instruments used are included in Appendices 3 to 14 and are discussed in the order in which they appear in the survey.

5.5.4.1. Demographic Questionnaire

In the first page of the survey, each participant was asked about his/her gender, date of birth, highest education received, marital status, vocational status, ethnic origin, nationality and length of IBS diagnosis. Although the ethnicity question was multiple-choice in nature, participants could choose an “other” category and provide a written description (see Appendix 3).

5.5.4.2. Irritable Bowel Syndrome Symptom Severity Scale (IBSSSS)

The Irritable Bowel Syndrome Symptom Severity Scale (see Appendix 4) was developed by Francis et al. (1997) to be an easy-to-use scoring system to assess the severity of Irritable Bowel Syndrome. It was the first of its kind since only one scale of severity directed at functional bowel disorders in general had been developed before (Drossman, Toner, & Diamant, 1995). From clinical experience and research the authors managed to reduce the scale to the key components of IBS severity. This scale has been suggested to have satisfactory reliability and to be sensible to change (Gonsalkorale et al., 2003; Kennedy et al., 2006) and has been judged to have sound psychometric and methodological qualities by a panel of expert reviewers (Knottnerus et al., 1997).

The scale comprises 5 questions that assess the components of Pain Severity, Pain Duration, Distension, Bowel Satisfaction and General Impact on Quality of Life. Each question is answered in a 100mm Visual Analogue Scale, with 4 to 5 anchor points (see Appendix 4), giving a possible score ranging between 0 and 100. The only exception is the Pain Duration question, in which the patient is asked to report how many days out of the last 10 he/she has experienced pain. This number is then multiplied by 10, giving a possible scoring range from 0-100. The maximum score on the scale is therefore 500 and patients may be considered to have mild IBS (75–174), moderate IBS (175–299) or severe IBS (300–500). Scores below 75 indicate normal bowel function.

5.5.4.3. Rome III Questionnaire – Irritable Bowel Syndrome Module

Developed by the Rome Foundation Board the Rome III questionnaire is based on the Rome III criteria for the diagnosis of Functional Gastrointestinal Disorders (Longstreth et al., 2006). The Rome III questionnaire developed from the previous Rome I and Rome II questionnaires. It includes new questions and modules that might be helpful in identifying a possible structural disorder that might require further investigation or possible psychosocial difficulties that might require mental health support. Although designed for clinical practice and research this

questionnaire is not a diagnostic tool itself but a guide to help physicians and researchers in their clinical assessment.

For ease of use in research or in specialist clinics, eight modules can be derived from the overall questionnaire:

- Irritable Bowel Syndrome (IBS) Module
- Constipation Module
- Functional Dyspepsia Module
- Nausea, Vomiting and Belching Disorders Module
- Functional Oesophageal Disorders Module
- Functional Abdominal Pain Syndrome (FAPS) Module
- Functional Biliary Disorders Module
- All Functional Bowel Disorders Module

For this study only the IBS module was used (see Appendix 5). The IBS module of the Rome III questionnaire is used to aid in the confirmation of the diagnosis and to investigate the specific subtype that the participant/patient is presenting with. The IBS Module is comprises 10 questions that assess the essential criteria for IBS. It also defines whether the patient belongs to a Constipation Predominant (IBS-C), Diarrhoea Predominant (IBS-D), a Mixed (IBS-M) or an Unspecified (IBS-U) subtype of IBS.

5.5.4.4. Acceptance and Action Questionnaire (AAQ-9)

The 9 item Acceptance and Action Questionnaire (see Appendix 6) is a brief self - report measure of general Experiential Avoidance/Acceptance developed by Hayes et al. (2004). Respondents rate truthfulness of how each item applies to themselves on a 7 point Likert scale ranging from 1 (“Never True”) to 7 (“Always True”). Items 2, 3, 7, 8, 9 are reverse scored and summed with the remaining items to give a total possible score ranging between 9 and 63. Higher scores indicate higher levels of acceptance while lower scores indicate a predominance of Experiential Avoidance.

According to the authors the items of the scale tap different aspects of Experiential Avoidance/Acceptance as specified in theory, namely the ability to take effective action when experiencing inhibitory thoughts (item 1) or feelings (item 3), presence of fear or negative evaluations of private events (items 5 and 8), attempts to control or eliminate private events (items 4 and 9), presence of negative comparisons with others (item 7), use of day-dreaming as a form of behavioural regulation (item 2), and ability to distance one-self from the literal content of negative evaluations.

During the validation study carried out by the authors and using a 460 clients sample from a student counselling centre, internal consistency was found to be adequate (Cronbach's $\alpha = 0.70$) as well as test-retest reliability ($r = 0.64$). Also, moderate to high correlations with measures of psychopathology (e.g. Depression, anxiety, post-traumatic stress), with measures of specific coping (e.g. Thought suppression, dissociation, specific avoidance) and Quality of Life add to the validity of the AAQ as a measure that taps into the construct of general experiential avoidance as a broad based phenomenon (Boelen & Reijntjes, 2008; Hayes et al., 2004; Mairal, 2004).

5.5.4.5. Irritable Bowel Syndrome Acceptance and Action Questionnaire (IBSAAQ)

The IBSAAQ (see Appendix 7) is a measure adapted by the researcher whose development has been previously described. It is a 20 item scale that assesses Acceptance in IBS. The items are answered in a Likert type scale ranging from 0 ("Never True") to 6 ("Always True") with items 4, 7, 11, 13, 14, 16, 17, 18, 20, being reverse scored. The total score is obtained by summing the individual item scores and can range from 0 to 120 with higher scores indicating greater levels of Acceptance of IBS related contents.

Psychometric testing of the IBSAAQ was conducted as part of Study 1 and will be described in detail in section 6.4.

5.5.4.6. Visceral Sensitivity Index (VSI)

The VSI (see, appendix 8; Labus et al., 2004) is the first self-report questionnaire designed to measure specific GI Specific Anxiety in IBS patients. The 15 items of this scale assess the cognitive and behavioural aspects of fear, anxiety and hyper-vigilance responses to common GI specific sensations or discomfort. Each item asks the responder to state how much he/she agrees (“Strongly agree” – 1, “Strongly Disagree” - 6) with the statement presented. The items are then reverse scored, 1-6 becomes 5-0, and summed to yield a possible range of scores between 0 (no GI specific anxiety) to 75 (severe GI specific anxiety).

A validation study with 96 IBS patients found that the scale has good internal reliability (Cronbach's $\alpha = 0.93$) and good face validity. Convergent validity for anxiety measurement was also found to be good with moderate to high correlations with general State Anxiety and Anxiety Sensitivity scales. In a later study the VSI's internal reliability was confirmed across IBS and non-IBS samples. In the same study the VSI was also found to be good at discriminating between IBS and non-IBS patients (Labus et al., 2007). The concept of GI specific anxiety as measured by the VSI has also been posited as a good predictor for health care seeking in IBS populations (Ringstrom et al. 2007).

5.5.4.7. Cognitive Scale for Functional Bowel Disorders (CSFBD)

The CSFBD (see Appendix 9; Toner et al., 1998) allows the assessment of the cognitions a patient has in relation to his/her functional bowel disorder. The questionnaire's 25 items include essential cognitive thematic areas observed in Functional Bowel Disorder patients by clinicians and researchers involved in this area. Themes and examples include: Bowel performance anxiety (“I worry about not finding a toilet when I need one”), control (“I worry about losing control of my bowels in public”), pain (“My bowel symptoms are agony”), perfectionism (“I do my absolute best at everything”), anger/frustration (“I am frustrated by my bowel symptoms”), self-efficacy (“My symptoms are too much to handle”), social approval (“With frequent toilet visits others think something is wrong”),

embarrassment/shame (“It’s embarrassing to keep going to the toilet”), and self-nurture (“I feel guilty if I nurture myself”). Patients indicate for each item how much they agree with the content of the presented items in a Likert scale ranging from 1 (“Completely Disagree”) to 7 (“Completely agree”). Scores range from 25-175 with higher scores indicating higher strength of these particular cognitions. The scale has shown good reliability (Cronbach $\alpha = 0.93$), low social desirability contamination and good construct validity. It is important to note that the validation sample was composed of 96% of IBS patients, therefore making this scale very appropriate for this study.

In a Randomized Control Trial comparing the use of antispasmodic medication vs. medication plus a course of Cognitive Behavioural Therapy this scale was used to measure cognitive change, where it proved to be sensitive to change (Kennedy et al., 2006).

5.5.4.8. Behaviour Scale for Irritable Bowel Syndrome (BSIBS)

This scale (see Appendix 10) assesses the frequency of use of specific coping behaviours by patients with IBS. Twenty eight coping behaviours specific to IBS are described and scored on a Likert scale from 1 (“Never”) to 7 (“Always”) indicating how often the behaviour is carried out. A total score is obtained by summing the responses to the 28 questions, giving the scale a range from 28 to 196. The items of the scale cover situations such as the avoidance of: certain foods, social situations, intimate situations, exercise or work. Other situations relate to efforts to control the bowel function by using medication, food or cigarettes or by changing toilet habits. Although the authors of the scale report that it was developed and validated for an RCT study, they provide no description or values regarding this development and validation of the scale (Kennedy et al., 2006). However a recent study by (Reme et al., 2010) has reported the reliability of the scale to be $\alpha=0.89$. The fact that this scale addresses avoidant and control behaviours in IBS makes it quite appropriate for this study. Therefore a higher score indicates stronger attempts at controlling/changing/eliminating IBS experiences.

5.5.4.9. Irritable Bowel Syndrome Impact on Quality of Life (IBS36)

The IBS36 (see Appendix 11) is an illness specific measure of Quality of Life created by Groll et al. (2002) that addresses the impact on quality of life in areas as diverse as food, symptoms, family relations, emotional impact, work/school/daily activities impact, social impact, sleep/fatigue, and sexual relations. This self administered scale consists of 36 questions that ask the patient to think how IBS has impacted on his/her Quality of life over the course of the last 2 months. Each question is scored on a 7 point Likert Scale ranging between 0 (“Never”) and 6 (“Always”). The overall score is obtained by summing the individual item scores with a possible minimum of 0 and a possible maximum of 216. A higher score implies a higher impact on Quality of Life. The scale has a high internal consistency (Cronbach $\alpha = 0.95$), high test-retest reliability over a period of 2 weeks (Spearman's $r = 0.92$) is responsive to change (Groll et al., 2002; Lowe, Depew & Vanner, 2000).

Other measures of Quality of Life in IBS are also currently available like the IBS-QOL (Patrick et al., 1998), the IBSQOL (Hahn et al., 1997 b) or the IBS-HRQOL (Wong et al., 1998). The IBSQOL and the IBS-HRQOL were considered but not used due to lack of proper validation (Groll et al., 2002). Although the IBS-QOL is the most commonly used measure of Quality of Life in IBS, it has been critiqued for only having been validated in an all female population (Drossman et al., 2000), and because its response to change was evaluated against a telephonic self-report rather than a self-report plus expert clinical evaluation (Patrick et al., 1998). The IBS36 addressed all the short-comings of these previous measures and was consequently selected as the most suitable measure of Quality of Life in IBS for this study.

5.5.4.10. Brief Illness Perception Questionnaire (B-IPQ)

Designed by (Broadbent et al. (2006), the B-IPQ (see Appendix 12) was developed to be a quicker and less taxing tool for the assessment of Illness Perceptions. The Brief IPQ is a self report measure that allows the assessment of 9 Illness representation dimensions. The first 5 items assess cognitive representations of Consequences (Item 1 - How much IBS affects life), Timeline (Item 2 - How long it

will last), Personal Control (Item 3 - How much control does one feel over IBS), Treatment Control (Item 4 – How much will treatment help) and Identity (Item 5 – How much are symptoms experienced). Items 6 and 8 assess the emotional representations of Concern (Concern about IBS) and Emotions (How much does IBS affect emotionally) respectively, while Item 7 assesses Comprehensibility (How much does one understand IBS). All items from 1 to 8 are scored in an 11 point linear-scale (0-10) with higher scores representing a higher endorsement of that dimension. Finally an open ended question asking the patient to list the 3 most important causal factors in their Illness (Item 9) assesses the Causal representation. After categorical analysis, answers to the causal item can be grouped into the categories of Psychological (e.g. stress, state of mind), Biological (e.g. diet, heredity) or External (e.g. infection, poor medical care) causes.. In this study the general word “Illness” present in the original version of the Brief IPQ was changed for “Irritable Bowel Syndrome”, in accordance with the suggestion of the authors for studies regarding a specific illness. The authors found this to be a valid and reliable measure, with good predictive and discriminant validity.

The Brief IPQ has also been shown to be sensitive to changes in Illness Perceptions after an intervention (diagnostic procedure) in patients referred for routine outpatient angiogram (Devcich et al, 2008).

5.5.4.11. EUROHIS-QOL

Derived from the WHOQOL-100 and WHOQOL-BREF, the EUROHIS-QOL (see Appendix 13; Power, 2003) is an 8 item general Quality of Life measure. The scale covers general Quality of Life and Health domains (items 1 and 2) as well as Physical (Items 3 and 5), Environmental (Items 4 and 8), Psychological (Item 6) and Social (Item 7) domains. Each item is scored on a 5 point Likert scale and depending on the item the range will be from 1 (“Very Poor/Very dissatisfied/Not at all”) to 5 (“Very Good/Very Satisfied/Completely”). The overall score is attained by summing the scores of the eight items giving the scale a possible range from 8 to 40 with higher scores indicating better Quality of Life. The scale has shown good internal

consistency with Cronbach's $\alpha = 0.86$ satisfactory convergent and divergent validity and good cross cultural performance, and has been recommended for public health research (Bullinger, Power, & Schmidt, 2008; Schmidt, Mühlan, & Power, 2006).

Since its validation, the EUROHIS-QOL has been used for general Quality of Life assessment in a range of populations, including Chronic Fatigue, Dementia and Somatic Stress (Hornung et al., 2008; Martin et al., 2007; Morina et al., 2009).

5.5.4.12. Depression Anxiety and Stress Scales - 21 (DASS 21)

This self-report measure is the 21 item version of the Depression Anxiety and Stress Scales (DASS) (see Appendix 14; Lovibond & Lovibond, 1995). The DASS is a set of 3 scales designed to assess distress along the dimensions of depression, anxiety and stress/tension. The 21 item version has three sub-scales with 7 items each concerning Anxiety (Items 2, 4, 7, 9, 15, 19, 20), Depression (Items 1, 6, 8, 11, 12, 14, 18) and Stress (Items 3, 5, 10, 13, 16, 17, 21). In a 4 point Likert scale ranging between 0 ("Did not apply to me at all") and 3 ("Applied to me very much or most of the time") the respondents indicate the frequency or extent to which they experienced each of the symptoms described on the items. The scores for each scale are obtained by summing the responses and multiplying them by 2.

Each of the scales has been shown to be reliable with Cronbach α 's of 0.88; 0.82 and 0.90 for Depression, Anxiety and Stress respectively (Henry & Crawford, 2005). The factor structure of the scale has also proven to be quite stable, with the DASS-21 showing good convergent and divergent validity in both clinical and non-clinical samples and in different ethnic and age groups (Antony et al. 1998; Daza et al. 2002; Henry & Crawford, 2005; Ng et al., 2007; Szabo, 2009). DASS is recommended for research purposes and as a routine clinical outcome measure for anxiety, depression and stress (Lovibond & Lovibond, 1995; Ng et al., 2007).

5.5.5. Statistical Analyses Study 1

Prior to any analyses all data was examined for missing data or data entry errors. For interval or ratio data with data missing completely at random and not exceeding 5% per item or 20% per subject, mean imputation was used to replace values (Chavance, 2004; Fox-Wasylyshyn & El-masri, 2005).

Univariate analyses were used to describe the demographic characteristics of the sample and the survey measures. All variables were examined for distribution according to the recommendations of Field (2005. p72) in order to ensure they all met the assumptions for parametric analysis.

Regarding the first aim of study 1, initial considerations of the IBSAAQ, included the examination of item frequency distributions to identify items with extremely skewed response distribution or low variability. Sample size and factorability of the correlation matrix were also examined using the Kaiser-Meyer-Olkin sampling adequacy measure and Bartlett's test of sphericity Field (2005. p.640). Exploratory Factor analysis using Maximum Likelihood extraction was conducted to examine the underlying factor structure of the items of the IBSAAQ according to the recommendations of Costello & Osborne (2005). The scale's internal consistency was analyzed through Cronbach's alpha and Item-Scale correlations were also assessed to help determine if any item should be removed. Convergent validity of the IBSAAQ was investigated by analyzing the relationship of the IBSAAQ with a general measure of Acceptance (AAQ-9). Concurrent validity was investigated by analyzing the relationship of the IBSAAQ with a set of criterion variables (e.g. General Quality of Life, IBS Related Behaviours) through Pearson's product moment correlations.

Regarding the second aim of this study, differences in Acceptance measures (General or IBS specific) due to categorical variables were explored using t-tests or one-way ANOVA (depending on the number of categories in each variable). The relationships

of Acceptance (General or IBS specific) with continuous measures were investigated via Pearson's product moment correlation.

For the third aim, Pearson's product moment correlation analyses were used to investigate the association of Acceptance (General and IBS specific) with key outcomes (Symptom Severity, use of Illness Related Behaviours, Impact on Quality of Life and general quality of life) and psychological factors known to be related to IBS (General Depression, General Anxiety, General Stress, Specific Visceral Anxiety and frequency of Illness Related cognitions).

Regarding the fourth aim, multiple regression analyses were conducted to investigate the contributions of Acceptance (General and IBS specific) in predicting IBS Outcomes and psychological factors known to be related to IBS beyond the effects of demographic variables.

A series of Z-score tests, comparing correlated correlation coefficients (Meng et al., 1992), were conducted to investigate the fifth aim of examining the strength of association of general and IBS specific measures of Acceptance with general and IBS specific variables.

Regarding the sixth aim of comparing the contributions of Acceptance (general or IBS specific) with GI specific anxiety in predicting IBS outcomes; a series of hierarchical multiple regression analyses were used with each predictor being alternately entered at the last step.

The mediation model described by (Preacher & Hayes, 2004) was used to investigate the seventh aim of this study; the investigation of the possible mediating role of Acceptance in the relationships between established predictors and outcomes.

Regarding the eighth and final aim of study 1, the relation between Acceptance (general and IBS specific) and Illness Perception Dimensions (except for Causal Attribution) was investigated by examining the significance and direction of

Pearson's product moment correlations between them. Differences in Acceptance by Causal Attributions were investigated by one-way ANOVA. A series of path analyses based on multiple linear regressions as described by Pedhazur (1997) were used to examine the possibility that the relation between Illness Representations and IBS outcomes was mediated by Acceptance. In the case of a significant indirect path being detected, a test of mediation was carried according to the model described by (Preacher & Hayes, 2004).

More detailed descriptions of the statistical analyses carried are done in the results chapters.

5.6. STUDY 2

The second study of this research was designed to investigate if an intervention based on Acceptance and Commitment Therapy would produce changes in acceptance and outcomes in IBS. It also intended to study if changes in outcomes are mediated by changes in acceptance.

5.6.1. Design

A repeated measures or within subject design was used to study the effects of treatment upon participants. Participants were asked to complete the same questionnaires before and after treatment. This design has the advantages of requiring fewer participants and reducing the effects of natural variation between individuals (Shuttleworth, 2009). The collection of data was undertaken at four separate time points (see Figure 5.2). Data for Time 1 was collected when participants responded to the survey of study 1. Data for Time 2 was collected 1-2 months later, on the day of the workshop when participants answered a survey prior to the beginning of the workshop. Therefore Time 1 and Time 2 were considered as part of a non-intervention baseline. Data for Times 3 and 4 was collected by survey 2 and 6 months after the intervention.

5.6.2. Protocol

During the recruitment phase for study 1, potential participants were also invited for a new experimental intervention based on ACT. They were made aware that this was a psychological intervention directed at improving their Quality of Life by learning new skills that would enable them to live better with IBS. Participants were also informed that this intervention would entail attending a one day workshop and working with a self-help workbook (see Appendix 1).

The selection of this intervention format involving a workshop and a self-help workbook was guided by previous intervention studies both in IBS and in ACT. As reviewed in chapters 2 (section 2.7.4.5) and chapter 3 (section 3.6.2), self-help interventions in IBS (Forbes, Macauley & Chiotakakou-Faliakou, 2000; Robinson et al., 2006; Sanders, Blanchard, & Sykes, 2007), short group interventions using ACT (Gregg et al., 2007; Lundgren, 2004; Masuda et al., 2007), and the combination of workshop plus workbook using ACT (Lillis et al., 2009) have been moderately to highly effective at improving outcomes. According to Williams & Withfield (2001) some of the advantages in using self-help interventions are their easy access, low cost, popularity and acceptance by patients, maintenance of patient privacy, flexibility of use, promotion of empowerment, possibility of learning being easily reinforced and consolidated, and permanently possibility of re-use.

Participants who responded to Study 1 and who also returned the consent form for Study 2 were contacted by telephone by the researcher in order to ascertain their availability to participate in the one day workshop. Several dates were usually proposed (usually within 1 to 2 months) in order to maximise the participation rate. After agreeing on a date the participant would be sent a letter with directions and a brief description of the day of the workshop. On the day of the workshop, participants answered a survey containing part of the measures used in study 1, prior to the commencement of the workshop. The workshop was then delivered in the following 7 hours (with a 1 hour lunch break and two, 15 minutes breaks). At the end of the workshop all participants were given the Self-Help Workbook entitled "Living

with IBS – A workbook applying ACT to IBS” (Appendix 15) with the instruction to use it as a way of extending the topics and skills covered during the day of the workshop. Details about the workshop and workbook and their development will be presented in the section 5.6.5.

During the weeks following the workshop the researcher made 2 telephone calls to support the use of the workbook. The telephone calls were usually scheduled for 3 weeks and 7 weeks after the workshop, although participants’ availability was also taken into consideration. The survey was sent to all Study 2 participants again at two and six months after their participation in the workshop. It was expected that participants would take about 8 weeks to fully complete the reading and the exercises suggested in the workbook, hence the decision to use 2 months as the first time point for follow-up. The surveys used for Times 2, 3 and 4 contained part of the variables presented in Table 5.1. Variables selected for these surveys were symptom severity, general acceptance, IBS acceptance, IBS related behaviours, IBS quality of life and general quality of life. Figure 5.2 provides a flowchart diagram of the procedure (this diagram was part of the Patient Information Sheet given to all possible Study 2 participants).

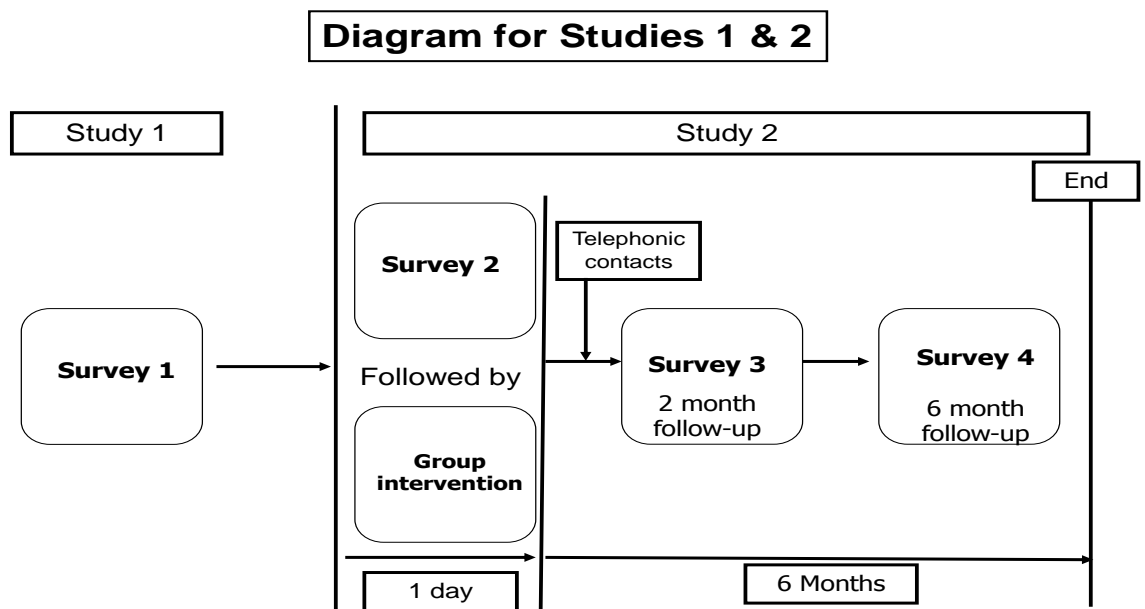


Figure 5.2: Flowchart diagram for Study1 and Study 2

5.6.3. Sampling

An a-priori sample size calculation was conducted in order to know how many participants would have to be enrolled in a repeated measures design in order to detect an effect size of $\eta^2=.06$ (medium), with a power of 0.95 ($p<0.05$). The program G*Power (Erdfelder, Faul, & Buchner, 2008) gave a minimum sample size of 36 subjects for the selected parameters. A minimum recruitment target of 72 participants was set for study 2 in order to accommodate up to a 50% drop out rate between agreement to participate and the end of the study.

Figure 5.3 indicates that 79 of the 191 patients invited agreed to participate in study 2. Of these 22 did not attend the workshop giving a 27.8% drop out rate at this first stage. All patients who did not attend were again contacted to arrange a new possible date; however they either did not attend again or changed their minds about participating in study 2. Fifty six patients attended and completed the baseline measures. One patient also attended but was later excluded at her own request.

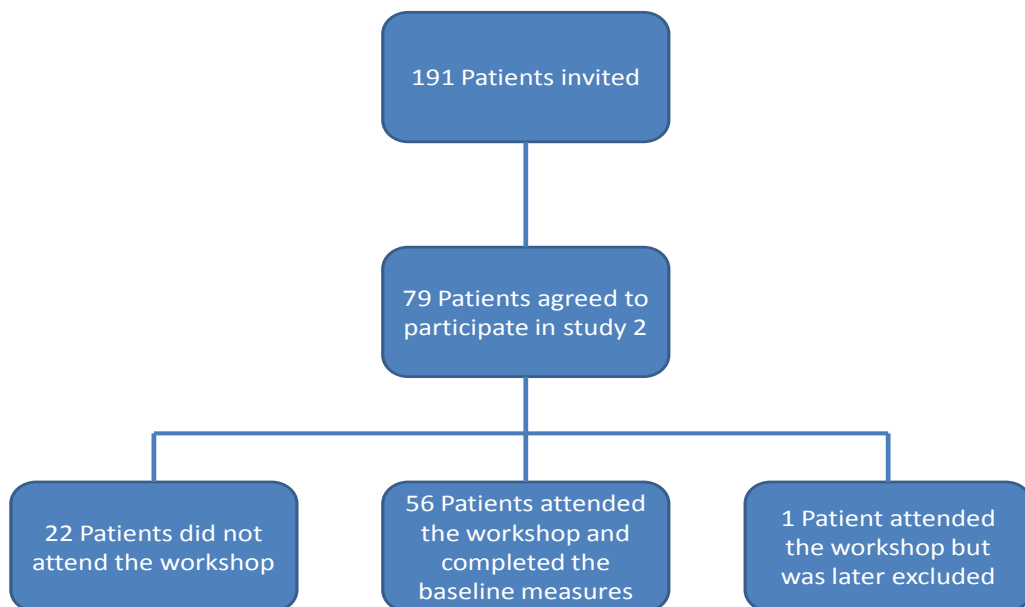


Figure 5.3: Recruitment diagram for study 2

5.6.4. Therapists

All intervention workshops were delivered by the researcher and by Dr David Gillanders. The researcher is a licensed clinical psychologist in Portugal, with post-graduate experience in clinical practice both in Portugal and the UK. Dr David Gillanders is an HPC registered Clinical Psychologist with extensive clinical experience and expertise in ACT.

5.6.5. Materials

For study 2, a workbook and a workshop were developed to carry out the intervention. The workbook was designed so that the workshop could be based on the workbook, making the transition from workshop to workbook easier for the participants. A brief description of the development and key features of the workbook and workshop will follow.

5.6.5.1. Workbook

For the purposes of this study a self-help workbook that addressed IBS from an ACT perspective was developed, since no similar material has ever been published. The workbook was intended to improve quality of life in IBS patients by undermining Experiential Avoidance and promoting Acceptance of IBS distressing content in the context of living a more successful life according to one's own values. This would be accomplished by guiding the reader through a series of metaphors and exercises consistent with the original ACT model (Hayes et al., 1999). Chapters on the workbook addressed the processes of creative hopelessness, values, defusion, acceptance, self as context, awareness of present moment and committed action. Due to the common lack of knowledge or misconceptions about IBS by patients (Lacy et al., 2007), a chapter was included to provide information about IBS definition, diagnosis and possible causes. As the workbook is a self-help material, particular attention was taken to follow some of Williams (2003) recommendations for these types of materials. Therefore, although information about IBS was addressed, it was made clear that the workbook was not an information/education only material. The model of treatment was clearly established as being focused on problems of

relevance to the patient, in this case quality of life. The approach was also described in sufficient detail so that the reader could work independently on the content provided.

The workbook was mainly inspired by the ACT self-help workbook “Living beyond your pain” by Dahl & Lundgren (2006) which addresses Chronic Pain from an ACT perspective and has proven to be effective as a treatment for this condition (Johnston et al., 2010). It was thought to be a suitable starting point due to chronic pain being one of the key symptoms of IBS (Longstreth et al., 2006). The Dahl & Lundgren (2006) workbook was mainly a source of inspiration regarding the structure of the manual being created. A similar organization of chapters that covers all of ACT processes was followed by the researcher. Many exercises and metaphors presented in this manual were also adapted for use with the IBS population.

Other self-help manuals were also a source of inspiration for the production of the workbook. The self-help workbook “Breaking the bonds of Irritable Bowel Syndrome” by Bolen (2000) was particularly helpful in the delineation of the information chapter. ACT workbooks like “Get out of your mind and into your life” (Hayes & Smith, 2005) and “The diabetes lifestyle book” (Gregg, Callaghan, & Hayes, 2007) were also instrumental in refining some of the metaphors and exercises used throughout the workbook. Although inspired by these materials the researcher maintained his own originality creating new or adapted versions of exercises and metaphors that were considered to be functionally equivalent to the original ones.

Throughout the whole workbook several pictures were also used, to help illustrate some points and to make the manual more pleasing to the eyes. These base pictures were selected by the researcher from copyright free websites, and were then composed by Mr Tim Fawns (e-learning coordinator) under the instructions of the researcher. Finally, some fictional IBS sufferer characters were also included in the workbook. These characters were a composite collection of several statements left by IBS sufferers in an on-line forum (<http://www.ibsgroup.org/forums>). One character

in particular was used throughout the whole workbook as an example of how the reader could complete some of the exercises.

Another form of material included in the workbook was 2 audio CDs that had the instructions/guidance to some of the exercises presented in the workbook recorded. This was thought to be a way to encourage and facilitate the practice of these exercises by the reader.

The development of the workbook would also not have been possible without the instrumental help of Dr David Gillanders. Dr Gillanders not only helped to write the book, revise and edit chapters, he also contributed with the voice recordings of the audio CDs.

The final version of the manual can be seen in Appendix 15. Due to the extent of the manual (130 pages), only a brief description of the chapters and their contents will be provided here. The reader is invited to consult the full manual for more detail.

Chapter 1 – “What is IBS”

In this chapter information about the symptoms and diagnosis of IBS is provided in simple and non-medical terms, to familiarize the reader with the different forms of IBS presentation. Also a brief introduction to the brain-gut interaction model is provided, with particular emphasis on the role played by food, hormones, infection and stress in the aetiology and maintenance of IBS.

Chapter 2 – “Psychological stressors in IBS”

In this chapter the reader is encouraged to become aware of emotions and cognitions that are associated with his/her IBS and how this affects behaviour. It uses a series of diary based exercises to track emotions or thoughts relating to IBS.

Chapter 3 – “What you do and what is the cost”

This chapter addresses the process of creative hopelessness by introducing the reader to the notion that experiential avoidance comes associated with a cost in Quality of

Life. Diary type exercises are used to identify situations in which the reader is engaging in experiential avoidance and how much impact that has on his/her life both on the short-term and the long-term. A brief introduction to Acceptance as an alternative is also made at the end of the chapter.

Chapter 4 – “Mapping your direction”

In this chapter the reader is introduced to the concept of values. Several exercises are then used to explore the reader’s own values, how valued living can be translated into actions and what barriers might come up to valued living. Finally the reader is invited to assess how successfully they are living their values at this moment.

Chapter 5 – “When to use your mind, when to lose your mind”

In this chapter an introduction to cognitive fusion in its various forms is made through some brief exercises. Creative hopelessness is again introduced by inviting the reader to try to control their thoughts or emotions. The notion of the impossibility of controlling thoughts and emotions is addressed through the use of exercises and metaphors. Defusion as an alternative to thought/emotion control is then presented along with a diary for tracking moments of fusion. Several defusion skills are then presented through exercises that the reader is invited to practice over a period of a week.

Chapter 6 – “Mindfulness: A new perspective”

In this chapter exercises and metaphors are used to develop in the reader a sense of an observing self that can carry all experiences, good, bad and IBS related. Several mindfulness skills are then presented in exercise form, as a way to foment present moment awareness.

Chapter 7 – “Are you willing to have IBS?”

In this chapter Acceptance is re-introduced. The characteristics of Acceptance, what it is and what it is not are discussed with the aid of several metaphors. A series of exercises that encourage the readers to come into contact with their difficult IBS experiences are presented with the intent of fostering Acceptance of IBS.

Chapter 8 – “Committing to make your own music”

In this chapter the concept of committed actions is introduced and explained via the use of metaphors. All the skills presented in the previous 2 chapters are brought together to help the reader to create a pattern of committed actions that are values consistent. An example of a committed action plan is presented and the reader is encouraged to try to stick to that plan for a week. A final exercise is then directed at evaluating the success of the previous exercise in assessing if the reader experienced any differences in vitality.

Chapter 9 – “Staying committed”

This final chapter is directed at helping the readers continue their committed action patterns. Through exercises it helps the reader identify possible barriers to committed action and uses the ACT model to deal with these barriers. It also focuses on the importance of helping the reader build a support team.

5.6.5.2. Workshop

For the purposes of Study 2 a 1 day workshop based on the finalized version of the workbook was created. Several reasons influenced the choice of a 1 day format. The first reason was related with attrition problems. It was thought that by doing a single session it would be less likely that anyone who started the session would not complete it. A model of multiple weekly sessions was considered but discarded because if a participant missed one week of treatment he/she would miss a vital component of the model. It was also thought that it would be easier for participants to arrange for a single day commitment rather than multiple days. The second reason was related to the model itself. Acceptance and Commitment Therapy works as a full model with all the different processes overlapping each other. It was thought then that it would make more sense for participants to experience the model as a whole, rather than broken down in weekly modules. The final reason for choosing this format was related to the previous success of these types of short group interventions in ACT. Gregg et al. (2007), Lundgren (2004), Masuda et al. (2007) and Lillis et al.

(2009) studies, have all shown that 1 day group interventions (ranging from 3 to 8 hours) are effective for the ACT model, and well tolerated by participants.

Further considerations were taken into account regarding the setting and the catering for the workshops. The characteristics of the IBS population were taken into account, so particular attention was taken to make sure that the workshops were run in rooms with large toilet facilities in the near vicinity. Both morning and afternoon sessions had a break and there was a 1 hour lunch break between them. Participants were informed that at any time they could leave to use the bathroom. Due to the different dietary requirements of the participants no lunch was provided, but biscuits and hot drinks (with non-caffeinated options available) were provided.

This protocol was designed to be delivered by two facilitators with each one taking the lead on alternative modules while the other attended to whether or not key material had been addressed. It was decided as well that group size should not exceed 12 participants, in order to receive feedback from the exercises from all participants.

The final considerations made in the production of the workshop protocol were related to the transposition of the workbook content to a workshop format. The final structure of the workshop included all the processes involved in ACT by using representative exercises from the workbook. This was intended to facilitate the uptake of these exercises by the participants after the workshop. Some processes had to be delivered together in the same module due to time restraints, but attention was paid to ensure that it was done in a functionally sound manner. Some exercises were changed in order to address more than one process at a time.

The workshop protocol can be seen in Appendix 16. A brief description of the modules, the key concepts addressed and the associated activities are outlined below. The reader is invited to consult the full protocol for more detail.

Introduction Module (30 minutes)

Group facilitators and participants introduced themselves. Group facilitators then presented the goals of the workshop and the overview of the day. Treatment rationale, group guidelines and informed consent were then discussed.

Module 1 (30 minutes)

Information was presented to the participants regarding IBS symptoms and diagnosis, the brain gut model, and about how emotional and cognitive IBS related content can influence behaviour.

Module 2 (1 hour and 15 minutes)

Creative hopelessness was fostered by engaging participants in an exercise that looked at what they have been doing so far to deal with IBS, why they have been doing that, and what were the short-term and long-term consequences. During debrief, experiential avoidance was drawn out and evidenced in participants experiences. Acceptance was then presented as an alternative, illustrated by metaphors.

Module 3 (45 minutes)

A definition of Values was presented followed by an experiential exercise (100th birthday, p. 42 of the workbook) designed to get participants in contact with their values. Debrief of this exercise was then used to pin point some valued directions that the participant could work on for the rest of the workshop.

Module 4 (45 minutes)

Short exercises were used to illustrate the concept of fusion and how much language plays a part in human suffering. Defusion skills were then presented through two exercises (Words, words, words, p. 66 of the workbook; Kicking your butts, p.71).

Module 5 (45 minutes)

Self as context, present moment awareness and defusion were all approach in a single extended exercise that incorporated the “Observer Self” (p. 78 of the

workbook) and the “Buses on the street” (p. 68 of the workbook) exercises. Brief mindfulness techniques were also described.

Module 6 (45 minutes)

In the final exercise participants were invited to fill a “Committed Action Form” (p. 114 of the workbook) and were invited to share their commitment with the group. Some time for questions about the day’s session was then allowed.

5.6.6. **Statistical Analyses Study 2**

Prior to any analyses all data was examined for missing data or data entry errors. For interval or ratio data with data missing completely at random and not exceeding 5% per item or 20% per subject, mean imputation was used to replace values (Chavance, 2004; Fox-Wasylyshyn & El-masri, 2005).

Univariate analyses were used to describe the demographic characteristics of the sample and the survey measures. All variables were examined for distribution according to the recommendations of Field (2005, p72) in order to ensure they all met the assumptions for parametric analysis.

Differences between Completers and Non-Completers on demographic characteristics and survey measures were assessed through t-tests (or non-parametric equivalent) and Chi-Square tests.

Test-retest reliability of the IBSAAQ was investigated using Pearson’s product moment correlation between scores of IBS Acceptance at the time of the first survey (T1), and the scores of the same variable at the pre-workshop time point (T2).

Repeated measure ANOVAs were used to investigate the first aim of study 2 (Field, 2005); whether an ACT based intervention significantly changes Acceptance and outcome scores between pre and post intervention. Completers and Intent-to-treat (ITT) analyses were conducted.

Regarding the second aim of examining the possible mediating role of Acceptance (general or IBS specific) in the changes of outcome scores between pre and post intervention, the ordinary least squares regressions (OLS) method proposed by Judd, Kenny, & McClelland (2001) was used. Completers and Intent-to-treat (ITT) analyses were conducted.

More detailed descriptions of the statistical analyses carried are done in the results chapters.

CHAPTER SIX
STUDY 1 RESULTS

CHAPTER SIX - STUDY 1 RESULTS

6.1. MISSING VALUES

Preliminary analyses indicated that all items had been correctly entered for all variables used in this study. A missing values analysis of each variable of interest (interval or ratio) revealed that missing values did not exceed 5% per item or 20% per subject and that these were missing completely at random. Missing values were therefore replaced by simple mean imputation as recommended for these cases (Chavance, 2004; Fox-Wasylyshyn & El-masri, 2005).

6.2. DEMOGRAPHIC CHARACTERISTICS OF THE FINAL SAMPLE

The final sample for study 1 comprised 121 participants as described in section 5.5.3. The demographic characteristics of these participants is presented in Table 6.1

The age of participants (at the time the survey was responded to) ranged between 20 and 77 years, with the mean age being of 47.10 years (12.96 SD). Age distribution was normal.

Participants reported having been diagnosed with IBS between 1 and 360 months before responding to the survey with the median length of diagnosis being 63 months (lower quartile 24 months, upper quartile 120 months). The median was chosen as the best central tendency measure to describe this variable as the distribution is highly positively skewed.

Out of the 121 participants, 88.4% (n=107) were female and 11.6% (n=14) were male giving a female-to-male ratio of 7.64:1. This high female-to-male ratio is in line with most reports in IBS research within tertiary care settings (Frissora & Koch, 2005).

Regarding ethnicity and nationality, the majority of the sample was Caucasian (96.7%) and British (97.5%).

Table 6.1: Demographic characteristics of Study 1 participants

Continuous Variables	
Mean Age in Years (SD)	47.10 (12.96)
Range (Years)	20-77
Median Length of Illness (Months)	63
Range (Months)	1-360
Categorical Variables	
	N (%)
Gender	
Male	14 (11.6)
Female	107 (88.4)
Ethnicity	
Caucasian	117 (96.7)
Asian	1 (0.8)
Other	3 (2.5)
Nationality	
British	118 (97.5)
Other	3 (2.5)
Education	
College or University	77 (63.6)
Secondary education	43 (35.5)
Primary education	1 (0.8)
Marital status	
Married	52 (43)
Living as married	15 (12.4)
Single	29 (24)
Separated	5 (4.1)
Divorced	15 (12.4)
Widowed	5 (4.1)
Vocational Status	
Full-time working	59 (48.8)
Part-time working	21 (17.4)
Not working due to IBS	10 (8.3)
Not working due to other reason	29 (24)
Full-time training	1 (0.8)
Part-time training	1 (0.8)
Type of IBS	
No IBS	6 (5.3)
IBS-M	65 (57)
IBS-D	26 (22.8)
IBS-C	15 (13.2)
IBS-U	2 (1.8)

With regards to educational background, most participants (63.6%) reported having a higher education qualification (college or university) with about a third (35.5%) reporting secondary schooling as their highest qualification achieved.

Regarding marital status; 55.4% were married or in a relationship, while the remaining 44.6% reported not being in a relationship (mostly single or separated).

The majority of participants were working either full-time (48.8%) or part-time (17.4%). Close to a quarter (24%) of participants reported not working due to retirement, unemployment or being a housewife/husband, however 10 participants reported not working due to IBS (8.3%).

Type of IBS presentation was evaluated with the IBS module of the Rome III criteria (Longstreth et al., 2006). Out of the 121 participants, 7 (5.8%) did not supply data for this screening tool. However, because the clinical diagnosis was also provided by a consultant gastroenterologist these cases were retained for all study 1 analysis. Regarding the 114 participants that provided data for the ROME-III module, 57% had a mixed type of IBS (IBS-M) alternating between diarrhoea and constipation, 22.8% had diarrhoea predominant type of IBS (IBS-D), 13.2% had constipation predominant form of IBS (IBS-C), and 1.8% had an undefined form of IBS (IBS-U). Although all patients had been diagnosed with IBS by the consultant gastroenterologist, 5.3% of all participants (n=6) were not considered to have IBS according to this assessment tool. However these cases could be considered to be sub-threshold as they all exhibited the symptoms of IBS, although not with enough severity or frequency to meet the stringent criteria of the assessment tool. This was not considered to be strange as the strict criteria proposed by this classification system has been found to produce lower inclusion rates when compared for instance with its predecessor, Rome II (Park et al., 2010). It should be noted that the Rome III questionnaire is not a diagnostic tool, but a clinical assessment aid, therefore it is not unexpected that occasionally an individual would be given a diagnosis of IBS even if this is not indicated by the measure. Also the fluctuating nature of IBS symptoms and the fact that the measure is self-report might have influenced this result. It is of note

however, that the agreement between consultant diagnosis and assessment tool was quite high with almost 95% of concurrent diagnosis from both parties.

6.3. DESCRIPTIVE STATISTICS OF SURVEY MEASURES

Table 6.2 presents the means, standard deviations, minimum, maximum, skewness and kurtosis values for all of the survey measures except the IBSAAQ which will be described in section 6.4.2. All variables demonstrated a normal distribution with the exception of the Depression and Anxiety subscales of the DASS that were positively skewed ($z_{\text{skewness}} > 3.96$; Field, 2005. p72). A logarithmic transformation of both these variables was successful in restoring normality so that parametric tests could be conducted in further analyses (LogDepression $z_{\text{skewness}}=2.70$; Log Anxiety $z_{\text{skewness}}=2.57$)(Field, 2005, p.80).

With an mean IBS Symptom Severity score of 272.34 (IBSSSS), participants in our sample were close to the upper limit of the moderate symptom severity range (175-299)(Francis, Morris, & Whorwell, 1997). According to the subscales of the DASS of Depression (M=13.83) and Anxiety (M=10.19) participants were considered to be in the moderate category while regarding Stress they were considered to be in the mild category according to the severity cut-off points proposed by Lovibond (2010).

None of the other measures have agreed cut-off points therefore they were compared with the mean values obtained in other studies. The mean use of illness related behaviours (M=101.45) and of frequency of IBS related cognitions (M= 117.00) in our sample were above those reported by Kennedy et al. (2006) (M=92.2 and M=108.7 respectively) in their study with a primary care IBS population. Mean General quality of Life (M=26.39) was slightly below that reported by Schmidt, Mühlhan, & Power (2006) for ill populations (M=28.16). Mean Gastrointestinal Anxiety (M=59.48) was above the one reported by Labus et al., (2004) in their scale development study (M=36.5).

Mean general acceptance (M=37.42) was within the range expected for clinical populations (32.8-44.0; Hayes et al., 2004). The mean score on the Impact on Quality of Life measure (M=95.71) was above that reported by Groll et al. (2002) in their scale development study (M=23.2).

Table 6.2: Descriptive statistics of survey measures

Measure	Mean	SD	Min	Max	Skewness	Kurtosis
IBSSSS	272.34	100.18	80	463	0.215	-0.815
BSIBS	101.45	30.37	35	175.17	0.281	-0.345
IBS36	95.71	45.98	1	204	0.157	-0.807
EUROQOL 8	26.39	6.50	9	39	-0.339	-0.302
DASS(Depression)	13.83	12.09	0	42	0.933	-0.076
DASS(Anxiety)	10.19	9.3	0	38	1.062	0.560
DASS(Stress)	17.92	10.63	0	42	0.424	-0.607
VSI	59.48	17.92	17	90	-0.359	-0.551
CSIBS	117.00	30.11	31	175	-0.309	-0.208
AAQ 9	27.42	8.52	11	57	-0.160	0.173

Note: IBSSSS – IBS Symptom Severity Scale; BSIBS - Behaviour Scale for IBS; IBS36 - IBS Impact on Quality of Life; EUROQOL 8 – General Quality of Life; DASS – Depression Anxiety and Stress Scales; VSI – Visceral Sensitivity Index; CSIBS – Cognitive Scale for IBS, AAQ 9 – Acceptance and Action Questionnaire

6.4. MEASURING ACCEPTANCE IN IBS

The first aim of this study was to create a specific measure of IBS acceptance and to investigate its psychometric qualities. In this section we analyse the factor structure of the scale, its internal consistency and its convergent and concurrent validity.

6.4.1. Preliminary Analyses

Frequency distributions of the initial 20 items of the IBSAAQ were analyzed to identify items with extremely skewed response distribution or low variability. Also, item-total correlations were used to detect and remove any item showing low correlations (<0.3) with the overall score of the questionnaire. Frequency distributions showed that none of the 20 initial items had extremely skewed response

distribution or low variability. All items showed acceptable correlations with other items and item-total correlations above 0.3 (all correlations were in the expected direction). Therefore no item was excluded in these preliminary analyses.

6.4.2. Factor analysis

Initial considerations of the IBSAAQ factor analysis included examining the adequacy of sample size and the factorability of the correlation matrix. The Kaiser-Meyer-Olkin measure of Sampling adequacy (0.87) indicated satisfactory factorability of the correlation matrix (values above 0.5 are acceptable; between 0.8 and 1 are considered very good). In conjunction with the high significance ($p < 0.001$) of Bartlett's test of sphericity, the data were considered suitable for factor analysis (Field, 2005).

Exploratory Factor analysis using Maximum Likelihood extraction was conducted to examine the underlying factor structure of the items of the IBSAAQ according to the recommendations of Costello & Osborne (2005). The number of factors to extract for rotation was determined by the criteria of eigenvalues above 1 and inspection of the scree plot. Possible factors were assumed to be related, therefore an oblique oblimin rotation with $\delta = 0$ was used. The rotated factor structure was analysed for items with weak factor loadings (< 0.32) or significant cross loadings (second loading higher than 0.3). After Maximum Likelihood extraction, five components attained eigenvalues above 1 explaining a total of 65% of variance. Inspection of the shift in slope of the scree plot suggested that a two or three factor solution was the most appropriate. Interpretation of the pattern matrix of the rotated three factor solution presented problems as 2 items of the third factor had significant cross-loadings with the other 2 factors and only one item loaded highly (> 0.5) on this factor. Therefore a three factor solution was discarded.

When a two factor solution was tested the interpretation of the pattern matrix revealed that all items loaded above the recommended cut-off (> 0.32) with the exception of item 8 ("There are many activities I do when I feel Bowel Discomfort"),

therefore item 8 was excluded from further analyses. Factor loadings of the IBSAAQ items are presented in Table 6.3. Inspection of the pattern matrix revealed that a two factor solution did not present any item with significant cross-loadings and that each factor had at least 5 high loading items (>0.5) therefore meeting the criteria for factor retention (Costello & Osborne, 2005). Therefore the final solution consisted of 19 items with two interpretable factors with eigenvalues of 7.14 and 2.56 accounting for a total 48.5% of variance in item response. The mean score of the total IBSAAQ in our sample was $M=56.22$ ($SD= 18.68$) (see Table 6.4).

Items loading on Factor 1 (8 items: 1, 2, 5, 6, 9, 12, 15 and 19) seemed to reflect the pursuit of valued life activities regardless of the presence of IBS. This factor was therefore named Activity Engagement like in the CPAQ (the scale in which the IBSAAQ was based). Items loading on Factor 2 (11 items: 3, 4, 7, 10, 11, 13, 14, 16, 17, 18 and 20) seemed to reflect the willingness to be in contact with difficult experiences of IBS both physical and psychological while at the same time recognizing that this is achieved by letting go of strategies that are aimed at the elimination or control of these experiences. This factor was therefore named IBS Willingness similarly to the Pain Willingness factors in the CPAQ. As Table 6.4 demonstrates participants means for the IBSAAQ subscales were $M=28.50$ ($SD=9.40$) for Activity Engagement and $M=27.72$ ($SD=12.20$) for IBS Willingness. Both IBSAAQ total scale and its subscales presented a normal distribution.

When compared to the CPAQ, the items on the IBSAAQ loaded on the same factors with the exception of items 3 (“It’s OK to experience Bowel Discomfort”) and 10 (“Controlling my IBS is less important than any other goals in my life”) which loaded on the activity engagement factor in the CPAQ but loaded on the Willingness factor in the IBSAAQ.

Table 6.3: Rotated Factor loadings for the two-factor solution

Item number	Content summary	Factor 1	Factor 2
6	Living a normal life despite IBS	.88	-
9	Leading a full life even with IBS	.88	-
2	Life is going well even with IBS	.84	-
1	Getting on with living despite bowel discomfort	.71	-
12	Sticking to life course despite IBS	.67	-
15	Ability to take care of responsibilities even with increased bowel discomfort	.48	-
19	No need to change bowel discomfort to get on with life	.45	-
5	No necessity to control IBS to live well	.38	-
13	Keeping IBS under control when active*	-	.86
14	Controlling IBS before making plans*	-	.77
4	Sacrifice important things in order to get more IBS control*	-	.67
11	Thoughts and feelings about IBS have to change before life gets better*	-	.66
16	Control over IBS thoughts will lead to better control in life*	-	.61
7	Getting rid of IBS as primary target*	-	.58
18	Believability in worries and fears about IBS*	-	.55
17	Avoidance of IBS related situations*	-	.51
20	Activity struggle when bowel discomfort is present*	-	.44
3	Feeling comfortable with IBS experiences	-	-.35
10	Controlling IBS as a less important focus in life	-	-.32

Note: Bolded text indicates factor loading (values below the 0.32 cut-off are not represented)

*** These items are reverse scored**

Table 6.4: Descriptive data and internal consistency of the IBSAAQ and its subscales

Scale	Number of items	M	SD	Min	Max	Skewness	Kurtosis	Cronbach's α	Correlations	
									Activity Engagement	IBS Willingness
Activity Engagement	8	28.50	9.40	0	48	-0.630	0.435	.87		
IBS Willingness	11	27.72	12.20	0	57	-0.041	-0.399	.86	.48*	
Total Scale	19	56.22	18.68	0	104	-0.233	0.359	.89	.82*	.89*

Note:*Correlations significant at $p < 0.001$ (two-tailed)

6.4.3. Internal consistency

Total scale and subscales internal consistencies were analyzed through Cronbach's alpha. Alpha levels above .7 are considered good and levels above 0.8 are considered very good (Field, 2005). In order for reliability analysis to be carried all reverse-phrased items had their scores reversed prior to analysis. As Table 6.4 demonstrates the alpha level for the whole scale was .89 indicating very good reliability. The Activity Engagement and IBS Willingness factors also had good reliability, with alpha levels of .87 and .86 respectively. As Table 6.4 demonstrates the total scale was highly correlated with the Activity Engagement subscale and the IBS Willingness subscale. The two IBSAAQ subscales significantly correlated with each other ($r=.48$, $p<.001$) indicating good association, however the correlation was not so strong as to suggest a complete overlap of concepts being measured. Item-Total correlations for the total scale were all above the .3 cut-off (Field, 2005) indicating adequate internal consistency, with the exception of item 7 ($r=.26$, $p<.05$). This would normally lead to the exclusion of this item, however it was retained because there was no significant improvement to the overall alpha if this item was deleted ($\alpha=.9$).

6.4.4. Convergent and concurrent validity

Convergent and concurrent validity of the IBSAAQ (subscales and total scale) were investigated by analyzing its relationships with criterion variables of general acceptance, IBS outcomes (Symptom Severity, illness related behaviours, General Quality of Life and IBS specific Quality of Life) and psychological factors known to be associated with IBS (Anxiety, Depression, Stress, GI Anxiety, Illness related cognitions). It was expected that the IBSAAQ total and its subscales would be associated with better outcome scores and lower levels of psychological indices of distress or cognitions that are associated with IBS.

Table 6.5 presents the correlations of the total scale and the two subscales of the IBSAAQ with the selected variables. Pearson's product moment correlations are

reported with the logarithmic transformations for the depression and anxiety scales of the DASS used.

Table 6.5: Correlations between the IBSAAQ and its subscales with criterion variables

	IBSAAQ (Total)	Activity Engagement	IBS Willingness
General Acceptance	.58*	.55*	.46*
Symptom Severity	-.57*	-.56*	-.43*
IBS Related Behaviours	-.67*	-.50*	-.64*
IBS Impact on Quality of Life	-.70*	-.58*	-.62*
General Quality of Life	.54*	.63*	.34*
Depression	-.48*	-.47*	-.37*
Anxiety	-.45*	-.42*	-.37*
Stress	-.44*	-.42*	-.34*
GI Anxiety	-.71*	-.56*	-.66*
IBS Related Cognitions	-.72*	-.53*	-.70*

Note:*Correlations significant at $p < .001$ (two-tailed) (N=121)

The IBSAAQ Total scale significantly correlated ($r=.58$) with general acceptance (AAQ-9) as expected, indicating that the IBSAAQ is measuring the concept of acceptance as it operates in relation to the problems of IBS. The strength of this correlation is not so high as to indicate an overlap in concepts. The same was found for both subscales, with General Acceptance correlating significantly with Activity Engagement ($r=.55$) and IBS Willingness ($r=.46$).

As shown in Table 6.5, IBS Acceptance significantly negatively correlated with the IBS outcomes measures indicating that higher levels of IBS Acceptance are associated with lower symptom severity, less use of avoidant coping behaviours and less impact on quality of life. Activity Engagement and IBS Willingness also showed inverse correlations with the same IBS outcomes. Better General Quality of Life was associated with higher levels of IBS Acceptance, Activity Engagement and IBS Willingness. Regarding psychological predictor variables, higher IBS Acceptance was associated

with lower levels of Depression, Anxiety, Stress, GI Anxiety and IBS Related cognitions. Similarly Activity Engagement and IBS Willingness also showed inverse correlations with the same variables. All of these 30 correlations were significant at $p < .001$ and thus would meet criteria for significance if corrections were made for multiple significance tests (i.e. adjusted alpha = $.05/30 = .00167$).

These results indicate that IBS Acceptance and its two components of Activity Engagement and IBS Willingness were associated in the expected direction with IBS outcomes and psychological predictors known to be related to IBS.

Following this preliminary validation study, all values of the IBSAAQ used for the rest of the analyses were calculated using the 19 item solution described above.

6.5. DEMOGRAPHIC COMPARISONS OF SCORES IN THE ACCEPTANCE MEASURES

The second aim of this study was to explore whether Acceptance (General and IBS specific) was affected by demographic variables in this sample. Two types of demographic variables were considered; categorical (Gender, Education, Marital Status, Vocational status, ethnicity, nationality or IBS type) and continuous (Age and Length of Illness).

6.5.1. Comparisons of scores on acceptance measures according to categorical demographic variables

Gender

Preliminary analyses indicated a normal distribution for both groups (Male and Female), equal variances for the General Acceptance scores and unequal variances for the IBS Acceptance scores (t-statistics presented are for Equal variance not assumed). As Table 6.6 shows, there were no significant differences in the AAQ-9 scores between the Male ($M=34.77$, $SD=7.73$) and Female participants ($M=37.77$, $SD=8.59$), $t(119)=-1.24$, $p=.22$,

showing no gender differences in General Acceptance. Table 6.6 also shows that there were no significant differences in the IBSAAQ scores between the Male ($M=54.43$, $SD=28.17$) and the Female participants ($M=56.45$, $SD=17.25$), $t(119)=-0.26$, $p=.80$, showing no gender differences in IBS Acceptance.

Table 6.6: Results of the t-tests comparing general and IBS specific acceptance according to dichotomous demographic variables

Scale	Variable (N)	M	SD	<i>t</i>	Sig.	Effect Size (<i>r</i>)
AAQ-9 (General Acceptance)	Gender					
	Male (14)	34.77	7.73	-1.24	.220	.11
	Female (107)	37.77	8.59			
	Education					
	Higher education (77)	37.85	8.49	-0.72	.470	.06
	No higher education (44)	36.68	8.62			
IBSAAQ (IBS Acceptance)	Marital Status					
	Married/Cohabiting (67)	39.00	8.04	-2.31	.023	.21
	Single (54)	35.47	8.77			
	Gender					
	Male (14)	54.43	28.17	-0.26	.800	.02
	Female (107)	56.45	17.25			
	Education					
	Higher education (77)	59.42	18.93	-2.55	.010	.23
	No higher education (44)	50.61	17.04			
	Marital Status					
	Married/Cohabiting (67)	59.50	16.67	-2.18	.031	.20
	Single (54)	52.15	20.35			

Education

Because there was only one participant with only primary school education, this case was pooled with participants reporting secondary schooling as highest educational level attained to form a sample of participants with No Higher Education. The second group comprised participants who reported to have attained a higher education degree (Higher Education). Preliminary analysis indicated normal distributions for both groups (Higher Education and No Higher Education) and equality of variances for both the General and IBS Acceptance scores. As Table 6.6 demonstrates, there were no significant differences in the AAQ-9 scores between the Higher Education ($M=37.85$, $SD=8.49$) and No Higher

Education participants ($M=36.84$, $SD=8.66$), $t(119)=-0.62$, $p=.47$, showing no differences in General Acceptance depending on educational background.

There were significant differences in the IBSAAQ scores between the Higher Education ($M=59.42$, $SD=18.93$) and No Higher Education participants ($M=51.07$, $SD=16.97$), $t(119)=-2.40$, $p=.01$, showing that participants with a Higher Education were more accepting of their IBS than participants with No Higher Education (see Table 6.6). However the effect size ($r=.22$) found was only small to medium.

Ethnicity and Nationality

Because the sample was predominantly Caucasian (96.7%) and of British Nationality (97.5%), making it therefore a fairly homogenous sample no investigations were made regarding any differences on these variables.

Marital Status

Regarding marital status, participants reporting being married or living as married were pooled into a new group named Married/Cohabiting while participants reporting being single, divorced, separated or widowed were pooled into a new group named Single. Preliminary analysis indicated normal distributions for both groups (Married/Cohabiting and Single) and equality of variances for both the General and IBS Acceptance scores. As Table 6.6 demonstrates, there were significant differences in the AAQ-9 scores between the Married/Cohabiting ($M=39.00$, $SD=8.04$) and Single participants ($M=35.47$, $SD=8.77$), $t(119)=-2.31$, $p=.023$, showing that Married/Cohabiting participants were generally more acceptant than Single participants. There were also significant differences in the IBSAAQ scores between the Married/Cohabiting ($M=59.50$, $SD=16.67$) and Single participants ($M=52.15$, $SD=20.35$), $t(119)=-2.18$, $p=.031$, showing that Married/Cohabiting participants were more accepting of their IBS

than Single participants (see Table 6.6). However the effect sizes found were only small to medium ($r=.21$ for General Acceptance and $r=.20$ for IBS Acceptance).

Vocational Status

For ease of analyses and due to low number of participants ($N=1$) in the full-time and part-time training categories of this variable a new category labelled as “Employed or in Training” was created that encompassed all participants in full or part-time employment or training. The remaining categories were “Not employed due to IBS” and “Not employed due to other reason”. Table 6.7 presents the means and Standard deviations for these groups. Preliminary analyses indicated that both General and IBS specific Acceptance had normal distributions on these new categories and that there was homogeneity of variance between the groups; therefore the data met the parametric requirements for a One-Way ANOVA analysis of mean differences.

As shown in Table 6.7 there was a significant effect of vocational status on General Acceptance $F(2,118)=5.87$, $p=.004$, with a medium to large effect size of $\eta^2=0.09$ (Green & Salkind, 2004). As the groups were uneven and the variances were homogenous, post-Hoc comparisons were done using Hochberg’s GT2 test (Field, 2005; p341). Post-hoc tests indicated that participants “Not employed due to IBS” had significantly lower levels of General Acceptance when compared with “Employed or in training” participants and with participants “Not employed due to other reason” ($p=.001$ and $p=.016$ respectively). Similarly, vocational status had a significant effect on IBS Acceptance $F(2,118)=11.14$, $p<.001$, with a large effect size of $\eta^2=.16$. Post-Hoc comparisons using Hochberg’s GT2 test, indicated that participants “Not employed due to IBS” had significantly lower levels of IBS Acceptance when compared with “Employed or in training” participants and with participants “Not employed due to other reason” ($p<.001$ and $p=.004$ respectively).

IBS status

Table 6.7 presents the means and Standard deviations for the different categories according to IBS status (no-IBS, IBS-C, IBS-D, IBS-M, IBS-U). The 7 participants who did not supply data for the Rome-III module were excluded from the present analysis. Preliminary analyses indicated that both General and IBS specific Acceptance had normal distributions and variances were homogenous across the categories of the IBS status variable; therefore the data met the parametric requirements for a One-Way ANOVA analysis of mean differences. There was no significant effect of IBS status on General Acceptance scores $F(4,113)=0.94$, $p=.45$. Similarly, IBS status does not seem to exert any effect of IBS specific acceptance scores $F(4,113)=1.60$, $p=.28$.

Table 6.7: Results of the ANOVAs comparing general and IBS specific acceptance according to demographic variables with more than two levels

Scale	Variable (N)	M	SD	F	Sig.	Effect Size(η^2)
AAQ-9	Vocational Status					
	Employed or in training (82)	38.47	7.90	5.87	.004	.09
	Not employed due to IBS (10)	29.08	9.60			
	Not employed due to other reason (29)	37.32	8.54			
	IBS Status					
	No IBS (6)	43.00	5.25	0.94	.450	.03
	IBS-C (15)	36.11	9.02			
	IBS-D (26)	37.49	6.22			
	IBS-M (65)	37.10	9.48			
	IBS-U (2)	32.00	2.83			
IBSAAQ	Vocational Status					
	Employed or in training (75)	60.02	15.88	11.14	<.001	.16
	Not employed due to IBS (10)	33.34	22.78			
	Not employed due to other reason (29)	53.37	19.02			
	IBS Status					
	No IBS (6)	68.00	12.85	1.28	.280	.04
	IBS-C (15)	60.03	17.23			
	IBS-D (26)	56.52	18.73			
	IBS-M (65)	54.79	19.91			
	IBS-U (2)	38.00	9.90			

6.5.2. Interaction of acceptance with continuous demographic variables

Age and length of illness effects on General and IBS specific Acceptance were studied by correlation analyses. Both Acceptance variables had a normal distribution as did age, therefore Pearson's product moment correlations were used to assess the relationship between the variables. However length of illness did not meet the assumptions for parametric testing due to excessive skewness. Several transformations were attempted to obtain a normal distribution with no success. Therefore the effect of this variable was investigated using the non-parametric Spearman's Rank correlation test. Age was not significantly associated with either General Acceptance ($r=.12$, $p=.19$) or IBS Acceptance ($r=-.07$, $p=.41$). Similarly self reported length of illness was not significantly associated with General Acceptance ($\rho=-.06$, $p=.51$) or IBS Acceptance ($\rho=-.09$, $p=.35$).

6.6. ASSOCIATION OF ACCEPTANCE WITH IBS OUTCOMES AND PSYCHOLOGICAL FACTORS

The third aim of this study was to investigate how Acceptance (general and IBS specific) relates to IBS outcomes (Symptom Severity, IBS Related Behaviours, General Quality of Life and IBS Impact on Quality of Life) and to psychological factors known to be related to IBS (Depression, Anxiety, Stress, GI Anxiety, IBS Related cognitions). It was expected that higher levels of acceptance (general and IBS specific) would be associated with higher General Quality of Life and with lower Symptom Severity, IBS Related Behaviours and IBS Impact on Quality of Life. It was also expected that higher levels of Acceptance (General and IBS specific) would be associated with lower levels of Depression, Anxiety, Stress, GI Anxiety and IBS Related Cognitions. Correlations of the IBS specific measure of Acceptance with these variables has already been described in section 6.4.4; therefore only the correlations of the general measure of Acceptance with the variables of interest will be described in this section. As shown in section 6.4.4, all correlations of IBS specific Acceptance with outcome and predictor variables were in the expected direction.

6.6.1. Correlations of General Acceptance with outcome and psychological factors

Correlation coefficients of General Acceptance with outcome and psychological predictor measures are presented in Table 6.8. As predicted, General Acceptance was significantly associated with better outcomes. Higher levels of General Acceptance were positively associated with better General Quality of Life. Higher levels of General Acceptance were significantly associated to lower levels of Symptom Severity, IBS Related Behaviours and IBS Impact on Quality of Life. Also as predicted, General Acceptance was significantly associated with lower levels of psychological factors known to be related to IBS. Higher levels of General Acceptance were significantly associated to lower levels of Depression, Anxiety, Stress, GI Anxiety and IBS Related cognitions. All of these 9 correlations were significant at $p < .001$ and thus would meet criteria for significance if corrections were made for multiple significance tests (i.e. adjusted alpha = $.05/9 = .005$). These results show that General Acceptance was associated in the expected direction with IBS outcomes and psychological factors known to be related to IBS.

Table 6.8: Correlations of Acceptance (General and IBS specific) with IBS outcomes and psychological predictors and correlation magnitude Z-scores

	Correlations		Z-Score
	General Acceptance (AAQ-9)	IBS Acceptance (IBSAAQ)	
Symptom Severity	-.37*	-.57*	-2.676*
IBS Related Behaviours	-.40*	-.67*	-4.058*
IBS Impact on Quality of Life	-0.46*	-.70*	-3.655*
General Quality of Life	.53*	.54*	-0.188
Depression	-.62*	-.48*	2.154*
Anxiety	-.39*	-.45*	-0.778
Stress	-.63*	-.44*	2.801*
GI Anxiety	-.49*	-.71*	-3.555*
IBS Related Cognitions	-.46*	-.72*	-4.227*

* $p < .001$ (N=121)

6.7. UTILITY OF ACCEPTANCE AS A PREDICTOR OF IBS OUTCOMES AND PSYCHOLOGICAL FACTORS

The fourth aim of this study was to investigate the contribution of Acceptance in the prediction of IBS outcomes and psychological factors known to be associated with IBS. A series of multiple regression analyses were carried out to investigate the contribution of General Acceptance or IBS acceptance in the prediction of the dependent variables of Symptom Severity, IBS Related Behaviours, IBS Impact on quality of Life, General Quality of Life, Depression, Anxiety, Stress, GI Specific Anxiety and IBS Related Cognitions. The influences of background variables like age, gender, Length of Illness, Marital Status and Education were tested for entry as a block at the first step of each regression using the stepwise method and retained based on statistical criteria (probability of F to enter <.05, and to remove >.10). General acceptance or IBS Acceptance was then entered at step 2.

A series of tests were carried out to examine the suitability of the present data for regression analysis. Normality tests and probability plots showed a normal distribution of residuals for all models tested. The Durbin-Watson values for each model were within the range of 1.7-2.3, indicating homoscedasticity of residuals. No multicollinearity was suggested, as tolerance values were all above .4 (.1 is the minimum; Field, 2005, p.196) in every model tested. Therefore data was considered adequate for regression analysis.

6.7.1. Contributions of General Acceptance in predicting criteria variables

Regression analyses revealed that regarding IBS Related Behaviours, IBS Impact on Quality of Life and Anxiety, background variables did not contribute any significant amounts of explained variance. Regarding the remaining dependent variables, background variables contributed only with small amounts of explained variance (4% to 8%). Even after General Acceptance was added in step 2, Marital status and Length of Illness were considered significant predictors (significant β values) of Depression and

General Quality of Life, and Symptom Severity and IBS Related cognitions respectively (see Table 6.9).

Results illustrated that General Acceptance accounted for a significant amount of variance (12% to 36%) in every dependent variable tested beyond the effects of background variables. As illustrated by the highly significant beta coefficients, General Acceptance was a good predictor of Symptom Severity, IBS Related Behaviours, IBS Impact on quality of Life, General Quality of Life, Depression, Anxiety, Stress, GI Specific Anxiety and IBS Related Cognitions (see Table 6.9).

6.7.2. Contributions of IBS Acceptance in predicting criteria variables

Background variables contribution to the explained variance in the dependent variables was the same as described in the previous section. When IBS Acceptance was added in step 2, Marital status and length of Illness were considered significant predictors (significant β values) of Depression and General Quality of Life, and Symptom Severity respectively (see Table 6.10).

Similarly to General Acceptance, results illustrated that IBS Acceptance accounted for a significant amount of variance (16% to 49%) in every dependent variable tested beyond the effects of background variables. As illustrated by the highly significant beta coefficients, IBS Acceptance was considered a good predictor of Symptom Severity, IBS Related Behaviours, IBS Impact on quality of Life, General Quality of Life, Depression, Anxiety, Stress, GI Specific Anxiety and IBS Related Cognitions (see Table 6.10).

Table 6.9: Hierarchical regression analyses looking at the contribution of General Acceptance in predicting criteria variables

Dependent Variables	Step	Predictor Variables	R ²	R ² change	F Change (df)	Sig. F change	Standardized coefficients beta (β)		
							β (final)	t	Sig. β
Symptom Severity	1	Background variables Length of Illness	.06	.06	7.05 (1, 119)	.009			
	2	AAQ-9	.18	.12	18.53 (1, 118)	<.001	.21	2.56	.012
IBS Related Behaviours	1	AAQ-9	.16	.16	22.90 (1, 119)	<.001	-.40	-4.79	<.001
IBS Impact on Quality of Life	1	AAQ-9	.21	.21	32.3 (1, 119)	<.001	-.46	-5.69	<.001
General Quality of Life	1	Background variables Marital Status	.07	.07	9.39 (1, 119)	.003			
	2	AAQ-9	.31	.24	39.39 (1, 118)	<.001	.17	2.15	.034
Depression-DASS	1	Background variables Marital Status	.08	.08	10.15 (1, 119)	.002			
	2	AAQ-9	.37	.29	54.90 (1, 118)	<.001	-.17	-2.22	.028
Anxiety-DASS	1	AAQ-9	.17	.17	23.56 (1, 119)	<.001	-.55	-7.41	<.001
Stress-DASS	2	Background variables Marital Status	.04	.04	4.43 (1, 119)	.038			
		AAQ-9	.40	.36	72.52 (1, 118)	<.001	-.41	-4.85	<.001
GI Anxiety	2	Background variables Education	.04	.04	4.39 (1, 119)	.038			
		AAQ-9	.26	.22	36.05 (1, 118)	<.001	-.15	-1.92	.057
IBS Related Cognitions	1	Background variables Length of Illness	.04	.04	4.74 (1, 119)	.031			
	2	General Acceptance	.24	.20	31.02 (1, 118)	<.001	-.48	-6.00	<.001

In all analyses the demographic variables of Age, Gender, Length of Illness, Marital Status and Education were tested for entry as a block using the stepwise method (and are presented as step 1 if significant). These were followed by the AAQ-9 in step 2. Dichotic variables were coded as follows: Male, Single and secondary schooling were coded as 0 while Female, Married/Cohabiting and Higher education were coded as 1

Table 6.10: Hierarchical regression analyses looking at the contribution of IBS Acceptance in predicting criteria variables

Dependent Variables	Step	Predictor Variables	R ²	R ² change	F Change (df)	Sig. F change	Standardized coefficients beta (β)		
							β (final)	t	Sig. β
Symptom Severity	1	Background variables Length of Illness	.06	.06	7.05 (1, 119)	.009			
	2	IBSAAQ	.35	.29	53.10 (1, 118)	<.001	.17	2.31	.022
IBS Related Behaviours	1	IBSAAQ	.45	.45	98.92 (1, 119)	<.001	-.67	-9.95	<.001
IBS Impact on Quality of Life	1	IBSAAQ	.48	.48	111.59 (1, 119)	<.001	-.70	-10.56	<.001
General Quality of Life	1	Background variables Marital Status	.07	.07	9.39 (1, 119)	.003			
	2	IBSAAQ	.32	.25	42.85 (1, 118)	<.001	.17	2.21	.029
Depression-DASS	1	Background variables Marital Status	.08	.08	10.15 (1, 119)	.002			
	2	IBSAAQ	.30	.22	37.12 (1, 118)	<.001	-.19	-2.37	.019
Anxiety-DASS	1	IBSAAQ	.21	.21	31.55 (1, 119)	<.001	-.48	-6.09	<.001
Stress-DASS	1	Background variables Marital Status	.04	.04	4.423(1, 119)	.038			
	2	IBSAAQ	.20	.16	24.40 (1, 118)	<.001	-.11	-1.29	.200
GI Anxiety	2	Background variables Education	.04	.04	4.39 (1, 119)	.038			
		IBSAAQ	.50	.46	111.35 (1, 118)	<.001	-.01	-.25	.800
IBS Related Cognitions	1	Background variables Length of Illness	.04	.04	4.74 (1, 119)	.031			
	2	IBSAAQ	.53	.49	127.31 (1, 118)	<.001	-.70	-10.55	<.001

In all analyses the demographic variables of Age, Gender, Length of Illness, Marital Status and Education were tested for entry as a block using the stepwise method (and are presented as step 1 if significant). These were followed by the IBSAAQ in step 2. Dichotic variables were coded as follows: Male, Single and secondary schooling were coded as 0 while Female, Married/Cohabiting and Higher education were coded as 1

6.8. COMPARISON OF THE RELATIVE STRENGTH OF RELATIONS BETWEEN GENERAL ACCEPTANCE AND IBS ACCEPTANCE WITH GENERAL AND SPECIFIC VARIABLES

The fifth aim of this study was to investigate the strength of relations between general acceptance and IBS acceptance with general and specific variables. It was predicted that General Acceptance would be more strongly associated with general outcomes and general psychological predictors (Depression, Anxiety, Stress and General Quality of Life) than IBS Acceptance. Conversely, IBS Acceptance would be more strongly associated with IBS specific outcomes and IBS specific psychological predictors (Symptom Severity, IBS related Cognitions and Behaviours, GI Anxiety and IBS Impact on Quality of Life).

6.8.1. Z-score tests comparing correlated correlation coefficients

A series of Z-score tests for comparing correlated correlation coefficients were conducted according to the method proposed by Meng, Rosenthal, & Rubin, (1992). Significant Z-scores indicate a significant difference in the magnitude of the correlation of two measures, X (in this case General Acceptance) and Y (in this case IBS specific Acceptance) with a third measure Z (in this case, any of the outcome or psychological factor variables). Table 6.8 shows that there were no significant differences in the correlations of General and IBS Acceptance with General Quality of Life and Anxiety, however General Acceptance proved to have stronger correlations with a measure of Depression and Stress than IBS Acceptance. IBS Acceptance proved to have stronger correlations with specific measures of Symptom Severity, IBS Related behaviours, IBS Impact on Quality of Life, GI Anxiety and IBS Related Cognitions. These results support in most part the assumption that an IBS specific measure of Acceptance is more strongly related to IBS specific factors than a general measure of Acceptance. These results also show that factors like general Anxiety and general Quality of Life are equally related to general and specific measures of acceptance while depression and stress are more strongly related with a general measure of acceptance.

6.9. COMPARISON BETWEEN ACCEPTANCE AND GI SPECIFIC ANXIETY AS PREDICTORS OF IBS OUTCOMES

The sixth aim was to compare the contributions of Acceptance (General or IBS specific) with those of GI specific anxiety in the amount of explained variance in the IBS outcomes of Symptom Severity, IBS Related Behaviours, IBS Impact on Quality of Life and General Quality of Life. For this aim, a series of hierarchical multiple regression analyses were performed in which the order of entry of Acceptance (General or IBS specific) and GI Specific Anxiety were alternated. As in section 6.7 the influences of background variables like age, gender, Length of Illness, Marital Status and Education were tested for entry as a block at the first step of each regression using the stepwise method and retained based on statistical criteria (probability of F to enter < .05, and to remove > .10). In the first set of analysis Symptom Severity was used as a dependent variable; however as this variable is also considered to be a predictor variable in many studies (e.g. Jerndal et al., 2010; Lee et al., 2008) in the latter analyses Acceptance (General or IBS specific) and GI Specific Anxiety were only entered after the background variables and Symptom Severity had been controlled for.

A series of tests were carried out to examine the suitability of the present data for regression analysis. Normality tests and probability plots showed a normal distribution of residuals for all models tested. The Durbin-Watson values for each model were within the range of 1.8-2.1, indicating homoscedasticity of residuals. No multicollinearity was suggested, as tolerance values were all above .5 (.1 is the minimum; Field, 2005, p.196) in every model tested. Therefore data was considered adequate for regression analysis.

6.9.1. Acceptance vs. GI Anxiety as a predictor of Symptom Severity

Regression analyses demonstrate that background variables contributed with a small amount of explained variance (6%) in Symptom Severity. Length of Illness remained a significant predictor of Symptom Severity even after all predictor variables were added to the model (see Table 6.11).

Table 6.11: Hierarchical regression analyses comparing the contributions of GI Anxiety and Acceptance (General or IBS specific) in predicting Symptom Severity when controlling for background variables

Comparison	Step	Predictor Variables	R ²	R ² change	F Change (df)	Sig. F change	Standardized coefficients beta (β)			
							β (final)	t	Sig. β	
GI Anxiety and General Acceptance	1	Background variables Length of Illness	.06	.06	7.05 (1, 119)	.009	.18	2.44	.016	
	GI Anxiety entered first									
	2	GI Anxiety	.36	.30	55.24 (1, 118)	<.001	.49	5.84	<.001	
	3	General Acceptance	.37	.01	2.04 (1, 117)	.156	-.12	-1.43	.156	
	General Acceptance entered first									
	2	General Acceptance	.18	.13	18.53 (1, 118)	<.001	-.12	-1.43	.156	
	3	GI Anxiety	.37	.18	34.05 (1, 117)	<.001	.49	5.84	<.001	
GI Anxiety and IBS Acceptance	1	Background variables Length of Illness	.06	.06	7.05 (1, 119)	.009	.17	2.33	.022	
	GI Anxiety entered first									
	2	GI Anxiety	.36	.30	55.24 (1, 118)	<.001	.33	3.29	.001	
	3	IBS Acceptance	.41	.05	9.26 (1, 117)	.003	-.31	-3.04	.003	
	IBS Acceptance entered first									
	2	IBS Acceptance	.35	.29	53.10 (1, 118)	<.001	-.31	-3.04	.003	
	3	GI anxiety	.41	.06	10.84 (1, 117)	.001	.33	3.29	.001	

In all analyses the demographic variables of Age, Gender, Length of Illness, Marital Status and Education were tested for entry as a block using the stepwise method (and are presented as step 1 if significant). Male, Single and secondary schooling were coded as 0 while Female, Married/Cohabiting and Higher education were coded as 1. General acceptance and GI Anxiety are alternately entered as steps 2 and 3.

When compared to General Acceptance, GI anxiety significantly explained 30% of variance when entered first and 18% when entered after General Acceptance. On the other hand General Acceptance only significantly explained 13% of variance in Symptom Severity when entered first, while it did not achieve significance when GI Anxiety was controlled for. The standardized beta coefficients show the significant contribution of GI anxiety ($\beta=.49$, $p<.001$) but not of General Acceptance ($\beta=-.42$, $p=.156$) in predicting Symptoms Severity in the models tested (see Table 6.11).

When compared to IBS Acceptance, GI Anxiety significantly explained 30% of variance in Symptom Severity when entered first and 6% when entered last. IBS Acceptance was able to significantly explain 29% of variance in Symptom Severity when entered first and 5% when entered last. The standardized beta coefficients illustrate statistically significant contributions in predicting Symptom Severity from both GI anxiety ($\beta=.33$, $p=.001$) and IBS Acceptance ($\beta=-.31$, $p=.003$) when controlling for each other and background variables (see Table 6.11).

6.9.2. Acceptance vs. GI Anxiety as a predictor of IBS Related Behaviours

As described in section 6.7.1 background variables did not contribute with any significant amount of variance in IBS Related Behaviours. Symptom Severity accounted for a significant 29% of explained variance in IBS Related Behaviours. Symptom Severity remained a significant predictor in the final model (β significance, $p=.025$) when GI Anxiety and General Acceptance were added. However when GI Anxiety and IBS Acceptance were added to the model Symptom Severity was no longer a significant predictor (β significance, $p=.140$).

Table 6.12: Hierarchical regression analyses comparing the contributions of GI Anxiety and Acceptance (General or IBS specific) in predicting IBS Related Behaviours when controlling for background variables and symptom severity

Comparison	Step	Predictor Variables	R ²	R ² change	F Change (df)	Sig. F change	Standardized coefficients beta (β)			
							β (final)	t	Sig. β	
GI Anxiety and General Acceptance	1	Symptom Severity	.29	.29	48.34 (1, 119)	<.001	.17	2.27	.025	
	GI Anxiety entered first									
	2	GI Anxiety	.56	.28	74.38 (1, 118)	<.001	.62	7.84	<.001	
	3	General Acceptance	.57	.00	.23 (1, 117)	.629	-.03	-.48	.629	
	General Acceptance entered first									
	2	General Acceptance	.34	.05	8.39 (1, 118)	.004	-.03	-.48	.629	
3	GI Anxiety	.57	.23	61.44 (1, 117)	<.001	.62	7.84	<.001		
GI Anxiety and IBS Acceptance	1	Symptom Severity	.29	.29	48.34 (1, 119)	<.001	.11	1.49	.140	
	GI Anxiety entered first									
	2	GI Anxiety	.56	.28	74.38 (1, 118)	<.001	.48	5.56	<.001	
	3	IBS Acceptance	.60	.03	9.52 (1, 117)	.003	-.27	-3.09	.003	
	IBS Acceptance entered first									
	2	IBS Acceptance	.49	.20	46.54 (1, 118)	<.001	-.27	-3.09	.003	
3	GI anxiety	.60	.11	30.93 (1, 117)	<.001	.48	5.56	<.001		

In all analyses the demographic variables of Age, Gender, Length of Illness, Marital Status and Education were tested for entry as a block using the stepwise method, however in this case, background variables were not significant therefore they were not retained. Symptom Severity was therefore entered at step 1 and General acceptance and GI Anxiety are alternately entered as steps 2 and 3.

When compared to General Acceptance, GI anxiety significantly explained 28% of variance of IBS Related Behaviours when entered first and 23% when entered after General Acceptance. On the other hand General Acceptance only significantly explained 5% of variance in IBS Related Behaviours when entered first, while it did not achieve significance when GI Anxiety was controlled for. The standardized beta coefficients show the significant contribution of GI anxiety ($\beta=.62$, $p<.001$) but not of General Acceptance ($\beta=-.03$, $p=.629$) in predicting IBS Related Behaviours in the models tested (see Table 6.12).

When compared to IBS Acceptance, GI Anxiety significantly explained 28% of variance in IBS Related Behaviours when entered first and 11% when entered last while IBS Acceptance significantly explained 20% of variance when entered first and 3% when entered last. The standardized beta coefficients illustrate statistically significant contributions in predicting IBS Related Behaviours from both GI anxiety ($\beta=.48$, $p<.001$) and IBS Acceptance ($\beta=-.27$, $p=.003$) when controlling for each other, for background variables and Symptom Severity.

6.9.3. Acceptance vs. GI anxiety as a predictor of IBS Impact on Quality of Life

Regarding IBS Impact on Quality of Life, background variables did not account for any significant amount of variance and Symptom Severity accounted for a significant 42% of explained variance. As the standardized beta coefficients show Symptom Severity remained a significant predictor ($p<.001$) in the models tested (see Table 6.13).

When compared to General Acceptance, GI Anxiety accounted for a significant 26% of variance when entered first and 20% when entered last, while General Acceptance only significantly explained 6% of variance when entered first. As before, beta coefficients show that GI Anxiety remained a significant predictor ($\beta=.59$, $p<.001$) while General acceptance did not ($\beta=-.07$, $p=.260$) (see Table 6.13).

Table 6.13: Hierarchical regression analyses comparing the contributions of GI Anxiety and Acceptance (General or IBS specific) in predicting IBS Impact on Quality of Life when controlling for background variables and symptom severity

Comparison	Step	Predictor Variables	R ²	R ² change	F Change (df)	Sig. F change	Standardized coefficients beta (β)			
							β (final)	t	Sig. β	
GI Anxiety and General Acceptance	1	Symptom Severity	.42	.42	86.05 (1, 119)	<.001	.29	4.48	<.001	
	GI Anxiety entered first									
	2	GI Anxiety	.68	.26	92.71 (1, 118)	<.001	.59	8.58	<.001	
	3	General Acceptance	.68	.00	1.28 (1, 117)	.260	-.07	-1.13	.260	
	General Acceptance entered first									
	2	General Acceptance	.48	.06	12.78 (1, 118)	.001	-.07	-1.13	.260	
3	GI Anxiety	.68	.20	73.57 (1, 117)	<.001	.59	8.58	<.001		
GI Anxiety and IBS Acceptance	1	Symptom Severity	.42	.42	86.05 (1, 119)	<.001	.25	3.86	<.001	
	GI Anxiety entered first									
	2	GI Anxiety	.68	.26	92.71 (1, 118)	<.001	.50	6.59	<.001	
	3	IBS Acceptance	.70	.02	6.91 (1, 117)	.010	-.20	-2.63	.010	
	IBS Acceptance entered first									
	2	IBS Acceptance	.58	.16	44.751 (1, 118)	<.001	-.20	-2.63	.010	
3	GI anxiety	.70	.12	43.435 (1, 117)	<.001	.50	6.59	<.001		

In all analyses the demographic variables of Age, Gender, Length of Illness, Marital Status and Education were tested for entry as a block using the stepwise method, however in this case, background variables were not significant therefore they were not retained. Symptom Severity was therefore entered at step 1 and General acceptance and GI Anxiety are alternately entered as steps 2 and 3.

When compared to IBS Acceptance, GI Anxiety significantly explained 26% of variance in IBS Impact on Quality of Life when entered first and 12% when entered last while IBS Acceptance significantly explained 16% of variance when entered first and 2% when entered last. The standardized beta coefficients illustrate the statistically significant contributions in predicting IBS Impact on Quality of Life from both GI anxiety ($\beta=.50$, $p<.001$) and IBS Acceptance ($\beta=-.20$, $p=.010$) when controlling for each other, for background variables and Symptom Severity.

6.9.4 Acceptance vs. GI anxiety as a predictor of General Quality of Life

Regarding General Quality of Life, background variables and Symptom Severity accounted for 7% and 15% of significant amount of variance respectively. As the standardized beta coefficients show only Marital Status remained a significant predictor ($p=.017$ and $p=0.014$) in the models tested (see Table 6.14).

When compared to General Acceptance, GI Anxiety accounted for a significant 8% of variance when entered first and 3% when entered last, while General Acceptance significantly explained 6% of variance when entered first and 13% when entered last. Standardized beta coefficients demonstrate that GI Anxiety ($p=.027$) and General Acceptance ($p<.001$) remained significant predictors (see Table 6.14).

When compared to IBS Acceptance, GI Anxiety only significantly explained 8% of variance in General Quality of Life when entered first, while IBS Acceptance significantly explained 12% of variance when entered first and 5% when entered last. The standardized beta coefficients show the significant contribution of IBS Acceptance ($p<.001$) but not of GI Anxiety ($p=.146$) in predicting General Quality of Life in the models tested (see Table 6.14).

Table 6.14: Hierarchical regression analyses comparing the contributions of GI Anxiety and Acceptance (General or IBS specific) in predicting General Quality of Life when controlling for background variables and symptom severity

Comparison	Step	Predictor Variables	R ²	R ² change	F Change (df)	Sig. F change	Standardized coefficients beta (β)			
							β (final)	t	Sig. β	
GI Anxiety and General Acceptance	1	Background variables Marital Status	.07	.07	9.39 (1, 119)	.003				
	2	Symptom Severity	.22	.15	22.36 (1, 118)	<.001	.18	2.43	.017	
	GI Anxiety entered first									
	3	GI Anxiety	.30	.08	13.62(1, 117)	<.001	-.21	-2.24	.027	
	4	General Acceptance	.38	.08	14.82(1, 116)	<.001	.33	3.85	.000	
	General Acceptance entered first									
	3	General Acceptance	.35	.13	24.20(1, 117)	<.001	.33	3.85	<.001	
	4	GI Anxiety	.38	.03	5.02(1, 116)	.027	-.21	-2.24	.027	
GI Anxiety and IBS Acceptance	1	Background variables Marital Status	.07	.07	9.39 (1, 119)	.003				
	2	Symptom Severity	.22	.15	22.36 (1, 118)	<.001	.19	2.49	.014	
	GI Anxiety entered first									
	2	GI Anxiety	.30	.08	13.63(1, 117)	<.001	-.16	-1.46	.146	
	3	IBS Acceptance	.35	.05	8.09(1, 116)	.005	.32	2.85	.005	
	IBS Acceptance entered first									
	2	IBS Acceptance	.34	.12	20.21(1, 117)	<.001	.32	2.85	.005	
	3	GI anxiety	.35	.01	2.14(1, 116)	.146	-.16	-1.46	.146	

In all analyses the demographic variables of Age, Gender, Length of Illness, Marital Status and Education were tested for entry as a block using the stepwise method (and are presented as step 1 if significant). Male, Single and secondary schooling were coded as 0 while Female, Married/Cohabiting and Higher education were coded as 1. Symptom Severity was entered at step 2 and General acceptance and GI Anxiety are alternately entered as steps 3 and 4

6.9.5 Summary of general findings for Acceptance vs. GI anxiety comparisons

The regression results demonstrate that GI Anxiety when compared to Acceptance (general and IBS specific) seems to be a better predictor of IBS specific outcomes like Symptom Severity, IBS Related Behaviours and IBS Impact on Quality of Life. However regarding a more general outcome like General Quality of Life, Acceptance (General and IBS specific) seems to be a better predictor than GI anxiety.

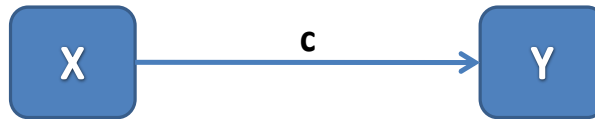
It is also important to notice that although GI anxiety is a better predictor of specific IBS outcomes, IBS Acceptance still remains a significant predictor explaining a significant amount of variance in the dependent variables beyond the effects of background variables, symptom severity and GI Anxiety.

6.10 ACCEPTANCE AS A MEDIATOR BETWEEN IBS PREDICTORS AND OUTCOMES

The seventh aim of this study was to investigate if Acceptance (General or IBS specific) could be a significant mediator between predictors such as Symptom Severity and GI Anxiety and the outcomes of General Quality of Life, IBS Related Behaviours and IBS Impact on Quality of Life.

Simple mediation is said to occur when the effect of one variable (X) is transmitted to a second variable (Y) at least partially through a third intervening or mediating variable (M) (Fritz, 2007). Therefore mediation analyses explore the impact of the mediating variable (M) on the relationship between the independent variable (X) and the dependent variable (Y). Panel A of Figure 6.1 depicts the effect of a proposed causal variable (X) on some outcome (Y) while panel B represents what occurs when one variable (M) mediates the effect of X on Y (i.e. simple mediation) (Preacher & Hayes, 2004).

Panel A



Panel B

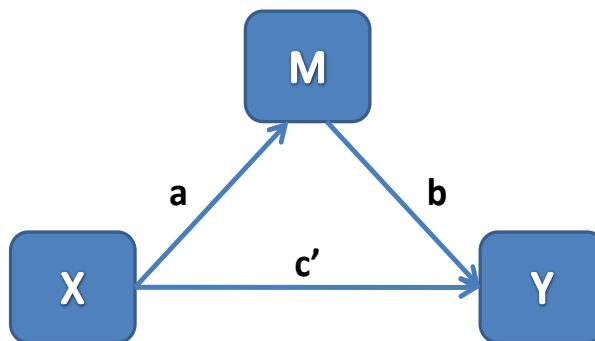


Figure 6.1: Simple mediation diagram - Panel A illustrates X directly affecting Y. Panel B illustrates a simple mediation in which X affects Y indirectly through M

The most common method to study a simple mediation effect (with over 15000 citations) has been the causal steps approach proposed by Baron & Kenny (1986). However, several criticisms have been directed at this method (see Hayes, 2009 for more detail) and more effective alternatives have been proposed. It is now generally accepted that the cross-product of the coefficients approach is the best overall test of mediation (MacKinnon, Fairchild, & Fritz, 2007). In this method, the significance for the overall $a*b$ cross-product is tested, where the a path is the coefficient for the relation between X and M and the b path is the coefficient for the relation between M and Y controlling for

X (figure 6.1, Panel B). Mediation is usually tested calculating $c-c'$, however because in finite datasets $c-c' = a*b$, the cross-product method directly assesses the mediating effect. This method is sensitive to violations of normality and the distribution of $a*b$ is usually not normal in finite datasets. To address this problem Preacher & Hayes (2004) created a procedure that uses nonparametric re-sampling, or bootstrapping, in which the $a*b$ cross-product is calculated in n random samples of the original size taken from the obtained data with replacement after each value is drawn. The point estimate of the indirect effect is given by the mean $a*b$ value of the computed samples. A 95% Confidence Interval ($p < .05$) is derived from the obtained distribution of the $a*b$ scores, with z-score based corrections for bias due to the underlying distribution. If zero is not contained within the upper and lower bounds of the confidence interval, then the indirect or mediated effect is significant at the level specified.

The cross-product method was used to analyse simple mediation to evaluate the role of Acceptance (General and IBS specific) as a mediator between the predictors of Symptom Severity and GI Anxiety (Jerndal et al., 2010) and the outcomes of General Quality of Life, IBS Related Behaviours and IBS Impact on Quality of Life. As GI anxiety has also been suggested to predict Symptom Severity (Jerndal et al., 2010), Acceptance (General and IBS specific) was also tested as a mediator between these two variables. Each analysis was based on 5000 bootstrapped samples as suggested by (Preacher & Hayes, 2004).

6.10.1 Mediation analyses with Symptom Severity as the predictor

Table 6.15 shows the six mediation models tested by analysing both the significance of the indirect effect ($a*b$) produced using normal theory (Z-scores), as well as by analysing the significance of the bootstrap results for the indirect effect at 95% Confidence Interval level. If the z-score was significant ($p < .05$) and zero was not contained within the upper and lower bounds of the confidence interval then the indirect or mediated effect was considered significant.

Table 6.15: Mediation Analyses results with Symptom Severity scores as the predictor

Outcome	Mediator	Product of coefficients			Bootstrap results for indirect effects (BCa; 95% CI)			Effect size (r)
		Coefficient (SE)	Z	p	Point estimate (SE)	Lower	Upper	
General Quality of Life	General Acceptance	0.011 (.003)	-3.365	<.001	0.011 (0.003)	0.017	0.005	.33
	IBS Acceptance	0.017 (.004)	-4.119	<.001	0.017 (0.004)	-0.026	-0.009	.38
IBS Impact on Quality of Life	General Acceptance	0.044 (.016)	2.726	.006	0.044 (0.016)	0.017	0.079	.39
	IBS Acceptance	0.126 (.025)	4.960	<.001	0.126 (0.024)	0.085	0.176	.57
IBS Related Behaviours	General Acceptance	0.026 (.011)	2.372	.017	0.027 (0.011)	0.008	0.052	.34
	IBS Acceptance	0.093 (.019)	5.014	<.001	0.093 (0.018)	0.061	0.132	.50

As presented in Table 6.15 General Acceptance significantly mediated the effect of Symptom Severity on General Quality of Life, IBS Impact on Quality of Life and IBS Related Behaviours.

Table 6.15 also shows that IBS Acceptance significantly mediated the effect of Symptom Severity on General Quality of Life, IBS Impact on Quality of Life and IBS Related Behaviours.

Although theorists have still not agreed on the best method for the estimation of the effect size of a mediation effect (MacKinnon, Fairchild, & Fritz, 2007), the SPSS macro provided by Preacher & Hayes (2004) gives us the variance (R^2) accounted by the indirect effect as calculated by the procedure developed by Fairchild, MacKinnon, Taborga, & Taylor (2009). These authors recommend that the square of the variance obtained be reported as a Cohen's *r* effect-size. The effect sizes for all mediator models were medium to large, ranging between 0.33 and 0.57 (Table 6.15).

These results give support to the hypothesis that Acceptance (general or IBS specific) mediates the effect that Symptom Severity has on IBS outcomes at the level tested (95% Confidence Interval).

6.10.2 Mediation analyses with GI Anxiety as the predictor

As the normal theory and bootstrap methods show in Table 6.16, General Acceptance did not mediate the relationships between GI anxiety and Symptom Severity, IBS Impact on Quality of Life and IBS Related Behaviours. However it did significantly mediate the relationship between GI Anxiety and General Quality of Life.

Table 6.16: Mediation Analyses results with GI Anxiety scores as the predictor

Outcome	Mediator	Product of coefficients			Bootstrap results for indirect effects (BCa; 95% CI)			Effect size (r)
		Coefficient (SE)	Z	p	Point estimate (SE)	Lower	Upper	
Symptom Severity	General Acceptance	0.338(0.244)	1.385	.166	0.338(0.236)	-0.080	0.842	.36
	IBS Acceptance	1.287(0.427)	3.012	.003	1.287(0.405)	0.520	2.117	.52
General Quality of Life	General Acceptance	-0.069(0.019)	-3.623	<.001	-0.069(0.020)	-0.113	-0.036	.40
	IBS Acceptance	-0.108(0.030)	-3.625	<.001	-0.108(0.028)	-0.160	-0.053	.45
IBS Impact on Quality of Life	General Acceptance	0.131(0.085)	1.538	.124	0.131(0.087)	-0.028	0.319	.45
	IBS Acceptance	0.510 (0.148)	3.449	.001	0.510 (0.146)	0.234	0.813	.67
IBS Related Behaviours	General Acceptance	0.046(0.060)	0.759	.448	0.046(0.061)	-0.068	0.177	.40
	IBS Acceptance	0.365(0.106)	3.429	.001	0.365(0.109)	0.159	0.587	.64

IBS Acceptance on the other hand was a significant mediator of all relationships between GI Anxiety and Symptom Severity, General Quality of Life, IBS Impact on Quality of Life and IBS Related Behaviours (see Table 6.16). The effect sizes for all mediator models were medium to large, ranging between 0.36 and 0.67 (see Table 6.16).

These results support the hypothesis that IBS acceptance significantly mediated the effect of GI anxiety on IBS outcomes; however General Acceptance is only a mediator when more general outcomes are considered.

6.11 THE ILLNESS REPRESENTATIONS MODEL AND ACCEPTANCE

Finally, it was intended to explore how the dimensions of the Illness Representations Model were related to Acceptance (General and IBS specific) as a coping strategy and if acceptance had a mediating role between Illness Representations and IBS outcomes.

6.11.1 Correlations with continuous dimensions

Correlation analyses were used to investigate the association of the continuous dimensions of Consequences (How much IBS affects life), Timeline (How long it will last), Personal Control (How much control does one feel over IBS), Treatment Control (How much will treatment help), Identity (How much are symptoms experienced), Concern (Concern about IBS), Comprehensibility (How much does one understand IBS) and Emotions (How much does IBS affect emotionally) with Acceptance (General and IBS specific).

Table 6.17 demonstrates that higher levels of Acceptance (General and IBS specific) were significantly associated with a lower perception of Consequences; a perception that the Timeline will be shorter; a higher perception of Personal Control; a higher perception of Treatment Control; a lower perception of illness Identity; a lower Concern about IBS and a lower perception of Emotional impact. Comprehensibility was significantly (though rather weakly) positively associated with General

Acceptance ($r=0.19$). These results support in general the hypothesis that higher levels of acceptance are related to more positive Illness Representations.

Table 6.17: Correlations of Acceptance (General and IBS specific) with Illness Representations Dimensions

	General Acceptance	IBS Acceptance
Consequences	-0.48*	-0.72*
Timeline	-0.34*	-0.48*
Personal Control	0.28*	0.32*
Treatment Control	0.22*	0.28*
Identity	-0.30*	-0.40*
Concern	-0.44*	-0.55*
Comprehensibility	0.19*	0.13
Emotions	-0.57*	-0.57*

Note:*Correlations significant at $p<0.01$ (two-tailed)

6.11.2 Differences amongst attribution levels

Due to the causal attribution scale being categorical (Psychological, Biological or External), One-Way ANOVA was used to investigate if levels of acceptance differed across the attribution categories (Psychological, Biological or External). Table 6.18 presents the means and standard deviations of general acceptance and IBS specific acceptance according to causal attribution as well as the F-statistics and η^2 effect sizes ($N=92$). According to the results, there was no significant effect of Causal Attribution on General Acceptance or IBS Acceptance scores.

Table 6.18: Results of the ANOVAs comparing general and IBS specific acceptance according to causal attribution

Scale	Variable (N)	M	SD	F	Sig.	Effect Size(η^2)
General Acceptance (AAQ-9)	Psychological Causes (50)	35.88	8.56	2.23	0.114	0.22
	Biological Causes (27)	39.91	7.43			
	External Causes (15)	37.64	7.13			
IBS Acceptance (IBSAAQ)	Psychological Causes (50)	58.15	18.28	0.71	0.496	0.13
	Biological Causes (27)	58.22	14.69			
	External Causes (15)	52.33	18.81			

6.11.3 Path analyses

A series of path analyses based on multiple linear regressions as described by Pedhazur (1997) were used to examine the possibility that the relation between Illness Representations and IBS outcomes was mediated by Acceptance. In this model, the path coefficients for the full model represent the beta coefficients of two layers of multiple regression analyses. In the first layer, the predictors (Illness Representations dimensions) are regressed on the proposed mediator (General or IBS specific Acceptance), and on the second layer both predictors and mediator are regressed on the outcome (General Quality of Life, IBS Impact on Quality of Life, IBS Related Behaviours or Symptom Severity). Indirect paths were calculated by multiplying the path coefficients between predictor and mediator, and mediator and outcome. In the case of a significant indirect path being detected, a test of mediation was carried as previously described in section 6.9.

Because Causal Attribution had shown not to influence acceptance (general or IBS specific) and because this variable had a high number of missing values, it was excluded from the analyses. All other continuous dimensions were included. Data was considered adequate for regression analysis with a normal distribution of residuals; Durbin-Watson values ranging from 1.7 to 2.4; and multicollinearity tolerance values were all above 0.3 (0.1 is the minimum; Field, 2005, p.196) in every model tested. Figures 6.2 to 6.9 show the final path analysis model with only the significant paths included.

The first analysis (Figure 6.2) shows that the model tested accounted for 32% of variance in General Quality of Life with General Acceptance contributing with a significant 6% of explained variance. Consequences had a direct effect on the outcome: those who perceived fewer consequences reported greater General Quality of Life. A significant indirect path was detected from Emotion through General Acceptance and to General Quality of Life ($-0.43 \times 0.32 = -0.14$; $p < 0.05$). The test of indirect effects showed that General Acceptance was a significant mediator between these two variables ($Z = -3.674$, $p < .001$; bootstrapped point estimate $= -0.561$, 95% CI Lower-Upper = $-0.925, -0.284$).

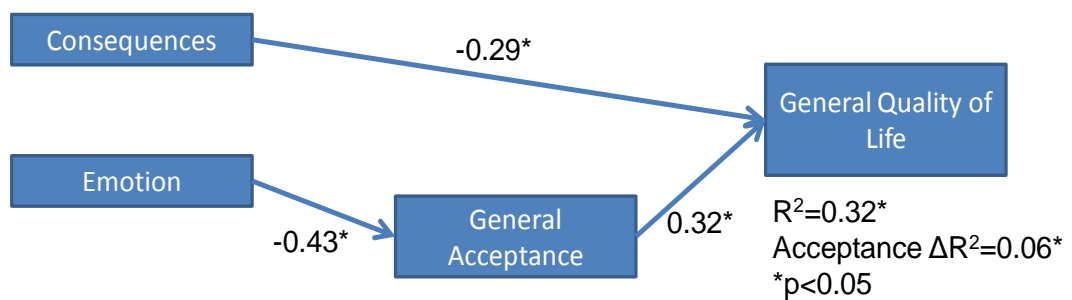


Figure 6.2: Path analytic model of relationships between Illness Representations and General Quality of Life (General Acceptance as mediator)

Figure 6.3 illustrates that the second model tested accounted for 61% of variance in IBS Impact on Quality of Life with General Acceptance not contributing a significant amount of explained variance. Both Consequences and Comprehensibility had a direct effect on the outcome: those who perceived more consequences and who felt they didn't understand their condition reported more severe impact of IBS on quality of life. No indirect paths were detected.

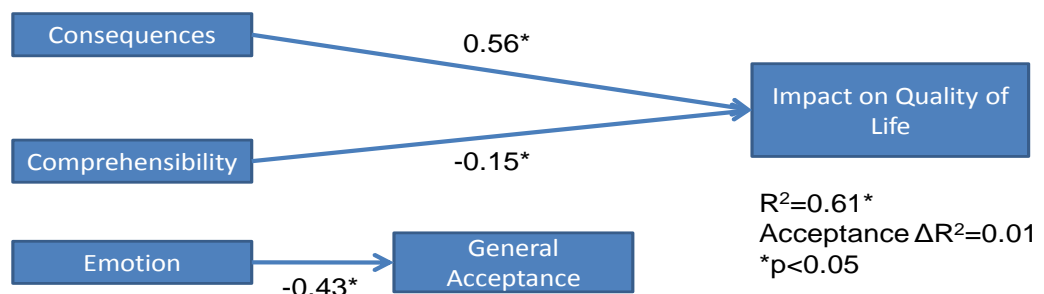


Figure 6.3: Path analytic model of relationships between Illness Representations and IBS Impact on Quality of Life (General Acceptance as mediator)

The third analysis (Figure 6.4) shows that the model tested accounted for 50% of variance in IBS Related Behaviours with General Acceptance not contributing with a significant amount of explained variance. Consequences, Comprehensibility and Timeline all had a direct effect on the outcome: those who perceived more consequences, who felt they didn't understand their condition and that predicted their condition would last a long time reported more use of IBS Related Behaviours. No indirect paths were detected.

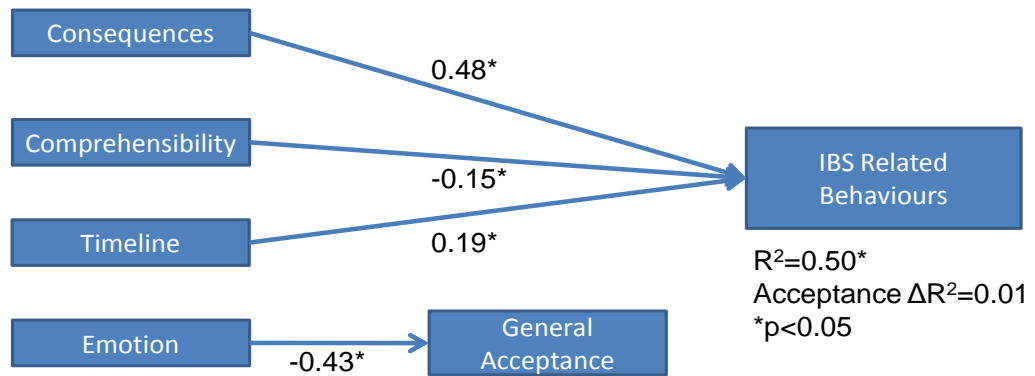


Figure 6.4: Path analytic model of relationships between Illness Representations and IBS Related Behaviours (General Acceptance as mediator)

(Figure 6.5) demonstrates that the fourth model tested accounted for 49% of variance in Symptom Severity with General Acceptance not contributing a significant amount of explained variance. Both Consequences and Identity had a direct effect on the outcome: those who perceived more consequences and who felt they experienced more symptoms reported a higher Symptom Severity. No indirect paths were detected.

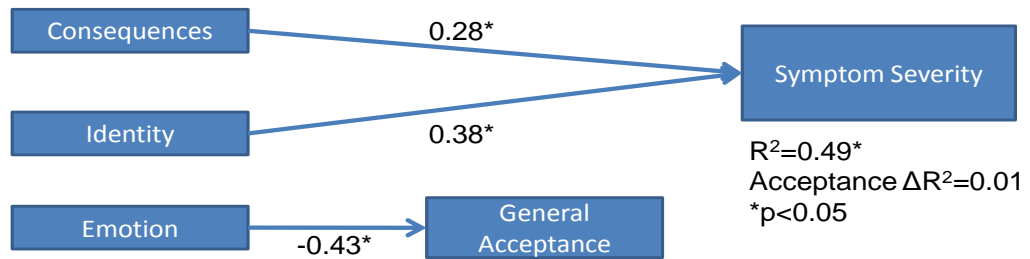


Figure 6.5: Path analytic model of relationships between Illness Representations and Symptom Severity (General Acceptance as mediator)



Figure 6.6: Path analytic model of relationships between Illness Representations and General Quality of Life (IBS Acceptance as mediator)

The fifth analysis (Figure 6.6) shows that the model tested accounted for 32% of variance in General Quality of Life with IBS Acceptance contributing a significant 3% of explained variance. No significant direct effect of any of the Illness representations was detected after controlling for IBS acceptance. However an indirect path was detected from Consequences through IBS Acceptance to General Quality of Life ($-0.63 \times 0.28 = -0.17$; $p < 0.05$). The test of indirect effects showed that IBS Acceptance was a significant mediator between these two variables ($Z = -3.054$, $p = 0.002$; bootstrapped point estimate = -0.658 , 95% CI Lower-Upper = -1.082 , -0.231).

Figure 6.7 demonstrates that the sixth model tested accounted for 61% of variance in IBS Impact on Quality of Life with IBS Acceptance contributing with a significant 3% of explained variance. Consequences had a direct effect on the outcome: those who perceived more consequences reported a higher impact of IBS on their quality of Life. An indirect path was also detected from Consequences through IBS Acceptance to IBS Impact on Quality of Life ($-0.63 \times -0.27 = -0.17$; $p < 0.05$). The test of indirect effects showed that IBS Acceptance was a significant mediator between these two variables ($Z = 3.742$, $p < .001$; bootstrapped point estimate = 4.452 , 95% CI Lower-Upper = 2.411 , 6.808).

The seventh analysis (Figure 6.8) shows that the model tested accounted for 50% of variance in IBS Related Behaviours with IBS Acceptance contributing with a significant 5% of explained variance. Both Consequences and Timeline had a direct effect on the outcome: those who perceived more consequences and that predicted their condition would last a long time reported more use of IBS Related Behaviours. An indirect path was also detected from Consequences through IBS Acceptance to IBS Related Behaviours ($-0.63 \times -0.36 = 0.23$; $p < 0.05$). The test of indirect effects showed that IBS Acceptance was a significant mediator between these two variables ($Z = 4.139$, $p < .001$; bootstrapped point estimate = 3.650 , 95% CI Lower-Upper = 2.089 , 5.417).

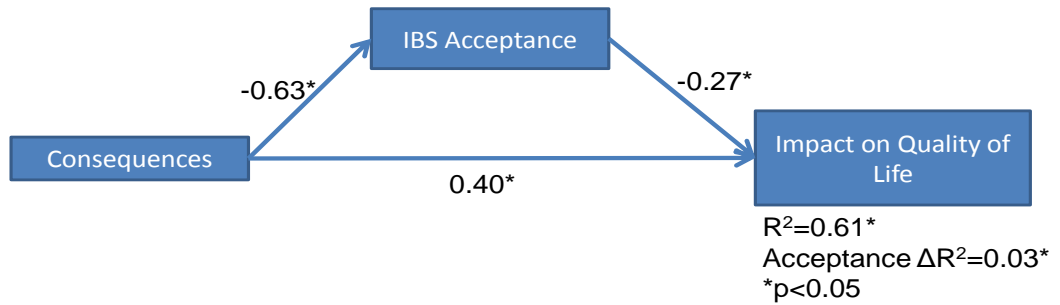


Figure 6.7: Path analytic model of relationships between Illness Representations and IBS Impact on Quality of Life (IBS Acceptance as mediator)

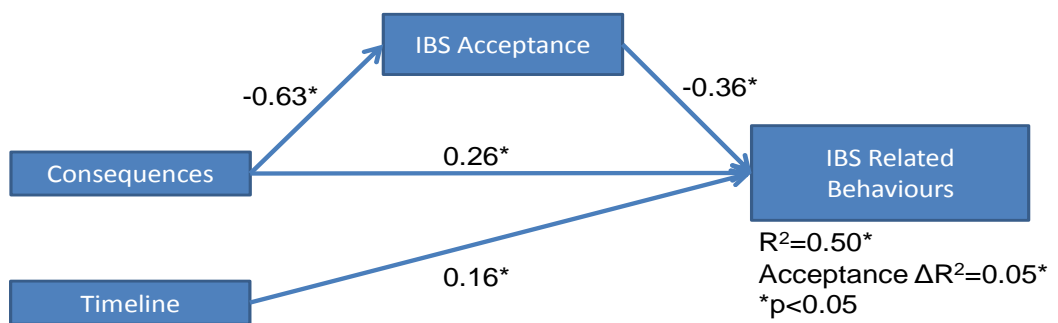


Figure 6.8: Path analytic model of relationships between Illness Representations and IBS Related Behaviours (IBS Acceptance as mediator)

In the eighth and final analysis (Figure 6.9) we can see that the model tested accounted for 49% of variance in Symptom Severity with IBS Acceptance contributing with a significant 3% of explained variance. Identity had a direct effect on the outcome: participants who felt they experienced more symptoms reported a higher Symptom Severity. An indirect path was detected from Consequences through IBS Acceptance to Symptom Severity ($-0.63 \times -0.28 = 0.17$; $p < 0.05$). The test of indirect effects showed that IBS Acceptance was a significant mediator between these two variables ($Z = 2.343$, $p = .020$; bootstrapped point estimate = 7.6145, 95% CI Lower-Upper = 1.240, 13.398).

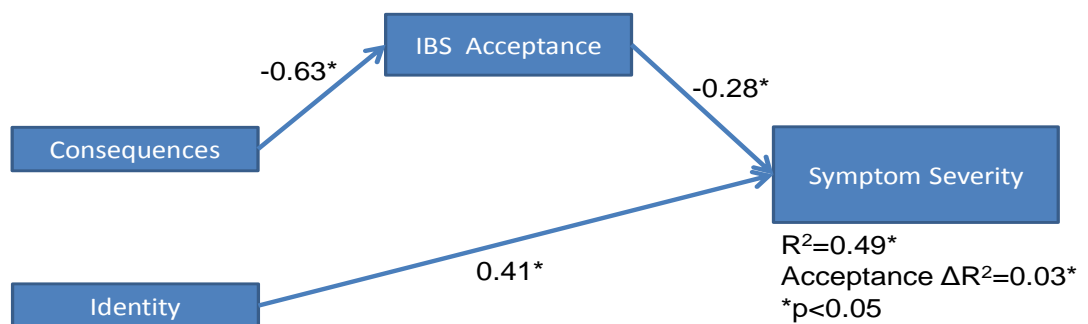


Figure 6.9: Path analytic model of relationships between Illness Representations and Symptom Severity (IBS Acceptance as mediator)

In summary the path analyses results suggest that Acceptance (General and IBS specific) mediates the relations between some dimensions of Illness Representations and IBS Outcomes. More specifically we found General Acceptance to be a significant mediator between Emotions and General Quality of Life. IBS Acceptance consistently mediated the relationship between the dimensions of Consequences and

all outcomes. It should be noted however that only some Illness Representations (Consequences, Emotion, Comprehensibility, Timeline and Identity) were shown to be significantly associated with the outcomes (directly or indirectly) when the influence of Acceptance (general or IBS specific) was controlled for.

CHAPTER 7
STUDY 2 RESULTS

CHAPTER 7 – STUDY 2 RESULTS

7.1. MISSING VALUES AND PRELIMINARY ANALYSES

Preliminary analyses indicated that all items had been correctly entered for all variables used in this study. A missing values analysis of each variable of interest (interval or ratio) revealed that missing values did not exceed 5% per item or 20% per subject and that these were missing completely at random. Missing values were therefore replaced by simple mean imputation as recommended for these cases (Chavance, 2004; Fox-Wasylyshyn & El-masri, 2005).

All criteria variables of IBS outcomes and Acceptance (General and IBS specific) were also shown to have a normal distribution ($z_{\text{skewness}} < 3.96$ and $z_{\text{kurtosis}} < 3.96$; Field, 2005. p72) across all time points measured, therefore they were considered appropriate for parametric testing.

7.2. CHARACTERISTICS OF THE SAMPLE

Of the 56 participants that attended the workshops, 20 were lost to follow-up and were considered as non-completers. Therefore two separate statistical analyses for the main hypotheses of this study will be conducted. The first included only the participants who completed all four measurement points (Completers, N=36). The second included both completers and non-completers (completed only initial survey and pre-workshop measures) in an intent-to-treat analysis (ITT, N=56). ITT analyses will be conducted to control for possible inflated effectiveness estimates from participants who completed all measures. In the ITT analyses, the participant's last available score (Time 2: pre-workshop) was carried forward.

The demographic characteristics of the completers and non-completers groups are presented in Table 7.1. The completer group had a mean age of 47 years and a median length of illness of 84 months while the non-completers group had a mean age of 48 and a median length of illness of 63 months. Both groups had predominantly female participants with a mixed form of IBS. Most participants in both groups had attained a higher education degree and were employed or in training.

Percentages of single and married/cohabiting participants were also similar between groups.

Table 7.1: Demographic characteristics of Study 2 participants

Continuous Variables	Non-Completers (N=20)	Completers (N=36)	Statistics	Sig
Age in years – Mean (SD)	48.00 (13.24)	47.41 (13.03)	t-test	.874
Length of Illness in Months - Median	63	84	Mann-Whitney U	.632
Categorical Variables	N (%)	N (%)	Statistics	
Gender				
Male	2(10)	2(6)	Fisher's Exact Test	.611
Female	18(90)	34(94)		
Education			Pearson	
Higher Education	13(65)	24(67)	Chi-Square	.900
No higher Education	7(35)	12 (33)		
Marital Status			Pearson	
Married/Cohabiting	10(50)	21(58)	Chi-Square	.548
Single	10(50)	15(42)		
Vocational Status				
Employed or in training	14(70)	27(75)	Fisher's Exact Test	.999
Not employed due to IBS	1(5)	1(3)		
Not employed due to other reason	5(25)	8(22)		
Type of IBS				
No IBS	1(5)	3(8)	Fisher's Exact Test	.361
IBS-C	1(5)	4(11)		
IBS-D	2(10)	10(28)		
IBS-M	15(75)	18(50)		
IBS-U	1(5)	1(3)		

In order to confirm if any demographic factors differentiated these two groups, statistical comparison tests were carried out. Regarding the continuous variables of Age (normally distributed) and Length of Illness (non-normally distributed), an independent samples t-test and a Mann-Whitney test were respectively used to

compare completers and non-completers. As shown in Table 7.1, no significant differences were found for Age and Length of Illness ($p=.874$ and $p=.632$ respectively). Regarding the categorical variables of Gender, Education, Marital Status, Vocational Status and Type of IBS, chi-square tests of differences were carried out. In the case of variables not meeting the criteria for chi-square testing (groups with $n<5$) the value of Fisher's exact test was used instead. Table 7.1 illustrates that no differences were found for any of the categorical variables (all $p>.05$). Therefore, demographic variables did not seem to influence whether or not a participant completed the study.

The two groups were also compared regarding the pre-treatment criteria variables of Symptom Severity, IBS Related Cognitions, GI Anxiety, IBS Related Behaviours, IBS Impact on Quality of Life, General Quality of Life, Anxiety, Depression, Stress, General Acceptance and IBS Acceptance. As Table 7.2 shows, groups only differed in GI Anxiety with non-completers having slightly higher values for this variable; However, since the significance of this difference was only marginal ($p=.046$). Therefore initial criteria variables assessed were in general similar between groups indicating that these variables, with the exception of GI Anxiety, did not seem to influence drop-out in participants.

Table 7.2: Pre-treatment criteria variables comparisons for completers and non-completers

Pre-treatment Criteria Variables	Non-Completers (N=20) Mean (SD)	Completers (N=36) Mean (SD)	t
Symptom Severity	281.40 (112.48)	254.53 (94.57)	0.95
IBS Related Cognitions	122.74 (24.90)	115.06 (26.41)	1.06
GI Anxiety	66.56 (15.42)	58.19 (14.24)	2.05*
IBS Related behaviours	108.05 (24.65)	98.79 (23.79)	1.38
IBS Impact on Quality of Life	106.60 (39.16)	91.74 (37.72)	1.39
General Quality of Life	25.58 (6.30)	26.13 (6.74)	-0.29
Anxiety	13.60 (11.26)	8.37 (6.76)	1.89
Depression	17.20 (13.32)	13.38 (9.78)	1.22
Stress	20.20 (11.10)	18.51 (10.14)	0.57
General Acceptance	34.85 (9.90)	36.87 (7.09)	-0.88
IBS Acceptance	50.61 (18.55)	57.22(16.61)	-1.36

7.3. ADDITIONAL PSYCHOMETRIC ANALYSIS OF THE IBSAAQ

To supplement the psychometric analyses of the IBSAAQ undertaken in Study 1, an additional analysis was carried out using the treatment study data. Test-retest reliability was investigated using Pearson's product moment correlation between scores of IBS Acceptance at the time of the first survey, and the scores of the same variable at the pre-workshop time point for all 56 participants that completed both these measurements. Time between reception of postal survey and attendance at workshop was on average 55 days (SD=13.2) ranging between 35-97 days. With no

intervention targeting Acceptance between these two time points it was expected that the correlation would be strong.

There was a significant and large positive correlation between time 1 and time2 with $r=.87$ ($p<0.001$). This indicates that in the absence of intervention, the measurement of IBS Acceptance is relatively stable over a period of 1 to 3 months.

7.4. EFFECTIVENESS OF AN ACT INTERVENTION IN INCREASING ACCEPTANCE

The first aim of study 2 was to investigate if participation in an ACT based intervention (workshop + workbook) by IBS patients would result in an increase in Acceptance (general or IBS specific). It was expected that Acceptance (general or IBS specific) levels would not significantly change between 1st survey (T1) and pre-workshop (T2) measures since no intervention to change Acceptance (general or IBS specific) was being made between these two time points. It was also expected that Acceptance (general or IBS specific) would significantly increase after participation in an ACT based intervention, at 2 month (T3) and 6 month (T4) follow-up. Therefore significant differences between pre-intervention (T2) and post-intervention (T3 or T4) measures would show the effectiveness of the intervention. Repeated measures ANOVA and post-hoc Bonferroni adjusted pairwise comparisons were conducted to investigate the effectiveness of the intervention. Mauchly's test was used to investigate if data met the assumption of sphericity. In case Mauchly's test was significant (data did not meet sphericity assumption) the Greenhouse-Geisser correction (if $\epsilon<.75$) or Huynh-Feldt (if $\epsilon>.75$) correction was used for degrees of freedom. Effect sizes (η^2) were considered small if $\approx.01$, medium if $\approx.06$ and large if $>.14$ (Green & Salkind, 2004).

7.4.1. Completers' analyses

As Table 7.3 shows, participants' mean levels of General Acceptance were very similar at the two time points prior to the intervention (T1 and T2) and slightly increased after the intervention (T3 and T4). Mauchly's test indicated that the

assumptions of sphericity had been violated ($\chi^2(5)=12.45$, $p<0.05$). Therefore the degrees of freedom were corrected using the Huynh-Feldt estimates of sphericity ($\epsilon=.794$). The repeated measures ANOVA indicated that General Acceptance scores significantly changed across the time points studied [$F(2.57,89.83)=2.957$, $p=.044$], with a small to medium effect size ($\eta^2=.08$). Post-Hoc comparisons (see Table 7.4) showed there were no significant differences between participants' General Acceptance pre-intervention scores (T1-T2) as expected. However, no significant differences were detected between the pre intervention (T2) and post-intervention (T3 or T4) scores of General Acceptance.

These results show that although mean General Acceptance scores increased after the intervention, this change was not powerful enough to produce significant differences between pre and post intervention scores.

As shown in Table 7.3, participants mean IBS Acceptance scores were very similar prior to the intervention (T1 and T2) and increased after the intervention (T3 and T4). Mauchly's test indicated that the assumptions of sphericity had been violated ($\chi^2(5)=25.21$, $p<0.05$). Degrees of freedom were corrected using the Greenhouse-Geisser estimates of sphericity ($\epsilon=.674$). A repeated measures ANOVA indicated that IBS Acceptance scores significantly changed across the time points studied [$F(2.02,70.81)=34.107$, $p<.001$], with very large effect size ($\eta^2=.49$). Post-Hoc comparisons (see Table 7.4) showed that differences between pre-intervention IBS Acceptance scores (T1-T2) were not significant. Significant differences in IBS Acceptance scores were detected between the pre-intervention score (T2) and both post-intervention scores (T3 and T4).

These results show that the intervention significantly changed IBS Acceptance with a clear increase between pre and post intervention scores. It also showed that the effects of treatment continued to be maintained at 6 months.

Table 7.3: Repeated Measures ANOVA for Completer means: 1st survey, pre-workshop, 2 month follow-up, and 6 month follow-up

Variable	Time Point Mean (SD)				F	Sig	Effect Size Partial η^2
	T1 1 st Survey	T2 Pre-Workshop	T3 2 month follow-up	T4 6 month follow- up			
General Acceptance	36.87 (7.10)	36.76(7.20)	37.99(7.80)	39.31(9.39)	2.957	.044	.08
IBS Acceptance	57.22 (16.62)	60.11 (15.80)	70.41 (15.03)	72.67 (16.17)	34.107	<.001	.49
General Quality of Life	26.14 (6.75)	26.61 (6.13)	28.42 (6.49)	29.61 (6.31)	11.119	<.001	.24
IBS Impact on Quality of Life	91.75 (37.72)	90.65 (34.68)	67.97 (41.42)	63.93 (40.20)	19.031	<.001	.35
IBS Related Behaviours	98.80 (23.80)	100.14 (25.48)	84.80 (27.75)	84.00 (25.53)	14.180	<.001	.29
Symptom Severity	254.53 (94.54)	248.25 (82.03)	191.42 (88.13)	185.39 (103.57)	14.226	<.001	.29

Table 7.4: General and IBS Acceptance Post –Hoc Comparisons between all time points (Completers and ITT)

General Acceptance (Completers)	Time 2 (Pre-workshop)		Time 3 (2 month follow-up)		Time 4 (6 month Follow-up)	
	M _{diff}	p	M _{diff}	p	M _{diff}	p
Time 1 (1 st survey)	0.11	.999	1.12	.999	2.44	0.185
Time 2 (Pre-workshop)			1.22	.999	2.54	0.164
Time 3 (2 month follow-up)					1.32	0.713
IBS Acceptance (Completers)						
Time 1 (1 st survey)	2.89	0.445	13.19	<.001	15.45	<.001
Time 2 (Pre-workshop)			10.30	<.001	12.56	<.001
Time 3 (2 month follow-up)					2.26	0.277
General Acceptance (ITT)						
Time 1 (1 st survey)	0.16	.999	0.57	.999	1.81	0.159
Time 2 (Pre-workshop)			0.73	.999	1.97	0.101
Time 3 (2 month follow-up)					1.24	0.190
IBS Acceptance (ITT)						
Time 1 (1 st survey)	1.96	0.682	9.20	<.001	11.78	<.001
Time 2 (Pre-workshop)			7.24	<.001	9.82	<.001
Time 3 (2 month follow-up)					2.58	0.053

Note: Bolded numbers indicate significance at $p < .05$; M_{diff} – Mean Difference

7.4.2. ITT analyses

As previously noted (section 7.1) Intent-to-treat (ITT) analyses with both completers and non-completers pooled together (N=56) were conducted to control for possible inflated effectiveness estimates from participants who completed all measures.

Table 7.5 demonstrates that participants' mean General Acceptance was similar prior to the intervention (T1 and T2) and tended to slightly increase after the intervention (T3 and T4). Mauchly's test indicated that the assumptions of sphericity had been violated ($\chi^2(5)=17.88$, $p<0.05$). Degrees of freedom were corrected using the Huynh-Feldt estimates of sphericity ($\epsilon=.810$). Similar to the completers' analysis, the repeated measures ANOVA for the ITT analysis indicated that General Acceptance scores significantly changed across the time points studied [$F(2.55,140.35)=3.163$, $p=0.034$], with a small to medium effect size ($\eta^2=0.05$). Post-Hoc comparisons (see Table 7.4) confirmed that General Acceptance scores did not significantly change before the intervention (T1-T2) however these analyses also did not find any significant differences between pre-intervention (T2) and post-intervention (T3-T4) scores.

These results show that although the intervention significantly changed General Acceptance scores in the expected direction, the change was not powerful enough to produce significant differences between pre and post intervention scores.

As shown in Table 7.5 participants' mean IBS Acceptance scores were very close prior to the intervention (T1 and T2) and tended to increase after the intervention (T3 and T4). Mauchly's test indicated that the assumptions of sphericity had been violated ($\chi^2(5)=45.49$, $p<0.05$). Degrees of freedom were corrected using the Greenhouse-Geisser estimates of sphericity ($\epsilon=.634$). A repeated measures ANOVA indicated that IBS Acceptance scores significantly changed across the time points studied [$F(1.90,104.65)=27.813$, $p<.001$], with a large effect size ($\eta^2=.34$).

Table 7.5: Repeated Measures ANOVA for ITT means: 1st survey, pre-workshop, 2 month follow-up, and 6 month follow-up

Variable	Time Point				F	Sig	Effect Size Partial η^2
	T1	T2	T3	T4			
	1 st Survey	Pre-Workshop	2 month follow-up	6 month follow-up			
General Acceptance	36.15 (8.17)	35.99 (8.18)	36.72 (8.92)	37.96 (9.64)	3.163	.034	.05
IBS Acceptance	54.86 (17.46)	56.82 (18.65)	64.06 (20.17)	66.64 (20.43)	27.813	<.001	.34
General Quality of Life	25.94 (6.54)	26.28 (6.61)	27.66 (6.85)	28.82 (6.63)	10.991	<.001	.17
IBS Impact on Quality of Life	97.05 (38.56)	99.07 (37.06)	81.66 (45.95)	76.07 (45.64)	17.710	<.001	.24
IBS Related Behaviours	102.10 (24.29)	102.46 (23.33)	93.89 (29.27)	92.28 (28.50)	8.095	<.001	.13
Symptom Severity	264.13 (101.14)	264.55 (94.38)	223.07 (107.51)	214.77 (115.45)	13.471	<.001	.20

Post-Hoc comparisons (see Table 7.4) showed that differences between pre-intervention (T1-T2) IBS Acceptance scores were not significant, while differences between the pre-intervention score (T2) and both post-intervention scores (T3 and T4) were significant as predicted.

These results show that the intervention significantly changed IBS acceptance with a clear increase between pre and post intervention scores. It also showed that the effects of treatment continued to be maintained at 6 months.

The similarity of results between the ITT and Completers analyses indicates that the effectiveness of the intervention was maintained even taking into account the data carried forward from non-completers. Also in both sets of analyses it was observed that the intervention was more significant in changing IBS Acceptance scores rather than General Acceptance scores.

7.5. EFFECTIVENESS OF AN ACT INTERVENTION IN IMPROVING OUTCOMES

Part of the first aim of study 2 was also to investigate if participation in an ACT based intervention (workshop + workbook) by IBS patients would result in an improvement in outcomes (General Quality of Life, IBS Impact on Quality of Life, IBS Related Behaviours and Symptom Severity). It was expected that outcome scores would not significantly change between 1st survey (T1) and pre-workshop (T2) measures since only treatment as usual was being carried between these two time points. It was also expected that outcomes would significantly improve after at 2 month (T3) and 6 month (T4) follow-up. Therefore significant differences between pre-intervention (T2) and post-intervention (T3 or T4) measures would show the effectiveness of the intervention. More specifically it was expected that General Quality of Life scores would increase and IBS Impact on Quality of Life, IBS Related Behaviours, Symptom Severity scores would decrease after the intervention. The same statistical analyses described in section 7.4 were used to investigate this aim.

7.5.1. Completers analyses

A brief inspection of the change in mean scores of the outcomes considered (Table 7.3) shows that mean scores tended to remain similar prior to intervention (T1 and T2), and increased (in the case of General Quality of Life) or decreased (in the case of IBS Impact on Quality of Life, IBS Related Behaviours and Symptom Severity) after the intervention (T3 and T4). The specific results regarding the effectiveness of the intervention at changing outcomes were as follows:

General Quality of Life

Mauchly's test indicated that the assumptions of sphericity had not been violated ($\chi^2(5) = 5.17, p > 0.05$). As shown in Table 7.3, a repeated measures ANOVA indicated that General Quality of Life mean scores significantly changed across the time points studied [$F(3,105) = 11.119, p < .001$], with a large effect size ($\eta^2 = .24$). Post-Hoc comparisons (see Table 7.6) confirmed that mean General Quality of Life scores did not significantly change before the intervention (T1-T2). Although no significant change in scores was detected between pre-intervention (T2) and 2 month follow-up (T3), this became significant at 6 month follow-up.

These results show that the intervention was effective in significantly increasing General Quality of Life scores between pre and post intervention, although this increase was not immediate.

IBS Impact on Quality of Life

Mauchly's test indicated that the assumptions of sphericity had not been violated ($\chi^2(5) = 10.897, p > 0.05$). As shown in Table 7.3, a repeated measures ANOVA indicated that IBS Impact on Quality of Life mean scores significantly changed across the time points studied [$F(3, 105) = 19.031, p < .001$], with a large effect size ($\eta^2 = .35$). Post-Hoc comparisons (Table 7.6) showed that differences between pre-intervention (T1 and T2) IBS Impact on Quality of Life scores were not significant, while differences between the pre-intervention score (T2) and both of the post-intervention scores (T3 and T4) were significant as predicted.

Table 7.6: Outcomes Post –Hoc Comparisons between all time points for Completers

General Quality of Life (Completers)	Time 2 (Pre-workshop)		Time 3 (2 month follow-up)		Time 4 (6 month Follow-up)	
	M _{diff}	p	M _{diff}	p	M _{diff}	p
Time 1 (1 st survey)	0.47	.999	2.28	0.021	3.47	<.001
Time 2 (Pre-workshop)			1.81	0.094	3.00	<.001
Time 3 (2 month follow-up)					1.19	0.625
IBS Impact on Quality of Life						
IBS Impact on Quality of Life (Completers)						
Time 1 (1 st survey)	1.09	.999	23.78	0.002	27.82	<.001
Time 2 (Pre-workshop)			22.69	<.001	26.73	<.001
Time 3 (2 month follow-up)					4.04	.999
IBS Related Behaviours (Completers)						
Time 1 (1 st survey)	1.34	.999	14.00	0.012	14.80	0.001
Time 2 (Pre-workshop)			22.69	<.001	16.14	<.001
Time 3 (2 month follow-up)					0.80	.999
Symptom Severity (Completers)						
Time 1 (1 st survey)	6.28	.999	63.11	0.002	69.14	0.001
Time 2 (Pre-workshop)			56.84	0.001	62.86	0.001
Time 3 (2 month follow-up)					6.03	.999

Note: Bolded numbers indicate significance at $p < 0.05$; M_{diff} – Mean Difference

These results show that the intervention significantly changed IBS Impact on Quality of Life with a clear decrease between pre and post intervention scores. It also showed that the effects of treatment continued to be maintained at 6 months follow-up.

IBS Related Behaviours

Mauchly's test indicated that the assumptions of sphericity had been violated ($\chi^2(5) = 30.053, p < 0.05$). Degrees of freedom were corrected using the Greenhouse-Geisser estimates of sphericity ($\epsilon = 0.658$). As shown in Table 7.3, a repeated measures ANOVA indicated that IBS Related Behaviours mean scores significantly changed across the time points studied [$F(1.98, 69.13) = 14.180, p < .001$], with a large effect size ($\eta^2 = .29$). Post-Hoc comparisons (Table 7.6) showed that differences between pre-intervention (T1 and T2) IBS Related Behaviours scores were not significant; while differences between the pre-intervention score (T2) and both post-intervention scores (T3 and T4) were highly significant as predicted.

These results show that the intervention significantly changed IBS Related Behaviours with a clear decrease between pre and post intervention scores. It also showed that the effects of treatment continued to be maintained at 6 months follow-up.

Symptom Severity

Mauchly's test indicated that the assumptions of sphericity had been violated ($\chi^2(5) = 12.87, p < 0.05$). Degrees of freedom were corrected using the Huynh-Feldt estimates of sphericity ($\epsilon = 0.793$). As shown in Table 7.3, a repeated measures ANOVA indicated that Symptom Severity mean scores significantly changed across the time points studied [$F(2.57, 89.80) = 14.226, p < .001$], with a large effect size ($\eta^2 = .29$). Post-Hoc comparisons (Table 7.6) showed that differences between pre-intervention (T1 and T2) Symptom Severity scores were not significant while differences between the pre-intervention score (T2) and both post-intervention scores (Time 3 and 4) were highly significant as predicted.

These results show that the intervention significantly reduced Symptom Severity between pre and post intervention. It also showed that the effects of treatment continued to be maintained at 6 months follow-up.

7.5.2. ITT analyses

As Table 7.5 shows, the changes in mean scores for all outcomes considered were very similar to the ones obtained for the Completers analyses. That is, mean scores remained similar prior to intervention (T1 and T2), and increased (in the case of General Quality of Life) or decreased (in the case of IBS Impact on Quality of Life, IBS Related Behaviours and Symptom Severity) after the intervention (T3 and T4). The specific results regarding the effectiveness of the intervention at changing outcomes were as follows:

General Quality of Life

Mauchly's test indicated that the assumptions of sphericity had not been violated ($\chi^2(5) = 6.41, p > 0.05$). As shown in Table 7.5, a repeated measures ANOVA indicated that General Quality of Life mean scores significantly changed across the time points studied [$F(3,165) = 10.991, p < 0.05$], with a large effect size ($\eta^2 = .17$). Post-Hoc comparisons (Table 7.7) showed that differences between pre-intervention (T1 and T2) General Quality of Life scores were not significant while differences between the pre-intervention score (T2) and both post-intervention scores (T3 and T4) were highly significant as predicted.

These results show that in the ITT analysis, the intervention significantly changed General Quality of Life with a clear increase between pre and post intervention scores. It also showed that the effects of treatment continued to be maintained at 6 months follow-up.

Table 7.7: Outcomes Post –Hoc Comparisons between all time points for ITT

General Quality of Life (ITT)	Time 2 (Pre-workshop)		Time 3 (2 month follow-up)		Time 4 (6 month Follow-up)	
	M _{diff}	p	M _{diff}	p	M _{diff}	p
Time 1 (1 st survey)	0.333	.999	1.718	0.043	2.877	<.001
Time 2 (Pre-workshop)			1.385	0.039	2.545	<.001
Time 3 (2 month follow-up)					1.159	0.217
IBS Impact on Quality of Life (ITT)						
Time 1 (1 st survey)	2.02	.999	15.39	0.012	20.99	<.001
Time 2 (Pre-workshop)			17.41	<.001	23.00	<.001
Time 3 (2 month follow-up)					5.59	0.402
IBS Related Behaviours (ITT)						
Time 1 (1 st survey)	0.36	.999	8.22	0.101	9.82	0.013
Time 2 (Pre-workshop)			8.57	0.017	10.18	0.003
Time 3 (2 month follow-up)					1.61	.999
Symptom Severity (ITT)						
Time 1 (1 st survey)	0.43	.999	41.05	0.008	49.36	0.001
Time 2 (Pre-workshop)			41.48	<.001	49.79	<.001
Time 3 (2 month follow-up)					8.30	.999

Note: Bolded numbers indicate significance at $p < 0.05$; M_{diff} – Mean Difference

IBS Impact on Quality of Life

Mauchly's test indicated that the assumptions of sphericity had been violated ($\chi^2(5) = 24.48, p < 0.05$). Degrees of freedom were corrected using the Huynh-Feldt estimates of sphericity ($\epsilon = 0.765$). As shown in Table 7.5, a repeated measures ANOVA indicated that IBS Impact on Quality of Life mean scores significantly changed across the time points studied [$F(2.40, 132.06) = 17.710, p < 0.05$], with large effect size ($\eta^2 = .24$). Post-Hoc comparisons (Table 7.7) showed that differences between pre-intervention (T1 and T2) IBS Impact on Quality of Life scores were not significant while differences between the pre-intervention score (T2) and both post-intervention scores (T3 and T4) were highly significant as predicted.

These results show that the intervention significantly changed IBS Impact on Quality of Life with a clear decrease between pre and post intervention scores, in the ITT analysis. It also showed that the effects of treatment continued to be maintained at 6 months follow-up.

IBS Related Behaviours

Mauchly's test indicated that the assumptions of sphericity had been violated ($\chi^2(5) = 54.95, p < 0.05$). Degrees of freedom were corrected using the Greenhouse-Geisser estimates of sphericity ($\epsilon = 0.618$). As shown in Table 7.5, a repeated measures ANOVA indicated that IBS Related Behaviours mean scores significantly changed across the time points studied [$F(1.86, 102.04) = 8.095, p < 0.05$], with a medium to large effect size ($\eta^2 = .13$). Post-Hoc comparisons (Table 7.7) showed that differences between pre-intervention (T1 and T2) IBS Related Behaviours scores were not significant while differences between the pre-intervention score (T2) and both post-intervention scores (T3 and T4) were significant as predicted.

These results show that the intervention significantly decreased IBS Related Behaviours mean scores between pre and post intervention in the ITT analysis. It also showed that the effects of treatment continued to be maintained at 6 months follow-up.

Symptom Severity

Mauchly's test indicated that the assumptions of sphericity had been violated ($\chi^2(5) = 26.25, p < 0.05$). Degrees of freedom were corrected using the Huynh-Feldt estimates of sphericity ($\epsilon = 0.753$). As shown in Table 7.5, a repeated measures ANOVA indicated that Symptom Severity mean scores significantly changed across the time points studied [$F(2.36, 129.80) = 13.471, p < 0.05$], with a large effect size ($\eta^2 = .20$). Post-Hoc comparisons (Table 7.7) showed that differences between pre-intervention (T1 and T2) Symptom Severity scores were not significant while differences between the pre-intervention score (T2) and both post-intervention scores (T3 and T4) were highly significant as predicted.

These results show that, in the ITT analysis, the intervention significantly changed Symptom Severity with a clear decrease between pre and post intervention scores. It also showed that the effects of treatment continued to be maintained at 6 months follow-up.

Although effect sizes were slightly reduced in the ITT analyses when compared with the Completers analyses, the results remained similar with the intervention showing to be effective at changing the mean outcome scores of General quality of Life, IBS Impact on Quality of Life, IBS Related Behaviours and Symptom Severity. The similarity of results between the ITT and Completers analyses also indicates that the effectiveness of the intervention remained significant despite the inclusion of non-completers.

7.6. IBS ACCEPTANCE AS A MEDIATOR OF OUTCOME CHANGE

The second aim of study 2 was to investigate if changes in IBS outcomes from pre intervention (T2) to post intervention (T4) were mediated by changes in Acceptance (General or IBS specific).

Although much has been written on how to carry mediation analyses in between-subjects designs (e.g. Baron & Kenny, 1986; Hayes, 2009; MacKinnon, Fairchild, &

Fritz, 2007), literature is scarce regarding pure within-subjects designs, such as the one used in this study.

An exception is the method proposed by Judd, Kenny, & McClelland (2001) that uses ordinary least squares regressions (OLS) which was used in this study. Although other methods using mainly multilevel modelling (e.g. Cheong, Mackinnon, & Khoo, 2003; Snidjers & Bosker, 1999) are also present in literature, these tend to be quite cumbersome and to rely on large samples for some estimation procedures. The approach used also has the advantage of not being dependent on the statistical methods used to estimate the parameters of the mediation model as it occurs in multilevel modelling.

According to the OLS model, several conditions have to be met for mediation to be said to occur. First, both mediator and outcome must be scaled in a way that they have a positive relationship, that is, as the mediator scores increase so should the outcome scores (or vice-versa). Secondly, the proposed mediator has to be a significant predictor of the outcome at both time points being compared. This is assessed by regression analyses. A third condition is that both mediator and outcome change significantly from one time point to another. This is assessed by pairwise comparisons. A final condition is that the mean difference between the two time points of the mediator has to be a significant predictor of the mean difference between the two time points of the outcome over the mean sum of the mediator. That is, by regressing both the mean sum and the mean difference of the mediator on the outcome, the mean difference has to be a significant predictor while the mean sum is not.

In order to meet the first condition presented above, and prior to any analyses, the outcome scores of IBS Impact on Quality of Life, IBS Related Behaviours and Symptom Severity were reversed in order for a positive relationship to occur with the mediator of Acceptance (General or IBS specific).

Regarding the third condition presented above it was noted that General Acceptance could not be considered as a possible mediator variable because, as shown in Table 7.4, General Acceptance did not significantly vary between pre-intervention (T2) and post- intervention (T4) in both Completers and ITT analyses; therefore only IBS Acceptance was tested as a possible mediator as it fulfilled this third condition. As Tables 7.6 and 7.7 show all IBS outcomes considered (General Quality of Life, IBS Impact on Quality of Life, IBS Related Behaviours and Symptom Severity) were shown to differ significantly between the pre (T2) and post (T4) intervention time points, therefore also satisfying the third condition for mediation analyses.

Therefore the following results are related only with the regression analyses needed to satisfy the second and last criteria for mediation. Preliminary analyses showed that data was considered adequate for regression analysis with a normal distribution of residuals; Durbin-Watson values ranging from 1.3 to 2.5; and multicollinearity tolerance values were all above 0.9 (0.1 is the minimum; Field, 2005, p.196) in every model tested.

7.6.1. Mediation (regression) analyses Completers

General Quality of Life

As shown in Table 7.8 IBS Acceptance was a significant predictor of General Quality of Life both at Time 2 ($\beta=0.577$, $p<.001$) and at Time 4 ($\beta=0.695$, $p<.001$) significantly explaining 33.3 % and 48.3% of variance respectively. Mediation was confirmed as the mean difference of IBS Acceptance (T2–T4) was a significant predictor of the mean difference of General Quality of Life ($\beta=0.676$, $p<.001$) over the mean sum of IBS Acceptance (T2+T4) ($\beta=0.094$, $p=.463$). Therefore these results indicate that changes in IBS Acceptance significantly mediated changes in General Quality of Life in the Completers analyses.

Table 7.8: Mediation effect of IBS Acceptance on Outcomes for Completers (Part I)

Dependent Variables	Step	Predictor Variable(s)	R ²	R ² change	F Change	Sig. F change	Standardized coefficients beta (β)		
							β (final)	t	Sig. β
T2 General Quality of Life	-	T2 IBS Acceptance	.333	-	16.946	<.001	0.577	4.117	<.001
T4 General Quality of Life	-	T4 IBS Acceptance	.483	-	31.756	<.001	0.695	5.635	<.001
T4-T2 General Quality of Life	1	T4+T2 IBS Acceptance	.014	-	0.479	.493	0.094	0.742	.463
	2	T4-T2 IBS Acceptance	.470	.456	28.445	<.001	0.676	5.333	<.001
T2 IBS Impact on Quality of Life	-	T2 IBS Acceptance	.420	-	24.614	<.001	0.648	4.961	<.001
T4 IBS Impact on Quality of Life	-	T4 IBS Acceptance	.481	-	31.465	<.001	0.693	5.609	<.001
T4-T2 IBS Impact on Quality of Life	1	T4+T2 IBS Acceptance	.017	-	0.591	.447	0.111	0.778	.442
	2	T4-T2 IBS Acceptance	.328	.310	15.238	<.001	0.558	3.904	<.001

Table 7.9: Mediation effect of IBS Acceptance on Outcomes for Completers (Part II)

Dependent Variables	Step	Predictor Variable(s)	R ²	R ² change	F Change	Sig. F change	Standardized coefficients beta (β)		
							β (final)	t	Sig. β
T2 IBS Related Behaviours	-	T2 IBS Acceptance	.574	-	45.784	<.001	0.758	6.766	<.001
T4 IBS Related Behaviours	-	T4 IBS Acceptance	.447	-	27.531	<.001	0.669	5.247	<.001
T4-T2 IBS Related Behaviours	1	T4+T2 IBS Acceptance	.039	-	1.367	.251	-0.218	-1.644	.110
	2	T4-T2 IBS Acceptance	.419	.380	21.570	<.001	0.617	4.644	<.001
T2 Symptom Severity	-	T2 IBS Acceptance	.273	-	12.766	.001	0.522	3.573	.001
T4 Symptom Severity	-	T4 IBS Acceptance	.339	-	17.441	<.001	0.582	4.176	<.001
T4-T2 Symptom Severity	1	T4+T2 IBS Acceptance	.017	-	0.572	.455	0.109	0.762	.451
	2	T4-T2 IBS Acceptance	.326	.309	15.138	<.001	0.556	3.891	<.001

IBS Impact on Quality of Life

As Table 7.8 demonstrates, IBS Acceptance was a significant predictor of IBS Impact on Quality of Life both at Time 2 ($\beta = 0.648$, $p < .001$) and at Time 4 ($\beta = 0.693$, $p < .001$) significantly explaining 42 % and 48.1% of variance respectively. Mediation was confirmed as the mean difference of IBS Acceptance (T2–T4) was a significant predictor of the mean difference of IBS Impact on Quality of Life ($\beta = 0.558$, $p < .001$) over the mean sum of IBS Acceptance (T2+T4) ($\beta = 0.111$, $p = .442$). Therefore these results indicate that changes in IBS Acceptance significantly mediated changes in IBS Impact on Quality of Life in the Completers' analyses.

IBS Related Behaviours

As shown in Table 7.9 IBS Acceptance was a significant predictor of IBS Related Behaviours both at Time 2 ($\beta = 0.758$, $p < .001$) and at Time 4 ($\beta = 0.669$, $p < .001$) significantly explaining 57.4 % and 44.7% of variance respectively. Mediation was confirmed as the mean difference of IBS Acceptance (T2–T4) was a significant predictor of the mean difference of IBS Related Behaviours ($\beta = 0.617$, $p = .000$) over the mean sum of IBS Acceptance (T2+T4) ($\beta = -0.218$, $p = .110$). Therefore these results indicate that changes in IBS Acceptance significantly mediated changes in IBS Related Behaviours in the Completers analyses.

Symptom Severity

As presented in Table 7.9 IBS Acceptance was a significant predictor of Symptom Severity both at Time 2 ($\beta = 0.522$, $p = .001$) and at Time 4 ($\beta = 0.582$, $p < .001$) significantly explaining 27.3 % and 33.9% of variance respectively. Mediation was confirmed as the mean difference of IBS Acceptance (T2–T4) was a significant predictor of the mean difference of Symptom Severity ($\beta = 0.556$, $p < .001$) over the mean sum of IBS Acceptance (T2+T4) ($\beta = 0.109$, $p = .451$). Therefore these results indicate that changes in IBS Acceptance significantly mediated changes in Symptom Severity in the Completers analyses.

7.6.2. Mediation (regression) analyses ITT

General Quality of Life

As shown in Table 7.10, IBS Acceptance was a significant predictor of General Quality of Life both at Time 2 ($\beta=0.681$, $p<.001$) and at Time 4 ($\beta=0.746$, $p<.001$) significantly explaining 46.3 % and 55.7% of variance respectively. Mediation was confirmed as the mean difference of IBS Acceptance (T2–T4) was a significant predictor of the mean difference of General Quality of Life ($\beta=0.559$, $p<.001$) over the mean sum of IBS Acceptance (T2+T4) ($\beta=-0.085$, $p=.466$). Therefore these results indicate that changes in IBS Acceptance significantly mediated changes in General Quality of Life in the ITT analyses.

IBS Impact on Quality of Life

As presented in Table 7.10, IBS Acceptance was a significant predictor of IBS Impact on Quality of Life both at Time 2 ($\beta=0.714$, $p<.001$) and at Time 4 ($\beta=0.764$, $p<.001$) significantly explaining 50.9 % and 58.4% of variance respectively. Mediation was confirmed as the mean difference of IBS Acceptance (T2–T4) was a significant predictor of the mean difference of IBS Impact on Quality of Life ($\beta=0.613$, $p<.001$) over the mean sum of IBS Acceptance (T2+T4) ($\beta=-0.806$, $p=.424$). Therefore these results indicate that changes in IBS Acceptance significantly mediated changes in IBS Impact on Quality of Life in the ITT analyses.

IBS Related Behaviours

As Table 7.11 demonstrates, IBS Acceptance was shown to be a significant predictor of IBS Related Behaviours both at Time 2 ($\beta=0.720$, $p<.001$) and at Time 4 ($\beta=0.754$, $p<.001$) significantly explaining 51.8 % and 56.9% of variance respectively. Mediation was confirmed as the mean difference of IBS Acceptance (T2–T4) was a significant predictor of the mean difference of IBS Related Behaviours ($\beta=0.617$, $p<.001$) over the mean sum of IBS Acceptance (T2+T4) ($\beta=0.063$, $p=.563$). Therefore these results indicate that changes in IBS Acceptance significantly mediated changes in IBS Related Behaviours in the ITT analyses.

Table 7.10: Mediation effect of IBS Acceptance on Outcomes for ITT (Part I)

Dependent Variables	Step	Predictor Variable(s)	R ²	R ² change	F Change	Sig. F change	Standardized coefficients beta (β)		
							β (final)	t	Sig. β
T2 General Quality of Life	-	T2 IBS Acceptance	.463	-	46.584	<.001	0.681	6.825	<.001
T4 General Quality of Life	-	T4 IBS Acceptance	.557	-	67.866	<.001	0.746	8.238	<.001
T4-T2 General Quality of Life	1	T4+T2 IBS Acceptance	.000	-	0.001	.971	-0.085	-0.735	.466
	2	T4-T2 IBS Acceptance	.304	.304	23.195	<.001	0.559	4.816	<.001
T2 IBS Impact on Quality of Life	-	T2 IBS Acceptance	.509	-	56.045	<.001	0.714	7.486	<.001
T4 IBS Impact on Quality of Life	-	T4 IBS Acceptance	.584	-	75.708	<.001	0.764	8.701	<.001
T4-T2 IBS Impact on Quality of Life	1	T4+T2 IBS Acceptance	.035	-	1.935	.170	0.087	0.806	.424
	2	T4-T2 IBS Acceptance	.401	.367	32.439	<.001	0.613	5.696	<.001

Table 7.11: Mediation effect of IBS Acceptance on Outcomes for ITT (Part II)

Dependent Variables	Step	Predictor Variable(s)	R ²	R ² change	F Change	Sig. F change	Standardized coefficients beta (β)		
							β (final)	t	Sig. β
T2 IBS Related Behaviours	-	T2 IBS Acceptance	.518	-	58.102	<.001	0.720	7.622	<.001
T4 IBS Related Behaviours	-	T4 IBS Acceptance	.569	-	71.356	<.001	0.754	8.447	<.001
T4-T2 IBS Related Behaviours	1	T4+T2 IBS Acceptance	.026	-	1.467	.231	0.063	0.582	.563
	2	T4-T2 IBS Acceptance	.397	.370	32.555	<.001	0.617	5.706	<.001
T2 Symptom Severity	-	T2 IBS Acceptance	.407	-	37.008	<.001	0.638	6.083	<.001
T4 Symptom Severity	-	T4 IBS Acceptance	.499	-	53.679	<.001	0.706	7.327	<.001
T4-T2 Symptom Severity	1	T4+T2 IBS Acceptance	.032	-	1.785	.187	0.077	0.724	.472
	2	T4-T2 IBS Acceptance	.421	.389	35.676	<.001	0.632	5.973	<.001

Symptom Severity

As shown in Table 7.11, IBS Acceptance was a significant predictor of Symptom Severity both at Time 2 ($\beta=0.638$, $p<.001$) and at Time 4 [$F(1, 54) = 53.679$, $p<0.05$] with ($\beta=0.706$, $p<.001$) significantly explaining 40.7 % and 49.9% of variance respectively. Mediation was confirmed as the mean difference of IBS Acceptance (T2–T4) was a significant predictor of the mean difference of Symptom Severity ($\beta=0.632$, $p<.001$) over the mean sum of IBS Acceptance (T2+T4) ($\beta=0.077$, $p=.472$). Therefore these results indicate that changes in IBS Acceptance significantly mediated changes in Symptom Severity in the ITT analyses.

The similar results between the ITT and Completers analyses indicate that the mediation effect of IBS Acceptance in changes in outcomes is significant and is maintained even when effect sizes are slightly reduced due to the more conservative use of ITT analyses.

CHAPTER 8
DISCUSSION

CHAPTER 8 – DISCUSSION

8.1. STUDY 1 DISCUSSION

Over the years, several studies have highlighted the importance of psychosocial factors in the aetiology, progression and management of IBS (e.g. Levy et al., 2006). Recently, the functional contextual approach proposed by Acceptance and Commitment Therapy has shown psychological (In)Flexibility to be a key factor in several chronic health conditions (e.g. chronic pain, diabetes) (Gregg et al., 2007; Vowles, McCracken, & Eccleston, 2008). However, Psychological (In)Flexibility has never, to the authors' knowledge, been studied in IBS; therefore the main objective of the first study of this thesis was to investigate the role of Psychological (In)Flexibility in IBS.

One of the first challenges of this study concerned the measurement of psychological (In)Flexibility processes in this specific population. Acceptance as a key metric representative of Psychological (In)Flexibility was chosen, as this concept seems to be the most well studied in literature (Ruiz, 2010). A well-known general measure of Acceptance was used; however several authors advocate the construction/adaptation of measures specific to the population being studied as these might be more sensitive to the characteristics of that population (e.g. Hayes et al., 2004; Wicksell et al. 2008). Therefore, the present study included the development of such a measure, the IBSAAQ. Results suggested that the IBSAAQ was a reliable and valid measure of Acceptance in IBS measuring two separate processes, Activity Engagement and IBS Willingness. The Activity Engagement subscale comprised items related to engagement in everyday activities even in the presence of IBS while the IBS Willingness subscale comprised items related to being willing to contact difficult IBS experiences (physical or psychological) while at the same time letting go of strategies aimed at the elimination or reduction of contact with IBS experiences. This two-factor structure and the content of the factors are consistent with those proposed for the CPAQ-R (McCracken, Vowles, & Eccleston, 2004), the measure on which the IBSAAQ was based. However, when compared to the CPAQ, items 3 (“It’s OK

to experience Bowel Discomfort”) and 10 (“Controlling my IBS is less important than any other goals in my life”) loaded on the IBS Willingness factor in the IBSAAQ while in the CPAQ they loaded on the Activity Engagement factor. These results seem to make more sense from a theoretical point of view, since both items relate to two essential characteristics of willingness, being able to contact difficult experiences and relinquishing attempts to control these difficult experiences. It must be noted though, that these items had low factor loadings when compared to the rest of the items in the scale. This is in accordance with the study by McCracken, Vowles, & Ecclesston (2004) in which these two items were shown to have low factor loadings as well with item 3 having an almost significant cross-loading with the alternative factor. These results suggest therefore that further investigations regarding these particular items would be of importance in order to clarify their role and possibly refine them. Despite this, good reliabilities, convergent and concurrent validities were found for the total scale and the two subscales. Also, results obtained from study 2, show this new IBSAAQ scale to be reliable over time and to be sensitive to treatments designed to improve Acceptance. Overall the data suggests that the IBSAAQ can be used as a reliable and valid measure to assess Acceptance in adults with IBS.

Some interesting findings resulted from the investigation of how acceptance differed according to demographic variables. Some differences were found for education and marital status, with higher acceptance being linked to participants who had a higher level of education or who were married/cohabiting. As there are no published guidelines regarding the clinical significance of the differences observed, one can only speculate on the causes of these differences based on their statistical significance. Perhaps participants with higher education have a better understanding of IBS and/or are more aware of ways to cope with their illness giving them therefore a wider repertoire of behavioural choices that is then reflected in a greater behavioural flexibility. Regarding married/cohabiting participants, it might be that having a partner acts as a form of increased social support, which in turn opens the door to a wider and more flexible behavioural repertoire. Further studies are therefore needed to explore if these differences are clinically significant and what

may cause them. Regarding vocational status it was unsurprising to find that participants who reported having stopped working due to their IBS had significantly lower levels of acceptance when compared to working participants or participants not working due to other reasons. This seems to be in line with our proposal that lower acceptance is related to a behavioural repertoire narrowing that can affect important activities such as work. Similarly, previous research in chronic pain has consistently found that acceptance is associated with and predicts work status (e.g. McCracken & Eccleston, 2006; McCracken & Vowles, 2008). Patients who have stopped work or struggle to keep working due to their IBS might therefore constitute a specific group to target in terms of interventions designed to increase psychological flexibility.

Overall, the results of this study seem to support the general hypothesis that acceptance might be a key factor in the biopsychosocial model of IBS. As expected, higher levels of acceptance were associated with and predicted lower engagement in avoidant behaviours, better quality of life and lower levels of IBS experiences (symptoms, difficult cognitions, depression, stress and anxiety).

As proposed by the ACT model, people more willing to contact their difficult IBS experiences (physical or psychological) seem to engage in fewer attempts to control/eliminate their experiences. According to the ACT model this would keep their behavioural agenda free to pursue more valued activities and therefore improve Quality of Life; however engagement in valued behaviours was not measured in this study. It can only be speculated that higher engagement in valued activities was at foot, however higher levels of Acceptance were found to be associated with better Quality of Life as proposed by the ACT model. Results also seem to support the proposition that a willingness to contact IBS experiences of symptoms, distressing cognitions or emotional states while engaging in valued activities is paradoxically associated with lower levels of these experiences. This has been theorized to occur because the more a patient focuses on trying to change/eliminate these difficult experiences the more functionally important they become (Hayes, Strosahl, & Wilson, 1999; Hayes et al., 2006). Therefore, by letting go of these control attempts, content associated with ones suffering is less likely to be activated resulting in a

lower experience of distress. Alternatively it could also be the case that it is easier to be accepting when symptoms are low; however the cross-sectional nature of this study does not allow us to determine directionality. These results are in accordance with the general literature on ACT in which higher levels of acceptance have been consistently associated with better psychological, physical and quality of life outcomes (Hayes et al., 2006; Ruiz, 2010). More specifically these results concur with the findings in the chronic pain literature in which psychological (In)flexibility processes have been found to be significant predictors of psychological, emotional, functional and quality of life outcomes (McCracken, Vowles, & Zhao-O'Brien, 2010; Vowles, McCracken, & Eccleston, 2008; Wicksell et al., 2008). Finally, similar to McCracken & Zhao-O'Brien's (2009) observations for chronic pain, differences in the strength of association and predictive utility of criteria variables were found for the general and IBS specific measure of Acceptance. Overall, the IBS specific measure of Acceptance was more strongly associated with IBS specific variables and as strongly associated as the general measure of acceptance with some of the more general variables. The overall better performance of the IBS Acceptance measure in this study was further emphasized by the greater predictive utility it had across all variables (general or IBS specific), when compared to GI Anxiety and when it was used as a mediator. These results seem to support the increased utility in the development or adaptation of measures to the specific characteristics of the populations being studied.

Of particular importance was the strong association between Acceptance and GI Anxiety, as this latter concept seems to include many items akin to psychological inflexibility. It is possible to equate the GI Anxiety characteristics of increased vigilance, worry and fear of GI symptoms and the sensations or contexts in which these might arise as a form of both cognitive fusion and dominance of a feared future. So it could be hypothesised that GI anxiety and our measures of Acceptance could be tapping aspects of the same construct.

Comparing both General and IBS specific Acceptance with GI anxiety it was found that the latter construct was a better predictor of IBS specific outcomes like symptom

severity, use of avoidant behaviours and IBS specific quality of life. These results are in line with the ones reported by Jerndal et al. (2010), where GI Anxiety was found to be a strong predictor of IBS outcomes. However, even taking into account the effect of GI Anxiety, specific IBS Acceptance was still a significant predictor of IBS outcomes, suggesting that this latter construct has a significant added value to the explanation of variance in IBS outcomes. A possible explanation for these results might be that although GI anxiety seems to share some common ground with Acceptance and the overall concept of psychological inflexibility, it can also be seen essentially as a group of psychological experiences, specific to IBS patients, that might result or not in avoidance behaviours. It is therefore possible that among patients with significant levels of GI anxiety, some will be more dominated by these experiences and develop patterns of avoidance while others will be able to distance themselves from their IBS experiences in order to continue to engage in valued activities. The extra predictive ability of our IBS Acceptance measure might therefore be related to the fact that it attends to these processes of engagement with the experiences of IBS (willingness) and with the behavioural results of this engagement (activity engagement). Overall, similar results have been recently described by Wicksell, Olsson, & Melin (2009), regarding comparisons between the Chronic Pain Acceptance Questionnaire and a measure of kinesiophobia (fear of injury by physical activity) in a chronic pain sample. In their study however, psychological flexibility was consistently found to be a better outcome predictor than kinesiophobia. Although any comparison is fraught with criticism as the two studies can be considered at best analogous, one can speculate that the poorer predictive ability of Acceptance in our study is mainly related to the use of a much more complex comparator (GI Anxiety), that entails many more dimensions assessed than the comparator used in Wicksell, Olsson, & Melin's study (kinesiophobia) that seems to assess a single dimension. Also of note was the fact that IBS Acceptance was a better predictor than GI anxiety of general quality of life. This is possibly related to the activity engagement component as well, since the items of this factor are more contextually broad, that is, they apply to engagement in general life activities, while the items of the GI Anxiety scale are limited to the context of IBS situations.

The choice of acceptance as a mediator being tested can be contentious as some might think of it as equally likely to occupy the role of an outcome following treatment. However, from a theoretical point of view, the conceptualization of Acceptance defines it as a means of reaching desired behavioural outcomes, rather than an end in itself (Hayes et al., 2006). Tests of indirect effects suggested that Acceptance may function as a mediator of the relationships between key predictors and IBS outcomes. Therefore, although difficulties with physical (symptom severity) and cognitive-emotional (GI anxiety) factors might lead to poorer outcomes, this relationship seems to be influenced to an important extent by how willing one is to be in contact with these experiences while at the same time continuing to engage in valued activities. It seems therefore that the way IBS patients are relating to their experiences (more or less flexibly) is having an impact on the way they behave (more or less avoidantly) resulting in a better or worse quality of life. Several recent studies (Vowles, McCracken, & Eccleston, 2008; Westin, Hayes, & Andersson, 2008; Wicksell et al., 2010) have similarly showed that Psychological (In)flexibility or some of its components (e.g. acceptance, fusion, avoidance) are important mediators in the relationship between illness experiences (physical, emotional or cognitive) and functional outcomes (e.g. quality of life, distress, disability). These findings seem therefore to support the overall assumption of the ACT model in health, that the main cause of suffering is not in the nature, content or frequency of the distressing experiences related to the health condition, but rather in the functional importance that is given to these experiences in the context of pursuing valued activities.

Regarding the Self-Regulation model, the findings from this study also seem to support the role of Acceptance as a key factor in this model. This model is particularly relevant to the ACT model, as illness representations are concerned with the patients' beliefs about their condition, such as how long it will last or how consequences from the IBS will affect their future. Therefore, from an ACT point of view, patients who have strong negative beliefs about their IBS could be seen as being particularly fused with the content of these thoughts. The degree of fusion would then be expressed by how flexibly these patients would react to the content of

their beliefs. Results from the current study showed that similarly to the findings of Rutter & Rutter (2002) positive illness representations were associated with higher levels of Acceptance (i.e. a more flexible stance). The Self-Regulation model also posits that how someone copes with the content of their beliefs will mediate the impact of these cognitive representations on outcomes. From an ACT perspective we could say that how flexibly one reacts to the representations of IBS will affect one's outcomes. Our findings seem to partially support this, as general Acceptance was shown to significantly mediate the relations between the representation of emotional impact and general quality of life, and IBS acceptance significantly mediated the relations between the consequences representations and all outcomes. These results are similar to the ones reported by Rutter & Rutter (2002, 2007), in which Acceptance, as defined by the coping model of Carver, Scheier, & Weintraub (1989), was shown to significantly mediate the relations between the Illness Representation of consequences and IBS outcomes. However another important finding from these analyses was that when taking into account the influence of Acceptance, especially IBS specific, few illness representation dimensions remained significantly associated with IBS outcomes. This again seems to support the notion defended by ACT that it is not the content or frequency of the experiences that influences outcomes like behaviours or quality of life but rather the way one reacts to these experiences, more or less flexibly.

8.1.1. Study 1 Implications

Regarding our understanding of IBS, this study has shown that a functional contextual model might be of great value in the understanding of the processes at work between the physical, cognitive and emotional experiences of IBS patients and the impact these have on their lives. Importantly, this research has highlighted that patients experiencing distressing IBS symptoms, cognitions or emotions in a more accepting context were less likely to report a high impact of the condition in their lives. Although preliminary, these findings could indicate the need to shift the focus of present research from the nature, content and frequency of IBS experiences to the context (accepting vs. avoidant) in which they are experienced as a way to better

understand why some patients seem to adjust easily to this condition while others don't.

This research has also highlighted the importance of Acceptance as a key factor in the prediction of IBS outcomes and the mediation between IBS experiences and outcomes. The assessment of this factor might therefore be of great interest in future biopsychosocial research looking at the impact of the interactions between physical and psychological variables in IBS. Also it might be of particular value for practitioners to take Acceptance into account in their case formulation as outcomes like quality of life are more commonly regarded as the key target in chronic illness rather than symptom elimination. Being able to assess therefore, how a patient relates to her experience of IBS or how she integrates these experiences in the pursuit of valued activities might be important in the planning stages of an intervention as it might indicate particular areas that can be targeted. The validated, reliable and easy-to-use measure developed in this study might therefore be of particular interest to use as a tool for researchers and practitioners.

In terms of ACT theory, the findings of this study confirm once again the flexibility of the ACT model of pathology to be adapted and applied to several health related conditions. This study also adds to the growing empirical support for the key role that psychological (in)flexibility may have in health related conditions. It also supports the use of a functional contextual approach in the assessment of health related conditions, both in research and in clinical practice as a useful step in the development of new therapeutic formats to target psychological (In)flexibility. This study also supports the development and use of condition specific measures to assess psychological (In)flexibility rather than general measures as these might not be sensitive enough to detect some differences between subjects.

8.1.2. Study 1 Limitations and future research

Several limitations can be highlighted regarding the research design of this study. First, the sample used in this study was a very specific sample presenting at a tertiary

gastrointestinal service with a relatively high symptom severity, a lengthy history of IBS, predominantly female and middle aged. Therefore, these individuals may differ in some respects from IBS patients in primary care services, IBS patients who do not seek NHS consultations for their problems or recently diagnosed patients. Future studies including these populations would be worthwhile in order to get a more complete picture of the range of Acceptance of IBS and the range of consequences that come with Acceptance.

A second limitation was that all data was collected using self-report measures. One problem from this data collection method is that shared method variance among the measures used in this study is likely to account for the magnitude of some of the relations observed. Also, although this form of data gathering is more convenient for large samples, it can be biased by factors like response style or external incentives. Therefore future studies could look at ways to include corroborating evidence from additional reporters such as family members and care providers or observations that independently reflect the patients' behaviour such as medication use, work absence, number of health consultations, etc.

Another limitation was the cross-sectional nature of data collection; therefore although significant associations were found between Acceptance and other variables, no causal influences can be inferred. The predictive ability and mediational analyses should therefore be taken as useful preliminary explorations of a possible model of causal influence guided by theoretical assumptions rather than a test of said assumptions. Future prospective or treatment outcome studies would be helpful in determining the directionality of the relations between the variables studied.

Regarding the measure development presented there are also some limitations in this part of the study. Although the sample was large enough to adequately conduct an exploratory factor analysis of the measure being developed it was however insufficient for a confirmatory factor analysis, curtailing therefore the claims that can be made regarding the factor structure of the scale developed. Further collection of data on this measure would be useful to the psychometric development of the

IBSAAQ. Another limitation concerns the development of the scale items. In this study all items were adapted from an existing scale potentially biasing or restricting the scope of the scale's assessment. Although this proved to be a good starting point in the measurement of Psychological (In)flexibility processes in IBS, future studies could benefit from a more conventional scale development approach. Therefore, the integration of some of the findings presented in this study (e.g. the relations between Acceptance and GI Anxiety) with future qualitative and quantitative studies exploring other dimensions of psychological (In)flexibility such as values or cognitive fusion would be useful in the development of a more complete and integrative measure.

Finally some strengths should also be highlighted in this study. The first concerns the adequacy of the sample size in terms of obtaining a significant level of power. According to a-priori calculations, the sample size collected exceeded the minimum theoretically required to detect at least medium effects of predictors on outcome variables. Another strength concerns the recruitment of participants. As self-reported measures have been shown to vary in their reliability to clearly detect IBS, more studies are using clinical expert assessment as a way to reliably recruit patients. In the current study, in addition to self-report measures, all participants were clinically assessed and had their diagnosis confirmed by a gastroenterology consultant.

8.2. STUDY 2 - DISCUSSION

Due to the limited efficacy of conventional medical treatments in providing adequate relief for IBS patients, and the myriad of studies highlighting the importance of psychosocial factors in this condition, psychological management therapies have been increasingly recognized as an effective adjunctive form of treatment in recent years (Spiller et al., 2007). Recent studies have shown Acceptance and Commitment Therapy to be an effective treatment for several forms of health related problems such as diabetes, epilepsy, tinnitus or chronic pain (Ruiz, 2010). Some authors have defended the potential use of this form of psychological therapy in IBS (Naliboff, Frese, & Rappay, 2008), however only one study with considerable limitations

(Greco et al., under review) has used ACT in the treatment of IBS patients (Greco et al., under review). The aim of this study was therefore to gather preliminary evidence of the usefulness of an ACT based treatment in improving IBS outcomes.

In this study a short ACT based intervention emphasizing strategies to promote psychological flexibility (e.g. acceptance, defusion) and thereby improve quality of life was developed and evaluated. Most traditional psychological approaches to IBS (e.g. CBT, Hypnosis) have had as their target the reduction or control of IBS experiences (symptoms, thoughts, emotions) as a way of improving outcomes such as quality of life. In contrast the present intervention had as a main target the increase of psychological flexibility in IBS patients. That is, it promoted the acceptance and non-judgemental observation of IBS symptoms, thoughts or related emotions and the choice of values-oriented behaviours over avoidant behaviours in the presence of these difficult experiences.

Overall the results of this study show that an ACT based intervention was effective at improving IBS patients' outcomes; that this happened through the hypothesized process of increasing Acceptance and that effects of the intervention were maintained at 6 month follow-up. These results are in line with the findings of previous studies in which psychological approaches (e.g. CBT, Hypnosis) were effective at improving symptoms and outcomes such as quality of life in IBS (e.g. Kennedy et al., 2006; Smith, 2006). Also the results correspond well with other studies evaluating ACT based interventions for people with health related conditions as diverse as chronic pain (Veehof et al., 2011), diabetes (Gregg et al., 2007) or epilepsy (Lundgren, Dahl, & Hayes, 2008; Lundgren et al., 2006).

More specifically, analyses of change in Acceptance, both general and specific, showed no significant shift in Acceptance levels between the two time points collected prior to the intervention. After treatment, patients showed significant increases in both Acceptance variables with a tendency for continued increase (acceptance values at 6 month follow-up tended to be on average higher although not significantly different from the 2 month follow-up values). These findings are of

particular importance as they show that changes in acceptance are unlikely to be due simply to the passage of time or to events coinciding with the intervention period. Changes in Acceptance are therefore more likely to be due to the intervention itself. The main target of any ACT based intervention is primarily the increase of psychological flexibility, with the promotion of acceptance processes as one of the key foci in these treatments. These results are therefore encouraging in demonstrating that not only is the intervention designed for this study consistent with the ACT principles, it is also successful at changing one of its intended targets. This is consistent with the literature in which a large number of studies have shown Acceptance to be one of the key processes changed by ACT interventions (Hayes et al., 2006; Ruiz, 2010).

The same pattern of no change prior to intervention followed by a significant improvement following the intervention was observed for the outcomes of IBS Related Behaviours, Quality of Life (General and IBS specific) and Symptom Severity. The changes in the use of avoidant behaviour after the intervention are of particular interest as ACT is a behavioural form of therapy that seeks to promote behavioural change (Hayes et al., 2006). From a behavioural perspective ACT has two main goals, encouraging disengagement from behaviours that promote avoidance/control/elimination of experiences without any functional gain and the promotion of behaviours that are related to valued activities. Regarding the first objective, the results from the current study seem to support the effectiveness of this ACT intervention at reducing avoidant behaviours, as patients had a significant reduction in avoidant behaviours after the intervention was carried out. No data was collected regarding valued activity in the current study and thus we are unable to determine whether this also increased subsequent to the intervention. However, according to ACT theory by increasing Acceptance and reducing the number of avoidant behaviours, there would be more space in the patient's behavioural repertoire to pursue value guided actions. Therefore, if patients were living a life that is more in accordance to what is important to them and less according to an elimination/control agenda, this would be reflected in a more positive perception of quality of life. We can therefore speculate that the significant improvements in

quality of life after intervention observed in our study can be seen as a reflection of an improved engagement with valued activities. Future studies using measures of valued activity engagement as a process variable would therefore be helpful in clarifying this point. It could be argued as well, that the improvements in behaviour and quality of life are nothing but a reflection of the improvements observed in symptom severity. Regarding this point, it is hard to say if this happened indeed as the design did not allow us to control for this effect. However, we can see from the multiple time-point data collection that improvements in symptom severity seem to have occurred at the same time as the improvements in the target variable of psychological flexibility. Some support for the possibility of increased psychological flexibility affecting symptoms severity comes from the fact that patients did not receive any changes to their medical management during the whole period of study, therefore if any changes in symptom were to occur due to medical management, they would have been observed in the baseline period before the intervention. If anything, given the ACT intervention's emphasis on exposure to activities that might trigger difficult experiences such as symptoms, it could be expected that this would result in an increase in symptom severity. Instead what was observed was a dramatic reduction in symptom severity, illustrated by the fact that prior to the intervention patients who completed all measures had average scores in the higher threshold between moderate and severe, while at 6 month follow-up their average scores were in the lower threshold between moderate and mild. As previously stated, symptom reduction is not one of the targets of ACT interventions; however reductions in symptoms have been observed in several ACT studies (Hayes et al., 2006) and are not uncommon. This is thought to occur because ACT processes such as mindfulness, defusion and acceptance encourage patients to dispassionately observe their experiences of illness such as symptoms, rather than engage with them in a control/avoidance/elimination stance. Therefore the naturally occurring pattern of negative reinforcing "Aversive Experience → Control Behaviour → Immediate Relief" cycle is disturbed. So in this case, it is thought that some of the aversive features of the symptoms were removed by lowering their functional importance, therefore resulting in a lower reporting of the symptoms. Finally it is important to notice that the results suggest a slight cumulative effect of the intervention as all

outcomes continued to improve (albeit non-significantly) over time after the intervention. This is in line with the tenets of a behavioural intervention, since it is expected that continued practice of more useful behaviours will lead to better outcomes and become sustained by the consequences of these new behaviours.

The mediation analyses carried out were also of great value in supporting the efficacy of this intervention. The results showed that the improvements in outcomes seemed to occur through the hypothesized process of changes in psychological flexibility, in this case the development of greater acceptance, particularly towards the experience of IBS. The present study contributes to the growing evidence that changes in psychological (In)flexibility variables (e.g. acceptance, activity engagement, avoidance and fusion) are part of the process through which ACT based interventions work (Hayes et al., 2006; Ruiz, 2010). More specifically it adds to the growing evidence that changes in psychological (In)flexibility are an important mediator of change in outcomes of health conditions such as chronic pain (e.g. Wicksell, Olsson, & Hayes, 2010), diabetes (Gregg et al., 2007) or epilepsy (Lundgren, Dahl, & Hayes, 2008). Research on processes of change is of particular importance as it clarifies the key ingredients at work in an intervention, and has been one of the distinctive features of ACT research (Hayes et al., 2006). The clarification of the mechanisms of change highlighted in this study is therefore useful to the continuation of the development of this type of intervention rather than the simple establishment of its efficacy. In fact, this has been one of the key issues with other validated forms of psychological interventions for IBS. For example, although hypnosis has been found to be mainly effective for refractory IBS patients (Spiller et al., 2007), little is known regarding the mechanisms that make it work or why these patients benefited more from this treatment. Lack of research and knowledge regarding the active ingredients of Hypnosis has therefore resulted in a form of treatment that although effective, has not progressed much and that it continues to be very labour intensive and hard to access. Another example of the utility of process change research can be drawn from the studies regarding the effectiveness of CBT for IBS. Although this form of treatment has been shown to be generally effective (Zijdenbos et al., 2009), only a few studies have addressed change processes. These

studies seem to suggest that changes in cognition (one of the key features targeted by CBT) are not particularly effective and that most improvements are achieved through behaviour modification (Kennedy et al., 2006; Lackner et al., 2007; Reme et al., 2010). These studies not only suggest that the CBT model of intervention might need to be revised as they reinforce the ACT proposition that cognitive change might not be an necessary step for improvement in IBS, therefore giving more relevance to the findings of this study.

In a time when empirical support for psychological interventions for IBS is growing (Spiller et al., 2007), access to this form of interventions is still cumbersome and restricted. This happens mostly due to the high economic and human resource costs involved in this form of specialized care, therefore short interventions with a substantial component of self-management are being put forward as possible alternatives (Dorn, 2010). Given this context, the results presented here are encouraging as the intervention designed can be delivered in a brief (7 hours) group session and followed by a self-management program, therefore reducing the number of therapist contact hours. This is in fact in line with the ACT literature, where relatively large effects for similar interventions in health contexts involving a brief workshop (Gregg et al., 2007; Lundgren, 2004; Masuda et al., 2007), workshop plus workbook (Lillis et al., 2009) or solely workbook (Johnston et al., 2010) have been reported. Encouraging as well was the fact that this program worked quite well in a group format with some sessions including as many as 12 patients. Therefore this shows that this program can be delivered to relatively large audiences within a day.

Another encouraging observation from this study is that only 35% of participants were lost to follow-up, suggesting that this intervention was generally well accepted by patients. This is relevant when compared to other self-management studies in IBS where drop-out rates are around 50% (e.g. Forbes, Macauley, & Chiotakakou-Faliakou, 2000; Sanders, Blanchard, & Sykes, 2007). It was also interesting to notice that the only difference between the participants that completed the study and those lost to follow-up was in their levels of GI Anxiety, with these levels being higher in the latter group. It can be hypothesized that participants with higher levels of GI

anxiety may have a greater level of fusion not only with their experiences but with an avoidance/elimination/control agenda, and therefore might benefit from either a different type of program (CBT, hypnosis) or a more lengthy/intense/ individualized ACT program in which the initial steps of creative hopelessness and values assessment can be addressed as a motivator for a change in agenda.

Finally it is worth noting that the development of this intervention follows many of the steps in the process of development-evaluation-implementation of a complex intervention as proposed by the Medical Research Council (2008). Regarding development this intervention is clear about what it targets and how it produces behavior change; it has a coherent theoretical basis; it is fully described allowing implementation and replication; the literature review supports this kind of intervention as being both effective and cost-effective. Although this is still a pilot trial, great care was put into the design, recruitment, sample size and effect sizes expected to be observed in order to make this an adequate first step to future implementation.

8.2.1. Study 2 Implications

The biggest implications from this study concern the possible clinical applications of the model studied for the management of IBS. This study has shown that ACT has the potential to be integrated in clinical practice as an alternative form of psychological treatment that can be delivered quickly and with low costs to large number of patients attending tertiary services. This study also implies that symptom reduction might not always have to be the target of interventions with IBS populations and that targeting the relation patients have with their symptoms can be an effective way to produce changes in both physical and psychological outcomes. Alternatively this study suggests that ACT might be indicated for cases in which improvements either plateaued or were not obtained via the normal symptom focused approach.

Regarding our theoretical understanding of IBS, this study confirms the findings of study 1 regarding the importance of psychological (In)flexibility processes such as Acceptance in IBS. More specifically it showed that as theoretically predicted, by changing these processes it is possible to obtain a significant change in IBS outcomes. Again this makes a case for the necessity to either shift the focus from the nature/content/frequency of IBS experiences to the context in which these occur or to at least integrate contextual assessments in clinical and research practice.

In terms of ACT theory and practice, the findings of this study confirm the flexibility of the ACT model of pathology and clinical application to be adapted and applied to different health related conditions. Further to that it suggests that one of avenues for the development of ACT should include the development of interventions that can be delivered in a short, group and self-management format. Finally, by providing evidence that suggests that the intervention worked through the hypothesized processes, this study further highlights the importance of clarifying the links between the theoretical roots and practical applications of any psychological model. This confirms the necessity for a continuation of research in process changes not only in ACT but also in all other psychological models of intervention, whether applied to physical or mental health, as a way to further develop these models.

8.2.2. Study 2 Limitations

A major limitation of this study was the absence of a formal control group condition as would be present in a randomized control trial, the gold standard proof of the efficacy of a treatment. However, the study employed a within subjects design using treated subjects as their own controls in order to compensate for this design limitation. This was thought to be adequate given that this study was intended to be a small-scale preliminary investigation. In the future randomized control trials comparing this model of intervention with, waiting list, placebo conditions or other models shown to be effective (e.g. CBT or hypnosis) will produce important data.

Another limitation of the study concerns the very specific format used to deliver the intervention of a 1 day workshop plus workbook. Future studies might compare the efficacy of the ACT model delivered in other formats, for example individually, in multiple group sessions, with or without the support of the workbook, using only the workbook, with internet or phone support, etc... In future studies, it would also be important to compare ACT with another intervention model (e.g. CBT) using this workshop + workbook delivery format.

As with study 1, study 2 was limited by the use of a highly selected IBS population. Studies with different patient groups, such as primary care patients, would provide valuable data regarding generalization of ACT as a treatment for IBS. Further studies are needed that use alternative measures that either tap into different constructs of psychological flexibility (e.g. values) or that use behavioural observations in order to strengthen the case that the intervention is working through the theoretically hypothesized processes.

Despite the limitations, this study also had some methodological strengths. The sample size used was adequate in terms of obtaining a significant level of power to detect medium effect sizes. Also, the use of ITT analyses corroborated the findings of the analyses of the data for the participants who completed all measures. Therefore possible inflated effectiveness estimates were controlled for.

8.3. SUMMARY AND CONCLUSIONS

In summary, the findings from the studies presented in this thesis make a significant contribution regarding the usefulness of ACT as an approach to both the understanding and the treatment of IBS. The first study highlighted the importance of psychological (In)flexibility processes in the interaction between the experiences (physical, cognitive and emotional) of having IBS, how patients choose to respond to these experiences and the impact this has on their life. Results support the psychometric properties of a self-report questionnaire that assesses the central component of Acceptance in IBS and the key role of this construct both as a

predictor and as a mediator in the biopsychosocial model of IBS. Thus, it is suggested that the instrument developed and the contextual behavioural model on which it was based could be of use in both future research and clinical practice in the IBS field.

The second study highlighted the impact that a brief intervention promoting increased psychological flexibility, had on IBS outcomes. Data supported not only the effectiveness of this intervention, but also suggested that it worked through the theoretically hypothesized processes. Given that implementing this intervention involves a relatively low level of human and economic investment, it is suggested that it could be made available as part of the standard treatment for these patients. Although these findings are preliminary, they suggest that future studies in IBS would benefit from a contextual behavioural approach such as ACT.

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